Differences in HPV genotypes distribution among young women in two biggest Croatian counties

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Abstract E-Book

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Oral Abstracts

O001 / #771

Early Career Researchers
EARLY CAREER AWARD WINNERS: ORAL ABSTRACTS SESSION
04-19-2023 8:15 AM - 9:15 AM

CIN3+-SPECIFIC METHYLATION MARKER ANALYSIS TO IMPROVE THE TRIAGE OF HRHPV-POSITIVE SELF-SAMPLES IN THE DUTCH POPULATION-BASED CERVICAL CANCER SCREENING PROGRAMME

Jolien De Waard[1], Arkajyoti Bhattacharya[2], Martine De Boer[1], Karin Vermeulen[3], Truuske De Bock[3], Ed Schuuring[4], Bea Wisman[1]
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Introduction: The Dutch cervical cancer screening programme consists of primary high risk human papilloma virus (hrHPV) testing with cytology as triage test. To increase participation, women are offered self-sampling. As triage cytology is not feasible on this self-sampled material, women with a hrHPV-positive test need to visit their GP for cytology. We aim to identify a methylation marker panel as an alternative triage test to detect CIN3 or worse (CIN3+) in hrHPV-positive self-sampled material.

Methods: Fifteen methylation markers, selected from literature with high sensitivity and specificity for CIN3+, were analysed using quantitative methylation-specific PCR (QMSP) on 208 hrHPV-positive self-samples of women with a CIN2 or less (<CIN2) and 96 with CIN3+. The diagnostic performance was determined by area under the curve (AUC) of receiver operating characteristic (ROC) analysis. Self-samples were divided into a train and test set. Model-based recursive partitioning and robustness analysis were applied to identify the best marker panel.

Results: QMSP analysis of these individual markers showed discriminative DNA methylation levels between <CIN2 and CIN3+ for all markers ($p<0.05$). ROC analysis for CIN3+ showed an AUC of ≥0.7 ($p<0.001$) for 9/15 markers The most promising and robust panel consisted of three methylation markers with an AUC of 0.83 in the training set and 0.84 in the test set. Sensitivity to detect CIN3+ was 82% in the training and 84% in the test set, with a specificity of 74% and 71%, respectively. Furthermore, all cancer cases (n=5) were identified.

Conclusions: In this study we identified a methylation panel, consisting of three methylation markers, which revealed good diagnostic performance. This panel of methylation markers shows potential clinical applicability to replace cytology and avoid the extra GP visit after a hrHPV-positive self-sampling test. Currently, we are performing external validation of this optimized panel in a large cohort of >2400 hrHPV-positive self-samples.

O002 / #1104

Early Career Researchers
EARLY CAREER AWARD WINNERS: ORAL ABSTRACTS SESSION
04-19-2023 8:15 AM - 9:15 AM

OPTIMAL MANAGEMENT OF HPV POSITIVE WOMEN IN PRIMARY HPV SCREENING PROGRAMS: EXAMPLE FROM NEW ZEALAND

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Introduction: Many countries transitioning to primary HPV testing are considering triage and management strategies to optimise colposcopy referrals. New Zealand will transition to five-yearly HPV testing with HPV16/18 genotyping and LBC triage for women with HPV not-16/18 in mid-2023, with colposcopy referral potentially delayed by two years in those aged<50 with HPV not-16/18 detected and negative/low-grade cytology. These women will receive follow-up at 12 months, and if they continue to have HPV (not-16/18) detected and LBC≤LSIL, are recommended to attend for follow-up in another 12 months, instead of being referred to colposcopy. In this analysis, we examine the health and resource implications.

Methods: Using the Policy1-Cervix model, we simulated a transition from 3-yearly cytology to 5-yearly HPV testing with HPV16/18 genotyping and LBC triage for HPV not-16/18 positive women, in the context of New Zealand's cervical screening and vaccination programmes. We compared cervical cancer cases and deaths, and colposcopy volumes over 2023-2032 for two management pathways for women with HPV (not 16/18) detected and LBC≤LSIL at both their primary and at 12-month follow-up visits: colposcopy referral at 12 months, and, repeat follow-up in 12 months and referral if still HPV-positive.

Results: Cumulatively over 2023-2032, delaying colposcopy in these women is predicted to prevent 15,667-19,445 colposcopies, but result in 8-11 excess cervical cancer diagnoses, and up to 1 additional cervical cancer death (compared to the alternative strategy which would result in 1,963-2,035 and 755-794 cases and deaths over the 10-year period). Referral at 12-month follow-up therefore implies 1,818-1,914 additional colposcopies per case averted and 22,320-22,721 additional colposcopies per death averted.

Conclusions: Delaying colposcopy in HPV not-16/18 positive women with negative/low-grade cytology by up to 24 months will substantially lower the number of HPV-positive women referred to colposcopy and would provide a more favourable balance of benefits to harms.

O003 / #566

Early Career Researchers
EARLY CAREER AWARD WINNERS: ORAL ABSTRACTS SESSION
04-19-2023 8:15 AM - 9:15 AM

INNOVATIVE HIGH-THROUGHPUT METABOLOMICS IN SCREENING, TRIAGE, DIAGNOSIS AND TREATMENT OF CERVICAL DISEASE

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Introduction: Given the high prevalence of HPV, reflex cytology is used in hrHPV positive women to select those that need to be referred to colposcopy. However, cytology only performs moderately and is prone to human error. Given the high prevalence of HPV infections with no carcinogenic potential and the mediocre performance of triage tests, novel technologies that offer rapid and simultaneous HPV testing and triaging of women at risk of precancer are needed. Screen-positive women referred to colposcopy often require multiple biopsies prior to local excision at a separate visit. Excision of precancer with clear margins is important as the risk of high-grade recurrence drops significantly in the case of positive margins. Innovative technologies are needed to offer bedside diagnosis at one-stop clinics minimising the risk of non-compliance, repeat visits and over-treatment.

Methods: Cytology and tissue samples were analysed with Rapid Evaporative Ionisation Mass Spectrometry (REIMS) and the diagnostic accuracy parameters were measured to investigate whether the technology could discriminate between women with or without a hrHPV infection and detect the presence of CIN2+ using cell pellets. We further assessed whether REIMS could detect precancerous changes in tissue.

Results: REIMS in the cell pellets achieved 94% sensitivity and 83% specificity (AUC: 91.6%) after comparing women with and without hrHPV infections (n=130) using a validated hrHPV assay as the gold standard(3). The technique also discriminated CIN2+ from normal with 91% sensitivity and 73% specificity (AUC: 86.7%). We have also tested the technology's feasibility in tissue biopsies taken during colposcopy, showing good discrimination between normal and CIN.

Conclusions: REIMS has the potential to offer a single, automated highly-accurate screening and triage test that will enhance disease prevention at reduced cost for the health services. The expansion of laser-REIMS in colposcopy could further enhance diagnostics and 'precision' treatment.

O004 / #848

Early Career Researchers
EARLY CAREER AWARD WINNERS: ORAL ABSTRACTS SESSION
04-19-2023 8:15 AM - 9:15 AM

ACTIVE SURVEILLANCE OF CIN2 AND RISK OF CERVICAL CANCER

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Introduction: Within the past decade many countries have implemented active surveillance of CIN2. However, the long-term consequences remain unclear. As active surveillance began in the 90's in Denmark, we used data from Danish registries to compare the risk of cervical cancer in women with CIN2 undergoing active surveillance or immediate loop electrosurgical excision procedure (LEEP).

Methods: We conducted a nationwide cohort study on all women diagnosed with incidental CIN2 in Denmark from 1998 to 2020. Women were categorized into active surveillance (i.e., record of subsequent punch biopsy/cytology) or immediate LEEP. We used a Weibull survival model for interval-censored time-to-event data to estimate the cumulative risk of cervical cancer in women undergoing active surveillance or immediate LEEP for CIN2. Estimates were adjusted for age, index cytology, calendar time, and residing area.

Results: We included 27,524 women with CIN2 of whom 15,041 (55%) had immediate LEEP and 12,483 (45%) underwent active surveillance. During follow-up, we identified 104 cases of cervical cancer: 48 (46%) in the LEEP group and 56 (54%) in the active surveillance group. The cumulative risk of cervical cancer was comparable during the first 2 years of follow-up. Hereafter, the cumulative risk remained stable in the LEEP (0.60% (95% CI 0.41-0.57)), whereas it increased in the active surveillance group reaching 1.66% (95% CI 1.30-2.02) after 10 years of follow-up corresponding to a nearly 3-fold increase. The tendency of increased risk of cancer among women undergoing active surveillance for CIN2 continued after 10 years, but the number of events after 10 years was limited in both groups.

Conclusions: Active surveillance for CIN2 is associated with increased risk of cervical cancer compared to immediate LEEP. These findings demonstrate the importance of increased surveillance of these women.

O005 / #684

Early Career Researchers
EARLY CAREER AWARD WINNERS: ORAL ABSTRACTS SESSION
04-19-2023 8:15 AM - 9:15 AM

TISSUE-RESIDENT MEMORY T CELL RESPONSES IN HIV+ PATIENTS WITH HUMAN PAPILLOMAVIRUS-DRIVEN ANAL DYSPLASIA

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Introduction: Despite antiretroviral therapy, HIV+ men who have sex with men (MSM) have poor HPV clearance, thereby increasing their risk of developing high-grade squamous intraepithelial lesions (HSIL), an anal cancer precursor. High proportions of $CD103^+CD8^+$ tissue-resident memory T cells ($CD8^+$ T_{RMs}) are associated with increased survival in HPV-associated oropharyngeal cancer. We aim to delineate T_{RM} immunity responses in HIV+MSM and HIV-MSM that result in HPV clearance.

Methods: To determine the effects of HIV co-infection with HPV16 on T-cell profile, quantitative and qualitative analysis using multispectral microscopy was performed on 67 MSM anal biopsies. Using spatial transcriptomics, differences in signalling pathways between pre-cancerous (CL) and peri-lesion (PL) regions were identified in HSIL regression (R) or non-regressive disease (NR).

Results: While $CD8^+$ T cell numbers were similar in both cohorts, lower $CD4^+$ T cell numbers and $CD8^+$ T_{RMs} were evident in HIV+MSM compared to HIV-MSM (Fig.1). In HPV16+HSIL, $CD103^-CD4^+$ T cells and $CD103^+CD4^+$ T cell ($CD4^+$ T_{RM}) numbers were lower in HIV+MSM compared to HIV-MSM (Fig.2). In both cohorts, total $CD8^+$ T cell counts positively correlated with $CD4^+$ T cells (HIV+: $r=0.504, p<0.01$; HIV-: $r=0.617, p<0.001$) and $CD8^+$ T_{RMs} (HIV+: $r=0.779, p<0.0001$; HIV-: $r=0.747, p<0.0001$). Only in HIV+MSM did $CD4^+$ T_{RMs} positively correlate with $CD8^+$ T_{RMs} ($r=0.45; p=0.0059$). In PL, 144 (NR) and 218 (R) genes were upregulated. In DL, 140 (NR) and 73 (R) genes were upregulated. Investigation of canonical gene sets found immune response to tumour cell signals in R compared to MHC regulation and viral gene expression signals in

NR.

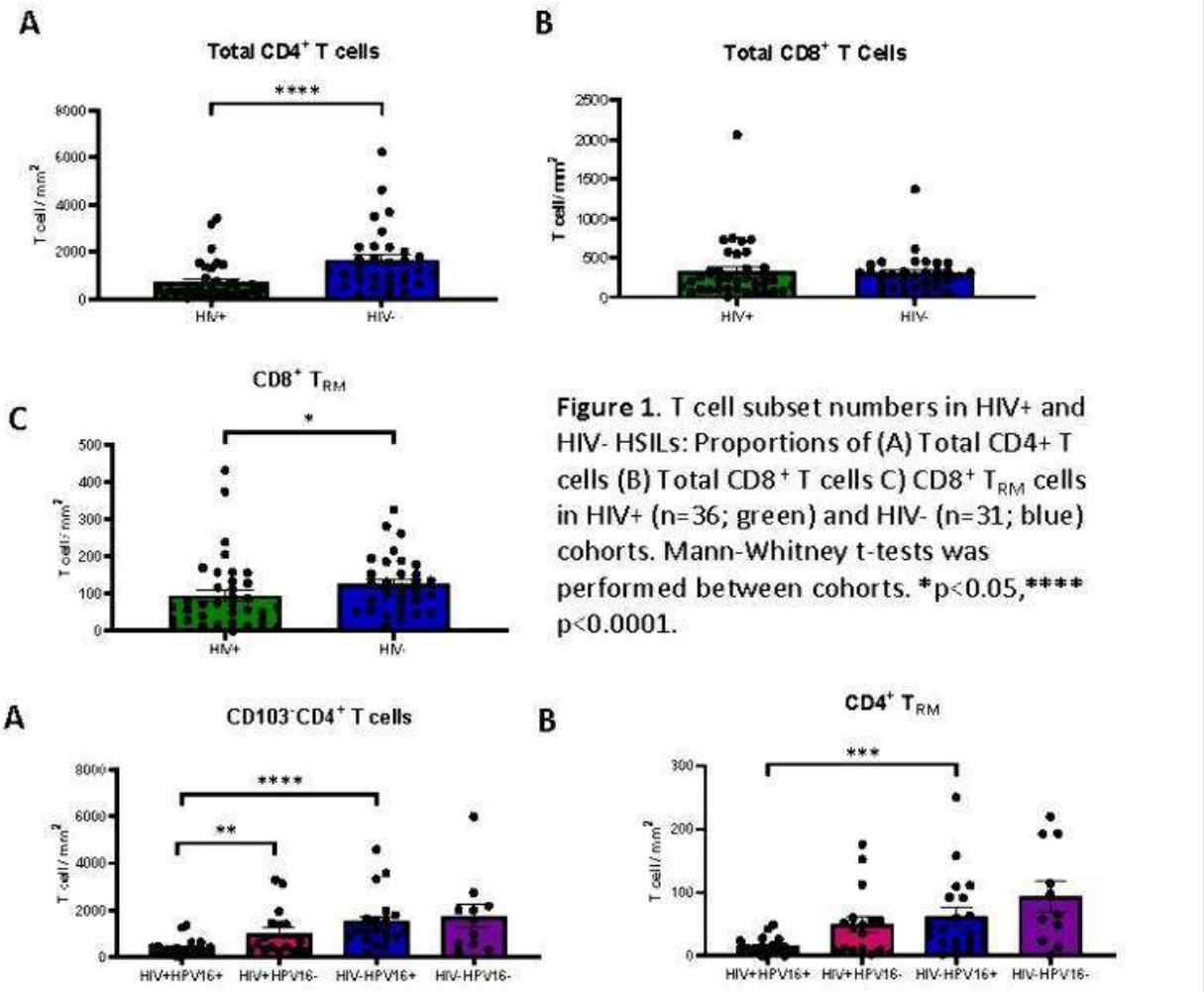

Figure 1. T cell subset numbers in HIV+ and HIV- HSILs: Proportions of (A) Total CD4+ T cells (B) Total CD8+ T cells C) CD8+ T_{RM} cells in HIV+ (n=36; green) and HIV- (n=31; blue) cohorts. Mann-Whitney t-tests was performed between cohorts. *p<0.05,**** p<0.0001.

Figure 2. T cell subset numbers in HIV+ and HIV- HSILs with or without HPV16: The proportions of A) CD103-CD4+ classical T cells and B) CD4+ T_{RM}s within the four main cohorts: HIV+HPV16+ : n=19 (green), HIV+ HPV16- : n=17 (pink), HIV-HPV16+: n=20 (blue); HIV-HPV16-: n=11 (purple). Mann-Whitney t-tests was performed between cohorts. **p<0.005,***p<0.0005,****p<0.0001.

Conclusions: HIV infection is characterized by low CD8+ T_{RM}s, CD4+ T_{RM}s, and CD103-CD4+ T cell numbers. Low CD8+ T_{RM} numbers may be linked to CD4+ T cell tissue lymphopenia resulting in poor HPV clearance and HSIL progression. The immune response signals in R but not NR suggest differential cellular and molecular signals in response to HPV infection.

O006 / #676

Early Career Researchers
EARLY CAREER AWARD WINNERS: ORAL ABSTRACTS SESSION
04-19-2023 8:15 AM - 9:15 AM

VIRAL WHOLE-GENOME SEQUENCING REVEALS HIGH VARIATIONS IN APOBEC3-EDITING BETWEEN HPV RISK CATEGORIES

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Introduction: Little is known about differences among HPV types regarding genetic diversity and APOBEC3-induced mutations between risk categories (low-risk HPVs [lrHPVs] and high-risk HPVs [hrHPVs]). The role of APOBEC3-induced mutations in HPV-driven carcinogenesis is discussed and whether they could contribute to the carcinogenic potential of some HPV types more than others is yet to be explored.

Methods: Using a capture-based next-generation sequencing, 156 HPV whole-genome sequences covering 43 HPV types were produced from paired cervical and anal swabs of 30 Togolese female sex workers sampled in 2017. Genomes or genes were considered edited by APOBEC3 when the $Ratio^{C>T}$ between C>T mutations in all TCW nucleotide motifs and C>T mutations in any other nucleotide context was above 2.

Results: High variations in genetic diversity among HPV types were observed. The E6 gene was less conserved in lrHPVs, in contrast to hrHPVs (p=0·009). APOBEC3-induced mutations were found to be more common in lrHPVs than in hrHPVs (p=0·005). To generalize these observations, we conducted a similar analysis using a large sequence dataset containing the most prevalent lrHPVs (HPV6 and HPV11, n=375) and hrHPVs (HPV16 and HPV18, n=777) types retrieved from the GenBank database. By performing 100 replicates corresponding to a random draw of 50 sequences, equally distributed, we observed that HPV6 and HPV11 significantly accumulated more APOBEC3-induced mutations than HPV16 and HPV18. APOBEC3-induced mutations were highly found in E4 and E6 genes for lrHPVs 6 and 11, with a $Ratio^{C>T} > 2$ in 91·9% and in 726% of the sequences, respectively, but were almost absent in hrHPVs 16 and 18.

Conclusions: Our findings unraveled striking genetic differences between lrHPVs and hrHPVs. Overall, lrHPVs accumulated APOBEC3-induced mutations at a higher rate compared to hrHPVs. These various rates of APOBEC3-induced mutations could contribute to different oncogenic potentials between HPV types and risk categories.

O007 / #1128

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: MODELLING - HEALTH ECONOMICS AND MATHEMATICAL MODELING 1
04-19-2023 8:15 AM - 9:15 AM

COST-EFFECTIVENESS OF NONAVALENT HPV VACCINATION AND HPV-DNA-BASED CERVICAL CANCER SCREENING IN SOUTH AFRICA

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Introduction: The WHO set ambitious targets to achieve cervical cancer (CxCa) elimination within the next century. Elimination may be reached if vaccination, screening, and linkage to treatment coverage of 90-90-90 are achieved and maintained and if nonavalent vaccination and HPV-DNA-based primary screening are performed. However, South Africa does not use either of these technologies and the question remains whether they are cost-effective.

Methods: We used MicroCOSM-HPV, an individual-based transmission dynamic model that simulates infection with both HIV and HPV, to estimate the impact and cost-effectiveness of several alternative screening and vaccination scenarios. Previously estimated costs of elements in the CxCa care cascade (such as bivalent vaccination, Pap screening, and cancer treatment) were inflated to 2022 values, and the cost at which nonavalent vaccination would be affordable determined using a threshold analysis based on incremental cost per DALY averted (costs and life years discounted at 3%).

Results: We estimate that if current rates of coverage of bivalent vaccination (~80%) and Pap-smear screening (~50%) and linkage to treatment (~50%) are maintained, age-standardised CxCa incidence will reduce from 50 to 12 per 100,000 women between 2023 and 2120. Changing to HPV-DNA-based screening could reduce CxCa incidence from 40 to 25 per 100,000 in 2040 – a cost-saving strategy. Nonavalent vaccination will be cost-saving over the next century if the cost of a dose can be negotiated to be the same as the bivalent vaccine (~$13). Using current prevention strategies to establish willingness-to-pay thresholds, nonavalent vaccination will be cost-effective at a maximum price of $39 per dose.

Conclusions: Switching from mainly Pap smear screening to HPV-DNA-based primary screening strategies will be cost-saving in South Africa. Nonavalent vaccination can be cost-effective at reduced prices. Both of these technologies will be required for South Africa to get closer to CxCa elimination in the next century.

O008 / #576

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: MODELLING - HEALTH ECONOMICS AND MATHEMATICAL MODELING 1
04-19-2023 8:15 AM - 9:15 AM

HPV VACCINE ATTITUDES ON TWITTER DURING THE COVID-19 PANDEMIC: A SOCIAL NETWORK, TOPIC, AND SENTIMENT ANALYSIS

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Introduction: The COVID-19 pandemic has increased online interactions and the spread of misinformation. Some researchers anticipate benefits stemming from improved public awareness of the value of vaccines while others worry that concerns around vaccine development and mandates may have damaged public trust. There is a need to understand whether the COVID-19 pandemic, vaccine development, and vaccine mandates have influenced HPV vaccine attitudes and sentiments to inform health communication strategies.

Methods: We collected 596,987 global English-language tweets from January 2019-May 2021 using Twitter's Academic Research Product track. First, we determined vaccine confident and hesitant networks discussing HPV immunization using social network analysis. Second, we used a neural network approach to natural language processing to measure narratives and sentiments pertaining to HPV immunization.

Results: Most of the tweets in the vaccine hesitant network were negative (54.9%) and focused on safety concerns surrounding the HPV vaccine while most of the tweets in the vaccine confident network were neutral (51.6%) and emphasized the health benefits of vaccination. A growth in negative sentiments among the vaccine hesitant network corresponded with legislative efforts in New York State to mandate the HPV vaccine for public school students in 2019 and the WHO declaration of COVID-19 as a Global Health Emergency in 2020. In the vaccine confident network, the number of tweets concerning the HPV vaccine decreased during the COVID-19 pandemic but in both vaccine hesitant and confident networks, the sentiments and themes of the HPV vaccine were unchanged.

Figure 1: Full network of HPV Immunization Tweets

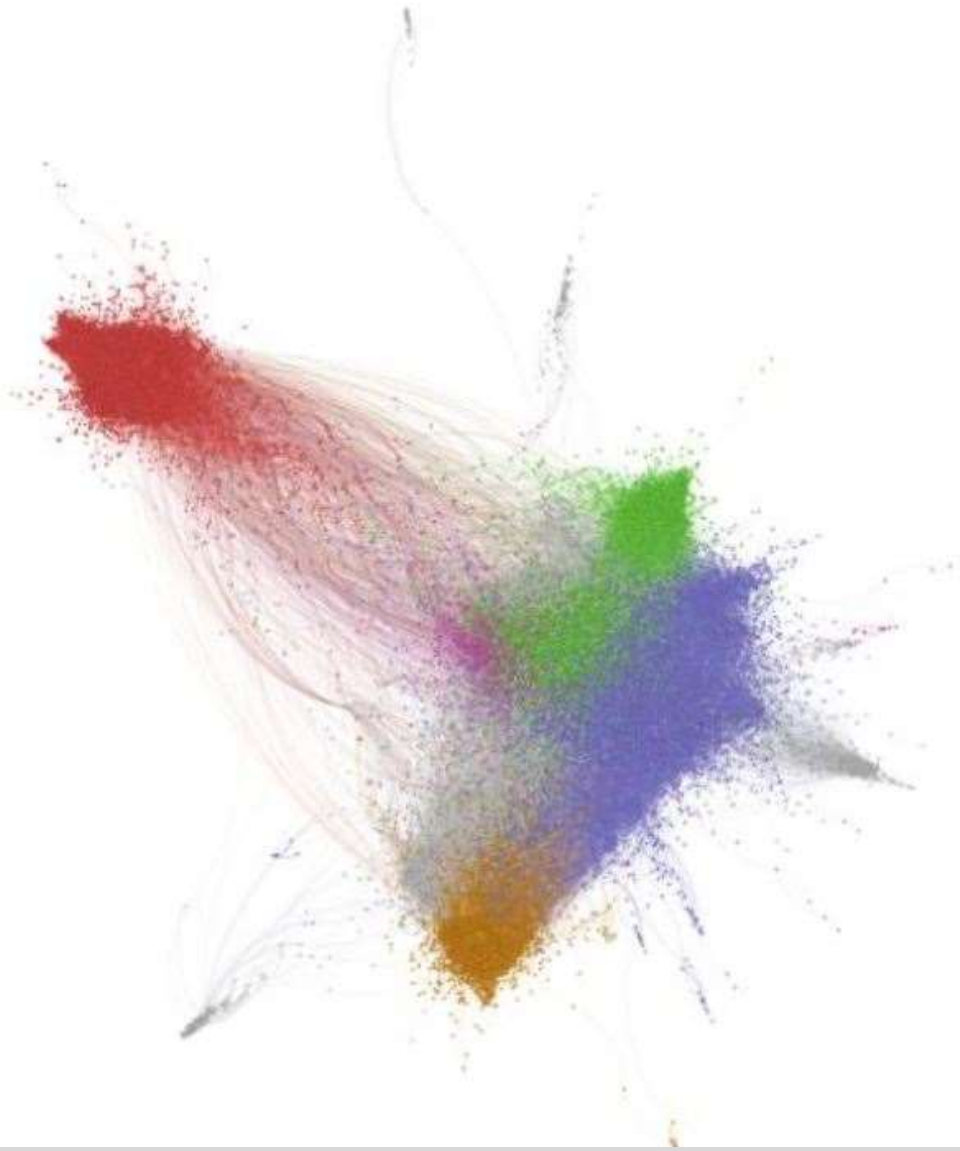
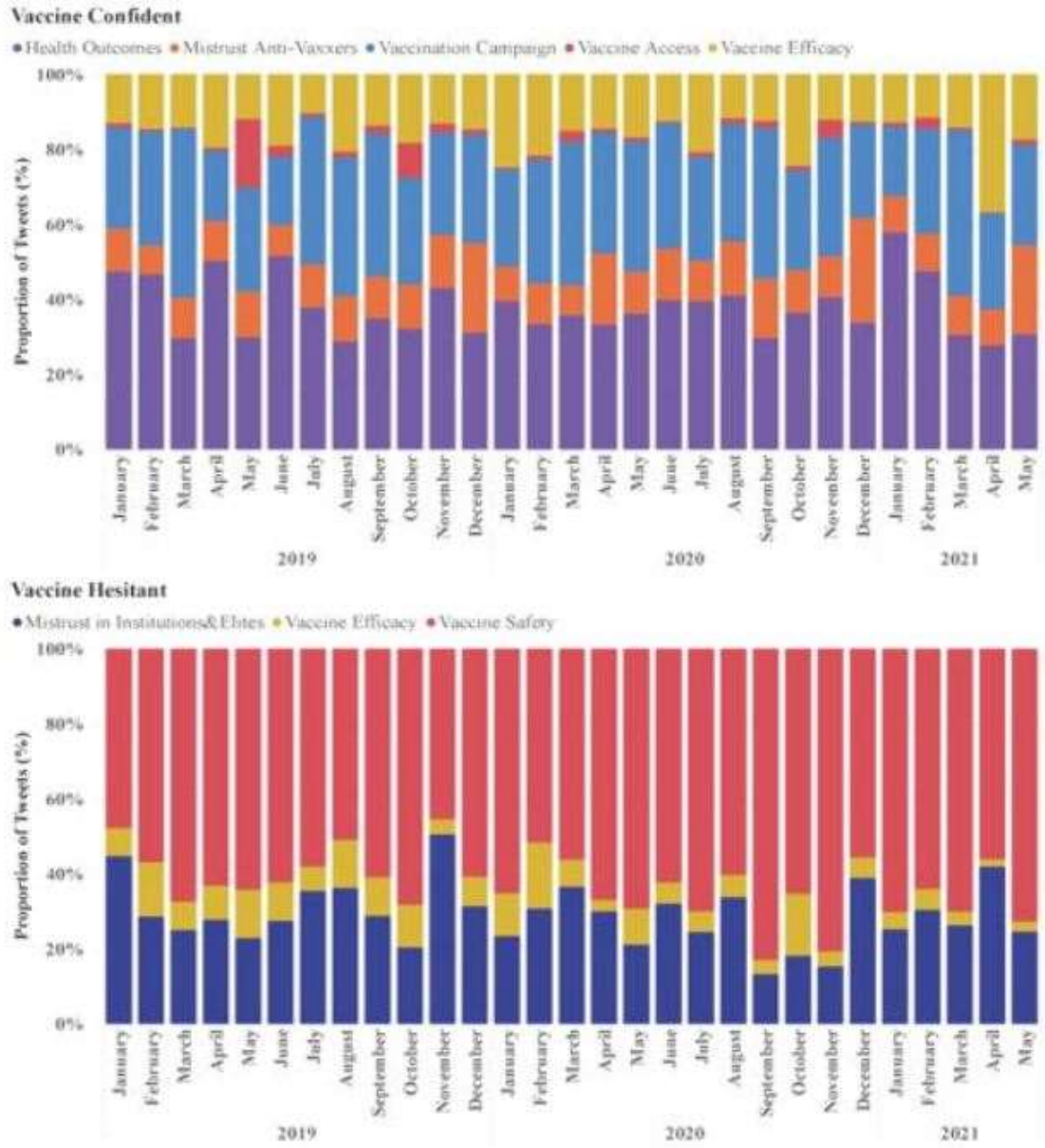


Figure 2: Occurrence of HPV Immunization Themes by Vaccine Confident and Vaccine Hesitant Networks



Conclusions: Although we did not observe a difference in narratives or sentiments surrounding the HPV vaccine during the COVID-19 pandemic, we observed a decrease in focus on the HPV vaccine among vaccine confident groups. As routine vaccine catch-up programs restart, there is a need to invest in health communication online to raise public awareness about the benefits and safety of the HPV vaccine.

O009 / #535

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: MODELLING - HEALTH ECONOMICS AND MATHEMATICAL MODELING 1
04-19-2023 8:15 AM - 9:15 AM

COST-EFFECTIVENESS OF PRIMARY HPV TRIAGE APPROACHES AMONG VACCINATED WOMEN IN NORWAY: A MODEL-BASED ANALYSIS

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Introduction: The Norwegian organized cervical cancer (CC) screening program involves three-yearly cytology starting at age 25, followed by five-yearly HPV testing for women aged 34–69 years. As Norway considers revising guidelines following their first adolescent-vaccinated cohort entering screening in 2022, we analyzed the impact and cost-effectiveness of alternative primary HPV triage approaches for women entering screening in 2023.

Methods: We used a multi-modeling approach that captured HPV transmission and cervical carcinogenesis to estimate the CC screening and treatment costs per person, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratios (ICERs) associated with alternative triage scenarios for primary HPV testing compared with a status-quo scenario for women born in 1998 (i.e., age 25 in 2023). We examined 72 scenarios that varied the inclusion and management of women who tested positive for alternative grouped HPV genotypes to either direct colposcopy referral or active surveillance (genotype groups: 16/18, 16/18/45, or 16/18/31/33/45/52/58) as well as the age that women switch from cytology to HPV-based screening (age 25, 28, 31, or 34 years) (Figure 1).

Figure 1. Analyzed scenarios.

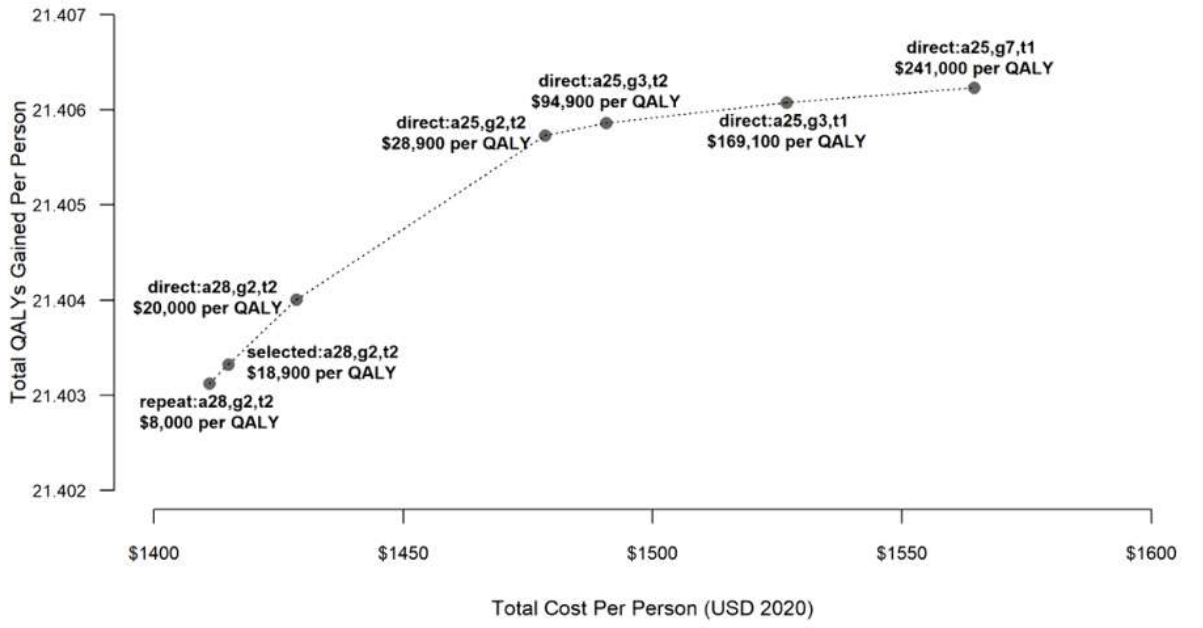
Strategy	Variations in age to switch from cytology to HPV testing	Genotyping (referred to as 'selected genotypes')	Triage HPV+ for selected genotypes and cytology normal	Triage HPV+ for non-selected genotypes and cytology low-grade	Variations in wait time for re-testing HPV+ selected / non-selected genotypes risk groups (months)
repeat:g2	25; 28; 31; 34	16/18	Repeat HPV	Repeat HPV	current: 12 / 24; extended:18 / 36
repeat:g3	25; 28; 31; 34	16/18/45	Repeat HPV	Repeat HPV	current: 12 / 24; extended:18 / 36
repeat:g7	25; 28; 31; 34	16/18/31/33/45/54/58	Repeat HPV	Repeat HPV	current: 12 / 24; extended:18 / 36
direct:g2	25; 28; 31; 34	16/18	Direct colposcopy	Direct colposcopy	current: NA / 24; extended: NA / 36
direct:g3	25; 28; 31; 34	16/18/45	Direct colposcopy	Direct colposcopy	current: NA / 24; extended: NA / 36
direct:g7	25; 28; 31; 34	16/18/31/33/45/54/58	Direct colposcopy	Direct colposcopy	current: NA / 24; extended: NA / 36
selected:g2	25; 28; 31; 34	16/18	Direct colposcopy	Repeat HPV	current: 12 / 24; extended:18 / 36
selected:g3	25; 28; 31; 34	16/18/45	Direct colposcopy	Repeat HPV	current: 12 / 24; extended:18 / 36
selected:g7	25; 28; 31; 34	16/18/31/33/45/54/58	Direct colposcopy	Repeat HPV	current: 12 / 24; extended:18 / 36

Note: direct = all HPV+ genotypes with normal or low-grade cytology sent to direct colposcopy; g = number of genotypes included; HPV = human papillomavirus; intermediate-risk = positive for the strategy-specific HPV genotypes and reflex-cytology-negative; lower-risk = negative for strategy-specific HPV genotypes but positive for other high-risk HPV types and reflex-cytology-normal; NA = not applicable; repeat = all HPV+ genotypes repeat HPV test; selected = only selected HPV+ genotypes sent to direct colposcopy and non-selected HPV+ genotypes repeat HPV test.

Results: Given benchmarks for severity-specific cost-effectiveness thresholds in Norway, we found that the preferred strategy for vaccinated women aged 25 years in 2023 involved starting primary HPV-based screening at age 25 with direct colposcopy referral for 16/18-positive women alongside extended re-testing wait times for women referred to triage (ICER of $28,900 per QALY gained) (Figure 2). Strategies directly referring women who test positive for additional genotypes to colposcopy yielded ICERs above the maximum threshold in Norway ($90,000 per QALY gained), while the currently-recommended strategy (switching to primary HPV testing at age 34) was dominated and therefore not considered efficient or

cost-effective.

Figure 2. Cost-effectiveness results for alternative HPV triage strategies for women vaccinated against HPV infections in adolescence.



Note: Only efficient strategies are included (i.e., strategies along the efficiency frontier). The 'repeat:a28,g2,t2' strategy is compared to no intervention, i.e., natural history, but this strategy is excluded from the graph. ICERs are rounded to the nearest hundred. All costs are discounted (4% annually) and expressed in 2020 USD (USD1 = NOK9.4004). a = age that women switch from cytology to HPV-based screening; direct = all HPV+ genotypes with normal or low-grade cytology sent to direct colposcopy; g = number of genotypes included; HPV = human papillomavirus; QALY = quality-adjusted life-years; repeat = all HPV+ genotypes repeat HPV test; selected = only selected HPV+ genotypes sent to direct colposcopy and non-selected HPV+ genotypes repeat HPV test; t = wait time for re-testing if HPV+: (1) 12 months for selected genotypes and 24 months for non-selected genotypes, (2) 18 months for selected genotypes and 36 months for non-selected genotypes.

Conclusions: The Norwegian program should consider transitioning the program away from using primary cytology-based screening towards exclusively primary HPV-based screening and use triage approaches to improve program effectiveness and efficiency.

O010 / #1147

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: MODELLING - HEALTH ECONOMICS AND MATHEMATICAL MODELING 1
04-19-2023 8:15 AM - 9:15 AM

HPV VACCINATION IN MIDDLE INCOME COUNTRIES INELIGIBLE FOR GAVI SUPPORT: EFFECTIVENESS, COST-EFFECTIVENESS, AND RETURN ON INVESTMENT IN VIETNAM

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Introduction: The Vietnam Ministry of Health and UNFPA are reassessing the cost-effectiveness of HPV vaccination and we aimed to estimate updated effectiveness, cost-effectiveness, and return-on-investment (ROI).

Methods: The extensively validated platform ('Policy1-Cervix') was calibrated to Vietnam. HPV vaccination was considered by sex, dose-schedule, and price given two alternate background situations for other cervical cancer control interventions: i) current screening coverage and precancer/cancer treatment access ('status quo') and ii) 10-yearly HPV-screen-triage-and-treat for women 30-50 years implemented with 70% coverage and 90% of women with a cancer diagnosis offered adequate treatment and care ('WHO 2030 targets'). We assessed use of quadrivalent vaccine ('HPV4') in a female-only program assuming a 2-dose schedule and a vaccine price-per-dose of ~1.5X and ~3X the Gavi-supported price (i.e. US$6.5 and US$15).

Results: Under the status quo, female-only two-dose HPV4 vaccination was cost-effective up to 3X Gavi prices regardless of coverage reached (ICER<US$300/LYS, CE-threshold:1GDPpc of US$3640). At 90% coverage, ~149,000 cases and ~109,000 deaths could be prevented by 2100 and the 4/100,000 threshold would be reached by 2078. If screen-triage-and-treat and cancer treatment were scaled up to WHO 2030 targets, HPV4 vaccination continued to be cost-effective regardless of coverage, up to 3X Gavi-supported price (ICER=US$<1,600/LYS). The triple-intervention could prevent ~286,000 cases and ~302,000 deaths by 2100 and reach elimination by 2052. An estimated US$8.0-$9.5 and US$6.5-7.7 will be returned to the economy for every-dollar invested in HPV4 vaccination alone or the triple intervention at WHO 2030 targets, respectively, in Vietnam through 2100 (with vaccine at 3X Gavi prices).

Conclusions: At up to 3X Gavi-price and two-doses, female-only HPV4 vaccination would be cost-effective in Vietnam either at current or scaled up screening and treatment. However, implementing HPV4 vaccination combined with screening and treatment scale-up could prevent substantially more cases and deaths, lead to earlier elimination, and would further improve ROI.

O011 / #1476

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: MODELLING - HEALTH ECONOMICS AND MATHEMATICAL MODELING 1
04-19-2023 8:15 AM - 9:15 AM

PROJECTED HEALTH IMPACT AND COST-EFFECTIVENESS OF HPV VACCINATION IN KENYA: A MODELLING STUDY

Valerian Mwenda[1], Joan Paula Malenya[1], Mary Nyangasi[1], Rose Jalango[2], Christine Miano[2], Edward Kariithi[3], Vincent Were[4], Andrew Clark[5]
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Introduction: Cervical cancer is the leading cause of cancer deaths among women in Kenya, accounting for approximately 12% of deaths. Kenya launched HPV vaccination in 2019, targeting 10-year old girls, and subseqently extended vaccination to 10-14 year old girls. The country will enter the accelerated phase of transitioning from Gavi support from 2023. We conducted HPV vaccination economic modelling study to inform policy planning within Kenya.

Methods: We adapted a proportional outcomes model (UNIVAC, version 1.5) to assess health impact and cost-effectiveness of various HPV vaccination scenerios in Kenya: four vaccine types (Cervarix, Cecolin, Gardasil-4 and Gardasil-9); government and societal perspectives; multi-age cohort of 10-year old girls and a one-time catch-up; focus period 2022-2030; combined delivery strategy (80% school-based, 15% health-facilty and 5% community outreach). Health outcomes, including cervical cancer cases, hospitalizations, deaths, and disability-adjusted life years (DALYs) were compared between vaccination and no vaccination scenerios. All costs and outcomes were discounted at 3% and monetary units are reported in USD 2021.

Results: Depending on the vaccined type, cervical cancer cases averted through HPV vaccination range from 140,906 to 202,085 (Gradasil-9), deaths averted range from 99,596 to 142,839 (Gardasil-9) and the vaccine program costs over the entire period would range from $81-110 million. Cost per DALY averted ranges from $7-$55 using the government perspective. Using the societal perspective, the vaccination program would result in cost-saving for all vaccine types.

Conclusions: HPV vaccination scale-up would be cost-effective for Kenya. Adequate financing is necessary in the context of upcoming transition, for the country to move advance towards cervical cancer elimination.

O012 / #490

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: MODELLING - HEALTH ECONOMICS AND MATHEMATICAL MODELING 1
04-19-2023 8:15 AM - 9:15 AM

THE COST OF ELIMINATING CERVICAL CANCER IN A LOWER MIDDLE-INCOME COUNTRY: A SCENARIO ANALYSIS FOR THE REPUBLIC OF TANZANIA

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Introduction: The WHO-SUCCESS C4P costing tool has been developed for countries to plan and estimate the costs of introducing upgraded methods of screening and precancer treatment from the perspective of the public health sector. The tool allows the users to compare the costs of different scenarios and assists government planners to decide among different options. We previously estimated the costs of the national cervical cancer strategic plan in Tanzania, a lower-middle income country. We are adding to this analysis by conducting various scenarios for comparison.

Methods: First, the cost of implementing the national plan for screening and treatment in Tanzania was estimated. Secondly, the cost of alternative scenarios were estimated: 1) increasing the proportion of screening with the modality of HPV DNA testing and lowering the proportion with VIA; 2) increasing the proportion of treatment of precancerous lesions through thermal ablation; and 3) varying key assumptions for referral dropout. Data were sourced from literature and local consultation, and entered into the tool for target populations, HIV prevalence, epidemiology, service utilization, available infrastructure, and prices and quantities used of resource used.

Results: The total financial and economic costs of the planned cervical cancer screening and pre-cancer treatment programme during 2020-2024 are projected to be US$29.2 million and US$47.6 million, respectively. The financial and economic costs per woman screened for cervical cancer with 10% of total screening conducted with HPV DNA testing, are, on average, US$4.02 and US$5.83, respectively. In comparison, for example, a scenario of increasing HPV DNA testing to 50% of all screening would result in costs of $5.05 and $6.79, respectively.

Conclusions: As countries consider WHO recommendations for high-performance primary screening modalities, the WHO-SUCCESS C4P costing tool can assist national cervical cancer programmes to estimate monetary resources needed for various implementation strategies of screening and pre-cancer treatment.

O013 / #670

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SCREENING, DIAGNOSIS, AND MANAGEMENT OF HPV-RELATED NON-CERVICAL ANOGENITAL CANCERS
04-19-2023 8:15 AM - 9:15 AM

METHYLATION MARKERS ON ANAL SMEARS ARE ASSOCIATED WITH HIGHER ANAL CANCER RISK

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Introduction: Molecular markers stratifying anal cancer risk are needed. Host-cell DNA methylation markers (ZNF582 and ASCL1) have been associated to AIN3 and anal carcinoma in a cross-sectional study on biopsies from HIV-infected men.

Methods: This is an ancillary prospective study of the French COAIN3 cohort, including patients with AIN3 history. Methylation levels were expressed in log2(ΔΔddct). C/D time dependent AUC was estimated to assess discrimination of methylation markers. Similarly to Youden Index, methylation thresholds were determined for a one year follow-up.

Results: Methylation analyses were successful for 424 patients (60% male, median age=59 years, 45% HIV-positive, median follow-up=36 months [IQR=32-40]). Twenty patients evolved through anal cancer. A higher methylation level of each gene was significantly associated with HSIL cytology, HPV16 or hrHPV detection and p16/ki67 positivity ($p<0.01$ for all, Wilcoxon test) on the same anal smear. Higher methylation levels were associated with higher anal cancer risk, in univariate analysis (HR=1.34 [1.15-1.56], $p<0.001$ for ZNF582 and HR=1.35 [1.12-1.63], $p=0.002$ for ASCL1, Cox model). In our study, C/D AUC at one year were 82% (82-95) and 80% (64-99) for ZNF582 and ASCL1, respectively. On our dataset, thresholds of 0.62 and 1.95 could be defined for ZNF582 and ASCL1, respectively, with corresponding sensitivities of 86% and 78% and specificities of 63% and 67%. Regarding cancer risk,

ZNF582 methylation >0.62 had a HR=5.02 (1.67-15.1,p=0.004) and ASCL1 methylation >1.95 a HR=6.07 (2.02-18.3,p=0.001). At least one methylation marker above the corresponding threshold was associated with higher risk of cancer in univariate analysis with a HR=4.19 (1.39-12.6, p=0.011).

Conclusions: This is the first study evaluating the potential role of methylation markers for anal cancer risk stratification in a real-life cohort on non-invasive sample such as anal smears. Further studies are needed to confirm these markers prognostic value, notably in a less “at-risk” population, to define methylation thresholds that can be generalized.

O014 / #854

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SCREENING, DIAGNOSIS, AND MANAGEMENT OF HPV-RELATED NON-CERVICAL ANOGENITAL CANCERS
04-19-2023 8:15 AM - 9:15 AM

INCIDENCE, PERSISTENCE AND CLEARANCE OF PENILE HIGH-RISK HUMAN PAPILLOMAVIRUS AMONG RWANDAN MEN WHO HAVE SEX WITH MEN

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Introduction: Men who have sex with men (MSM) are at high risk of anogenital HPV infection. High-risk HPV (hrHPV) is responsible for over 50% of penile cancer, with increasing prevalence globally including in Rwanda. Little is known about hrHPV among MSM living in low-and-middle income countries, therefore we aimed to determine the incidence, persistence and clearance of penile hrHPV among Rwandan MSM.

Methods: We analyzed data from 345 MSM, aged ≥18 years who participated in a study to assess the prevalence and incidence of anogenital high-risk HPV (hrHPV). In five visits (6-12 months apart), we followed the cohort and collected penile and anal PreservCyt specimens for HPV testing, blood for HIV testing, socio-demographic and behavioral variables. HPV testing (15 individual HPV types) was performed using the Ampfire genotyping assay. Overall and type-specific penile hrHPV incidence and clearance /1000 person-months, persistence and incidence-persistence (proportions) were computed and compared by HIV status.

Results: The mean age was 27.7±6.7 years and 19.4% were living with HIV. The overall penile hrHPV incidence was 34.8/1,000 person-months (95% CI: 29.1, 41.8); HPV16 followed by HPV59 had the highest incidence rates (11.7: 9.26, 14.9 and 6.1: 4.52, 8.39, respectively). The overall clearance was 23.5/1,000 person-months (17.4, 31.6); HPV18 had the lowest clearance rate and HPV68 the highest (37.8: 17.0, 84.0 and 92:4 44.0, 193.7, respectively). Overall persistence was 47.5%; HPV66/52/16 had the highest proportions (33.3%, 30.8% and 29.2%, respectively) and overall incidence-persistence (newly detected genotypes) was 46.6%; HPV33/31/16 had the highest proportions (53.8%, 46.7% and 42.6%, respectively), Table 1. No differences were found (all outcomes) by HIV status except for HPV45, for which MSM with HIV had higher incidence rates (IRR: 3.63 [1.41,

9.38]).

Table 1: Overall incidence, clearance, persistence and incidence-persistence among Rwandan MSM

HPV Type	Incidence/1000 Person-Months (95% CI)	Clearance/1000 Person-Months (95% CI)	Persistence	Incidence-Persistence
HPV 16	11.7 (9.26, 14.9)	45.8 (27.6, 76.0)	29.2%	42.6%
HPV 18	4.06 (2.79, 5.92)	37.8 (17.0, 84.0)	25.0%	33.3%
HPV 31	4.61 (3.22, 6.60)	56.2 (26.8, 117.9)	23.1%	46.7%
HPV 33	1.94 (1.13, 3.34)	77.9 (43.1, 140.7)	15.4%	53.8%
HPV 35	5.65 (4.09, 7.80)	62.4 (28.0, 138.8)	16.7%	32.4%
HPV 39	4.48 (3.12, 6.45)	91.9 (53.4, 158.3)	5.6%	20.7%
HPV 45	2.69 (1.70, 4.27)	50.9 (22.9, 113.4)	22.2%	33.3%
HPV 51	5.57 (4.00, 7.75)	56.2 (33.9, 93.2)	12.5%	31.4%
HPV 52	4.43 (3.08, 6.38)	51.5 (24.6, 108.1)	30.8%	24.1%
HPV 53	4.68 (3.29, 6.66)	51.3 (19.2, 136.6)	18.2%	41.9%
HPV 56	3.29 (2.17, 5.00)	58.4 (29.2, 116.8)	21.4%	18.2%
HPV 58	3.24 (2.14, 4.92)	54.8 (22.8, 131.6)	36.4%	22.7%
HPV 59	6.16 (4.52, 8.39)	53.0 (26.5, 106.0)	9.1%	22.5%
HPV 66	3.97 (2.71, 5.84)	46.9 (24.4, 90.0)	33.3%	30.8%
HPV 68	3.28 (2.16, 4.99)	92.4 (44.0, 193.7)	10.0%	18.2%
Any high-risk HPV	34.8 (29.1, 41.8)	23.5 (17.4, 31.6)	47.5%	46.6%

Conclusions: We found high rates of penile hrHPV incidence and proportions of persistence/incidence-persistence among Rwandan MSM. This highlights the importance of preventive strategies for HPV-associated anogenital cancers.

O015 / #507

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SCREENING, DIAGNOSIS, AND MANAGEMENT OF HPV-RELATED NON-CERVICAL ANOGENITAL CANCERS
04-19-2023 8:15 AM - 9:15 AM

ANAL HISTOLOGIC HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS (HHSIL) IN WOMEN LIVING WITH HIV (WLHIV)-- 2 YEAR OUTCOMES AND SCREENING IMPLICATIONS: AIDS MALIGNANCY CONSORTIUM (AMC) 084

Elizabeth Stier[1], Himanshu Joshi[2], Mayuri Jain[2], Teresa Darragh[3], Jeannette Lee[4], Joel Palefsky[3], Naomi Jay[3], Mark Einstein[5], Timothy Wilkin[6], Elizabeth Chiao[7]
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Introduction: Detection and treatment of anal hHSIL is essential for anal cancer prevention. Anal high-risk (hr)HPV infection is associated with prevalent anal hHSIL in WLHIV. However, it is unknown whether anal hrHPV or anal cytology (anal-cyt) is predictive of 2-year detection or absence of anal hHSIL.

Methods: Evaluations over 2 years included annual anal hrHPV testing, anal-cyt and concurrent high-resolution anoscopy, where >2 biopsies were obtained. The baseline prevalence was estimated as a ratio of number of participants having hHSIL at baseline to the number of total participants. 2-year cumulative incidence (2y-cum-inc) of anal hHSIL by hrHPV and anal-cyt results was visualized as Weibull cumulative incidence curves by combining the prevalent and incident anal hHSIL cases.

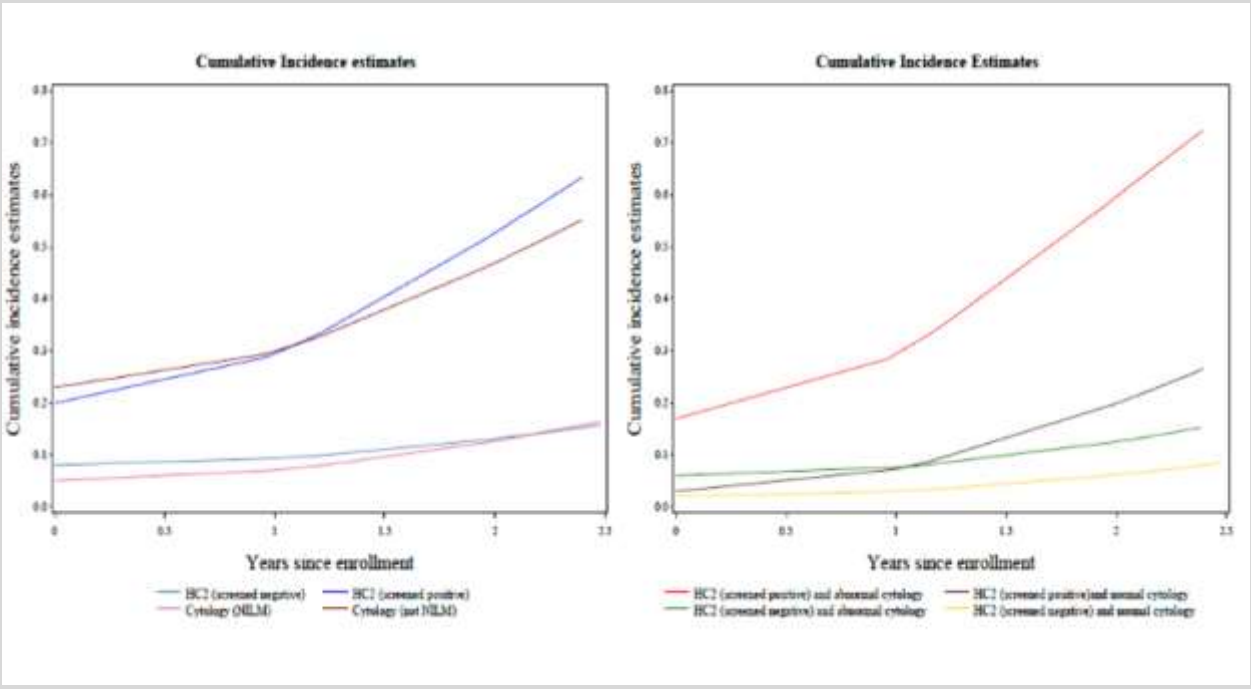
Results: 229 (89%) of 256 enrolled WLHIV having complete baseline anal assessment data were included in this analysis. Mean age was 50, 62% were Black and 22% were Hispanic. Prevalent anal hHSIL and incident anal hHSIL were detected in 64 (28%) and 19 (17%) women respectively over 223.3 person-years (py) of follow-up. As shown in the cumulative incidence curves, occurrence of 2y-cum-inc anal hHSIL did not differ significantly between participants with baseline anal hrHPV positivity and those with abnormal anal-cyt (0.54(95%CI:0.36-0.72) and 0.47(95%CI:0.32-0.66), respectively; p-value=0.18). Similarly, no significant difference of 2y-cum-inc anal hHSIL was observed between those with negative anal hrHPV and those with normal anal-cyt (0.13(95%CI: 0.08-0.41) and 0.13(95%CI:0.05-0.36), respectively; p>0.5). Co-testing or triaging with cytology and hrHPV did not improve prediction of detection or absence of 2y-cum-inc anal hHSIL, as compared with hrHPV or anal-cyt tests alone (p>0.05).

Prevalence and incidence of anal HSIL by baseline anal screening results

	Study Cohort	Provalent Anal HSIL Cohort	Non-Prevalent Anal HSIL Cohort (excludes participants with no follow up)[1]	Incident HSIL	Person years	Incidence per 100 PY	95% CI (incidence per 100 py)	Incidence ratio	95% CI (incidence per 100 py)	P value
Overall	N=229	64 (28)	114 (100)	19 (16.7)	222.9	8.5	5.45-13.40			
Age, median (IQR)	50 (44-55)	51.5 (45.5- 55.5)	51 (44-55)							
Baseline Anal Screening Results										
Anal Cytology										
NILM[2]	94 (41)	11 (17)	57 (50)	5 (8.8)	118.0	4.2	1.76-10.17	ref		
ASCUS/LSIL	114 (50)	36 (56)	55 (48)	14 (25.4)	100.0	14.0	8.28-23.62	3.3	1.19-9.17	0.02
ASC-H/HSIL	21 (9)	17 (27)	2 (2)	0 (0)	4.2	0.0	0-0	NA	NA	NA
Anal Cytology										
NILM[2]	94 (41)	11 (17)	57 (50)	5 (8.8)	118.0	4.2	1.76-10.17	ref		
Not NILM	135 (59)	53 (83)	57 (50)	14 (24.6)	104.9	13.4	7.95-22.67	3.2	1.14-8.80	0.03
Anal HPV HC2										
HPV+	111 (48)	46 (72)	45 (39)	15 (33.3)	79.3	18.9	11.41-31.38	6.8	2.34-20.38	<0.001
HPV-	118 (52)	18 (28)	69 (61)	4 (5.8)	143.0	2.8	1.05-7.45	ref		
Anal HPV and Cytology										
HPV+ and abnormal cytology	84 (36.7)	40 (62.5)	39 (35.4)	12 (41.4)	47.5	25.0	14.3-44.08	10.9	3.43-48.49	0.00
HPV+ and normal cytology	27 (11.8)	6 (9.4)	16 (14.0)	3 (18.7)	31.3	9.6	3.09-29.87	4.2	0.89-24.82	0.12
HPV- and abnormal cytology	53 (23.3)	13 (20.3)	38 (34.6)	2 (7.1)	56.3	3.6	0.88-14.19	1.5	0.33-10.93	0.67
HPV- and normal cytology	67 (29.3)	5 (7.8)	41 (36.0)	2 (10.5)	90.7	2.3	0.68-9.22	ref		

[1] 51 study participants were excluded from the follow-up cohort
30 were lost or refused to follow-up
1 death
1 withdrawn for poor health
11 research site closed
8 no follow-up pathology

[2]Negative for intraepithelial lesion or malignancy



Conclusions: Detection of anal hrHPV or abnormal anal-cyt are comparable predictors for 2-year cumulative anal hHSIL whereas negative anal hrHPV or normal cytology confer a reasonable margin of safety for 2-year screening interval. This data will inform anal cancer screening guidelines in WLHIV.

O016 / #573

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SCREENING, DIAGNOSIS, AND MANAGEMENT OF HPV-RELATED NON-CERVICAL ANOGENITAL CANCERS
04-19-2023 8:15 AM - 9:15 AM

COMPARABLE PREVALENCE OF ANAL HUMAN PAPILLOMAVIRUS INFECTION AND ABNORMAL CYTOHISTOLOGY IN PRE-EXPOSURE PROPHYLAXIS-USING MSM AND MSM LIVING WITH HUMAN IMMUNODEFICIENCY VIRUS

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Introduction: Persistent high-risk HPV infection(HR-HPV) can lead to (pre)cancerous anal lesions. HR-HPV prevalence in HIV-negative MSM and in MSM living with HIV(MSM-HIV) is 41% and 74%, respectively (Wei,2021). HR-HPV prevalence in PrEP-using MSM in Belgium is currently unknown. The aim of this study was to determine whether HPV infection and/or abnormal anal cytohistology is more prevalent in MSM-HIV compared to PrEP-using MSM. Preliminary data are reported here.

Methods: PrEP-using MSM and MSM-HIV were enrolled in this mono-centric study during appointments at the S-clinic. Patient characteristics, sexual behavior and demographics were collected using a questionnaire, filled in on the day of the anal swab testing. Patients with HR-HPV infection, abnormal cytology or both were subsequently sent for High Resolution Anoscopy(HRA).

Results: We enrolled 149 PrEP-using MSM and 87 MSM-HIV. Quality of anal swabs was sufficient in respectively 95%(n=142) and 82%(n=71) of the participants. HR-HPV prevalence in PrEP-using MSM was comparable with HR-HPV prevalence in MSM-HIV; respectively 74%(n=105) and 74%(n=52) tested positive for at least one HR-HPV (p=1.000). No significant difference in abnormal cytology was seen; 53%(n=75) of PrEP-using MSM and 56%(n=40) of MSM-HIV had either ASC-US, ASC-H, LSIL or HSIL (p=0.664). Until today, 40 PrEP-using MSM and 12 MSM-HIV underwent a HRA and biopsies were performed in 33 PrEP-using MSM and 12 MSM-HIV. Preliminary results on histology of lesions show presence of Anal Intraepithelial Neoplasia grade 3 in 20%(n=8) and 25%(n=3) respectively (p= 0.593).

Conclusions: PrEP-using MSM have a similar risk of HPV infection and abnormal anal cytohistology than HIV-positive MSM, which is higher than what has been reported in HIV-negative MSM. ANCHOR showed that treating anal HSIL reduces the incidence of anal cancer in HIV-positive patients, but the risk of progression to anal cancer and thus the need for screening and treatment is to be investigated in this immunocompetent population.

O017 / #1562

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SCREENING, DIAGNOSIS, AND MANAGEMENT OF HPV-RELATED NON-CERVICAL ANOGENITAL CANCERS
04-19-2023 8:15 AM - 9:15 AM

EFFICACY OF THE AS04-ADJUVANTED HPV16/18 VACCINE IN WOMEN WITH EXISTING CERVICAL HR-HPV INFECTION AT FIRST VACCINATION: POOLED ANALYSIS OF DATA FROM THREE LARGE CLINICAL TRIALS

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Introduction: Human papillomavirus (HPV) vaccines are efficacious against HPV infections and associated lesions in women who are predominantly HPV-naive at vaccination. However, whether women with cervical HR-HPV infection at the time of first vaccination would benefit from HPV vaccination remains unclear. This study aimed to evaluate AS04-adjuvanted HPV16/18 vaccine efficacy (VE) among women infected with HR-HPV at first vaccination (baseline).

Methods: Data were available from three large-scale, double-blind randomized controlled trials of the AS04-adjuvanted HPV16/18 vaccine (PATRICIA: NCT00122681; VIVIANE: NCT00294047; HPV-039: NCT00779766) [1-3]. Endpoints were HPV-16/18/31/33/45 incident and persistent infections (6-month persistent infection, 6MPI; 12-month persistent infection, 12 MPI) in women DNA-negative to the considered HR-HPV type but DNA-positive to any other HR-HPV type at baseline; and reinfections in women DNA-positive to the considered HR-HPV type at baseline but cleared naturally during later follow-up. Initial serostatus was not considered.

Results: A total of 5,151 women infected with any HR-HPV type at first vaccination were included (vaccine group =2,605, control group =2,546) in the analyses. In terms of women DNA-negative to the considered HR-HPV type but DNA-positive to any other HR-HPV type at baseline, VE against HPV-16/18 6-month and 12-month persistent infections (6MPI and 12MPI) was 87.8% (95% Confidence Interval [CI]: 82.5–91.8) and 84.7% (76.7–90.4), respectively. VE against HPV-31/33/45 6MPI and 12MPI was 50.3% (37.3–60.9) and 49.9% (32.5–63.2), respectively. Among women DNA-positive to the considered HR-HPV type at baseline followed by natural clearance, no statistical significant VE against HPV-16/18 incident reinfection, 6MPI, and 12MPI was
observed.

Table 1. Baseline demographic characteristics and follow-up characteristics of women DNA-positive to any HR-HPV type at baseline (pooled)

Characteristic	Vaccine Group (n=2605)	Control Group (n=2546)	P-value
Age at first vaccination, y			
Mean (SD)	22.71 (6.24)	22.86 (6.60)	0.405
Median (IQR)	22.00 (18.00 to 24.00)	22.00 (19.00 to 24.00)	0.978
Region, n (%)			
Asia Pacific	932 (35.8)	922 (36.2)	0.315
Europe	709 (27.2)	658 (25.8)	
Latin America	502 (19.3)	470 (18.5)	
North America	462 (17.7)	496 (19.5)	
Race, n (%)			
Black	111 (4.3)	128 (5.0)	0.316
White or Caucasian	1275 (48.9)	1245 (48.9)	
Arabic or North African	1 (0.0)	3 (0.1)	
East or Southeast Asian	306 (11.7)	325 (12.8)	
South Asian	5 (0.2)	0 (0.0)	
Hispanic	271 (10.4)	249 (9.8)	
Chinese	560 (21.5)	531 (20.9)	
Malay	3 (0.1)	4 (0.2)	
Indian	3 (0.1)	2 (0.1)	
Other	70 (2.7)	59 (2.3)	
Total follow-up time per woman, mo			
Median (IQR)	48.00 (45.96 to 51.12)	48.00 (45.96 to 51.96)	0.931

Table 2. Vaccine efficacy against HPV-16/18/31/33/45 infection in women DNA-negative to the considered HR-HPV type but DNA-positive to any other HR-HPV type at first vaccination

VE against		Group	n	N	Person-years	VE %, (95% CI)
Incident infection[a] with:	HPV-16/18	HPV vaccine	151	2516	10274.2	73.5 (68.3 to 78.0)
		Control	507	2419	9141.6	
	HPV-16	HPV vaccine	81	1908	7914.6	75.5 (68.8 to 80.9)
		Control	305	1871	7302.6	
	HPV-18	HPV vaccine	73	2318	9657.6	75.2 (68.1 to 81.0)
		Control	276	2255	9043.7	
	HPV-31/33/45	HPV vaccine	260	2534	10038.7	50.6 (42.7 to 57.5)
		Control	495	2483	9438.4	
	HPV-31	HPV vaccine	132	2270	9274.4	55.0 (44.8 to 63.5)
		Control	284	2265	8975.0	
	HPV-33	HPV vaccine	99	2432	9993.5	40.8 (24.1 to 54.0)
		Control	162	2382	9681.4	
	HPV-45	HPV vaccine	63	2486	10302.4	60.5 (47.3 to 70.7)
		Control	154	2416	9956.8	
6-month persistent infection[b] with:	HPV-16/18	HPV vaccine	31	2469	10574.0	87.8 (82.5 to 91.8)
		Control	234	2374	9698.8	
	HPV-16	HPV vaccine	21	1865	8060.2	87.8 (81.2 to 92.5)
		Control	163	1829	7588.3	
	HPV-18	HPV vaccine	10	2267	9781.2	89.7 (81.1 to 95.0)
		Control	94	2205	9361.6	
	HPV-31/33/45	HPV vaccine	105	2504	10501.8	50.3 (37.3 to 60.9)
		Control	203	2449	10073.6	
	HPV-31	HPV vaccine	52	2229	9499.4	58.9 (43.6 to 70.6)
		Control	124	2216	9281.0	
	HPV-33	HPV vaccine	38	2379	10137.6	29.6 (-6.6 to 53.9)
		Control	53	2338	9943.2	
	HPV-45	HPV vaccine	23	2425	10383.2	56.9 (30.4 to 74.2)
		Control	52	2359	10070.8	
12-month persistent infection[c] with:	HPV-16/18	HPV vaccine	23	2470	10597.7	84.7 (76.7 to 90.4)
		Control	142	2383	9952.4	
	HPV-16	HPV vaccine	16	1866	8078.8	84.9 (75.3 to 91.5)
		Control	103	1836	7759.9	
	HPV-18	HPV vaccine	7	2267	9786.3	86.2 (71.4 to 94.3)
		Control	50	2209	9476.3	
	HPV-31/33/45	HPV vaccine	64	2514	10650.6	49.9 (32.5 to 63.2)
		Control	124	2463	10324.6	
	HPV-31	HPV vaccine	27	2233	9580.7	65.4 (47.0 to 78.1)
		Control	77	2223	9428.1	
	HPV-33	HPV vaccine	21	2385	10208.5	26.2 (-29.8 to 58.7)
		Control	28	2343	10023.8	
	HPV-45	HPV vaccine	17	2426	10401.2	36.1 (-17.2 to 66.1)
		Control	26	2361	10134.0	

Abbreviations: HPV, human papillomavirus; HR-HPV, high risk human papillomavirus (HPV-16/18/31/33/35/39/45/51/52/56/58/59/66/68); VE, vaccine efficacy

[a] Incident infection was defined as the first detection by PCR of an episode of infection by HPV type(s) in a subject previously negative for the considered HPV type(s).

[b] 6-month persistent infection was defined as detection of the same HPV type at two consecutive evaluations over 6 months or greater (>150 days).

[c] 12-month persistent infection was defined as detection of the same HPV type at two consecutive evaluations over 12 months or greater (>300 days).

Table 3 Vaccine efficacy against HPV-16/18/31/33/45 reinfection in women DNA-positive to the considered HR-HPV type at first vaccination followed by natural infection clearance[a]

VE against		Group	n	N	Person-years	VE % (95% CI)
Incident infection[b] with:	HPV-16/18	HPV vaccine	55	681	2109.92	2.7 (-42.2 to 33.4)
		Control	53	647	1978.42	
	HPV-16	HPV vaccine	40	498	1535.36	-10.8 (-76.1 to 29.9)
		Control	34	475	1446.59	
	HPV-18	HPV vaccine	15	213	675.22	24.9 (-48 to 62.6)
		Control	19	210	640.51	
	HPV-31/33/45	HPV vaccine	33	395	1257.42	3.6 (-58.3 to 41.1)
		Control	31	356	1139.2	
	HPV-31	HPV vaccine	24	224	689.45	-3.7 (-92.3 to 43.2)
		Control	19	195	567.19	
	HPV-33	HPV vaccine	6	121	404.91	35.8 (-88.1 to 79.3)
		Control	8	101	344.5	
	HPV-45	HPV vaccine	5	85	280.7	-13.9 (-323.3 to 69.4)
		Control	5	92	319.66	
6-month persistent infection[c] with:	HPV-16/18	HPV vaccine	20	681	2170.9	-4.3 (-99.7 to 45.2)
		Control	18	646	2038.59	
	HPV-16	HPV vaccine	14	498	1583.08	-19.4 (-171.5 to 46.1)
		Control	11	475	1489.82	
	HPV-18	HPV vaccine	6	213	690.07	17.9 (-152.4 to 74.2)
		Control	7	210	658.41	
	HPV-31/33/45	HPV vaccine	15	395	1291.21	-4.0 (-123.5 to 50.9)
		Control	13	356	1165.93	
	HPV-31	HPV vaccine	10	224	717.25	9.9 (-129.6 to 64.1)
		Control	9	195	582.4	
	HPV-33	HPV vaccine	4	121	409.47	-12.4 (-509.8 to 76.5)
		Control	3	101	349.32	
	HPV-45	HPV vaccine	2	85	284.52	-116.6 (-6698.1 to 82.5)
		Control	1	92	327.9	
12-month persistent infection[d] with:	HPV-16/18	HPV vaccine	13	681	2185.2	-10.7 (-154.2 to 50.9)
		Control	11	646	2050.5	
	HPV-16	HPV vaccine	10	498	1591.41	-33.5 (-273.8 to 49.4)
		Control	7	475	1497.22	
	HPV-18	HPV vaccine	3	213	696.04	27.7 (-245.7 to 86.7)
		Control	4	210	662.92	
	HPV-31/33/45	HPV vaccine	8	395	1310.81	-2.5 (-197.9 to 63.8)
		Control	7	356	1179.49	
	HPV-31	HPV vaccine	5	224	728.16	19.1 (-200.6 to 78.2)
		Control	5	195	588.9	
	HPV-33	HPV vaccine	2	121	413.52	-62.0 (-4983.7 to 86.9)
		Control	1	101	356.38	
	HPV-45	HPV vaccine	1	85	290.08	-13.0 (-4308.5 to 97.1)
		Control	1	92	327.9	

Abbreviations: HPV, human papillomavirus; HR-HPV, high-risk human papillomavirus (HPV-16/18/31/33/35/39/45/51/52/56/58/59/66/68); VE, vaccine efficacy

[a] Natural infection clearance was defined as the detection of type-specific HPV DNA in a cervical sample at baseline, followed by two consecutive negative samples for the same HPV type during the follow-up period.

[b] Incident reinfection was defined as a new detection by PCR of an episode of infection by HPV type(s) in a subject previously positive for the considered HPV type(s) but cleared naturally during later follow-up.

[c] 6-month persistent infection was defined as detection of the same HPV type at two consecutive evaluations over 6 months or greater (>150 days).

[d] 12-month persistent infection was defined as detection of the same HPV type at two consecutive evaluations over 12 months or greater (>300 days).

Conclusions: Pooling individual-level data from three large RCTs worldwide, our study demonstrated that women with existing cervical HR-HPV infection at first vaccination would still benefit from the AS04-adjuvanted HPV16/18 vaccine. However, no evidence was found for VE against HR-HPV reinfections in women infected with the considered HR-HPV type at first vaccination followed by natural clearance.

O018 / #1286

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: REGULATION OF GENE EXPRESSION
04-19-2023 8:15 AM - 9:15 AM

GENE EXPRESSION PROFILE SIGNATURES ASSOCIATED WITH HIGH GRADE PRECANCER AND INVASIVE CANCER VULVAR LESIONS

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Introduction: Vulvar squamous cell carcinoma (VSCC) associated to Human Papillomavirus (HPV) infection is a rare cancer and arise from the precursor lesions, vulvar intraepithelial neoplasia (VIN). Patients diagnosed with VIN2/3, also known as high grade lesions (HSIL), are candidates for treatment but only a percentage of them will progress to cancer. The aim of this study is to identify features associated with the grade of malignancy of vulvar lesions and the viral variability of the HPV16 infection.

Methods: RNA-expression analysis was performed with the n-Counter NanoString technology using a custom panel of 85 candidate genes, associated with HPV or VSCC cancer development, on a set of 48 vulvar samples (HSIL, n=21; VSCC, n=27). We analyzed 32 samples positive for HPV16 from different known sublineages, 4 HPV18-positive, 4 HPV33-positive, and 8 HPV-negative. Principal Component Analysis (PCA) and differential expression analysis using DESeq2 (v1.26.0) were performed.

Results: PCA showed that HSIL and VSCC have different expression profiles, suggesting a different progression state (Figure 1). We identified 11 genes (APOBEC3A, APOBEC3B, APOC1, CCNA1, CDKN2A, FN1, HOXA1, KRT17, MCM2, MMP9 and SOX2) overexpressed and 9 (AR, CALML5, CASZ1, ESR1, HOTAIR, ITGA8, KLF4, SLIT2 and TIMP3) underexpressed in VSCC (adjusted p-value <0.05) (Figure 2) compared to HSIL samples. Moreover, 4 genes upregulated in VSCC, were also differentially expressed (adjusted p-value <0.05) in HPV16-A and HPV16-B/C/D sublineages of cancer samples.

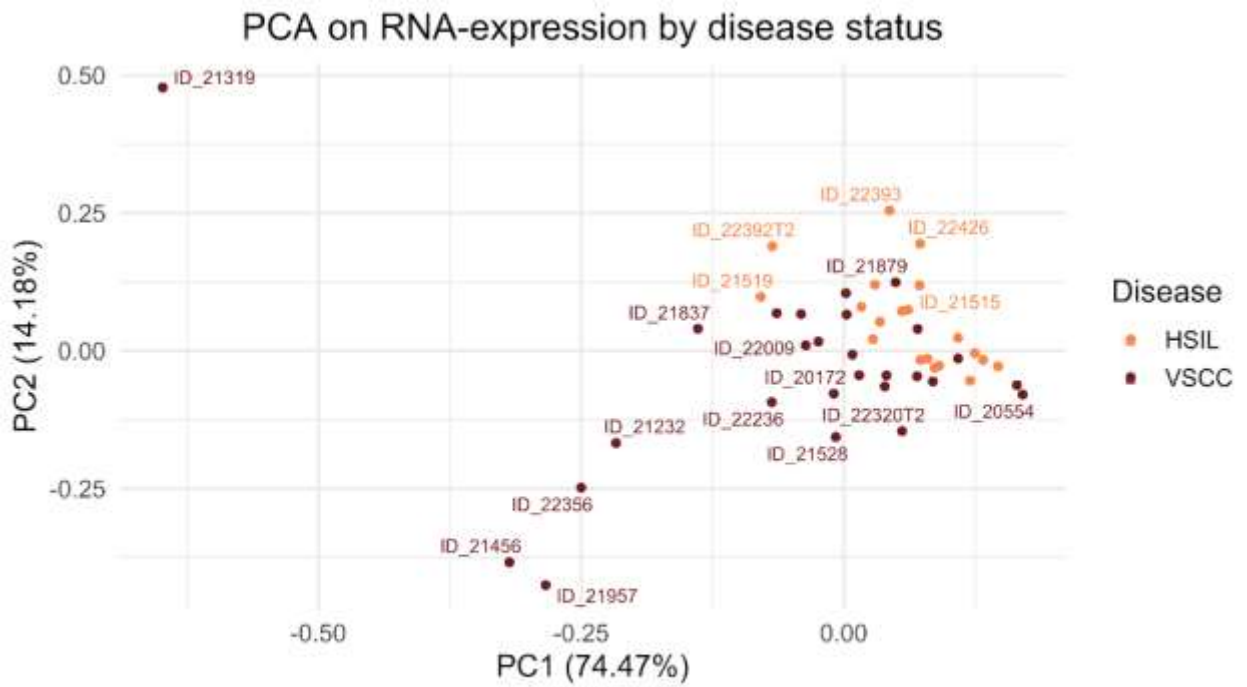

Figure 1: Principal Component Analysis (PCA) of the RNA expression counts of the 85 candidate genes performed on the 48 samples. In dark red, VSCC samples; In orange, HSIL samples.

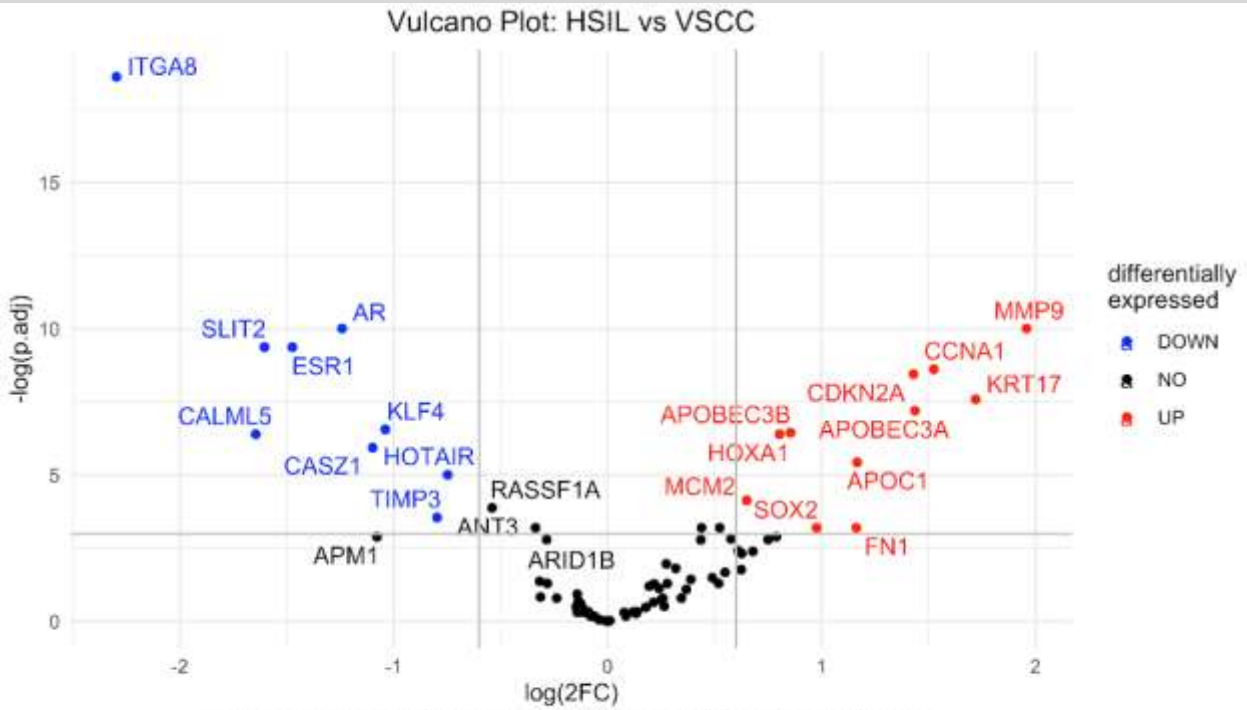

Figure 2: Vulcano plot generated from the DESeq results comparing HSIL and VSCC samples. In red, significantly (adjusted p-value <0.05) upregulated genes in VSCC samples. In blue, significantly downregulated genes in VSCC compared to HSIL.

Conclusions: VSCC is associated with upregulation of immune response, cell proliferation and cell migration, and the downregulation of cell cycle and tumor suppressor genes. Differences in the expression profile of HPV16-A and HPV16-B/C/D sublineages suggest the activation of different

carcinogenic pathways. Further studies including follow-up in a large set of samples are needed to confirm if the candidate genes could be used as potential biomarkers to predict the risk of progression from HSIL to VSCC.

O019 / #1423

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: REGULATION OF GENE EXPRESSION
04-19-2023 8:15 AM - 9:15 AM

HOXA3 AND SOX7 REGULATE THE TRANSCRIPTIONAL ACTIVITY OF DIFFERENT HPV-6 VARIANTS

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Introduction: The presence of two early promoters (P90 and P270) in low risk HPVs allows independent regulation of viral genes but little is known concerning low-risk transcription regulation. Previously studies from our group demonstrated that HPV variants differentially influence the clinical outcome of infections. The present work aimed to better understand the transcriptional role of the P90 early promoter of different HPV-6 variants.

Methods: Promoter transcriptional activity was analyzed using GFC-Transfection Array™ and ONE-Glo™ Luciferase Assay System. Putative binding sites observed in silico using JASPAR (jaspar.genereg.net) were confirmed by chromatin immunoprecipitation assays (ChIP).

Results: Among 524 TFs tested, 78 were found to affect HPV-6 P90 transcriptional activity. Among these 30 activated and 7 inhibited exclusively B1 P90 activity, while 4 activated and 33 inhibited solely B3 P90 activity. Putative bindings sites within the LCR of both HPV-6 variants were found for ten of the 78 TFs. Validation assays demonstrated that HOXA13 activated HPV-6 B1 sublineage variant exclusively whereas SOX7 repressor role in HPV-6 B3 sublineage variant was observed. The presence of two SOX7 binding sites within the HPV-6 B3 variant was verified using ChIP. The expression levels of both TFs in RRP (recurrent respiratory papillomatosis) samples are ongoing.

Conclusions: Identification of cellular TFs that interact differentially with the LCR of different HPV variants could explain, at least in part, the differences observed in the clinical outcome HPV related diseases.

O020 / #1453

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: REGULATION OF GENE EXPRESSION
04-19-2023 8:15 AM - 9:15 AM

HNRNP G/RBMX ENHANCES HPV16 E2 MRNA SPLICING THROUGH A NOVEL SPLICING ENHANCER AND INHIBITS PRODUCTION OF SPLICED E7 ONCOGENE MRNAS

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Introduction: Human papillomavirus type 16 (HPV16) E2 is an essential HPV16 protein to regulate HPV DNA replication and transcription as well as apoptosis induction. Despite the significany functions of E2 in the HPV lifecycle and carcinogenesis, regulation of E2 expression has not been elucidated well. When HPV16 mRNA is spliced from SD880 to SA2709, regulating in the upregulation of alternatively spliced E2-encoding mRNAs and E2 protein level. In this study, we have investigated a splicing enhancer that is required for production of HPV16 E2 mRNAs.

Methods: HPV16 subgenomic plasmids were transfected in HeLa cells, followed by RT-PCR to evaluate E2 alternative mRNA splicing. To identify a splicing enhancer of E2 mRNA, a series of deletion mutations were engineered and the influence on E2 mRNA splicing was evaluated. To isolate a trans-acting factor for E2 mRNA splicing through the interaction with the identified splicing enhancer, RNA oligo pulldown was performed, and the purified proteins were analysed by mass spectrometry (LC-MS).

Results: A splicing enhancer for HPV16 E2 mRNAs was identified at 25nt downstream of SA2709. The identified splicing enhancer sequence interacted with cellular RNA binding protein hnRNP G that promoted splicing to SA2709 and enhanced E2 mRNA production. hnRNP G interacted with splicing factor U2AF65 and the interactions between hnRNP G and HPV16 E2 mRNAs and U2AF65 increased in response to keratinocyte differentiation as well as by the induction of the DNA damage response (DDR). The DDR reduced sumoylation of hnRNP G and pharmacological inhibition of sumoylation enhanced HPV16 E2 mRNA splicing and interactions between hnRNP G and E2 mRNAs and U2AF65. Intriguingly, hnRNP G also inhibited production of spliced E7 oncogene mRNAs, resulting in reduced cellular viability.

Conclusions: These results indicate the significant role of hnRNP G on the regulation of HPV16 gene expression as well as carcinogenic development of HPV infected tissue.

O021 / #564

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: REGULATION OF GENE EXPRESSION
04-19-2023 8:15 AM - 9:15 AM

PAR-CLIP VALIDATION AND ANALYSIS OF MRNAS BOUND BY NFX1-123 WITH AND WITHOUT HPV TYPE 16 E6 CO-EXPRESSION

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Introduction: High-risk HPV oncoproteins partner with cellular proteins to drive gene expression changes. High-risk HPV type 16 E6 (16E6) binds to the cytoplasmic protein, NFX1-123, and together they collaboratively regulate gene expression through post-transcriptional regulation. NFX1-123 binds to other RNA processing proteins, such as cytoplasmic poly(A) binding proteins, through its PAM2 motif, and NFX1-123 has the presumptive ability to bind single-stranded nucleic acids at its R3H domain. However, it has not been demonstrated that NFX1-123 itself can directly bind RNA nor that it binds RNA both with and without co-expression of 16E6. We hypothesized that NFX1-123 could bind RNA directly as a part of its normal cellular function, and that this is co-opted by 16E6 to drive gene expression changes, and cellular pathway cascades, that would support a productive viral infection as well as oncogenesis.

Methods: Photo-Activatable Ribonucleoside Enhanced CrossLinked ImmunoPrecipitation (PAR-CLIP) was used to directly identify RNA bound to NFX1-123. 293T cells were transfected with FLAG-tagged NFX1-123, 16E6, or vector controls. Cells were then labelled, UV crosslinked, and lysed with TRIzol. RNA-bound proteins were immunoprecipitated, and RNA was released and digested into 50-75 nt sizes. RNA fragments were purified, adapters attached for cDNA conversion, and barcode primers added to create libraries for sequencing.

Results: NFX1-123 was found to bind RNA directly. Both endogenous NFX1-123 and FLAG-tagged NFX1-123 immunoprecipitated at least 5,000,000 unique RNA reads.

Conclusions: NFX1-123, an endogenous cellular protein that binds to RNA processing proteins, is itself a bona fide RNA binding protein. It binds to multiple RNAs, and this further supports the role co-opting post-transcriptional gene regulation plays in the HPV viral life cycle and in HPV-associated oncogenesis.

O022 / #1167

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: REGULATION OF GENE EXPRESSION
04-19-2023 8:15 AM - 9:15 AM

IDENTIFICATION OF HUMAN TRANSCRIPTION FACTORS THAT REGULATE THE TRANSCRIPTIONAL ACTIVITY OF HIGH-RISK HPV-18 AND -16.

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Introduction: Persistent infection with high-risk oncogenic human papillomaviruses (HR-HPVs) is the main etiological factor associated with the development of cancer of the cervix and other anatomical sites. Among the HR-HPV types, HPV-16 is the most prevalent in cervical tumors worldwide, followed by HPV-18. Several cellular transcription factors (TFs) bind to the viral LCR and regulate the transcriptional activity, modulating the expression of HPV oncogenes. Given the importance of the TF binding sites within the LCR, the nucleotide variability found between HPV-16 and -18 may be a key factor contributing to the differential oncogenic potential between HR-HPV types.

Methods: Initially, we evaluated the impact of over 500 human TFs upon the transcriptional activity of the LCR of HPV-16 and -18, by transfecting C33A cells with the TFs cDNA and LCR-luciferase constructs. In total, we identified 130 TFs with a differential impact upon the transcriptional activity of HPV-16 and -18, and the in silico analysis revealed that 70 of these factors directly bind to nucleotide sequences in the LCR. Among these, we arbitrarily selected four TFs for more detailed analysis: c-MYB, GATA3, FOXO1, and TBX21. Next, we performed promoter activity and gene expression assays to validate the TF's impact on the transcriptional activity of HPV-16 and -18.

Results: Validation assays showed that c-MYB activates both HPV-16 and -18, having a more accentuated effect on the HPV-18 transcriptional activity. The GATA3 factor repressed exclusively the HPV-18 early promoter, while TBX21 had a negative effect only upon HPV-16 transcription. Interestingly, FOXO1 exhibited a repressor activity in both high-risk HPV types. This TFs also have an intrinsic relationship with each other in regulating important oncogenic pathways.

Conclusions: Thus, the data found in this study could lead to a deeper understanding of the molecular mechanisms of viral transcription regulation and possible new therapeutic targets for the treatment of HPV-related malignancies

O023 / #896

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: REGULATION OF GENE EXPRESSION
04-19-2023 8:15 AM - 9:15 AM

BETA HUMAN PAPILLOMAVIRUS 8 E6 INDUCES MICRONUCLEUS FORMATION AND PROMOTES CHROMOTHRIPSIS

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Introduction: Cutaneous beta genus human papillomaviruses (β-HPVs) promote the development of cutaneous squamous cell carcinomas in people with compromised immune systems and may cause mutations in the general population. Multiple studies have established the genome destabilizing capacities of β-HPV proteins E6 and E7 as a cofactor with UV. However, the E6 protein from β-HPV8 (HPV8 E6) induces tumors in mice without UV exposure. Here, we examined a UV-independent mechanism of HPV8 E6-induced genome destabilization.

Methods: Fixed and live-cell microscopy as well as whole genome sequencing were used.

Results: We showed that HPV8 E6 reduced the abundance of anaphase bridge resolving helicase, Bloom syndrome protein (BLM). The diminished BLM was associated with increased segregation errors and micronuclei. These HPV8 E6-induced micronuclei had disordered micronuclear envelopes but retained replication and transcription competence. HPV8 E6 decreased antiproliferative responses to micronuclei and time-lapse imaging revealed HPV8 E6 promoted cells with micronuclei to complete mitosis. Finally, whole-genome sequencing revealed that HPV8 E6 induced chromothripsis in nine chromosomes.

Conclusions: These data provide insight into mechanisms by which HPV8 E6 induces genome instability independent of UV exposure.

O024 / #1426

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 1
04-19-2023 9:45 AM - 10:45 AM

IMPACT OF SINGLE DOSE HPV VACCINATION ON HPV 16/18 PREVALENCE IN ADOLESCENT GIRLS AND YOUNG WOMEN IN SOUTH AFRICA: RESULTS FROM THE HOPE STUDY

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Introduction: There is mounting interest in a single dose (SD) HPV vaccine regimen but data on the impact of this approach in high HIV burden settings is limited.

Methods: We delivered a bivalent SD HPV vaccine to adolescent girls and young women (AGYW) in grade 10 in a schools-based catch up program in one district in South Africa in 2019. Impact on HPV 16/18 prevalence was assessed using repeat cross-sectional surveys. In 2019, a baseline survey (S1) in AGYW aged 17-18 years (n=770) established HPV 16/18 prevalence in a pre-vaccine population who were above the target age for HPV vaccination in 2014. In 2021, the survey (S2) was repeated in the SD catch-up district (n=964). HPV DNA was detected on self-collected vaginal swabs using the Seegene AnyPlex TM II HPV28 assay. Population impact was estimated using prevalence ratios (PR) adjusted for differences in sexual behavior between surveys.

Results: SD vaccination coverage was 72% (4804/6673) of eligible AGYW attending high school (n=66) in the district. Survey populations were similar; in S2 fewer AGYW were sexually active or using contraception, but more reported a previous STI. HPV 16/18 prevalence was 51% lower in S2 compared to S1(12% (111/964) vs 22% (172/770) adjusted PR 0.49; 95% CI (0.39-0.62). Similar results were observed when restricted to those living with HIV (19% (25/130) vs. 32% (73/232); aPR 0.58, 95% CI 0.37-0.94). No impact was seen non-vaccine HPV types overall (51% (vs. 47%; aPR 1.0, 95% CI 0.91-1.11), or among those living with HIV (56% (73/130) vs 57% (132/232); aPR 0.96, 95% CI 0.79-1.16). In the post-vaccine sample (S2 only), vaccine effectiveness was 70% (RR 0.30, 95% CI 0.08-1.17).

Conclusions: These data provide reassuring evidence of population-level impact of a SD bivalent HPV vaccine regimen on HPV 16/18 prevalence in a South African population, irrespective of HIV status.

O025 / #777

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 1
04-19-2023 9:45 AM - 10:45 AM

POTENTIAL IMPACT OF SWITCHING FROM A TWO-DOSE TO ONE-DOSE ROUTINE HPV VACCINATION PROGRAM IN HIGH-INCOME COUNTRIES: A MATHEMATICAL MODELING STUDY USING NORTH AMERICA AS EXAMPLE

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Introduction: We examined the potential population-level impact of switching from a two- to one-dose 9-valent HPV vaccination schedule in high income countries with a high vaccination coverage, for different assumptions of one-dose efficacy and duration of protection.

Methods: We used HPV-ADVISE, an individual-based transmission-dynamic model of HPV transmission and disease, calibrated to two high-income countries (HIC; 2 models, Canada and US). Vaccination scenarios start with two doses of 4-valent among 10-year-old girls and catch-up in 10-14 year-olds, and include the addition of boys and the change to the 9-valent vaccine. The switch from a two to one-dose schedule of 9-valent occurs 15 years after start of vaccination. We assumed 85% vaccination coverage, 95% efficacy against vaccine-type infections and lifelong duration of two doses. We examined 3 scenarios of one-dose vaccine efficacy (VE) and duration (VD): 1) VE=95%, VD=20 years; 2) VE=85%, VD=20 years; 3) one dose non inferior to two doses for girls, but one-dose VE=85% and VD=20 years for boys. In sensitivity analysis, we examined a switchback to two doses 10 years after the switch to one dose.

Results: Figure 1 shows the base-case results for the impact of vaccination for the two-dose scenario (status quo) and the one-dose vaccine efficacy and duration of protection scenarios; and Figure 2 shows the sensitivity analysis results for the impact of switching back to two doses 10 years after the switch to one
dose.

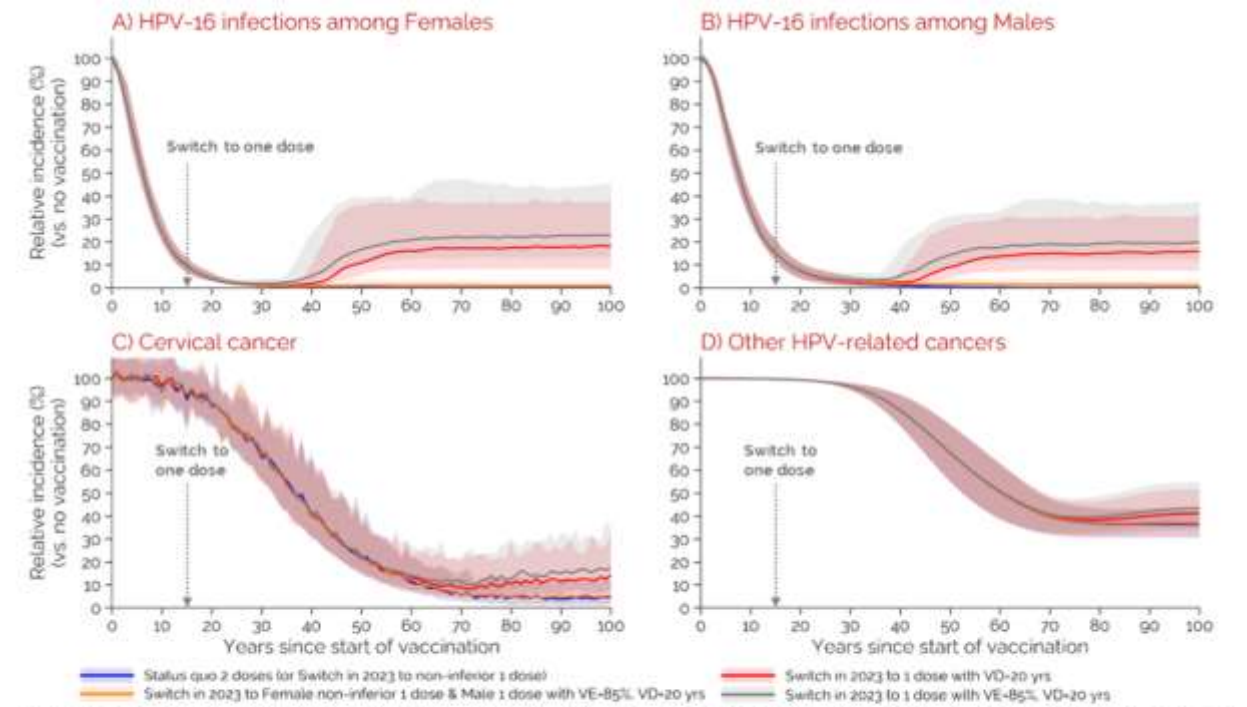

Figure 1. Base case results: Impact of vaccination for the two-dose scenario (status quo) and the one-dose vaccine efficacy and duration of protection scenarios. Relative reduction in incidence versus no vaccination of **A)** HPV-16 infection among females, **B)** HPV-16 infection among males, **C)** cervical cancer, and **D)** other HPV-related cancers among females and males (vagina, vulva, penis, anus, oropharynx), predicted by the 2 HPV-ADVISE models (US and Canada). The solid lines and shaded areas represent, respectively, the median and 80% uncertainty intervals (10^{th} and 90^{th} percentiles) of the predictions for the 2 models. We assumed 85% vaccination coverage for girls and boys. Note: In panel (A), blue and orange lines overlap.

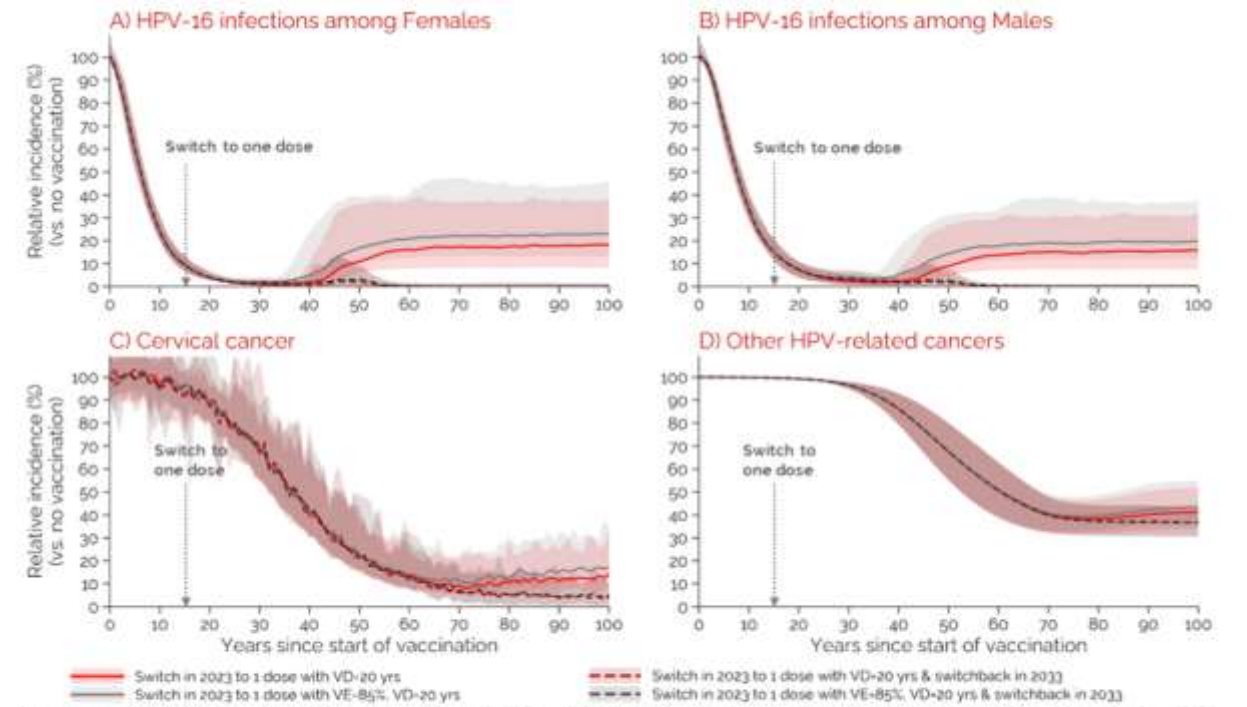

Figure 2. Sensitivity analysis: Impact of switching back to two doses 10 years after the switch to one dose for 2 scenarios of one-dose vaccine efficacy and duration. Relative reduction in incidence versus no vaccination of **A)** HPV-16 infection among females, **B)** HPV-16 infection among males, **C)** cervical cancer, and **D)** other HPV-related cancers among females and males (vagina, vulva, penis, anus, oropharynx), predicted by the 2 HPV-ADVISE models (US and Canada). The switch back to two doses occurs at year 25. The solid lines and shaded areas represent, respectively, the median and 80% uncertainty intervals (10th and 90th percentiles) of the predictions for the 2 models. We assumed 85% vaccination coverage for girls and boys.

Conclusions: A switch to one-dose routine HPV vaccination in HICs is not predicted to substantially increase cervical and other HPV-related cancers if duration of protection is greater than 20 years. If one-dose protection is shown to wane within the next 10 years, switching back to two-dose routine vaccination could mitigate losses in cervical and other HPV-related cancers prevention.

O026 / #857

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 1
04-19-2023 9:45 AM - 10:45 AM

HEAD-TO-HEAD IMMUNOGENICITY COMPARISON OF AN ESCHERICHIA COLI-PRODUCED 9-VALENT HPV VACCINE AND GARDASIL9 IN FEMALES AGED 18-26 YEARS: A RANDOMIZED BLINDED CLINICAL TRIAL

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Introduction: A safe and highly efficacious Escherichia coli (E. coli) -produced HPV 16/18 bivalent vaccine has been prequalified by the World Health Organization, here we conducted a randomized, blinded study to compare the immunogenicity and safety of its second generation nonavalent HPV 6/11/16/18/31/33/45/52/58 vaccine (Cecolin9) and Gardasil9.

Methods: Healthy women aged 18-26 years without HPV vaccination history were enrolled, and randomly (1:1) allocated by software to receive three doses of 0.5ml (270μg) of the Cecolin9 or 0.5ml (270μg) of Gardasil9 with a 0d/45d (39d-60d)/6m (150d-210d) schedule. Serum samples were collected at day 0 and 1 month after the third vaccination to evaluate HPV 6/11/16/18/31/33/45/52/58-specific neutralizing antibodies (nAbs). All participants were trained to record local and systemic AEs occurring within 30 days after each vaccination, and serious adverse events (SAEs) occurred in 7 months. This trial was registered with ClinicalTrials.gov, NCT04782895.

Results: From March 14, 2021 to May 30, 2022, totally 487 eligible volunteers were enrolled and randomly assigned to receive the Cecolin9 (n=244) or Gardasil9 (n=243) in Jiangsu province, China. Seroconversion of specific nAbs against the nine HPV types was observed in all the vaccine recipients in the per-protocol set (PPS). Neutralizing antibody titers of each HPV type were comparable between Cecolin9 and Gardasil9 groups, with GMC ratios (Cecolin9 group vs Gardasil9 group) of 0.79 (95%CI: 0.68-0.94) to 1.65 (95%CI: 1.39-1.97) for HPV types 6/11/6/18/31/33/45/52/58. The incidences of total adverse events (AEs) in the Cecolin9 group and Gardsil9 groups were 52.0% and 53.9%, respectively. A total of one and three participant reported adverse reactions of grade 3 in the Cecolin9 and Gardasil9 group, respectively.

Conclusions: The new E.coli-produced 9vHPV vaccine is similarly immunogenic as Gardasil9 and well tolerated, which encourages further efficacy studies in large cohorts, it holds the promise of contributing to eliminating cervical cancers.

O027 / #1148

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 1
04-19-2023 9:45 AM - 10:45 AM

EFFECTIVENESS OF SINGLE DOSE OR TWO DOSES OF BIVALENT HPV VACCINE (CERVARIX) IN FEMALE SCHOOL STUDENTS IN THAILAND – 2-YEAR POST-VACCINATION

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Introduction: With accumulating evidence of effectiveness of a single dose (SD) of HPV vaccine in young women, we are conducting a community vaccine effectiveness (VE) study comparing HPV SD and two dose (2D) regimen (0, 6 months) of Cervarix in Thailand among Grade 8 schoolgirls. VE at 2-year post vaccination is presented.

Methods: In 2018, eligible Grade 8 schoolgirls in Udon Thani (SD) and Buriram (2D) provinces were offered HPV vaccine per assigned dose regimen. Concurrently, a cross-sectional survey (CSS) of HPV prevalence was conducted in Grade 10 (N=2,600 in each province). HPV infection was assessed by self-collected urine via Colli-pee device and tested by DNA PCR Cobas 4800. Positive samples were also tested with Anyplex II HPV 28. In 2020, when vaccinated Grade 8 schoolgirls reached Grade 10, the CSS was repeated. VE was estimated by comparing prevalence of HPV 16 or 18 between baseline CSS (2018) and vaccinated schoolgirls in Year-2 CSS (2020). Adjustment methods were used in the analysis to account for potential changes in sexual behavior due to non-contemporaneous comparison.

Results: Prevalence of HPV 16 or 18 in baseline CSS was 2.92% (95% CI 2.57- 3.33) and 3.40% (95% CI 3.04-3.81) for Udon Thani and Buriram, respectively. In Year-2 CSS the prevalence among vaccinated schoolgirls was 0.5% (95% CI 0.34-0.71) for Udon Thani and 0.22% (95% CI 0.14-0.35) for Buriram. Crude VE for SD was estimated at 83.0% (95% CI: 76.4-89.6), and 2D at 93.6% (95% CI: 90.5-96.8). All adjustment methods minimally impacted VE for SD (80%~83%) and 2D (90%~93%).

Conclusions: The Year 2 survey demonstrated high levels of VE of SD HPV against HPV 16 and 18 infections among teenage schoolgirls in Thailand. As the Year 2 VE estimate is an interim result, re-assessment at Year 4 post-vaccination is critical to demonstrate the longer-term protection.

O028 / #1254

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 1
04-19-2023 9:45 AM - 10:45 AM

ESTIMATING HUMAN PAPILLOMAVIRUS (HPV) VACCINE EFFICACY FROM A SINGLE-ARM STUDY: PROOF OF PRINCIPLE IN THE COSTA RICA HPV VACCINE TRIAL

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Introduction: The WHO 2030 cervical cancer elimination targets call for vaccinating 90% of girls with one- or two-dose human papillomavirus (HPV) vaccination by the age of 15. One-dose HPV vaccination would be less costly and logistically easier to implement. Additional evidence of one-dose HPV vaccine efficacy (VE) is needed but randomized controlled trials (RCTs) are costly, slow, and may face ethical challenges. We propose a single-arm trial design of HPV VE using types unaffected by the vaccine as natural controls, thereby reducing costs and time to read-out.

Methods: We relied on similar early natural history of HPV infection across types, specifically 1) time-to-clearance in the absence of precancer; and 2) proportionality of type-specific incidence to population prevalence. In calculating VE using only the bivalent HPV16/18 vaccine (Cervarix®) arm of the Costa Rica Vaccine Trial, we estimated the incidence of the vaccine-targeted type(s) that would have occurred absent vaccination as the ratio of prevalences at enrollment of vaccine-targeted to vaccine-unaffected types times the incidence of vaccine-unaffected types. Confidence intervals (CIs) for VE were derived using exact methods and compared against bootstrapped versions.

Results: Estimated VE against persistent HPV16/18 infections was similar for the published two-arm RCT and our proposed single-arm design (ATP cohort: 91·0% (95% CI: 84·4%–96·7%) [single-arm] vs. 90·9% (95% CI: 82·0%–95·9%) [two-arm]; ITT cohort: 41·7% (95% CI: 35·5%–47·4%) [single-arm] vs. 49·0% (95% CI: 38·1%–58·1%) [two-arm]). Results were similar for additional pre-specified subgroups based on number of doses and baseline HPV serology.

Conclusions: We provide proof of principle that a single-arm design for VE against virologic endpoints generates valid estimates with similar precision as an RCT and requires approximately half the sample size. Important considerations include the HPV exposure prevalence at trial enrollment and existing data on vaccine untargeted
genotypes.

Table 1. Vaccine efficacy (VE) estimates against 1-year persistent HPV infections with vaccine types: Single-arm approach versus randomized controlled trial (RCT).*

Analysis group	HPV group	Single-arm VE, % (95% CI)	Equivalent VE from two-arm RCT, % (95% CI)
ITT	16/18	41.7 (32.4 - 49.8)	49.0 (38.1 - 58.1)
	31/33/45	19.6 (1.4 - 32.9)	15.5 (-5.0 - 32.0)
ATP	16/18	91.0 (82.9 - 95.3)	90.9 (82.0 - 95.9)
	31/33/45	44.4 (22.8 - 59.9)	44.5 (17.5 - 63.1)
HPV 16 serology negative	HPV 16	90.8 (76.0 - 96.5)	92.2 (80.3 - 97.6)
HPV 16 serology positive	HPV 16	71.9 (24.2 - 89.6)	50.6 (-63.3 - 87.0)
HPV 18 serology negative	HPV 16	90.8 (76.0 - 96.5)	90.9 (76.7 - 97.2)
HPV 18 serology positive	HPV 16	77.5 (28.0 - 93.0)	79.4 (33.5 - 95.3)
3 dose	16/18	80.2 (71.7 - 86.2)	80.9 (71.1 - 87.7)
2 doses	16/18	81.9 (43.9 - 94.1)	84.1 (50.2 - 96.3)
1 dose	16/18	100 (n/a)	100 (66.5 - 100.0)

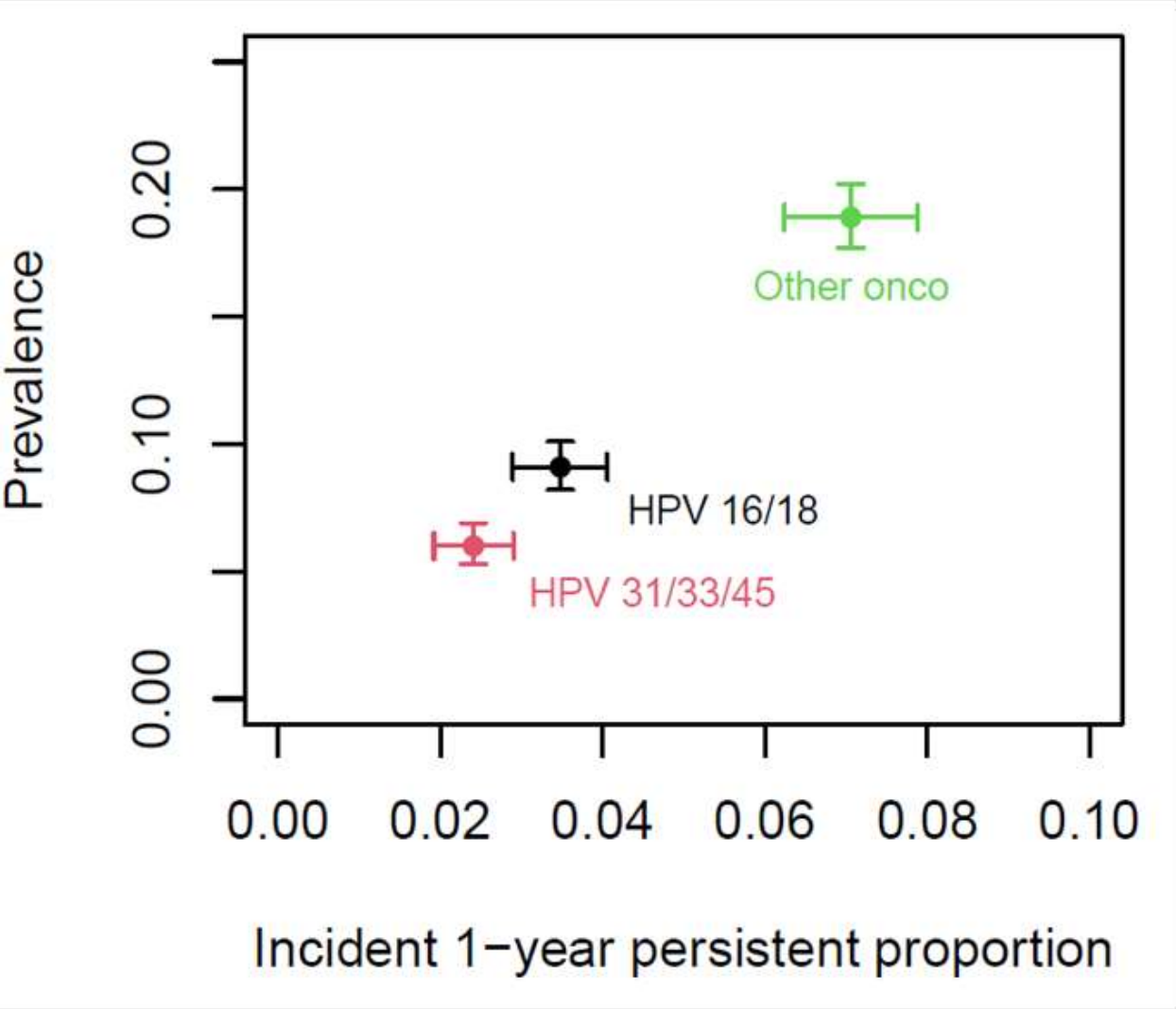
*ATP: According to protocol cohort; CI: confidence interval (delta method). HPV: human papillomavirus; ITT: intention to treat cohort; n/a: not estimable due to zero HPV 16/18 events; RCT: randomized controlled trial; VE: vaccine efficacy.

Table 2. Sample size calculations for single-arm trial versus two-arm randomized controlled trial.

Power	Vaccine efficacy	Minimum sample size needed to achieve 80% power under 1-arm trial	Minimum sample size needed to achieve 80% power under 2-arm study	Percent reduction in sample size with 1-arm study
80%	50%	953.3	2,180.2	56%
80%	55%	763.4	1,744.9	56%
80%	60%	620.8	1,418.0	56%
80%	65%	511.0	1,166.9	56%
80%	70%	424.9	969.9	56%
80%	75%	356.0	812.6	56%
80%	80%	300.0	684.8	56%
80%	85%	253.6	579.0	56%
80%	90%	214.2	489.5	56%
80%	91%	206.9	473.1	56%
80%	95%	179.3	410.5	56%

Power calculations estimated against null hypothesis of no vaccine efficacy. Assumes similar population prevalences and incidences as the CVT and no loss to follow-up.

Figure 1. HPV prevalence at enrollment in the control arm of the CVT by incidence rate of 1-year persistent infections in the control arm for vaccine-targeted types HPV 16/18; vaccine-targeted types HPV 31/33/45; and vaccine-unaffected types (other oncogenic) HPV 35/39/51/52/56/58/59/66, correlation=0.999.



O029 / #1302

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 1
04-19-2023 9:45 AM - 10:45 AM

FOLLOW-UP OF HPV VACCINATION USING FIRST-VOID URINE AS A NON-INVASIVE GENITAL TRACT LIQUID BIOPSY

Laura Teblick, Jade Pattyn, Severien Van Keer, Annemie De Smet, Ilse De Coster, Alex Vorsters
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Introduction: The initial stream of urine, defined as first-void urine (FVU), contains genital secretions accumulated between the small labia and urethra opening, including DNA, transudated antibodies, and other HPV-related biomarkers. This study assesses FVU as a tool for monitoring HPV vaccination based on HPV DNA and genotype-specific antibody response.

Methods: For this study, 63 women (21-46 years old) receiving three doses of the nonavalent HPV vaccine (EudraCT: 2015-005093-38) provided paired FVU and serum samples before vaccination (0M), 7 months after the 1st dose (7M), and approximately 3.5 years after the 1st dose (3.5Y). HPV-antibody concentrations were measured for all samples using the M9ELISA at the CDC (Georgia, U.S.A). We also determined total IgG concentrations (BioPlex Pro™ Human Isotyping Assay) for all samples. In addition, total protein (Pierce™ BCA Protein Assay Kit), human DNA, and HPV DNA (Cobas 6800, Riatol qPCR) concentrations were measured for FVU samples.

Results: show good correlations between HPV-antibody titers of paired FVU and serum samples (0M: $r_s = 0.52$, 7M: $r_s = 0.69$, 3.5Y: $r_s = 0.80$). In addition, ROC analyses showed high sensitivities for the classification of unvaccinated and vaccinated samples overall (0M vs. 7M; FVU: 97.5%, Serum: 98.1%, and 0M vs. 3.5Y; FVU: 93.9%, Serum: 98.1%) and per HPV vaccine type. At 0M and 7M, 11.1% (7/63) and at 3.5Y, 6.9% (4/58) of the women were HR-HPV positive, of which two had a persistent infection.

Conclusions: This study demonstrates that FVU contains not only HPV DNA but also HPV vaccine-induced antibodies. In addition, we could identify participants with naturally induced antibodies and observed boosting of these antibody titers after vaccination. By using FVU sampling, we require only one at-home collected sample for follow-up of vaccination (i/o blood) and infection (i/o cervical smear or vaginal self-samples) in, e.g., large epidemiological studies and follow-up of adjusted vaccination schedules.

O030 / #1295

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER AND CUTANEOUS LESIONS
04-19-2023 9:45 AM - 10:45 AM

CELL-FREE DNA FROM LIQUID BIOPSIES AS A NOVEL TOOL FOR DIAGNOSIS OF HEAD AND NECK CANCER

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Introduction: The diagnosis of head and neck cancer (HNC) is currently based on a clinical examination and imaging. In case of suspected cancer, a biopsy is obtained from the tumor area. The examinations leading to final diagnosis are often time consuming, expensive, and require specialized staff. A less invasive and readily available tool to aid in the detection of cancer is a blood sample, a so called “liquid biopsy”. Liquid biopsies utilize the fact that dividing cells continuously release a small portion of their DNA into the blood in the form of cell-free DNA (cfDNA). cfDNA originating from cancerous tissue will be different from the body's own DNA, and can be identified and used as a biomarker and indicator of the presence of cancer.

Methods: The aim of this project was to evaluate if the diagnosis and recurrence of HNC can be determined by analyzing liquid biopsies taken at time of diagnosis, during treatment and monitored during a five-year follow-up period. Since 2017, we have offered all patients referred to our institution to participate in this retrospective study. By targeted next-generation sequencing, we investigate cancer-specific mutations in cfDNA, and by droplet-digital PCR (ddPCR), we analyze the occurrence and quantity of cfHPV-DNA.

Results: We have included 1900 patients of whom 650 have a biopsy-verified HNC and are currently followed with serial blood samples after end of treatment. 33% of the patients have been diagnosed with oropharyngeal squamous cell carcinoma. By ddPCR, we have determined the HPV-status and subsequent HPV genotype in this patient group. Following successful treatment, the occurrence of cfHPV-DNA decreases or disappears completely. At relapse, before the cancer can be clinically verified by PET-CT, a rise in cfHPV-DNA can be observed.

Conclusions: cfHPV-DNA is a safe and reliable way of monitoring patients with HPV-positive oropharyngeal squamous cell carcinoma.

O031 / #1458

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER AND CUTANEOUS LESIONS
04-19-2023 9:45 AM - 10:45 AM

PROGNOSTIC IMPLICATION OF HPV SPECIFIC TYPES IN OROPHARYNGEAL CANCER: A MULTICENTER, MULTINATIONAL (EPIC-OP) STUDY

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Introduction: HPV-related oropharyngeal cancers (OPC) have better prognosis than non-related. However, 20% of cases still fail to treatment. This international multicenter study aims to identify the prognostic value stratified by $p16^{INK4a}$ and HPV (DNA/RNA) status, as well as HPV genotyping.

Methods: An international consortium comprising 13 cohorts of OPC patients from 9 countries with data on $p16^{INK4a}$, HPV (DNA/RNA), and clinical information were identified. Kaplan-Meier analysis estimated overall survival (OS) by HPV types (HPV16 vs other types, HPV16 vs HPV33 vs other types) and $p16^{INK4a}$ status(positive/negative). Multivariable analyses (MVA) identified prognostic value of p16 and HPV genotype.

Results: From the overall study, a total of 4069 patients from 8 cohorts with specific HPV type information were included. Positivity from these cohorts was 1733 (43%). HPV types identified were: 1057 (61%) HPV-16, 36 (2%) HPV-33, and 20 (1%) HPV-35, and 620 (36%) other HPV types. In univariate Kaplan Meier analyses we did not found differences in the OS between HPV16, HPV33, and Other HPV types. We did found differences when stratifying the results by p16 results. OS of any HPV type specific group showed better survival when p16 was overexpressed than not. MVA results would be presented at the meeting.

Conclusions: p16 remains a strong prognostic factor for OS while no survival difference is found by various HPV genotypes (16, 33, and others) in HPV-related OPC patients. Information on extended studies will help to elucidate which additional factors besides HPV-relatedness can help in stratifying prognosis within HPV-related OPC patients.

O032 / #1262

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER AND CUTANEOUS LESIONS
04-19-2023 9:45 AM - 10:45 AM

ORAL MICROBIAL TRANSCRIPTOME BETWEEN OSCCS AND ONCOGENIC HPVS

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Introduction: The association between high-risk (HR)-HPV and oral squamous cell carcinomas (OSCCs) remains unclear, and estimates vary from 3 to 73% of how many OSCCs are induced by oncogenic HPVs. Moreover, there is currently an increase in the incidence for HPV-related OSCCs worldwide, which leads to a great need to developed ways to screen and detect OSCC in early stage of disease. Here we investigated the oral microbiota in OSCCs with or without association of oncogenic HPVs and compared to healthy oral mucosal microbiota using high-throughput RNA sequence data.

Methods: These analyses included RNA-Seq sequence data of 356 OSCCs and 33 control biopsies with no lesions and taxonomic classification of the viral and bacterial transcripts from the cancer genome atlas dataset.

Results: Preliminary results of the viral transcripts showed 113 OSCCs associated to oncogenic HPV16 or HPV33, and both 243 OSCCs and 33 controls without any HPV association. A significant difference in the microbial composition was observed for OSCCs compared to normal oral mucosa. Moreover, some oral microbial taxa showed significant relative abundance differences between HR-HPV-related OSCCs compared to OSCCs without association to oncogenic HPVs.

Conclusions: These preliminary results suggest a shift in oral microbial composition from the healthy mucosa to OSCC. Interestingly, some of these microbial taxa changes seem to be more associated to HR oncogenic HPV-related OSCCs compared to other oral cancer etiologies. However, further work is required to confirm these differences in oral microbial structure associated to differential OSCC development.

O033 / #1080

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER AND CUTANEOUS LESIONS
04-19-2023 9:45 AM - 10:45 AM

CD4 T-CELLS LYMPHOPENIA IN DISTINCT IMMUNOLOGICAL CONTEXTS DIFFERENTIALLY AFFECTS THE HUMAN SKIN MICROBIOME AND ALPHA-, BETA- AND GAMMA HUMAN PAPILLOMAVIRUSES (HPV) COLONIZATION

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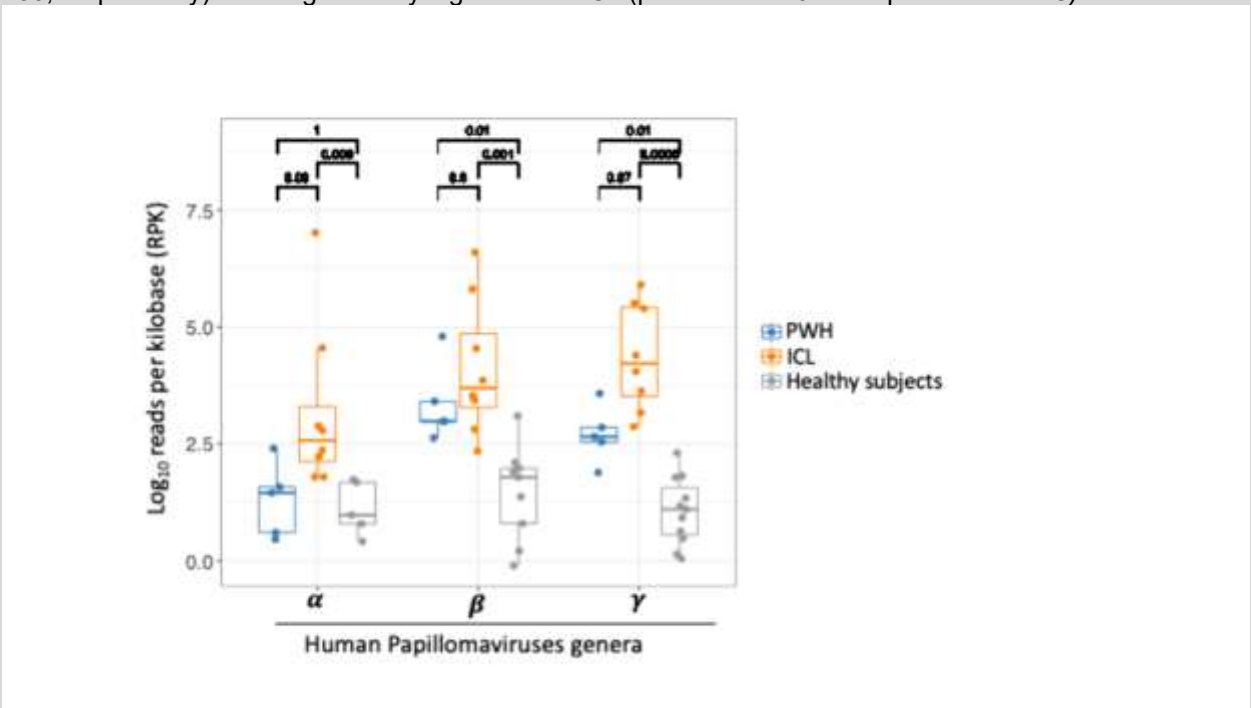
Introduction: The role of specific immune components in maintaining host-microbial homeostasis remains poorly defined. People with HIV (PWH) and Idiopathic CD4 Lymphocytopenia (ICL) patients exhibit low CD4 T-cells in distinct clinical and immunological contexts providing a unique opportunity to decipher the role of helper CD4 T-cells in skin host-microbial interactions. These patients' increased risk of comorbidities includes HPV-related diseases and other opportunistic infections and neoplastic, autoimmune and inflammatory skin disorders. We hypothesized that ICL and PWH have prominent skin microbiome shifts, related to distinct immunological dysfunction.

Methods: Skin microbiome topographical diversity (shotgun metagenomics) was analyzed in PWH, ICL and healthy controls (HCs).

Results: Skin samples from antiretroviral (ART)-naïve PWH (PWH-naïve, n=5, median CD4 48 cells/ mL, median plasma (p)HIV-RNA=361,206 copies/mL), ICL (n=8, median CD4 65 cells/mL), and HCs (n=11) were collected. HCs typically showed shared microbiome features; PWH and ICL exhibited greater inter-individual heterogeneity, consistent with prior immunodeficiency studies. As hypothesized, PWH and ICL had notable skin microbiome shifts: PWH-naïve and ICL exhibited higher HPV reads per kilobase (RPK). Median α-HPV RPK of inside elbow was higher in ICL than in HCs (420 and 9, respectively; p=0.003), while that in PWH (28; p=1) was not significantly different from HCs (Figure 1). Median β-HPV RPK of the same site in ICL and PWH (5300 and 967, respectively) and γ-HPV RPK in ICL and PWH (17906 and

450, respectively) were significantly higher than HCs (β-HPV RPK=61 and γ-HPV RPK=13).



Conclusions: Our data suggest that CD4 T cell lymphopenia may differentially affect skin microbiomes and HPV colonization based on the clinical and immunological context in which is observed. Studying human skin microbiomes based on underlying immunodeficiency can provide insights into the immunological determinants of the susceptibility to HPV colonization and consequent HPV-related diseases.

O034 / #822

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER AND CUTANEOUS LESIONS
04-19-2023 9:45 AM - 10:45 AM

NOVEL POLYMERASE CHAIN REACTION METHOD FOR DETECTING CUTANEOUS AND BETA GENUS HUMAN PAPILLOMAVIRUS DNA

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Introduction: In the field of dermatology, there is a need for primers that can be used for cutaneous warts and epidermodysplasia verruciformis (EV). Recently, we have reported efficient primer pairs, SK1, 2, for detecting cutaneous HPVs, however, few primers are available for detecting β-HPVs from EV. In this study, we attempted to develop PCR method that can efficiently detect β-HPVs as well as cutaneous HPVs.

Methods: The L1 regions of β-HPVs were aligned, common sequences were identified, and consensus SK3 and SK4 primers were newly developed. Plasmids of cutaneous types (HPV types1a, 2a, 3, 4, 7, 27, 57, 60, 63, 65) and β-HPVs (HPV types 5, 8, 37, 38, 47, 75, 76, 93, 96) were used as templates for amplification with the SK3, 4 primers. We also performed PCR by using SK1, 2 primer pairs and SK1, 2, 3, 4 primer pairs to compare the amplified HPV types. PCR conditions followed the previous report of SK1, 2. Direct sequencing of amplified products was performed. The sensitivity of the PCR method was confirmed by serial dilution.

Results: All β-HPVs were successfully detected with SK3, 4 primers. The sensitivity of this method was equivalent to detecting about 1,000 copies of HPV DNA. PCR using SK1, 2 was also performed and all the cutaneous types were amplified. We further did PCR by using SK1, 2, 3, 4 primers and all both cutaneous and β-HPVs were amplified. All PCR products were confirmed by a direct sequencing using primers from one side for each method.

Conclusions: Both SK1, 2, and SK3, 4 primer pairs were able to detect cutaneous and β-HPVs, respectively. SK1, 2, 3, 4 primer pairs could detect all the types. The type could be determined by a simple direct sequencing. SK1, 2, 3, 4 primers can be used in accordance with HPV types.

O035 / #1382

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER AND CUTANEOUS LESIONS
04-19-2023 9:45 AM - 10:45 AM

SAFETY RUN-IN OF INTRAMUSCULAR PNGVL4A-SIG/E7(DETOX)/HSP70 DNA AND TA-CIN PROTEIN VACCINATION AS TREATMENT FOR HPV16+ ASC-US, ASC-H, OR LSIL/CIN1

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Introduction: Patients with HPV16 infection and low-grade cervical dysplasia (LSIL/CIN1) or atypical squamous cells (ASC-US/ASC-H) require active surveillance for disease progression. A safe and effective immunotherapy to clear HPV16 is an unmet medical need. The safety run-in cohort of a randomized double-blind, placebo-controlled Phase II trial of PVX2 (vaccination twice with HPV16-targeting pNGVL4a-Sig/E7(detox)/HSP70 plasmid and once with the HPV16 L2E7E6 fusion protein “TA-CIN”) as immunotherapy for patients with HPV16+ ASC-US, ASC-H, or LSIL/CIN1 (NCT03911076) was recently completed.

Methods: Subjects were confirmed to have HPV16 infection and LSIL/CIN1, ASC-US, or ASC-H. Adverse events were evaluated using CTCAE v5.0. HPV typing by HPV16 18/45 Aptima Assay was done at week 0, month 6, and month 12, with simultaneous cytology analysis. Cervical biopsies and ECC were performed at week 0 and month 6.

Results: In the safety run-in cohort 12 eligible patients were enrolled. Each received three monthly immunizations. One was lost to follow-up after week 12. There were no serious adverse events. A total of five adverse events were noted by four patients; 4 were considered not vaccine-related, and one ‘unlikely related’ by the investigator. At month 6, 45% (5/11) of participants converted to HPV16-negative and 2 others developed CIN2+ and received a LEEP. At month 12, 64% (7/11) were HPV16-negative, including those HPV16-negative at month 6.

Conclusions: The PVX2 immunotherapy was well tolerated and associated with viral regression, supporting further testing.

O036 / #607

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: TAXONOMY, STRUCTURE, MICROBIOME
04-19-2023 9:45 AM - 10:45 AM

2.27Å CRYOEM STRUCTURE OF HPV16-HEPARIN COMPLEX REVEALS CAPSID STABILIZATION AND L2 DENSITY

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Introduction: Human papillomavirus (HPV) is a significant health burden and leading cause of virus-induced cancers. The capsid contains 72 capsomers comprised of major (L1) and minor (L2) structural proteins. Determining the structure of the minor capsid protein, L2, has been difficult due to the asymmetric incorporation of L2 and inherent flexibility of the HPV capsid. During entry, initial binding to heparin is known to result in a conformational change in the capsid.

Methods: HPV16 quasivirus, comprised of L1 and L2 capsid proteins with a packaged cottontail rabbit papillomavirus genome, was incubated with heparin, the complex was vitrified, and the data were collected for cryoEM single particle analysis. An icosahedral map was reconstructed. Subparticles were designated and extracted with a program called Icosahedral Subvolume Extraction and Correlated Classification (ISECC). Hexavalent and pentavalent capsomer subvolumes were refined separately. ISECC was used to analyze the capsid flexibility, both on a whole particle level and on an inter-capsomer level.

Results: In the resulting 2.27Å resolution structure, heparin was visualized bound to the HPV capsid, around the icosahedral fivefold capsomer. The asymmetric unit was built, and L1 and non-L1 (L2) densities were identified. The whole capsid flexibility analysis revealed less variation in the capsid diameter of HPV16-heparin complex compared to virus alone. Similarly, the inter-capsomer flexibility analysis showed that heparin binding reduced the flexibility between capsomers.

Conclusions: This high resolution 2.27Å HPV structure allowed a more confident assignment of rotamers than our previous 3.1Å resolution structures. The resolution allowed the entire asymmetric unit of HPV to be built unambiguously. Our results indicate that heparin binding stabilizes the entire HPV16 capsid, not just the fivefold region where heparin binds. This high resolution HPV virus structure links heparin binding and capsid stability and confirms the location of L2, which provides a framework for future HPV biochemical, genetic, and biophysical studies.

O037 / #614

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: TAXONOMY, STRUCTURE, MICROBIOME
04-19-2023 9:45 AM - 10:45 AM

ICOSAHEDRAL SUBPARTICLE EXTRACTION & CORRELATED CLASSIFICATION ALLOWS FOR RESOLUTION IMPROVEMENT, CAPSID FLEXIBILITY ANALYSIS, AND CORRELATION CLASSIFICATION OF HPV AND CPV

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Introduction: Icosahedral Subparticle Extraction and Correlated Classification (ISECC) was inspired by Local Reconstruction and Block Based Reconstruction. All three software packages enable determination of asymmetry in icosahedral viruses and have the ability to extract subparticles for refinement and classification in RELION. Although all of these software allow for subparticle extraction, ISECC retains subparticle metadata that allow each subparticle to be traced back to its original location on a virus capsid.

Methods: Human papillomavirus (HPV) quasivirus was vitrified, and the data were collected for single particle analysis. After construction of an icosahedral map, subparticles were extracted with ISECC and refined. The flexibility of the capsid was analyzed with ISECC by evaluating motions on a per-particle level by analyzing particle diameter and inter-capsomer distances. As a test model, complex of canine parvovirus (CPV) and antibody fragment (Fab) was also vitrified and data were collected for single particle analysis. After refinement and classification, correlated classification analysis was performed to identify binding patterns derived by normalizing the observed radial distribution functions to those of a hypothetical particle with all binding site occupied.

Results: Subparticle refinement of individual capsomers provided the first atomic resolution structure of HPV, and improved the resolution from 4.5Å to 3.1 Å. Refined papillomavirus capsomers allowed for flexibility analysis for two parameters: overall particle diameter and inter-capsomer distances. In CPV-Fab complex, correlated classification of an antibody binding site allows for clash predictions and cooperativity analysis of binding events.

Conclusions: Here we demonstrate the functionality of ISECC evaluate motions with human papillomavirus 16 (HPV 16) and the functionality of ISECC correlated classification with a canine parvovirus (CPV) Fab complex.

O038 / #976

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: TAXONOMY, STRUCTURE, MICROBIOME
04-19-2023 9:45 AM - 10:45 AM

COMPREHENSIVE GLOBAL EVALUATION OF THE ANTIGENICITY OF LINEAGE-SPECIFIC PSEUDOVIRUS VARIANTS USING ANTIBODIES ELICITED BY NATURAL INFECTION

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Introduction: Variants of HPV have been classified into lineages and sublineages based upon their whole genome sequence (WGS). Variants exhibit differential geographical distribution and disease risk but the consequences for natural or vaccine-induced immunity are unclear. We examined the specificity of antibodies developed after natural infection with variants of HPV16, HPV18, HPV31, HPV33, HPV45, HPV52 and HPV58 to determine whether lineage-specific serotypes exist for some genotypes.

Methods: Serum (or plasma) samples were assembled from existing archives representing individuals from Africa, The Americas, Asia and Europe (n=2,303). Inclusion criteria included sample availability from individuals with contemporary (<2 years) lineage-specific infection defined by WGS data derived from accompanying cervical samples. Serum samples (mean 329 samples per genotype) were tested against lineage-specific pseudoviruses (e.g., A, B, C and D) representing each genotype. The testing laboratory was blinded to individual lineage and other demographic data (country of origin, disease state) until testing was completed. Data are presented as two-dimensional arrays of lineage-specific seropositivity rates and GMT (95%CI). An assessment of the differential antigenicity of lineage variants was made using hierarchical clustering and Antigenic Cartography.

Results: Typical of natural infection, seropositivity rates were <50% and GMTs were low but highly reproducible (r^2 0.925). Many antigenic variants demonstrated differences in neutralization sensitivity compared to their consensus A variant, but these differences were of a low magnitude (<2 fold). Lineage variants of HPV33, HPV52 and HPV58 however exhibited >4-fold reduced sensitivities compared to their consensus A variant.

Conclusions: For most genotypes, these data suggest that natural infection antibodies recognize lineage variants similarly. However, these empirical observations provide support for the capsid proteins of some lineages of HPV33, HPV52 and HPV58 to be considered antigenically distinct within their respective genotypes. These data contribute to our understanding of the natural evolution of HPV and of host immunity.

O039 / #513

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: TAXONOMY, STRUCTURE, MICROBIOME
04-19-2023 9:45 AM - 10:45 AM

LONGITUDINAL ANALYSIS OF THE DYNAMICS OF CERVICOVAGINAL MICROBIAL COMMUNITIES IN HRHPV INFECTION

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Introduction: The cervicovaginal microbiome (CVM) is a dynamic microenvironment that assembles in microbial communities and is associated with women's cervical health. In particular, Lactobacillus-dominated community state types (CSTs) and Lactobacillus-depleted CSTs are associated with cervical protection and susceptibility to high-risk human papillomavirus (hrHPV) infections, respectively, but the long-term dynamics of CSTs in hrHPV-infected women remain poorly understood.

Methods: We implemented high-resolution microbiome profiling through circular probes-based RNA sequencing in cervical smears of a longitudinal cohort of 141 women with DNA confirmed hrHPV infection at the first visit, who returned for microbiome profiling six months post-initial hrHPV infection diagnosis to determine the dynamics of CSTs between both visits.

Results: Here we show the characteristic microbial shifts occurring six months after hrHPV infection diagnosis and describe that women with baseline CSTs I and III, characterized by Lactobacillus crispatus and Lactobacillus iners dominance, respectively, have more similar microbiome composition at the second visit than women with baseline CST IV. Analyses of the association of bacterial species with the stability of the CVM reveal that Lactobacillus acidophilus correlates with transitional microbiomes while Lactobacillus gasseri and several CST IV-associated bacteria correlate with stable microbiomes. We also determine that distinctive microbial species, dominance, and diversity are associated with the stability of CSTs I-A, III-A, IV-A, and IV-B.

Conclusions: Overall, we describe the dynamics of microbial communities in the CVM during hrHPV infection. Our data suggest distinct stability and changes of CSTs during infection, which could be applied to develop CVM-targeted therapies against infection progression towards disease.

O040 / #1132

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: TAXONOMY, STRUCTURE, MICROBIOME
04-19-2023 9:45 AM - 10:45 AM

HIGH-THROUGHPUT METAGENOMICS REVEALS DISTINCT MICROBIAL SIGNATURES IN THE VAGINAL MICROENVIRONMENT OF HIGH-RISK HPV-POSITIVE WOMEN

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Introduction: Increasing evidence highlights the potential significance of the vaginal microbiome (VM) in both shaping the severity of HPV infection and impacting on the development of cervical intraepithelial neoplasia. However, the precise role of certain bacteria in the context of HPV positivity and persistence of infection remains undisclosed. Here, we applied an NGS methodology to comprehensively profile the VM in a series of 877 women who tested positive for at least one high-risk HPV (hrHPV) type with the COBAS® 4800 assay, after self-collection of a vaginal smear sample.

Methods: Starting from gDNA, we PCR-amplified the V3-V4 region of the bacterial 16S rRNA gene and applied a paired-end NGS protocol (Illumina). Bioinformatics and statistical analyses were performed with dedicated software. Alpha diversity was calculated at the operational taxonomic unit (otu) level with the Shannon index.

Results: After quality filtering, we acquired 30,353,253 reads (median 26,516 reads/sample) that were processed for taxonomic assignment and meta-data analysis. Women were classified in 3 groups based on the hrHPV subtype detected during diagnosis: HPV16, HPV18, HPVother. No significant differences were found in terms of microbial diversity for women infected with different HPV subtypes. However, significant differences were observed in the abundance of certain bacteria compared to negative controls, and among different HPV-subtypes. In detail, we found Lacticaseibacillus to be significantly depleted in all HPV groups compared to the control group ($P<0.05$). Moreover, all three groups exhibited increased frequencies of species assigned to the genera Megasphaera and Sneathia compared to negative controls ($P<0.01$). Especially for Lacticaseibacillus, we observed significant depletion in the case of HPV16, HPV18 vs. HPVother ($P<0.01$) .

Conclusions: Overall, our results suggest that the presence or absence of specific microbial genera may be linked to the observed severity in hrHPV infection, particularly in the case of HPV16, 18 subtypes.

O041 / #1524

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: TAXONOMY, STRUCTURE, MICROBIOME
04-19-2023 9:45 AM - 10:45 AM

METAGENOMICS AND METABOLOMICS OF PERSISTENT HIGH-RISK HUMAN PAPILLOMA VIRUS (HRHPV) INFECTIONS AND CERVICAL CANCER

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Introduction: Persistent hrHPV infection is a non-oncolytic infection of the cervical epithelium and a necessary cause of cervical cancer. Evidence suggests significant roles for the vaginal microenvironment in establishment of persistence of the infection and progression to cervical cancer.

Methods: We conducted shotgun metagenomics sequencing and global metabolomics profiling of the cervical secretions from 84 women. Some 68 of these women were tested and categorized based on HPV results as negative (N) or positive (P) at 3 time points: baseline, 12 months, and 24 months, using DEIA/LiPA$_{25}$ into NNN (13), NNP (16), NPP (10), PPP (12), PPN (15) and PNN (1), while 16 women had either invasive squamous cell carcinoma (15) or papillary adenocarcinoma (1).

Results: There was a higher diversity of bacteria and lower Lactobacillus abundance comparing the PPP to NNN category. The commonest genus in PPP category were Gardnerella, Prevotella, Atopobium, Ureaplasma, Sneathia and Streptococus. Cervical cancer samples showed significantly decreased bacterial diversity, absence of Lactobacillus spp., and relatively high abundance of Cutibacterium. Our discriminative analysis showed that Prevotella prevalence and abundance discriminated between NNN and PPP categories. We found Mageeibacillus indolicus, in 4 members of the PPP group. The top five enriched pathways in the NNN group compared to the PPP group were: Folate transformations II, sucrose degradation III (sucrose invertase), lipid IVA biosynthesis, super pathway of thiamin diphosphate biosynthesis III (eukaryotes) and Guanosine ribonucleotides de novo biosynthesis mainly contributed by the Lactobacillus spp. and unclassified strata. The top enriched gene family in the NNN group: 3.1.22.4 Crossover junction endodeoxyribonuclease, 2.7.1.69 Protein-N(pi)- phosphohistidine—sugar phosphotransferase and 1.7.1.7 GMP reductase similarly contributed by diverse Lactobacillus spp. and unclassified. We identified HPV integration sites in 6/20 cervical cancer cases and 1/12 of the PPP cases.

Conclusions: hrHPV infection was associated with vaginal dysbiosis and several bacterial genera and species, gene families and pathways were different between groups.

O042 / #1123

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 3
04-19-2023 3:45 PM - 4:45 PM

CERVICAL CANCER ELIMINATION IN ONTARIO, CANADA

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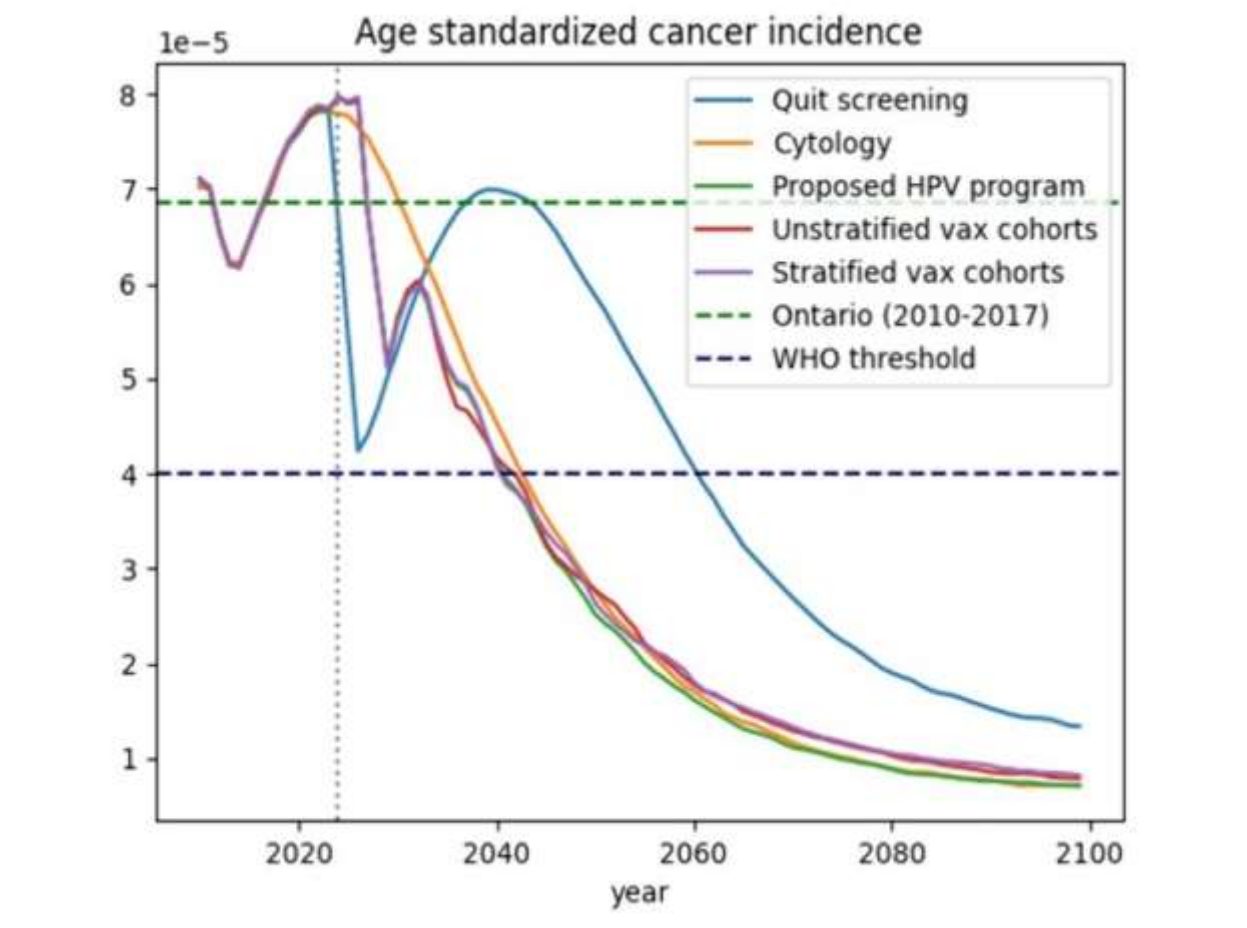
Introduction: In Ontario, Canada, an organized cytology-based screening program has been in place for multiple decades with plans to implement primary HPV-based screening. Students have been offered HPV vaccination through school-based programs since 2007. We examined if, and when, the cervical cancer elimination threshold of <4 cancers/100,000 person-years (as defined by the World Health Organization) could be reached in Ontario, under various screening conditions.

Methods: The hybrid microsimulation model STDSIM-MISCAN-Cervix has been calibrated to the Ontario setting using observed demographic and screening data. In previous analyses, optimal primary HPV-based programs were determined, using a harms-benefits analyses, for future cohorts offered HPV vaccination. Cervical cancer incidence rates were estimated from 2010 to 2100 for four different screening scenarios implemented in 2024. Current screening participation rates were applied to: 1) the current cytology-based program, 3) the future state HPV-based program, 3) the optimal unstratified program, 4) the optimal vaccination-status-stratified program. Additionally, two extreme scenarios were modeled: 1) No screening available, 2) HPV-based screening with 100% participation.

Results: All screening strategies reach relatively similar years of elimination of 2042, 2040, 2041 and 2040 for cytology, future state HPV testing, unstratified and stratified strategies respectively (Figure). In the hypothetical scenario where perfect screening participation is assumed, elimination is reached in the year 2028. However, If screening is discontinued after 2024, elimination will be reached in 2060 due to

immunization alone.



Conclusions: All selected realistic screening strategies reach relatively similar years of elimination around 2040. Adjusting screening strategies for cohorts offered HPV vaccination or even stratifying on vaccination status does not substantially affect the timing of elimination, but, can improve the overall screening harms-benefits balance.

O043 / #382

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 3
04-19-2023 3:45 PM - 4:45 PM

SPONTANEOUS PRETERM BIRTH RISK AMONG HPV VACCINATED AND UNVACCINATED WOMEN IN DENMARK

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Introduction: Recent evidence has suggested that HPV vaccination may reduce the risk of preterm birth (PTB). The objective of this analysis was to determine if the risk of PTB was lower among HPV-vaccinated women in Denmark, compared to unvaccinated women.

Methods: In this nationwide population-based retrospective cohort study of >240 000 women delivering infants in Denmark, individual level data on birth outcomes and HPV vaccination status from national registers were linked. Only data from primigravid women were included. We compared spontaneous PTB rates between vaccinated and unvaccinated women using regression analyses. We also performed a stratified analysis by vaccination before and after 17 years old.

Results: Of the women in this analysis, 174 504 had received no prior doses of HPV vaccine, while 68 632 had been vaccinated prior to pregnancy. Vaccinated and unvaccinated women were similar in age (27.2±3.7 vs. 29.4±4.9, respectively) and marital status (married: 82.0% vs. 81.7%, respectively). After adjusting for maternal age, education, marital status, smoking status during pregnancy, pre-pregnancy BMI, and pre-pregnancy cervical lesion/treatment history, there was no significant difference in the odds of PTB between vaccinated and unvaccinated women. There was also no difference in the odds of spontaneous PTB in relation to time between vaccination and pregnancy. In contrast, compared to unvaccinated women, the odds of PTB were lower among women vaccinated before age 17 (OR: 0.87, 95% CI: 0.75-1.00). This association was not present for women vaccinated at age ≥17.

Conclusions: In this large, population-based cohort, we found reduced odds of spontaneous PTB among women HPV vaccinated at an early age compared to those unvaccinated. It seems conceivable that HPV vaccination may not only reduce the incidence of cervical cancer and severe precursors, but also the risk of PTB related to HPV infection.

O044 / #1258

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 3
04-19-2023 3:45 PM - 4:45 PM

CORRELATES OF PARENTAL CONSENT TO VACCINATE DAUGHTERS AGAINST THE HUMAN PAPILLOMAVIRUS VACCINE: APPLICATION OF THE HEALTH BELIEF MODEL

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Introduction: The human papillomavirus (HPV) vaccine is one of the greatest inventions in preventing HPV-related conditions including cervical cancer. Zambia introduced a free national HPV vaccination program in 2019 restricted to 14-year-old girls. Parental consent is critical for vaccine uptake by adolescent girls, however, parental refusal is prevalent. Therefore, this study aimed to understand parents' beliefs and perceptions associated with consent for daughters' vaccine uptake, using the Health Belief Model (HBM) as a guiding framework.

Methods: This was a cross sectional study conducted in Lusaka district of Zambia between September and October 2021. We conveniently recruited parents of adolescent girls(15-18 years) from different social settings. The outcome variable was parental consent for HPV vaccination for their daughters. The primary explanatory variable was the HBM constructs and other exposures included knowledge of HPV and HPV vaccine, and social demographic characteristics.The odds ratios with 95% confidence intervals were computed to assess measures of effect.

Results: The study enrolled 400 participants. The median age of participants was 44years (IQR 36-54years), 350 (87.5%) were females, and 180 (45.0%) had attained secondary education. Approximately 330(82.8%) and 352(88.0%) were unemployed and reported that their daughters were going to school and 86 (21.5%) were in the poorest wealth index. A total of 215 (53.8%) parents reported consenting to the HPV vaccine for their daughters and that the daughters received the vaccine. In multivariable analysis, a unit increase in HPV knowledge (AOR=1.50, 95% CI=1.14, 1.97) and cues to action score (AOR=2.90, 95% CI=1.50, 5.61) increased the odds of parental consent to vaccinate a daughter after controlling for confounders.

Conclusions: Parental HPV vaccine consent was influenced by multiple factors including parents' knowledge and attitudes, cervical cancer screening and living with HIV. There is need for community education programs regarding the benefits of HPV vaccine and address perceived barriers.

O045 / #1356

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 3
04-19-2023 3:45 PM - 4:45 PM

TRIAGE PERFORMANCE AND PREDICTIVE VALUE OF THE HUMAN GENE METHYLATION PANEL AMONG WOMEN POSITIVE ON SELF-COLLECTED HPV TEST: RESULTS FROM A PROSPECTIVE COHORT STUDY

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Introduction: Triaging of women positive for high-risk human papillomavirus (hrHPV) on selfcollected samples requires a molecular reflex test to avoid recall for cytology or visual tests.

Methods: We assessed triage performance and predictive value of human gene methylation panel (ZNF671/ASTN1/ITGA4/RXFP3/SOX17/DLX1) alone and with combination of HPV16/18 genotyping in a longitudinal screening study.

Results: Out of 9526 women at baseline, 1758 women positive for hrHPV on self-collected samples followed up yearly were included in the current analysis. Satisfactory risk stratification to detect cervical intraepithelial neoplasia grade 2 or worse (CIN2+) was demonstrated by the methylation panel with an odds ratio (OR) of 11.3 among methylation-positive women compared to methylation-negative counterparts. Triaging with methylation panel reduced colposcopy referral rate by 67.2% with sensitivity and specificity of 83.0% and 69.9% to detect CIN2+. The corresponding values for the combining methylation and HPV 16/18 were 96.6% and 58.3%. The cumulative 3-year incident CIN2+ risk was 6.8% (95% CI: 4.9%-8.6%) for hrHPV positive women, which was reduced to 4.5% (95% CI: 2.7%-6.3%) and 2.9% (95% CI: 1.2%-4.5%) for women negative on methylation triaging alone and negative on the combined strategy. The corresponding risk for women positive for both methylation and HPV 16/18 reached 33.7% (95% CI: 19.0%-
45.8%)

Table 1 Risk of CIN 2+ and CIN 3+ among hrHPV positive women stratified by methylation and hrHPV genotype at baseline

HPV genotype	Methylation panel status	Cases detected (N)	Women tested (N)	Proportion % (95%CI)	OR (95%CI)	*P* value
			CIN2+			
hrHPV+	Any	88	1758	5.0 (4.1, 6.1)		
	-ve	15	1182	1.3 (0.8, 2.1)	1 (Ref.)	< 0.001
	+ve	73	576	12.7(10.2, 15.6)	11.3(6.4,19.9)	
HPV16/18+	Any	69	372	18.5 (14.9,22.8)		
	-ve	12	205	5.9 (3.4,10.0)	1 (Ref.)	< 0.001
	+ve	57	167	34.1(27.4, 41.6)	8.3 (4.3,16.2)	
non-16/18 HPV+	Any	19	1386	1.4 (0.9, 2.1)		
	-ve	3	977	0.3 (0.1, 0.9)	1 (Ref.)	< 0.001
	+ve	16	409	3.9 (2.4, 6.3)	13.2 (3.8, 45.6)	
			CIN3+			
hrHPV+	Any	34	1758	1.9 (1.4, 2.7)		
	-ve	2	1182	0.2 (0.0, 0.6)	1 (Ref.)	< 0.001
	+ve	32	576	5.6 (4.0, 7.7)	34.7 (8.3,145.3)	
HPV16/18+	Any	31	372	8.3 (5.9,11.6)		
	-ve	2	205	1.0 (0.3, 3.5)	1 (Ref.)	< 0.001
	+ve	29	167	17.4 (12.4,	21.3 (5.0,90.9)	
non-16/18 HPV+	Any	3	1386	0.2 (0.1, 0.6)		
	-ve	0	977	0 (0, 0.4)	1 (Ref.)	NA
	+ve	3	409	0.7 (0.2, 2.1)	NA	

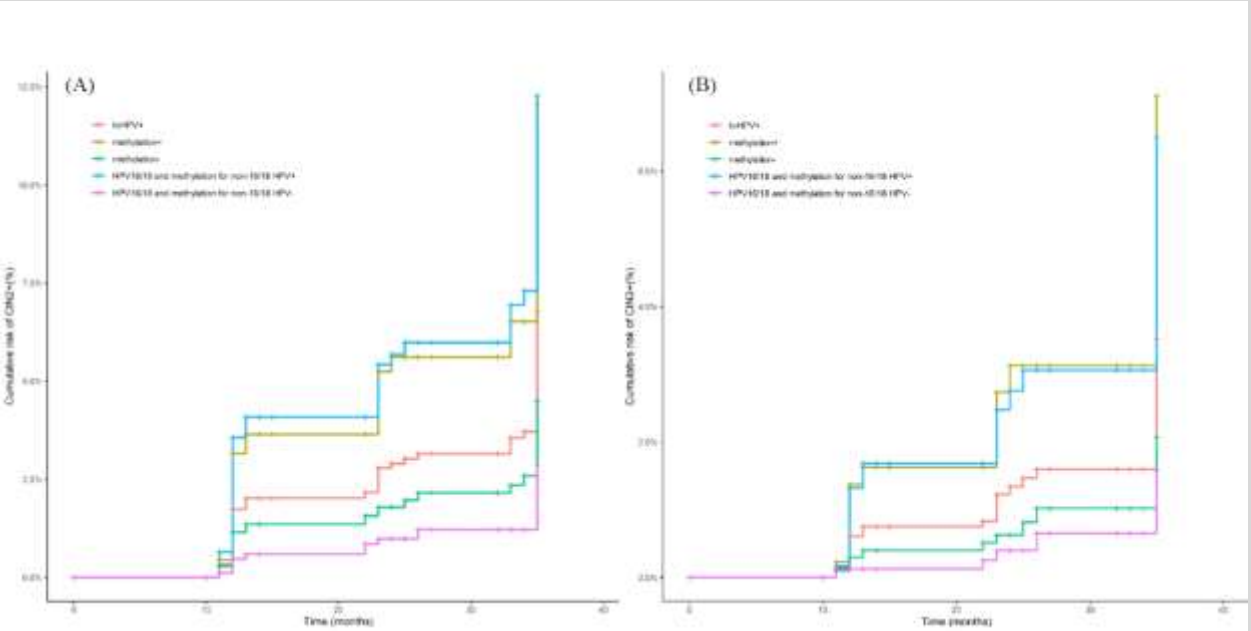
Abbreviations: hrHPV: high-risk human papillomavirus; CIN2+: cervical intraepithelial neoplasia grade 2 or worse; CIN3+: cervical intraepithelial neoplasia grade 3 or worse; OR: odds ratio; Ref. reference

Table 2 Cross-sectional triage performance of methylation alone or in combination with HPV 16/18 genotyping for detection of CIN 2+ and CIN 3+ lesions among hrHPV positive women at baseline

Triage strategy	Colposcopy referral rate (%)	Cases detected	Sensitivity (%) 95%CI	Specificity (%) 95%CI	PPV (%) 95%CI	NPV (%) 95%CI	AUC 95%CI
			CIN2+ (N= 88)				
hrHPV positive on either test		88					
Methylation panel	32.8	73	83.0	69.9	12.7	98.7	0.764
	(576/1758)		(73.8, 89.4)	(67.6, 72.0)	(10.2, 15.6)	(97.9, 99.2)	(0.716, 0.812)
HPV16/18 and methylation	44.4	85	96.6	58.3	10.9	99.7	0.775
panel for non-16/18 HPV	(781/1758)		(90.5, 98.8)	(55.9, 60.7)	(8.9, 13.3)	(99.1, 99.9)	(0.740, 0.810)
careHPV positive only		64					
Methylation panel	31.6	53	82.8	71.2	13.8	98.7	0.770
	(384/1215)		(71.8, 90.1)	(68.6, 73.8)	(10.7, 17.6)	(97.7, 99.3)	(0.714, 0.826)
hrHPV PCR positive only		86					
Methylation panel	32.9	71	82.6	69.9	13.3	98.6	0.762
	(534/1622)		(73.2, 89.1)	(67.5, 72.1)	(10.7, 16.4)	(97.7, 99.2)	(0.713, 0.811)
HPV16/18 and methylation	44.6	83	96.5	58.3	11.5	99.7	0.774
panel for non-16/18 HPV	(724/1622)		(90.2, 98.8)	(55.8, 60.7)	(9.3, 14.0)	(99.0, 99.9)	(0.738, 0.810)
			CIN3+ (N=34)				
hrHPV positive on either test*							
Methylation panel	32.8	32	94.1	68.4	5.6	99.8	0.813
	(576/1758)		(80.9, 98.4)	(66.2, 70.6)	(4.0, 7.7)	(99.4, 100)	(0.759, 0.866)
HPV16/18 and methylation	44.4	34	100	56.7	4.4	100	0.783
panel for non-16/18 HPV	(781/1758)		(89.9, 100)	(54.3, 59.0)	(3.1, 6.0)	(99.6, 100)	(0.739, 0.828)
careHPV positive only	25						
Methylation panel	31.6	24	96.0	69.7	6.3	99.9	0.829
	(384/1215)		(80.5, 99.3)	(67.1, 72.3)	(4.2, 9.1)	(99.3, 100)	(0.773, 0.884)
hrHPV PCR positive only		32					
Methylation panel	32.9	30	93.8	68.3	5.6	99.8	0.810
	(534/1622)		(79.9, 98.3)	(66.0, 70.5)	(4.0, 7.9)	(99.3, 100)	(0.754, 0.867)
HPV16/18 and methylation	44.6	32	100	56.5	4.4	100	0.782
panel for non-16/18 HPV	(724/1622)		(89.3, 100)	(54.0, 58.9)	(3.1, 6.1)	(99.6, 100)	(0.736, 0.829)

Figure 1 Risk of incident CIN 2+ (A) and CIN 3+ (B) among hrHPV positive women and hrHPV positive women with various HPV 16/18 and methylation test outcomes at

baseline



Conclusions: Our study demonstrated the satisfactory triage performance and predictive value of the methylation panel, especially in combination with HPV 16/18 genotyping. The substantially lower risk of CIN2+ among the triage negative women over the next 3 years suggests that the interval for repeat HPV test can be safely extended to at least 2 years.

O046 / #1390

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 3
04-19-2023 3:45 PM - 4:45 PM

HUMAN PAPILLOMAVIRUS PREVALENCE BY HPV VACCINATION STATUS IN RWANDAN WOMEN LIVING WITH AND WITHOUT HUMAN IMMUNODEFICIENCY VIRUS

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Introduction: Prophylactic HPV vaccines are highly effective in protecting women against cervical infections, precancer and cancer caused by the targeted HPV types. However, evidence for their long-term effectiveness in women with HIV (WWH) is less clear. Rwanda has had high HPV vaccination coverage, allowing for birth year to serve as a proxy for HPV vaccination status. We compared cervicovaginal HPV infection by HIV status and birth cohort.

Methods: Participants were enrolled based on their HIV status and birth year. At enrollment, participants completed a rapid HIV test for those with an unknown HIV status, and provided oral, cervicovaginal and anal specimens for HPV testing using Ampfire (Atila Biosystems), an HPV genotyping assay for HPV16/18/31/33/35/39/45/51/52/53/56/59/66/68/06/11. Baseline HPV point prevalence and ratios of vaccine targeted/cross-protected vs. non-targeted cervicovaginal HPV genotypes, stratified by HIV status and birth year were calculated.

Results: Preliminary data on 499/3,028 women were analyzed. The overall prevalence of vaccine targeted/cross-protected high-risk HPV types (16/18/31/33/45) was 13.8% and that of non-targeted HPV types was 39.2%. The prevalence of targeted/cross-protected HPV among 189 WWH born 1996+ (presumed-vaccinated) and 98 WWH born <1996 (presumed-not-vaccinated) was 19.6% and 19.4%, respectively vs. 6.5% and 9.1% among 185 HIV- participants born 1996+ and 22 HIV- participants born <1996, respectively (Omnibus p=0.001). The ratios of the prevalence of targeted/cross-protected vs. non-targeted HPV types among WWH born 1996+ and <1996, HIV- participants born 1996+ and <1996 were 0.45, 0.45, 0.18 and 0.22 respectively. The ratio of those ratios (HIV- women Vs. WWH) was 0.40 and 0.49 for those born 1996+ and <1996, respectively.

Conclusions: We found 60% lower protection (by Gardasil-4) against HPV infection among WWH compared to their HIV- counterparts, indicating that further studies are needed to determine if WWH will benefit from a combination of a booster dose of the vaccine and targeted screening for cervical precancer and cancer.

O047 / #1595

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 3
04-19-2023 3:45 PM - 4:45 PM

DIFFERENTIAL HPV16/18 VACCINE EFFICACY AGAINST HPV31 BY VARIANTS IN THE L1 SEQUENCE UP TO 11-YEARS POST-VACCINATION IN THE COSTA RICA HPV VACCINE TRIAL

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Introduction: The AS04-adjuvanted human papillomavirus (HPV)-16/18 vaccine (Cervarix®) induces partial cross-protection against phylogenetically-related HPV genotypes, which may be driven by variant-level [e.g., lineage and single nucleotide polymorphism (SNP)] heterogeneity. We examined vaccine efficacy (VE) across cross-protected genotype variants in the Costa Rica HPV Vaccine Trial.

Methods: We included 2846 HPV-vaccinated women (3-doses) and 5465 HPV-unvaccinated women [combined group of hepatitis-A-vaccinated women (3-doses) during the randomized study period (years 1-4) and all women in the screening-only, unvaccinated group during the observational study period (years 4-11)]. The analytical period started two-years post-vaccination (to ensure exclusion of infections present prior to vaccination) through 11-years. Outcomes were HPV31/33/35/45 detection among women HPV-negative for these types prior to the analytical period. Using viral whole genome sequencing, lineages were assigned based on the maximum likelihood tree topology. VEs and VE-ratios were evaluated by lineage and by SNPs in the L1 region.

Results: VE against HPV31 was 76.8% [95% confidence interval (95%CI)=67.5%-84.5%] overall. Compared to VE against HPV31-lineage-A (VE=90.0%; 95%CI=77.3%-98.0%), VE against HPV31-lineage-B (VE=61.6%; 95%CI=26.2%-83.1%) was significantly lower (VE-ratio=0.68; 95%CI=0.29-0.96), while VE against HPV31-lineages-B and-C were similar (VE-ratio=1.22; 95%CI=0.84-2.85) (Table 1). VE against HPV31 significantly differed at nucleotide positions 5921/6238/6367/6372/6772/6796 of L1 (all are lineage-defining positions). One of these SNPs was a nonsynonymous substitution at position 6372, and nucleotide A (defining lineages B/C) had significantly lower VE compared to nucleotide C (defining lineage A) (VE-ratio=0.79; 95%CI=0.65-0.94). Analyses for HPV33/35 were underpowered due to low prevalence of lineage-specific endpoints. VE against HPV45 was 83.0% (95%CI=73.8%-90.4%) overall and was similar between lineages and for L1

SNPs.

	# of events / N	Rate (95% CI)	VE (95% CI)	VE-Ratio (95% CI)	VE-Ratio (95% CI)
Overall					
HPV vaccine arm	35/2665	14.6 (9.7, 19.4)	**76.8 (67.5, 84.5)**	--	--
Combined HPV-unvaccinated group	162/5019	62.7 (53.3, 72.2)			
HPV 31 Lineage A					
HPV vaccine arm	4/2665	1.7 (0.0, 3.5)	**90.0 (77.3, 98.0)**	1.00 (ref)	--
Combined HPV-unvaccinated group	45/5019	17.4 (12.3, 22.4)			
HPV 31 Lineage B					
HPV vaccine arm	11/2665	4.4 (1.8, 7.1)	**61.6 (26.2, 83.1)**	**0.68 (0.29, 0.96)**	1.00 (ref)
Combined HPV-unvaccinated group	30/5019	11.6 (7.5, 15.7)			
HPV 31 Lineage C					
HPV vaccine arm	20/2665	8.4 (4.7, 12.1)	**75.4 (62.0, 86.0)**	0.84 (0.67, 1.02)	1.22 (0.84, 2.85)
Combined HPV-unvaccinated group	87/5019	33.8 (26.8, 40.8)			
Nucleotide Position 6372 = C [Lineage A defining]					
HPV vaccine arm	2/2665	0.9 (0, 2.2)	**94.1 (83.3, 100)**	1.00 (ref)	--
Combined HPV-unvaccinated group	40/5019	15.4 (10.7, 20.2)			
Nucleotide Position 6372 = A [Lineages B/C defining]					
HPV vaccine arm	26/2668	10.8 (6.6, 14.9)	**74.5 (62.3, 84.3)**	**0.79 (0.65, 0.94)**	--
Combined HPV-unvaccinated group	109/5019	42.3 (34.5, 50.1)			

Conclusions: Cross-protection afforded by Cervarix against HPV31 may be driven by high VE against lineage-A compared to lower VE against lineages-B/C. An important SNP impacting HPV31 VE may be position 6372, located within the FG loop of L1, established to be important in neutralization.

O048 / #1177

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENE EXPRESSION II
04-19-2023 3:45 PM - 4:45 PM

THE HPV SEROLOGY STANDARDIZATION INITIATIVE: AIMS AND PROGRESS TO DATE AT THE FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH

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Introduction: Protection against Human Papillomavirus (HPV) infection after vaccination is believed to be mediated by HPV-specific antibodies. However, the lack of standardized assays, procedures, and reagents accessible to the scientific community has precluded the comparison of different studies evaluating immunogenicity of HPV vaccines. With an increase in the number of trials relying on immunobridging for approval of new dosing schedules or vaccine formulations, there has been a critical need for standardized measurement and reporting of immunogenicity to reliably assess non-inferiority of antibody responses and improve overall comparability between studies.

Methods: The HPV Serology Standardization Initiative led by the HPV Serology Laboratory (HSL) at the Frederick National Laboratory was established in January 2017, working with the National Cancer Institute (USA) and The Bill & Melinda Gates Foundation to lead standardization and harmonization efforts for HPV serological testing within vaccine trials. The main goal has been to expedite serology assay standardization by assisting with the development of primary serology standards for HPV-6, 11, 31, 33, 45, 52, and 58, as well as testing samples from several one dose vaccine studies and immunobridging studies. Furthermore, standard operating procedures are also accessible on our laboratory website.

Results: HSL developed secondary standards calibrated against available WHO international standards, reference HPV VLP and a serology-based proficiency panel for the 9 HPV types included in licensed vaccines. Reference materials have been shared with 19 unique serology labs worldwide via Material Transfer Agreements. Furthermore, HSL co-lead efforts for WHO international standards production by NIBSC for HPV-6, 11, 31, 33, 45, 52, and 58.

Conclusions: Achievement of these aims will enable comparisons of data across different HPV vaccines and different studies and, therefore, it will facilitate vaccine development and implementation of new vaccine recommendations.

O049 / #973

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENE EXPRESSION II
04-19-2023 3:45 PM - 4:45 PM

KINETICS OF EXPRESSION OF VIRAL MRNA AND U-ISGF3-REGULATED INTERFERON STIMULATED GENES IN MPEK.BL6 KERATINOCYTES INFECTED WITH MMUPV1

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Introduction: The cell intrinsic anti-viral effectors are >300 interferon stimulated genes (ISG). HPV16 immortalized cells downregulate the 29 ISGs induced by the unphosphorylated STAT1/STAT2/IRF9 (U-ISGF3) complex, allowing persistence of a papillomavirus infection. We have shown that MmuPV1 causes a transient infection. We hypothesize that a functional U-ISGF3 response may limit MmuPV1 replication and promote clearance. We investigated expression of select ISGs driven by the U-ISGF3 complex in MPEK.BL6 spontaneously transformed mouse keratinocytes.

Methods: MmuPV1 infected-MPEK.BL6 cells were cultured over 144 hours, and early and late viral gene expression was monitored by quantitative RealTime-PCR. At serial timepoints, transcripts of genes coding for ISGs (STAT1, DDX58, IFIH1, ISG15, HERC6, IFI27, IFI35, IRF7, OAS1, OAS3, OASL1, PLSCR1, SP100, BST2, and SP100) were quantified by SYBR Green RT-PCR assays.

Results: Compared to undetectable levels of MmuPV1 transcripts at baseline, we detected ~50,000 copies/µg of early transcripts between 24-72 hours post infection (p.i.), which was then suppressed to ~2,000 copies/µg at later time points. As expected for an undifferentiated epithelial cell, no late transcripts were expressed. Compared to IFNα induced upregulation of ISGs, the expression of BST2, IFIH1, ISG15, OAS1, OASL1, and SP100 remain unchanged or were downregulated in MmuPV1 infected MPEK BL6 cells. The downregulation or absence of changes in expression of these genes is likely important in allowing the initial establishment of a MmuPV1 infection. Conversely, DDX58, HERC6, IFI27, IFI35, IRF7, OAS3, PLSCR1 and STAT1 were significantly (>3-fold) upregulated at late time points p.i., 96, 120 and 144 hours, coincident with the suppression of early MmuPV1 mRNA. STAT1, PLSCR1 and SP100 were >20-fold upregulated at 144hr p.i.

Conclusions: These findings suggest that these ISGs regulated by the U-ISGF3 complex are triggered by MmuPV1 infection and act to downregulate MmuPV1 early mRNA in this tissue culture model.

O050 / #692

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENE EXPRESSION II
04-19-2023 3:45 PM - 4:45 PM

HIV-1 PROTEINS GP120 AND TAT PROMOTE EPITHELIAL-MESENCHYMAL TRANSITION AND INVASIVENESS OF HPV-16-IMMORTALIZED GENITAL AND ORAL EPITHELIAL CELLS

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Introduction: The incidence of human papillomavirus (HPV)-associated anogenital and oropharyngeal cancer in human immunodeficiency virus (HIV)-positive individuals is substantially higher than in HIV-uninfected individuals. However, the molecular mechanisms underlying HIV-1-associated promotion of HPV malignancy are not fully understood. Here, we showed that HPV-16-immortalized genital and oral epithelial cells and HPV-negative oral cancer cells that undergo prolonged contact with cell-free HIV-1 virions or with viral proteins gp120 and tat respond by becoming more invasive.

Methods: HPV-16-infected cervical CaSki, anal AKC-2, oral SCC-47, and HPV-negative cervical C-33 A cancer cells were treated with cell-free HIV-1 virions and viral proteins gp120 and tat, each at 10 ng/ml for five to seven days. Cells were evaluated for epithelial-mesenchymal transition (EMT) with H&E staining, and Western blot and immunofluorescence assays. Live EMT cells were also examined by phase-contrast inverted digital microscopy. In vitro invasion assays were performed using the collagen cell Invasion assay.

Results: The interaction of cell-free virions and gp120 and tat proteins with epithelial cells substantially reduced the expression of E-cadherin and activated the expression of vimentin and N-cadherin. EMT induced by the HIV-1 gp120 and tat proteins was accompanied by activation of the Snail transcription factor. EMT induced by gp120 and tat led to detachment of poorly-adherent cells from the culture substratum; these cells remained capable of reattachment, upon which they co-expressed both E-cadherin and vimentin, indicative of an intermediate stage of EMT. The reattached cells also expressed stem cell markers CD133 and CD44, which may play a critical role in cancer cell invasion and metastasis.

Conclusions: These results suggest that the interaction of HIV-1 with neoplastic epithelial cells may lead to their de-differentiation into cancer stem cells that are resistant to apoptosis and anti-cancer drugs. Thus, this pathway may play a critical role in the development of invasive cancer.

O051 / #957

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENE EXPRESSION II
04-19-2023 3:45 PM - 4:45 PM

EXPRESSION OF E6/E7 ONCOGENES OF HPV-18 BUT NOT HPV-16 CONTRIBUTES TO THE FORMATION OF ADENOSQUAMOUS CARCINOMA PHENOTYPE IN THE CERVICOVAGINAL TRACT OF MOUSE

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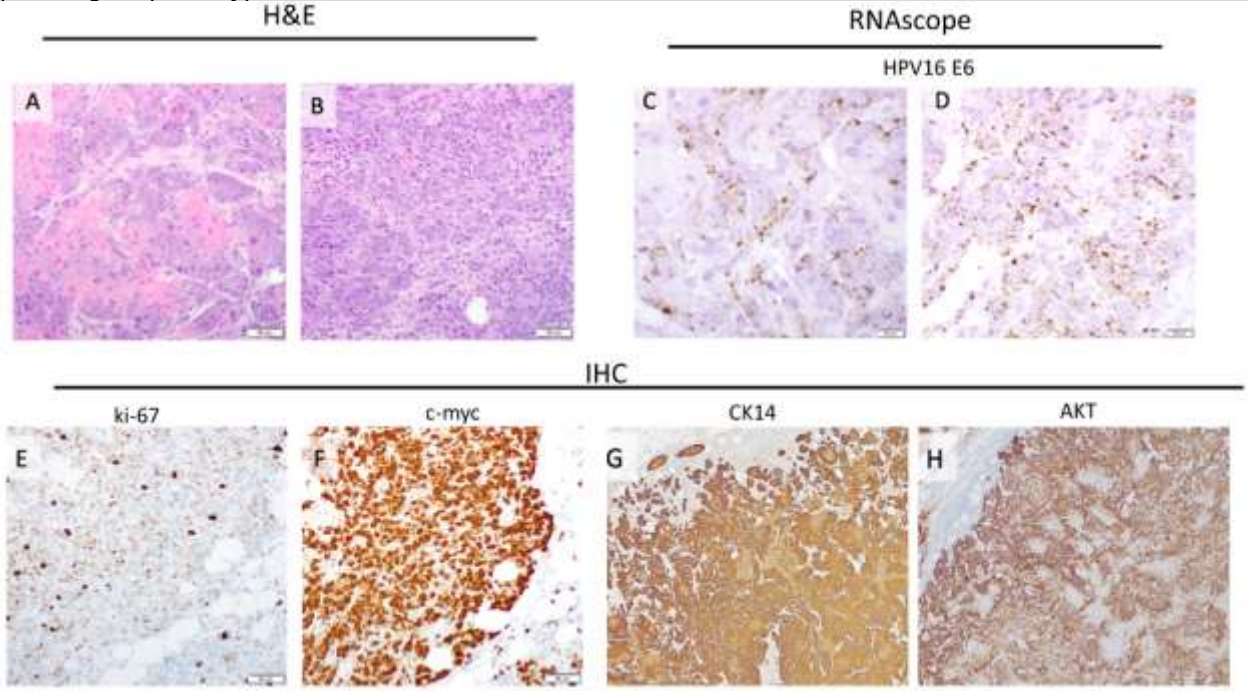
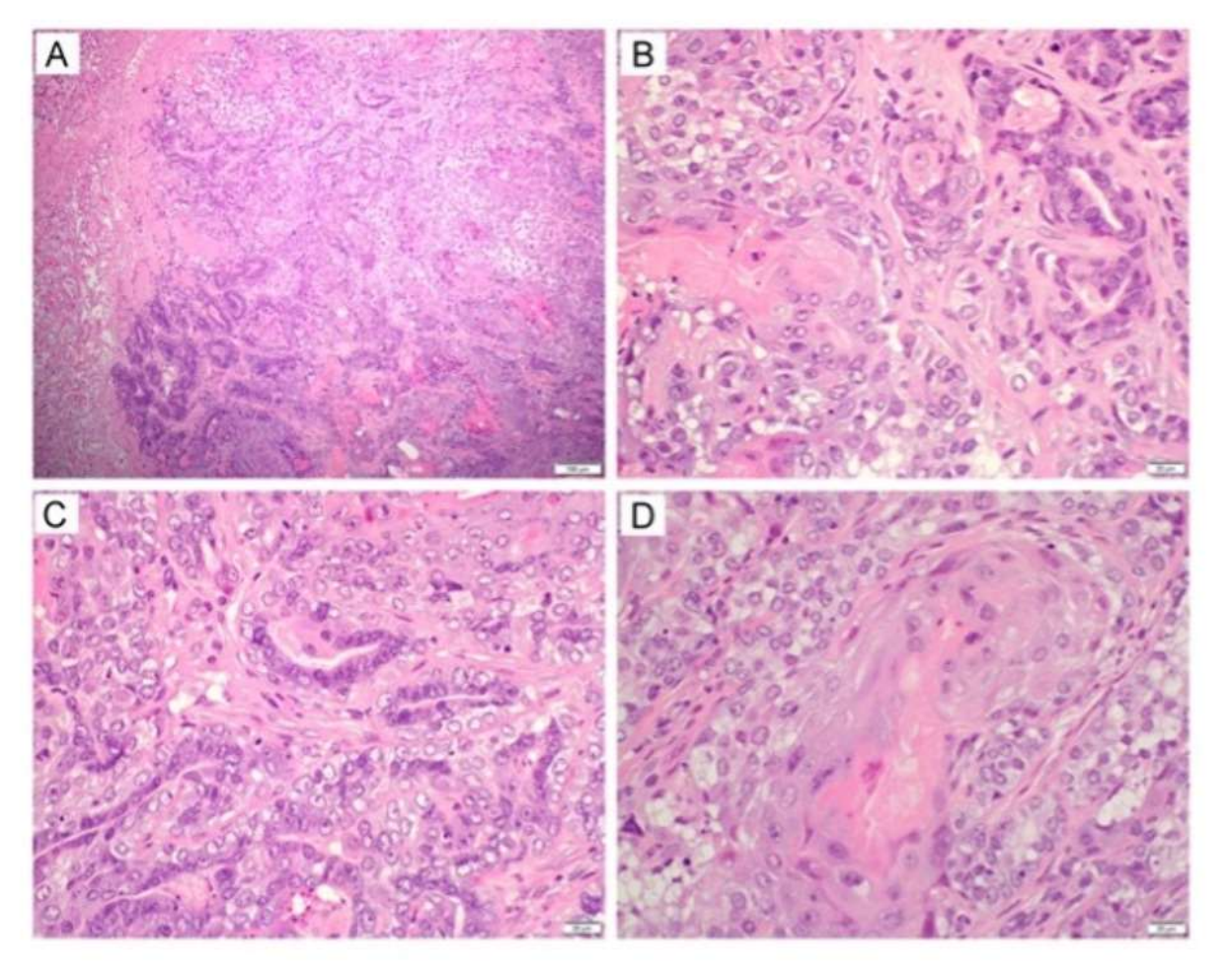
Introduction: We developed a novel, spontaneous HPV16-expressing squamous cell carcinoma model that captures major aspects of HPV-associated cancer in the female genital tract (Fig 1). Unfortunately, it cannot model the approximately 10% of cervical carcinomas that display adenosquamous morphology of mixed malignant squamous and glandular epithelial portions associated with HPV-18 infection. Furthermore, the molecular pathogenesis of how HPV-18 E6/E7 oncogene leads to the distinguished pathological phenotype has not been illustrated.



Methods: To establish HPV18 E6E7-expressing cervicovaginal tumor model using AKT and cMyc oncogenes, 5- to 8-week-old female HLA-A2 (AAD) transgenic mice (5 per group) were intraperitoneally injected with anti-mouse CD3 monoclonal antibody for three days. The following day, plasmids encoding Pkt2-Luc-T2a-HPV18E7E6, pKT2/CLP-AKT, Pkt2-cMyc, and pCMV(CAT)T7-SB100 were injected into the cervicovaginal area followed by electroporation. Anti-mouse CD3 monoclonal antibody treatment was administered once weekly. Tumor growth was monitored using bioluminescence imaging and gross inspection. Tumor-bearing mice were sacrificed when either the tumor diameter exceeded 15mm or body weight was reduced by 10% compared with age-matched untreated control mice. Spontaneously formed cervicovaginal tumors were surgically removed and examined by hematoxylin and eosin staining.

Results: At least 60% of mice had significant tumor outgrowth, demonstrated by the increase of luciferase activity. Histologic examination of the spontaneous cervicovaginal tumors harvested between

days 36 and 57 after plasmid electroporation showed an infiltrating mass lesion with intimately admixed squamous and glandular components. Some areas predominantly displayed features of adenocarcinoma, while others showed morphology of squamous cell carcinoma (Fig 2).



Conclusions: The expression of E6/E7 oncogenes of HPV-18, but not HPV-16, leads to formation of adenosquamous carcinoma phenotype in the cervicovaginal tract in our preclinical model. Such model may be useful for targeted therapy against HPV-18 E6E7 oncogenes. Furthermore, the experimental system would allow us to further dissect the contribution of E6 and/or E7 for the carcinogenesis.

O052 / #1601

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENE EXPRESSION II
04-19-2023 3:45 PM - 4:45 PM

KETOCONAZOLE INHIBITS NFX1-123 AND DECREASES CERVICAL CANCER CELLULAR GROWTH, MIGRATION, AND SURVIVAL

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Introduction: We have shown a critical role that NFX1-123 plays in cervical cancer through its partnership with the HPV type 16E6 protein, making NFX1-123 a good target for therapeutic interventions. We recently demonstrated that Ketoconazole, (KTZ), an antifungal agent, binds to NFX1-123, however there are no reported studies linking the pharmacological inhibition of NFX1-123 to changes in cellular growth, migration or survival. The current study was designed to evaluate both KTZ's effect on NFX1-123 and on cervical cancer cells.

Methods: Cervical cancer cell lines (C33A [HPV -ve]; SiHa, CaSki, HeLa [HPV +ve]) were used to determine the dose effect of KTZ on NFX1-123 protein levels. Cellular growth and survival were evaluated by MTT assays, which quantified the IC_{50} concentration of KTZ. Combination studies of KTZ with cisplatin were conducted to determine any synergistic effect on cell death by MTT assay, and CompuSyn analysis was performed to assess both the combination index and whether the drug combination effects were synergistic. Clonogenic assays were performed to assess the effect of KTZ on cellular growth. The effect of KTZ on cellular migration was measured by CytoSelect cell migration assay.

Results: NFX1-123 protein levels were decreased in a dose-dependent manner with KTZ treatment. KTZ also reduced cellular growth, migration, and survival. Clonogenic assays revealed a reduction in colony formation, and CytoSelect cell migration assays showed a slowing in cellular migration, when treated with KTZ. Furthermore, treatment with both cisplatin and KTZ synergistically increased cytotoxicity in cervical cancer cells.

Conclusions: Our results demonstrated that Ketoconazole reduced NFX1-123 and decreases the cellular growth, migration, and survival of cervical cancer cells. While the specific role of 16E6 in Ketoconazole's targeted actions on NFX1-123 needs to be further investigated, Ketoconazole, in combination with cisplatin, may be a potential additive drug treatment for cervical cancer patients.

O053 / #1652

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENE EXPRESSION II
04-19-2023 3:45 PM - 4:45 PM

PERMANENT AND MAINTAINED DELETION OF HPV E7 ONCOGENE ELIMINATES HPV+ OROPHARYNGEAL TUMORS BEFORE RELAPSING OVER TIME – A POTENTIAL 'HIT-AND-RUN" MECHANISM.

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Introduction: HPV+ cervical cancers are oncogene addicted as these tumors absolutely require major HPV oncogenes, E7 and E6, for their survival. However, we hypothesize that this may not be completely true in HPV+ oropharyngeal squamous cell carcinomas (OPSCCs). We propose that HPV+ OPSCCs initially arise from an HPV infection (the 'hit') to trigger the carcinogenic process until HPV is no longer required for tumor maintenance (the 'run'). Here, we aim to experimentally prove this 'Hit-and-Run' theory in HPV+ OPSCCs.

Methods: An inducible Tet On/Off CRISPR/Cas9 platform targeting E7 was engineered whereby the CRISPR system is only activated in the presence of doxycycline. An in vivo HPV+OPSCC xenograft model in nude mice was developed to evaluate tumor death in response to E7 loss and to see whether tumor relapse occurs and if an accumulation of mutations is observed that might compensate for the loss of HPV oncogenes.

Results: We showed complete regression of the tumor post-HPV E7 editing as early as 31 days. Remarkably, the tumor relapsed over time and continued to do so up to 100 days. We verified that E7 expression was lost in these tumors suggesting that E7 was no longer required for growth. This was consistent with the increased expression of the active form of Rb protein, an E7 host target. Remarkably, E7 deleted tumors developed new mutations not previously seen in HPV+ tumors. Importantly, a number of these new mutations are found to be already present in HPV− OPC tumors.

Conclusions: Our data implies that we may be underestimating the load of HPV-driven OPC as many HPV− malignancies may have originated as HPV+ tumors. Our work has important implications for HPV vaccination efforts as it would suggest that vaccination would not only reduce HPV+ OPC, but also HPV− OPCs.

O054 / #1111

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: NOVEL DIAGNOSTIC AND THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE
04-19-2023 3:45 PM - 4:45 PM

SIRT1 IS AN ACTIONABLE TARGET TO RESTORE P53 FUNCTION IN HPV-ASSOCIATED CANCER THERAPY

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Introduction: The possibility of pharmacologically targeting the cellular circuit that maintains E6-mediated permanent inactivation of p53 activity represents a promising therapeutic option against HPV-associated cancer. SIRT1, the principal NAD + -dependent deacetylase in mammalian cells, catalyzes the deacetylation of its substrates, which include histone and non-histone targets, such as p53. Although SIRT1-mediated regulation of p53 stability is well known—p53 acetylation at K382 competes with ubiquitination and promotes p53 stabilization and activation—its engagement in E6/E7-driven oncogenesis has never been explored.

Methods: Here, we reveal the existence of a novel SIRT1-dependent circuit whose disruption leads to restoration of a functional p53 in HPV-transformed cells. In addition to the cervical carcinoma-derived HeLa and CaSki cell lines, harboring integrated HPV18 and HPV16 genome respectively, a newly established precancerous cell line has also been used, namely NOKsHPV16E6/E7.

Results: We show that SIRT1 pharmacological or genetic inhibition restores a transcriptionally active K382-acetylated p53 in HPV + but not HPV - cell lines. Furthermore, SIRT1 inhibition by the specific inhibitor EX527 (Selisistat) promotes G 0 /G 1 cell cycle arrest and reduces cell viability and clonogenicity of HPV + vs HPV - cells. Lastly, EX527 treatment increases the sensitivity of HPV + cells to sublethal doses of standard genotoxic agents, such as doxorubicin and cisplatin. Enhanced sensitivity to the anticancer activity of cisplatin also occurs in an in vivo tumorigenicity assay based on subcutaneous injection of syngeneic C3.43 cells, harboring an integrated HPV16 genome, in C57BL/6J mice. This sensitization is likely due to restoration of a functional p53 as shown by immunohistochemistry of tumors from EX527-treated mice.

Conclusions: Altogether, these findings uncover an essential role of SIRT1 in HPV-driven oncogenesis, which may have direct translational implications for the treatment of HPV-associated cancers.

O055 / #1207

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: NOVEL DIAGNOSTIC AND THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE
04-19-2023 3:45 PM - 4:45 PM

INHIBITION OF CELLULAR MEK/ERK SIGNALING SUPPRESSES MURINE PAPILLOMAVIRUS TYPE 1 REPLICATIVE ACTIVITIES AND LEADS TO TUMOR REGRESSION

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Introduction: There is a lack of effective antiviral therapies for HPV-related diseases. We recently reported that cellular MEK signaling in the epidermis has a positive effect on HPV early gene expression and that increases in MEK-driven signaling strongly correlate with heightened HPV oncogene activities as cervical lesions progress from low-grade to high-grade disease (10.1371/journal.ppat.1009216). Additionally, we showed that FDA approved MEK inhibitors are potent antagonists of oncogenic HPV E6/E7 gene expression and the neoplastic phenotype in organotypic (raft) epithelial tissue cultures. MEK inhibition quashed the activity of cellular AP-1 transcription factors that modulate oncogene expression via the viral long control region, which harbors AP-1 transcription factor binding sites that are highly conserved across papillomavirus genera. Therefore, we hypothesized that MEK inhibition would have anti-viral and anti-tumor effects in the mouse papillomavirus type 1 (MmuPV1) infection and tumorigenesis model in vivo.

Methods: Tumors were initiated by tail scarification of 6-8 week-old female Hsd:athymic nude-Foxn1^{nu} outbred mice (T-cell deficient). When papillomas reached a volume of ≈40mm^3, the animals were stratified by size and placed into vehicle and treatment groups with equal average tumor volumes (n=6 animals per group). MEK inhibitor or vehicle was administered by oral gavage every 48 hr and tumor volumes were tracked. At 32 days post treatment, tumors were harvested, paraffin embedded, and analyzed for cellular and viral activities. MEK/ERK inhibitors are being topically formulated.

Results: MEK1/2 inhibitor treatment resulted in significant tumor regression and significantly decreased levels of MmuPV1 E6/E7 mRNAs, viral genomes, and L1 protein. MEK inhibitor treatment appeared to protect mice from developing secondary MmuPV1-induced facial tumors. Topical MEK/ERK inhibitors suppress HPV16 E6/E7 transcription in raft tissues.

Conclusions: MEK inhibitors have potent anti-papillomavirus properties in vitro and in the preclinical MmuPV1 tumorigenesis model, and topical drug formulations merit further investigation for treating papillomavirus-induced disease and preventing viral transmission.

O056 / #1078

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: NOVEL DIAGNOSTIC AND THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE
04-19-2023 3:45 PM - 4:45 PM

ANALYSIS OF OBSTRUCTIONS DETECTION IN AUTOMATED VISUAL EVALUATION QUALITY ASSESSMENT

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Introduction: Visualization is part of cervical cancer patient management in both high- and low-resource settings. For an image to be of sufficient visual quality, the entire squamo-columnar junction (SCJ) must be visible. In low-quality images, the SCJ is obstructed. Common obstructions include poor optical positioning, a medical instrument (i.e. swab), physiological fluid (blood, mucus), or anatomical changes (SCJ partially inside os, polyp). Recently, methods based on artificial intelligence (AI) have been proposed to assist in capturing obstruction-free images. Such approaches have yet to be developed - they require training multiple classifiers and integrating them into an image capture application.

Methods: A set of 1500 cervical images (either mobile colposcope images and cervigrams) were labeled by 2 experts for 14 different obstructions. Individual models were trained to detect 4 of the labels - blood, mucus, loose vaginal walls, and SCJ inside os. To speed up computations, a multi-task model was trained for detecting the presence of the 4 obstructions in a cervical image. The number of images in the training, validation, and test sets were 1000, 200, and 300, respectively. The multi-task model was exported to the TFLite format for rapid deployment on a smartphone.

Results: Receiver operating characteristic curves for the multi-task model outputs (the likelihood of the image being obstruction-free, or having any of the 4 obstructions) are shown in Fig. 1. The area under the (ROC) curve (AUC) was highest for loose vaginal walls and SCJ inside the os (0.82) and lowest for mucus ((0.66). No significant differences were observed between the 2 image

types.

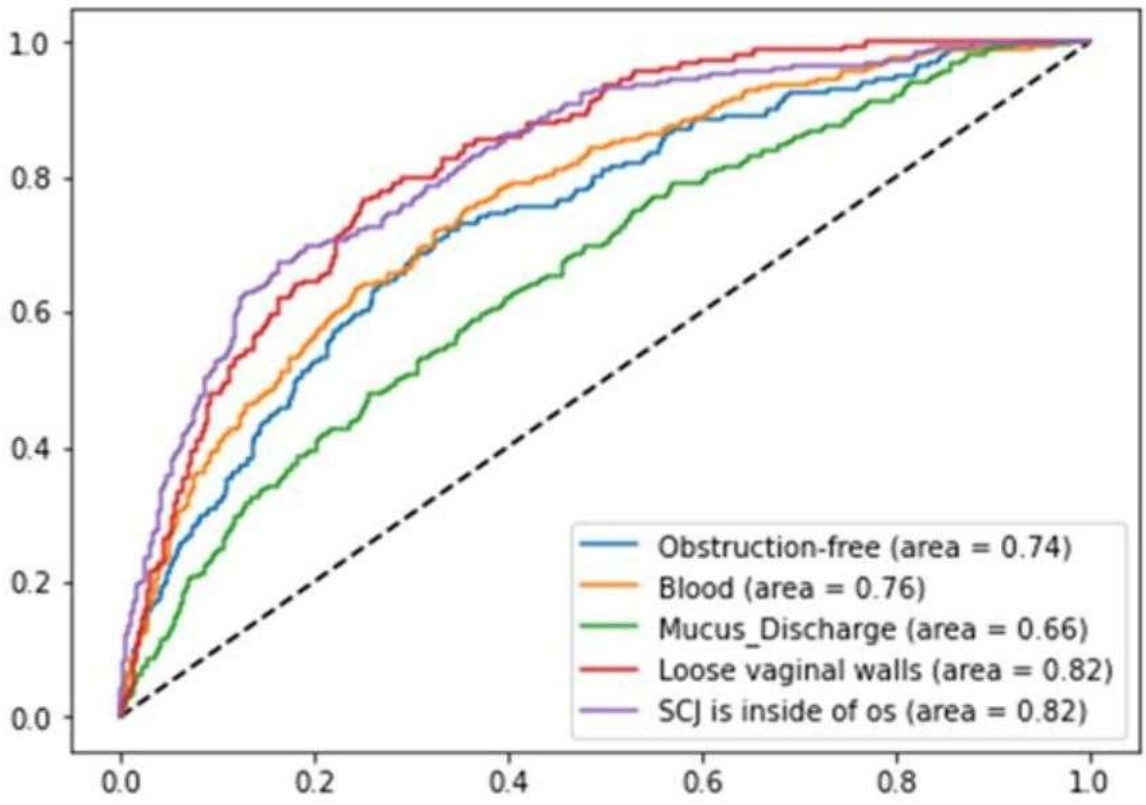

Fig. 1: ROC curves for 5 classes of the multi-task model. The legend contains the AUC values.

Conclusions: To our knowledge, this is the first automated analysis of obstructions in cervical images. This proof of concept experiment demonstrated it is possible to detect different obstructions with reasonable accuracy. The multi-task model enables parallelization of the computation, making it suitable for a smartphone.

O057 / #1181

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: NOVEL DIAGNOSTIC AND THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE
04-19-2023 3:45 PM - 4:45 PM

(INITIAL) VALIDATION OF A RAPID, LOW-COST HPV TYPING ASSAY TO SUPPORT CERVICAL SCREENING AND MANAGEMENT IN LMIC

Federica Inturrisi[1], Silvia De Sanjosé[1], Casey Dagnall[2], Rosemary Zuna[3], Nicolas Wentzensen[1], Mark Schiffman[1]
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Introduction: The WHO recommends primary HPV testing for cervical screening in all countries, including low- and middle-income countries (LMICs), where inexpensive and uncomplicated assays are key. Assays with (extended) genotyping are preferable as they can identify the highest-risk HPV-positive women. A 13-type isothermal amplification assay (ScreenFire, Atila Biosystems, US) was recently redesigned as having four hierarchical risk-group channels: HPV16, else HPV18/45, else HPV31/33/35/52/58, else HPV39/51/56/59/68. As hierarchical assignment facilitates management recommendations, we performed an initial validation of the novel ScreenFire HPV assay.

Methods: Aliquots of 1,045 samples of women (mean age 30.4) included in a previously conducted study (SUCCEED) were tested. HPV status using Linear Array and TypeSeq, as well as histology were known. We calculated the hierarchical channel positivity of ScreenFire according to histologic and virologic standards, defined as type-specific positivity/negativity from both Linear Array and TypeSeq and analyzed hierarchically.

Results: The overall clinical sensitivity for CIN2+ was 92.6% for ScreenFire, 92.5% for LinearArray, and 94.7% for TypeSeq. The channel concordance positivity by ScreenFire was 99.1% for HPV16, 83.0% for HPV18/45, 93.5% for HPV31/33/35/52/58, and 90.9% for HPV39/51/56/59/68 among cases (472 CIN2+) and 92.6%, 76.8%, 77.7%, and 89.6% among controls (548 <CIN2), respectively. The channel positivity by ScreenFire when the virologic standard was negative was low and the channel concordance negativity

was 81.3% among cases and 89.2% among controls (Table 1).

Table 1. Hierarchical analysis of ScreenFire initial validation.

Histologic Standard		Cases (472 CIN2+)		Controls (548 <CIN2)	
/ Virologic Standard		Pos	Neg	Pos	Neg
HPV16	N *	231	215	94	425
	n**	229	11	87	18
	%	**99.1**	**5.1**	**92.6**	**4.2**
HPV18/45	N *	53	407	56	480
	n**	44	0	43	1
	%	**83.0**	**0.0**	**76.8**	**0.2**
HPV31/33/35/52/58	N *	92	371	103	413
	n**	86	6	80	7
	%	**93.5**	**1.6**	**77.7**	**1.7**
HPV39/51/56/59/68	N *	22	442	77	431
	n**	20	5	69	25
	%	**90.9**	**1.1**	**89.6**	**5.8**
hrHPV negative	N *	435	32	375	130
	n**	6	26	28	116
	%	**1.4**	**81.3**	**7.5**	**89.2**

Abbreviations: CIN2, cervical intraepithelial neoplasia grade 2; HPV, human papillomavirus; hrHPV, high-risk HPV; Neg, negative; Pos, positive.

* channel-specific N total based on virologic truth: positive if both Linear Array and TypeSeq positive, negative if both Linear Array and TypeSeq negative. The few discrepant observations (positive/negative for one assay only) were deleted from this table.

** channel-specific n positives at ScreenFire out of N

Conclusions: The ScreenFire assay showed very good agreement with other clinically-validated HPV assays, very little evidence of false positives, and good sensitivity hierarchically for all channels except for HPV18/45. HPV18/45 channel sensitivity is under re-evaluation, and the results of ongoing experimental work will be presented. As ScreenFire is relatively affordable, simple, mobile, rapid (results <60 minutes), and it provides genotyping information, when fully validated, it could support implementation of HPV-based screening and management in LMICs.

O058 / #891

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: NOVEL DIAGNOSTIC AND THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE
04-19-2023 3:45 PM - 4:45 PM

MODIFICATION OF LIGER THERMAL ABLATION PROBES TO OPTIMIZE TREATMENT AND VISUALIZATION

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Introduction: The WHO approved thermal ablation (TA) for treatment of cervical pre-cancer in 2019, but did not have enough evidence to give standard protocols. The largest database of evidence is from Scotland where a desktop unit and a 2-step procedure are used. The two-step procedure involves treatment of the distal endocervix with a shallow endocervical probe followed by overlapping applications with a 16mm flat probe to cover the entire squamocolumnar junction (SCJ). This technique demonstrated biopsy-confirmed cure rates of 99.5% at five years in over 700 women. Cure rates from LMIC have not been as high. Currently, none of the handheld devices for use in LMIC have an endocervical probe. In addition, the existing probe lengths make optimal visualization of the cervix difficult in some patients.

Methods: Basic Health International (BHI) collaborated with Liger Medical (Lehi, Utah) to design a shallow endocervical probe and adapters to allow elongation of existing probes to allow for better visualization of the SCJ during treatment.

Results: The shallow endocervical probe prototype bench testing has been promising: temperatures at the endocervical tip range from 90-113°C with no deviations. All probes caused white ablation to 3mm depth and 10mm circumference. The endocervical probe heated to 100°C in ~6 seconds in air and ~9 seconds in chicken breast tissue at room temperature (20°C) and heat-up time is known to be faster at body temperature (37°C). In addition, 6cm probe lengthening adapters were created to optimize cervical visualization during treatment.

Conclusions: The equipment necessary to perform a 2-step TA approach with longer probes to allow better visualization and using a shallow endocervical probe to treat the endocervix, followed by overlapping applications of a 16mm flat probe to treat the entire SCJ, will soon be available for low-cost devices specifically designed for use in
LMIC.


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O059 / #1467

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 1
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THE IMPORTANCE OF REACHING SYSTEMATIC NON-ATTENDERS OF SCREENING FOR CERVICAL CANCER ELIMINATION

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Introduction: Reaching cervical cancer (CC) elimination (i.e. incidence <4 per 100.000) can be expedited by intensifying screening. Especially reaching women that never attended screening (i.e. systematic non-attenders) may contribute substantially to earlier elimination. We quantified the impact of increasing screening coverage among systematic non-attenders versus random non-attenders on the year in which CC elimination will be reached in the Netherlands.

Methods: We applied two microsimulation models (STDSIM and MISCAN) to simulate CC natural history, vaccination effects, and CC screening for the Dutch female population between 2022-2100. Assuming status quo vaccination coverage (55%, bivalent vaccine), we simulated the continuation of the current Dutch screening programme (five to seven lifetime HPV screenings) with current participation (61% coverage, distributed over 90% of the population, the remaining 10% never attends screening and has a higher CC risk). We compared this base case with a scenario in which we distributed the same coverage over the entire population. Both scenarios were repeated with 70% and 90% coverage (Table 1). Main outcome measure was the year in which CC elimination will be reached.

Results: Maintaining current screening participation is projected to eliminate CC by 2042 (Table 1). This can be expedited to 2040 or 2037 if screening participation is increased to 70% or 90% respectively, yet 10% never attends screening. However, if screenings are distributed over the entire population, i.e. assuming no systematic non-attendance, elimination is projected to be reached in 2036, 2035 or 2032 with 61%, 70% or 90% screening coverage respectively (Table 1).

Table 1. Screening coverage among random non-attenders and systematic non-attenders in the different scenarios and the corresponding year in which elimination will be reached.

Population level screening coverage	Base case: unequal distribution			Equal distribution		
	Coverage in random non-attenders (90% of population)	Coverage in systematic non-attenders (10% of population	Elimination year	Coverage in random non-attenders (90% of population)	Coverage in systematic non-attenders (10% of population	Elimination year
Current (61%)	68%	0%	2042	61%	61%	2036
70%	78%	0%	2040	70%	70%	2035
90%	100%	0%	2037	90%	90%	2032

Conclusions: Improving screening participation among systematically non-attending women is a powerful instrument to expedite cervical cancer elimination. Future interventions to reach cervical cancer elimination should specifically focus on strategies that increase participation of systematic non-attending women.

O060 / #998

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COMMUNITY-INTEGRATED SELF-COLLECTION HPV-BASED CERVIX SCREENING PROGRAMS TO INCREASE SCREENING AND TREATMENT COVERAGE: RESULTS FROM A PRAGMATIC, CLUSTER RANDOMIZED TRIAL

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Introduction: Eliminating cervical cancer in priority settings requires novel community-based innovations to rapidly improve screening coverage. The ASPIRE Mayuge trial compared the effectiveness of two screening models in Uganda.

Methods: In this pragmatic cluster-randomized trial, villages were randomized to receive HPV self-collection cervix screening through 1) Door-to-door recruitment by CHWs; or 2) at community health days. The primary trial outcome was attendance for treatment after screening positive. Interventions were integrated into existing community infrastructure. Female participants ages 25-49 without prior cervix treatment were eligible. Participants completed a survey and were offered self-collection. Those who self-collected received results from CHWs either at home (Arm 1) or at a community health day (Arm 2). Samples were tested for HPV using GeneXpert. Mixed-effects logistic regression models were used to compare outcomes between arms.

Results: A total of 31 villages and 2,019 participants were randomized (Arm 1: 16 clusters, 1,055 participants; Arm 2: 15 clusters, 964 participants). In both arms, 100% of participants chose to self-collect. HPV positive rate was 28% (n=296) in Arm 1; 25% (n=240) in Arm 2. In those HPV positive, attendance for follow-up treatment was 75% in Arm 1; and 66% in Arm 2. The adjusted regression model, including all participants, showed Arm 2 had lower odds of follow-up attendance (OR = 0·74, 95% CI: 0·57-0.95). Both arms demonstrated high reach, fidelity, acceptability, and adoption amongst participating communities.

Conclusions: Both door-to-door and community health day approaches for HPV self-collection implementation were integrated into existing health systems, leading to high rates of screening and follow-up. Both methods were acceptable to women. The door-to-door model, with individualized education, may encourage follow-up attendance; however, community health days required fewer personnel and allowed for health service bundling. This trial informs implementation roadmaps to help districts prioritize screening within the limits of their health system.

O061 / #575

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AN INNOVATIVE MOBILE HPV TESTING & TREATMENT MODEL FOR COMMUNITY-BASED CERVICAL CANCER PREVENTION

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Introduction: Cervical cancer is a leading cause of death for women in Kenya, claiming 3,400 lives in 2019; nearly 9 women each day. Less than 20% of women in Kenya have ever been screened for cervical cancer [1]. In Kisumu County that figure is even lower, with screening coverage at only 12% [2]. An innovative mobile model to bring HPV testing and treatment to rural, low resource communities using HPV DNA testing was piloted amongst women ages 30-49.

Methods: Community Health Volunteers (CHV) were provided a list of eligible women 30-49 years old. Women were educated about cervical cancer and offered the opportunity to test for HPV in their home. Samples were processed using a solar-powered PCR testing system with results disseminated by phone and SMS. Women who tested positive for high-risk HPV were met in their community by a mobile clinic team of trained healthcare providers, screened with Visual Inspection with Acetic Acid (VIA) for eligibility and, if eligible, offered thermal ablation treatment. Women who missed their appointment or were found to require higher levels of care were referred to the nearest healthcare facility by a trained social worker.


Two-step Mobile Clinic Model:
1. Household Mapping + Baseline Data
2. Training for CHVs, CHAs, HCPs, & Lab Technologist
3. Education + Awareness Campaign
4. Collect HPV test kit and client information
5. HPV Sample Processing
HPV +
6. Text/Call with Results
7. Scheduled treatment mobile clinics in community
8. Referrals
9. Follow Up

Results: 1,717 were screened using HPV testing. 28% of women tested positive for high-risk HPV. 247 women were treated with thermal ablation and 16 referred for treatment or higher levels of care at a local facility.

Summary of Mobile HPV Testing and Treatment Model	**N, %**
Community Health Volunteers (CHV)	
Community Health Volunteers trained and deployed	78
Average number of HPV tests returned per CHV	23, 76%
Screening Results	
Women tested positive for high risk HPV	1717, 28%
Women Living with HIV and tested positive for high-risk HPV	88, 5%
Women eligible and treated with thermal ablation	247, 52%
Women referred for higher level of care at local facility	16, 3%

Conclusions: The treatment algorithm implemented is in accordance with the World Health Organization's "screen, triage and treat approach [3]". Therefore, the decision to treat is based on a positive HPV test followed by VIA screening to determine eligibility for ablative treatment. In resource-limited settings, extended HPV genotyping to further inform risk of precancer/cancer may be a more appropriate strategy for triaging positive HPV screening results.

O062 / #680

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IMPLEMENTATION OF A PRIMARY SCREENING PROGRAM WITH DNA HPV TESTING IN LIMA, JUNIN AND LORETO (PERU): EXPERIENCE, CHALLENGES AND NEXT STEPS

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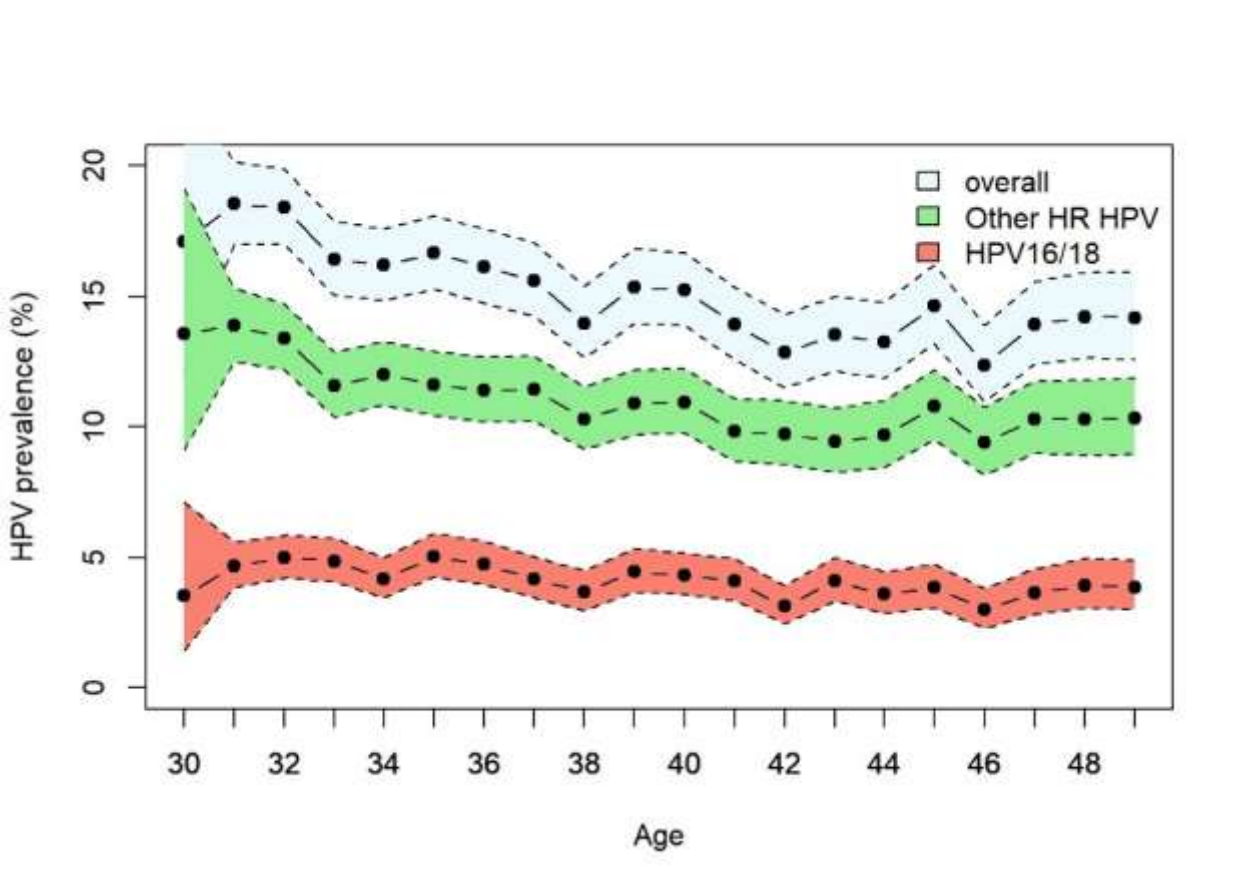
Introduction: Cervical cancer remains a public health problem in Peru. In 2020, incidence and mortality age-standardized rates were 22.2 and 11.5 per 100,000. Current WHO guidelines recommend HPV DNA testing within screen-and-treat or screen, triage and treat algorithms. National guidelines in Peru recommend cervical cancer screening with HPV testing followed by colposcopy referral of HPV-positives. In 2021, HPV testing was rolled out in 3 regions of Peru with different socio-demographics and cultural characteristics. Here we present first results of HPV implementation.

Methods: From July 2021 to April 2022, 45,708 women aged 30-49 from the regions of Lima, Loreto and Junin were screened in 848 primary care health centres. Women chose between self- or clinician-collected sampling. HPV testing was centralised in 7 hubs using real-time PCR HPV DNA testing with partial genotyping. The prevalence of HPV was estimated overall, by age, region, HPV genotype (16, 18, 16/18 or other high-risk genotypes), and sampling choice.

Results: Only 510 (1.3%) samples were unsatisfactory for HPV testing. Among 45,198 women with a valid test, the prevalence of HPV was 15.2% (95%CI 14.9-15.5) with a clear decreasing trend with age (from 18% in women 30-34 to 12% in women 45-49, p<0.001). Most participants (82%) chose self-sampling, showing a slightly higher HPV prevalence when compared to clinician-sampling (15.4% vs 14.4%, p=0.02). 4.2% (n=1,883) were positive for HPV 16, HPV 18 or both, and 11% (n=4,979) for other

high-risk types. Management of HPV positives is very challenging due to limited colposcopy capacity.



Conclusions: HPV testing can be effectively implemented at primary care. Self-sampling was strongly accepted by women, showed similar positivity as clinician-sampling, and facilitated scaling-up of HPV implementation. Colposcopy capacity is being built and both colposcopy and ablative treatment are being offered at primary care to improve screening and treatment adherence as recommended by WHO.

O063 / #1526

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RISK ASSESSMENT OF SELF-SAMPLING HPV TESTS BASED ON PCR, SIGNAL AMPLIFICATION TO GUIDE THE APPROPRIATE SCREENING INTERVALS: A PROSPECTIVE STUDY IN CHINA

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Introduction: We assessed the longitudinal risk of developing cervical intraepithelial neoplasia (CINs) with self-sampling HPV tests, based on polymerase chain reaction (PCR) and signal amplification (careHPV), to explore appropriate intervals for cervical cancer screening.

Methods: A prospective study was conducted in China during 2017–2020. Participants were invited for PCR and careHPV tests with self-samples at baseline. Women positive on either HPV test underwent colposcopy and biopsy if necessary. Women with baseline CIN grade one (CIN1) or less were followed up over 3 years. The absolute risk was assessed by immediate risk (IR) and cumulative risk (CR), and the relative risk was assessed by hazard ratio (HR) with a 95% CI.

Results: A total of 8126 women were included in the final analysis. Women positive for PCR HPV test had comparable IRs of CIN2+ and CIN3+ to those positive on careHPV test. With HPV genotyping triage, women with HPV 16/18 infection had the highest IRs of CIN2+ (21.15%) and CIN3+ (9.67%). For CR, women negative for PCR HPV test had lower risk of CIN2+ than that reported in women negative on careHPV test (0.57% versus 0.98%, HR=0.58, 95% CI 0.38, 0.87), but no significant difference was found in the CRs of CIN3+ between them (0.25% versus 0.39%, HR=0.64, 95% CI 0.34, 1.20). Among women with CIN1 or less at baseline, women who were persistent or recurrent positive on careHPV or PCR HPV test had a higher risk of developing CIN3+ (11.36-14.59%), compared with women remained HPV negative from baseline throughout follow-up (≤0.28%).

Conclusions: Routine screening with 3 years interval is acceptable for self-sampling HPV tests based on PCR or careHPV test. Women positive on HPV16/18 triaging at baseline or with CIN1 or less at baseline while being persistent or recurrent positive on careHPV or PCR HPV test during 3-year follow-up require immediate colposcopy or treatment.

O064 / #882

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RESULTS FROM TWO HPV-BASED CERVICAL CANCER SCREENING MODELS IN MALAWI: A CLUSTER RANDOMIZED TRIAL

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Introduction: The World Health Organization recommends HPV DNA detection as the primary screening test for cervical cancer among both the general population of women and women living with HIV. However, few studies have assessed the impact of HPV self-sampling on cervical cancer screening (CCS) at a population level.

Methods: We conducted a hybrid type 2 cluster randomized feasibility trial of two models for integrating HPV self-sampling into family planning services in Malawi. The trial was implemented at 16 health facilities in 2 districts (Lilongwe and Zomba) between March 2020-December 2021. Model 1 involved providing only clinic-based HPV self-sampling, whereas Model 2 included both clinic-based and community-based HPV self-sampling. An Endline Household Survey (EHS) was performed in households sampled through a two-stage sampling technique between October-December 2021 to assess trial effectiveness in the catchment areas of the health facilities. Weighted Chi-squared test and logistic regression were used to assess associations between the models and use of CCS services.

Results: We analyzed 7,664 surveys from 400 sampled villages. Participants from Model 2 areas were more likely to take >2 hours to get to the nearest health facility than participants from Model 1 areas (24.9% vs 13.5%, p=0.049). However, participants from Model 2 areas were more likely to have ever undergone CCS than participants from Model 1 areas, after adjusting for district, facility location (urban versus rural), and facility size (hospital versus health center) (adjusted odds ratio = 1.73, 95% CI: 1.29, 2.33). Among participants who had ever undergone CCS, participants from Model 2 were more likely to report having undergone HPV self-sampling than participants from Model 1 (Model 2: 50.5% versus Model 1: 22.8%, p=0.023).

Conclusions: Clinic-based plus community-based HPV sampling led to a significantly higher proportion of women who had ever undergone CCS and HPV self-sampling when compared to clinic-based sampling alone.

O065 / #561

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PRIMARY HPV TESTING VS. CO-TESTING: CLINICAL PARAMETERS IN POPULATIONS WITH DIFFERENT DISEASE PREVALENCE

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Introduction: Primary HPV testing is more cost-effective than HPV and cytology cotesting with similar program-sensitivity for cervical cancer. Many countries have introduced HPV-based screening programs. However, in some places like the US, the transition from co-testing to primary HPV screening is slow. To inform different settings about implications of the transition, we quantified clinical parameters of primary HPV testing vs. cotesting in four US populations with differing precancer/cancer prevalence.

Methods: Using the CDC's National Breast and Cervical Cancer Early Detection Program and the Kaiser Permanente of Northern California (KPNC) cohort, we assessed clinical parameters of primary HPV testing vs. HPV and cytology cotesting in 4 settings: 1) underinsured/uninsured women never screened or screened >5 years prior [never/rarely screened], 2) underinsured/uninsured women screened within 5 years, 3) women in KPNC receiving their first HPV test, and 4) women in KPNC whose prior HPV test was negative. We estimated for each setting and screening modality: the numbers of CIN3+ immediately diagnosed, CIN3+ with delayed diagnosis, lab tests, and colposcopy per 100,000 tested.

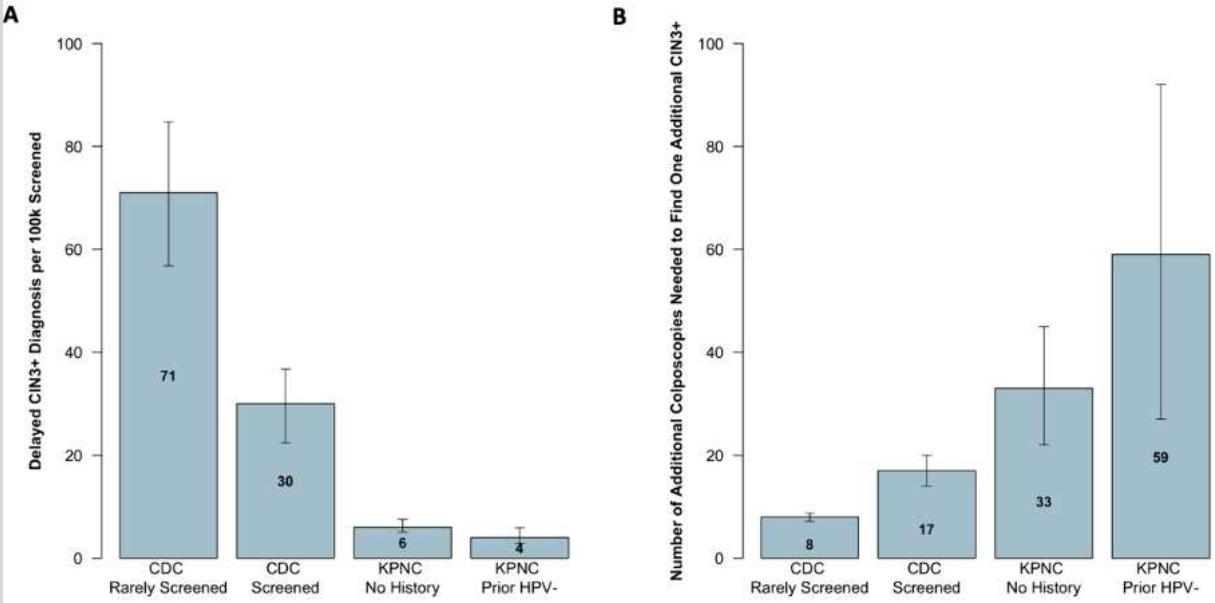
Results: Additional CIN3+ detected from cotesting vs primary HPV decreased with decreasing population-average CIN3+ prevalence, from 71 per 100,000 tested among never/rarely-screened women to 4 per 100,000 tested among individuals with prior HPV-negative results [Figure 1a]. Cotesting required more lab tests (85,000-90,000 more per 100,000 tested) and colposcopy (200-500 more per 100,000 tested) than primary HPV [Table 1]. Cotesting was less efficient in lower risk settings, with the number of additional colposcopies needed to find 1 additional CIN3+ increasing from 8 among never/rarely-screened women to 59 among individuals with prior HPV-negative results [Figure 1b].

Table 1. Estimated trade-offs of cotesting vs. primary HPV testing for CDC's NBCCEDP and KPNC cohorts across 4 population settings.

	CDC[a]		KPNC[b]	
	Not Up to Date With Screening: Est (95% CI)	Screened Within Past 5 Years: Est (95% CI)	No Past History: Est (95% CI)	Prior HPV-Negative Result: Est (95% CI)
Total CIN3+ per 100k screened	1,212 (1134–1290)	772 (727–816)	454 (442–466)	84 (77–92)
Cotesting				
Number of tests per 100k screened	200,000	200,000	200,000	200,000
Number of colposcopy referrals per 100k screened	8,536	8,669	4,277	2,092
CIN3+ detected per 100k screened	1,001 (950–1,052)	637 (605–670)	364 (355–374)	69 (63–75)
CIN3+ delayed diagnosis per 100k screened	211 (152–270)	134 (104–164)	90 (82–97)	16 (11–20)
NTN[c] to find 1 CIN3+	200 (190–210)	314 (298–330)	549 (535–563)	2,912 (2,659–3,165)
NCN[d] to find 1 CIN3+	7.7 (7.3–8.1)	13.6 (12.9–14.3)	11.7 (11.4–12.0)	30.4 (27.8–33.1)
Primary HPV				
Number of tests per 100k screened	114,230	113,589	108,175	103,851
Number of colposcopy referrals per 100k screened	8,089	8,167	4,067	1,831
CIN3+ detected per 100k screened	930 (882–979)	608 (576–640)	358 (349–367)	64 (58–70)
CIN3+ delayed per 100k screened	282 (221–343)	164 (133–195)	96 (89–104)	20 (15–25)
NTN[c] to find 1 CIN3+	121 (115–128)	187 (177–197)	302 (294–310)	1,616 (1,471–1,760)
NCN[d] to find 1 CIN3+	7.7 (7.3–8.1)	13.4 (12.7–14.1)	11.4 (11.1–11.7)	29 (26–31)
Cotesting vs. Primary HPV				
Number of tests per 100k screened	85,770	86,411	91,825	96,149
Number of colposcopy referrals per 100k screened	447	502	210	261
Delayed CIN3+ per 100k screened	71 (57–85)	30 (22–37)	6.3 (5.0–7.6)	4.4 (2.9–5.9)
NATN[e] to find 1 additional CIN3+	1,229 (1,101–1,358)	2,922 (2,399–3,445)	14,562 (9,434–19,690)	21,842 (9,820–33,865)
NACN[f] to find 1 additional CIN3+	7.9 (7.1–8.7)	17 (14–20)	33 (22–45)	59 (27–92)

[a] Age 30-64, includes co-testing and individuals triaged for ASC-US
[b] Age 25-65, just co-testing
[c] NTN – Number of tests needed
[d] NCN – Number of colposcopies/biopsies needed
[e] NATN – Number of additional tests needed
[f] NACN – Number of additional colposcopies/biopsies needed

Figure 1. Estimated number of delayed CIN3+ diagnosis and additional referred colposcopies needed comparing cotesting vs. primary HPV testing across 4 population settings.



A. Estimated number of women, from CDC's NBCCEDP and KPNC cohorts, receiving a delayed CIN3+ diagnosis per 100,000 individuals screened using primary HPV as opposed to cotesting. B. Estimated number of additional colposcopies needed to find one additional CIN3+. Settings: 1) CDC Rarely Screened – Women in the CDC cohort who were never screened or were screened 5+ years ago; 2) CDC Screened – Women in the CDC cohort who have been screened within the past 5 years; 3) KPNC No History – Women in the KPNC cohort who have received their first HPV-based test; 4) KPNC Prior HPV- – Women in the KPNC cohort who have received one prior HPV-negative result.

Conclusions: Prior studies show virtually no additional cancers are prevented by cotesting over primary HPV. Cotesting results in many additional tests and inefficient colposcopies, particularly in low prevalence settings and among HPV-negative individuals returning for retesting.

O066 / #499

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ACCEPTABILITY OF ANAL HPV HOME SELF-SAMPLING VERSUS CLINICIAN SAMPLING AMONG MEN WHO HAVE SEX WITH MEN: THE PREVENT ANAL CANCER STUDY

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Introduction: Men who have sex with men (MSM) are at a disproportionately high risk for anal cancer. Since anal cancer screening guidelines are anticipated given ANCHOR study findings, research is needed to assess the acceptability of different screening modalities among MSM.

Methods: Individuals 25 years and older identifying as MSM were recruited to participate in the Prevent Anal Cancer (PAC) Study in Milwaukee, Wisconsin. Eligible participants were randomized to either a home- or clinic-based arm. Home-based participants received a mailed anal self-sampling kit with instructions. Clinic-based participants scheduled and attended a clinic appointment where they received a clinician-collected anal swabbing. All participants were asked to complete a baseline and post-swabbing survey. This analysis examined acceptability (overall thoughts, pain, and willingness to swab in the future) among the first 75 participants in each study arm to complete a post-swab survey.

Results: Randomized participants in the home- and clinic-based arms reported being comfortable receiving the kit in the mail (100.0%) and getting the anal swabbing in the clinic (96.0%). Overall thoughts about the kit and clinician swabbing were mostly positive (73.3% and 68.0%, respectively). Participants in the home- and clinic-based arms indicated they were willing to do a self-swabbing (98.7%) and have a health care provider swab their anal canal (97.3%). Age, race/ethnicity, education, gender identity, sexual orientation, HIV status, and study arm were not significantly associated with home or clinic acceptability. Although baseline anal cancer worry was low and did not differ significantly by study arm, after completing anal swabbing clinic participants reported “moderate” or “quite a lot of concern” about getting anal cancer in the future (27.1%) compared to home participants (11.9%) (p=.03).

Conclusions: Acceptability was similar for home- and clinic-based anal swabbing and did not differ significantly by participant demographic characteristics.

O067 / #1741

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WOMEN'S EXPERIENCES OF TESTING POSITIVE FOR HPV AND RECEIVING SAME-DAY TREATMENT IN PAPUA NEW GUINEA: AN INTERPRETATIVE PHENOMENOLOGICAL ANALYSIS

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Introduction: Human papillomavirus (HPV) testing is transforming cervical screening globally. The World Health Organization (WHO) now recommends same-day HPV screen-and-treat for primary cervical screening in low- and middle-income countries (LMIC) but there is a lack of evidence on women's lived experience of testing positive for oncogenic HPV and receiving same-day treatment. This study aimed to address this knowledge gap among women participating in a same-day HPV screen-and-treat (HPV STAT) program in Papua New Guinea.

Methods: As part of a larger qualitative study, this paper explores the lived experiences of 26 women who tested positive for oncogenic HPV and were treated the same day. We analysed the data using the interpretative phenomenological analysis method. All data were managed using Nvivo 12.5.

Results: The interpretative phenomenological analysis led to three superordinate themes: 1) alleviating initial worries, (2) transforming the disclosure process, and (3) connecting to their faith. Women's experiences of the same day HPV screen-and-treat were framed by initial emotional reactions to their positive HPV test result, and having access to treatment on the same day, which helped address their worries and fears, and transformed their experience of disclosing their test result and subsequent treatment to family and friends.

Conclusions: This study shows that undergoing same day treatment quickly resolved the women's worries, making this program highly acceptable. Overall, women's engagement in the same day HPV screen-and-treat program confirmed its high acceptability and cultural congruence, leaving women feeling empowered and hopeful about their future, and the future of all Papua New Guinea women.

O068 / #644

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SELF-SAMPLING AND NEW CERVICAL SCREENING TECHNOLOGIES
04-19-2023 5:15 PM - 6:45 PM

EFFECTIVENESS OF APPROACHES FOR OFFERING HPV SELF-SAMPLING TO INCREASE CERVICAL CANCER SCREENING IN PREVIOUSLY-ADHERENT, OVERDUE, AND UNKNOWN SCREENING HISTORY POPULATIONS: U.S.-BASED STEP TRIAL RESULTS

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Introduction: Optimal strategies for increasing cervical cancer screening may differ by screening history and healthcare setting. While mailing HPV self-sampling kits to overdue individuals increases adherence, its effectiveness among previously-adherent individuals in the U.S. is unknown. Within a large U.S. healthcare system, STEP compared different approaches for offering self-sampling (direct-mail or opt-in) to individuals who were previously-adherent, overdue, or with unknown screening history.

Methods: From November 2020-January 2022, we used electronic medical record data to identify and randomize 19,213 individuals aged 30-64 years at Kaiser Permanente Washington. Previously-adherent individuals were randomized to Education (usual care+educational materials about screening) (n=3,960), Direct-Mail (Education+mailed self-sampling kit) (n=3,956), or Opt-In (Education+option to request a kit) (n=1,482). Overdue individuals were randomized to Education (n=1,408) or Direct-Mail (n=1,415) and unknown history individuals to Education (n=3,486) or Opt-In (n=3,506). The primary outcome, screening completion within ≤6 months, was defined as: in-clinic screening, kit return with negative or HPV16/18+ results, or kit return with in-clinic reflex Pap if kit results showed other high-risk HPV+ or unsatisfactory. We used intention-to-treat binomial regression to identify absolute risk differences and 95% confidence intervals (CI).

Results: Among previously-adherent individuals, compared with Education (47.6%), screening completion was 14.2% (95%CI:11.3%-17.0%) higher with Direct-Mail (61.7%) and 3.4% (95%CI:1.1%-5.6%) higher with Opt-In (51.0%). Among overdue individuals, screening was 16.6% (95%CI:13.5%-19.7%) higher with Direct-Mail (35.5%) versus Education (18.8%). Among unknown screening history individuals, screening was 2.1% (95%CI:0.4%-3.8%) higher with Opt-In (18.0%) versus Education (15.9%).

Conclusions: Within a U.S. healthcare system, direct-mail self-sampling screening increased by >14%, with absolute effect size similar between previously-adherent and overdue groups. Conversely, the opt-in approach minimally increased screening. To maximize screening adherence, systems implementing HPV self-sampling should prioritize direct-mail outreach for due and overdue individuals. For individuals with unknown history, testing alternative outreach approaches and/or additional efforts to document screening history are warranted.

O069 / #818

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SELF-SAMPLING AND NEW CERVICAL SCREENING TECHNOLOGIES
04-19-2023 5:15 PM - 6:45 PM

URINE HIGH RISK HUMAN PAPILLOMAVIRUS TESTING AS AN ALTERNATIVE TO ROUTINE CERVICAL SCREENING: THE ACES COLPOSCOPY STUDY

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Introduction: Testing urine for high-risk human papillomavirus (hr-HPV) may be an attractive option for non-attenders of routine cervical screening. The accuracy of urine hr-HPV testing varies with different collection protocols. We hypothesised that Colli-Pee has better sensitivity for CIN2+ detection than standard pot-collected urine through reliable first-void collection, standardisation of volume collected, and immediate preservative-fixation. The aim of the Alternative CErvical Screening (ACES) Colposcopy study was to compare the sensitivity of matched urine and cervical hr-HPV testing for CIN2+ detection using two urine collection devices.

Methods: Colposcopy attendees in Manchester (UK) with abnormal cervical screening results were randomised (1:1) to Colli-Pee® 10mls with preservative or standard pot for urine collection. Urine was self-collected and matched cervical samples taken immediately prior to colposcopy; hr-HPV testing used Roche Cobas 8800. Colposcopic opinion and/or histology informed clinical diagnosis. A power calculation indicated that 480 participants (with 120 CIN2+/group) would have 89.8% power to establish a sensitivity of urine for CIN2+ detection >80%.

Results: 465 participants were included in the analysis (Colli-Pee n=235, pot n=230). The groups were balanced in age (median 35.0 vs 36.3 years), ethnicity (79% vs 81% White) and referral screening results (44% vs 44% high grade; 43% vs 43% low grade/borderline; and 11% vs 12% persistent hr-HPV+/cytology-negative) in Colli-Pee and standard pot arms, respectively. Cervical hr-HPV was 97.58% sensitive (95%CI 94.81-99.11%) for CIN2+ detection (n=242/248). Urine hr-HPV sensitivity for CIN2+ was higher using Colli-pee (90.32%, 95%CI 83.84-94.38%, n=112/124) than when collected using the standard pot (73.39%, 95%CI 64.99-80.38%, n=91/124, p<0.001).

Conclusions: Hr-HPV tested Colli-Pee-collected urine shows similar clinical accuracy for CIN2+ detection compared to routine cervical screening. Further work in the general cervical screening population will establish its specificity and its potential to improve cervical screening uptake in current non-attenders.

O070 / #1098

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SELF-SAMPLING AND NEW CERVICAL SCREENING TECHNOLOGIES
04-19-2023 5:15 PM - 6:45 PM

A NATIONWIDE TRIAL OF RISK-STRATIFIED CERVICAL SCREENING FOR FASTER CERVICAL CANCER ELIMINATION

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Introduction: As the era is approaching when vaccinations will have resulted in that HPV infection is no longer transmitted, design of effective campaign strategies for targeting of screening to find infected women at risk will become important.

Methods: We used the Swedish national quality registry of cervical screening to identify cervical cancer risk profiles based on screening history. Profiles with an invasive cervical cancer risk of >1% were for the whole Sweden found for 4,918 women, and a self-sampling kit was sent to their registered address. There were 76,653 women in Sweden who had not taken a cervical smear for >20 years and these women (as well as a group of 12,038 women with risk profiles between 0.3-1%) were, by both online and physical letters, sent a link to order a self-sampling kit. Piloting during 2019-2021 also used reminders by SMS.

Results: In the 2020 pilot, we invited 6,398 women with high risk profile and 18,3% responded and ordered a self-sampling kit. In the 2021 pilot, we invited 23,318 women (mostly long-term non-attenders) and 6,4% responded. The full-scale campaign targeting 93,609 women all over Sweden was launched in September 2022. Direct send appears to have almost doubled the participation rate compared to the strategy with invitation to order a kit. HPV prevalences varied greatly by risk group, with a noteworthy finding being that almost one third of HPV positivities were HPV16/18 in the high-risk groups. Positive women are referred to a regionally responsible gynecologist in the vicinity of the woman´s home.

Conclusions: Effective campaigns to reaching populations at high risk of cervical cancer with cervical cancer will be important for faster cervical cancer elimination. We find that a nationwide campaign using self-sampling and multiple contact strategies can be readily implemented in the whole country as a regular process for complementing the routing screening program.

O071 / #1049

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SELF-SAMPLING AND NEW CERVICAL SCREENING TECHNOLOGIES
04-19-2023 5:15 PM - 6:45 PM

THE VALUE OF 7-TYPE HPV MRNA E6/E7 TESTING IN SELF-COLLECTED SAMPLES AS TRIAGE OF ABNORMAL CYTOLOGY RESULTS: A MEXICAN MULTICENTRICENTIC STUDY

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Introduction: Cervical cancer is a major problem in Mexico. Only 40% attend regular screening. Self-sampling increases access and screening-coverage. Most Mexican states have access to HPV-testing. Literature has shown advantages of E6/E7-mRNA detection over HPV-DNA test in triage of abnormal cytology, however few have evaluated the performance in self-sampled vaginal material. This study compared the performance of a 14-type HPV-DNA test to a 7-type HPV-mRNA test in triage of abnormal cytology with respect to PPV, sensitivity, specificity, and number of colposcopies per CIN2+ detected.

Methods: 418 Mexican women aged 25–65 years referred to colposcopy&biopsy after abnormal cytology (ASC-US+) at General Hospital of Mexico, Clinica Reina-Madre, and Clinica-Colposcopia underwent self-sampling (XytoTest, Mel-Mont Medical), completing a questionnaire evaluating acceptability. Samples were tested for HPV-DNA (Abbott-HPVm2000) and E6/E7 mRNA (PreTect HPV-Proofer`7 (16-18-31-33-45-52-58)). Study endpoint was histologically confirmed high-grade lesion (CIN2+).

Results: 93.1% felt confident performing self-sampling. 95.0% (397/418) had ASC-US+; 70.8% (296/418) low-grade (ASC-US/LSIL) and 24.2% (101/418) high-grade lesions. 55.5% (232/418) had positive HPV-DNA and 25.4% (106/418) HPV-mRNA+. Prevalence of CIN2+ was 12.0% (50/418) including 4 cases of cervical cancer. Sensitivity (CIN2+) for HPV-DNA was 94.0% (47/50) versus 62.0% (31/50) for the mRNA-test, $p<0.001$. Both tests detected all cancers. The specificity was 49.7% (183/368) versus 79.6% (293/368), $p<0.001$, PPV 20.3% (47/232) and 29.2% (31/106) for DNA versus mRNA-test, $p=0.09$. The number of colposcopies per CIN2+ detected by low-grade/high-grade cytology, HPV-DNA and HPV-mRNA was 19.7 and 3.3 compared to 4.9 and 3.4 respectively.

Conclusions: Self-sampling is suitable for HPV-testing and highly accepted by the women. The low PPV by low-grade cytology (5.1%) reflects the need for effective triage, reducing unnecessary colposcopies. A 7-type HPV-mRNA test has higher specificity, PPV and lower number of colposcopies per CIN2+ compared to a 14-type HPV-DNA, effectively discriminating women warranted for immediate colposcopy/biopsy from return to follow-up.

O072 / #1004

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SELF-SAMPLING AND NEW CERVICAL SCREENING TECHNOLOGIES
04-19-2023 5:15 PM - 6:45 PM

EXPERIENCE FROM HPV SELF-SAMPLING AS PART OF A POPULATION-BASED CERVICAL CANCER SCREENING PROGRAM IN THE REGION OF STOCKHOLM, SWEDEN

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Introduction: During the COVID-19 pandemic, the cervical cancer screening program was paused during 9 months as part of the public health restrictions. To compensate for the screening gap in the Region of Stockholm, Sweden, the Swedish Board of Health and Welfare allowed for a temporary transition from provider taken liquid-based cytology (LBC) with analysis of HPV and reflex cytology to HPV self-sampling in 2021. There is a paucity in data globally regarding participation rate using HPV self-sampling and an opt-out approach as the main screening strategy among participating women in the cervical cancer screening program.

Methods: Descriptive statistics from the cervical cancer screening program compared participation rate by HPV self-sampling strategy during March – December 2021 and provider taken LBC during 2018.

Results: During 2021, a total of 355,396 HPV self-sampling kits were sent by mail to eligible women of screening age in the Region of Stockholm. By comparison, in 2018 we invited 258,816 women for provider taken LBC with HPV analysis and reflex cytology. The participation rate was significantly higher with HPV-self-sampling strategy (51% vs. 38 %; p-value <0.0001). The largest increase in participation rate was among women 26-29 years (38% vs 54% ; p-value <0.0001) and 30-39 years (42% vs. 53%; p-value < 0.0001). The participation rate among non-responding women (defined as 4 or more screening invites), doubled with HPV self-sampling (12% vs 23%; p-value < 0.0001). The participation in follow-up LBC among HPV positive women after self-sampling was 90%. The time span from HPV-self-sample and appointment for a provider taken follow-up LBC was three months as per protocol.

Conclusions: Screening by HPV self-sampling in the Region of Stockholm has increased overall participation rate in the cervical cancer screening program, especially among younger women and non-responding women. However, follow-up testing among HPV positive women is crucial for early detection of pre-cancerous lesions.

O073 / #1228

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SELF-SAMPLING AND NEW CERVICAL SCREENING TECHNOLOGIES
04-19-2023 5:15 PM - 6:45 PM

MAILED SELF-SAMPLE HUMAN PAPILLOMAVIRUS (HPV) TESTING KITS AMONG UNDER-SCREENED WOMEN IN A U.S. SAFETY NET HEALTH SYSTEM: RESULTS OF A PRAGMATIC RANDOMIZED TRIAL

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Introduction: The PRESTIS trial (Prospective Evaluation of Self-Testing to Increase Screening) is the first pragmatic randomized controlled trial (RCT) in the U.S. to evaluate the effectiveness of mailed self-sample HPV testing in a safety net health system setting. Safety nets are a critical setting as they provide care to medically underserved individuals who are at disproportionate risk for cervical cancer. We hypothesized that patient navigation, a patient-centered healthcare intervention, would enhance self-sample HPV testing uptake.

Methods: PRESTIS is a 3-arm pragmatic RCT that compares screening uptake (self-sampling or clinic-based) and clinical follow-up among underscreened patients (target n=2,268) randomized to Arms: 1) recall to clinic-based screening (usual care); 2) mailed self-sample HPV testing; or 3) mailed self-sample HPV testing + patient navigation. Underscreened women (i.e., no Pap in 3.5 years or no Pap/HPV co-test in 5.5 years) were identified through the electronic medical record (EMR). Interventions were delivered by patient navigators. Mailed kits included low-literacy instructions, a vaginal swab collection kit, and a pre-paid return envelope. Kits were tested in the health system laboratory for high-risk (HR-) HPV, with reflex testing for HPV 16, 18/45. Results were documented in the EMR; HR-HPV+ patients were navigated to cytology or colposcopy.

Results: A total of n=1,955 patients (86% of target) have been enrolled and randomized as of 10/10/22. Accrual and outcomes ascertainment will be completed by 12/15/22 and 02/15/23, respectively. Currently, trial participants were predominantly Hispanic/Latina (66.6%); 52.2% indicated Spanish as their primary language; and 56.1% had healthcare coverage through the public financial assistance plan (Table 1). The average time since last screening was 9.2 years despite an average of 28.8 primary care encounters in the past 5 years.

Conclusions: PRESTIS trial results will provide critical data on the effectiveness of mailed self-sample HPV testing, alone and with patient navigation, in a medically underserved and racially/ethnically-diverse U.S. population.

O074 / #1364

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SELF-SAMPLING AND NEW CERVICAL SCREENING TECHNOLOGIES
04-19-2023 5:15 PM - 6:45 PM

PANDEMIC-PROOF CANCER SCREENING: USING HPV SELF-SCREENING TO PUT CERVIX HEALTH BACK INTO THE HANDS OF METIS CHARTERED COMMUNITIES IN NORTHERN BRITISH COLUMBIA

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Introduction: Métis Nation British Columbia (MNBC) provides programs and services that advocate for Métis people. While Métis-specific research is limited, available data shows Indigenous women and people with a cervix are at higher risk for cervical cancer diagnosis. Métis people are underrepresented in both health statistics and research, and as such MNBC provides a unique opportunity to highlight the specific health needs of the Métis people, and ultimately seeks to reduce barriers to cervix screening by putting screening back in the hands of community members, while providing participants with a connection to
community.


Regular Cervix Screening can help prevent cervical cancer by finding early signs
Have a screening kit MAILED TO YOU, giving you control to SCREEN YOURSELF
Sign up online
Get a kit by mail
Collect your sample
Mail to the lab
Get your results

Methods: Community engagement avenues were identified in partnership with MNBC and the Métis Chartered Communities, and carried out by local MNBC personnel, community champions and participating clinicians. This included roundtable dialogue with Elders, Community leaders and representatives, health care providers, MNBC's elected leadership, and other regional representatives to

evaluate cultural sensitivity and appropriate clinical pathways. As a result, Métis women and individuals with a cervix in Northwest and Northeast BC were invited to register for cervix screening online (www.CervixCheck.ca) and sent a self-collection kit in the mail if eligible (aged 25-65, more than 3 years since last screen). Online feedback surveys were distributed after participation.

Results: There have been N= 44 registered, N=30 eligible and N=14 ineligible participants. Overall, participants reported a very positive experience with self-collection. Other key themes identified through surveys included the need for a sense of belonging to community and access to culturally safe health care
services.

Conclusions: Using existing MNBC networks including mail outs, and social media platforms, this project has provided a unique approach to addressing barriers to cervix screening for Métis women and individuals with a cervix. Included is Article 23 of the United Nations Declaration on the Rights of Indigenous Peoples4. UNDRIP Article 23: Right to Development | Indigenous Rights Radio (culturalsurvival.org)

O075 / #1721

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SELF-SAMPLING AND NEW CERVICAL SCREENING TECHNOLOGIES
04-19-2023 5:15 PM - 6:45 PM

HUMAN PAPILLOMAVIRUS GENOTYPING FOR RISK ASSESSMENT AND PROGNOSIS OF CERVICAL INTRAEPITHELIAL NEOPLASIA: A POOLED ANALYSIS FROM PROSPECTIVE COHORT STUDIES

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Introduction: Cervical neoplasia progression risks based on non-16/18 HPV types are not well characterized. We sought to identify the absolute risk of 12 non-16/18 HPV genotypes for cervical intraepithelial neoplasia (CIN) or worse and to predict 3-years CIN transition probabilities and progression patterns between multiple states according to genotypes.

Methods: HPV genotyping was performed based on 3 prospective cohorts. 14 high-risk HPV types (HPV16/18/31/33/35/39/45/51/52/56/58/59/66/68) were detected. The absolute immediate and 3-year cumulative risks for each HPV genotype were calculated by 3 approaches, including minimum (Min.), any type (Any.), and hierarchical attribution estimate (Hier.). Meanwhile, we applied a continuous-time multistate Markov model to predict this CIN status by addressing the probability of transitions between multiple states according to the genotypes.

Results: At baseline, eligible data were available for 15 269 women with a median age of 46 years (interquartile range, 36–53 years). There were 2622 HPV-positive women (17.16%), including 915 (5.99%) with multiple and 1707 (11.17%) with single infections. In non-16/18 infections, single HPV31, 33, 51 infections carried a high immediate risk for CIN2+/3+ (≥4%). Among 5551 women who completed 3-year follow-ups, the cumulative risks of HPV45, 58, 51 were higher. Calculated by Min. and Hier., the cumulative risks for CIN3+ of HPV31/35/56/59/68 were 0%, though HPV31 carried high cumulative risks for CIN2+. The estimated probabilities for the 3-year transition from normal to CIN2 or more were the highest in HPV 16-positive patients (1.3%), followed by HPV 31(0.6%), 58(0.5%), 51(0.3%), 52(0.3%) and 33(0.3%).

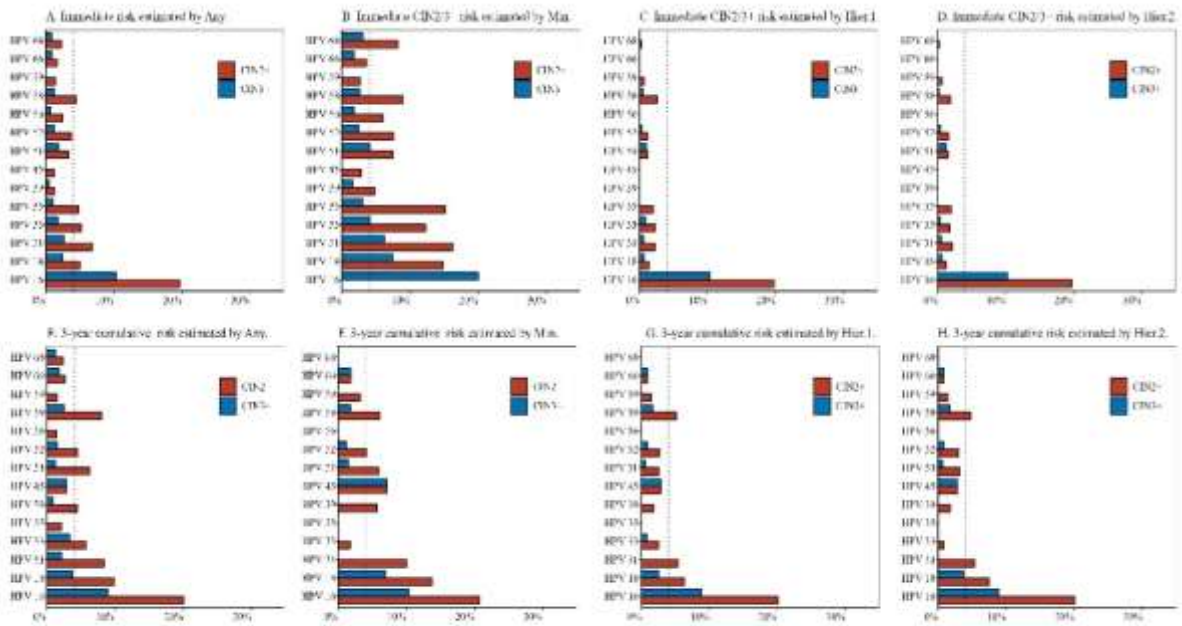

Figure 1. Immediate and 3-year cumulative risk of specific HPV genotype for CIN2+ and CIN3+

Table 1. Predicted 3-year transition probabilities from states to states

Current State	State after 3 Years			
	HPV Genotypes	Normal	CIN1	CIN2+
Normal	HPV 16	0.973	0.014	0.013
	HPV 18	0.983	0.014	0.003
	HPV 31	0.985	0.009	0.006
	HPV 33	0.99	0.007	0.003
	HPV 35	0.987	0.011	0.002
	HPV 39	0.991	0.007	0.002
	HPV 45	0.992	0.006	0.002
	HPV 51	0.989	0.008	0.003
	HPV 52	0.989	0.008	0.003
	HPV 56	0.99	0.009	0.001
	HPV 58	0.987	0.007	0.005
	HPV 59	0.995	0.004	0.001
	HPV 66	0.994	0.006	0
	HPV 68	0.994	0.005	0.001
CIN1	HPV 16	0.186	0.78	0.034
	HPV 18	0.145	0.794	0.061
	HPV 31	0.219	0.78	0.001
	HPV 33	0.227	0.743	0.03
	HPV 35	0.192	0.808	0
	HPV 39	0.219	0.739	0.042
	HPV 45	0.328	0.671	0
	HPV 51	0.19	0.78	0.03
	HPV 52	0.24	0.746	0.014
	HPV 56	0.231	0.769	0
	HPV 58	0.213	0.768	0.019
	HPV 59	0.117	0.883	0
	HPV 66	0.261	0.66	0.079
	HPV 68	0.138	0.803	0.059
CIN2+	HPV 16	0.279	0.002	0.719
	HPV 18	0.189	0.057	0.754
	HPV 31	0.338	0.002	0.66
	HPV 33	0.183	0.075	0.743
	HPV 35	0.22	0.001	0.779
	HPV 39	0.193	0.054	0.753
	HPV 45	0	0	1
	HPV 51	0.328	0.001	0.671
	HPV 52	0.391	0.002	0.607
	HPV 56	0	0	1
	HPV 58	0.182	0.076	0.742
	HPV 59	0	0	1
	HPV 66	0.392	0.001	0.607
	HPV 68	0.118	0.099	0.783

Conclusions: Based on immediate and 3-year cumulative risks, strategy makers should reckon with genotyping HPV 31, 33, 51, 52, and 58 in screening and management. In contrast, HPV 35, 56, 59, and 68 could be considered for low intensive follow-up, to reduce the screening costs and other technologies for triage.

O076 / #1520

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SELF-SAMPLING AND NEW CERVICAL SCREENING TECHNOLOGIES
04-19-2023 5:15 PM - 6:45 PM

CLINICAL PERFORMANCE OF DUAL STAIN VS. CYTOLOGY COMBINED WITH EXTENDED GENOTYPING IN A LARGE POPULATION OF HPV-POSITIVE INDIVIDUALS: IMPLICATIONS FOR CERVICAL CANCER SCREENING STRATEGIES

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Introduction: HPV primary screening is a safe and efficient strategy for cervical cancer prevention. Patients with negative HPV results have low risk of cancer for years. HPV-positive patients need triage to decide who requires colposcopy. Dual stain (DS) and extended HPV genotyping have been evaluated for HPV triage. Here, we compared the clinical performance of extended genotyping combined with DS vs. cytology.

Methods: Among 3,757 HPV-positive patients from Kaiser Permanente Northern California undergoing co-testing in 2018, DS and Onclarity were conducted from residual specimens. Follow-up continued through 2021. We estimated absolute risk of CIN3, AIS, or cancer (CIN3+) using prevalence-incidence mixture models for combinations of Onclarity results (16; 18; 31; 45; 51; 52; 33/58; 35/39/68; 59/56/66 and four risk groups: 16; 18/45; alpha9; other), DS, and cytology.

Results: Among all HPV-positives, 49.1% were DS-positive, and 56.2% were ASC-US or greater ($p<0.002$). The sensitivity for detection of CIN3+ was higher for DS compared to cytology (91.8% vs. 77.8%; $p<0.002$). Across the nine genotype channels, dual stain positivity reflected underlying carcinogenicity, ranging from 33.1% for HPV59/56/66 to 68.4% for HPV16 while abnormal cytology was more similar across genotype groups and did not track with HPV carcinogenicity. Across all genotype groups, DS had higher sensitivity for CIN3+ and lower risk among dual stain negatives (from 0.1% for HPV59/56/66 to 2.0% for HPV16), compared to cytology (from 0.4% for HPV59/56/66 to 8.4% for HPV16). The risk difference between HPV16-NILM and HPV16-DS-negative would result in different management recommendations in the US (colposcopy vs. 1-year

repeat).

	Total n	Total CIN3+	DS positivity	Sensitivity	Risk of CIN3+ in DS+	Risk of CIN3+ in DS-	Cytology positivity	Sensitivity	Risk of CIN3+ in cytology+	Risk of CIN3+ in cytology-
9-Level										
HPV16	545	97	68.4%	92.8%	23.4%	2.0%	63.2%	76.2%	20.5%	8.4%
HPV33/58	333	21	57.7%	85.7%	9.2%	0.7%	59.2%	81.0%	7.5%	2.8%
HPV18	134	13	63.4%	92.3%	10.2%	0.7%	61.8%	69.2%	8.8%	3.3%
HPV31	339	20	55.8%	90.0%	10.2%	0.7%	50.1%	80.0%	8.7%	3.3%
HPV35/39/68	652	11	45.2%	100%	3.5%	0.2%	53.2%	90.9%	2.4%	0.9%
HPV52	388	23	54.9%	95.6%	8.8%	0.6%	54.6%	82.6%	6.9%	2.6%
HPV45	112	4	48.2%	100%	5.4%	0.4%	42.9%	50.0%	4.3%	1.6%
HPV51	219	6	47.9%	100%	2.8%	0.2%	63.0%	100%	1.9%	0.7%
HPV59/56/66	514	6	33.1%	66.7%	2.2%	0.1%	57.8%	50.0%	1.1%	0.4%
4-Level										
HPV16	545	97	68.4%	92.8%	23.4%	2.0%	63.2%	76.2%	20.5%	8.4%
HPV18/45	307	21	63.4%	95.2%	8.4%	0.6%	51.4%	71.4%	7.4%	2.7%
Alpha9	1651	71	51.4%	91.5%	7.5%	0.5%	54.4%	81.7%	5.6%	2.0%
Other types	1254	16	35.5%	83.3%	2.5%	0.2%	55.6%	77.8%	1.4%	0.5%
All Types	3757	207	49.1%	91.8%	9.6%	0.5%	56.2%	77.8%	6.9%	2.2%

Conclusions: DS had lower positivity compared to cytology but had greater sensitivity and specificity. Across all HPV genotypes, DS-negative patients were reassured of very low risk, which would not require colposcopy. Extended genotyping providing four HPV risk groups paired with DS provides more efficient triage compared to current cytology-based approaches.

O077 / #806

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - I
04-19-2023 5:15 PM - 6:45 PM

GTP-BOUND RAB9A INHIBITS HUMAN PAPILLOMAVIRUS ENTRY

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Introduction: Rab GTPases play key roles in controlling intracellular vesicular transport. In general, when bound to guanosine triphosphate (GTP), Rab proteins are active and support vesicle trafficking. Human papillomavirus (HPV) entry into the nucleus requires various Rab proteins, but it remains largely unclear which Rab protein is employed at which specific steps of the virus entry. Rab7 plays a critical role in retromer-mediated endosome-to-Golgi trafficking of HPV; the cycling between GTP- and GDP-bound Rab7 is crucial for both association and dissociation of retromer from HPV during virus entry.

Methods: By employing biological, biochemical, and microscopic approaches in HeLa or 293 HEK cells infected with HPV16 pseudoviruses, we investigated the role of Rab9a protein in the HPV entry process.

Results: We report that the Rab7-dependent retrograde entry pathway used by HPV requires Rab9a in its GDP-bound form, unlike cellular protein cargos. Knockdown of Rab9a hampers HPV entry to the nucleus by enhancing the HPV-retromer interaction and impairing retromer-mediated endosome-to-Golgi transport of the incoming virus, resulting in the accumulation of HPV in the endosome. Proximity ligation assays showed that Rab9a is in proximity to HPV as early as 3.5 h post-infection, prior to the Rab7-HPV interaction. Endosome acidification is required for the HPV-Rab9a interaction, and thus is a prerequisite for Rab9a's action on HPV-retromer association. Rab9a knockdown activates Rab7, but Rab9a knockdown influences HPV-retromer interaction in the absence of GTP-bound Rab7. Lastly, by analyzing cells expressing constitutively active and dominant negative Rab9a mutants, we show that GTP-bound Rab9a inhibits HPV infection whereas GDP-bound Rab9a promotes it. In contrast, GTP-bound Rab9a enhanced cellular protein transport from endosome to Golgi.

Conclusions: Thus, Rab9a favors HPV trafficking by hindering HPV-retromer association. Our findings further reveal that HPV employs a trafficking mechanism distinct from that used by cellular proteins.

O078 / #1285

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - I
04-19-2023 5:15 PM - 6:45 PM

HPV E6 IS AN EVOLUTIONARILY CONSERVED BASAL EPITHELIAL HOMEOSTASIS REGULATOR, THAT FACILITATES VIRAL PERSISTENCE AND CAN BE TARGETED FOR DISEASE CLEARANCE

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Introduction: The evolution of PV has been the result of the coevolution of and adaptation to the specific epithelial niches where each PV colonises, resulting in their remarkable species and tissue specificity as well as unique pathogenicity. HPVs also share a general life cycle strategy, in which they establish a persistent reservoir of infection in the basal layer of stratified epithelium, for persistent infection as well as lesion formation. During persistent infection, E6 but not E7 viral protein is thought to play a major role in maintaining and expanding infected cells in the basal layers as a regulator of homeostasis.

Methods: Here, we describe a simple in vitro 2D/3D model system for studying basal epithelium homeostasis in the context of cell growth, contact inhibition, as well as the transition of cells from the basal to second layers (delamination/commitment of differentiation) independently.

Results: Taking HPV16 E6 as an example, which is most frequently causative of HPV-related cancers, we show how HPV16 E6 modulates basal epithelium homeostasis in those aspects via the degradation of p53, and PDZ-proteins, and contributes to lesion formation and maintenance overall. Also, other HPVs' E6s (α-HPV11/16/27, β-HPV8, γ-HPV65 and μ-HPV1) from different genera show similar phenotypes in different ways. Finally, we show that the model system could serve as a high-throughput screening system for the identification of small molecules which can inhibit E6's function in modulating basal epithelium homeostasis and therefore be potential candidates for anti-HPV reagents.

Conclusions: HPV E6 is an evolutionarily conserved basal epithelial homeostasis regulator, that contributes to viral persistence and can be targeted for disease clearance by small molecules which inhibit HPV E6 function.

O079 / #955

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - I
04-19-2023 5:15 PM - 6:45 PM

NOVEL HPV+ EPITHELIAL SUBPOPULATIONS DEFINED BY VIRAL REPROGRAMMING AND ASSOCIATED WITH ABNORMAL PROLIFERATION ARE IDENTIFIED BY SINGLE CELL TRANSCRIPTOMICS

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Introduction: Human papillomavirus (HPV) infection of stratified squamous epithelium, predominantly by high risk HPV16, is the cause of 5% of all cancers worldwide, with viral persistence being a major risk factor. HPV deregulates the cell cycle and drives tissue dysplasia, and hallmarks of infection include basal cell hyperproliferation and aberrant replication in the suprabasal epithelium.

Methods: We performed single cell RNA sequencing (scRNAseq) on an established model of persistent HPV16 replication, isogenic HPV16+ and HPV16- NIKS organotypic epithelial rafts, to generate a host/pathogen transcriptome atlas of infected epithelium.

Results: Pseudotemporal trajectory analysis aligned cells along the epithelial differentiation program, with cycling G2/M phase cells forming two branches. The first originated from basal-like cells, while the second originated from differentiated cells. Notably, the second branch included a differentiated cell subpopulation specific to HPV+ epithelium that transitioned in the trajectory to G2/M cells. This subset of G2/M cells may harbor HPV-driven suprabasal cycling cells. Transcriptome analysis of basal cell clusters, the HPV-specific subpopulation, and the G2/M cell cluster defined ontologies, biomarkers for spatial localization, and candidate phenotypic drivers. First, HPV reprogramming of ribosomal signaling and translation of basal cells which might enable proliferation was identified. Second, the HPV-specific subpopulation was determined to be the sole differentiated subpopulation to also express S-phase genes. Accordingly, its signature overlapped with basal and G2/M cell expression profiles, sharing ontologies that

suggest a transitory state induced by HPV reprogramming. Ongoing studies will define processes upregulated in HPV+ versus HPV- basal G2/M cells, the targets of HPV-driven hyperproliferation, as well as suprabasal HPV+ G2/M cells which represent the hypothesized aberrantly replicating suprabasal cell population.

Conclusions: Together, we defined the transcriptomic signatures of HPV-reprogrammed cells and HPV-driven pathologically proliferating cells in the basal and suprabasal stratified epithelium and identified potential disease drivers as a foundation for mechanistic studies.

O080 / #541

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - I
04-19-2023 5:15 PM - 6:45 PM

HUMAN PAPILLOMAVIRUS-ENCODED E6 PROTEIN EXPLOITS AURORA KINASE B FOR CARCINOGENESIS

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Introduction: The human papillomavirus E6 and E7 oncoproteins interact with a different subset of host proteins, leading to dysregulation of apoptotic, cell cycle and signalling pathways. In this study, we have identified for the first time that Aurora kinase B (AurB) as a bona fide interacting partner of E6.

Methods: We systematically characterised the AurB-E6 complex formation and its consequences in carcinogenesis, using a series of in vitro and cell-based assays. We also assessed the efficacy of Aurora kinase inhibitors in halting HPV-mediated carcinogenesis by using in vitro and in vivo models.

Results: We showed that AurB activity was elevated in HPV-positive cells, and this correlated positively with E6 expression. This could likely occur through interaction between E6 and AurB in the nucleus or mitotic cells. A previously unidentified region of E6, upstream of C-terminal E6-PBM, was important for AurB-E6 complex formation. AurB-E6 complex led to reduced AurB kinase activity. However, AurB-E6 complex activated histone H3, elevated the Ras/MEK/ERK signalling axis, and increased hTERT protein level and its telomerase activity. On the other hand, AurB inhibition led to an activation of the apoptotic pathway, inhibition on telomerase activity, cell proliferation and tumour formation, even though this may occur in an HPV-independent manner.

Conclusions: In summary, this study dissected the molecular mechanism on how E6 recruits AurB to induce cell immortalization and proliferation, leading to the eventual cancer development. Our findings revealed that the treatment of AZD1152 exerted a non-specific anti-tumour effect. Hence, a continuous effort in seeking a specific and selective inhibitor that can halt HPV-mediated carcinogenesis should be warranted.

O081 / #560

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - I
04-19-2023 5:15 PM - 6:45 PM

INTERACTION WITH TOPBP1 IS REQUIRED FOR E2 EXPRESSION DURING THE HPV16 LIFE CYCLE

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Introduction: The incidence of head and neck cancers are growing. Worldwide, it constitutes 10% or more of all cancers and is the fifth leading cause of cancer. Over the past decade,oral cancers have become apparent in a cohort of nonsmokers/ minimal smokers who are human papillomavirus (HPV) positive.Understanding interactions between HPV and host can provide new targets for infection control. We have previously identified an interaction between HPV16E2 and TopBP1 and shown that phosphorylation of E2 on serine 23 promotes a direct interaction between these two proteins. E2 recruits TopBP1 onto mitotic chromatin. Here, we demonstrate that interaction with TopBP1 protein is required for E2 expression during the HPV16 lifecycle.

Methods: We generated a serine to alanine mutant to generate HPV16 $E2^{-TopBP1}$ that fails to complex with TopBP1. Human foreskin keratinocytes (HFK) immortalized by HPV16+ WT and HPV16 + $E2^{-TopBP1}$ were used for organotypic rafting. These rafts were further processed for protein isolation and immunostaining. Furthermore, to study the HPV16 genome status of these E2 cells, we carried out Southern blots on DNA extracted from day 7 and day 14 rafts.

Results: Preliminarily studies demonstrate no detectable E2 expression in HFK+HPV16 $E2^{-TopBP1}$ cells in the raft culture. When we cultured the HFK+HPV16 $E2^{-TopBP1}$ in monolayer, in the presence of 3T3-J2 fibroblasts we also observed loss in E2 protein expression levels. This suggests that the stroma used during organotypic rafting studies (collagen plugs infused with 3T3-J2 fibroblasts) cross talks with the keratinocytes to regulate the expression levels of E2.Additionally, our results indicate that this loss of E2 expression due to a failure of interaction with TopBP1, impacts the viral life cycle, as viral replication is abrogated and the viral genomes integrate into that of the host during organotypic rafting.

Conclusions: Overall, we present evidence that E2-TopBP1 is a critical complex that regulates HPV16 life cycle.

O082 / #953

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - I
04-19-2023 5:15 PM - 6:45 PM

POST-GOLGI TRAFFICKING REQUIREMENTS OF HPV16 PSEUDOVIRIONS.

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Introduction: During infectious entry papillomavirus (PV) virions have been shown to traffic to the perinuclear region where they colocalize predominantly with Golgi components and to a lesser degree with ER marker proteins. Studies have shown an absolute requirement for mitosis to allow infection. We recently demonstrated that relatively intact PV particles were present within membrane-bound vesicles attached to mitotic chromosomes. This allows for nuclear delivery into daughter cells upon nuclear envelope reassembly. We are now interested in identifying the membrane source and trafficking mediators involved in formation of these transport vesicles.

Methods: As Rab GTPases are key regulators of membrane trafficking, we determined the effect of overexpression of a panel of dominant-negative Rabs and other GTPases on HPV16 pseudovirus (PsV) infection. Potential contributing pathways were examined by siRNA depletion of key proteins. Delivery of PV capsids to mitotic chromatin was evaluated by confocal microscopy.

Results: The analysis of dominant-negative GTPases indicated that disruption of retrograde Golgi to ER trafficking had no effect on infection. Surprisingly, we observed a requirement for anterograde mediators for HPV16 infection including Rab proteins 1b, 18, 30 and Sar1, the critical GTPase for COPII vesicle generation. Additionally, proteins that facilitate the bifurcation of the secretory COPII vesicles and autophagosomes from the ER/Golgi intermediate compartment (ERGIC) were found to contribute to virion trafficking.

Conclusions: The transitional ER and ERGIC sort anterograde cargo proteins. It was recently described that a novel contact between the ERGIC and transitional ER also serves as the membrane source for autophagosome biogenesis. Previous studies have demonstrated an inverse relationship between autophagic activity and HPV PsV infection. Interestingly, an interplay between this pathway and anterograde ER-derived COPII vesicles is apparently responsible for generation of the HPV-containing vesicles destined to interact with the mitotic chromatin.

O083 / #1009

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - I
04-19-2023 5:15 PM - 6:45 PM

HUMAN PAPILLOMAVIRUS 16 REPLICATION CONVERTS SAMHD1 INTO A HOMOLOGOUS RECOMBINATION FACTOR TO PROMOTE THE VIRAL LIFE CYCLE

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Introduction: Head and neck cancers are the fifth most common cancer worldwide, affecting more than 600,000 people per year. Human papillomaviruses (HPVs) are well established as the causative agents in a distinct subset of these cancers; in particular, high-risk HPV16 is responsible for 80-90% of these cases. As the incidence of HPV positive oropharyngeal cancers (HPV+OPC) are increasing to epidemic proportions, there is a need for diagnostics and HPV-targeted therapeutics to manage disease. Following infection, the initiation of viral replication activates the DNA damage response (DDR). The purpose of this is to enable recruitment of active homologous recombination (HR) factors to the viral genome to promote the fidelity of viral replication.

Methods: SAMHD1 is a cellular dNTPase that can restrict the intracellular nucleotide pool and control DNA replication levels. However, activation of the DDR results in phosphorylation of SAMHD1 on threonine 592 (T592) which disables the dNTPase function and promotes a SAMHD1 HR function. Using phosphorylation-null (T592A) and phospho-mimetic (T592D) mutants of SAMHD1, we investigate the replication of HPV16 and the recruitment of cellular factors to replication forks to promote HR.

Results: Here we demonstrate that in human foreskin keratinocytes immortalized by the entire HPV16 genome (HFK+HPV16) SAMHD1 is phosphorylated on T592. The E6/E7 oncoproteins by themselves are unable to promote SAMHD1 phosphorylation. We demonstrate that E1/E2 replication can enhance phosphorylation of SAMHD1 on T592 and that this promotes recruitment of SAMHD1 to E1/E2 replicating DNA. Using T592D and T592A SAMHD1 mutants, we demonstrate that the T592D mutant is hyper-recruited to E1/E2 replicating DNA and actively represses replication, perhaps due to “freezing” of replication forks. Alterations in replication are currently under investigation.

Conclusions: HPV16 replication converts SAMHD1 from a dNTPase to a HR factor in order to promote the viral life cycle. Thus, peptides mimicking the T592 phosphorylated SAMHD1 domain have potential anti-viral activity.

O084 / #1417

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - I
04-19-2023 5:15 PM - 6:45 PM

ECOLOGY OF ONCOGENIC HUMAN PAPILLOMAVIRUSES AFTER THE ERADICATION OF VACCINE-TARGETED TYPES

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Introduction: Comprehensive human papillomavirus (HPV) vaccine implementation will change the ecological conditions of the virus-host interaction. The long-term effects of HPV vaccine programs can only be estimated with long-term follow-up of randomized trials.

Methods: We performed a long-term follow-up of 33 communities randomized to either gender-neutral HPV16/18 vaccination, girls-only HPV16/18 vaccination and hepatitis B-virus (HBV) vaccination of boys, and control vaccination. In the 1992-94 birth cohorts, 8,618/31,117 eligible boys and 15,615/30,139 eligible girls were vaccinated. Follow-up visits for cervico-vaginal sampling at ages 18 and 22 years were attended by 8,782 and 4,273 participants, respectively. Difference in prevalence of HPV types 6/11/16/18/31/33/35/39/45/51/52/56/58/59/66/68 was assessed and further modeled from the observed data.

Results: Significant decrease of vaccine targeted oncogenic HPV types 16/18/31/45 and significant increase of low oncogenicity HPV52 and 66 was observed for the gender-neutral vaccination communities eight years post-vaccination compared to control and girls-only vaccinated. Moreover, gender-neutral vaccination associated with increased HPV type-level diversity distribution from four to eight years post-vaccination unlike with the control and girls-only communities.

Conclusions: Eight years post moderate coverage HPV vaccination enabled the detection of a vaccination strategy specific HPVs ecological response. The HPV types increasing after elimination of vaccine-targeted types have low oncogenicity and should thus not challenge the WHO milestone to eliminate cervical cancer. However, the post-vaccination diversity of remaining HPV types will affect future cervical cancer screening programs.

O085 / #1447

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - I
04-19-2023 5:15 PM - 6:45 PM

HUR INHIBITION WITH SRI-42127 REDUCES HR-HPV E6 AND E7 FUNCTIONS AND SENSITIZES CERVICAL CANCER MODELS TO CISPLATIN

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Introduction: The high-risk (HR) Human Papillomavirus oncoproteins E6 and E7 support productive viral DNA amplification in benign lesions by destabilizing p53, pRB/p130 and many other cellular proteins. They are also critically required for the development of cervical cancers. HPV E6 and E7 activities upregulate several RNA-Binding Proteins (RBPs) in HPV-induced benign lesions and cancers (Xu et al., 2019, DOI:10.1128/mBio.02687-18). In this study, we examined the functions of one RBP, HuR, in HPV-18 productive infection and cervical cancer (CxCa) models by using a novel HuR inhibitor SRI-42127 (Filippova et al., 2021, DOI:10.1158/0008-5472.CAN-20-2858), developed in UAB.

Methods: HPV-18 productive raft cultures (RC), submerged cultures of HPV-16+ and HPV-18+ cervical cancer (CxCa) cell lines (CaSki, SiHa and HeLa), CxCa PDX-derived organoids organoids, and CaSki cell RCs were treated with SRI-42127. In situ analyses and immunoblot analyses were performed to examine the effects of the HuR inhibitor. For in vivo evaluation, CxCa PDX420 was implanted inthe flanks of female SCID/Ncr mice. Xenograft bearing mice were treated for 4+ weeks with vehicle, cisplatin, SRI-42127 or cisplatin plus SRI-42127. Tumor growth was recorded every week.

Results: In productively infected HPV-18 raft cultures, SRI-42127 significantly reduced S-phase re-entry and induced apoptosis, thereby inhibiting virus production. In submerged cultures of CxCa cell lines and in CxCA PDX-derived organoids, we observed growth inhibition, DNA damage, loss of cell viability, and apoptosis. Interestingly, SRI-42127 stabilized and activated p53-regulated growth inhibition of CxCa cell lines. Furthermore, SRI-42127 enhanced cisplatin cytotoxicity against the CxCa model systems in vitro and in female SCID/Ncr mice.

Conclusions: HuR inhibition offers a new therapeutic opportunity against HPV infection and cancer because of its ability to suppress E6 and E7 functions and increase p53 activity.

O086 / #574

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 2
04-20-2023 10:30 AM - 12:00 PM

COMPARISON OF LONG-TERM COLPOSCOPY REFERRALS IN BRITISH COLUMBIA'S CERVIX SCREENING PROGRAM AMONG THOSE WHO DID OR DID NOT RECEIVE HRHPV-BASED SCREENING IN THE HPV-FOCAL TRIAL

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Introduction: Shifting from cytology to HPV cervix screening will initially raise colposcopy referral rates. The anticipated impact on health systems has been a barrier to implementing this shift. It is unclear if increased referrals persist past initial HPV screens or revert to new lower baselines due to earlier detection and treatment of precancer.

Methods: Participants of the HPV FOCAL trial received one (HPV1, N = 6204) or two (HPV2, N = 9540) rounds of HPV screening. After exit, they returned to the BC cytology screening program. A comparison cohort from the BC screening population (BCS, N = 1,140,745) was extracted, mirroring trial inclusion criteria. All participants were followed for up to 10 years through the provincial screening registry. Trial and post-trial referral rates per 1000 screens (totals– HPV1: 27,341; HPV2: 36,982; BCS: 5,076,312) were calculated for each group under two HPV screening scenarios: (1) all HPV+ referred to colposcopy; (2) HPV+ to cytology triage with ASCUS+ referred to colposcopy. A multivariate flexible survival regression model compared rates throughout follow-up.

Results: Scenario 2 referral rates were higher after an HPV screen versus cytology screening (HPV1: 28 per 1000 women, HPV2: 32, BCS: 8). However, post-trial rates in HPV1 and HPV2 were significantly less than those in BCS during post-trial follow-up. Cumulative rates in HPV1 and HPV2 approached the cumulative rate in BCS by the end of follow-up (HPV1: 11 per 1000 women, HPV2: 16, BCS: 11). Adjusted HRs for referral in HPV1 and HPV2 compared to BCS were <1 beginning 24 months post-final HPV
screen.

Figure 1. **Crude instantaneous and cumulative colposcopy referral rates among comparison groups.** Panel 1 shows colposcopy referral rates under scenario (1): after HPV-based screens (time periods 0 and 3-4 for HPV1 and HPV2) all HPV positive participants referred to colposcopy. Panel 2 shows colposcopy referral rates under scenario (2) after HPV-based screens (time periods 0 and 3-4 for HPV1 and HPV2) HPV positive participants are triaged with cytology and only those who are ASCUS+ are referred to colposcopy. All other time periods (and all time periods for BCS) are based on actual cytology-related colposcopy referral rates taken from the provincial screening program's registry database.

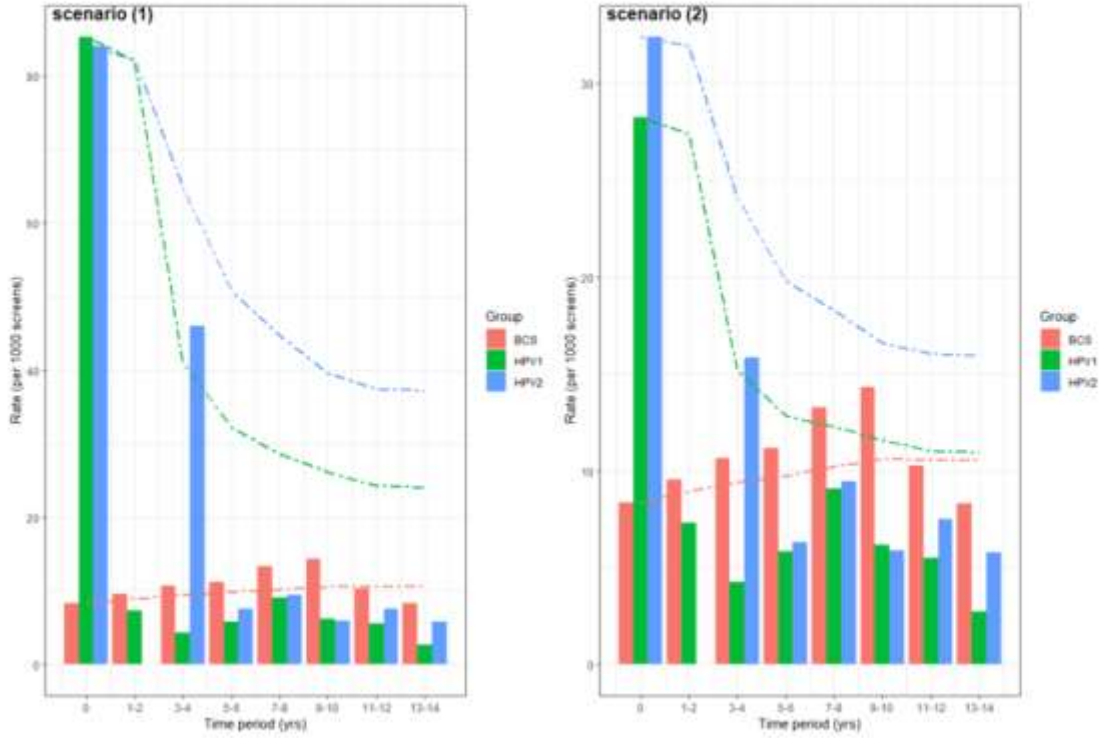

Figure 2. **Hazard ratios for HPV1 and HPV2 vs BCS.** Results from the flexible survival regression model demonstrating that the hazard ratios comparing colposcopy referral rates in HPV1 and HPV2 versus BCS quickly drop below 1 upon re-entry into the cytology-based screening program after participating in one or two rounds of HPV-based screening. Panel 1 shows hazard ratios under scenario (1): after HPV-based screens (time periods 0 and 3-4 for HPV1 and HPV2) all HPV positive participants referred to colposcopy. Panel 2 shows hazard ratios under scenario (2) after HPV-based screens (time periods 0 and 3-4 for HPV1 and HPV2) HPV positive participants are triaged with cytology and only those who are ASCU5+ are referred to colposcopy.

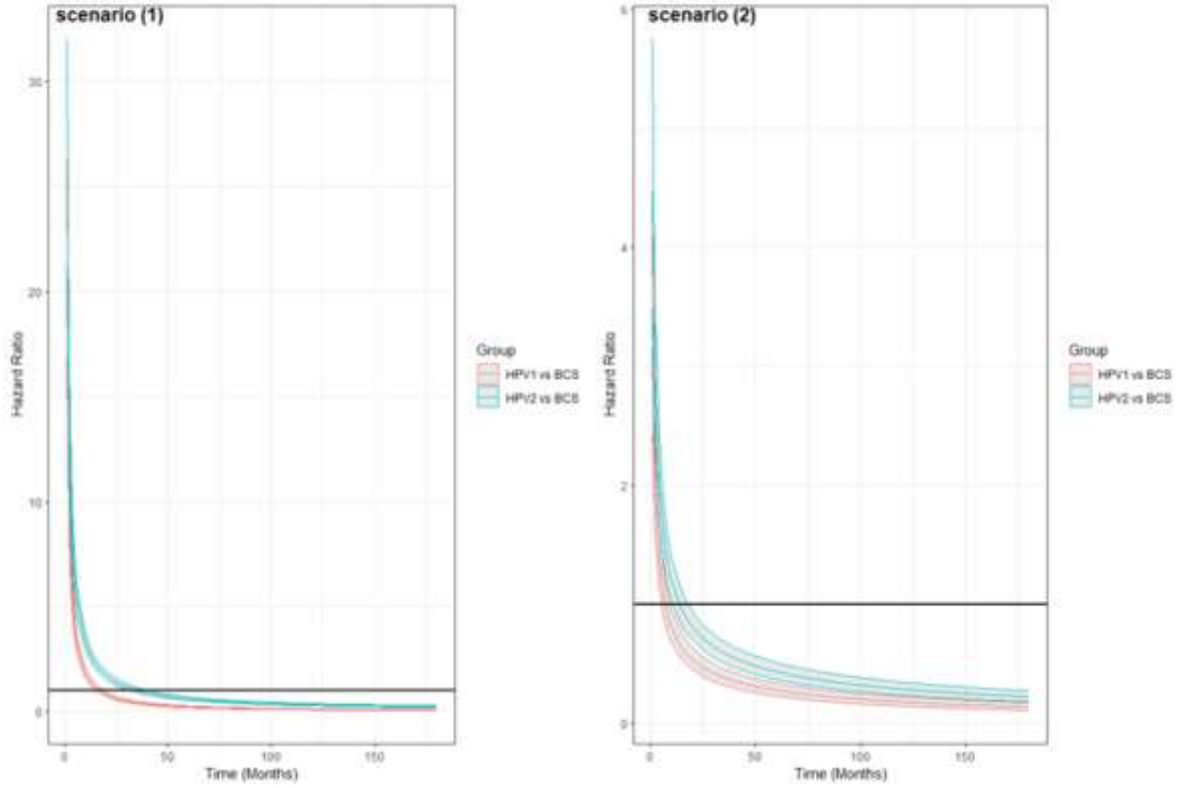

Table 1. Results from the flexible survival regression model demonstrating the hazard ratios between HPV1 and HPV2 versus BCS at various timepoints

Group	Time (months)	Scenario 1 (HR (95% CI))	Scenario 2 (HR (95% CI))
HPV1 vs BCS	6	3.17(2.73-3.65)	1.09(0.91-1.29)
	24	0.65(0.56-0.75)	0.48(0.41-0.57)
	54	0.25(0.21-0.30)	0.30(0.25-0.36)
	72	0.18(0.15-0.22)	0.25(0.20-0.31)
HPV2 vs BCS	6	5.27(4.58-6.06)	1.61(1.36-1.88)
	24	1.45(1.29-1.62)	0.73(0.63-0.84)
	54	0.67(0.59-0.76)	0.46(0.39-0.54)
	72	0.52(0.45-0.59)	0.39(0.33-0.46)

Conclusions: Reduced colposcopy referral rates are demonstrated after HPV screening implementation reached a steady state. After initial rounds of HPV screening, referral rates dropped below the current rates seen in a centralized cytology program. An expected increase in referrals could be moderated by program implementation strategies.

O087 / #1155

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 2
04-20-2023 10:30 AM - 12:00 PM

FIFTY-FIVE SCREEN-DETECTED CERVICAL CANCERS IN GENERAL POPULATION: RESULTS FROM ESTAMPA, A MULTICENTRIC CROSS-SECTIONAL SCREENING STUDY IN LATIN AMERICA

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Introduction: Cervical cancer screening aims to detect precancers that can be effectively treated to prevent progression to cancer. However, prevalent cancers can also be detected, particularly in under-screened populations. Here, cervical cancers detected by screening efforts in ESTAMPA are described.

Methods: From 2012 to 2021, 42,502 women aged 30-64 years from 9 Latin American countries were screened with HPV-testing and cytology which included visualisation of the cervix during a speculum exam. Those positive for any test were referred to colposcopy with biopsy and treatment as needed. Women without high-grade disease (≤CIN1) were followed-up at 18 months with HPV-testing; those positive were referred again to colposcopy for disease ascertainment.

Results: 55 cancers were detected, 47 at the initial screen and 8 at follow-up (mean age 43.8±9; 47 SCC and 8 ADC; 39, 5, 7 and 3 with FIGO stage I to IV; Figure 1). All cases were HPV-positive except for one SCC suspected of cancer at speculum exam (FIGO stage III, Figure 1-P55-45y). Cytology was abnormal for 32 cases (21 HSIL+, 6 LSIL and 5 ASC-US) and speculum exam for 24 (including 8 cancer suspicions). Initial colposcopy was positive for 51 cases, including 21 cancer suspicions, 16 major colposcopic changes (MCC) and 14 minor colposcopic changes (mCC); all histologically confirmed except for 4 mCC (3 CIN1 and 1 negative biopsy). Among those 8 cancers not initially detected (4 normal colposcopies and 4 mCC) follow-up colposcopy was positive for 7 (1 cancer suspicion, 3 MCC and 3 mCC; all histologically confirmed). One SCC was finally detected by LLETZ at 26 months (Figure 1-P50-36y).

Conclusions: Cancer detection by HPV-testing (98.2%) was superior to cytology (66.7%). Colposcopy with biopsy initially failed to detect 8 cancers (14.5%, assumed present at enrolment). Neither normal colposcopy nor negative biopsy provides absolute reassurance against cervical cancer, highlighting the

need for follow-up.

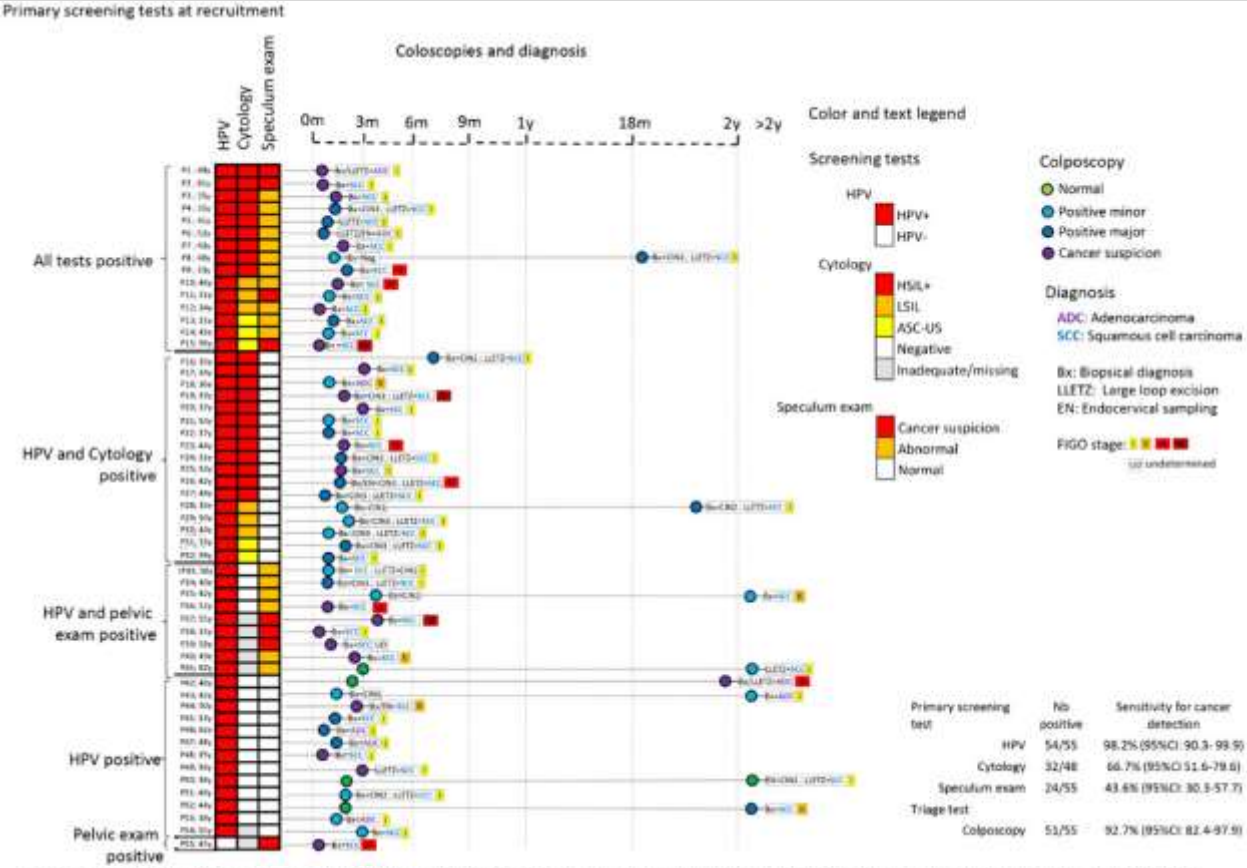

Figure 1. *Visualization of the 55 screen-detected cancers in ESTAMPA.* Results of the primary screening tests (HPV, cytology and speculum exam*), colposcopic and diagnostic assessments for the cancer cases detected in the ESTAMPA study (each represented as a row). Initial colposcopies undergone, generally, within 3 months after recruitment for all participants and follow-up colposcopies, when adequate, 18 months after (timeline truncated at 2 years). Participants ordered by the combined positivity of the primary screening tests. Histological diagnosis (Negative, CIN1, CIN2, CIN3 or Cancer, distinguishing between ADC and SCC) specifying the type of histological assessment (biopsy, LLETZ or endocervical sampling) and FIGO stage (from I to IV; one case undetermined) shown. Sensitivity for cancer detection of primary screening tests and initial colposcopy with 95%CI shown.
*Speculum exam consisted of a visualization of the cervix with a speculum without palpation classifying the findings as normal vs abnormal. Abnormalities included warts, vaginal discharge, polyps, suspicion of cancer or other abnormalities. Three categories depicted in the Figure, specifically distinguishing among cancer suspicion (red) from all other abnormalities (orange) and normal speculum exam (white) .

O088 / #1259

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 2
04-20-2023 10:30 AM - 12:00 PM

MANAGEMENT OF HPV-POSITIVE WOMEN IN MALAYSIA: AN EVALUATION OF TRIAGE STRATEGIES FOR COLPOSCOPY REFERRAL

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Introduction: As Malaysia phases in HPV-based screening, it is critical to evaluate the management pathway for women who are screened positive. This study aims to evaluate the performance of the current triage strategy (combined HPV16/18 genotyping and cytology) and explore alternative triage options for the detection of high-grade precancers among HPV-positive women.

Methods: Malaysian women aged 30-65 years old who were screened positive for primary HPV testing and attended to colposcopy clinic, University Malaya Medical Centre from July 2018 to June 2022 were recruited. Liquid based cytology (LBC) and biopsy samples were collected under colposcopic guidance. A repeat HPV testing was performed using an aliquot of LBC. Immediate CIN2+ and CIN3+ risks were estimated and the triage strategies for colposcopy referral were evaluated using sensitivity, number of colposcopy needed to detect 1 CIN2+/CIN3+ case and referral rate.

Results: This study recruited 477 eligible HPV-positive women but 45 of them were excluded due to invalid test outcomes. The median days to follow up was 49 days (IQR: 33 – 71). Using 20% CIN2+ risk threshold, all HPV16/18 positive women and non-HPV16/18 positive women with LBC ASCUS+ (current strategy) would be referred to colposcopy (Figure 1A). It reduced the referral rate to 42.6% compared to absence of triage but would miss 20% of CIN2+ cases (sensitivity: 79.5%, CI: 68.4 – 88.0). Compared to the current strategy, triage using HPV16/18 genotyping and repeat HPV testing at 4% CIN3+ risk threshold (Figure 1B) had a higher sensitivity (91.8%, CI: 83.0 − 96.9) but resulted in 1 additional colposcopy needed to detect 1 case of
CIN3+.

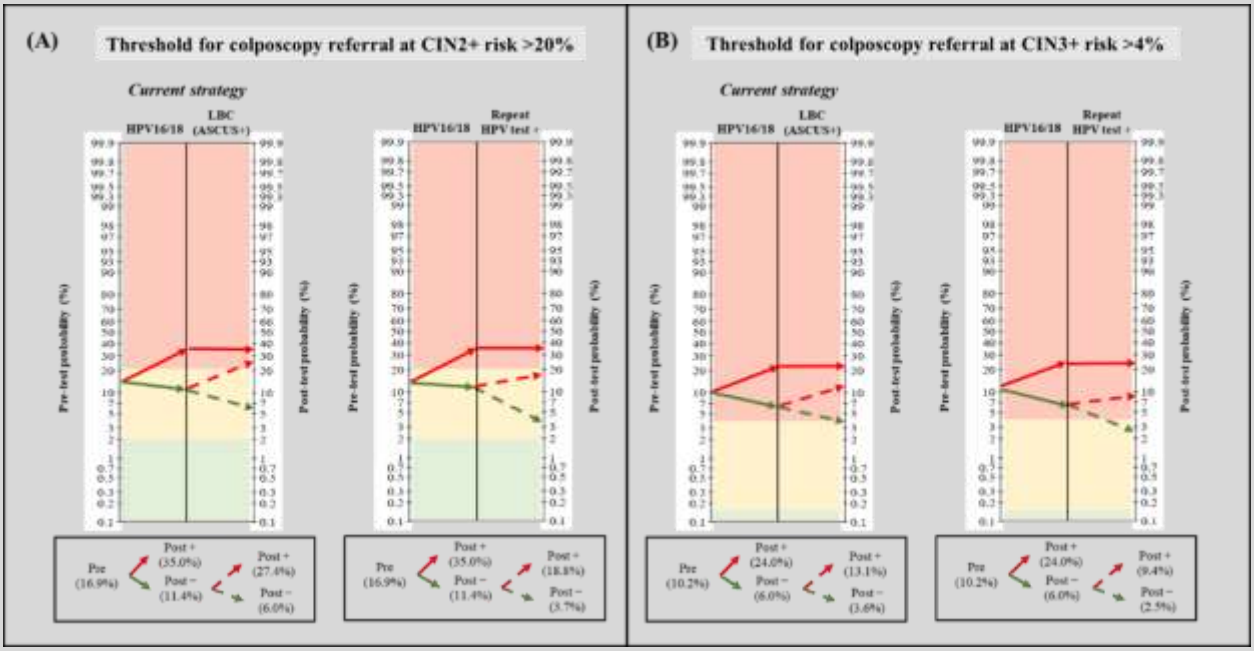

Figure 1. Pre-test-post-test probability plot associated with two triage strategies using 20% CIN2+ risk (A) and 4% CIN3+ risk (B) as the threshold for colposcopy referral.

Conclusions: The current strategy is 80% sensitive in detecting high-grade precancers. Repeat HPV-testing can be a potential triage strategy among non-HPV16/18 positive women.

O089 / #1420

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 2
04-20-2023 10:30 AM - 12:00 PM

LONG-TERM RISKS OF INVASIVE CERVICAL CANCER FOLLOWING HPV INFECTION: FOLLOW-UP OF TWO SCREENING COHORTS IN MANCHESTER

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Introduction: The rarity of invasive cervical cancer (ICC) means that most studies are not large enough to study cancer as an outcome and are obliged to report CIN2+ or CIN3+ as a surrogate. Long-term follow-up of large cohorts are therefore valuable for completing our understanding of risks following HPV infection.

Methods: Approximately 72,000 women were recruited to one of two large research studies when attending routine cervical screening in Greater Manchester, UK: 1987-93 for the Manchester Cohort (MC) and 2001-03 for the ARTISTIC Trial Cohort (AC). All women in the AC were tested for HPV using Hybrid Capture 2 and a random sample of stored samples taken from the MC were tested using HPV L1 MY09/MY11 consensus primers. Both cohorts were followed through national registration for cancer incidence and mortality to 2020.

Results: In 30 years of follow-up in the MC, 1152 women were diagnosed with CIN3 and 144 with ICC. A further 427 CIN3s and 32 ICC were diagnosed over the 17 years of follow-up of the AC. Risk patterns following HPV infection differed for CIN3 and ICC. Risk of ICC in the MC rises for 30 years following a single positive HPV test, reaching 2.4% (95%CI:1.3%-4.4%). A similar pattern was seen in the AC, but the risks of cancer were approximately halved. CIN3 was diagnosed much sooner in the AC due to more efficient cytology. More sensitive HPV testing was able to better predict future risk.

Conclusions: The sensitivity of HPV testing and cytology influence the CIN3 detection rate. Sensitive HPV testing enables effective risk stratification. Increased risk of ICC is observed 15-30 years after HPV infection. Women testing HPV+ should be followed until their infection clears. Discharging women from screening programmes whilst they remain HPV+ may not be safe, even if cytology and colposcopy tests are normal.

O090 / #1034

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 2
04-20-2023 10:30 AM - 12:00 PM

HUMAN PAPILLOMAVIRUS TESTING IN CERVICAL CANCER PREVENTION IN THE JUJUY DEMONSTRATION PROJECT IN ARGENTINA: EVALUATION OF THE SECOND ROUND OF SCREENING

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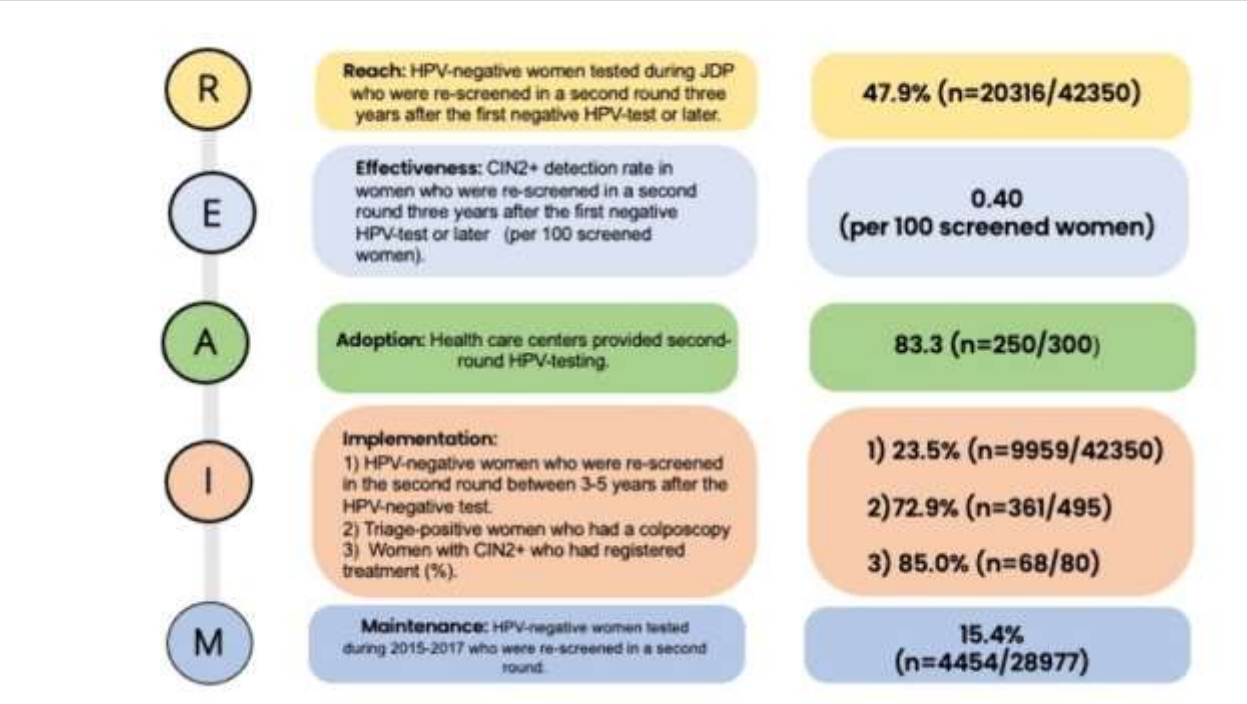
Introduction: In Argentina, HPV-testing was introduced in 2012-2014 through the Jujuy Demonstration Project (JDP) for women aged 30+. HPV-negative women were recommended re-screening in three years. In 2015 the screening protocol changed, and HPV-negative women were recommended re-screening in five years. Conventional cytology was used as triage. We evaluated implementation of the second round of screening in the JDP. We report preliminary results.

Methods: Retrospective cohort study. From the National Screening Information System (SITAM), we obtained data for all HPV-negative women tested in Jujuy from January 1, 2012 until December 31, 2014 (follow-up period January 2015-December 2021). We used the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework to evaluate implementation

Results: Of 42,350 previously HPV-negative women, 47.9% were re-screened in a second round (76.1% with clinician-collected tests and 23.9% with self-collected tests) three years after the first negative HPV-test or later (Average=5.4 years, range: 2.6-8.7). The HPV-test was HC2. Re-screening was opportunistic. 9959 (23.5%) of re-screened women were HPV-tested between 3-5 years after the first HPV-negative test. 83.3% of health centers provided second-round HPV-testing. Of the clinician-collected tests, 1884 were HPV-positive (8.8%), of which 395 (29.3%) were positive at cytology triage. Of the self-collected tests, 535 were HPV-positive (11.1%), of which 423 (79.1%) had triage Paps. 100 (24%) of self-collected tests were positive at cytology triage. 72.9% of the HPV-positive/abnormal Pap women had colposcopy. There were 80 CIN2+ (65 among clinician-collected tests; 15 among self-collected tests). CIN2+ detection was 0.40%. 85% of women with CIN2+ were treated. Re-screening of HPV-negative women first tested during 2015-2017 was

15.4%.



Conclusions: Re-screening of HPV-negative women at 3-5 years was relatively low, with most women being re-screened after 5 years. Adherence to follow-up was adequate, and most women received treatment. As CIN2+ detection was relatively high, strategies to increase women participation in second round should be implemented.

O091 / #1394

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 2
04-20-2023 10:30 AM - 12:00 PM

AGE TRENDS IN APPEARANCE OF MULTIPLE HPV INFECTIONS: IMPLICATIONS FOR DURABILITY OF CELLULAR IMMUNE PROTECTION

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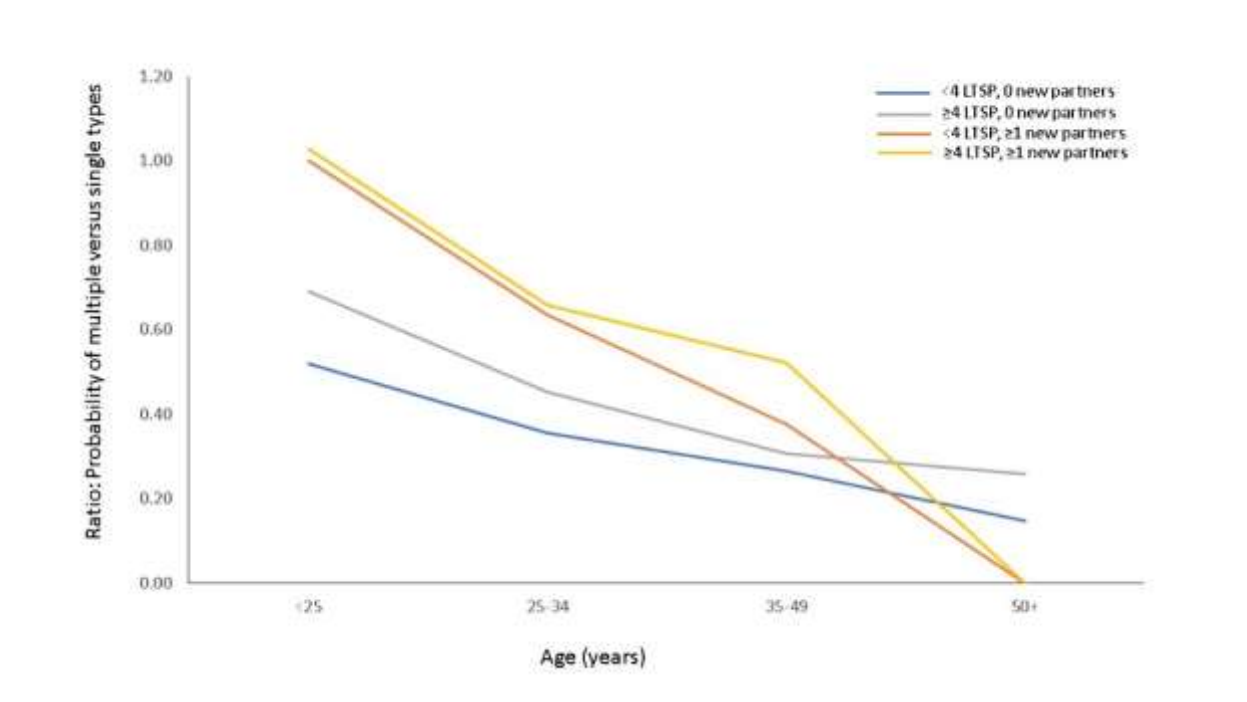
Introduction: In most high-resource populations in the Americas and Europe, HPV prevalence peaks shortly after sexual initiation and declines with age, with a moderate rebound around menopause often attributed to immune senescence. We hypothesized that, if viral latency is common, a general decline in cell-mediated immunity (CMI) around menopause would lead to increased appearance of multiple HPV types acquired cumulatively in prior years.

Methods: Using longitudinal data from the Guanacaste Natural History Study and the ASCUS-LSIL Triage Study, we identified women who were HPV-negative for all types at an index visit and tested HPV-positive for one or more HPV types at the subsequent visit (i.e., appearance). We grouped women based on age at appearance (<25; 25-34; 35-49; and ≥50 years) and number of HPV infections concurrently detected (1, 2, 3, ≥4 types). We calculated the ratio of multiple versus single types. We also calculated ratios after stratifying by recent and new sex partners, and lifetime sex partners (LTSP).

Results: The analytic population included 2146 women with at least one newly appearing HPV infection. Given new HPV appearance, the ratio of multiple versus single types was highest in the youngest age group and declined with age, contrary to the immune senescence hypothesis. This age-related decline held regardless of number of recent partners and LTSP, although multiple concurrently appearing infections were slightly more common among those with new partners and those with ≥4 LTSP at all ages (too few infections among women with new partners at ≥50 years to

assess).



Conclusions: The ratio of newly appearing HPV infections that are detected concurrently with multiple types declines with age, regardless of past and recent sexual behavior. Epidemiologic evidence did not support our hypothesis that general CMI senescence leads to increased appearance of multiple infections, or increased detectability of 'latent' infections, with age.

O092 / #1402

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 2
04-20-2023 10:30 AM - 12:00 PM

A TWO-YEAR COMMUNITY-BASED FOLLOW UP STUDY OF HPV INFECTION IN ETHIOPIA: MOLECULAR EPIDEMIOLOGY, GENOTYPING, PERSISTENCE, CLEARANCE, AND RE-INFECTION RATES AMONG RURAL WOMEN

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Introduction: In Ethiopia, cervical cancer is the second leading cause of morbidity and mortality from all cancers in women. We determined the population-based prevalence of HPV infection and genotype distribution, their persistence and clearance rates within 2 years of follow up.

Methods: A total of 893 rural women aged 30-49 years in Butajira, south-central Ethiopia were tested at baseline using self-sampling device (Evalyn Brush®, Rovers, Oss, The Netherlands). HPV testing was done using multiplexed genotyping (MPG) by BSGP5+/6+ PCR with Luminex read out. All the hr-HPV positive women at baseline were invited for follow-up testing at 6 and 24 months. Cervical examination using VIA, cytology, and colposcopy (if indicated) was done during the follow up visits.

Results: HPV positivity rate at baseline testing was 23.2%. Of these 20.5% and 10.3% women were hr- and lr- HPV positive, respectively. Age-specific hr-HPV infection peaked in the age-group 30-34 years old (58.6%) and decreased in 35-39, 40-44, and 45-49 years to 20.4%, 4.5% and 3.8% respectively. The top five prevalent hr-HPV genotypes were HPV16 (57.1%), 35 (20.3%), 52 (15.8%), 31 (14.1%), and 45 (9.6%) in the Butajira district. The loss to follow-ups were 47 (30%) at the 6 months and 63 (40.1 %) at the 24 months. hr-HPV infection clearance was observed in 70 women (73.7%) within 6 months and among 77 women (84.6%) within 2 years. HPV68, 82, 53, 52, 56 were the most persisted genotypes with 100%, 75%, 42.9%, 31%, and 25% persistence rates respectively after 24 months.

Conclusions: This study provided new data on the overall prevalence of HPV infection and distribution of specific HPV types in rural Ethiopia. Most of the hr-HPV infections among rural Ethiopian women were cleared within 2 years.

O093 / #912

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 2
04-20-2023 10:30 AM - 12:00 PM

EXPEDITING ELIMINATION IN ABORIGINAL AND TORRES STRAIT ISLANDER WOMEN: THE IMPACT OF SCALING UP PREVENTION MEASURES

Megan Smith[1], James Killen[1], Lisa Whop[2], Xavier O'Farrell[1], Diep Nguyen[1], Gail Garvey[3], Lisa Jamieson[4], Karen Canfell[1]
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Introduction: Australia is predicted to achieve cervical cancer elimination (<4 new cases per 100,000 women) at the national level within the next decade, but we have previously estimated this will take 20-25 years longer in Aboriginal and Torres Strait Islander women (hereafter respectfully referred to as Indigenous). Cervical cancer incidence among Indigenous women is around twice the national rate, driven by longstanding inequity in screening coverage. A policy change enabling universal access to self-sampling in Australia could increase screening participation. We aimed to predict if increased screening coverage and/ or vaccination uptake could expedite elimination of cervical cancer among Indigenous women.

Methods: We used an existing dynamic model of HPV transmission and vaccination and linked model of cervical screening and cancer in Australia (Policy1-Cervix) that has been adapted to reflect data on Indigenous women for HPV vaccination and screening coverage, and disease outcomes. We modelled a scenario that increased HPV vaccination from current levels (83%) to 90%, and several scenarios for screening improvements, including increased: i) uptake (ie reduce never-screened); ii) timeliness (reduce under-screening); and iii) attendance for follow-up tests in Indigenous women. The timing of cervical cancer elimination was estimated for each of these scenarios and compared with a scenario where coverage does not change.

Results: Improving vaccination coverage brought forward elimination in Indigenous women by one year (from 2049 to 2048). Increasing screening uptake, on-time attendance, and attendance for follow-up tests to all be consistent with national rates would expedite elimination of cervical cancer in Indigenous women by about eight years (to 2041). Improving screening uptake had the largest impact (three years, compared to two for follow-up attendance and two for routine screening timeliness) on reaching elimination.

Conclusions: Urgent action is required to close the gap in screening to ensure Indigenous women are not left behind in the goal to achieve elimination.

O094 / #1826

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 2
04-20-2023 10:30 AM - 12:00 PM

HPV TESTING FROM LIQUID-BASED CYTOLOGY: A REAL-WORLD EVIDENCE STUDY FOR A NEW HPV DEVICE INDICATION

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Introduction: The Food and Drug Administration supports innovations to facilitate new indications for high-risk human papillomavirus (HPV) testing. A new indication for Onclarity using PreservCyt liquid-based cytology (LBC) was evaluated.

Methods: The New Mexico HPV Pap Registry, a state-wide surveillance program was used to select an age- and cytology-stratified random sample of 19,879 women, ages 21-65 years, undergoing opportunistic cervical screening and follow-up in routine clinical practice. A subset of existing PreservCyt-based cervical specimens from these women (n=4,674) was utilized for comparison between Onclarity and cobas HPV assays. Point estimate differences and ratios were calculated for cervical disease detection and sensitivity, respectively, with 95% confidence intervals (95% CI). The cumulative risk of ≥CIN2 or ≥CIN3, with up to five -years of follow-up, was estimated for Onclarity by Kaplan-Meier.

Results: Negative HPV results (by either Onclarity or cobas) provided much lower CIN3+ risks (0.15%) than NILM cytology overall (0.44%), offering greater safety (Figure 1). Five-year cumulative ≥CIN3 detection was 5.55% and 4.59% for positive Onclarity and cobas, respectively (estimate difference=0.96% [0.47% to 1.51%]). Sensitivity for ≥CIN3 detected within <1 year for Onclarity and cobas was 95.3% and 94.5%, respectively (estimate ratio=1.01 [.98 to 1.06]) and sensitivity for Onclarity and cobas was also similar for ≥CIN3 detected up to five years. For ≥CIN3, positive agreement between Onclarity and cobas for HPV16 and HPV18, respectively, was 100% (95%CI=95.0% to 100%) and 90.9% (95%CI=62.3% to 98.4%). HPV16 carried the highest ≥CIN2/3 risk, followed by HPV18/31/33/58/52/45, and then

HPV35/56/59/51/56/59/66.

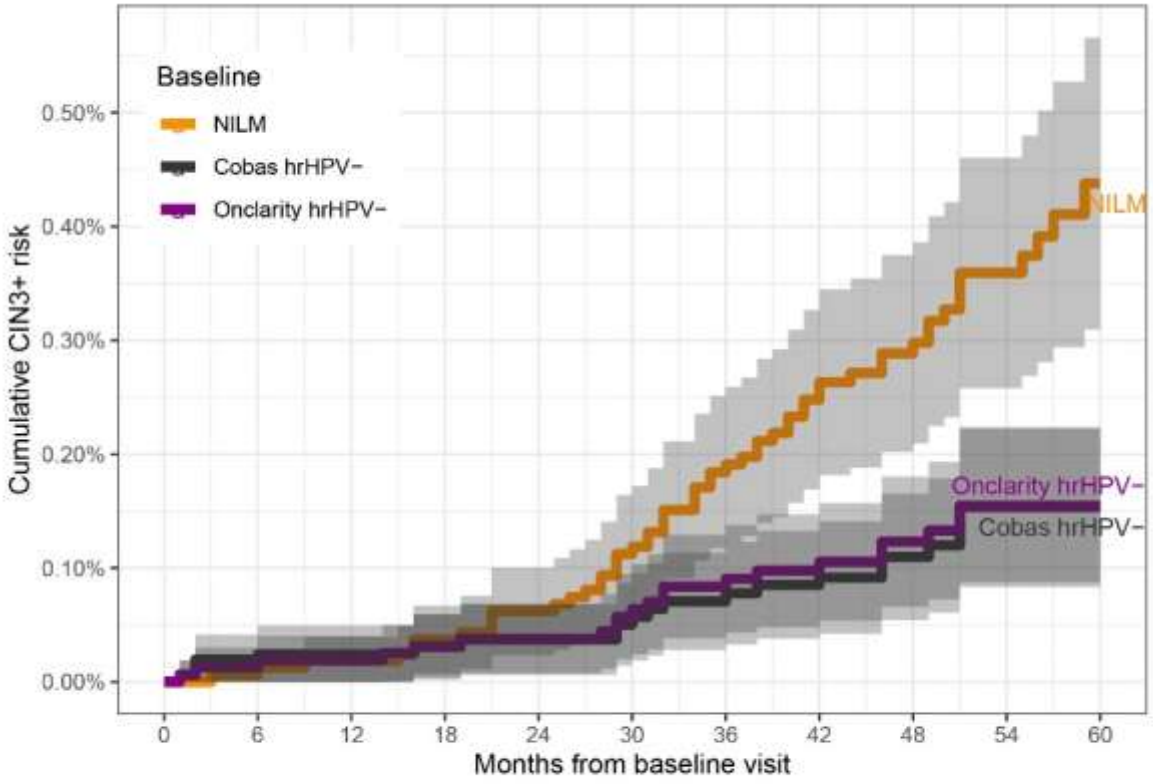

Figure 1. CIN3+ cumulative risk in screening population age 25 and above for Onclarity and cobas HPV-negative individuals at baseline

Conclusions: Onclarity and cobas show equivalent performance using PreservCyt LBC media, and Onclarity genotyping provides effective ≥CIN2 and ≥CIN3 risk stratification. This real-world evidence study involved a unique, population-based design and a rapid, cost-effective approach to support a new HPV-device indication that would offer many additional healthcare providers in the United States a risk-based approach for management through extended genotyping.

O095 / #1108

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON METHYLATION
04-20-2023 10:30 AM - 12:00 PM

TRIAGE PERFORMANCE OF HUMAN GENE EPB41L3 AND HPV 16/18 VIRAL DNA METHYLATION AMONG HRHPV POSITIVE WOMEN: A COHORT STUDY

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Introduction: Methylation-based biomarkers show promise in triaging hrHPV positive women, however, more evidence from population-based prospective studies is required to confirm its utility in real-world settings.

Methods: 2000 women from Xinjiang, China were screened for cervical cancer in 2018 and annually followed-up until 2020. Swab samples of baseline hrHPV positive women were used to perform a methylation test targeting the host gene EPB41L3 and HPV16/18 DNA L1/L2 regions. Triage accuracy and predictive values of the methylation test were evaluated in comparison with HPV16/18 and cytology triage using cross-sectional and 24-months outcomes.

Results: Overall methylation positivity was 12.4% among hrHPV-positive women, and test positivity increased by histology lesions (7.7% in normal, 9.1% in CIN1, 62.5% in CIN2, 75.0% in CIN3 and 100% in cancer cases, p_{trend} <0.05). Women being methylation positive at baseline had a significantly higher risk of hrHPV persistence at 12-month and 24-month follow-up (RR_{12M}=1.9, 95%CI: 1.4-2.5 and RR_{24M}=1.7, 95%CI: 1.1-2.5). The specificity of methylation (92.1%) was substantially higher than either HPV16/18 (78.7%, p<0.001) and cytology (79.2%, p <0.001). For CIN2+, the cross-sectional triage sensitivity of methylation appeared slightly higher than HPV16/18 but less than cytology triage with values of 70.6%, 64.7%, and 94.1% respectively (p_{exact}=1.000, and p_{exact}=0.213 respectively) .The longitudinal sensitivity of methylation over 24-month follow-up was 56.0%, as compared to 64.0% (p_{exact}=0.688) for HPV16/18 and 76.0%, (p_{exact}=0.125) for cytology. Methylation test showed high positive predictive values for CIN2+ (41.4% at baseline and 50.0% at 24-month follow-up), while the CIN2+ risk of methylation negative women remained considerable (2.5% at baseline and 6.9% at 24-month follow-up).

Conclusions: Methylation could improve triage specificity and colposcopy efficiency, and predict elevated risk of hrHPV persistence and CIN2+ during 24-month follow-up, suggesting DNA methylation could be a useful triage tool for hrHPV positive women. Women negative by either methylation, HPV16/18 or cytology would still require careful follow-up.

O096 / #542

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON METHYLATION
04-20-2023 10:30 AM - 12:00 PM

A NATIONAL QUALITY ASSURANCE PROGRAM BASED ON RE-ANALYSIS OF "HPV NEGATIVE" HSIL+

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Introduction: High quality HPV screening should have a low risk of false HPV negativity. Detecting HSILs and invasive cervical cancer adequately is essential as any deficit will directly translate to an inadequate cancer prevention of the screening program. The Swedish National HPV Reference Laboratory (NRL) offers re-testing of all CIN2+/HSIL cases that have previously been classified as "HPV negative" by HPV laboratories throughout the country.

Methods: Specimens (LBC, FFPE, self-sampling material) from women with HSIL/CIN2+, that had been tested as HPV negative by routine HPV laboratories throughout Sweden were sent to the NRL for further investigation. After nucleic acids extraction (MagNA Pure LC Total Nucleic Acid Isolation Kit for LBC/self-sampling samples and Qiagen kit, DNeasy Blood & Tissue Kits for FFPE specimens), beta-globin detection tested specimen adequacy. Extracted material was then genotyped using MGP primers and Luminex with 37 different HPV types included. Specimens where HPV negativity was still found, were thereafter subjected to unbiased whole genome RNA sequencing, using the SMARTer® Stranded Total RNA-Seq Kit and the NextSeq 500 system (Illumina, USA).

Results: Since February 2019, the NRL has received 81 "apparently HPV negative" CIN2+ specimens belonging to 47 women. Luminex detected HPV in 46/81 (56.8%) specimens, with HPV 16 (n=11), HPV 18 and HPV82 (n=5 for each of the genotypes) being the most common types detected. Unbiased RNA Sequencing detected HPV in further 6/30 samples, with types 18, 26, 30, 33, 56, 58 and 82 being found. A total of 24/81 samples were still HPV negative even after the whole transcriptome sequencing.

Conclusions: A standard protocol for re-analysis of "HPV-negative" enables ensuring adequate performance of HPV testing services. The results of the re-analyses are used for continuous quality improvement work, aiming to have an increasingly higher probability of finding the HSIL+ cases in the screening.

O097 / #543

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON METHYLATION
04-20-2023 10:30 AM - 12:00 PM

UTILITY OF DNA METHYLATION FOR RISK-STRATIFICATION OF WOMEN AGED ≥45 REFERRED FOR COLPOSCOPY

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Introduction: The performance of colposcopy is often impaired in older women because the transformation zone (TZ) retracts into the cervical canal, making sampling difficult and increasing risk of underdiagnosis. We recently showed that biopsies missed more than 50% of CIN2+lesions in older women without a fully visible TZ. To reduce the risk of overtreatment without increasing risk of underdiagnosis, there is a need to explore the use of biomarkers for risk-stratification. Host-cell DNA methylation has been shown to be useful for triage of HPV screen-positive women. Yet, the use of DNA-methylation for risk-stratification of older women at colposcopy is unknown. This study evaluated the clinical utility of host-cell DNA-methylation markers for risk-stratification of older women at colposcopy.

Methods: We conducted a cross-sectional study during 2019-2021. Eligible women were ≥45 years, referred for colposcopy due to an abnormal screening result, and did not have a fully visible TZ. Each woman had a cervical cytology sample and biopsies collected followed by a loop electrosurgical excision procedure (LEEP). Cervical samples were analysed for host-cell methylation using a new panel of methylation markers. We calculated sensitivity and specificity of the methylation markers for CIN2+ detection using the LEEP result as reference standard.

Results: A total of 96 women were included for analysis. Median age was 67.9 years (IQR: 62.8-70.3), and 80.3% were referred based on HPV-screening. Thirty-one (32.2%) had CIN2+ detected, and 61 (63.5%) women tested methylation positive. Sensitivity for the new methylation markers was 83.9% (95% CI: 66.4-94.5%) and specificity was 46.2% (95% CI: 33.7-59.0%).

Conclusions: The two new tested DNA-methylation markers showed promising results for risk-stratification of women aged ≥45 with abnormal cervical cytology. However, due to the lower specificity there was a significant risk of overtreatment. Further research into validated markers is needed.

O098 / #846

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON METHYLATION
04-20-2023 10:30 AM - 12:00 PM

DIAGNOSTIC ACCURACY OF HUMAN AND HUMAN PAPILLOMAVIRUS DNA METHYLATION TESTING IN CERVICAL CANCER: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Introduction: Cervical cancer is the fourth most common malignancy in women worldwide. Current cervical screening programmes use a primary screening test of high-risk HPV (HR-HPV) testing or cytology to identify at risk women. HR-HPV testing has a high sensitivity but low specificity for high-grade CIN and Cancer. As a result, DNA methylation testing has been suggested as a triage test for HR-HPV positive women. As yet, there is no consensus on the most accurate methylation markers for use in screening. We conducted a systematic review and meta-analysis to determine the diagnostic test accuracy of human and HPV DNA methylation markers.

Methods: MEDLINE, EMBASE, and ongoing trial registries were systematically searched from inception to February 2022. DNA methylation diagnostic test accuracy studies using histopathology as a reference standard were included. Sensitivity and specificity data were extracted: a bivariate random-effects model was applied to calculate pooled estimates and corresponding heterogeneity, which was explored in a series of sensitivity analyses.

Results: Twenty-eight studies including 6,956 women were meta-analysed, producing pooled estimates for genes C13ORF18, EPB41L3, FAM19A4, HPV16:L1, JAM3, PAX1, SOX1, and ZNF582. PAX1 was the most accurate marker of CIN2+ with a pooled area under the curve (AUC) of 0.93 (95% confidence interval (CI) 0.90-0.95) and pooled AUC of 0.87 (95%CI 0.84-0.90) for CIN3+. HPV16:L1 was the second-best marker of CIN2+; pooled AUC 0.83 (95%CI 0.80-0.86). JAM3 was the most accurate marker of CIN3+; pooled AUC 0.88 (95%CI 0.85-0.91).

Conclusions: PAX1 methylation testing appears to be the most accurate methylation marker for high-risk CIN and Cancer. Specificity may surpass cytology allowing the potential to triage patients more effectively to colposcopy or conservative management. Our analysis has also elucidated several other genes which show promise for use in methylation marker panels, combined panels may provide greater accuracy than stand-alone methylation markers.

O099 / #1209

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON METHYLATION
04-20-2023 10:30 AM - 12:00 PM

COMBINED HOST AND VIRAL METHYLATION PANEL IN DETECTING HIGH-GRADE CERVICAL LESIONS AMONG HPV-VACCINATED WOMEN

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Introduction: There is a great need to re-design cervical screening programs including triage tests as HPV-vaccinated women are entering the programs. We investigated the ability of a DNA methylation panel to identify high-grade cervical lesions among vaccinees.

Methods: The study comprised 9242 women, who had received three doses of HPV16/18 vaccine at age 12-15 (6958) or 18 (2284) in a community-randomized trial during 2007-2014. In 2014-2018, the vaccine recipients were re-randomized into a trial on (ages 22/25/28) vs. infrequent (age 28) screening. During 16 years of post-vaccination follow-up 39 histopathological confirmed high-grade squamous intraepithelial (HSIL) and 41 low-grade (LSIL) cases were identified. For this study 16 HSIL and 15 LSIL cases identified at the age 25+, and 370 age-matched HPV16/18 vaccinated controls were eligible. Methylation analyses were done with cervical samples obtained at the age of 25. DNA methylation of viral late regions in HPV16/18/31/33 and host gene EBP41L3 was measured with pyrosequencing assay. Cervical HPV genotyping at ages 18/22/25 was generated with Luminex technology.

Results: Persistent HPV types 33/51/52/59 at ages 22 and 25 were found in 8 of 16 HSIL and 3 of 15 LSIL cases. No HPV16/18/31/45 were identified. The mean age of HPV vaccination was among both HSIL and LSIL cases 15 years. A predefined methylation panel of host and viral genes for the detection of HSIL was comparable to ROC AUC against those of pap-cytology or HPV 33/51/52/59 genotyping. Evaluating only viral genes a few samples with HPV33 methylation only was detected.

Conclusions: Current methylation panel provided only slightly better triage than pap-cytology or HPV 33/51/52/59 genotyping for HPV-vaccinated women. The true progression potential of HSIL among HPV-vaccinated women warrants further investigations.

O100 / #512

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON METHYLATION
04-20-2023 10:30 AM - 12:00 PM

TEMPORAL COMPOSITION OF THE CERVICOVAGINAL MICROBIOME CORRELATES WITH HRHPV INFECTION OUTCOMES: A LONGITUDINAL COHORT STUDY

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Introduction: Persistent infections with high-risk human papillomavirus (hrHPV) can cause cervical squamous intraepithelial lesions (SIL) that may progress to cancer. The cervicovaginal microbiome (CVM) composition correlates with SIL development, but the dynamics of the CVM after hrHPV infections have not been fully clarified.

Methods: To determine the association between CVM composition and infection outcome, we performed high-resolution microbiome profiling on a longitudinal cohort of cervical smears obtained from 192 hrHPV DNA-positive women with normal cytology at first visit and of whom 74 were diagnosed by cytology with SIL six-months later.

Results: Here we show that women with Lactobacillus-dominated microbiomes have more stable microbial communities and associate with protection against SIL development at both visits, while women with community state type (CST) IV-A at first visit, characterized by high diversity and low Lactobacillus abundance, have a higher risk of developing SIL at second visit. Analyses at the species-level demonstrate that increased abundance of Gardnerella vaginalis and Atopobium vaginae in the microbiome correlate with adverse infection outcomes.

Conclusions: In conclusion, our results suggest that the CVM can be used as a predictive biomarker for cervical disease and SIL development after hrHPV infections.

O101 / #364

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON METHYLATION
04-20-2023 10:30 AM - 12:00 PM

THE ROLE OF PAX1 METHYLATION IN PREDICTING EARLY-STAGE CERVICAL CANCER AFTER COLD KNIFE CONIZATION

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Introduction: Colposcopy biopsy has some limitations in the diagnosis of early invasive cancer. Unexpected early-stage cervical cancer is sometimes incidentally found after cold knife conization (CKC), but no adequate method has been reported to predict pathological upgrade after CKC. In this study, we explored the ability of $PAX1^m$ to predict pathological upgraded to early-stage cervical cancer after cervical conization.

Methods: A total of 251 women biopsy confirmed CIN2+ from December 2020 to September 2021 were enrolled in the study, The methylation levels of PAX1 ($PAX1^m$) were determined by quantitative methylation-specific polymerase chain reaction (qMSP). Receiver operating characteristic curve was used to identify the optimal cut-off value of $PAX1^m$ for predicting pathological upgrade of disease.

Results: $PAX1^m$ increased with the severity of the cervical lesion with CIN2(9.5%), CIN3(38.9%), AIS (23.0%) and early-stage cervical cancer (87.0%). PAX1 methylation had more higher absolute risk (90.2%;95%CI:81.7-95.7%) than cytology of LSIL+ (70.3%;95%CI: 60.9-78.6%) and HPV16/18+ (78.3%;95%CI: 69.9-85.3%) in predicting CIN3+.The optimal $\triangle Cp$ cutoff value in predicting pathological early-stage cervical cancer after CKC was 7.1 and the area under the curve (AUC) was 0.88 (95% CI: 0.84–0.95, $P<0.001$). The adjusted odds ratio (OR) of $PAX1^m$ with $\triangle Cp \leq 7.1$ was significantly higher (OR24.9, 95% CI 7.6-81.2) than cytology of LSIL+ (OR3.5, 95% CI 1.1-11.2)and HPV16/18 (OR2.3, 95% CI 0.7-7.2) in predicting early-stage cervical cancer.

Conclusions: When of PAX1 methylation $\triangle Cp$ level is less than 7.1, it is highly suggestive of the possibility of pathologic upgrading to early-stage cervical cancer.

O102 / #1712

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON METHYLATION
04-20-2023 10:30 AM - 12:00 PM

INNOVAX BIVALENT HPV VACCINE: SAFETY AND IMMUNOGENICITY OF ONE- AND TWO-DOSE OF CECOLIN® VERSUS GARDASIL® IN GIRLS 9-14 YEARS - PHASE III INTERIM DATA

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Introduction: WHO recently revised HPV vaccination recommendations to include the use of a single- or two-dose schedule in girls and boys aged 9–20 years and advised generating data on efficacy or immunobridging for single-dose regimen. The ongoing Phase 3 trial of Innovax bivalent vaccine (Cecolin®) assesses alternative dosing schedules, generates immunogenicity data in low- and middle-income countries and following single dose versus Gardasil® in girls 9-14 years. Data from an interim analysis at Month 7 are presented.

Methods: 1025 girls in Bangladesh and Ghana were randomized to receive either 2 doses of Cecolin® at 6-, 12- or 24-months interval, one dose of Gardasil® followed by one dose of Cecolin® at Month 24, or 2 doses of Gardasil® at 6 months interval (referent). Serology, measured by VLP-ELISA and pseudovirion neutralization (subset), is assessed at baseline, prior to and one month following dose 2, and at Month 24 for study groups on a 6-month schedule. Primary objectives include immunological non-inferiority of the Cecolin® schedules to referent with a pre-defined margin for the GMT ratio. Safety endpoints include reactogenicity and unsolicited adverse events for 7 and 30 days post-vaccination, respectively as well as serious adverse events throughout the study period.

Results: Interim analyses included data from 205 participants per group. One month after Dose 2, 100% of participants were seropositive by binding (primary) assay for both antigens and non-inferiority of Cecolin® to Gardasil® on a 6-month schedule was demonstrated. Six months following a single dose, GMCs tended to be higher after Cecolin® administration (Table 1). Reactogenicity and safety were comparable between vaccines (Table
2).

Table 1 Immunogenicity of Cecolin® and Gardasil® on 0, 6-month schedule (PP)

	Cecolin®		Gardasil®		Non-Inferiority assessment*
ELISA	SCR (n/N)	GMC IU/ml (95% CI)	SCR (n/N)	GMC IU/ml (95% CI)	GMC ratio (Cecolin® / Gardasil®)
Month 7					
HPV-16	100% (198/198)	1567 (1390; 1767)	100% (195/195)	1444 (1287; 1621)	1.09 (0.89; 1.33)
HPV-18	100% (200/200)	424 (375; 480)	100% (198/198)	336 (296; 381)	1.25 (1.02; 1.54)
Month 6					N/A
HPV-16	98.5% (195/198)	18.2 (16.3; 20.4)	96.9% (190/196)	12.0 (10.8; 13.3)	
HPV-18	95% (190/200)	6.8 (6.1; 7.5)	82.4% (164/199)	4.2 (3.8; 4.7)	

* NI margin: lower bound of the 98.3% CI for the GMT ratio being > 0.5; formal statistics were performed only for the primary objective (ELISA GMT ratios one month post Dose 2); N/A: not applicable
SCR: Seroconversion rate; GMCs: Geometric Mean Concentrations; CI: Confidence Interval
Month 6: 6 months post Dose 1 and pre-dose 2; Month 7: one month post Dose 2
n: number of subjects having seroconverted; N: number of subjects in PP; PP: Per protocol population

Table 2 Safety of Cecolin® and Gardasil® on 0, 6-month schedule (TVC)

	Cecolin® N=205		Gardasil® N=205	
Safety endpoints	Number of subjects	% (95% CI)	Number of subjects	% (95% CI)
Any local reaction (solicited/ 7 days)	131	64 (57; 70)	138	67 (60; 74)
Any systemic reaction (solicited/ 7 days)	72	35 (29; 42)	76	37 (30; 44)
Any non-serious adverse event (unsolicited/ 30 days)	43	21 (16; 27)	52	25 (20; 32)
Any serious adverse event (unsolicited/ 30 days)	1	0.5 (0; 2.7)	0	
Any serious adverse event (unsolicited/ 7 months)	1	0.5 (0; 2.7)	1	0.5 (0; 2.7)
Any related serious adverse event (unsolicited/ 7 months)	0		0	
Any adverse event leading to withdrawal	0	0	0	

TVC: Total Vaccinated Cohort; CI: Confidence Interval

Conclusions: Cecolin® in a 0,6-month schedule elicits robust immunogenicity after 1 and 2 doses. Compared to Gardasil®, immunogenicity of a single dose was comparable up to 6 months, and non-inferior after two doses. Both vaccines were safe and well tolerated.

O103 / #1674

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON METHYLATION
04-20-2023 10:30 AM - 12:00 PM

METHYLATION ANALYSIS ON ANAL SWABS FOR SIMPLIFIED ANAL CANCER SCREENING

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Introduction: Screening for anal cancer in HIV+ men who have sex with men (HIV+MSM) is hampered by limited capacity and expertise of high resolution anoscopy (HRA), as well as costs and patient burden. Hence, there is an urgent clinical need for a minimally-invasive screening test on anal swabs. We previously showed that testing for DNA methylation markers on anal biopsies can accurately detect high-grade AIN at risk of progression to cancer (i.e. advanced HGAIN). Here, we examined the feasibility of methylation testing on anal swabs and performed genome-wide methylation profiling on anal swabs to identify most discriminatory markers.

Methods: Paired anal swabs and biopsies of 223 HIV+MSM undergoing anal cancer screening and 20 anal cancers were tested for 6 methylation markers, hrHPV and cytology (swabs only). Area's under the curve (AUCs) were determined using logistic regression analysis. Cases were defined as advanced HGAIN (i.e., methylation positive HGAIN). Genome wide methylation profiling was performed on anal swabs of 40 HIV+MSM diagnosed with AIN3 and 39 controls (<AIN1), using 850K Infinium MethylationEPIC BeadChip (Illumina).

Results: Methylation levels of all markers were significantly higher in cancer swabs as compared to controls and also increased in swabs of advanced HGAIN. Marker ZNF582 performed best for advanced HGAIN detection (AUC=0.68) and combined with hrHPV and cytology an AUC of 0.81 was obtained. Genome wide methylation profiling yielded a series of new markers which on the Infinium arrays reached an AUC of 0.8 for advanced HGAIN.

Conclusions: Testing for DNA methylation markers on anal swabs is feasible. Methylation levels increase with severity of underlying lesions and are extremely high in swabs of anal cancer patients. Present data indicate that methylation testing on anal swabs either or not combined with hrHPV and cytology may provide a valuable alternative to HRA for anal cancer screening in HIV+MSM.

O104 / #1342

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - II
04-20-2023 10:30 AM - 12:00 PM

VIRAL REPLICATION ACTIVATES THE DNA DAMAGE RESPONSE DURING THE HPV16 LIFE CYCLE

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Introduction: During the HPV16 lifecycle, the DNA damage response (DDR) is activated promoting recruitment of DDR factors to the viral genome. Overexpression studies demonstrate that viral oncoprotein E7 can induce the DDR, and it is proposed this is required during the viral lifecycle to enable viral DNA replication. However, viral replication also has the potential to activate the DDR. We utilize wild type and mutant HPV16 genomes to demonstrate that, rather than E7, it is viral replication that activates the DDR.

Methods: We generated human foreskin keratinocytes expressing the viral oncoproteins (E6E7), and isogenic lines which contain episomal HPV16 genomes (HPV16WT) and mutant genomes where we have introduced a stop codon into the E6 and/or E7 genes ($HPV16^{-E6}$, $HPV16^{-E7}$, $HPV16^{-E6E7}$). Using these keratinocytes, alongside relevant cancer cell lines, we investigate activation of the DDR in response to viral replication factors and oncogene expression.

Results: Isogenic foreskin keratinocytes immortalized by the entire HPV16 genome, or via E6/E7 oncogene expression, demonstrate full activation of the DDR only in the HPV16 full genome lines. In hTERT immortalized keratinocytes, we observe an indistinguishable DDR induced in cells replicating WT HPV16 or mutant genomes. In HFK cells immortalized by HPV16, integration of the viral genome retains expression of E7 but not activation of the DDR; corresponding isogenic lines with episomal genomes express equivalent levels of E7 and have a strong activation of the DDR. We propose that the role of E6/E7 is not to activate the DDR, but to manage the host replication stress induced by the DDR activated by viral replication.

Conclusions: The DDR is activated by viral replication during the HPV16 life cycle. This is important as activation of the DDR induces replication stress in infected cells, which can be oncogenic, therefore viral replication per se is a novel HPV oncogenic process.

O105 / #536

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - II
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HIGH APOBEC3B MRNA EXPRESSION IS ASSOCIATED WITH HUMAN PAPILLOMAVIRUS TYPE 18 INFECTION IN CERVICAL CANCER

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Introduction: The APOBEC3 (A3) proteins belong to a family of cytidine deaminases and exhibit the ability to insert mutations in DNA and/or RNA sequences. APOBEC3B (A3B) expression has been associated with increased risk of breast cancer and is also described as an important risk factor for cervical cancer development. Recent reports suggest a possible role of A3B as a DNA mutagen with consistent high expression in several cancer types. Nevertheless, the data concerning A3B influence on HPV infection and cervical cancer seem limited and show discrepancies. The aim of this study was to investigate the role of A3B expression levels on cervical cancer in affected women positive for infection by different HPV types.

Methods: Tumor biopsies from cancerous uterine cervix were collected from 216 women registered at Hospital do Câncer II of Instituto Nacional de Câncer José de Alencar Gomes da Silva (INCA). A3B expression levels were quantified from RNA samples extracted from cervical biopsies using real-time quantitative PCR, and differences in A3B expression levels comparing samples according to infecting HPV type and clinical variables were analyzed.

Results: Median A3B expression levels were higher among $HPV18^+$ samples when compared to $HPV16^+$ counterparts, and were also increased compared to samples positive to other HPV types. In squamous cell carcinoma, $HPV18^+$ samples also showed increased median A3B expression when compared to HPV Alpha-9 species or only to $HPV16^+$ samples.

Conclusions: Our findings suggest that A3B expression is differentially upregulated in human cervical cancer samples infected with HPV18 and indicate that A3B could be potentially used as a biomarker for cervical cancer and HPV infection.

O106 / #991

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - II
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COMPREHENSIVE MUTATIONAL ANALYSIS OF THE HUMAN PAPILLOMAVIRUS TYPE 16 L2 PROTEIN

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Introduction: Human papillomaviruses (HPVs) are non-enveloped viruses that cause approximately 5% of cancers. In addition to the L1 major capsid protein, the viral capsid contains the L2 protein, which plays an essential role in trafficking of viral DNA to the nucleus. During virus entry, a cell-penetrating peptide in the L2 C- terminus mediates penetration of much of the L2 protein through the endosomal membrane into the cytoplasm, allowing essential interactions with retromer and other cytoplasmic cellular proteins that mediate proper trafficking of the virus to the nucleus. The structural basis for L2 action is unknown.

Methods: AlphaFold, a protein structure modeling program, was employed to predict the structure of the L2 protein. To test the structural prediction, we constructed mutant pseudoviruses with small in-frame deletions and HA-tag insertions, and six nested deletions in the predicted unstructured region of HPV16 L2, generated pseudoviruses containing these mutant L2 proteins, and tested their ability to infect HeLa cells.

Results: The AlphaFold predicts that 60% of L2 is unstructured and a L2 C-terminal unstructured region (~100aa) immediately upstream of the retromer binding site and cell-penetrating peptide is present in diverse papillomaviruses, but its sequence is poorly conserved. The predicted C-terminal unstructured region was surprisingly tolerant of in-frame deletion and insertion mutations. The infectivity of the nested deletion mutant pseudoviruses is inversely proportional to the size of deletion. The largest deletion mutants in this segment are defective and accumulated in the endosome with poor interaction with retromer.

Conclusions: There are no required, unique sequence elements or structures in the predicted C-terminal unstructured segment of the L2 protein, but the length of this region appears crucial for HPV trafficking. Our findings provide new insight into the structural basis for the unusual biochemical and cell biological activities of the papillomavirus L2 capsid protein during virus entry.

O107 / #1033

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - II
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THE CELLULAR FAM133B PROTEIN INTERACTS WITH THE VIRAL E2 PROTEIN

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Introduction: The HPV E2 protein is essential for the viral life cycle. Besides its role as a transcriptional modulator, it is also an activator of viral replication and a segregation factor for viral genomes.

Methods: We performed a BioID proximity labelling screen to identify new interaction partners of the E2-proteins of HPV16, 18, 56, 8, 2, and 82. The protein that was most frequently enriched with the different E2 proteins was “Family with Sequence Similarity 133 Member A/B” (Fam133A/B). Since Fam133B is largely uncharacterized and its function within the cell is unknown and FAM133A is not expressed in keratinocytes, we focused on the interaction of Fam133B and E2 and explored its functional consequences.

Results: We confirmed by co-immunoprecipitation that Fam133B interacts with HPV31 and HPV16 E2, but not with the transcriptional repressor E8^E2. This suggests that the interaction is mediated by the N-terminal transactivation domain of E2 which is absent in E8^E2. Immunofluorescence analysis revealed a partial co-localization of overexpressed Fam133B with E2 in the nucleus, which was significantly reduced by the presence of the E1 protein and the viral origin. Knockdown of Fam133B using siRNA revealed a decrease in HPV16 E2 protein levels, which did not occur in the presence of HPV16 E1. Further knockdown and overexpression studies indicated that Fam133B increases the E1/E2 dependent replication of the viral origin. Interestingly, knockdown of Fam133B reduced spliced late viral E4^L1 transcripts in undifferentiated keratinocytes maintaining replicating HPV16 genomes.

Conclusions: Our study identifies Fam113B as a conserved interactor of E2 proteins. This interaction may contribute to the stability of E2 and modulate viral transcription and replication. Ongoing studies will explore the role of Fam133B in the productive replication cycle of HPV16.

O108 / #1064

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - II
04-20-2023 10:30 AM - 12:00 PM

HPV IS A NOVEL CARGO FOR THE COPI SORTING COMPLEX DURING VIRUS ENTRY

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Introduction: During entry, HPV traffics from the cell surface to the endosome and then to the trans-Golgi network (TGN) and Golgi apparatus. HPV must then transit across the TGN/Golgi and exit this compartment to reach the nucleus. The HPV L2 minor capsid protein plays important roles in proper HPV trafficking during virus entry by interacting with multiple cellular factors.

Methods: To identify TGN/Golgi-associated host factors that interact with L2, HeLa cells were infected with wild-type (WT) or R302/5A mutant HPV, which accumulates in the TGN/Golgi. TGN/Golgi-containing fractions of infected cells were collected, immunoprecipitated with antibody recognizing L2, and subjected to the mass-spectrometry. To verify the mass-spectrometry findings, we performed co-immunoprecipitation (co-IP) and peptide pull-down experiments. To investigate the effects of cellular factors on HPV infection, we used siRNA-mediated knockdown (KD) strategies and proximity ligation assay (PLA).

Results: Mass-spectrometry detected peptides of COPI protein sorting complex in the TGN/Golgi-containing fractions derived from cells infected with WT but not from R302/5A mutant HPV. This interaction was confirmed by co-IP and PLA in infected cells and begins at 16 hours post infection. In vitro, the purified L2 fusion protein or a 14-residue peptide from the central region of L2 bound to purified COPI, and R302/5A mutant protein or peptide displayed reduced binding. Knockdown of COPI inhibited HPV infection and caused accumulation of wild-type virus in the TGN/Golgi.

Conclusions: These experiments indicate that HPV L2 directly interacts with the COPI complex during HPV entry. Knockdown experiments demonstrate that COPI plays a critical role during HPV infection by supporting trafficking of the incoming virus from the TGN to the Golgi and within the Golgi stacks. These results suggest that upon TGN/Golgi arrival, HPV binds directly to COPI, which engages HPV L2 as a cargo and mediates passage of the incoming virus through the TGN/Golgi to enable infection.

O109 / #1352

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - II
04-20-2023 10:30 AM - 12:00 PM

MATHEMATICAL MODELING OF EPITHELIAL TISSUE HOMEOSTASIS UNDER PERSISTENT HPV16 INFECTION

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Introduction: Human Papillomavirus (HPV) 16 confers cell growth advantage in comparison with uninfected keratinocytes and enhances colony competitiveness at the basal epithelium. In normal epithelial tissue, homeostasis is maintained as a stochastic balance between progenitor cells and cells committing differentiation. The presence of viral proteins establishes a new tissue homeostasis balance during persistence.

Methods: We used quantitative analysis of HPV infected NIKS cells investigating E6 conferred ability on cells to persist in basal layer of stratified epithelium. eGFP NIKS/LXSN, mCherry NIKS/LXSN/16E6 and non-colour NIKS were used in a competition and clone assay context at confluent density. Data were collected in terms of number of competing cells and colony size probability distribution over time.

Results: Our results showed that 16E6 expressing cells colonize the basal layer reaching higher saturation density before commit to differentiate. Clone assay results showed that the probability distributions of colony size characteristic of 'empty' NIKS and NIKS/16E6 were found to diverge from each other over time, showing that 16E6 clones have a higher probability to increase their size compared to normal NIKS (Figure 1). Interestingly, MAGI knock down results in larger clones with a higher percentage of cycling cells composing each clone and with a higher saturation density related to a lower K10 expression. We built a deterministic mathematical model describing the competition assay proving that 16E6 expressing cells have a higher division rate and a lower differentiation propensity. We are building a stochastic mathematical model describing how colonies genereated by single progenitors stochastically maintain tissue homeostasis.

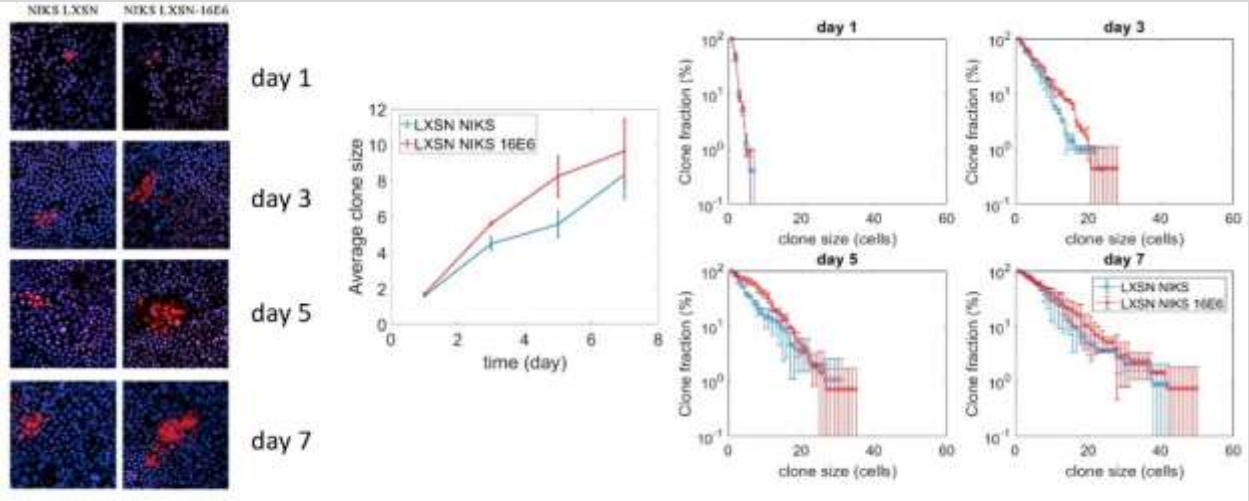

Figure 1. Probability distributions of colony size of NIKS (non color (blue)) and NIKS 16E6 (mCherry (red)) cells. Cells were seeded at confluent density and were collected at day 1, 3, 5 and 7. Immunofluorescent images from day 1-7 are shown on the right.

Conclusions: In conclusion, the deterministic model reinforced the experimental insights suggesting 16E6 confers higher proliferation capability and reduced contact inhibition and that MAGI may be an important actor in the basal layer modified homeostasis. We expect the stochastic model to reveal the complexity behind infected progenitor cells dynamics in regulating tissue homeostasis.

O110 / #1462

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - II
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E6AP IS IMPORTANT FOR HPV E6'S ROLE IN REGULATING EPITHELIAL HOMEOSTASIS AND ITS LOSS IMPAIRS KERATINOCYTE COMMITMENT TO DIFFERENTIATION

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Introduction: E6AP is a conserved binding partner and cellular target of all Alpha group HPV E6 proteins, but its precise role in modulating keratinocyte phenotype and associated signalling pathways have not been defined.

Methods: NIKS and primary foreskin keratinocytes transduced with the FUCCI cell cycle reporter, were used in combination with EGFP/mCherry cell-cell competition assays to model the epithelial basal layer. Digital imaging approaches and molecular analysis were used complement these studies.

Results: The homeostasis functions of E6 are dependent on E6AP and NHERF1, with both proteins involved in regulating basal cell density and differentiation. Interestingly, both 16 and 11 E6 required E6AP and NHERF1 binding to promote YAP nuclear localisation and YAP-reponsive gene activation to stimulate cell proliferation. Deletion of E6AP delayed the onset of differentiation, as determined by K10 immunofluorescence and PCR/RNAseq analysis. Furthermore, cells lacking E6AP resembled those expressing E6, and showed activation of the same YAP-responsive genes. NHERF1 downregulation was also common to both E6-expressing and E6AP $^{-/-}$ cells, suggesting that E6 and E6AP differentially regulate NHERF1 level transcriptionally and at the protein level. NHERF1 is known to interact with signalling proteins including PTEN, YAP1, beta-catenin and frizzled. Knock down NHERF1 in NIKS cells, led to YAP nuclear localisation and the activation of downstream genes. Importantly, immunostaining studies on clinical material revealed that both E6AP and NHERF1 are clearly detectable in the human epithelial basal layer, and that their abundance decreases significantly following HPV infection.

Conclusions: E6AP$^{-/-}$ keratinocytes phenotypically resemble E6-expressing cells, with E6AP impairing keratinocyte differentiation commitment, which is critical for HPV E6's ability to regulate epithelial homeostasis. We suspect that E6 modulates homeostasis by inhibiting E6AP function, which impairs NHERF1 function to activate the YAP pathway, and that this accentuates the established impact of E6 on commitment to differentiation is mediated through p53.

O111 / #1486

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - II
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SINGLE-CELL TRANSCRIPTOMICS IDENTIFIES PRMT1 AS A REGULATOR OF PAPILLOMAVIRUS TRANSCRIPTION.

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Introduction: Human papillomavirus (HPV) infections occur in host epithelial tissues. HPVs establish persistent infections in the basal cells of the epithelia and rely on the epithelial differentiation program to complete their productive viral lifecycle. We used single-cell genomics methods to identify the transcriptome of HPV(+) cells shortly after infection in monolayer and again after culturing cells in 3D organotypic raft cultures.

Methods: Bioinformatic analyses of these data, using 10X Genomics Cell Ranger for custom mapping of human and viral reads and the R-based Seurat package for dimensional reduction and clustering, identify cellular pathways targeted by HPV to reprogram the infected cells.

Results: HPV clearly disrupted the overall transcriptional profiles of these cells, including the proportion of differentiated and proliferative cells, as confirmed histologically via immunofluorescence. We detected viral reads across the differentiation gradient and are identifying the host genes and pathways that co-vary with early and late viral expression. By comparing HPV(+) and HPV(-) cells, differential gene expression analysis identified Protein Arginine Methyltransferase 1 (PRMT1) as a host factor upregulated in the HPV-specific gene expression patterns. PRMT1 is the primary enzyme driving asymmetric arginine dimethylation of proteins in human cells and regulates DNA damage response, RNA splicing, RNA transcription, and RNA degradation. We demonstrate that PRMT1 regulates viral maintenance in cells, probably by regulating viral transcription.

Conclusions: In this work, we leveraged single-cell RNA-Seq to study the viral lifecycle from infection to productive replication. We establish a novel role for the host enzyme PRMT1 as a regulator of HPV gene expression in primary mucosal keratinocytes and for arginine dimethylation in the HPV lifecycle.

O112 / #1162

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: VIRUS HOST INTERACTIONS COMBINED WITH LIFE CYCLE - II
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IMPACT OF E6_E7 MRNA SPLICING ON THE TRANSLATION EFFICIENCY OF THE E7 ONCOPROTEIN IN ONCOGENIC ALPHA HPVS.

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Introduction: Chronic infection by oncogenic viruses deregulates cellular homeostasis, proliferation and interaction with the environment, eventually leading to malignant progression. The early viral proteins E6 and E7 are the main actors responsible for these oncogenic processes. In non-oncogenic Alpha-HPVs the E6 and E7 ORFs overlap, and they are transcribed into two independent transcripts; in oncogenic Alpha-HPVs these ORFs do not overlap and are transcribed into a single, E6_E7 bicistronic mRNA, which further undergoes splicing, resulting in the production of an E6*I_E7 mRNA. The literature reports abundant contrasting findings about E6, E6*I and E7 translation regulation from the different viral transcripts. In non-oncogenic HPVs the balance between E6 and E7 protein production is probably governed mainly at the transcriptional level, while in oncogenic HPVs it is regulated at the post-transcriptional and translational levels.

Methods: We have evaluated the ability of bicistronic mRNAs encoding for E7 to actually lead to E7 production. We have transfected U2OS cells with different E6_E7 constructs based on Alpha-7 and Alpha-9 HPVs and have measured mRNA and protein production using molecular biology, cell biology and flow cytometry approaches.

Results: Regarding transcription, we state significant differences in mRNA levels as well as in splicing efficiency between closely related HPVs. Regarding translation, all E6_E7 transcripts tested, spliced or not, were able to produce E7 proteins. After correcting for mRNA levels, E7 was preferentially translated from the spliced transcripts with in average a 2-fold increase compared to the non-spliced ones.

Conclusions: We interpret that in oncogenic HPVs, splicing within the E6 ORF results in an increase in the diversity of E6_E7 transcripts that allows for an additional layer of gene expression control. This transcriptional and translational complexity may result in differential balance between the E6 and E7 oncoproteins contributing to the broad repertoire of clinical presentations of the infection by closely related viral genotypes.

O113 / #1281

Public Health Oral Abstracts Session
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GARDASIL VACCINE EFFECTIVENESS ON CIN2+ IN NORWAY: OBSERVATIONAL REGISTRY-BASED COHORT STUDY WITH INDIVIDUALLY MERGED DATA FROM NATIONAL HEALTH REGISTRIES

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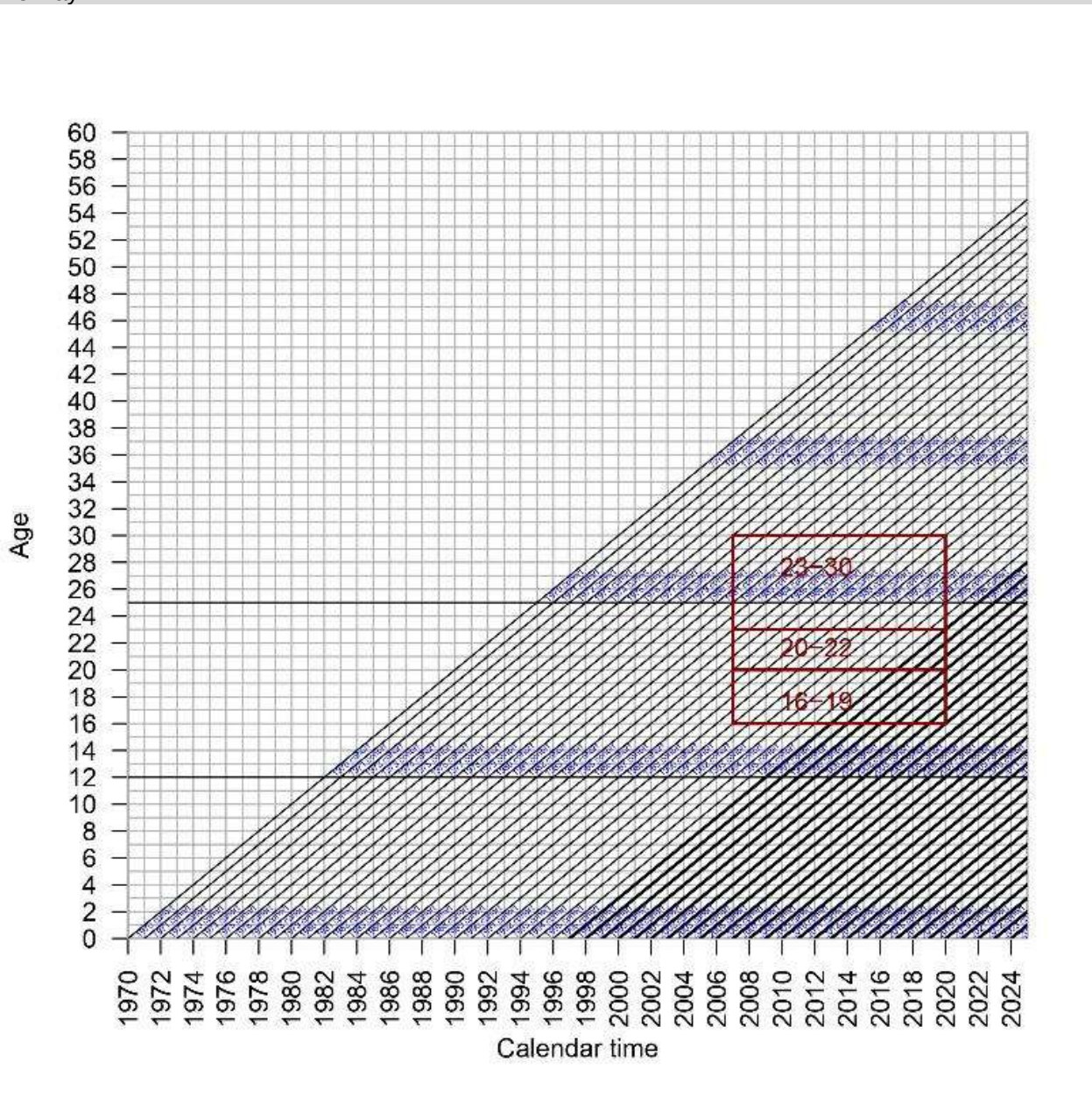
Introduction: In Norway, a single-cohort school-based national HPV vaccination program with 4-valent Gardasil was initiated for 12-year-old girls in 2009. Gardasil was replaced by a 2-valent vaccine in 2017. In 2020, the first girls vaccinated with Gardasil reached age of 23 years (Figure 1). The present observational registry-based cohort study estimates the effectiveness of Gardasil on cervical neoplasia grade 2 or worse (CIN2+) in

Norway.



Methods: Female residents aged 16 to 30 years in 2007 to 2020 in Norway were included in the study. They were linked with the Norwegian Immunization Registry for HPV vaccination information, and the Cancer Registry for CIN2+ incidences. To calculate vaccine effectiveness, we treated vaccination status as a time-varying exposure, i.e., a woman contributed person-time as “unvaccinated” until receipt of her first dose of Gardasil (if any), censoring (migration, death, other HPV vaccination), or end of study. Incidence rates were stratified by vaccination status, CIN2+ attained age, and vaccination age, with corresponding 95% confidence intervals (CI), and were calculated by Poisson regression with the natural log of person-time as offset. We calculated incidence rate ratios (IRR) between the groups.

Results: Out of 1,063,746 women included, 20,285 had CIN2+ diagnosis, and 222,834 had received at least one dose of Gardasil. Among women vaccinated before age of 14, IRR for acquiring CIN2+ diagnosis at age of 16-19 was 0.29 (95% CI: 0.18-0.46), at age of 20-22 it was 0.68 (95% CI: 0.56-0.82), and at age of 23-30 IRR was 0.44 (0.31-0.63) compared to unvaccinated women. Table 1. CIN2+

incidence by attained age and vaccination age.

	Unvaccinated		Vaccinated before age of 14			Vaccinated after age of 14		
Attained age	No. of cases	IR (95% CI)	No. of cases	IR (95% CI)	IRR (95% CI)	No. of cases	IR (95%CI)	IRR (95% CI)
16-19	168	11.6 (9.8, 13.3)	20	3.3 (1.9, 4.8)	0.29 (0.18, 0.46)	1	3.9 (-3.8, 11.7)	0.34 (0.05, 2.43)
20-22	1363	99.0 (93.7, 104.2)	120	67.3 (55.3, 79.4)	0.68 (0.56, 0.82)	25	122.1 (74.2, 169.9)	1.23 (0.83, 1.83)
23-30	18,121	533.3 (525.6, 541.1)	29	234.4 (149.1, 319.7)	0.44 (0.31, 0.63)	438	1176.8 (1066.6, 1287.0)	2.21 (2.01, 2.43)

Abbreviations: IR, incidence rate per 100,000 person-years; IRR, incidence rate ratio. IRR are comparing vaccinated group IRs to unvaccinated.

Conclusions: Gardasil was highly effective against CIN2+ among the girls who were vaccinated before age of 14. Among girls vaccinated after 14 years of age there was no significant vaccine effect.

O114 / #345

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 2
04-20-2023 2:30 PM - 4:00 PM

IMPACT OF COVID ON HPV VACCINATION COVERAGE IN UGANDA

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Introduction: Globally, cervical cancer is the fourth most common type of cancer with 528,000 new cases annually. Cervical cancer is responsible for 266,000 deaths among women worldwide predominantly affecting women in limited-resource countries including. Uganda is among the five countries with the highest cervical cancer incidence rates in the world. It is the most commonly diagnosed cancer and has the highest incidence of malignancy and mortality among women. The country's age-standardized incidence rate is more than three times the global estimate. In 2015, the Ministry of Health (MOH) recognized primary prevention of cervical cancer as a very important factor in the prevention of cervical cancer by launching the HPV vaccination program for girls aged 9–14 years before exposure to sex/ HPV and therefore, preventing the initial onset of cervical cancer. The program was introduced as predominantly school based program targeting girls in the primary four class with girls outside school accessing the vaccine directly from their communities. Following the first covid cases in early 2020, Uganda initiated its first nationwide lockdown, closing access to all schools thus affecting routine access to health services including vaccinationsThis article reviews the impact of Covid on the HPV vaccination program.

Methods: We reviewed immunisation data from the national health information management system DHIS2 from the period between 2019 to 2021. We obtained authorisation from the Ministry of Health. We run a simple excel data analysis of the monthly and annual data for the review period.

Results: By the end of 2020, HPV2 coverage had dropped by 44% compared to coverage of DPT3 vaccination which remained stable

	HPV2	HPV2	DPT3
Year	Target population	Annual coverage	Target p
2019	620,743	65%	1,733,24
2020	640,387	36%	1,788,09
2021	659,258	56%	1,840,76

Conclusions: The findings show a negative impact of covid on HPV vaccination

O115 / #641

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 2
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THE IMPACT OF HPV VACCINATION IN THE UNITED STATES (U.S.): A STATE-WIDE POPULATION-BASED EVALUATION OF CHANGES IN GENOTYPE-SPECIFIC PREVALENCE AND INFECTION RISK WITHIN SCREENING CYTOLOGY

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Introduction: Studies have demonstrated 4-valent (HPV6/11/16/18) HPV vaccine impact on HPV genotype detection in various settings. Here we report the largest population-based investigation of changes in HPV genotype-specific distributions detected in screening cytology a decade after vaccine implementation.

Methods: Two state-wide random stratified samples of liquid-based cytology from women aged 15-30y undergoing routine cervical screening in New Mexico [2007-2009 (N=28,268) and 2013-2016 (N=42,453)] were genotyped by Roche Linear Array. Weighted genotype-specific relative prevalence (RP) and 95% confidence intervals (95%CI) were calculated among women aged 15-20y, 21-25y and 26-30y. Weighted logistic regression models were fit to estimate relative risks of HPV genotype-specific infection, restricted to the period 2013-2016 and adjusted for birth cohort and age.

Results:

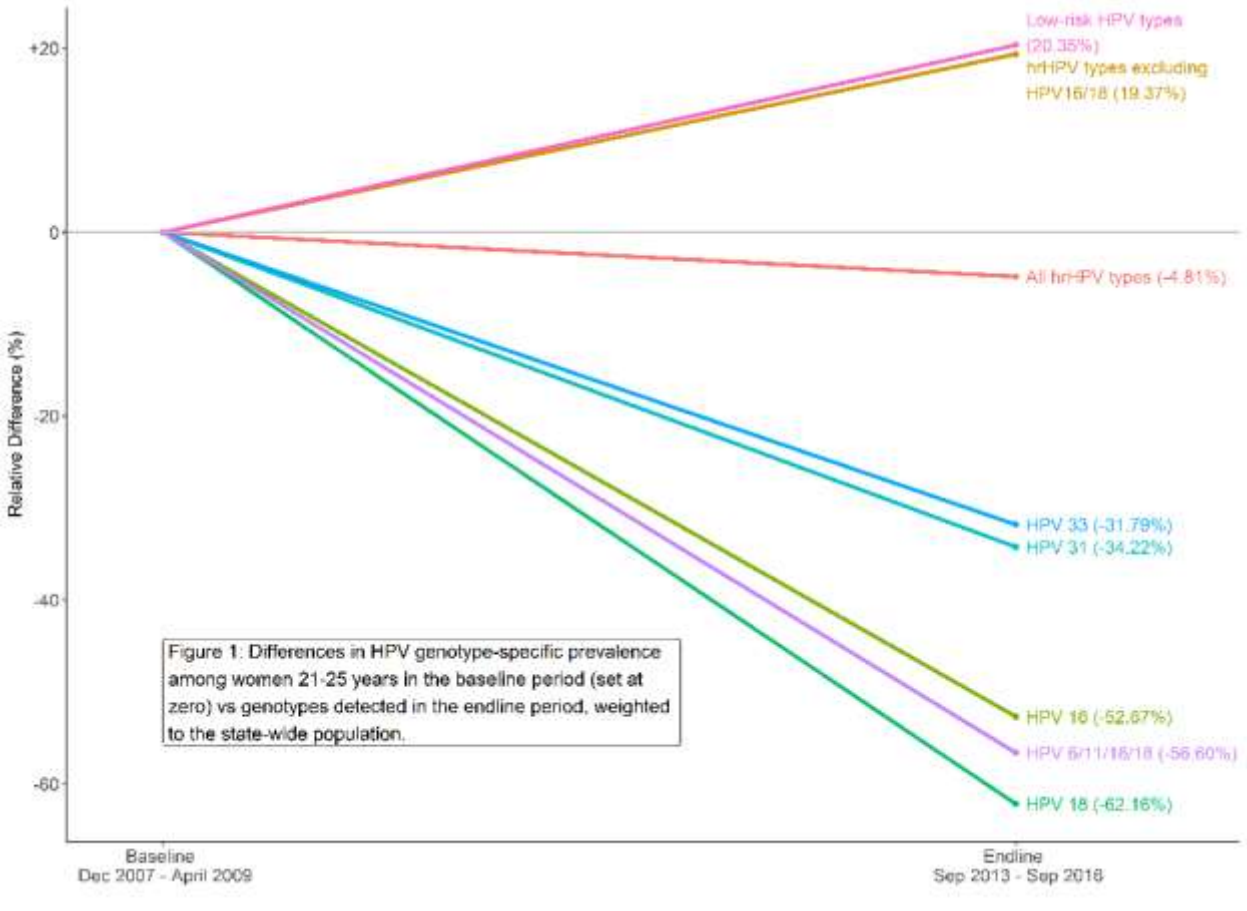

Figure 1: Differences in HPV genotype-specific prevalence among women 21-25 years in the baseline period (set at zero) vs genotypes detected in the endline period, weighted to the state-wide population.

Among women 21-25y, between 2007-2019 the incidence of low-grade and high-grade squamous intraepithelial lesions (LSIL and HSIL) decreased by 9.95% and 55.98%, respectively. Genotype-specific changes, showed significant reductions for HPV16 (RP=–52.67%, 95%CI=–56.97%, –48.37%), HPV18 (RP=–62.16%, 95%CI=–68.52%, –55.80%), HPV31 (RP=–34.22%, 95%CI=–42.40%, –26.34%) and HPV33 (RP=–31.79%, 95%CI=–48.41%, –15.18%). However, when excluding HPV16/18, an increase in RP was observed for all other high-risk HPV types (Figure 1). A significant increase in RP was observed individually for several high-risk HPV types as well as for all low-risk HPV types combined, although prevalence significantly decreased for HPV6 and HPV11. Comparing women born in 1996 to those born in 1989, the risk of infection by any 4-valent HPV type decreased by 80.18%.

Conclusions: Incidence of HSIL has decreased significantly over the past decade. Large reductions in the prevalence of vaccine types, as well as HPV31 and HPV33 through cross-protection, were observed across the study period. However, increases in some high- and low-risk HPV types may modulate anticipated reductions in cancer. Continuing surveillance of HPV vaccine impact remains essential to informing screening tests, clinical practice, and prevention strategies across the U.S..

O116 / #647

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 2
04-20-2023 2:30 PM - 4:00 PM

BUILDING EFFECTIVE AND RESILIENT CANCER PREVENTION THROUGH GENDER-NEUTRAL HPV VACCINATION

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Introduction: Modelling studies have showed that the WHO threshold for elimination of cervical cancer can be reached in most countries through HPV vaccination with 90% coverage in adolescent girls. However, only few countries could reach such coverage, rendering their cervical cancer prevention programme more vulnerable.

Methods: Using an IARC agent-based model, EpiMetHeos, recently used to assess the impact of single-dose vaccination in India, we illustrate how gender-neutral vaccination would improve the impact of HPV vaccination with suboptimal coverage in girls on A) the feasibility of reaching elimination and B) the resilience of cervical cancer prevention against disruption in vaccination, here simulated as no vaccination for five birth cohorts at year 10 since the introduction of vaccination.

Results: We predicted that with the quadrivalent HPV vaccine (95% efficacy against HPV16/18 types and 9% against HPV31/33/45) and a suboptimal coverage of 60% in girls, the age-standardized incidence rate (ASIR) of cervical cancer would decrease by 59% in vaccinated birth cohorts in India, i.e., from 11.0 to 4.5 cases per 100,000 women-years. Extending vaccination to boys would further reduce the ASIR to 2.3 cases per 100,000 women-years, hence below the WHO elimination threshold. It would also improve the resilience of the vaccination programme, by increasing the number of cervical cancer cases prevented in the five birth cohorts unvaccinated due to disruption from 101 to 296 per 100,000 women born.

Conclusions: Gender-neutral HPV vaccination is an effective and equitable strategy to expand the impact of cervical cancer prevention programme and to build on its resilience against future disruptions (e.g., pandemics, vaccine hesitancy, or geopolitical unrest), which may be unpredictable but are expected to occur.

O117 / #1018

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 2
04-20-2023 2:30 PM - 4:00 PM

CHANGES IN AGE-SPECIFIC INCIDENCE OF CERVICAL PRECANCERS (CIN2+ AND CIN3+), HUMAN PAPILLOMAVIRUS VACCINE IMPACT MONITORING PROJECT (HPV-IMPACT), UNITED STATES—2008–2019

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Introduction: In the United States, quadrivalent HPV vaccine was introduced for females at age 11-12 years in 2006, with catch-up through age 26. The 9-valent vaccine, introduced in 2015, has been the only HPV vaccine available since late 2016. We describe changes in incidence of cervical intraepithelial neoplasia grade 2 and worse (CIN2+; grades 2, 3 and adenocarcinoma in situ [AIS]) and CIN3+ (CIN grade 3 and AIS).

Methods: We conducted active laboratory-based surveillance for CIN2+ in catchment areas in five states, 2008–2019. Annual cervical cancer screening for each catchment area was estimated using administrative claims or laboratory data. Among women aged 20-64 years, we estimated age-stratified incidence rate ratios (IRR) of CIN2+ and CIN3+ per 100,000 screened women for 2-year periods compared to baseline years 2008-2009, adjusted for site.

Results: A total of 33,483 CIN2+ and 11,066 CIN3+ cases were reported. Among women aged 20-24 years, CIN2+ rates declined starting in 2010-2011, with greater declines in each 2-year period; by 2018-2019 there was a 64% decline (IRR=0.34, 95% CI 0.30-0.38). Similarly, CIN3+ rates in 20-24 year-olds declined in each period, with a 76% decline by 2018-2019 (IRR=0.24, 95% CI 0.18-0.32). Among women aged 25-29 years, CIN2+ rates were higher than baseline during 2012-2017, and similar to baseline in 2018-2019 (IRR=1.04, 95% CI 0.97-1.12); CIN3+ rates were higher than baseline during 2012-2017, and 21% lower in 2018-2019 (IRR=0.79, 95% CI 0.69-0.90). In age groups ≥30 years, CIN2+ and CIN3+ rates were higher in 2018-2019 than in 2008-2009.

Conclusions: Following HPV vaccine introduction, CIN2+ and CIN3+ rates progressively declined among women aged 20-24 years, and in 2018-2019, for the first time, modest declines in CIN3+ were also observed among women aged 25-29 years. Incidence increases in older groups may be attributable to changing screening recommendations.

O118 / #1422

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 2
04-20-2023 2:30 PM - 4:00 PM

CHALLENGES IN REACHING HIGH HPV VACCINE COVERAGE IN SOCIO-DEMOGRAPHIC DIVERSE MUNICIPALITIES IN SWEDEN: SCHOOL NURSES' PERSPECTIVE

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Introduction: Human papillomavirus (HPV) vaccines effectively prevent, and can even eliminate, HPV-related cancers. As of today, the Swedish school-based HPV vaccination program does not reach the target goal of >90%, in several municipalities. School nurses are responsible for all aspects of vaccinations, which require parental consent, and therefore play a key role. This study aims to explore school nurses' perceived challenges of HPV vaccination in the recently introduced pan-gender vaccination programme. The results will be used to develop an educational intervention to increase vaccine coverage in municipalities with low coverage.

Methods: Seven semi-structured focus group interviews were conducted with school nurses (N=35) working in nine socio-demographically diverse municipalities in mid-Sweden (November 2021- April 2022). Data were analyzed using qualitative content analysis.

Results: The analysis resulted in three categories. "Encountering various reasons for vaccine hesitancy". Participants described various parental concerns regarding the vaccine and communication was perceived to be challenging depending on the parents' reasons for hesitancy. Outspoken vaccine-skeptical parents were experienced as the most difficult to reach. Another challenge was to ensure enough information had been given for parents to make a well-informed decision while still being respectful of their right to decide. "Interpreting professional responsibilities'" described an uncertainty in defining the extent of professional responsibilities in vaccine promotion, lacking guidelines for working with vaccine hesitancy, and supporting the child to be involved in decision-making. "Creating a safe space for the individual child" was seen as crucial and prompted challenges of using strategies to overcome children's fear of needles, supporting children who do not get vaccinated, and being confronted with remaining gender inequities of the pan-gender vaccination program.

Conclusions: Our results suggest that school nurses may benefit from supportive informational tools and guidelines in order for homogeneity in HPV vaccine promotion and support children's right to be involved in decisions regarding their future health.

O119 / #888

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 2
04-20-2023 2:30 PM - 4:00 PM

COVID-19 PANDEMIC IMPACTS ON UPTAKE OF HUMAN PAPILLOMAVIRUS VACCINE AMONG GAY, BISEXUAL, AND OTHER MEN WHO HAVE SEX WITH MEN IN CANADA

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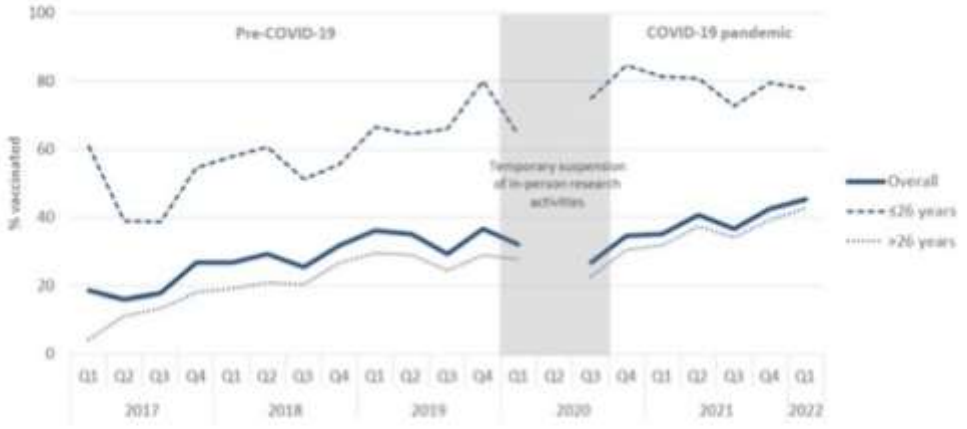
Introduction: Gay, bisexual, and other men who have sex with men (GBM) aged ≤26 years are eligible for publicly-funded human papillomavirus (HPV) vaccine in most Canadian provinces. We assessed the impact of the COVID-19 pandemic on uptake of HPV vaccine among GBM.

Methods: The Engage study is a community-recruited cohort of sexually-active GBM aged ≥16 years in Montreal, Toronto, and Vancouver, Canada, initiated in 2017-2019. We calculated the proportion of GBM who self-reported receiving ≥1 dose of HPV vaccine each quarter until February 2022. Among participants who were unvaccinated at enrollment, we calculated incidence rate ratios (IRR) comparing uptake (≥1 dose) during the pre-COVID-19 and COVID-19 pandemic periods using a mixed effects Poisson model with a random effect for subject and fixed effects for age group, city, and period.

Results: Of 2,449 GBM enrolled, 1961 (80.1%) completed ≥1 follow-up (median=5, interquartile range [IQR]=3-6) visit over a median of 42 (IQR=30-48) months. At enrollment, 416 (21.2%) were aged ≤26 years and eligible for publicly-funded vaccine. Cumulative uptake increased over time among all men but appeared to stabilize around 80% among men aged ≤26 years during the pandemic (Figure). Among 1452 unvaccinated men, incident uptake diminished during the pandemic but the magnitude differed by age (p<0.001). Among men aged ≤26 years, uptake per 100 person-years was 37.76 (95%CI=29.30-48.67) pre-pandemic and 20.64 (95%CI=12.43-34.26) during the pandemic (IRR=0.55, 95%CI=0.31-0.96). Among men aged >26 years, uptake per 100 person-years was 6.79 (95%CI=5.61-8.21) pre-pandemic and 5.78 (95%CI=4.72-7.08) during the pandemic (IRR=0.85, 95%CI=0.65-

1.19).

Figure. HPV vaccine uptake among GBM who completed ≥1 follow-up visit stratified by age-eligibility for publicly-funded programs, Canada, February 2017-February 2022



GBM=gay, bisexual and other men who have sex with men; HPV=human papillomavirus; Q1=January-March, Q2=April-June, Q3=July-September, Q4=October-December. Q1 of 2017 includes interviews conducted in February-March; Q1 of 2022 includes interviews conducted in January-February.

Conclusions: HPV vaccine uptake increased from 2017-2019 with diminishing gains among GBM aged ≤26 years from 2020 onwards. This may be a result of limited access during the COVID-19 pandemic or higher initial uptake among early adopters. Further monitoring should assess the longer-lasting impacts of the COVID-19 pandemic on HPV vaccination among GBM.

O120 / #1718

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 2
04-20-2023 2:30 PM - 4:00 PM

PAY-IT-FORWARD TO INCREASE HPV VACCINE UPTAKE AMONG 15–18-YEAR-OLD GIRLS COMPARED TO USER-PAID VACCINATION IN CHINA

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Introduction: Over 15% of global cervical cancer deaths occur in China but the HPV vaccination rates are low (<10%) among teenage girls. Barriers to vaccination included limited public funding and delayed use of HPV vaccines available in the market. Novel approaches are needed to address these issues. Pay-it-forward offers an individual a subsidized service and an opportunity to donate to support other people. Our two-arm randomized control trial (ChiCTR2200055542) assesses the effectiveness of pay-it-forward against user-paid vaccination (control) in improving HPV vaccination among girls aged 15-18 years in China.

Methods: Eligible girls (via caregivers) were randomly selected using a resident name list and invited via telephone recruitment. Participants randomized to the pay-it-forward arm received an educational pamphlet about HPV vaccination, a community supported subsidy (US$48.8) to encourage the participant to receive HPV vaccination, an opportunity to donate to support others, and postcard messages from the community. Participants in the control arm received the educational pamphlet and could self-pay for vaccination. Between 11 July 2022 and 19 January 2023, data with 244 girls and their caregivers were collected. The primary outcome was uptake of the first-dose HPV vaccination ascertained by administrative records.

Results: A total of 244 participants were recruited and randomized to the control arm (n=122) and the pay-it-forward arm (n=122). Forty-nine of 122 (40.2%) participants in the pay-it-forward arm and 23/122(19.9%) in the control made an appointment for the first-dose HPV vaccination (p<0.001). Regarding vaccine uptake, 38/122(31.2%) participants in the pay-it-forward arm and 20/122(16.4%) in the control arm received an HPV vaccination within 2 weeks after the deliver of the treatment (p=0.007). Among 38 girls in the pay-it-forward arm who received the vaccination already, 31 (81.6%) donated to support future teenage girls, totaling US$314.8 and covering 17.0% of subsidies provided to pay-it-forward participants.

Conclusions: The pro-social pay-it-forward strategy seemed to be effective in increasing HPV vaccination among teenage girls.

O121 / #1641

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: VACCINATION 2
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HPV VACCINE INITIATION AT AGE 9/10 AND BETTER SERIES COMPLETION BY AGE 13 AMONG PRIVATELY AND PUBLICLY INSURED CHILDREN IN THE US

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Introduction: The US Advisory Committee on Immunization Practice (ACIP) recommends routine human papillomavirus (HPV) vaccination at 11–12 years of age, but states that vaccination may be initiated as early as 9 years. Our primary goal was to assess whether initiating HPV vaccination at 9–10 years of age, compared to 11–12, was associated with a higher rate of series completion by 13 years of age, and to identify factors associated with series completion by age 13

Methods: The study used vaccine claims data from the IBM MarketScan Commercial Claims and Encounters (privately insured) and IBM MarketScan Multi-State Medicaid (publicly insured) databases. Participants were 9–12 years of age at the time of first dose and initiated HPV vaccination between January 2006 and December 2018 (publicly insured) or March 2019 (privately insured). The key outcome measure was completion of HPV vaccination series by 13 years of age. Descriptive statistics were used to compare groups initiating HPV vaccination at different ages, and factors associated with completion of HPV vaccination series by 13 years of age were modeled in a multivariable logistic regression model.

Results: Among 100,117 privately insured individuals, those initiating the HPV vaccination series at 9–10 years of age had a significantly higher series completion rate by 13 years of age than did those initiating at 11–12 years of age (76.2% versus 48.1%; $p < 0.001$). The same pattern was observed for 115,863 publicly insured individuals (70.4% versus 40.0%; $p < 0.001$). Provider and health care plan type, female sex, race / ethnicity, and wellness checks or non-HPV vaccinations during the baseline period were significantly associated with series completion by 13 years of age.

Conclusions: Initiation of HPV vaccination at 9–10 years of age was associated with higher rates of series completion by age 13. These findings can inform provider education and other interventions to encourage timely HPV vaccination series completion.

O122 / #852

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENOMICS
04-20-2023 2:30 PM - 4:00 PM

TAME-SEQ2: TAGMENTATION-ASSISTED MULTIPLEX PCR ENRICHMENT FOR VIRAL GENOMIC PROFILING

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Introduction: The tagmentation-assisted multiplex PCR enrichment sequencing protocol (TaME-seq) is a cost-efficient method for deep sequencing of human papillomaviruses (HPV). It allows identification of the consensus sequence, low-frequency variable sites and chromosomal integration events. This protocol has been applied to the high-risk HPV genotypes HPV16/18/31/33/45. Here, we present TaME-seq2, with an updated laboratory workflow and bioinformatics pipeline, and its expanded repertoire to HPV51/52/59 and SARS-CoV-2

Methods: Cervical cell samples positive for HPV51, 52 or 59 (n=12 per type) and 27 SARS-CoV-2 cDNA samples were included. HPV51/52/59 specific primers (in total 57, 59, and 54, respectively) were designed, while SARS-CoV-2 ARTIC Version 3 primer set were modified by adding the Illumina TruSeq-compatible adapters to their 5'ends. Total DNA extracted from the HPV sample material and SARS-CoV-2 cDNA was tagmented before two separate multiplex-PCR reactions with either forward or reverse virus-specific primers and unique dual index primer pairs (i5/i7) were conducted. Consensus sequences, low-frequency variable sites, and chromosomal integration events were identified using an in-house bioinformatics pipeline.

Results: Updated laboratory workflow increased the amplification yield, while the bioinformatics pipeline was up to 40x faster compared to the TaME-seq v1. In total, 23 HPV-positive samples and 7 SARS-CoV-2 samples passed the quality threshold and were included in the analysis. Viral integration into the human genome was detected in one HPV59-positive sample. The average number of minor nucleotide variants was similar between samples infected with different HPV types (~ 20), while this number was ~ 6x higher in SARS-CoV-2 samples. C>T and T>C, and T>C and C>A substitutions were the most prevalent in HPV and SARS-CoV-2 samples, respectively.

Conclusions: TaME-seq2 has proved its efficiency in the detection of low-frequency viral genome variation, and viral integration sites. Its successful application in the analysis of SARS-CoV-2, implies the ease of the TaME-seq2 adaptation to a wide variety of viruses.

O123 / #638

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENOMICS
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SUB-LINEAGE TYPING AND SINGLE NUCLEOTIDE VARIANTS OF HPV16, 31, 33, 52, AND 58 POSITIVE SAMPLES FROM NORWAY

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Introduction: High-risk (HR) human papillomaviruses (HPV) assorted to the α-9 clade encompass 6/14 HR-HPV types and are responsible for a high proportion of cervical cancers worldwide. Here, we focus on analysing the sub-lineage distribution of HPV16/31/33/52/58 in a Norwegian cohort and identification of type-specific single nucleotide variants (SNVs) in cervical HPV-positive samples categorised as either high-grade lesions/cancer (HGL) or normal/low-grade lesions (LGL) by using the TaME-seq2 HPV whole-genome deep-sequencing method.

Methods: 268 cervical cell samples positive for at least one of the selected types were included. The sub-lineage for each sample was determined and SNVs were identified. SNV positions in different sub-lineages within an HPV type were aligned. Type-specific SNVs were counted and classified as nonsynonymous/synonymous or as intergenic noncoding.

Results: A1 was the most prevalent sub-lineage of HPV16/33/52, respectively, while B2 and A2 were the most prevalent sub-lineages of HPV31 and 58, respectively (Figure 1). Preliminary analysis of SNVs in HPV33/52/58 HGL samples revealed a low number of SNVs, most of them classified as synonymous mutations or noncoding (Figure 2) indicating lower genomic variability. Conversely, HPV31, followed by HPV16 in HGL samples had the highest number of SNVs classified as nonsynonymous. Several of the HPV16 nonsynonymous mutations have been previously correlated with an increased risk of high-grade lesions/cancer.

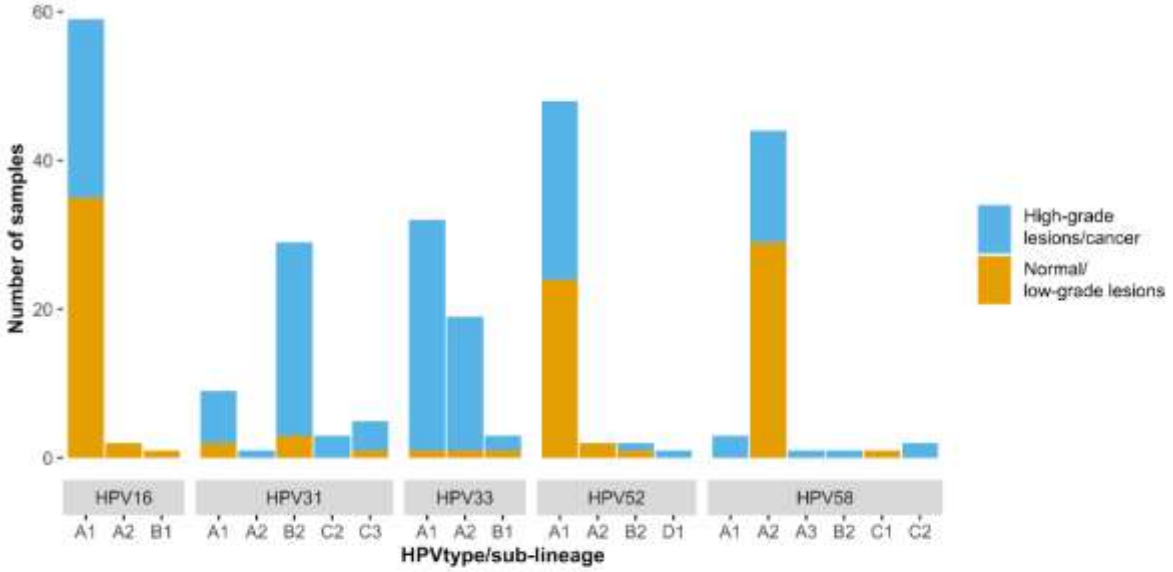

Figure 1. Results of the sub-lineage typing of HPV16/31/33/52/58 positive samples collected in Norway between 2005-2008.

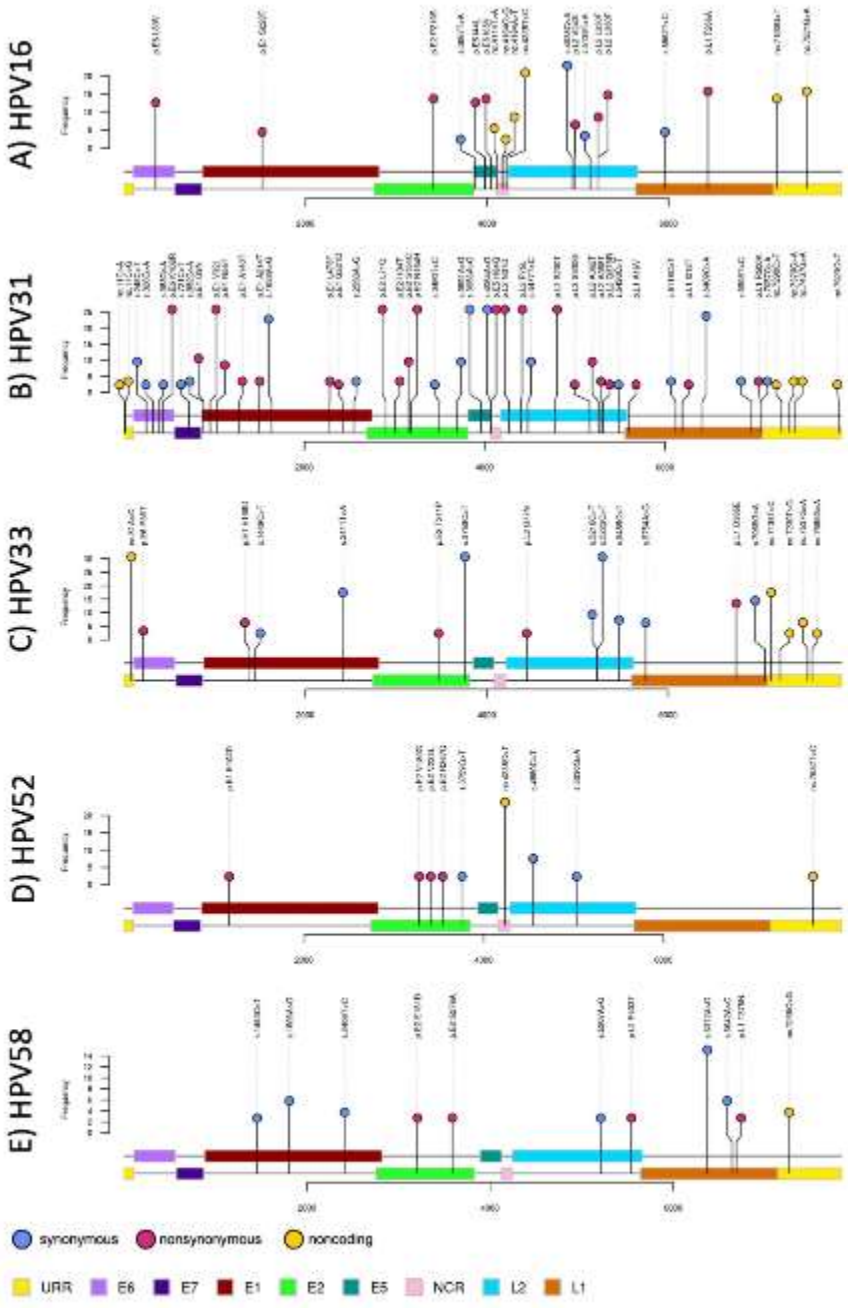

Figure 2. Single nucleotide variants (SNVs) found in HPV16 (A), HPV31 (B), HPV33 (C), HPV52 (D), HPV58 (E). SNVs found in < 3 samples were not presented. SNVs are classified as synonymous (blue lollipops), nonsynonymous (red lollipops), and noncoding (yellow lollipops). Length of the lollipops indicates the number of samples with the specific SNV (y-axis). HPV genes are represented by different colour.

Conclusions: This is the first report of sub-lineage distribution of HPV16/31/33/52/58 in a Norwegian cohort and SNV analysis within selected types. High-frequency nonsynonymous mutations in HPV31 will be assessed and presented, as well as comparison between LGL and HGL samples for all types in terms of detected SNVs and their frequencies. The within-patient minor nucleotide variation (MNV) analysis

complementing the SNVs analysis, will also be presented. We hypothesize that combined results from SNV and MNV analysis might be indicative for early cancer prediction.

O124 / #877

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENOMICS
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CHANGES IN INTRA-HOST GENETIC DIVERSITY ACCORDING TO DIAGNOSTIC CATEGORIES IN LONGITUDINAL HPV16 SAMPLES

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Introduction: A persistent HPV16 infection is responsible for half of cervical cancers worldwide. On the other hand, most infections will be cleared by the immune system, and it is currently challenging to differentiate progressing HPV16 infections from those that will regress. Further investigation of specific biomarkers and a better understanding of HPV mutations that might reveal cancer development is needed.

Methods: From a research biobank with cervical cell material collected from women attending the Norwegian screening program between 2005 and 2008, 250 longitudinal samples from 90 women were selected. Samples were chosen aiming to select samples from women with progressive disease or stable diagnosis over time. TaME-seq2 (tagmentation-assisted multiplex PCR enrichment sequencing) was used to generate HPV whole genome deep sequencing data. Stringent filtering steps were applied, and single nucleotide variants were called. We will present the accumulation of gene diversity over time in samples with different diagnoses and explore how the genetic distance between samples develop over time.

Results: In total, 141 samples from 54 women passed the conservative filtering steps and were analysed in depth. Out of these, 44 samples represented high-grade changes/cancer, 46 low-grade changes and 51 non-progressive. The total number of women having a stable diagnosis over time was 23 (54 samples), while 31 women (87 samples) had diagnoses changing over time.

Conclusions: We have sequenced in depth a unique longitudinal set of HPV16 positive samples from women attending the Norwegian cervical cancer screening program. With this dataset, we can trace changes in intra-host genetic diversity over time and relate these to progressive or regressive outcomes.

O125 / #1245

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENOMICS
04-20-2023 2:30 PM - 4:00 PM

HPV16 GENOMICS: THE UNTOLD STORY OF SUBLINEAGE DIFFERENCES AND CARCINOGENICITY

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Introduction: Human papillomavirus type 16 (HPV16) is the most oncogenic HPV. Nevertheless, risk of cervical cancer can differ by up to ~29-fold (adenocarcinoma up to ~137-fold) depending on which of its 16 sublineages (A1-4, B1-4, C1-4, D1-4) infects a patient. Although sublineages differ by only ~0.3%-2.2% (20-170 nucleotides), the link between these genetic differences and carcinogenicity remains uncertain. To understand this association, we utilized a dataset of >6,000 HPV16 whole-genomes from HPV16-positive cervical samples.

Methods: We used phylogenetic methods to identify a set of 249 genome sites at which sublineage-defining nucleotide differences occur. We independently identified specific sites with evidence for positive selection within each sublineage using both π_N/π_S (SNPGenie) and d_N/d_S (HyPhy) methods. Finally, we characterized the relationship between the aforementioned sites and known (Immune Epitope Database) or predicted (NetMHCPan) T cell epitopes.

Results: Sublineage differences were enriched for synonymous (not amino-acid changing) variants, supporting that random genetic drift was responsible for the majority of fixations (evolutionary substitutions) in HPV16 history. However, a large number of nonsynonymous (amino-acid changing) differences between sublineages showed evidence for positive selection within sublineages, a significant enrichment ($P<0.0014$, simulation). Many codons were under selection in multiple sublineages. Finally, within all C and D sublineages, sites under putative positive selection were depleted for immune epitopes ($P<0.0094$, simulation).

Conclusions: Our results suggest that many nonsynonymous differences between HPV16 sublineages were driven by selection, implying they were beneficial to the virus (non-neutral). Findings also suggest that present-day selective pressures have been operating for ~500 thousand years and continue to drive the maintenance of genetic diversity in HPV16. We hypothesize that the primary selective pressure is host human leukocyte antigen (HLA) genotype, which is itself under positive selection. Such immune selection could explain both the differing prevalences of the sublineages and the differing risks of cancer they confer.

O126 / #1379

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENOMICS
04-20-2023 2:30 PM - 4:00 PM

ASSOCIATION OF HUMAN PAPILLOMAVIRUS GENOMES WITH TRANSCRIPTIONAL REGULATORY HUBS

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Introduction: Oncogenic human papillomavirus (HPV) genomes are often integrated into host chromatin in HPV-associated cancers. HPV genomes are found integrated in all human chromosomes but there is a high frequency of integration at certain regions (hotspots). These often overlap common fragile sites (regions susceptible to replication stress and genomic instability) and transcriptionally active regions. We have previously demonstrated that HPV genome integration can capture and amplify cellular enhancers to drive high levels of viral oncogene expression.

Methods: To determine whether enhancer-hijacking and viral-host DNA amplification are common at integration loci, we compiled cervical (CESC) and head and neck squamous cell carcinoma (HNSCC) datasets and assessed host genome copy number at each insertion site. Common fragile sites and active cellular enhancers are cell-type specific, therefore we mapped these regions in cervical cell lines using FANCD2 and Brd4/H3K27ac ChIP-seq as markers for common fragile sites and active enhancers, respectively. Large enhancer clusters, or super-enhancers, were also defined using the Brd4/H3K27ac ChIP-seq dataset.

Results: Tumor genomes frequently contained multiple distinct HPV integration sites but often only one "driver" site that expressed viral RNA. HPV integration breakpoints were enriched at both FANCD2-associated fragile sites and enhancer-rich regions, and frequently showed adjacent focal DNA amplification in CESC tumors. We identified recurrent integration "hotspots" that were enriched for super-enhancers, some of which function as regulatory hubs for cell-identity genes.

Conclusions: We propose that during persistent infection, extrachromosomal HPV minichromosomes associate with host transcriptional epicenters to ensure an active infection. These epicenters are enriched in active chromatin and super-enhancers and accidental integration here could result in high viral gene expression, which could promote oncogenesis. We are currently investigating viral-host genome interactions at transcriptional hubs in cervical keratinocytes containing extrachromosomal HPV genomes.

O127 / #1026

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENOMICS
04-20-2023 2:30 PM - 4:00 PM

HPV16 EPISOMAL MULTIMERS CAN FORM DOUBLE-MINUTE CHROMOSOMAL STRUCTURES AND CONTRIBUTE TO CHROMOSOME REARRANGEMENTS

Michael Dean[1], Isabel Rodriguez[2], Nicole Rossi[1], Hong Lou[1], Yi Xie[2], Darawalee Wangsa[3], Kerstin Heselmeyer[3], Ayse Keskus[4], Mikhail Kolmogorov[4], Lisa Mirabello[5]
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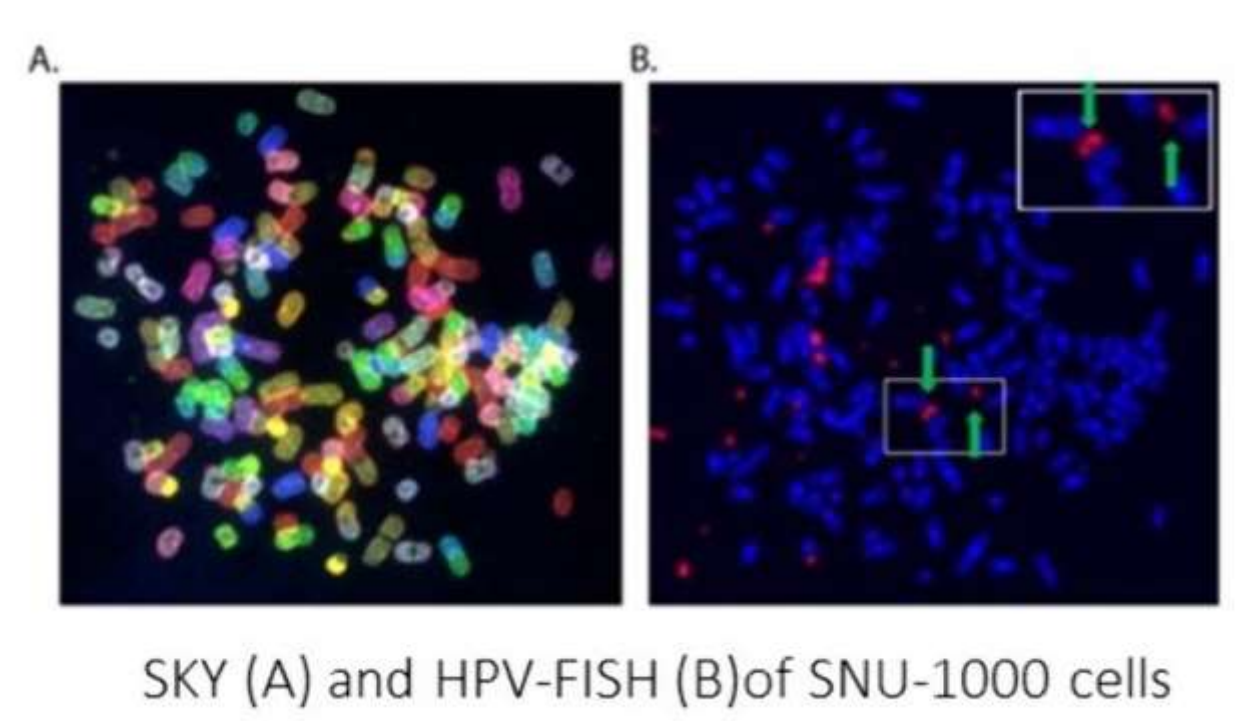
Introduction: Human Papillomavirus (HPV) type 16 (HPV16) causes cervical, anal, and head and neck squamous cell carcinoma (HNSCC). In contrast to other HPV types, 33% of HPV16 tumors do not integrate into the human genome.

Methods: We applied long-read whole-genome sequencing (WGS) to HPV16+ cervical cancer cell lines and spectral karyotyping (SKY) and fluorescent in situ hybridization (FISH) to the SNU-1000 cell line. In addition, we developed a BGA (breakpoint graph assembler) pipeline to identify recurrent viral and host DNA junctions.

Results: We previously described large tandem arrays of integrated full-length and deleted HPV16 sequences in CaSki and SCC152 cells and large episomal multimers in SNU-1000. Ultra-long sequencing shows these episomes are >350kb in length. HPV-FISH reveals very large extrachromosomal HPV multimers in SNU-1000. Some of these structure form double-minute chromosome-like molecules estimated to be >1 megabase in
length.



SKY (A) and HPV-FISH (B)of SNU-1000 cells

High-coverage long-read sequencing confirms that a 150bp fragment of HPV integrated into chromosome 11 is the only consistently integrated form of HPV in SNU-1000. SKY shows chromosomal translocations telomeric to this integration validated by DNA sequencing. In CaSki and SCC152 cells, we found recurrent rearranged fragments of HPV16 on multiple chromosomes, consistent with the propagation of episomal multimers and deleted copies of HPV before integration. SCC152 is derived from a relapsed HNSCC in the same patient as the SCC090 line. We document that SCC152 lost HPV sequences integrated on chromosome 6 but retains HPV integrations on chromosomes 2, 3, and 9. DNA methylation and full-length transcription analysis show that the HPV16 integration on chromosome 9 results in rearrangement, demethylation, and over-expression of the FOXE1 transcription factor.

Conclusions: HPV16 can cause cancer without integration through aberrant episomal replication. However, the integration of these multimer episomes contributes to tumor genome instability and evolution.

O128 / #1222

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENOMICS
04-20-2023 2:30 PM - 4:00 PM

STRUCTURAL CHARACTERIZATION OF HPV INTEGRATION SITES IN AN ANAL DYSPLASIA RAFT TISSUE CULTURE MODEL

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Introduction: Anal cancer is associated with human papillomavirus (HPV) infection and is one of few malignancies for which the incidence continues to rise worldwide. Host genome integration of HPV is considered a key step in malignant transformation and may serve as a marker of disease progression. We sought to define and characterize genome-wide viral integration sites in an in vitro raft tissue culture system model of HPV-induced anal squamous neoplastic progression.

Methods: Primary human anal keratinocytes (HAK) were transfected with HPV16 and HPV18 DNA and propagated in a raft tissue culture system with subsequent histologic documentation of progression through increasing stages of dysplasia with determination of HPV status at 5-passage intervals. Concomitant identification of HPV integration sites was performed using MyGenostics GenCap NGS technology and validated via RNA-Seq and Sanger sequencing. Integration sites were examined for adjacent viral-host microhomology (proprietary Python Script), repeat sequences (RepeatMasker), and signature motif sequences (MEME-ChIP, FIMO).

Results: A cumulative total of 166 HPV16 and 109 HPV18 high-confidence integration breakpoints were identified throughout various stages of anal neoplastic progression. Adjacent 2-, 3-, and 4 bp viral-host microhomologies were noted in more than 80% of both HPV16 and HPV18 breakpoints. Significant enrichment of transposable elements (e.g. Line-L1, SINE-Alu, SINE-MIR, LTR-ERV etc.) known to be associated with genomic instability and tumor development was observed in the host breakpoints flanking regions in both HPV16 and HPV18 rafts. Previously reported fragile site motif sequences were identified adjacent to multiple breakpoints in HPV16 (n=11) and HPV18 (n=11) models.

Conclusions: We have demonstrated that HPV transfection in HAK raft culture progression models is associated with subsequent viral integration events with known structural features including viral-host microhomology, repeat element enrichment and fragile site motif sequences. Raft models may provide a streamlined method to identify and investigate key viral integration-associated drivers of HPV-associated carcinogenesis.

O129 / #1022

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: GENOMICS
04-20-2023 2:30 PM - 4:00 PM

A PANEL OF 22 CERVICAL CANCER CELL LINES CHARACTERIZED BY LONG-READ DNA AND RNA SEQUENCING: INSIGHTS INTO HPV INTEGRATION AND TRANSCRIPTION

Isabel Rodriguez[1], Yi Xie[1], Nicole Rossi[1], Hong Lou[2], Joseph Boland[2], Jieqiong Dai[2], Wen Luo[2], Jia Liu[2], Genevieve Parkey[1], Nina Rao[1], Yuko Yuki[2], Mary Carrington[2], Darawalee Wangsa[3], Kerstin Heselmeyer[3], Lisa Mirabello[4], Michael Dean[1]
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Introduction: Despite the high global impact of cervical cancer, there are few cell lines with multi-omics data. To expand the available models, we established a panel of 22 cell lines from European, Asian, and African subjects.

Methods: We characterized these cell lines using long-read DNA and RNA sequencing, HLA, targeted sequencing, and cytogenetics. Identified HPV types and sublineages, expression of viral and cellular oncogenes, HLA types, integration sites/patterns, DNA methylation, and developed methods for investigating HPV structure in cervical tumors.

Results: The panel has 11 cell lines with HPV16, five with HPV18, and single lines with HPV30, HPV31, HPV33, HPV45, HPV68B, and one HPV- (C33A). Of the 11 HPV16 lines, six had the very-high-risk sublineages: A4 (4) and D3 (2). SNU-1000 cells are an HPV16 line with nearly all HPV sequences as extrachromosomal DNA, confirmed by HPV in situ hybridization. All other lines had HPV integrated at divergent sites in the human genome. Of interest, the SCC152 integration activated the FOXE1 transcription factor gene, the SNU778 integration activated the RAB18 oncogene, HT-3 was near the RB1 gene, and the SNU-1005 integration inactivated the RAD51B DNA repair gene. We validated integration sites by Sanger sequencing and identified microhomologies. Long-read sequencing analysis revealed the structure and level of full-length HPV RNA transcripts, with most cell lines expressing predominantly spliced E6 (E6*I) and full-length E7. However, the level of HPV transcription varied between cell lines. Analysis of the human genome revealed somatic mutations in PIK3CA, TP53 and RB1 genes and amplification of the YAP1/BIRC2/BIRC3 locus, known drivers of cervical cancer. HLA gene sequencing revealed frequent loss of heterozygosity of the Class I HLA genes 56%-61%.

Conclusions: Our panel provides models for all the major HPV types and subtypes of cervical cancer that will aid in developing new therapeutic approaches.

O130 / #544

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON HPV DNA AND MRNA DETECTION
04-20-2023 2:30 PM - 4:00 PM

INFLUENCE OF TLR4 AND TLR9 POLYMORPHISMS AND HAPLOTYPES ON MULTIPLE HR-HPV INFECTIONS, HPV16 COPY NUMBER, AND CERVICAL CANCER SUSCEPTIBILITY

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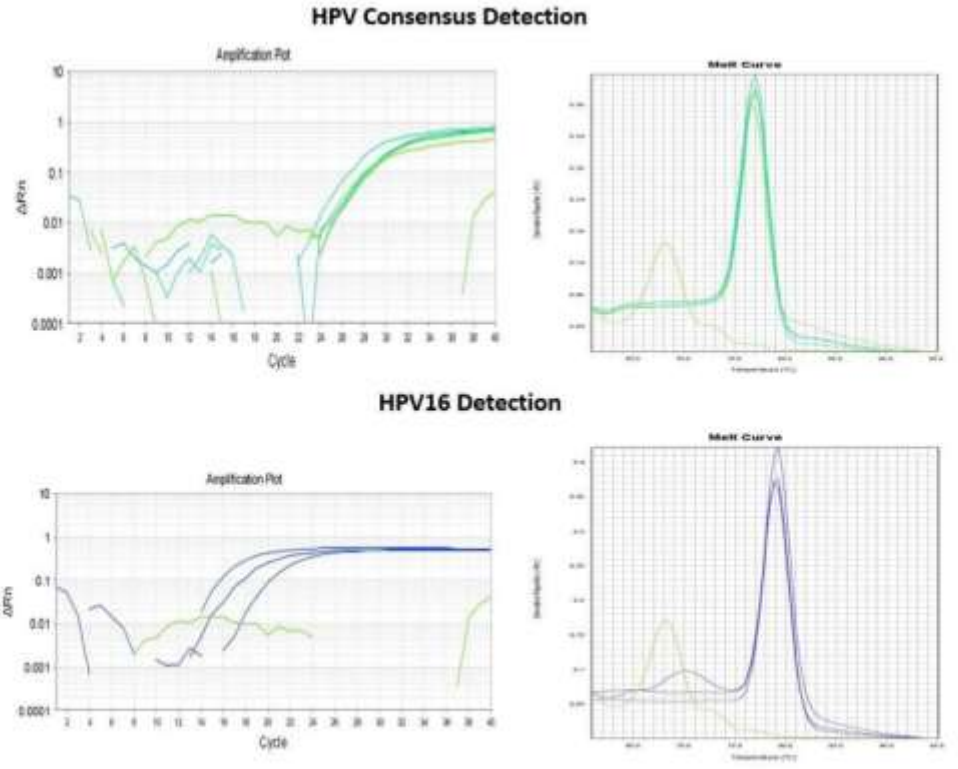
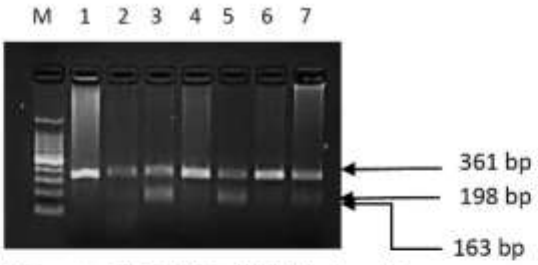
Introduction: Toll-like receptors play an essential role in immunity by targeting pathogen-associated molecular patterns. Additionally, genetic variations in the form of single nucleotide polymorphisms in TLR genes tend to influence infection and disease susceptibility; therefore may serve as a crucial biomarker. Here we present the association of TLR4 and TLR9 gene polymorphisms and haplotypes with susceptibility to multiple hrHPV infections, HPV16 copy number, and cervical cancer.

Methods: The study comprised 110 cervical cancer and 200 healthy controls. Real-Time PCR was performed to detect hrHPVs and HPV16 copy number. Eight SNPs, four each in TLR4 and TLR9 of coding and non-coding regions, were genotyped either by PCR-RFLP or AS-PCR. Association of SNPs with HPV infection, HPV16 load and cervical cancer susceptibility were estimated using SPSS 24.0. Haploview and FAMHAP were used for haplotype association.

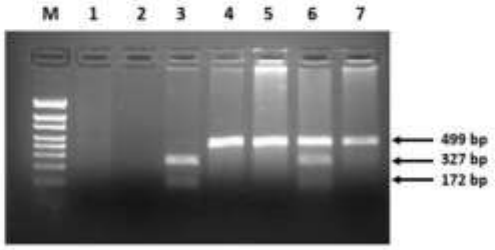
Results: HPV was detected in 81.6% and HPV16, HPV45 and HPV18 in 64.5%, 13.6%, 3.6% cases respectively, and co-infection in 23.2% patients. Mean HPV16 copy number estimated was 264.4±58.7. TLR4 rs4986790, rs1927911 and TLR9 rs187084 showed association with HPV16/18 infection. TLR4 rs11536889 CC and rs1927911 CT genotypes, TLR9 rs187084 TC, CC genotypes were associated with cervical cancer risk. TLR9 SNPs were associated with decreased risk of high HPV16 copy number. TLR4 and TLR9 haplotypes GCAG and GATC showed association to hrHPV infection. TLR4 haplotype ACAC was associated with increased risk of multiple hrHPV infections. TLR4 and TLR9 haplotypes GTAC and GATC were associated with increased cervical cancer
risk.



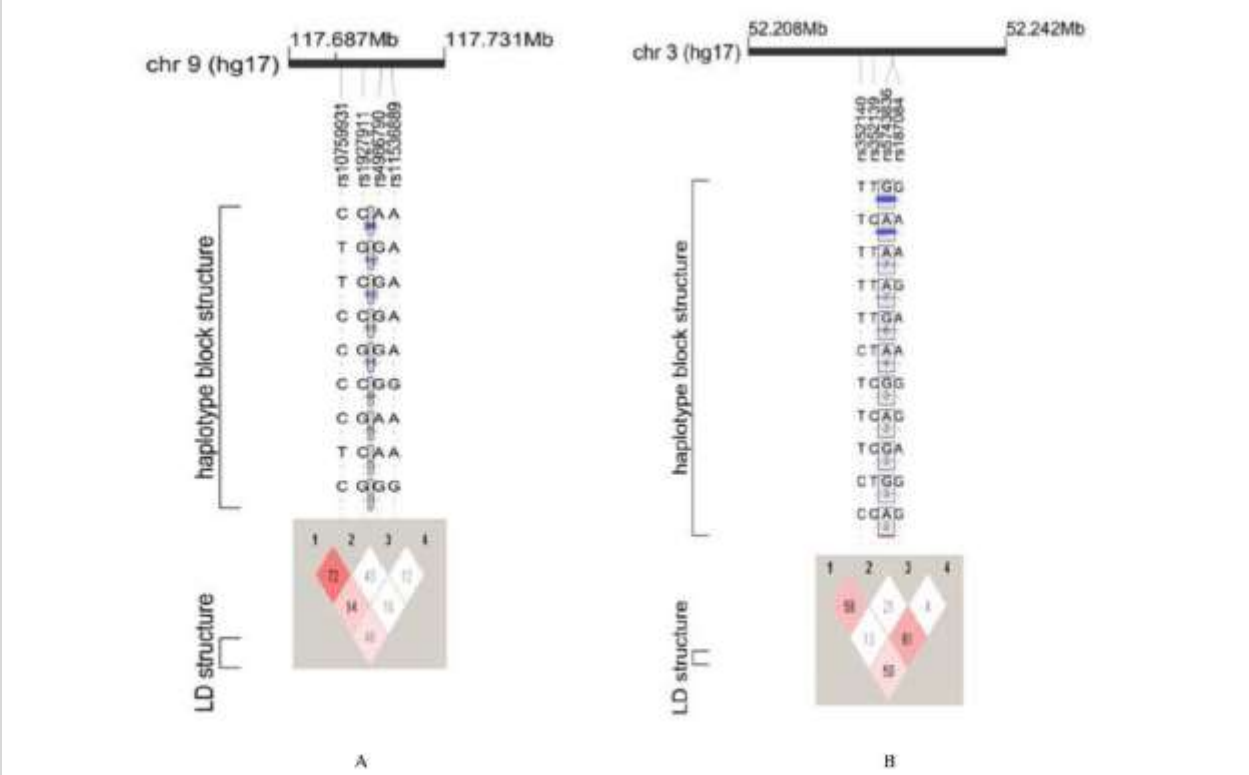
Representative Real-time PCR results of HPV consensus and HPV16 specific sequences in cervical cancer



RFLP results of TLR4 G3725C (rs11536889) polymorphism on ethidium bromide-stained 2% agarose gel. Lane M is 100 bp ladder. Lane 1 is undigested PCR product. Lanes 3, 5 and 7 show GC genotype and Lanes 2, 4 and 6 show CC genotype after digestion with EarI.



RFLP results of TLR9 -1486 T/C SNP on ethidium bromide-stained 2% agarose gel. Lane M is 100 bp ladder. Lane 1 is negative control and Lane 2 is empty. Lane 3 and 6 shows TT TC genotypes respectively and Lanes 4, 5, and 7 show CC genotype after digestion with AflII.



(A) *TLR4* and (B) *TLR9* haplotype block structures and linkage disequilibrium plot

Conclusions: Focus on multivalent HPV vaccination is suggested. TLR4 and TLR9 polymorphisms/haplotypes may serve as a potential biomarker for hrHPV and cervical cancer risk. These polymorphisms also modulated hrHPV co-infections and HPV16 load. Evaluation of a larger sample size covering diverse ethnic populations is warranted. Published in: Scientific Reports 2019. https://doi.org/10.1038/s41598-019-46077-z. Microbial Pathogenesis 2021. https://doi.org/10.1016/j.micpath.2021.105149.

O131 / #927

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON HPV DNA AND MRNA DETECTION
04-20-2023 2:30 PM - 4:00 PM

TRANSLACOL PROJECT: NODAL HPV TUMORAL DNA DETECTION FOR SURVIVAL PREDICTION IN EARLY CERVICAL CANCER PATIENTS WITHOUT PELVIC LYMPH NODE INVASION

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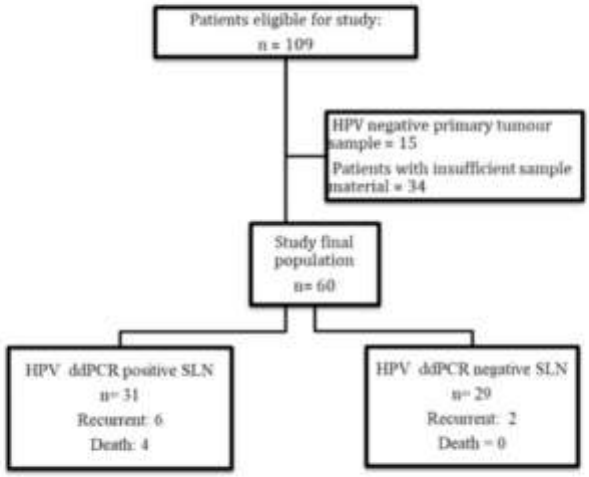
Introduction: In early cervical cancer, 10 to 15% of patients without nodal metastasis (N-) will suffer from recurrences with further similar survival as N+ patients. However, no clinical, imaging or pathological risk-factor is today available to identify them.

Methods: In the present study, we hypothesized that the N- histologically characterized patients who present a poor prognosis could be patients for whom metastasis are missed by classical procedure. Therefore, in the present study, we propose to research HPV tumoral DNA (HPVtDNA) in pelvic Sentinel Lymph Nodes (SLN) biopsy using ultrasensitive droplet-based digital PCR (ddPCR) to detect eventual occult metastasis in a cohort of 109 early cervical cancer patients.

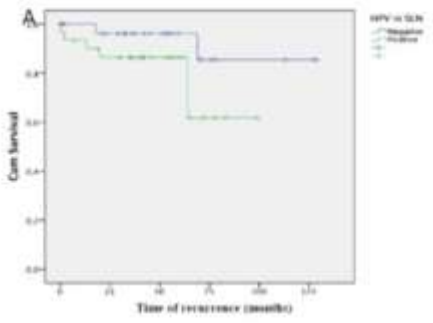
Results: Very interestingly, more than half (51.7 %) patients finally showed positive HPVtDNA positivity in SLN firstly diagnosed negative by histology. Furthermore, patients positive for HPVtDNA in their SLN showed significantly lower disease-specific survival to 10 years than those doubly negative by histology and ddPCR. Taken together, these observations indicate that the use of ultrasensitive ddPCR to evidence HPVtDNA in SLN allows to better define N- early cervical cancer in two subgroups of patients with different prognostic and likely
care.

Figure 1. Flow chart of study inclusions and results of tumoral HPV DNA detection in pelvic Sentinel Lymph Nodes (SLN) using ddPCR.

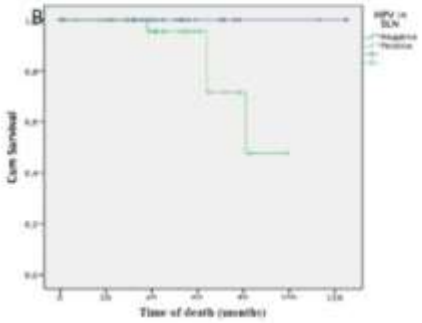


Variables		HPV dPCR negative SLN n= 29 (%)	HPV dPCR positive SLN n= 31 (%)	p- value
Mean follow up (months)	**Mean ± SD (range)**	(52.2 SD 32.9) (1 - 129)	(48 SD 22.3) (7 -99)	0.30
Recurrent disease	**None**	27 (93.1%)	25 (80.6%)	0.15
	Yes	2 (6.9%)	6 (19.4%)	
Mean time for recurrence (months)	**Mean ± SD (range)**	(43.5 SD 36) (18 - 69)	(29.2 SD 29.3) (2 - 64)	0.22
Death for cervical cancer	**Alive**	29 (100%)	27 (87.1%)	0.07
	Death	0	4 (12.9%)	
Mean time for death (months)	**Mean ± SD (range)**		61.75 (38- 81)	

Figure 2. Kaplan Meyer curves in the group of negative SLN and ddPCR results, and in the group of negative SLN with positive detection of cryptic HPVtDNA: A. Progression-free survival to 125 months (10 years and 5 months); B. Disease-specific survival to 125 months (10 years and 5 months).



	Negative	Positive	
PFS (%) to 10 years	93.1%	80.6%	p=0.103



	Negative	Positive	
DSS (%) to 10 years	100%	87.1%	p=0.040

Conclusions: To our knowledge, our study is the first one to evaluate the detection of HPVtDNA in SLN in early cervical cancer using ddPCR and to highlight the interest of such new biomarker as a complementary tool for N- specific early cervical cancer diagnosis in terms of estimating risk of overall survival and recurrence.

O132 / #1046

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON HPV DNA AND MRNA DETECTION
04-20-2023 2:30 PM - 4:00 PM

IMPACT OF HPV MRNA TYPES 16, 18, 45 DETECTION ON THE RISK OF CIN3+ IN YOUNG WOMEN WITH NORMAL CERVICAL CYTOLOGY

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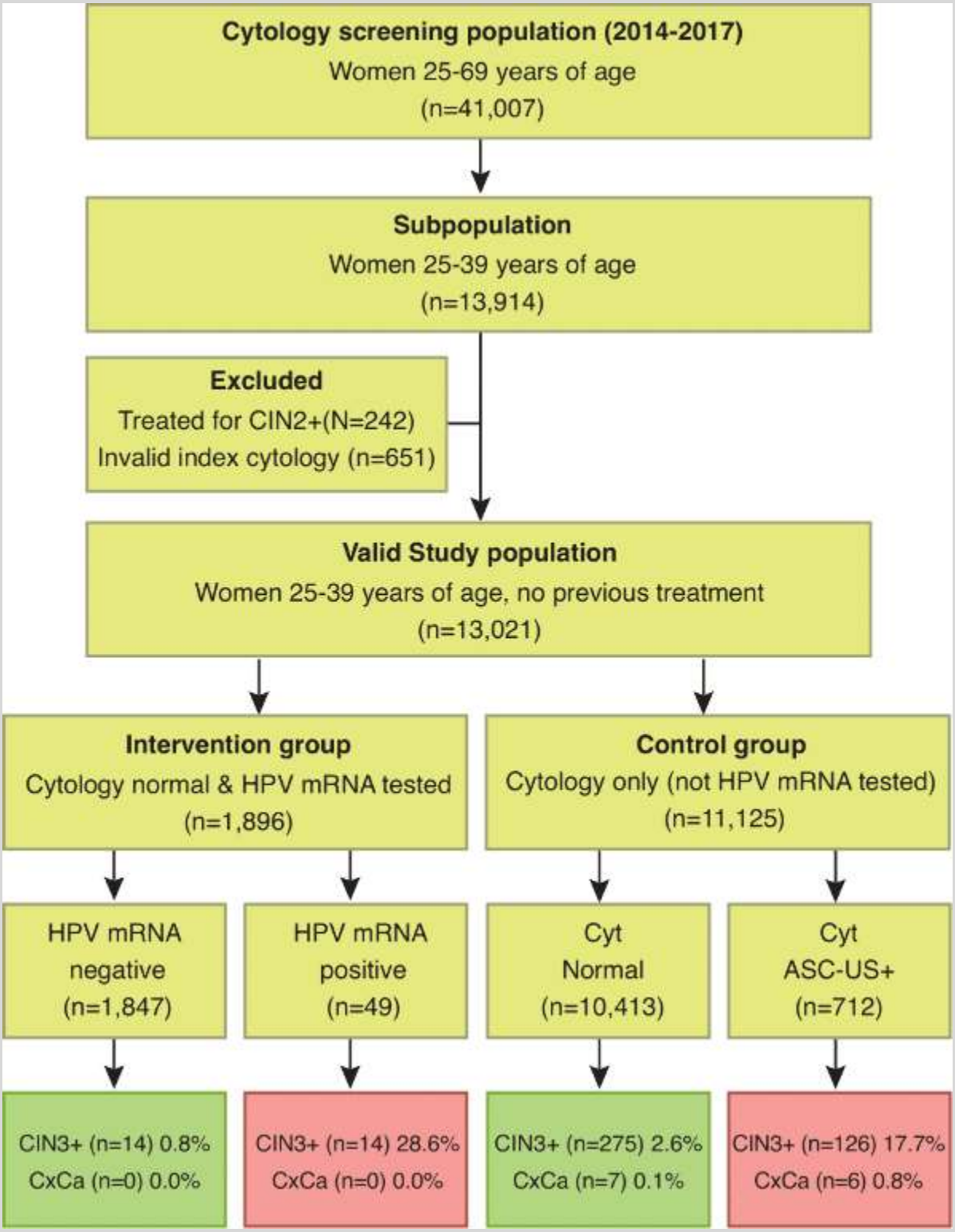
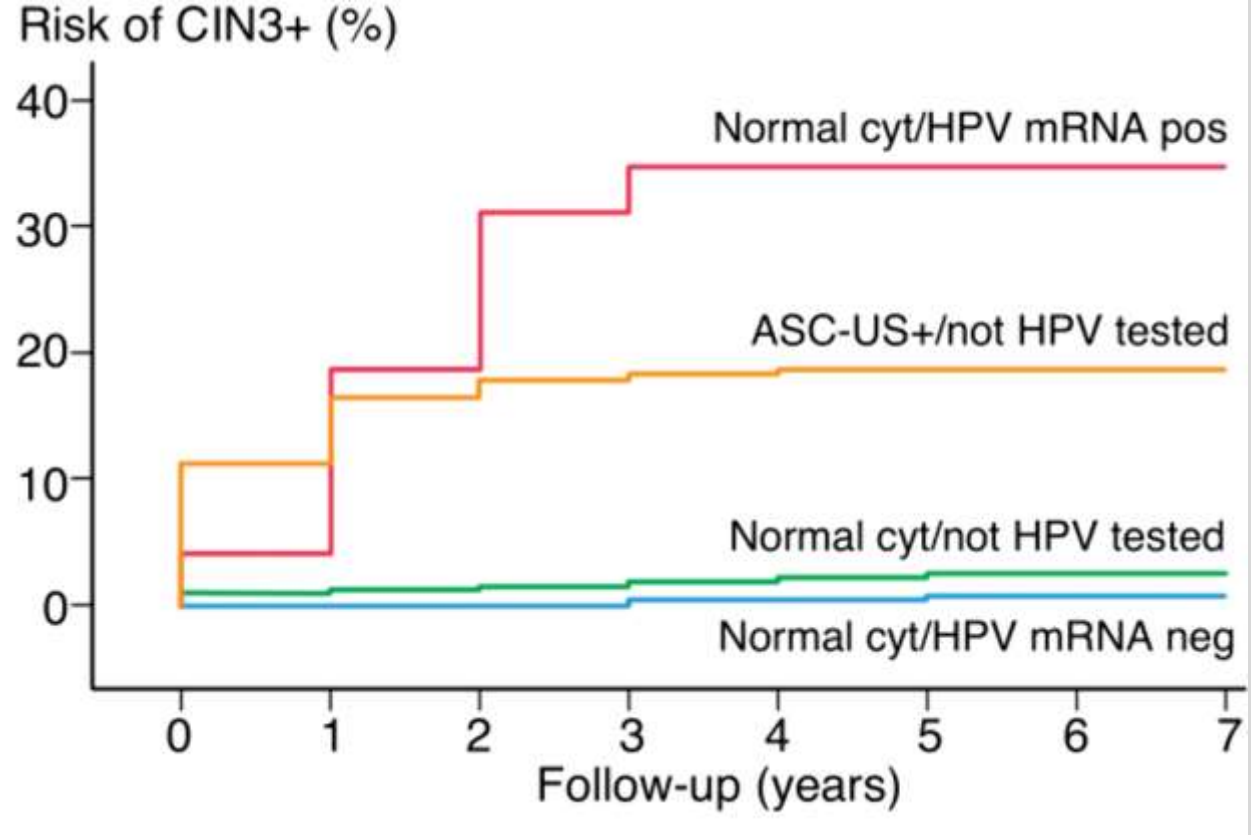
Introduction: Despite a well-established cervical cancer (CC) screening program in Norway, the incidence of CC in young women is increasing. 25% of all women diagnosed with CC had normal cytology three years prior to cancer diagnosis. To reduce cancer incidences missed by cytology, HPV-primary screening has been gradually implemented (2019), while cytology remains for women 25-33 years old. HPV-types (16-18-45) are shown to be the most prevalent types in cervical cancer among young women. This study investigated the detection rate of CIN3+ in women 25-39 years with normal cytology by using a 3-type HPV mRNA test as targeted quality assurance measure compared to cytology only.

Methods: During 2014-2017, samples from 13,021 women 25-39 yrs. attending screening were analyzed at Nordlandssykehuset, Bodø, Norway. Intervention group included 1,896 women with normal cytology and HPV-mRNA test (PreTect SEE, genotyping 16-18-45). Index cytology for HPV-mRNA positive women was re-evaluated. Control group comprised 11,125 women with cytology only. All women were followed-up according to national guidelines throughout December 2021.

Results: 3.3% (429/13,021) had CIN3+ confirmed by biopsy, including 13 cases of invasive CC. In the intervention group, 2.6% (49/1,896) had positive mRNA-test. The risks of CIN3+ among women with positive or negative HPV-mRNA test were 28.6% (14/49) versus 0.8% (14/1847). In the control group, 6.4% (712/11,125) had abnormal cytology (ASC-US+). The risks of CIN3+ among women with abnormal or normal cytology were 17.7% (126/712) versus 2.6% (275/10,413).

Conclusions: Applying a 3-type HPV-mRNA test as an adjunct to cytology will identify women at elevated risk, enabling targeted quality control of cytology readings, improving programme sensitivity by early detection of cell abnormalities. The volume of re-screened cytology samples is low. The risk of CIN3+ among cytology normal, HPV-mRNA (16-18-45) positive women during follow-up is high (28.6%) while double negative women remain at very low risk
(0.8%).


Cytology screening population (2014-2017)
Women 25-69 years of age
(n=41,007)
Subpopulation
Women 25-39 years of age
(n=13,914)
Excluded
Treated for CIN2+(N=242)
Invalid index cytology (n=651)
Valid Study population
Women 25-39 years of age, no previous treatment
(n=13,021)
Intervention group
Cytology normal & HPV mRNA tested
(n=1,896)
Control group
Cytology only (not HPV mRNA tested)
(n=11,125)
HPV mRNA negative (n=1,847)
HPV mRNA positive (n=49)
Cyt Normal (n=10,413)
Cyt ASC-US+ (n=712)
CIN3+ (n=14) 0.8%
CxCa (n=0) 0.0%
CIN3+ (n=14) 28.6%
CxCa (n=0) 0.0%
CIN3+ (n=275) 2.6%
CxCa (n=7) 0.1%
CIN3+ (n=126) 17.7%
CxCa (n=6) 0.8%


Risk of CIN3+ (%)
40
30
20
10
0
Normal cyt/HPV mRNA pos
ASC-US+/not HPV tested
Normal cyt/not HPV tested
Normal cyt/HPV mRNA neg
0
1
2
3
4
5
6
7
Follow-up (years)

O133 / #1050

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON HPV DNA AND MRNA DETECTION
04-20-2023 2:30 PM - 4:00 PM

7-TYPE HPV MRNA TEST IN TRIAGE OF HPV-DNA PRIMARY SCREEN POSITIVE WOMEN

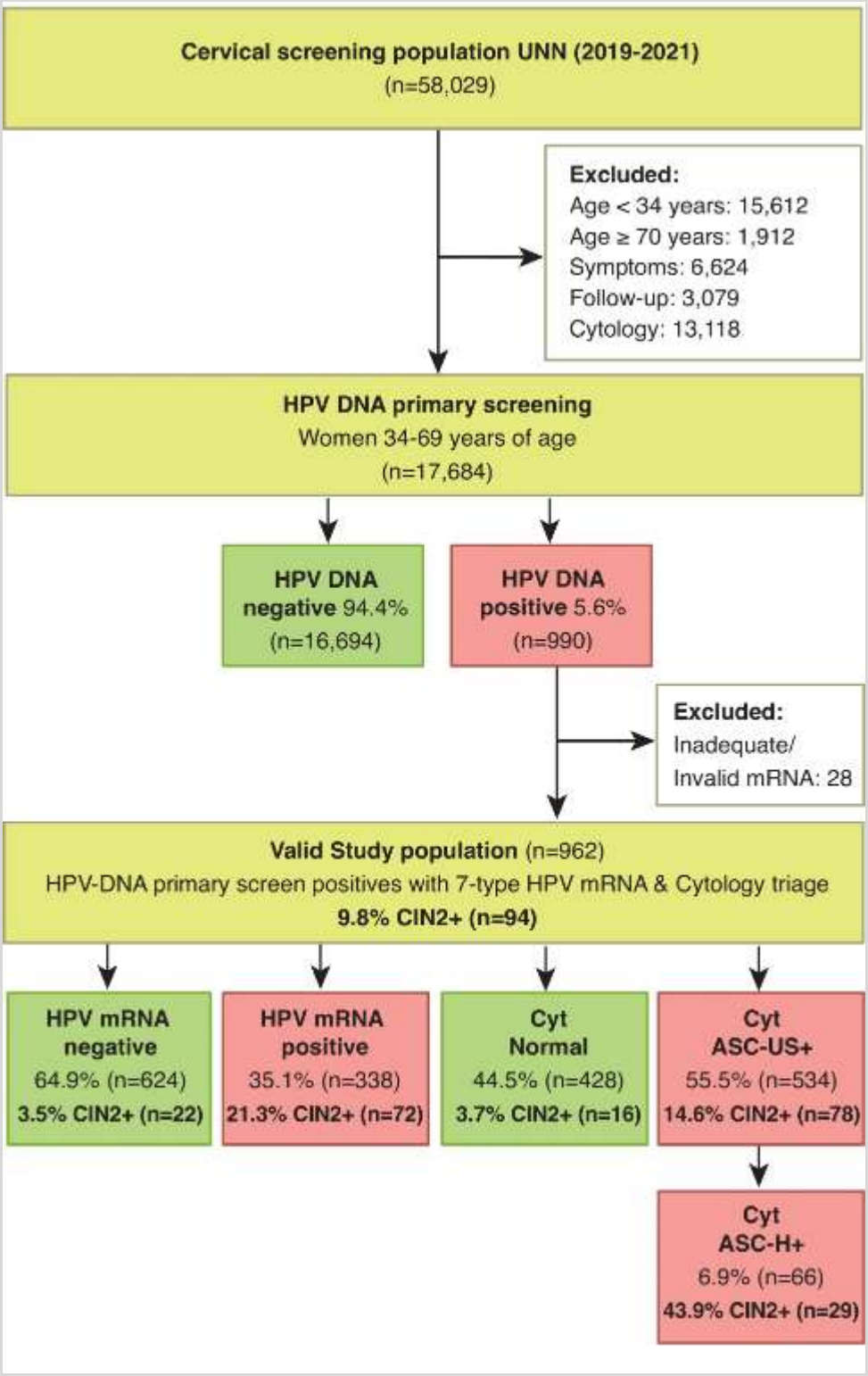
Sveinung Sørbye[1], Bente Falang[2], Mona Antonsen[1]
[1]University Hospital of North Norway, Clinical Pathology, Tromsø, Norway, [2]PreTect AS, Hpv Mrna, Klokkarstua, Norway

Introduction: A plethora of scientific data supports HPV-based screening to be the preferred strategy for cervical cancer prevention. The shift to a more sensitive first line test brings the need of effective triage up for discussion. In 2019, Norway implemented HPV-DNA testing in primary screening for women 34-69 years of age. We studied the performance of a 7-type HPV-mRNA test in triage of HPV+ women compared to cytology as the established reference method.

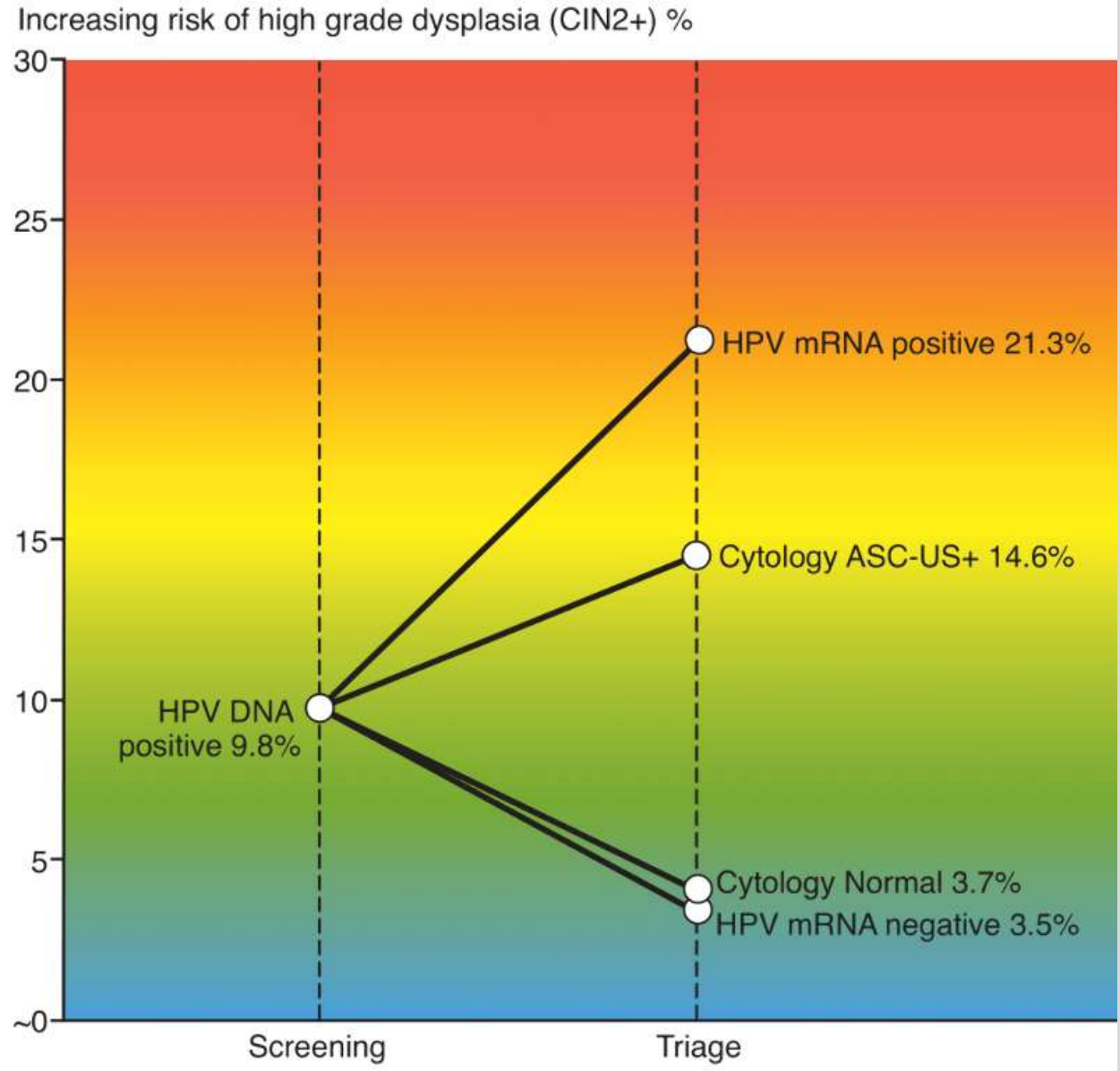
Methods: From 2019 throughout 2021, cervical samples from 17,684 women were enrolled HPV primary screening (Cobas 4800, Roche) at the department of Clinical Pathology, University Hospital of North-Norway. All screen positives were triaged by cytology and by a 7-type HPV mRNA E6/E7 test (PreTect HPV-Proofer'7, genotyping 16-18-31-33-45-52-58) and followed-up according to national guidelines. Study endpoint was histologically confirmed high grade lesion (CIN2+).

Results: 5.6% (990/17,684) had a positive HPV-DNA test, of whom 962 had a valid HPV-mRNA test. 55.5% (534/962) had abnormal cytology (ASC-US+) and 35.1% (338/962) had a positive HPV-mRNA test. Prevalence of CIN2+ was 9.8% (94/962). The sensitivity of cytology and HPV-mRNA was 83.0% (78/94) versus 76.6% (72/94), p=0.36. The specificity was 47.5% (412/868) versus 69.4% (602/868), p<0.001. The PPV for CIN2+ was 14.6% (78/534) for cytology and 21.3% (72/338) for the HPV-mRNA test, p=0.014. NPV was 96.3% (412/428) and 96.5% (602/624). The number of colposcopies per CIN2+ detected by cytology and HPV-mRNA test was 6.8 versus 4.7.

Conclusions: The 7-type HPV mRNA test was significantly more specific than cytology in triage of HPV-DNA screen positive women. Using this biomarker as a threshold for referral to colposcopy may better balance the benefits and harms of screening. Ensured by the triage test`s NPV, women with a positive HPV-DNA test and negative HPV-mRNA test safely can be followed up with repeat HPV-DNA testing



after 12 months.


Increasing risk of high grade dysplasia (CIN2+) %
30
25
20
15
10
5
~0
HPV mRNA positive 21.3%
Cytology ASC-US+ 14.6%
HPV DNA positive 9.8%
Cytology Normal 3.7%
HPV mRNA negative 3.5%
Screening
Triage

O134 / #1296

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON HPV DNA AND MRNA DETECTION
04-20-2023 2:30 PM - 4:00 PM

HPV IN ATYPICAL GLANDULAR CELLS: ASSESSMENT OF NON-HPV16/18 SPECIFIC RISKS

Camilla Lagheden, Emel Yilmaz, Mehran Ghaderi, Joakim Dillner, Miriam Elfström
Karolinska Institutet and Karolinska University Hospital, Center For Cervical Cancer Prevention, Stockholm, Sweden

Introduction: Atypical glandular cells (AGC) are associated with a higher risk for cervical cancer, in particular adenocarcinoma. Most human papillomavirus (HPV) positive AGC contain non-HPV16/18 HPV ("other HPV"), but the risk associated with specific "other HPV" types is not well known.

Methods: Registry linkages identified the women resident in the capital region of Sweden who had had an AGC during 2014-2018, where the index sample had been HPV tested and a subsequent histopathology existed during a follow-up until 2019. Cervical specimens that had been positive for "other HPV" were retrieved and HPV genotyped using general primer PCR with subsequent hybridization to type-specific probes. The 1 minus Kaplan-Meier function defined the cumulative incidence proportion of CIN3+, by specific HPV type. Hazard ratios (HR) for CIN3+ were generated using multivariate Cox regression.

Results: Overall, 341 women with AGC positive for "other HPV" were included. In subsequent histopathology, we found 139 CIN3+ cases (134 were CIN3/AIS and 5 were invasive cervical cancers (ICC)). Four of 5 ICC cases were HPV 45 positive, and one ICC was positive for HPV 31. The cumulative incidence of CIN3+ was highest (83%, 95% CI: 58–97%) among HPV 33 positive women with AGC. HPV 31 positivity conferred the highest HR for CIN3+ relative to other types, both in primary cytology and primary HPV screening (HR: 3.93, 95% CI: 1.12–13.73 and HR: 5.33, 95% CI: 1.55–18.34, respectively).

Conclusions: Among the "other HPV" types, HPV31, 33 and 45 constitute higher risk for CIN3+ among women with AGC, implying that extended HPV genotyping may be useful for AGC management.

O135 / #841

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON HPV DNA AND MRNA DETECTION
04-20-2023 2:30 PM - 4:00 PM

COMPARISON BETWEEN HR-HPV E6/E7 MRNA AND PCR-RDB HPV DNA TEST IN PREDICTING RECURRENCE/RESIDUAL IN HSIL PATIENTS AFTER CONIZATION

Guanxiang Huang[1], Dabin Liu[1], Bin-Hua Dong[1,2], Wenyu Lin[3], Hang-Jing Gao[4], Pengming Sun[2]
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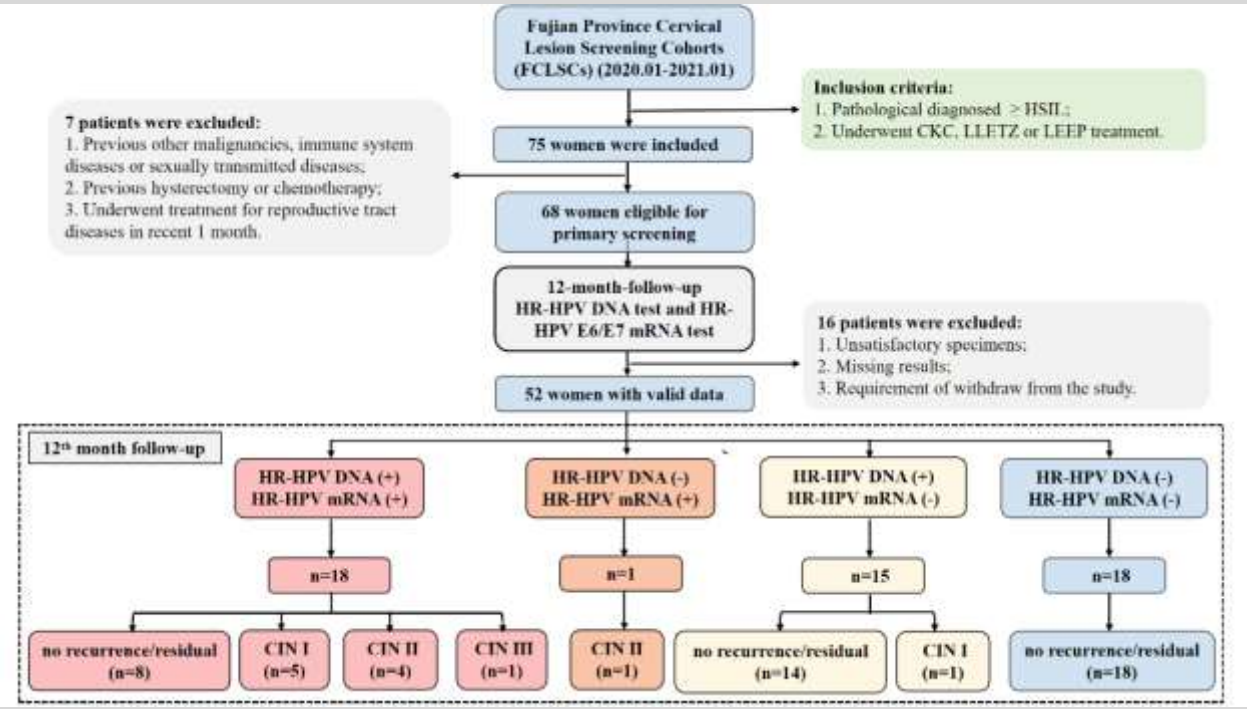
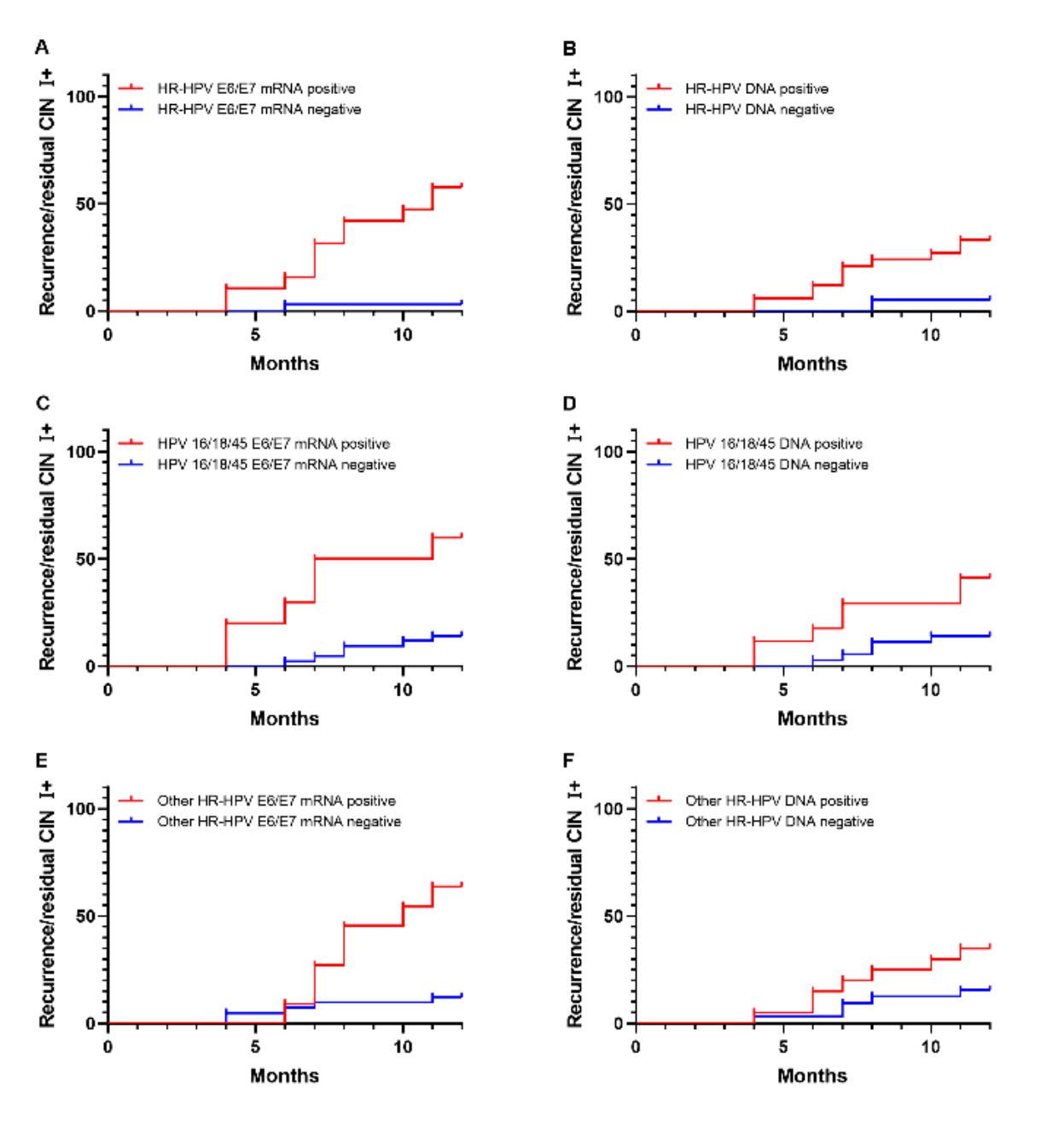
Introduction: HPV DNA test showed high sensitivity and comparatively lower specificity for cervical cancer screening , which might lead to unnecessary invasive examinations for patients. So a new method for HPV test during post-treatment follow-up is urgently needed.

Methods: The study participants was selected from the Fujian Cervical Lesions Screening Cohorts (FCLSCs) from January 2020 to January 2021. A total of 52 women with pathological diagnosis of high-grade squamous intraepithelial lesion (HSIL) or worse after cervical conization were enrolled and under a 12-month follow-up. PCR-RDB HPV DNA and E6/E7 mRNA test were conducted closely within 3-6 months as manifestation for the same HPV infection status.



Results: During 12 months follow-up, 40 patients with no recurrence/residual, 6 patients with CIN (cervical intraepithelial neoplasia) Ⅰ, 5 patients with CIN Ⅱ and 1 patient with CIN Ⅲ were found. Both HR-HPV E6/E7 mRNA and PCR-RDB HPV DNA test showed high sensitivity, while higher specificity

(80.00% in CIN Ⅰ+ & 71.74% in CIN Ⅱ+), positive predictive value (PPV, 57.89% in CIN Ⅰ+, 31.58% in CIN Ⅱ+) were detected in HR-HPV E6/E7 mRNA test, along with a higher specificity and PPV in detection of post-treatment CIN Ⅰ+ (67.50% vs 40.00% for Specificity, 45.83% vs 33.33% for PPV) and CIN Ⅱ+ (60.87% vs 34.78% for Specificity, 25.00% vs 16.67% for PPV) when combining with cytology. Referral colposcopy ratio dropped from 69.23% (36/52) to 46.15% (24/52) when HR-HPV E6/E7 mRNA test was adopted in co-
testing.


A
Recurrence/residual CIN I+
HR-HPV E6/E7 mRNA positive
HR-HPV E6/E7 mRNA negative
Months
B
Recurrence/residual CIN I+
HR-HPV DNA positive
HR-HPV DNA negative
Months
C
Recurrence/residual CIN I+
HPV 16/18/45 E6/E7 mRNA positive
HPV 16/18/45 E6/E7 mRNA negative
Months
D
Recurrence/residual CIN I+
HPV 16/18/45 DNA positive
HPV 16/18/45 DNA negative
Months
E
Recurrence/residual CIN I+
Other HR-HPV E6/E7 mRNA positive
Other HR-HPV E6/E7 mRNA negative
Months
F
Recurrence/residual CIN I+
Other HR-HPV DNA positive
Other HR-HPV DNA negative
Months

Comparison of diagnostic efficiency of different tests in cervical lesions (N=52)

Items	Cytology	HR-HPV DNA	HR-HPV E6/E7 mRNA
CIN I+			
Sensitivity (95% CI)	50.00% (22.29%-77.71%)	91.67% (59.75%-99.56%)	91.67% (59.75%-99.56%)
Specificity (95% CI)	82.50% (66.64%-92.11%)	67.50% (50.76%-80.93%)	80.00% (63.86%-90.39%)
PPV (95% CI)	46.15% (20.40%-73.88%)	45.83% (26.17%-66.76%)	57.89% (33.97%-78.88%)
NPV (95% CI)	84.62% (68.79%-93.59%)	96.43% (79.76%-99.81%)	96.97% (82.49%-99.84%)
PLR (95% CI)	2.86 (1.19-6.88)	2.82 (1.75-4.55)	4.58 (2.41-8.72)
NLR (95% CI)	0.61 (0.34-1.08)	0.10 (0.02-0.83)	0.10 (0.02-0.69)
CIN II+			
Sensitivity (95% CI)	50.00% (13.95%-86.05%)	83.33% (36.48%-99.12%)	100.00% (51.68%-100.00%)
Specificity (95% CI)	78.26% (63.24%-88.55%)	39.13% (25.46%-54.61%)	71.74% (56.32%-83.54%)
PPV (95% CI)	23.08% (6.16%-54.02%)	15.15% (5.72%-32.67%)	31.58% (13.56%-56.51%)
NPV (95% CI)	92.31% (78.03%-97.99%)	94.74% (71.89%-99.72%)	100.00% (87.02%-100.00%)
PLR (95% CI)	2.30 (0.87-6.07)	1.37 (0.89-2.10)	3.54 (2.23-5.61)
NLR (95% CI)	0.64 (0.28-1.44)	0.43 (0.07-2.72)	0.00 (0.00-NaN)

Notes: CIN I+, cervical intraepithelial neoplasia including CIN I, CIN II and CIN III; CIN II+, cervical intraepithelial neoplasia including CIN II and CIN III; PPV, positive predicting value; NPV, negative predicting value; PLR, positive likelihood ratio; NLR, negative likelihood ratio; 95% CI, 95% confidence interval.

Comparison of diagnostic efficiency of different co-testing methods in cervical lesions (N=52)

Items	HR-HPV DNA & cytology co-testing[a]	HR-HPV E6/E7 mRNA & cytology co-testing[b]
CIN I+		
Sensitivity (95% CI)	100.00% (69.87%-100.00%)	91.67% (59.75%-99.56%)
Specificity (95% CI)	40.00% (25.28%-56.61%)	67.50% (50.76%-80.93%)
PPV (95% CI)	33.33% (19.10%-51.05%)	45.83% (26.17%-66.76%)
NPV (95% CI)	100.00% (75.93%-100.00%)	96.43% (79.76%-99.81%)
PLR (95% CI)	1.67 (1.29-2.15)	2.82 (1.75-4.55)
NLR (95% CI)	0.00 (0.00-NaN)	0.12 (0.02-0.83)
Proportion of referral colposcopy	69.23% (36/52)	46.15% (24/52)
False positive rate	66.67% (24/36)	54.17% (13/24)
False negative rate	0.00% (0/16)	3.57% (1/28)
CIN II+		
Sensitivity (95% CI)	100.00% (51.68%-100.00%)	100.00% (51.68%-100.00%)
Specificity (95% CI)	34.78% (21.77%-50.32%)	60.87% (45.40%-74.54%)
PPV (95% CI)	16.67% (6.97%-33.47%)	25.00% (10.60%-47.05%)
NPV (95% CI)	100.00% (75.93%-100.00%)	100.00% (84.98%-100.00%)
PLR (95% CI)	1.53 (1.24-1.89)	2.56 (1.78-3.66)
NLR (95% CI)	0.00 (0.00-NaN)	0.00 (0.00-NaN)
Proportion of referral colposcopy	69.23% (36/52)	46.15% (24/52)
False positive rate	83.33% (30/36)	75.00% (18/24)
False negative rate	0.00% (0/16)	0.00% (0/28)

Notes: CIN I+, cervical intraepithelial neoplasia including CIN I, CIN II and CIN III; CIN II+, cervical intraepithelial neoplasia including CIN II and CIN III; [a] HR-HPV DNA & cytology co-testing includes cytology≥ASCUS and/or HR-HPV DNA positive; [b] HR-HPV E6/E7 mRNA & cytology co-testing includes cytology≥ASCUS and/or HR-HPV E6/E7 mRNA positive. PPV, positive predicting value; NPV, negative predicting value; PLR, positive likelihood ratio; NLR, negative likelihood ratio; 95% CI, 95% confidence interval.

Conclusions: HPV E6/E7 mRNA can provide a reliable clinical reference for post-treatment patients with ≥HSIL, the specificity, PPV and PLR was higher than those of PCR-RDB HPV DNA test, and the sensitivity was similar.

O136 / #1376

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON HPV DNA AND MRNA DETECTION
04-20-2023 2:30 PM - 4:00 PM

GENOME-WIDE IDENTIFICATION OF MIRNAS THAT PREDICT THE PRESENCE OF CIN3 AND CERVICAL CANCER (CIN3+) IN CERVICAL SCRAPES OF HPV+ WOMEN

Martha González-Ramírez[1], Juan Floréz[1], Samuel Agudelo[1], Maria Agudelo Fernandez[1], Carlos Orozco Castaño[1], Li Li[2], Jone Garai[2], Jovanny Zabaleta[3], Gloria Sanchez[1]
[1]University of Antioquia, Infection And Cancer Group, School Of Medicine And Corporación Académica Para El Estudio De Patologías Tropicales, Medellín, Colombia, [2]Louisiana State University Health Sciences Center,, Stanley S. Scott Cancer Center, New Orleans, United States of America, [3]Louisiana State University Health Sciences Center,, Department Of Interdisciplinary Oncology,stanley And S. Scott Cancer Center, New Orleans, United States of America

Introduction: hrHPV testing followed by treatment of precancerous lesions is effective for reducing cervical cancer mortality especially in LMICs, where operator-dependent approaches are challenging. But it has low specificity, increases referrals to clinical management, and overtreatment of women with non-progressive disease. Deregulated expression of miRNAs are markers of hrHPV-induced cervical carcinogenesis and offer the possibility to develop operator-independent tests. We identified differentially expressed miRNAs that distinguished CIN3+ and <CIN1 in HPV+ women.

Methods: Baseline cervical scrapes of 45 of CIN3+ cases diagnosed after 2-years follow-up of the 1.122 hrHPV+ women of the ASCUS-COL trial, and of age-matched 45 ≤CIN1 controls were retrospectively retrieved (Table 1, Figure 1). QIAseq kits for miRNA-specific libraries and Quality Control (QC) Assays were used for miRNAseq in NextSeq platform. Legacy Analysis Pipelines (GeneGlobe Data Analysis Center) was used for data processing. miRNAs were counted and annotated to miRBase v.21 with exact match settings using Bowtie2 algorithm. DESeq2 algorithm was used for normalization and differential expression analysis. Only miRNAs with an average of ≥10 read counts, were analyzed. Area Under the Curve (AUC) with DeLong confidence intervals and Odds Ratios were estimated using the RNAseq normalized counts. Normalized counts of each miRNA with significant p values in the 3 estimates, were averaged and included in Multivariate Logistic Regression models with CIN3+ as

Table 1. Distribution of sociodemographic characteristics and risk factors of study population set.

Characteristic	≤CIN1 n 45	%	CIN3+ n 45	%	All n 90	%	p-Value[a]
NEG	33	(100)	0	(0)	33	(36.67)	-
CIN1	12	(100)	0	(0)	12	(13.33)	
CIN3	0	(0)	41	(100)	41	(45.56)	
Cancer (SSC -ASC)	0	(0)	4	(100)	4	(4.44)	
Age (years)							
Median [IQR]	31 [25 - 40]		31 [26 -39]		31 [25 - 40]		
≤30	21	(48.84)	22	(51.16)	43	(47.78)	1
>30	24	(51.06)	23	(48.94)	47	(52.22)	
Marital status							
Married/cohabiting	20	(45.45)	24	(54.55)	44	(48.89)	0.616
Divorced/separated/widowed	5	(62.5)	3	(37.5)	8	(8.89)	
Single	20	(52.63)	18	(47.37)	38	(42.22)	
Education level							
College or higher	15	(42.86)	20	(57.14)	35	(38.89)	0.551
High School	15	(53.57)	13	(46.43)	28	(31.11)	
Up to some/Incomplete High School	15	(55.56)	12	(44.44)	27	(30)	
Age of first sexual intercourse (years)							
Median [IQR]	17 [15 - 20]		17 [16 -18]		17 [16 - 18]		
≤ 16	16	(42.11)	22	(57.89)	38	(42.22)	0.285
> 16	29	(55.77)	23	(44.23)	52	(57.78)	
Lifetime sexual partners							
Median [IQR]	3 [2 - 5]		4 [3 - 6]		3 [2 - 5]		
1 - 2	13	(56.52)	10	(43.48)	23	(25.56)	0.711
3 - 4	18	(50)	18	(50)	36	(40)	
≥ 5	14	(45.16)	17	(54.84)	31	(34.44)	
Parity							
Median [IQR]	1 [1- 2]		1 [1 - 2]		1 [1 - 2]		
Never	11	(52.38)	10	(47.62)	21	(23.33)	0.966
1 - 2	25	(49.02)	26	(50.98)	51	(56.67)	
≥ 3	9	(50)	9	(50)	18	(20)	
Oral contraceptive intake (years)							
Median [IQR]	2 [2- 5]		3 [1- 7]		3 [1- 6]		
Never	11	(78.57)	3	(21.43)	14	(15.56)	0.067
< 5	20	(44.44)	25	(55.56)	45	(50)	
≥5	14	(45.16)	17	(54.84)	31	(34.44)	
Frequency of cytology use							
Once or more than once every year	33	(48.53)	35	(51.47)	68	(75.56)	0.822
Once every 2-5 years	7	(58.33)	5	(41.67)	12	(13.33)	
Do not know/no answer	5	(50)	5	(50)	10	(11.11)	
hrHPV types frequency							
HPV 16 and/or 18	20	(41.67)	28	(58.33)	48	(53.33)	0.139
Other hrHPV types[b]	25	(59.52)	17	(40.48)	42	(46.67)	

Abbreviations: ≤CIN1 Low-grade neoplasia (NEG and CIN1); NEG: Negative or without lesion; CIN1: Cervical intraepithelial neoplasia grade 1; CIN3+: High-grade neoplasia (CIN3 and Cancer); CIN3: Cervical intraepithelial neoplasia grade 3; IQR: Interquartile range.

[a]Person's chi-squared test.

[b]Other hrHPV types = HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.

Table 1. Distribution of sociodemographic characteristics and risk factors of study population.

outcome.

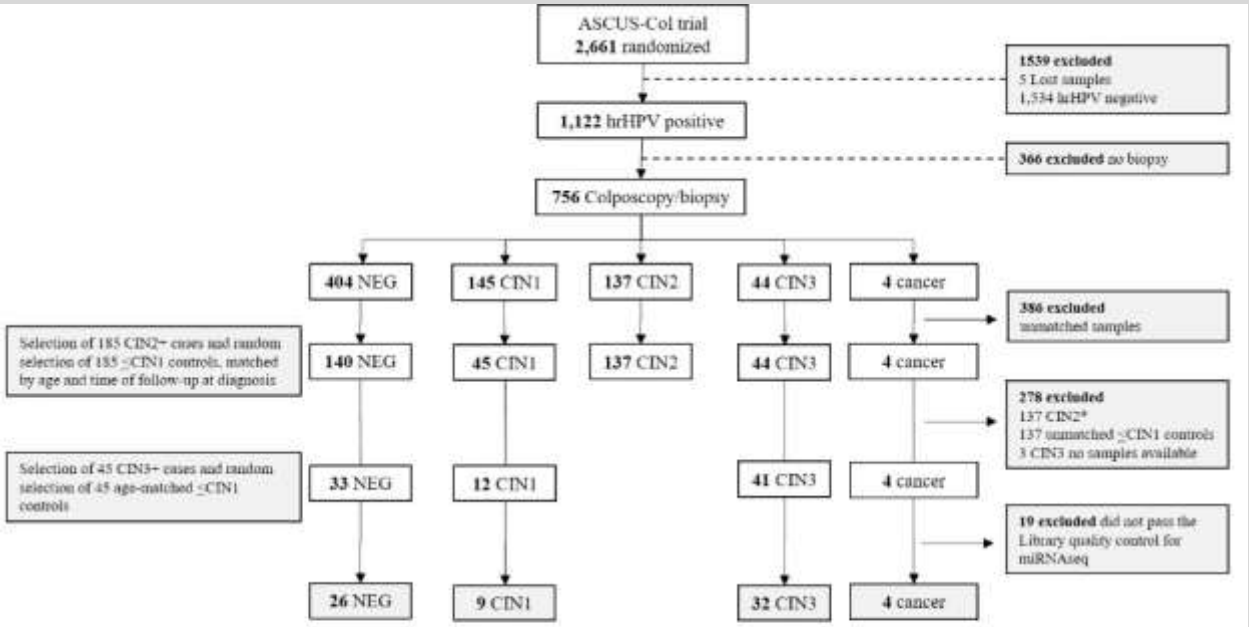


Figure. 1. Flowchart of the selection of samples. CIN1: Cervical Intraepithelial Neoplasia grade 1, CIN2: Cervical Intraepithelial Neoplasia grade 2, CIN3: Cervical Intraepithelial Neoplasia grade 3. Cancer (SCC, Squamous Cervical Carcinoma). *CIN2 lesions do not were selected.

Results: 71 samples (35 <CIN1 and 36 CIN3+) passed QIAseq®-miRNA-libraries QC. Nineteen of the 93 differentially expressed miRNAs showed AUCs >0.6 ($p<0.05$) and significant ORs ($p<0.05$). The model that best predicted CIN3+ included 11 miRNAs (AUC: 0.91, 95%CI 0.84-0.98). At a Youden-Index-based optimal cut-off (0.618), the sensitivity was 0.75 (95%CI 0.61-0.89) and the specificity 0.94 (95%CI 0.86-1) (Figure

2).

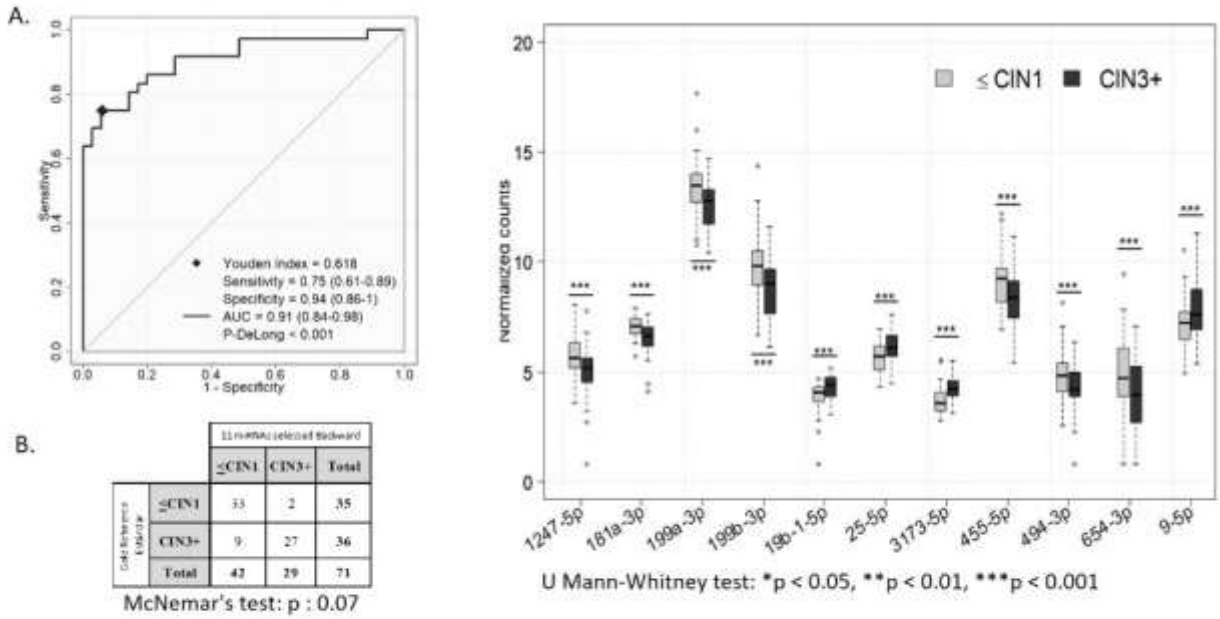


Figure 2. Performance of miRNAs signature to detect CIN3+ in exfoliated samples of HPV-positive women. (A) Receiver operating characteristics (ROC) curve and area under the curve (AUC) of the 11-miRNA panel for detection of CIN3+ in cervical exfoliates HPV-positive samples (35 ≤CIN1 and 36 CIN3). (B) Table 2x2 at cutoff 0.618, selected via Youden's index (C) Expression levels of the 11 miRNAs in HPV-positive exfoliated samples, ≤CIN1(gray light color box) and CIN3+(black box).

Conclusions: Our findings warrant further clinical independent validation of this panel of miRNAs as biomarkers to distinguish HPV+ women with or without progressive disease.

O137 / #856

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON HPV DNA AND MRNA DETECTION
04-20-2023 2:30 PM - 4:00 PM

HOME-BASED HPV SELF-SAMPLING ASSISTED BY A CLOUD-BASED ELECTRONIC DATA SYSTEM_ LESSONS LEARNT FROM A PILOT COMMUNITY CERVICAL CANCER SCREENING CAMPAIGN IN RURAL ETHIOPIA

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Introduction: Primary HPV testing and triage of HPV -positive women is an effective cervical cancer screening strategy. Such a multi-visit screening algorithm is also promising for community-based screening in resource-poor communities, provided a robust tracking system is in place.

Methods: A cervical cancer screening campaign was conducted in a rural community in Ethiopia. All women aged 25-65 years were offered genital self-sampling using the Evalyn Brush. Samples were HPV-DNA-tested at a central laboratory. Key indicators were captured on tablet computers and linked by a cloud-based information system. HPV-positive women were examined at the local clinic using portable colposcopy, p16/ki-67 dual stain cytology and biopsy examination. CIN2 + women were referred for LEEP to the referral hospital.

Results: Of 749 enumerated age-eligible women 634(85%, (95% CI 82-88)) consented to screening, 429 samples were adequate for HPV testing, giving a total testing coverage of 57% (95% CI 53-62). The hrHPV prevalence was 14% (95% CI 5-22), 72% (95% CI 60-64) attended the clinic for a triage examination. Home-based HPV-DNA self-sampling and clinic-based triage assisted by cloud-based information technology is feasible in rural Ethiopia. Key components of such strategy are broad community awareness, high competency of community workers, and establishment of an adequate self-sampling and HPV-DNA testing platform.

Conclusions: Our pilot study has provided a proof of concept to the approach of a community based, multi-contact cervical cancer screening when assisted by a robust digital data collection system. The results of our cervical cancer screening campaign lend promise to implementation of high access and high quality cervical cancer screening programs also in rural and resource-poor communities. Main elements are a broad community awareness and high competency of community workers as well as establishment of an adequate self-sampling and HPV-DNA testing platform.

O138 / #1704

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: BIOMARKERS FOR MANAGEMENT OF CERVICAL LESIONS WITH AN EMPHASIS ON HPV DNA AND MRNA DETECTION
04-20-2023 2:30 PM - 4:00 PM

A RANDOMIZED DOUBLE-BLIND PHASE II CLINICAL TRIAL OF AN HPV THERAPEUTIC VACCINE, PEPCAN, AND CANDIDA ADJUVANT FOR TREATING CERVICAL INTRAEPITHELIAL NEOPLASIA 2/3 (CIN2/3)

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Introduction: A non-surgical alternative for treating CIN2/3 would be desirable for women of childbearing age due to a risk of cervical incompetency in subsequent pregnancies following surgical treatments. PepCan consists of four current good manufacturing-grade HPV 16 E6 peptides and a Candida skin testing reagent (Candin®, Nielsen Biosciences), because of Candida's ability to regress common warts in humans, and to promote T cell proliferation and interleukin 12 secretion in vitro.

Methods: In this single-center, randomized, double-blind Phase II study (NCT02481414), women with biopsy-confirmed CIN2/3 were treated with PepCan or Candida (1:1). Four intradermal injections were given 3 weeks apart which were followed with two visits 6 months apart. Histological responses were assessed using quadrant biopsies, and those whose lesions regressed to no CIN were considered to be responders. Regression rate of each treatment group was compared to that of a historical placebo group following the same treatment schedule. Adverse events (AEs) were assessed using Common Terminology Criteria for Adverse Events Version 4.

Results: Of 99 subjects screened, 81 (81.8%) qualified for vaccination, and 80 received at least one vaccination. No dose-limiting toxicity was observed. Delayed injection site reactions and myalgia were more frequent with PepCan compared to Candida (Table 1). With the intention-to-treat analysis, PepCan showed 30.8% efficacy (12 of 39, p=0.16) while Candida demonstrated 47.6% efficacy (20 of 42, p=0.0004). Likewise, with the per-protocol analysis, PepCan showed 45.8% efficacy (11 of 24, p=0.06) and Candida showed 62.1% efficacy (18 of 29, p=0.0002). There was no difference between efficacy of PepCan and Candida (Figure 1). Virological response, immunological response, cervical microbiome, and plasma cytokine/chemokine/metabolites are being analyzed.

Table 1. A comparison of injection-related AEs occurring in ≥5% of injections with PepCan or *Candida*

	PepCan n = 152			*Candida* n = 164			
	Grade 1 n (%)	Grade 2 n (%)	All Grades n (%)	Grade 1 n (%)	Grade 2 n (%)	All Grades n (%)	*P* value*
Fever	9 (5.9%)	1 (0.7%)	10 (6.6%)	3 (1.8%)	0 (0.0%)	3 (1.8%)	0.06
Headache	13 (8.6%)	4 (2.6%)	17 (11.2%)	15 (9.2%)	3 (1.8%)	18 (11.0%)	0.91
Injection site reaction, < 24 h	63 (41.5%)	25 (16.5%)	88 (57.9%)	58 (35.4%)	31 (18.9%)	89 (54.3%)	0.54
Injection site reaction, ≥ 24 h	23 (15.1%)	31 (20.4%)	54 (35.5%)	39 (23.8%)	18 (11.0%)	57 (34.8%)	**0.02**
Myalgia	35 (23.0%)	2 (1.3%)	37 (24.3%)	9 (5.5%)	1 (0.6%)	10 (6.1%)	**<0.001**
Nausea	19 (12.5%)	0 (0.0%)	19 (12.5%)	18 (11.0%)	0 (0.0%)	18 (11.0%)	0.73

n=number of injections, * Fisher's exact test, bold indicates statistically significant comparisons

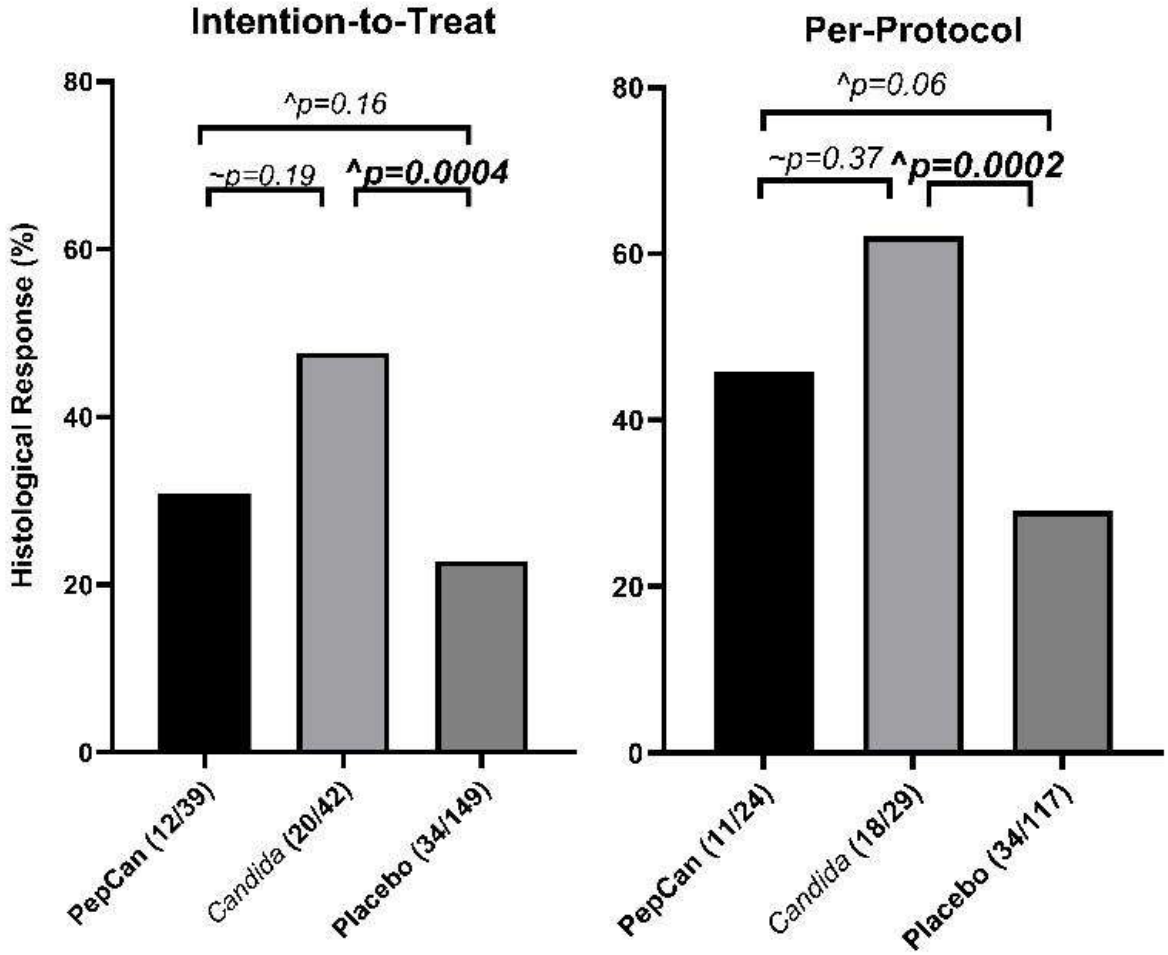

Figure 1 Histological responses of PepCan and *Candida* treatment groups in comparison to a historical placebo group (Meyskens et al., J Natl Cancer Inst, 1994). ^binomial test. ~Fisher's exact test.

Conclusions: PepCan and Candida treatments are safe. Only Candida was effective in inducing histological regression in the intention-to-treat and per-protocol analyses. Candida alone could become a new treatment for CIN2/3, which can be administered by non-physicians.

O139 / #721

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: EPIDEMIOLOGY & RISK FACTORS
04-21-2023 8:00 AM - 9:30 AM

GLOBAL AND REGIONAL ESTIMATES OF HPV TYPE-SPECIFIC ATTRIBUTION IN CERVICAL CANCER: A SYSTEMATIC REVIEW AND META-ANALYTICAL COMPARISON VERSUS NORMAL CERVICAL CYTOLOGY

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Introduction: Estimates of cervical cancer (CC) fractions attributable to HPV genotypes are essential to inform CC prevention programmes, but are hampered because of confounding by sharing common transmission routes and distinguishing causal types in multiple HPV infections.

Methods: We performed a systematic review and meta-analysis, including 917 studies with 90,353 CC and 1,663,790 cytologically normal controls. Type-specific odds ratios (ORs) of HPV prevalence in cases versus controls were calculated by multivariate generalized linear models (GLM), adjusted for region and HIV status. Types with OR>1 were judged as attributable. Regional attributable fractions (AFs) were calculated as prevalence in CC multiplied by (1-1/OR). Global AFs were calculated from regional AFs weighted by regional CC burden in 2020 (GLOBOCAN). AFs were proportionally adjusted to sum to 100%.

Results: Nineteen types were attributable to CC. HPV16 had highest global AF (60.6%), followed by HPV18(16.2%), HPV45(5.6%), HPV33(3.6%), HPV58(3.3%), HPV52(2.5%), HPV31(2.0%), and HPV35(1.5%). The remaining attributable types (HPV59, HPV39, HPV56, HPV73, HPV51, HPV26, HPV68, HPV30, HPV67, HPV69, and HPV82) had individual AFs <1%, and a combined AF of 4.7%. For each region, HPV16 and 18 were the most attributable types, with a combined AF of 73.5% in Eastern Asia, 76.9% in Africa, 76.3% in Southern/Western Asia, 82.5% in North America, 83.0% in Europe, 83.5% in Central/South America, and 91.7% in Oceania, respectively. The third most attributable type was HPV45 in Oceania (4.5%), North and Central/South Americas (each 5.4%), Southern/Western Asia (6.3%) and Africa (9.9%), but HPV33 in Europe (4.7%) and HPV58 in Eastern Asia (8.0%). AF of HPV35 was higher in Africa (3.1%) than in other regions (0.7-1.6%). Combined HPV16/18/31/33/45/52/58 AF was >93% in every region.

Conclusions: This novel methodological approach, based on up-to-date and large meta-analytic datasets, provides robust estimates of AFs of HPV types causally related to CC, at global and regional levels.

O140 / #1000

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: EPIDEMIOLOGY & RISK FACTORS
04-21-2023 8:00 AM - 9:30 AM

HPV-RELATED PRECANCEROUS CERVICAL LESIONS AND PRETERM BIRTHS: A DATA LINKAGE STUDY OF BIRTHS IN NSW, AUSTRALIA, 2000-2020

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Introduction: Excisional treatment for precancerous cervical lesions has been linked to preterm births (PTBs) in future pregnancies. Women with untreated/pre-treatment precancerous abnormalities, have also been shown to have an increased, albeit lower, risk of PTBs. We examined PTB rates in NSW women with a previous precancerous abnormality, as a benchmark for future HPV vaccination impact studies. Treatment is recommended for most histologically-confirmed high-grade lesions, and many women with low-grade lesions also received treatment prior to changes in recommendations in 2006.

Methods: Using linked data from the NSW Perinatal Data Collection and Pap Test Register, we compared rates of PTBs (<37 weeks gestation) in women with a previous histologically-confirmed high-grade/ low-grade lesion and women with no prior histological abnormalities (previous negative/benign cervical histology or no previous histology recorded) using logistic regression in live singleton births 01/01/2000-30/06/2020. We adjusted for year of birth of infant, and a range of relevant socio-demographic/health/obstetric factors (Table).

Results:

Table: Rates and odds ratios for preterm births (<37 weeks gestation) in singleton liveborn infants in NSW between 01/01/2000-30/06/2020 in women with a previous histologically-confirmed low-grade or high-grade cervical lesion compared to women with no previous abnormality (either no previous recorded cervical histology or only negative/benign cervical histology).

Histological lesion prior to birth	Preterm births/Total n/N (%)	Unadjusted OR (95%CI)	Adjusted OR* (95%CI)
No or only negative/benign histological lesion	506,295/9,252,083 (5.47%)	Reference	Reference
Low-grade histological lesion	5,284/74,927 (7.05%)	1.31 (1.26-1.36)	1.22 (1.18-1.27)
High-grade histological lesion	6,897/85,064 (8.11%)	1.52 (1.47-1.58)	1.39 (1.34-1.43)
Total	518476/9,412,074 (5.51%)		

* Adjusted for year of birth of infant, number of previous pregnancies, previous PTBs, and maternal diabetes, chronic hypertension, pregnancy-induced hypertension, remoteness of residence, area-level socio-economic status, smoking in 2nd half of pregnancy and region/country of birth.
n/N: Number of preterm births/total number of women with the confirmed histological lesion prior to the birth of a live singleton infant
OR: odds ratio; CI: confidence interval

Of 9,412,074 live singleton births, 5.51% were preterm (8.11% in women with previous high-grade histology; 7.05% with previous low-grade histology) (Table). Compared to women with no previous

abnormality, women with previous high-grade histology (odds ratio [OR] 1.52, 95% confidence interval [95%CI]:1.47-1.58) and previous low-grade histology (OR 1.31, 95%CI:1.26-1.36) were significantly more likely to have a PTB ($p<0.001$). Increased odds of a PTB post a high-grade (adjusted OR [aOR] 1.39, 95%CI:1.34-1-43) and low-grade (aOR 1.22, 95%CI:1.18-1.27) lesion ($p<0.001$) remained after adjusting for socio-demographic/health/obstetric factors (Table)

Conclusions: Women with abnormal cervical histology, especially a previous high-grade diagnosis, had increased PTBs in future pregnancies. Excisional treatment hasn't been recommended for women with low-grade histology since 2006. Ongoing analysis is examining whether women with low-grade lesions who were less likely to receive treatment (i.e., after 2006) were also at increased risk of PTB, which may relate to HPV infection itself, residual confounding or other factors.

O141 / #1110

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: EPIDEMIOLOGY & RISK FACTORS
04-21-2023 8:00 AM - 9:30 AM

SEXUALLY TRANSMITTED INFECTIONS AND HPV CO-INFECTION AMONG FEMALE SEX WORKERS FROM MUMBAI, INDIA: A COMPARATIVE STUDY OF 2009 AND 2019 COHORTS

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Introduction: Objectives: To compare the prevalence of syphilis, hepatitis B, hepatitis C, HIV and high-risk HPV co-infection and associated factors among two cohorts (2009 and 2019) of female sex workers (FSWs) receiving care at a Women's health clinic in Mumbai, India.

Methods: We performed a retrospective cohort study. All consecutive FSWs 18 years and older during the years 2009 and 2019 who consented were eligible for inclusion. Participants were clinically evaluated using blood, vaginal and endocervical swabs for at least five STIs: high-risk HPV (HR-HPV), HCV, HBV, HIV, and syphilis. The difference in demographic characteristics and HPV/STI co-infection patterns between the 2009 and 2019 cohorts was assessed using binary logistic regression, chi-square test or Mann-Whitney U test (as applicable).

Results: Altogether, 300 participants in the 2009 cohort and 400 in the 2019 cohort met the eligibility criteria. There was a statistically significant difference between the 2009 and 2019 cohort for age (30 years versus 33 years, p=0.002), and condom usage (74% versus 99%, p<0.001). There was a statistically significant decline in the prevalence of syphilis (40% versus 14%, p<0.001), HBV (40% versus 14%, p=0.02), HCV (3% versus 0.5%, p=0.02), HPV/HIV co-infection (26% versus 16%, p=0.003). The decline in HPV infection prevalence from 2009 to 2019 (40% versus 38%, p=0.53) was not statistically significant. All the results remained unchanged when adjusted for age and condom use.

Conclusions: The significant decline in syphilis, HBV, HCV, and HPV/HIV coinfection prevalence among FSWs in Mumbai is possibly due to the success of targeted intervention programs for key populations in India. Cervical cancer screening must be launched and bundled with STI screening given the high HPV infection prevalence among these women. The indigenously crafted Indian HPV vaccine Cervavac may protect this high-risk population from future cervical disease and may also reduce transmission risk.

O142 / #631

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: EPIDEMIOLOGY & RISK FACTORS
04-21-2023 8:00 AM - 9:30 AM

HUMAN PAPILLOMAVIRUS INTERMITTENCE, REDETECTIONS, AND ASSOCIATED RISK OF CYTOLOGICAL ABNORMALITIES IN THE LUDWIG-MCGILL COHORT STUDY OF ADULT WOMEN

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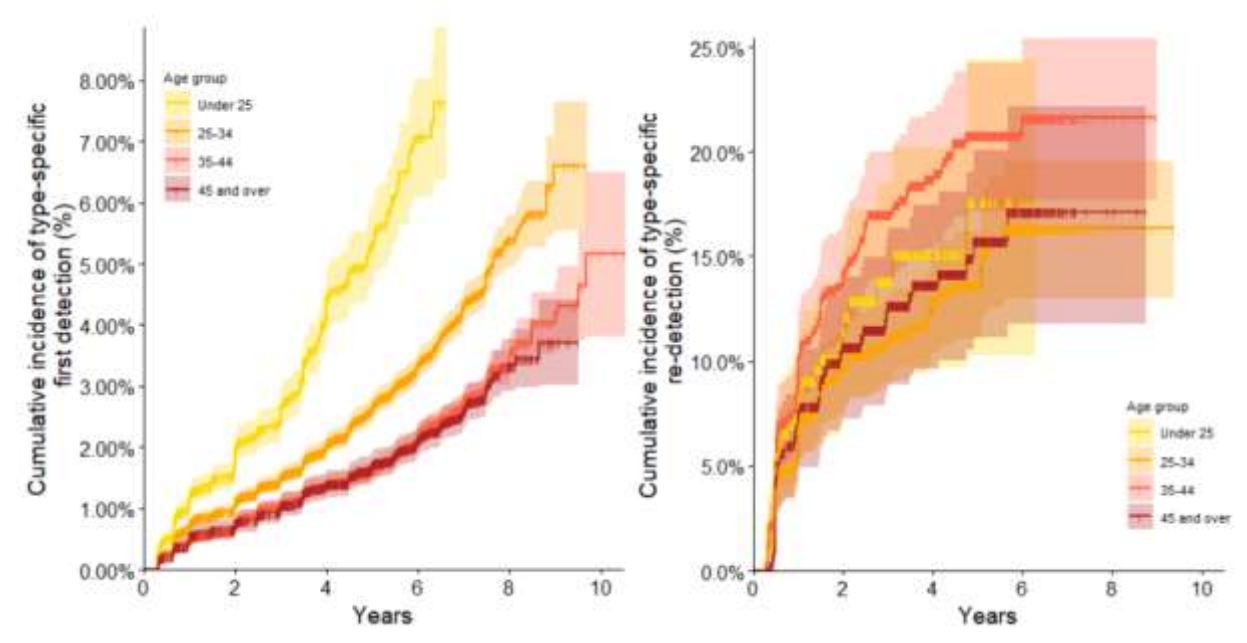
Introduction: Human papillomavirus (HPV) infections sometimes have intermittent positivity detection patterns. We assessed the cumulative incidence of redetection with the same HPV type, predictors of first HPV detections compared with redetections, and prevalence of cytological abnormalities during redetection episodes with the same HPV type.

Methods: The Ludwig-McGill cohort study followed-up women aged 18-60 years recruited in São Paulo, Brazil in 1993-1997 at visits 4-6 months apart for up to 10 years. Women provided cervical samples for cytology testing and HPV DNA testing at each visit. HPV DNA was extracted and amplified by PCR using the MY09/11 and PGMY protocols, with genotyping of over 40 HPV types. A redetection was defined as a recurring type-specific HPV positive result after one or more intervening negative visits. Predictors of type-specific redetection were assessed using Cox regression modeling, with the observation level being the HPV type.

Results: 2184 women contributed 2368 incident HPV type-specific first detections and 308 redetections over a median of 6.5 years of follow-up. The cumulative incidence of redetection with the same type was 7% (95%CI 6-8%) 1 year after the clearance of the first detection, and 15% (95%CI 13-17%) 5 years after the clearance of the first detection (average over all HPV types). There were differences in redetection probabilities across HPV types ($p<0.0001$), with HPV72 & 62 having the highest redetection probability of all types. Age and new sexual partner acquisition were strong risk factors for first HPV detections but were not statistically associated with type-specific redetection. The prevalence of high-grade squamous intraepithelial lesions was similar across visits with first detections and subsequent redetections with the same

type.



Conclusions: Redetections of the same HPV type after one or more intervening negative results were common. Our findings suggest many HPV redetections were likely reactivations of latent recurring infections.

O143 / #978

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: EPIDEMIOLOGY & RISK FACTORS
04-21-2023 8:00 AM - 9:30 AM

ORAL HPV PREVALENCE AND RISK FACTORS AMONG POPULATIONS ATTENDING DENTAL CARE IN THE UNITED STATES: RESULTS FROM PROGRESS (PREVALENCE OF ORAL HPV INFECTION GLOBAL ASSESSMENT)

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Introduction: In the United States (US) oropharyngeal squamous cell carcinoma is the most frequent HPV-associated cancer, surpassing cervical cancer. Oral HPV prevalence and genotype distribution can inform the burden of HPV-related head and neck diseases and planning of effective prevention programs. This study assessed oral HPV prevalence and risk factors in a general US population.

Methods: Between November 2021 and March 2022, 18–60-year-olds were recruited from 42 dental offices across the US. Participants provided oral rinse and gargle specimen for HPV-DNA detection and genotyping and completed sociodemographic and behavioral questionnaires. HPV-DNA detection and genotyping was performed using the SPF10/DEIA/LiPA25 system at a central laboratory.

Results: Of the 3,180 participants enrolled, 55.4% were women, with a median age of 40; 12.2% self-reported having received HPV vaccination. Oral HPV prevalence was 6.5% for any detected genotype, 2% for high-risk types, 1.5% for HPV types in the 9-valent HPV vaccine, and 0.7% for HPV16. Among oral HPV positive participants, HPV 16 was the most prevalent genotype (10.6%) followed by HPV 51 (7.2%) and HPV 66 and 44 (both 5.8%). HPV prevalence was higher in men (9.0%) than women (4.5%), and increased with age with 3.1%, 5.5%, 5.1% and 11.8% prevalence among ages 18-30, 31-40, 41-50 and 51-60, respectively. When stratified by sex and age, HPV was most commonly detected among men aged 51-60 (16.8%). Factors significantly associated with any oral HPV infection included sex, age, smoking status, lifetime number of sex partners, and presence of periodontal disease.

Conclusions: The highest oral HPV burden was among older men, highlighting the need to increase HPV prevention efforts among males. Prevalence and risk factors in the US will be compared to PROGRESS studies currently being conducted in Europe and China using similar methodologies to increase knowledge of the global oral HPV burden.

O144 / #1450

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: EPIDEMIOLOGY & RISK FACTORS
04-21-2023 8:00 AM - 9:30 AM

TRENDS IN INCIDENCE RATES OF HEAD AND NECK SQUAMOUS CELL CARCINOMAS IN COSTA RICA, WITH A SPECIAL FOCUS ON HUMAN PAPILLOMAVIRUS-RELATED AND-UNRELATED CANCERS

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Introduction: In Costa Rica (CR) only a single report on head and neck cancer (HNC) incidence trends (1985-2007) has been published and no investigations on the epidemiology of potentially HPV-related and -unrelated HNCs have been done. We examined the age-adjusted incidence rates (IRs) and trends of HNCs and compared incidence trends of potentially HPV-related and -unrelated HNCs to understand HNC in CR.

Methods: We obtained all available HNC cases for the period 2006-2015 from the National Cancer Registry of CR and the population estimates from the National Institute of Statistics and Census of CR. The analysis was restricted to invasive squamous cell carcinomas (n=1577). IRs and incidence rate ratios were calculated using SEER*Stat software and were age-adjusted to the 2010 Costa Rican population. Joinpoint Regression Analysis program was used to calculate trends and annual percent changes (APCs) in rates.

Results: For all HNCs the age-adjusted IR was 34.02/1,000,000 person-years; 95% CI 32.36, 35.75. Laryngeal cancer was the most common cancer site followed by oral cavity and oropharynx (Table 1). The incidence for all HNCs non-significantly declined (APC= -3.20; 95% CI -6.38,0.09).There was a significant decline in the incidence of nasopharyngeal cancer (APC= -5.86% per year; 95% CI -10.79, -0.66) and laryngeal cancer (APC= -5.41% per year; -9.19,1.47). The incidence trends for hypopharyngeal, oropharyngeal and oral cavity cancers remained stable over time (Figure 1). HNCs were categorized by their potential relatedness to HPV infection. IRs of potentially-HPV-related HNCs tended to trend upward, while HPV-unrelated HNCs tended to trend downward (Figure 2); the difference in these trends was marginally significant (p for parallelism = 0.061).

Table 1. Head and neck squamous cell carcinomas incidence rates, Costa Rica 2006-2015, n= 1577

	All head and neck a			Oral cavity			Pharynx									Larynx		
							Nasopharynx			Oropharynx			Hypopharynx and pyriform sinus					
	n (%)	IR	95% CI	n (%)	IR	95% CI	n(%)	IR	95% CI	n(%)	IR	95% CI	n (%)	IR	95% CI	n (%)	IR	95% CI
All invasive	1577(100)	34.02	(32.36-35.75)	427(27.71)	9.41	(8.55-10.34)	180(11.41)	3.94	(3.38-4.56)	260(18.39)	6.24	(5.54-7.00)	66 (4.06)	1.38	(1.06-1.76)	581(36.84)	12.31	(11.32-13.37)
Sex																		
Female	373 (24.03)	16.04	(14.47-17.63)	177(40.50)	7.47	(6.32-8.54)	56(31.11)	2.46	(1.85-3.19)	67(29.10)	2.83	(2.19-3.59)	12(18.75)	0.50	(0.26-0.87)	61(11.15)	2.70	(2.09-3.45)
Male	1198(75.97)	53.55	(50.56-56.67)	250(59.50)	11.59	(10.22-13.09)	124(68.89)	5.42	(4.51-6.46)	223(20.90)	9.92	(8.68-11.31)	52(81.25)	2.24	(1.75-2.87)	510(88.81)	22.25	21.29-25.35
Age (years)																		
<15	205(13.25)	9.19	(5.59-7.97)	5(12.19)	1.55	(1.16-2.05)	98(50.00)	2.67	(2.24-5.26)	25(10.00)	0.89	(0.54-1.22)	5(7.63)	0.09	(0.02-0.26)	52(5.51)	0.95	(0.69-1.52)
45-54	153(14.77)	43.70	(36.27-49.68)	62(14.42)	11.82	(9.08-15.12)	26(14.44)	4.90	(3.20-7.18)	58(18.62)	10.93	(7.59-13.18)	10(15.63)	1.88	(0.90-3.46)	75(12.91)	14.05	(11.05-17.62)
55-64	367(24.59)	115.03	(104.59-127.59)	101(24.05)	31.61	(25.89-38.02)	42(23.33)	12.91	(9.32-17.20)	63(32.07)	27.83	(22.45-34.08)	15(23.91)	4.92	(2.51-7.49)	124(21.34)	37.11	(30.86-44.25)
65-74	371(24.53)	208.80	(188.35-231.24)	105(24.04)	59.00	(48.25-71.42)	12(6.67)	6.78	(3.50-11.84)	60(30.69)	33.80	(25.79-43.55)	16(25.00)	9.00	(5.14-14.61)	174(29.95)	98.05	(84.03-113.76)
75+	377(23.92)	307.20	(276.97-339.80)	111(25.40)	90.45	(74.43-108.92)	10(5.56)	8.15	(3.91-14.99)	34(18.62)	44.00	(30.86-57.41)	20(31.25)	16.30	(9.96-25.17)	176(30.29)	143.41	(123.01-166.24)
Province																		
San Jose	649(41.15)	48.66	(45.04-54.52)	191(44.71)	15.30	(9.75-12.03)	66(36.67)	4.74	(3.78-5.40)	119(45.80)	7.67	(5.86-78.47)	30(46.88)	1.50	(0.98-2.71)	240(41.31)	14.13	(17.40-16.04)
Limon	116(7.36)	35.08	(28.93-42.06)	28(6.41)	8.23	(5.45-11.66)	9(5.00)	2.43	(1.10-4.62)	22(7.59)	6.57	(4.10-9.92)	3(4.69)	1.03	(0.21-2.85)	51(8.78)	16.00	(11.89-21.00)
Puntarenas	179(8.12)	30.85	(25.74-36.68)	32(7.32)	7.74	(5.42-10.66)	22(12.22)	5.10	(3.59-7.77)	21(7.24)	5.09	(3.15-7.76)	3(4.69)	0.74	(0.15-2.12)	68(8.74)	11.65	(8.56-15.66)
Alajuela	270(17.12)	30.84	(27.18-34.52)	83(15.10)	7.48	(5.79-9.52)	38(21.11)	4.30	(3.04-5.90)	48(15.86)	5.23	(3.83-6.96)	11(17.19)	1.24	(0.62-2.22)	102(17.55)	11.59	(9.45-14.07)
Cartago	150(9.51)	29.80	(25.22-34.97)	50(11.44)	9.93	(7.35-13.06)	21(11.67)	4.18	(2.59-6.39)	20(6.90)	3.93	(2.41-6.11)	10(15.63)	1.99	(0.95-3.66)	49(8.44)	9.78	(7.25-12.93)
Heredia	139(8.81)	28.57	(24.06-35.06)	30(8.24)	7.60	(5.07-10.62)	15(8.33)	3.80	(1.83-5.45)	34(11.72)	7.20	(4.89-10.08)	2(2.13)	0.42	(0.05-1.53)	48(8.26)	10.20	(7.50-13.61)
Guanacaste	91(5.77)	26.24	(21.32-32.23)	22(5.04)	6.35	(3.88-9.99)	8(4.44)	2.46	(1.04-4.64)	20(6.90)	5.94	(3.62-9.17)	9(14.06)	2.66	(1.21-5.05)	41(5.44)	8.81	(6.38-12.52)
Unknown	34(2.16)	*	*	12(2.75)	*	*	1(0.56)	*	*	4(2.76)	*	*	0(0.00)	*	*	12(2.07)	*	*
Year of diagnosis																		
2006-2007	328(20.79)	40.07	(35.83-44.73)	86(19.94)	10.51	(8.46-13.07)	44(24.44)	5.22	(3.79-7.00)	46(19.91)	7.33	(5.38-9.75)	16(25.00)	2.00	(1.16-3.20)	110(18.93)	13.85	(11.38-16.80)
2008-2009	331(20.99)	38.53	(34.48-42.91)	79(18.08)	9.23	(7.30-11.48)	41(22.78)	4.66	(3.34-6.32)	49(21.02)	5.71	(4.26-7.60)	13(20.31)	1.52	(0.81-2.59)	148(26.78)	16.81	(14.18-19.79)
2010-2011	309(19.59)	33.01	(29.43-36.95)	59(21.51)	10.18	(8.22-12.76)	32(17.78)	3.49	(2.38-4.96)	30(16.00)	5.30	(3.92-7.01)	6(10.94)	0.76	(0.31-1.57)	114(23.57)	12.54	(10.38-15.09)
2012-2013	272(17.25)	27.50	(24.33-30.98)	80(18.31)	8.06	(6.39-10.06)	34(18.89)	3.53	(2.44-4.94)	48(16.55)	4.81	(3.55-6.36)	9(14.06)	0.91	(0.42-1.73)	99(17.04)	9.99	(8.12-12.17)
2014-2015	349(22.13)	32.83	(29.47-36.48)	103(22.93)	9.23	(7.49-11.27)	29(16.11)	2.92	(1.95-4.21)	88(30.34)	8.29	(6.65-10.23)	10(29.69)	1.76	(1.06-2.77)	112(19.28)	10.35	(8.52-12.47)

Median age 69.00 years (Q1 54- Q3 79

Incidence rates are per 100000 and age adjusted to the Costa Rica 2012 population

Abbreviations: IR: incidence rate; CI: confidence interval

6.3% cases from overlapping lesion of lip, oral cavity and pharynx to NOS (Not otherwise specified) are not shown

*Rates not calculated, population unknown or unsure

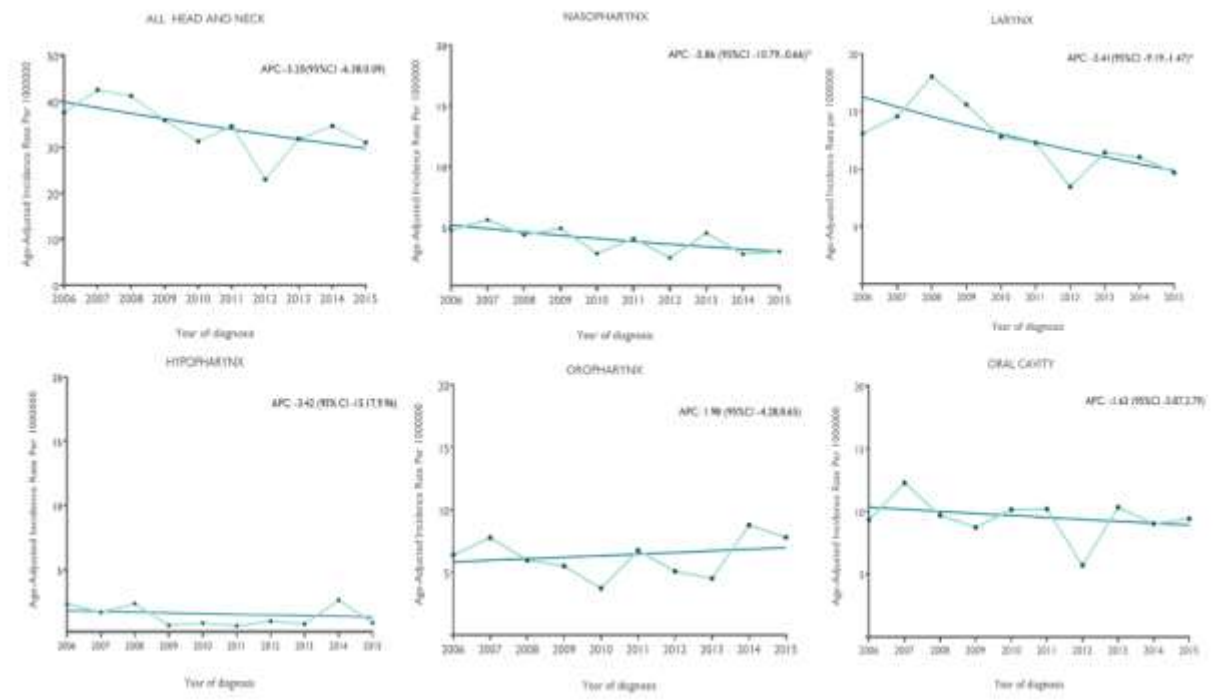

Figure 1. Head and neck squamous cell carcinomas age-adjusted incidence rates and trends, Costa Rica 2006-2015

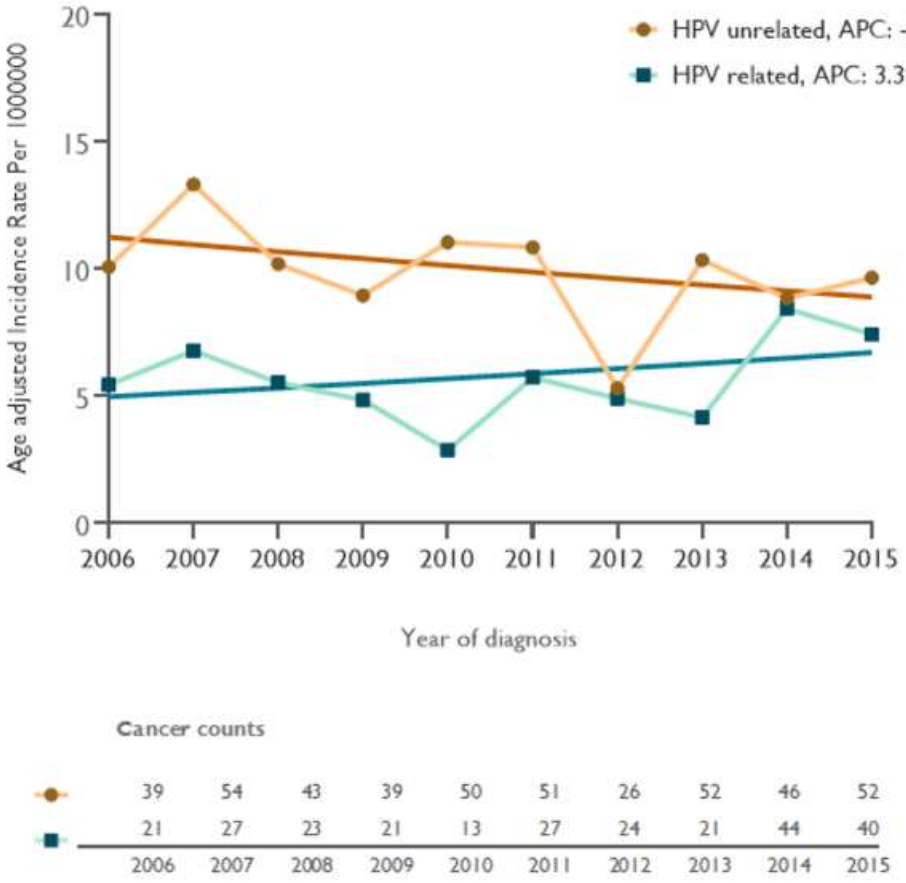

Figure 2. HPV-related and unrelated head and neck squamous cell carcinomas age-adjusted incidence rates and trends, Costa Rica 2006-2015, n=713. HPV-related anatomic sites include base of tongue, lingual tonsil, tonsil and oropharynx. HPV-unrelated anatomic sites include oral tongue, gum, floor of mouth, hard palate, soft palate, uvula, other and unspecified parts of the mouth.

Conclusions: HNCs are uncommon in CR and decreased over time. We observed a divergent pattern of decreasing HPV-unrelated with increasing HPV-related HNCs. Additional research is needed to understand the role of HPV in HNCs in CR.

O145 / #1430

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: EPIDEMIOLOGY & RISK FACTORS
04-21-2023 8:00 AM - 9:30 AM

RISK FACTORS FOR ANAL HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS AMONG HEALTHY WOMEN: FINDINGS FROM THE COSTA RICA HPV VACCINE TRIAL STUDY

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Introduction: The incidence of anal cancer has increased over the last five decades and HIV-negative women continue to bear the greatest burden of this disease. The Costa Rica HPV Vaccine Trial (CVT) study tested the efficacy of the HPV vaccine in healthy women. We aimed to describe the women from the CVT referred to high-resolution anoscopy (HRA) based on abnormal anal cytology and anal HPV infection and to identify risk factors for biopsy-confirmed anal high-grade squamous intraepithelial lesions (hHSIL), the anal cancer precursor.

Methods: At year 7 of the CVT, anal samples were collected and tested for abnormal cytology and high-risk HPV 16/18/45 infection (HR-HPV) infection using SPF10-LiPA25. A subset of these women were invited to participate in an anal follow-up study. Women were referred for HRA if they had any abnormal anal cytology or anal HR-HPV at their final study visit. We estimated prevalence ratios (PR) for associations with biopsy-proven hHSIL at first HRA using univariate regression.

Results: Among 1,023 women in CVT in the anal long-term follow-up study (age-range=23–35-years), 56 women were referred to, and attended, at least one HRA visit (Table 1). Among women referred to HRA, 27 (48%) were diagnosed with anal hHSIL. Women referred to HRA were more likely to never have been vaccinated at the year 7 visit (51% vs. 33%;Table 1). Compared to women referred for HRA but not vaccinated against HPV in the CVT, HPV-vaccinated women had a 69% reduction in prevalence of hHSIL (PR=0.3;95%CI=0.1–0.9;p=0.03). Having ³2 or lifetime anal sex partners was associated with nearly 4-fold increased prevalence of hHSIL (PR=3.8;95%CI=1.0–13.9;p=0.04)(Table 2).

Conclusions: HIV-negative women with abnormal anal cytology or anal HPV infection had a high prevalence of anal HSIL. HPV vaccination status and history of anal intercourse provided additional measures of anal HSIL risk.

O146 / #1692

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: EPIDEMIOLOGY & RISK FACTORS
04-21-2023 8:00 AM - 9:30 AM

THE OVERALL IMPACT OF HPV TESTING VERSUS CYTOLOGY FOR CERVICAL CANCER SCREENING AMONG THOSE 50 YEARS AND OLDER: EVIDENCE FROM HPV FOCAL RANDOMIZED CONTROLLED TRIAL.

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Introduction: With a global transition to HPV-based screening, the overall effectiveness of primary HPV testing, particularly in those over 50 years, and those soon to exit screening age of eligibility, must be investigated to inform updated recommendations.

Methods: The current analysis includes participants aged ≥50 who participated in the HPV For Cervical Cancer prevention (FOCAL) randomized clinical trial. A total of 6471 women aged ≥50 were randomly allocated to receive liquid-based cytology (LBC) testing (CA: Control Arm) (3248, 50.19%) at baseline and at 24-months or to receive HPV testing (IA: Intervention Arm) (3223, 49.81%) at baseline. Both groups received co-testing (LBC and HPV) at the 48-month exit. Incidence rates and risk ratios for CIN2+ detection at exit were calculated by arm. Additionally, we compared the number of CIN2+ detections missed by cytology alone in the CA to those missed by HPV alone in the IA during the 48-month exit with co-testing.

Results: At exit, those who received HPV testing at baseline had fewer CIN2+ lesions than those who received cytology. Among those with baseline negative results (LBC or HPV), at exit, the CIN2+ incidence rate was 1.61/1000 (95% CI, 0.52,3.76) in the IA compared to 5.36/1000 (95% CI, 3.13,8.59) in the CA, a risk ratio of 0.30 (95% CI,0.11,0.81). Furthermore, at the 48-month exit, cytology every two years missed more cervical pre-cancers (5 cases) than HPV-based screening every four years (0 cases).

Conclusions: In the ≥50 population, those who were HPV negative at baseline had a statistically significant (70%) rate reduction in cervical pre-cancer at the 48-month exit relative to those who were cytology negative. HPV-based screening identifies pre-cancerous lesions earlier and more accurately than cytology. Our findings suggest that including cytology co-testing may not add any additional value in HPV-based screening programs among those ≥50 years old.

O147 / #1618

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: EPIDEMIOLOGY & RISK FACTORS
04-21-2023 8:00 AM - 9:30 AM

THE BROADEN STUDY: BURDEN OF HUMAN PAPILLOMAVIRUS-RELATED HEAD AND NECK CANCERS IN JAPAN

Ken-Ichi Nibu[1], Nobuhiko Oridate[2], Yuki Saito[3], Montserrat Roset[4], Marta Fores Maresma[4], Edith Morais[5], Craig Roberts[6], Ya-Ting Chen[6], Jacqueline C. Spitzer[7], Kayo Sato[8], Itori Saito[8], Ichiro Tazaki[8], Shin Sasaki[8], Laia Alemany Vilches[9], Hisham Mehanna[10], Haitham Mirghani[11], Anna Giuliano[12], Miquel Angel Pavon Ribas[9], Tim Waterboer[13]
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Introduction: Head and neck cancers (HNC) represent one of the most common and fatal cancers in Japan. HPV, smoking, and alcohol consumption are known key contributors. Despite decreasing rates of smoking and alcohol consumption, HNC incidence has increased, particularly for oropharyngeal cancers (OPC). This study aimed to assess HPV attributability in HNC at two time periods in Japan.

Methods: BROADEN is a non-interventional, cross-sectional, multi-center study of HNC patients diagnosed in 2008-2009 and 2018-2019. FFPE tumor samples were collected from patients in a consecutive-retrospective manner, using stringent ICD coding to avoid site misclassification. Tumors were centrally tested for presence of HPV-related biomarkers. HPV attributability required at least two positive tests (SPF_{10} HPV-DNA PCR, $p16^{ink4a}$ immunohistochemistry, or E6*I HPV-mRNA test) for OPC, and HPV PCR DNA plus mRNA positivity for non-OPC.

Results: Nineteen oncology centers participated, enrolling 1,108 patients with 950 valid and 158 invalid FFPE tumor samples (valid samples included 473 OPC and 477 non-OPC; 435 for 2008-2009 and 515 for 2018-2019). HNC patients were mainly males (82.3%) with mean(SD) age of 65.8(11.8) years at diagnosis, including 42.7% current smokers, 30.5% ex-smokers and 34.5% heavy drinkers. HPV attributability in OPC increased from 44.9% (95%CI: 38.1%-51.8%) in 2008-2009 to 52.1% (95%CI: 45.9%-58.3%) in 2018-2019. In 2008-2009, HPV attributability in nasopharynx and larynx was 3.4% (95%CI: 0.4%-11.7%) and 5% (95%CI: 0.6%-16.9%), respectively; in oral cavity and hypopharynx were 0%. In 2018-2019, HPV attributability in nasopharynx was 7.7% (95%CI: 2.5%-17.0%), and 0% in hypopharynx, larynx, and oral cavity. High-risk HPV genotypes (16/18/31/33/45/52/58) were found in 97.5% of HPV-attributable HNC.

Conclusions: This study aimed to assess the burden of HPV in HNC by applying stringent HNC classification and HPV testing methodology. Results demonstrate the impact of HPV in HNC in Japan, especially in males, and the increase of HPV attributability over time, particularly in OPC.

O148 / #870

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: IMMUNOLOGY & VACCINES
04-21-2023 8:00 AM - 9:30 AM

SINGLE-CELL TRANSCRIPTIONAL PROFILING REVEALS A DIVERSE IMMUNE LANDSCAPE IN HUMAN PAPILLOMAVIRUS 6 OR 11-DRIVEN RECURRENT RESPIRATORY PAPILLOMAS

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Introduction: Immune constituency within HPV 6 or 11-related recurrent respiratory papillomas (RRP) is incompletely understood.

Methods: We performed single-cell transcriptomics and single-cell T cell receptor (TCR) sequencing on 13 papilloma specimens obtained from adult patients with RRP.

Results: Bioinformatic study of the myeloid cell compartment revealed multiple distinct clusters of neutrophilic and monocytic cells, including several that express high levels of immunosuppression-associated transcripts TREM2 and ARG1. Small populations of FOXP3, IL2RA and CTLA4 positive CD4 regulatory T cells were identified. Other CD4 T cell populations harbored expression profiles indicative of skewing away from anti-tumor Th1 helper function and toward production of Th2-related cytokines. Study of CD8 T cells revealed a broad diversity of transcriptional phenotypes, with some populations expressing high levels of exhaustion markers TOX, PDCD1, and LAG3 and the tissue retention marker CD103, all previously associated with tumor-antigen specificity in studies of malignancy. Overall, expression of activation markers IFNG, PRF and GZMs was low in most CD8 and CD4 clusters, indicating a lack of strong active HPV-specific T cell immunity and possibly local immunosuppression. TCRs from clonotypes within two distinct exhausted, CD103+ CD8 clusters were reconstructed and cloned into expression vectors to allow determination of antigen-specificity. Using a panel of in silico predicted HLA class I binding HPV6 and 11 epitopes and autologous antigen presenting cells, co-culture experiments are underway to identify and validate a library of HPV6 and 11-specific TCRs.

Conclusions: Our single cell analysis of RRP reveals immune-related cellular diversity and transcriptional phenotypes implying the presence of immunosuppressive myeloid cells and regulatory CD4 T cells. Experimental validation of the antigen-specificity of TCRs from papilloma infiltrating CD8 T cells is underway to determine if the inability of CD8 TIL to detect and eliminate HPV infected epithelial cells is due to lack of HPV antigen-specificity or local immunosuppression.

O149 / #1362

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: IMMUNOLOGY & VACCINES
04-21-2023 8:00 AM - 9:30 AM

OROPHARYNGEAL TUMOR CELLS INDUCE COX-2 EXPRESSION IN PERIPHERAL BLOOD MONOCYTES BY SECRETION OF IL-1ALPHA

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Introduction: Oropharyngeal squamous cell cancer (OPC) accounts for 3% of all cancers and greater than 1.5% of all cancer deaths in the United States, with marked treatment-associated morbidity in survivors. More than 80% of OPC is caused by HPV-16. Tumors induced by HPV have been linked to impaired immune functions in the local tumor microenvironment, with less focus on the effects these tumors have on systemic immune responses, especially innate responses.

Methods: PGE2 and IL-1 levels were measured by ELISA. COX-2 mRNA was determined by RT-Q-PCR, and COX-2 protein measured by Western Blot. RNA-SEQ was performed with Next-seq 550 (Ilumina) and analyzed with Partek software.

Results: Plasma levels of PGE2 are elevated in OPC patients ($p<0.0001$) and decrease post-treatment. HPV-16+ OPC patients have higher plasma PGE2 levels than HPV- patients ($p<0.01$). COX-2 mRNA is elevated in patients' monocytes compared to monocytes from controls ($p<0.01$). Conditioned media from primary cultures of OPC biopsies and tumor cell lines can induce COX-2 in monocytes, with induction significantly greater in patient's monocytes than controls ($p=0.002$). We identified IL-1α expression by these tumors, and confirmed the presence of IL-1α, but not IL-1β, in the conditioned medium. Finally, both Anakinra, and rilonacept significantly block the effect of conditioned medium on monocytes, confirming that IL-1α is a major paracrine factor secreted by oropharyngeal tumors and tumor cell lines.

Conclusions: IL-1α secreted by oropharyngeal tumors activates monocytes to produce PGE2, a known immunosuppressant, suggesting that there is an enhanced immune-mediated feed-back on the tumors. Studies are ongoing to characterize additional pro-tumor immune modulators made by monocytes in response to tumor-conditioned medium. This should identify novel targets for immune intervention.

O150 / #1496

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: IMMUNOLOGY & VACCINES
04-21-2023 8:00 AM - 9:30 AM

REDIRECTING PRE-EXISTING VIRAL IMMUNITY TOWARDS CANCERS VIA MURINE PAPILLOMAVIRUS T=1 VIRUS-INSPIRED PARTICLES (VIPS)

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Introduction: VerImmune is developing “Anti-tumor Immune Redirection” (AIR). This involves redirecting immune memory from viral infections to destroy tumor cells. Our strategy utilizes a T=1 icosahedral structure assembled from murine papillomavirus L1 capsid proteins. The assembled structure is termed 'Virus-inspired Particles' (ViPs) to differentiate them from conventional papillomavirus T=7 virus-like particles (VLPs) or Pseudovirions (PsVs). Here we show both in vitro and in vivo how ViPs can serve as a novel delivery system that redirects viral CD8+ T-cells to target non-virally related tumors for destruction

Methods: Tumor HSPG specific binding of our murine ViP was assessed against a panel of murine and human cancer cell lines in vitro. Cytotoxicity against these same murine and human cancer cell lines was next evaluated using co-culture T-cell assays. Demonstration of in vivo anti-tumor activity of the murine ViP via AIR was performed utilizing B16.F10 tumor bearing mice C57/BL6 mice harboring HPV16 E7 pre-existing immunity. Finally, to assess if murine ViPs are affected by pre-existing HPV or MusPV neutralizing antibodies, murine ViPs were mixed with these antibodies prior to binding and cytotoxicity assays.

Results: Characterization of ViPs reveals distinct biophysical differences from VLPs or PsVs. However, ViPs retain specificity to tumors via HSPG similar to HPV VLPs. In CD8+ T-cell co-culture assays, ViPs exerted specific HPV16 E7 and/or CMV pp65 “NLV” cytotoxic CD8+ T-cells respectively to kill non-antigenically related tumors. Pre-mixing of ViPs with either Gardasil-9 or mouse papillomavirus specific neutralizing sera did not block binding or cytotoxicity of the ViPs in vitro. Finally, in vivo anti-tumor activity against murine B16.F10 which does not contain any HPV E7 antigen was demonstrated.

Conclusions: Our results demonstrate the potential of AIR as a tumor antigen–agnostic immunotherapeutic. Additionally, the specificity of ViPs to tumor HSPGs makes AIR potentially applicable across many solid tumors regardless of their origin.

O151 / #831

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: IMMUNOLOGY & VACCINES
04-21-2023 8:00 AM - 9:30 AM

IN-DEPTH ASSESSMENT OF INNATE AND ADAPTIVE RESPONSES TO NINE-VALENT HPV VACCINE IN HUMANS

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Introduction: It is not known how human papillomavirus (HPV) vaccines stimulate the immune system to generate potent and durable antibody responses, but this information is valuable to vaccinology.

Methods: We are conducting a pilot cohort study to evaluate in-depth innate immune, B-, and $CD4^+$ T-cell responses to the nine-valent HPV vaccine (9vHPV). Participants include 16 men and women, 18-45 years of age, who have never received an HPV vaccine, have no history of HPV disease, and are seronegative for all 9vHPV types in a validated M9ELISA (Panicker et al. J. Immunol. Methods 2021). Our goals are to identify innate immune pathways activated by the vaccine and determine if early gene expression signatures of vaccine-activated B- and $CD4^+$ T-cells in secondary lymphoid tissues predict their fate in peripheral and primary lymphoid memory compartments. To assess peripheral and secondary lymphoid B- and $CD4^+$ T-cell responses, blood samples and lymph node aspirates will be collected before and after each 9vHPV dose. Participants will also have bone marrow aspirates collected two years after the first 9vHPV dose, when HPV-specific antibody titers have plateaued, to identify long-lived HPV-specific plasma cells. We will determine the magnitude of vaccine-elicited B-cell, plasma cell, and $CD4^+$ T-cell responses and conduct single cell RNAseq on these cells to determine gene expression signatures and paired antibody sequences for clonal fate mapping.

Results: We have screened 14 participants, 43% (n=6) were seronegative for all 9vHPV types by M9ELISA. The rest screen-failed, with one failing safety lab criteria and seven being seropositive for one or more HPV types. Baseline lymph node aspirates yielded $0.21\text{-}3.8 \times 10^6$ lymphocytes. Study design and current demographic and laboratory data (screen results, FNA yields pre- and post-vaccination) will be presented.

Conclusions: Our study is 37.5% enrolled and our results will advance critical human tissue immunology studies and vaccine development efforts for other pathogens.

O152 / #1439

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: IMMUNOLOGY & VACCINES
04-21-2023 8:00 AM - 9:30 AM

RG2-VLP: A VACCINE DESIGNED TO BROADLY PROTECT AGAINST ANOGENITAL AND SKIN HUMAN PAPILLOMAVIRUSES CAUSING HUMAN CANCER

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Introduction: Licensed preventive HPV vaccines are composed of VLPs derived by expression of major capsid protein L1. They confer protection generally restricted to infection by the αHPVs targeted by the up-to-9-valent vaccine, and their associated anogenital cancers and genital warts, but do not target βHPV that are associated with CSCC in EV and immunocompromised patients. We describe the development of a two-antigen vaccine, RG2-VLP which is both protective in animal models against known oncogenic αHPVs as well as diverse βHPVs by incorporation into HPV16 and HPV18 L1 VLP of 20-amino-acid conserved protective epitopes derived from minor capsid protein L2.

Methods: We developed a two-component VLP vaccine, RG2-VLP, in which L2 protective epitopes derived from a conserved αHPV epitope (amino acids 17 to 36 of HPV16 L2) and a consensus βHPV sequence in the same region are displayed within the DE loop of HPV16 and HPV18 L1 VLP, respectively. We vaccinated rabbits and as well as FVB mice, including TMC6 or TMC8 knockouts as models of EV, to study the immunogenicity of the RG2-VLP vaccines across a wide variety of HPV genotypes. Longevity of RG2-VLP responses compared to Gardasil-9 over 1 year was also studied.

Results: Unlike vaccination with Gardasil 9, vaccination of wild-type and EV model mice ($Tmc6^{\Delta/\Delta}$ or $Tmc8^{\Delta/\Delta}$) with RG2-VLP induced robust L2-specific antibody titers and protected against β-types. RG2-VLP also protected rabbits against 17 αHPV, including those not covered by Gardasil 9. HPV16- and HPV18-specific neutralizing antibody responses were similar between RG2-VLP- and Gardasil 9-vaccinated animals even after one year. However, only transfer of RG2-VLP antiserum effectively protected naive mice from challenge with all βHPVs tested.

Conclusions: Our observations suggest RG2-VLP's potential as a broad-spectrum vaccine to prevent αHPV-driven anogenital, oropharyngeal, and βHPV-associated cutaneous cancers. The duration of both 16/18 L1-VLP as well as RG1 specific responses by RG2-VLP also support long term immunogenecity.

O153 / #1122

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: IMMUNOLOGY & VACCINES
04-21-2023 8:00 AM - 9:30 AM

INTRA-TUMOR IMMUNOTHERAPY OF HPV-ASSOCIATED CANCER.

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Introduction: In situ vaccination (ISV) is becoming a therapeutic strategy to stimulate and diversify anti-tumor immune responses. Ano-genital and part of oropharyngeal cancers (OPC) are HPV-associated. Since OPC therapy is burdened by comorbidities and high recurrence rates, new approaches like immunotherapy are needed. Both genital and oropharyngeal cancers are easily accessible for ISV. Our previous studies showed several HPV DNA vaccines were able to affect tumor growth in mouse models. Similar results were achieved by antibodies (intrabobies) in single-chain format (scFvs) against HPV16 E6 and E7 proteins. Present study was developed to determine if ISV may enhance immunotherapy effectiveness.

Methods: Several pre-clinical mouse models of HPV-associated cancer in subcutaneous or oral orthotopic localizations were utilized. Two DNA plasmids expressing anti-HPV16 E6 or E7 intrabodies were delivered intra-tumor, respectively. PGIPss-L2-E7 and E7-Sap (Italian and International Patent) DNA vaccines were utilized for ISV. PGIPss-L2-E7 vaccine is based on fusion HPV16 antigens (L2 and E7) linked to signal sequence (ss) of polygalacturonase-inhibiting protein (PGIPss) from Phaseolus vulgaris. E7-Sap vaccine is a fusion construct of a non-toxic saporin mutant (SAP) with harmless version of HPV16 E7 gene.

Results: Part of these results were already presented at 6th Meeting on Emerging Issues in Oncogenic Virus Research (June 2022 –Italy). We showed that both anti-HPV16 E6 and HPV16 E7 scFvs affected tumor progression in all experimental mouse models increasing apoptosis within the tumor. Systemic administration of PGIPss-L2-E7 was able to decrease tumor growth and additional intra-tumor delivery of DNA vaccines improved tumor growth control and induced strong apoptosis in neoplastic cells

Conclusions: ISV with HPV DNA vaccines as well as with intrabodies are effective in increasing antitumor responses. This activity seems to rely on driving tumor cells towards the apoptotic pathway. This scenario could open new perspectives of therapy by introducing ISV in immunotherapy scheduling.

O154 / #1150

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: IMMUNOLOGY & VACCINES
04-21-2023 8:00 AM - 9:30 AM

NEXT GENERATION L2-BASED HPV VACCINES CROSS-PROTECT AGAINST CUTANEOUS PAPILLOMAVIRUS INFECTION AND TUMOR DEVELOPMENT

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Introduction: Licensed L1-VLP-based vaccines have been a great success in reducing anogenital cancers, but are limited regarding cross-protection against human papillomavirus (HPV) types not covered by the vaccine. Next generation vaccines induce broad cross-protection against highly conserved sequences of L2. We tested two novel L2-based HPV vaccine candidates, HPV16 RG1-VLP and CUT-PANHPVAX, in the preclinical model Mastomys coucha. These animals are naturally infected with the cutaneous Mastomys natalensis papillomavirus (MnPV), which induces cutaneous tumors.

Methods: In an exploratory setting, virus-free animals were vaccinated with HPV16 RG1-VLP, CUT-PANHPVAX, MnPV-VLPs (positive control) or PBS (negative control) prior to experimental MnPV-infection. Seroconversion against L2 peptides, presence of (cross-)neutralizing antibodies, viral load at the infection site and occurrence of skin tumors were examined. Microscopical examinations and immunofluorescent stainings were used to check the skin even for premalignant changes.

Results: Besides vaccine-specific seroconversion against HPV16 RG1 and CUT-PANHPVAX, the animals also developed cross-reactive antibodies against MnPV L2, which were cross-neutralizing MnPV pseudovirions in vitro. Like for the MnPV-VLP control group, both L2-based vaccines conferred in vivo protection since after experimental infection, viral loads in plucked hair were lower when compared to mock-vaccinated controls. Importantly, the formation of neutralizing antibodies, whether directed against L1-VLPs or L2, was able to prevent skin tumor formation. Consequently, while 83% of animals from the PBS group developed skin tumors, only 33% of the HPV16 RG1-VLP group, 17% CUT-PANHPVAX and 0% of those from the VLP group did so. Protected animals not even showed microscopical signs of MnPV infection in the skin.

Conclusions: For the first time, our study shows the proof-of-principle of two next generation L2-based vaccines that are currently entering clinical trials in an infection model with its genuine PV. Even across different PV genera, these L2-based vaccines have a promising efficacy to protect against HPV-induced skin tumors.

O155 / #1454

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: IMMUNOLOGY & VACCINES
04-21-2023 8:00 AM - 9:30 AM

REPURPOSING ANTIVIRAL VACCINES FOR LOCAL IMMUNOTHERAPY AGAINST SOLID TUMORS

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Introduction: Local immunotherapy against solid tumors is considered a viable approach to stimulate the tumor immune microenvironment and to promote anti-tumor immune responses. We have previously shown that intratumoral recall of anti-cytomegalovirus memory CD4+ and CD8+ T cells was effective to control primary tumor growth and to promote epitope spreading in murine preclinical cancer models. Here, we interrogate whether preexisting anti-vaccine immunity induced by licensed subunit vaccines could be leveraged for local cancer immunotherapy in the TC-1 murine tumor model expressing the HPV16 oncogenes E6 and E7.

Methods: We selected Shingrix, a varicella zoster vaccine containing the glycoprotein E (gE) antigen and adjuvant AS01B, and Gardasil-9, a human papillomavirus vaccine containing the L1 virus-like particles and alum adjuvant for their unique ability to induce CD4 and CD8 T cell responses, respectively.

Results: Intratumoral injection of Shingrix alone or with immune checkpoint blockade (CTLA-4), in prevaccinated mice delayed tumor growth and often led to complete regression. These responses were associated with the induction of CD8+ T cell responses against the HPV16 E7 tumor antigen, to tumor immune activation and a profound alteration of the myeloid compartment. The injection of selected MHC-II-restricted gE minimal peptide epitopes combined with polyI:C also led to durable remission suggesting a contribution of gE-specific CD4 T cells. In contrast, Gardasil-9 i.t. injection did not delay tumor growth or cause tumor rejection which suggests inefficient class I cross-presentation of native VLP in the tumor cells. However, the injection of selected MHC-I-restricted L1 minimal peptide epitopes led to complete and durable remissions suggesting efficient tumor control by L1-specific CD8 T cells.

Conclusions: Together our results provide evidence that anti-viral subunit vaccines can be repurposed for local cancer therapy as safer and off-the-shelf agents. Such immunotherapeutics could be broadly implemented and provide greater access to cancer treatment in low-resource settings.

O156 / #1817

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: IMMUNOLOGY & VACCINES
04-21-2023 8:00 AM - 9:30 AM

ROLE OF GENETIC DRIFT IN HPV EVOLUTION

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Introduction: Pervasive purifying selection on non-synonymous substitutions is a hallmark of papillomavirus genome history. However, codon-based evolutionary models do not explain HPV evolution.

Methods: More than a thousand complete genomes representing Alphapapillomavirus types, lineages and SNP variants were examined phylogenetically and interrogated for the number and position of DNA sequence motifs. Non-coding evolutionary signatures were investigated with Principal Components Analyses, Ancestral State Reconstructions and Phylogenetic Independent Contrasts. Natural selection on expressed amino acids was also evaluated with codon models of evolution.

Results: For anciently diverged Alphapapillomavirus types, composition of the 4 nucleotides and 14 established non-coding DNA sequence motifs suggested two groups. Among the more recently diverged highly oncogenic Alphapapillomavirus 9 types, DNA sequence motifs and nucleotide composition were also able to discriminate most viral types and even some lineages. Ancestral state reconstruction and Phylogenetic Independent Contrasts recovered ancient genome alterations, including CpG, APOBEC3, and TLR9 motifs. Features that were common to Alphapapillomavirus types included a predominance of APOBEC3 sites on the non-coding strand and CpG sites within the E2/E4 overlapping open reading frames. Surprisingly, ancestral state reconstruction recovered punctuated changes in the genome of HPV16 resulting in the fewest CpG sites and the largest number of palindromic motifs of all Alphapapillomavirus types. Bayesian Graphic Models indicated that the E6 locus contains a high proportion of amino acid changes that phylogenetically covary with other sites in the genome. Patterns of nonsynonymous substitutions reflected purifying selection as expected.

Conclusions: Whole genome phylogenetic comparative methods do not indicate a single mode of evolution to explain the diversity of Alphapapillomavirus. Implicit in non-recombining genomes is their evolutionary independence after genetic isolation, divergence, and expansion. Each evolutionary analytical method supports the unanticipated conclusion that genetic drift and different evolutionary drivers have structured Alphapapillomavirus genomes in distinct ways during successive epochs, even extending to differences in variant lineages.

O157 / #1153

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSTICS FOR CERVICAL LESIONS AND CONSIDERATIONS FOR MANAGEMENT OF IMMUNOCOMPROMISED POPULATIONS
04-21-2023 8:00 AM - 9:30 AM

SAME-DAY VISIT HPV SCREEN-AND-TREAT: INITIAL IMPLEMENTATION RESULTS

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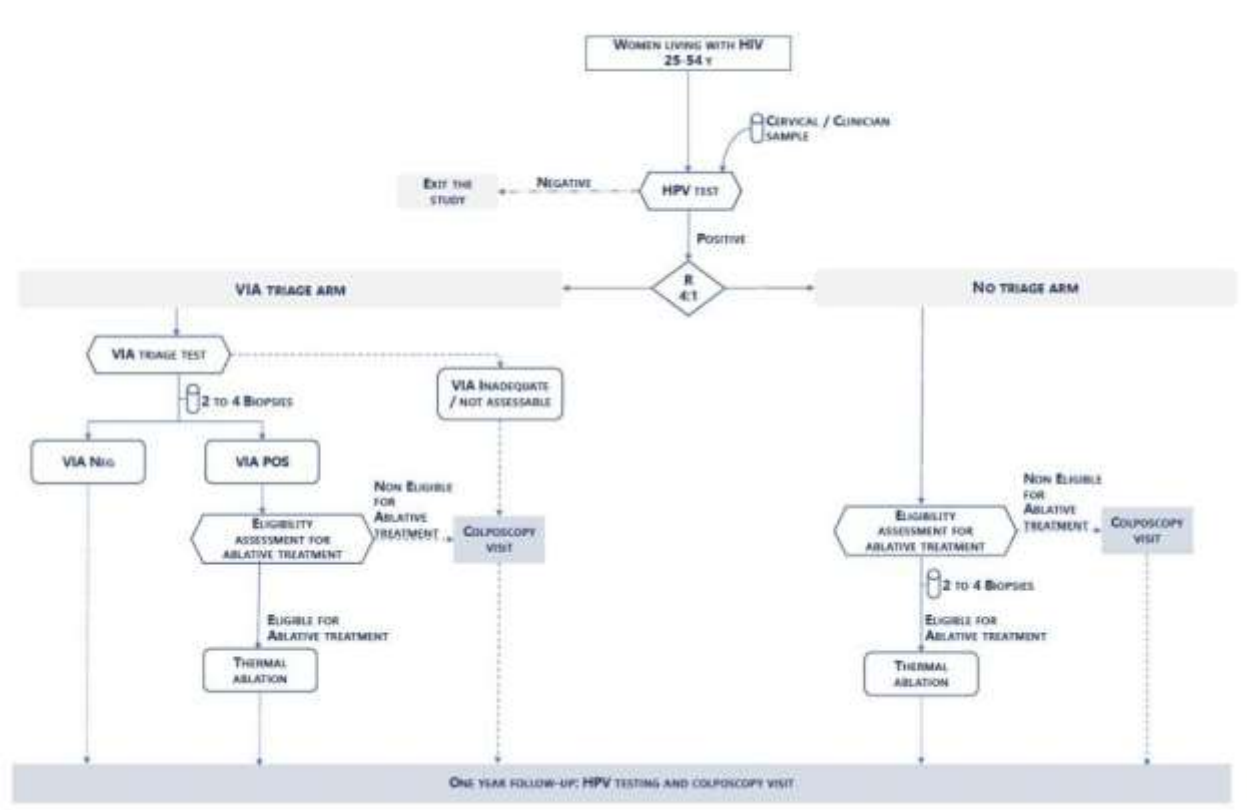
Introduction: Sub-Saharan African countries suffer from a high burden of cervical cancer (CC) and HIV infection. Effective cervical screening and treatment is not yet widely available and there is lack of colposcopy, histopathology and follow-up installed capacity. We present preliminary results of the initial implementation of the same-day screen-and-treat (with and without triage) approach for women living with HIV (WLWH) participating in the CESTA study.

Methods: In CESTA (Fig.1), WLWH aged 25-54 years are screened for HPV with a clinician sample tested directly on site in one hour using GeneXpert®. HPV positive WLWH are randomised in a 4:1 ratio into VIA triage followed by thermal ablation (TA) treatment (VIA-triage arm) or direct TA (no-triage arm). Ineligible women for TA are referred to colposcopy. Proportions of women completing the screen-and -treat or screen, triage, treatment approach are

estimated.



Results: Except for one woman with repeated invalid sample for HPV testing, all women followed the same-day HPV-based screen-and-treat approach. 193 of 281 women were HPV positive (prevalence 69%, 95%CI: 63-74). In the VIA-triage arm (n=154), 137 WLWH were evaluable for VIA (89%, 95%CI: 83-95, Fig. 2); VIA positivity among them was 120/137 (88%, 95%CI: 81-93). Overall, 146/193 WLWH (74%, 95%CI: 69-82) received TA the same day. Colposcopy referral was mainly due to the squamous-columnar junction not fully visible (mostly WLWH older than 44 y/o, p<0.05). 163 of 193 randomised women completed the one visit screen-and-treat algorithm approach (84%, 95%CI: 79-89).

	VIA-triage Arm (n=154, 80%)				No-triage Arm (n=39, 20%)				All HPV positive women (n=193, 100%)			
Participant pathway by study arm	**n**	**n/N**	**%**	**95% CI**	**n**	**n/N**	**%**	**95%CI**	**n**	**n/N**	**%**	**95%CI**
VIA Assessable	**137**	**137/154**	**89%**	**83-93**	-	-	-	-	-	-	-	-
VIA negative women	17	17/137	12%	7-20	-	-	-	-	17	17/193	9%	5-14
VIA positive women	120	120/137	88%	81-93	-	-	-	-	-	-	-	-
Eligible women treated by thermal ablation	**114**	**114/154**	**74%**	**66-81**	**32**	**32/39**	**82%**	**66-92**	**146**	**146/193**	**76%**	**69-82**
Ineligible women for thermal ablation	6	6/154	4%	1-8	1	1/39	3%	0-13	7	7/193	4%	1-7
VIA not Assessable	**17**	**17/137**	**12%**	**7-20**	-	-	-	-	-	-	-	-
SCJ* not fully visible	12	12/154	8%	4-13	6	6/39	15%	6-31	18	18/193	9%	6-14
Suspicion of cervical cancer	5	5/154	3%	1-7	-	-	-	-	5	5/193	3%	1-6
Completion of the screen-and-treat algorithm												
Completed the screen-and-treat process	**131**	**131/154**	**85%**	**78-90**	**32**	**32/39**	**82%**	**66-92**	**163**	**163/193**	**84%**	**79-89**
Colposcopy referral	23	22/154	15%	9-21	7	7/39	18%	7-34	30	30/193	16%	11-21

*Squamous-Columnar Junction

Conclusions: Same-day screen-and-treat approach is feasible, should reduce the lost to follow-up and provide ablative treatment on the same day for eligible women. However, it should be noted that a

proportion of women will always be referred to colposcopy (i.e., older women, advanced disease). Finally, the high positivity of HPV DNA testing as well as visual triage on WLWH deserve further evaluation.

O158 / #1366

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSTICS FOR CERVICAL LESIONS AND CONSIDERATIONS FOR MANAGEMENT OF IMMUNOCOMPROMISED POPULATIONS
04-21-2023 8:00 AM - 9:30 AM

UNDERSTANDING THE CELLULAR ORIGIN OF METAPLASIA AT THE CERVICAL TZ AND THE INVOLVEMENT OF HPV INFECTION IN NEOPLASIA

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Introduction: The majority of cervical cancers occur at the cervical transformation zone (TZ), an epithelial site which is thought to be sustained by a specialized type of epithelial stem cell known as the ‘reserve cell’. Reserve cells, which resemble basal epithelial cells, are found beneath the columnar epithelium of TZ -and during metaplasia, can drive the development of a stratified epithelium like that of the ectocervix.

Methods: We have used immunofluorescence and RNAscope analysis to characterize cervical reserve cells in relation to their local niche within the TZ, their response to HPV infection, immune surveillance, and their role in cervical metaplasia using hysterectomy and LLETZ biopsies from uninfected women, women with HPV infection and HPV-HIV coinfections, treated for cervical precancer.

Results: Reserve cells were prominent at the entrance of cervical crypts. They resemble basal cells in expressing p63, a biomarker of stratification potential, along with the keratins K5 and K14 and more variably K17. At crypts entrances, HPV infection leads to an expansion of the infected K5/P63 reserve cell population, which showed high levels of HPV E6/E7 (CIN3) expressions, along with extensive P16 and MCM expression. By contrast, the epithelium between the cervical crypts, typically showed more modest levels of E6/E7 (CIN2). This contrasts with the very low E6/E7 levels seen in the p63-positive epithelial basal layer during productive papillomavirus infection. In the epithelia where immune infiltrates were apparent, E6/E7 expressing cells at crypts entrances were spared. The immune cells had a distinctive, non-uniform distribution and were typically most prominent in follicles adjacent to infected crypt entrances.

Conclusions: We suggest that E6/E7 may have dual roles in proliferation and immune evasion. Our work identifies an epithelial site at the TZ associated with ‘deregulated HPV gene expression’ and neoplasia, and suggests that HPV gene expansion modulates reserve cell expansion, immune evasion, and disrupts metaplastic processes.

O159 / #1276

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSTICS FOR CERVICAL LESIONS AND CONSIDERATIONS FOR MANAGEMENT OF IMMUNOCOMPROMISED POPULATIONS
04-21-2023 8:00 AM - 9:30 AM

THE 2022 GLOBAL HPV DNA TYPING AND HPV SCREENING PROFICIENCY STUDIES

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Introduction: The International HPV Reference Center supports quality and order in HPV research and diagnostics. Notably, the center assigns HPV type numbers to novel HPV types, maintains a reference clone repository, and issues international proficiency panels for HPV genotyping and screening. In 2022, we issued two different proficiency panels: The HPV DNA genotyping panel assesses the proficiency of the different HPV typing assays as used in different laboratories. The HPV DNA screening panel assesses the sensitivity and specificity of the various HPV screening assays, as used in different laboratories.

Methods: Participating laboratories were asked to perform HPV testing using one or more of their usual assays on coded samples composed of purified whole genomic plasmids of sixteen HPV types (HPV 6, 11, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68a and 68b) in a background of human cellular DNA. Proficient genotyping requires detection in both single and multiple infections of 50 International Units of HPV 16 and HPV 18 DNA/ 5µl and 500 genome equivalents in 5 µl for the other types, with no false positive results. The screening study has the same requirements for HPV 16 and HPV 18. HPV 31, 33, 45, 52 and 58 are also include as single infections, whereas HPV types rarely found in cancers are included only as pools.

Results: The 2022 genotyping proficiency study was subscribed to by 73 different laboratories worldwide. The screening study had 92 panels distributed, particularly to laboratories from Latin America, Europe, and Asia. Both public health laboratories, research laboratories and diagnostic test manufacturers are participating.

Conclusions: A continuing global proficiency program will promote reliable laboratory services both for genotyping in HPV vaccine research and monitoring as well as for HPV-based cervical screening.

O160 / #947

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSTICS FOR CERVICAL LESIONS AND CONSIDERATIONS FOR MANAGEMENT OF IMMUNOCOMPROMISED POPULATIONS
04-21-2023 8:00 AM - 9:30 AM

LIQUID BIOPSY FOR DETECTING AND MONITORING HPV-RELATED CANCER

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Introduction: Human papillomavirus (HPV) is a major etiological agent in cancer worldwide, and is associated with the development of cervical and oropharyngeal cancers (OPC), amongst others. Liquid biopsy is an emerging method for non-invasively monitoring diseases using bodily fluids such as blood, urine, and saliva. Circulating tumour (ct)DNA isolated from liquid biopsy has been shown to have clinical utility as a biomarker in cancer, especially for monitoring disease progression and recurrence.

Methods: In this study, we aimed to detect circulating HPV DNA across different analytes (plasma, saliva, urine, and vaginal swab) in patients with HPV-related cancer to determine the link between HPV-DNA in liquid biopsy and disease status. Samples were collected from 45 patients with prior to treatment for p16+ primary or recurrent cervical cancer or OPC at the McGill University Health Centre. Samples were analyzed using droplet digital PCR (ddPCR) with primers and probes for HPV16/18/33. ctDNA levels were correlated with disease course.

Results: HPV-ctDNA was detectable in 42/47 (89%) patients prior to treatment. In our cohort, 28 patients had matched pre- and post-treatment samples. All patients sampled longitudinally showed significant reductions in ctDNA post treatment compared to pre-treatment (range: 86-100%), with 25 patients having a complete loss of detectable ctDNA. Post-treatment patients with no detectable ctDNA had no signs of recurrence/residual disease on follow-up imaging. In contrast, patients who tested positive for ctDNA post-treatment showed signs of recurrence on follow-up imaging.

Conclusions: HPV16, 18, and 33 ctDNA was successfully detected in saliva and blood of patients with HPV-positive OPC, and vaginal swab, urine, and blood of patients with cervical cancer with 89% sensitivity. The inclusion of multiple analytes increased the sensitivity of the assay, especially in patients with low plasma cfDNA. The presence of ctDNA correlated with treatment response, indicating the potential of HPV ctDNA for monitoring tumor progression in patients.

O161 / #790

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSTICS FOR CERVICAL LESIONS AND CONSIDERATIONS FOR MANAGEMENT OF IMMUNOCOMPROMISED POPULATIONS
04-21-2023 8:00 AM - 9:30 AM

REPRODUCIBILITY OF P16/KI-67 DUAL-STAIN CYTOLOGY INTERPRETATION: PRELIMINARY RESULTS IN THE ESTAMPA STUDY

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Introduction: p16/Ki-67 dual-stain cytology has been proposed to triage HPV-positive women with good reproducibility and accuracy. However, its implementation could be challenging, particularly, in low-resource settings. We aimed to evaluate the reproducibility of the dual-stain cytology within ESTAMPA among local and external pathologists.

Methods: In 12 study centres across Latin-America, 42,502 women have been screened with cytology and HPV testing; those screened positive were referred to colposcopy with biopsy/treatment as needed. Residual material from HPV-positive women were centralized in Costa Rica for dual-stain processing. Dual-stain was performed using Ventana Benchmark Automated Stainer after preparation of the ThinPrep liquid-based cytology. Dual-stained slides were interpreted blindly to cytology, histology, and all clinical data by a local pathologist. Ten percent of interpreted slides are being randomly selected for a second reading by an external pathologist. So far, 92 dual-stained slides of 933 available by May 2022 have been reinterpreted. Reproducibility was measured using the percentage agreement and the Cohen's kappa coefficient (κ).

Results: 4,228 HPV-positive women are being tested by dual-stain, including 493 CIN3+. Of 92 dual-stained slides reinterpreted, six and 11 were unsatisfactory due to low cellularity for the local and external pathologist, respectively. Pathologists agreed on 80 slides (54 negative, 21 positive and 5 unsatisfactory), leading to an overall agreement of 87% and concordance κ =0.74 (95%CI 0.61-0.87). The external pathologist reported five slides positive of which four were negative and one unsatisfactory for the local pathologist, one slide negative that was positive for the local, and six slides unsatisfactory that were

reported as negative for the local pathologist

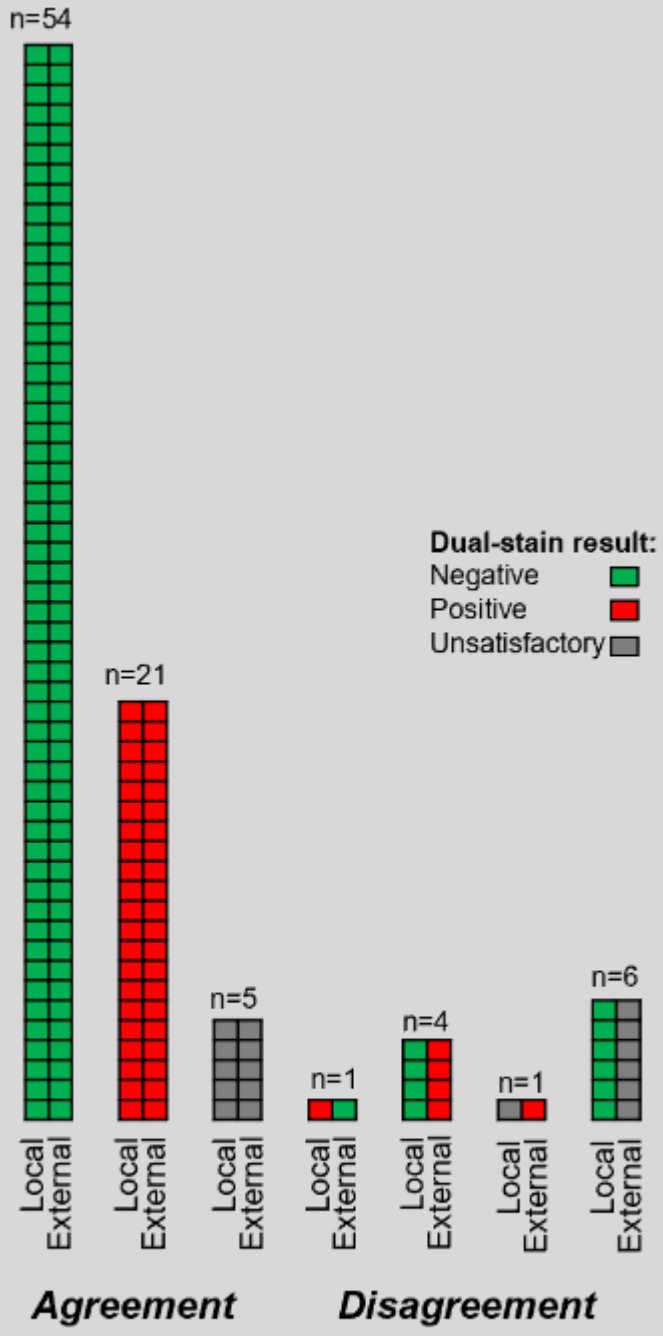

Figure 1. Representation of 92 slides according to the dual-stain result between pathologists.

(Figure1).

Conclusions: Preliminary results suggest that dual-stain exhibits good reproducibility. However, local pathologist seems to be less rigid to determine low cellularity. Further external review of more slides and

discussion between both pathologists on discordant results will bring some new evidence to understand reasons behind discordance.

O162 / #1293

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSTICS FOR CERVICAL LESIONS AND CONSIDERATIONS FOR MANAGEMENT OF IMMUNOCOMPROMISED POPULATIONS
04-21-2023 8:00 AM - 9:30 AM

CERVICAL CELL LIFT - A NOVEL METHOD FOR THE SPATIAL MAPPING BIOLOGICAL MARKERS AND GRADING OF HPV-INFECTED CERVICAL LESIONS

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Introduction: The persistent infection of high-risk HPV in the cervical transformation zone is the cause of cervical cancer. The majority of sexually active people become infected with high-risk HPV at some point in their life, however, only a small proportion of infected females develop cancer. In general, after the initial infection, HPV develops a temporal productive lesion and then the infection is controlled by the host immune system, leading to the latent persistent infection. In later life, the infection may be re-activated, develop into a pre-cancerous lesion, and in rare cases, progress to malignant cancer. The aim of cervical screening is to identify HPV-associated lesions that may progress to cancer in order to allow treatment.

Methods: Infected lesions can be categorised from productive low-grade lesions to non-productive high-grade lesions. These lesions are characterised based on the regulation/expression of viral oncogenes, and their morphological phenotype which provides insight into the different probabilities of cancer progression. The phenotypes (the biological markers) include the surrogate molecular markers of viral oncogene expression (MCM, Ki67, and p16) and the viral productive life cycle (E4) as well as cellular morphologies.

Results: We showed a new method to lift the surface cells of the cervix (Cervical cell lift, CCL) and generate a spatial map of the biological markers there. We have successfully located and characterised the infected lesion on the CCL. Compared to the normal cytology, the major advantage of the CCL is the preservation of native cell topology, and by preserving this spatial information, the lesions can be visualised in their entirety. The CLL detected CIN2+ lesion with 80% of sensitivity.

Conclusions: The CCL potentially can replace the current triage test (cytology) of cervical screening by providing the location and the grade (CIN1-CIN3) of the infected lesion without biopsy and histopathological assessment.

O163 / #344

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSTICS FOR CERVICAL LESIONS AND CONSIDERATIONS FOR MANAGEMENT OF IMMUNOCOMPROMISED POPULATIONS
04-21-2023 8:00 AM - 9:30 AM

DIFFERENTIATED CERVICAL INTRAEPITHELIAL NEOPLASIA (D-CIN) REPRESENTS A RARE HPV-INDEPENDENT PRECURSOR LESION OF SQUAMOUS CELL CANCER

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Introduction: Although our knowledge of HPV-independent squamous cell cancers (SCC) of the cervix is growing, the current 2020 WHO classification does not describe HPV independent cervical precancers. The main reason for this was that these exceedingly rare cervix HPV-independent precancerous lesions were not described at time of publication.

Methods: This review will focus on recent aspects of HPV-independent cervical carcinogenesis.

Results: In 2020 we reported for the first time a preinvasive cervical lesion negative with 3 different HPV tests in a series of 474 cone specimens (Reich O. Gynecol Oncol 2020). In 2022 we demonstrated detailed characteristics of HPV-negative cervical intraepithelial precursors (Regauer S. Am J Surg Path 2022). HPV-negativity was defined as lack of both, DNA of 32 HPV subtypes and E6/E7 mRNA of 14 HPV subtypes, and additionally by the absence of HPV sequences in ~5 Mio´s WGS reads. The morphological hallmark of this cervical lesion was the presence of atypical keratinocytes confined to the basal and parabasal layers in squamous epithelium with hyper- and parakeratosis with elongated rete ridges. The subepithelial stroma had a dense inflammation with plasma cells and eosinophilic granulocytes. Finding an appropriate terminology for these differentiated intraepithelial precursor lesions, however, proves difficult. In analogy to terminology of vulvar carcinogenesis, differentiated cervical intraepithelial neoplasia (d-CIN) may be appropriate.

Conclusions: The existence of primarily HPV-negative squamous cervical precancers (d-CIN type and basaloid type) needs to be recognized (Regauer S. Int J Gynecol Cancer 2022). In a future classification squamous intraepithelial cervical precancers should be grouped into two categories: HPV-associated and HPV-independent.

O164 / #903

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSTICS FOR CERVICAL LESIONS AND CONSIDERATIONS FOR MANAGEMENT OF IMMUNOCOMPROMISED POPULATIONS
04-21-2023 8:00 AM - 9:30 AM

COMPARISON OF ACCURACY AND REPRODUCIBILITY OF COLPOSCOPIC IMPRESSION BASED ON A SINGLE IMAGE VERSUS A TWO-MINUTE TIME SERIES OF COLPOSCOPIC IMAGES

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Introduction: Colposcopy is an important part of cervical screening/management programs. Colposcopic appearance is often classified, for teaching and telemedicine, based on static images that do not reveal the dynamics of acetowhitening. We compared the accuracy and reproducibility of colposcopic impression based on a single image at one minute after application of acetic acid versus a time-series of 17 sequential images over two minutes.

Methods: Approximately 5,000 colposcopic examinations conducted with the DYSIS colposcopic system were divided into 10 random sets, each assigned to a separate expert colposcopist. Colposcopists first classified single two-dimensional images at one minute and then a time-series of 17 sequential images as ‘normal,’ ‘indeterminate,’ ‘high grade,’ or ‘cancer’. Ratings were compared to histologic diagnoses. Additionally, 5 colposcopists reviewed a subset of 200 single images and 200 time series to estimate intra- and inter-rater reliability.

Results: Of 4,640 patients with adequate images, only 24.4% were correctly categorized by single image visual assessment (11% of 64 cancers; 31% of 605 CIN3; 22.4% of 558 CIN2; 23.9% of 3412 <CIN2). Individual colposcopist accuracy was low; Youden indices (sensitivity plus specificity minus one) ranged from 0.07 to 0.24. Use of the time-series increased the proportion of images classified as normal, regardless of histology. Intra-rater reliability was substantial (weighted kappa=0.64); inter-rater reliability was slight (Fleiss’ unweighted kappa=0.17).

Conclusions: Substantial variation exists in visual assessment of colposcopic images, even when a 17-image time series showing the two-minute process of acetowhitening is presented. We are currently evaluating whether deep-learning image evaluation can assist classification.

O165 / #1208

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: DIAGNOSTICS FOR CERVICAL LESIONS AND CONSIDERATIONS FOR MANAGEMENT OF IMMUNOCOMPROMISED POPULATIONS
04-21-2023 8:00 AM - 9:30 AM

CYTOKINE AND CHEMOKINE LEVELS AMONG HPV-RESPONSIVE AND NON-RESPONSIVE LUNG CANCER CASES

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Introduction: Human papillomavirus (HPV) has been detected in lung tumors, but its role as an etiologic agent for lung cancer remains controversial. HPV infection may foster a pro-inflammatory environment that increases lung cancer risk. We sought to examine differences in lymphocyte and cytokine/chemokine profiles between lung cancer cases and HPV-vaccinated controls, as well as whether cytokine/chemokine levels were associated with mortality among cases.

Methods: Peripheral blood mononuclear cells (PBMCs) and plasma were isolated from 137 newly diagnosed lung cancer cases and 11 HPV-vaccinated controls. Cells from controls and 45 randomly selected cases were exposed to media or to 3 doses of Gardasil as an HPV challenge. Interleukin (IL-) 4, IFN-g, and IL-17A secreting cells were quantified using an ELISpot assay. Individuals were categorized as HPV-responsive if the HPV challenge resulted in an increase of at least 2 types of secreting cells, compared to media-exposed cells. The Milliplex human cytokine assay was used to assess circulating levels of 38 cytokines in plasma of all cases and controls. Multivariable Cox proportional hazards models were used to estimate hazard ratios by high versus low cytokine levels.

Results: All 11 HPV-vaccinated controls demonstrated an increase in cells secreting IFN-g and IL-4. Of the 45 challenge cases, 20 (44.4%) were classified as HPV-responsive. Levels of IL-17A were significantly higher among HPV-responsive (89.1 cells/10^6) compared to non-responsive cases (9.8 cells/10^6) (p=0.012). There were no differences in circulating cytokines at baseline by HPV-responsiveness. High levels of circulating IL-10 (HR: 2.02, 95% CI: 1.18-3.46), IL-7 (1.94, 1.11-3.39), IL-9 (1.85, 1.08-3.17), and GRO (2.10, 1.08-4.09) were associated with mortality compared to cases with low levels. There were no differences in survival by HPV-responsiveness.

Conclusions: High cytokine levels at diagnosis were associated with survival which may indicate that immunoregulatory factors may be of importance in lung cancer prognosis.

O166 / #1040

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: INTERVENTIONS, HEALTH ECONOMICS AND MATHEMATICAL MODELING
04-21-2023 10:00 AM - 11:30 AM

EVALUATING THE ONGOING COSTS OF HPV VACCINE DELIVERY IN MATURE PROGRAMS: EVIDENCE FROM GUYANA, RWANDA, AND UGANDA

Mercy Mvundura[1], Rose Slavkovsky[2], Ganesh Tatkan[3], Ertenisa Hamilton[3], Teddy Naddumba[4], Elisabeth Vodicka[5], Clarisse Musanabaganwa[6], Hassan Sibomana[7], Francois Uwinkindi[6], Frederick Debellut[8], Abdou Diop[9], Immaculate Ampaire[10], Alfred Driwale[10], D. Scott Lamontagne[11]
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Introduction: Perceptions about program costs may be one reason why about 50% of low- and middle-income countries have not yet introduced HPV vaccination nationwide. While studies have estimated the program costs of HPV vaccine delivery to inform country decision-making, most were conducted during demonstration projects or in the initial years of vaccine introduction, which may not reflect the ongoing costs of mature programs. We conducted a multi-country study to estimate the ongoing financial and economic costs of HPV vaccine delivery for mature programs.

Methods: Micro-costing methods were used to retrospectively collect data to estimate the annual ongoing financial and economic costs of HPV vaccine delivery. Facility staff responsible for providing HPV vaccination services were interviewed using structured costing questionnaires. Vaccine dose and session data were extracted from program records in each facility. Stratified random sampling was used to select the health facilities in Guyana (n=43), Rwanda (n=42), and Uganda (n=66). The costing was done from the health system perspective with a 2019 reference year.

Results:

Table 1. HPV vaccine doses delivered, vaccination sessions held, mean costs per facility, cost per dose and 95% confidence intervals (CI), excluding the costs of the vaccines in 2019 US$.

	Guyana	Rwanda	Uganda
Total HPV vaccine doses delivered and HPV vaccination sessions held by the health facilities in the study sample[a]	6,398 doses delivered at 216 HPV vaccination sessions by 40 health facilities.	25,121 doses delivered at 388 HPV vaccination sessions by 41 health facilities.	8,438 doses delivered at 331 HPV vaccination sessions by 52 health facilities.
Annual financial costs per health facility (mean and 95% CI)	$254 [$177–$331]	$166 [$97–$235]	$419 [$145–$639]
Annual economic costs per health facility (mean and 95% CI)	$2,010 [$847–$3,174]	$1,466 [$816–$2,116]	$1,310 [$733–$1,886]
Financial cost per HPV vaccine dose delivered (volume-weighted mean and 95% CI)	$1.26 [$0.05–$2.48]	$0.37 [$0.20–$0.54]	$3.17 [$0.45–$5.89]
Economic cost per HPV vaccine dose delivered (volume-weighted mean and 95% CI)	$9.99 [$7.05–$ 12.92]	$3.26 [$2.14–$4.37]	$9.90 [$3.15–$16.64]

*Sample sizes on doses delivered are less than stated above because some health facilities had no stock data either because records were missing, or the health facilities did not conduct HPV vaccination sessions in 2019.

Across the three countries, financial costs were a relatively small proportion of the total economic costs of HPV vaccine delivery (Table 1). Per diems were generally not paid for program activities. Cost of time for health workers accounted for the largest share of program costs, with the bulk of the time spent on service delivery. There was a wide range, within country and across countries, in the cost drivers and the estimated cost per dose.

Conclusions: When HPV vaccine programs mature, there are relatively low ongoing financial costs compared to nascent programs at the coverage levels currently being achieved. However, additional financial investments may be required to implement activities to increase coverage. Implementing single-dose schedules may further reduce HPV vaccine program costs making it more affordable and sustainable.

O167 / #772

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: INTERVENTIONS, HEALTH ECONOMICS AND MATHEMATICAL MODELING
04-21-2023 10:00 AM - 11:30 AM

IMPACT OF SCREENING BEHAVIOR ON OPTIMAL GUIDELINES: SHOUD WE DESIGN SCREENING GUIDELINES BASED ON THOSE WHO DON'T FOLLOW THEM?

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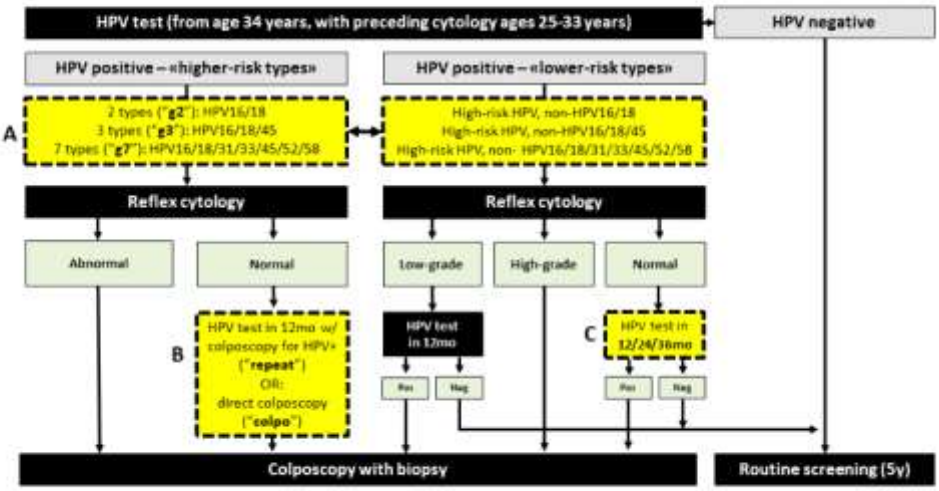
Introduction: Model-based cost-effectiveness analyses can inform optimal screening guidelines by quantifying consequences of alternative algorithms. Although actual screening adherence is <100%, incorporating non-adherence into analyses that aim to determine optimal guidelines, may impact the policy recommendations. It could lead to inefficient screening of compliant women. We evaluated the impact of alternative non-adherence assumptions on the optimal cervical cancer screening strategies in Norway.

Methods: We used an individual-based model of cervical carcinogenesis to project the long-term health and economic outcomes under alternative screening algorithms and adherence patterns for unvaccinated women. We compared 18 screening strategies involving primary HPV testing (5-yearly), that varied follow-up management of different HPV genotype groupings (16/18, 16/18/45, or 16/18/31/33/45/52/58) (Figure 1). We applied 12 analytic approaches to account for non-adherence: perfect compliance, eight high- and low-coverage 'random-complier' scenarios, and three 'complier-profile' scenarios that reflect conditional screening behavior over a lifetime. Non-adherence was incrementally applied across the entire screening pathway, including primary testing, follow-up, colposcopy and precancer treatment. We calculated incremental cost-effectiveness ratios (ICERs) and considered a strategy with the highest ICER below USD55,000/QALY as 'optimal'.

Figure 1. Overview of the 18 alternative screening strategies considered in the analysis. Strategies varied by: A) number of genotypes to include as "higher-risk types" versus "lower-risk types", B) follow-up of HPV positive "higher-risk types" and reflex cytology normal, and C) follow-up wait time for HPV positive "lower-risk types" and reflex cytology normal. Abbreviations: mo = months.



Results: Under perfect compliance, the least intensive screening strategy, involving partial 16/18-genotyping, was optimal; in contrast, assuming any non-adherence resulted in a more intensive 'optimal' strategy (Table 1). Accounting for lower compliance resulted in both lower costs and health benefits, which allowed a more intensive 'optimal' strategy, but more harms for compliant women. For example, a woman screening according to guidelines informed by the 'optimal' strategy when assuming the lowest non-adherence rates, could increase colposcopies by up to 41% compared to if she followed her own 'optimal' guidelines.

Table 1: Cost-effectiveness results across 12 screening compliance scenarios. Strategies with an incremental cost-effectiveness ratio just below USD55,000 are denoted by green shaded cell, while strategies on the cost-efficiency frontier are denoted by blue shaded cell. Random scenarios (i.e., individual compliance to a single procedure was independent of previous behavior): high-A/low-A=85%/60% compliance to primary screening; high-B/low-B=85%/60% compliance to primary screening and follow-up; high-C/low-C=85%/60% compliance to screening and follow-up, 90%/75% compliance to colposcopy procedure; high-D/low-D= 85%/60% compliance to screening and follow-up, 90%/75% compliance to colposcopy procedure, and 95%/80% compliance to treatment. Profile-perfect=10% never-screeners, 40% under-screeners, 20% guideline-screeners, 30% over-screeners; Profile-high/low=Profile-perfect in combination with high-D/low-D. Abbreviations: mo = months.

Strategy label (variation A/B/C)	Perfect	Random ("high-A")	Random ("high-B")	Random ("high-C")	Random ("high-D")	Random ("low-A")	Random ("low-B")	Random ("low-C")	Random ("low-D")	Profile-perfect	Profile-high	Profile-low
G2 / repeat / 36m												
G2 / repeat / 24m												
G2 / repeat / 12m												
G3 / repeat / 36m												
G3 / repeat / 24m												
G3 / repeat / 12m												
G7 / repeat / 36m												
G7 / repeat / 24m												
G7 / repeat / 12m												
G2 / colpo / 36m												
G2 / colpo / 24m												
G2 / colpo / 12m												
G3 / colpo / 36m												
G3 / colpo / 24m												
G3 / colpo / 12m												
G7 / colpo / 36m												
G7 / colpo / 24m												
G7 / colpo / 12m												

Conclusions: Assuming non-adherence in analyses designed to inform national guidelines may lead to a relatively more intensive recommendation. Accounting for non-adherence in guideline development may lead to over-screening of compliant women.

O168 / #1140

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: INTERVENTIONS, HEALTH ECONOMICS AND MATHEMATICAL MODELING
04-21-2023 10:00 AM - 11:30 AM

IS IT TIME FOR INDIVIDUALIZED SCREENING: DETERMINING THE OPTIMAL CERVICAL CANCER SCREENING STRATEGY IN A MIXED-VACCINATED POPULATION IN ONTARIO, CANADA.

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Introduction: In Ontario, a population-based cytology screening program has been in place for multiple decades, underway to implement HPV-based screening in the future. The first cohorts of school-based HPV vaccinated individuals are currently starting cervical screening. We examined how screening strategies should be adjusted for these (partly) protected individuals in the future.

Methods: The hybrid microsimulation model STDSIM-MISCAN-Cervix has been calibrated to the Ontario setting using observed demographic and screening data. Ten birth cohorts (1998-2007) who were recently offered vaccination were simulated over their entire lifetime. The efficiency of 309 different primary HPV screening strategies, varying by screening ages and triage methods, was assessed. Effects of screening were evaluated for the cohorts as a whole with a mixed vaccination status (i.e. unstratified screening) and separately for vaccinated individuals and for unvaccinated individuals within the vaccinated cohorts (i.e. stratified screening). Harms were measured as number of cervical tests and colposcopy referrals, benefits as cancers prevented and life years gained. A harms-benefits analysis and extensive sensitivity analyses were performed.

Results: In an unstratified screening scenario, five lifetime screens with HPV16/18 genotyping at ages 25, 30, 35, 40 and 55 along with one optional screen at age 45 was found to be optimal. In a stratified screening scenario, three lifetime screens with HPV16/18/31/33/45/52/58 genotyping at ages 30, 40 and 55 among vaccinated individuals, and 6 lifetime screens with HPV16/18 genotyping at ages 25, 30, 35, 40, 50 and 60 with two optional screens at ages 45 and 55 among unvaccinated individuals was found optimal. Sensitivity analyses showed that, in general, these results were robust.

Conclusions: To maintain the harms-benefits balance of screening, Ontario could consider reducing the number of lifetime screens in the future for vaccinated cohorts or for the population as a whole as more people in the screening ages are vaccinated.

O169 / #534

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: INTERVENTIONS, HEALTH ECONOMICS AND MATHEMATICAL MODELING
04-21-2023 10:00 AM - 11:30 AM

IMPACT OF 'EVEN FASTER' CONCEPT TO ACCELERATE CERVICAL CANCER ELIMINATION IN NORWAY: A MODEL-BASED ANALYSIS

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Introduction: Experts have proposed an 'EVEN FASTER' concept involving intensifying concomitant screening and vaccination to age-groups maintaining human papillomavirus (HPV) infection circulation. Advocates suggest this approach could accelerate elimination of cervical cancer (CC) as a public health problem (currently projected in 2039 under existing policies) and the reduced need for screening. We explored the effects of these proposals on age-standardized incidence rate (ASR) and CC elimination timing in Norway.

Methods: We used a multi-modeling approach capturing HPV transmission and cervical carcinogenesis to estimate ASR associated with alternative vaccination and screening scenarios compared to the status-quo reflecting previous vaccination and screening policies. For cohorts ages 25–35 years, we examined 11 vaccination scenarios that incrementally increased vaccination coverage from current cohort-specific rates to 90% for girls and 89% for boys, with each scenario adding successive cohorts (e.g., increasing coverage to age 35 includes increasing coverage for ages 25–34). Each vaccination scenario was coupled with a screening scenario that lowered the age that women switch to HPV-based screening, if eligible (from age 34 years (status-quo) to age 30 or 25 in 2022) and varied the frequency of HPV-based screening (5-yearly (status-quo) or 10-yearly), resulting in a total of 56 scenarios.

Results: Twenty-one vaccination strategies coupled with de-intensified screening frequencies lowered ASR by 2050, but vaccination would have to be offered to additional cohorts and HPV screening-age

would need to be lowered to accelerate CC elimination (Figure 1).

Figure 1. Elimination timeframe and age-standardized incidence rate (ASR) associated with selected 'EVEN FASTER' scenarios in Norway, stratified into two categories of ASR and elimination timeframe.

Vaccinate at maximum coverage up to specified age in 2022	Eligibility age for HPV-based screening in 2022 (frequency)	Year elimination (<4 cases per 100,000 women) achieved	Age-standardized incidence rate (cases per 100,000 women) in year 2050
Status-Quo	Status-Quo (5)	2039	2.505
Strategies that accelerated cervical cancer elimination and decreased age-standardized incidence rate in year 2050 compared to status-quo			
26	30 (5)	2038	2.391
27	30 (5)	2038	2.363
28	Status-Quo (5)	2038	2.363
28	30 (5)	2038	2.353
29	Status-Quo (5)	2038	2.342
29	30 (5)	2038	2.332
30	Status-Quo (5)	2038	2.317
30	30 (5)	2038	2.298
31	Status-Quo (5)	2038	2.294
31	30 (5)	2038	2.277
32	Status-Quo (5)	2038	2.264
32	30 (5)	2038	2.249
33	Status-Quo (5)	2038	2.232
33	30 (5)	2038	2.220
25	25 (5)	2038	2.200
34	Status-Quo (5)	2038	2.197
34	30 (5)	2038	2.187
26	25 (5)	2038	2.185
35	Status-Quo (5)	2038	2.181
35	30 (5)	2037	2.168
27	25 (5)	2038	2.163
28	25 (5)	2037	2.152
29	25 (5)	2037	2.131
30	25 (5)	2037	2.100
31	25 (5)	2037	2.081
32	25 (5)	2037	2.049
33	25 (5)	2037	2.018
34	25 (5)	2037	1.987
35	25 (5)	2037	1.966
Strategies that de-intensified screening and either accelerated cervical cancer elimination or decreased age-standardized incidence rate in year 2050 compared to status-quo			
26	30 (10)	2039	2.495
27	30 (10)	2039	2.466
28	30 (10)	2039	2.456
29	30 (10)	2039	2.455
30	30 (10)	2039	2.404
31	30 (10)	2038	2.373
32	30 (10)	2038	2.338
25	25 (10)	2038	2.333
26	25 (10)	2038	2.319
33	30 (10)	2038	2.303
27	25 (10)	2038	2.297
28	25 (10)	2038	2.290
34	30 (10)	2038	2.270
29	25 (10)	2038	2.269
35	30 (10)	2038	2.250
30	25 (10)	2038	2.247
31	25 (10)	2038	2.218
32	25 (10)	2038	2.180
33	25 (10)	2037	2.144
34	25 (10)	2037	2.114
35	25 (10)	2037	2.093

Note: Strategies organized in order of decreasing age-standardized incidence rate within group. Heat map formatting for age-standardized incidence rate shows lower cervical cancer incidence compared to the rate estimated under existing prevention policies (2.505 cases per 100,000 women in year 2050). We selected the year 2050 to align with a previous analysis (Portnoy, et al., *MDM Policy & Practice* 2022).

Conclusions: Increasing vaccination and decreasing HPV switch-age paired with less intensive screening frequencies can lead to greater benefits and accelerate CC elimination compared to current prevention policies, but changing screening for the youngest birth cohorts contributed the majority of

declines rather than increasing vaccination age. Evaluations of HPV 'EVEN FASTER' need to estimate the full economic implications of these policies.

O170 / #805

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: INTERVENTIONS, HEALTH ECONOMICS AND MATHEMATICAL MODELING
04-21-2023 10:00 AM - 11:30 AM

ACCELERATING CERVICAL CANCER ELIMINATION IN LMICS THROUGH DEVELOPMENT OF A COSTING TOOL FOR PLANNING FOR SCALING-UP

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Introduction: Cervical Cancer Elimination efforts in low- and middle-income countries (LMICs) are being hampered because the cost of scaling-up screening and treatment programmes is unknown. To assist in programme planning and advocacy for additional funding, the SUCCESS project has developed an Excel-based tool for estimating the cost of scaling-up cervical cancer programmes. The tool builds upon a previously released costing tool: the WHO Comprehensive Cervical Cancer Costing and Planning (C4P) tool. The SUCCESS-C4P version aims to build costing capacity in LMICs by improving the user interface. The tool and course package is undergoing field testing in four countries, Burkina Faso, Cote d'Ivoire, Guatemala, and the Philippines, as part of the SUCCESS Project to integrate recommended secondary prevention strategies into the national continuum of care.

Methods: We extensively reviewed the C4P tool with subject matter experts, previous users, and health economists to identify revisions needed to simplify the costing process. Special emphasis was placed on making data collection and input more streamlined for public health program managers and planners. Outputs were redesigned to facilitate report and presentation generation. We collaborated with program managers from the four countries to collect cost data and will be conducting validation workshops in each country. Online training materials for global use of the SUCCESS-C4P tool will incorporate learning experiences from these countries.

Results: Users demonstrated a greater understanding of how to estimate the cost of a cervical cancer elimination scale-up plan. The costing provided the prerequisite data for a sustainability analysis and financial gap analysis. Not least, country engagement strengthened collaborative ownership of the planned initiative by key participating organizations responsible for championing, supporting, and implementing it.

Conclusions: Cervical Cancer Elimination efforts in LMICs can be accelerated and strengthened through the use of a standardized scale-up costing process and tool developed by the SUCCESS Project.

O171 / #700

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: INTERVENTIONS, HEALTH ECONOMICS AND MATHEMATICAL MODELING
04-21-2023 10:00 AM - 11:30 AM

MODELING THE IMPLICATIONS OF A SINGLE DOSE HPV VACCINE REGIMEN IN A LOW/MIDDLE INCOME COUNTRY SETTING: AN ANALYSIS IN INDONESIA

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Introduction: While no HPV vaccine is indicated for single dose administration, some evidence suggests that an off-label 1-dose (OLSD) regimen might reduce the risk of HPV infection and offer comparable levels of protection against HPV infection as two or three doses. This study estimated the potential impact of implementing an OLSD HPV vaccination program relative to a 2-dose program, with 9-valent vaccine (9vHPV) for adolescents in a low/middle income country, using Indonesia as a use case.

Methods: A previously published dynamic HPV transmission infection and disease model was adapted to the Indonesia population to compare the long-term health outcomes and cost-effectiveness of OLSD versus two-dose 9vHPV vaccination programs in girls and boys aged 9-14. A probabilistic sensitivity analysis was performed with uncertainty distributions for the vaccine model parameters for a single dose estimated from fitting data to interim KENSHE results. Scenarios analyses were run to show the impact of different coverage levels.

Results: 2-dose girls only (GO) or GNV program may avoid 70,000-1.96 million additional cancer cases, over 100 years compared to an OLSD GO or GNV program. Compared to OLSD, a 2-dose GNV program has nearly 100% probability of being cost-effective at a WTP of 0.5x GDP ($1935/QALY). None of the 1-dose scenarios were likely to reach cervical cancer elimination. Dose price, coverage, and parameter uncertainty sensitivity analyses led to similar results.

Conclusions: Our modeling shows adoption of the one-dose 9vHPV vaccination program resulted in more vaccine-preventable HPV-related cancer cases, introduced substantial uncertainty in both health and economic outcomes, and had a low to zero probability of being cost-effective compared to the two-dose programs. The health impact on a low/middle income country is substantially larger and more uncertain due to differences in attributes related to disease burden, vaccine coverage (including historical HPV immunization program), lack of screening practices and parameters related to socio-economic conditions.

O172 / #1802

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: INTERVENTIONS, HEALTH ECONOMICS AND MATHEMATICAL MODELING
04-21-2023 10:00 AM - 11:30 AM

SUSTAINED IMPACT OF THE COVID-19 PANDEMIC ON ADOLESCENT WELL-CHILD VISITS AND HPV VACCINATION IN THE UNITED STATES

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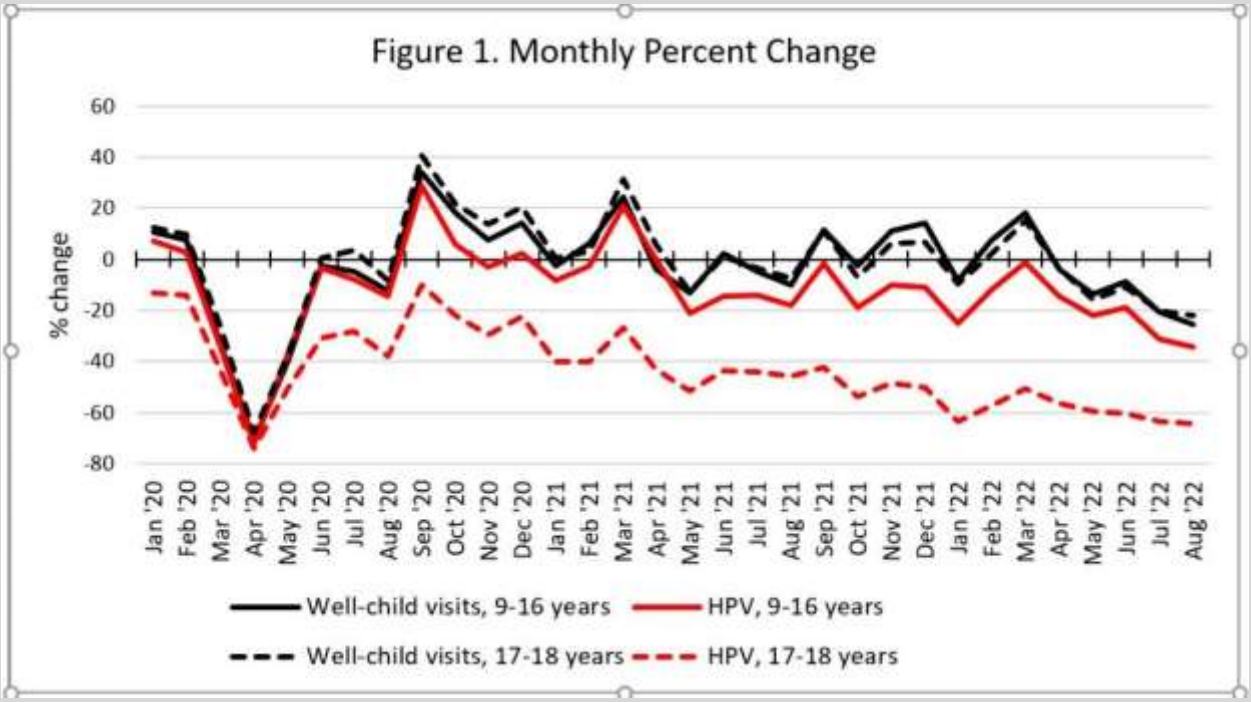
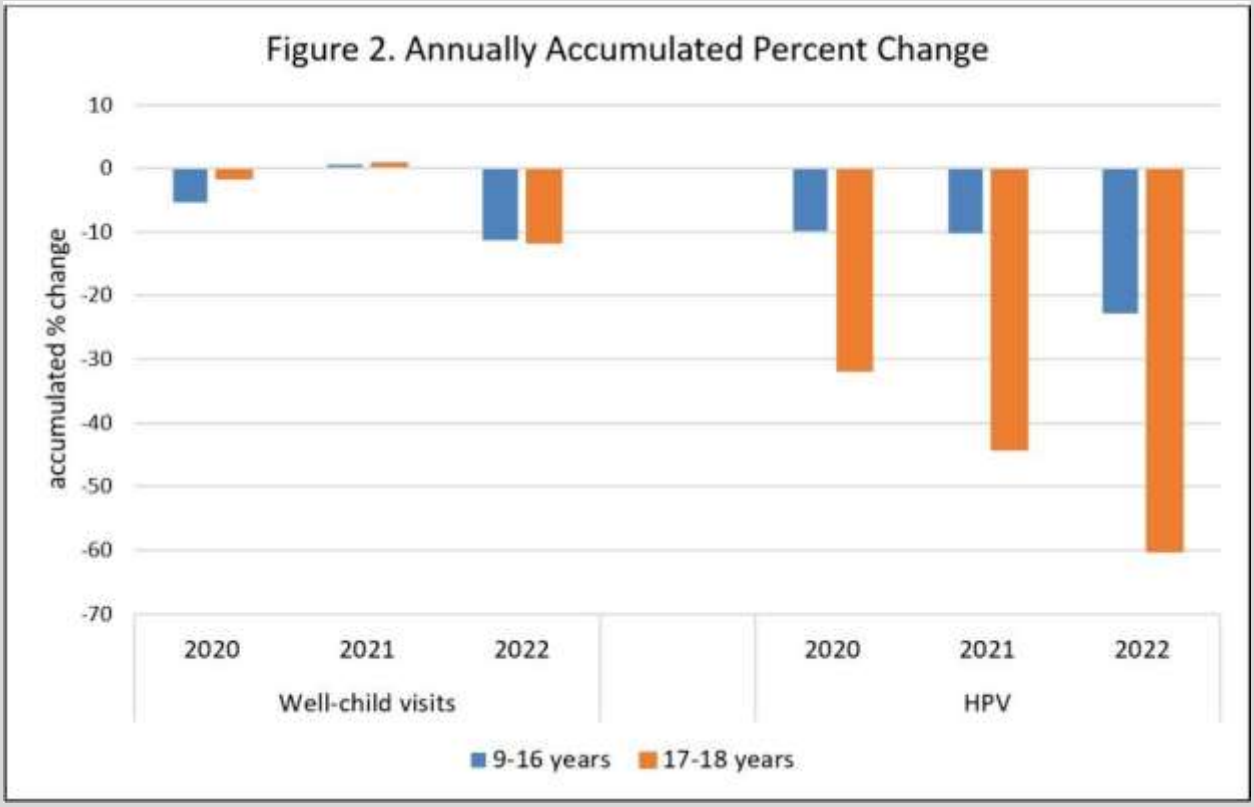
Introduction: Previous studies have reported significant disruption in well-child visits and in routine pediatric and adolescent vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP) in the United States (US) between 2020 and early 2021; adolescent vaccination, including human papillomavirus (HPV), was shown to have the most significant disruption. We sought to provide an update on the trends in adolescent well-child visits and HPV vaccination up to August 2022.

Methods: We utilized the Merative™ MarketScan Commercial Database (Early View) and analyzed enrolled individuals from January 1, 2018 until August 31, 2022. The monthly rates of in-person well-child visits and HPV vaccinations were calculated for the study period (January 2020 to August 2022) and compared to the respective monthly rates from the baseline period (January 2018 to December 2019). Monthly rates were aggregated over time as annual accumulated percent change.

Results: Relative to the baseline period, adolescent well-child visits (9-16 years of age) declined with the greatest decrease in April 2020 (-71.2%); some recovery was observed later in 2020 but declined again in early 2021 and remained low through August 2022. HPV vaccination rates followed a similar trend but with lower rates (Figure 1); there were 9.9% fewer vaccine administrations than expected in 2020 and 22.8% fewer in 2022 as of August (Figure 2). Those aged 17-18 years experienced even greater declines, suggesting these lost vaccinations were not made up in subsequent years.





Conclusions: The negative impact of the COVID-19 pandemic on adolescent well-child visits and HPV vaccinations in the US continues to be substantial through August 2022 with vaccination deficits worsening and little evidence of catching up of missed HPV vaccination. Concerted multi-stakeholder efforts to reverse these trends are urgently needed to prevent increase in HPV-related disease and economic burden.

O173 / #1784

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: INTERVENTIONS, HEALTH ECONOMICS AND MATHEMATICAL MODELING
04-21-2023 10:00 AM - 11:30 AM

DURABILITY OF HPV-16/18 ANTIBODIES 16 YEARS AFTER A SINGLE DOSE OF THE BIVALENT HPV VACCINE: THE COSTA RICA HPV VACCINE TRIAL

Byron Romero[1], Rolando Herrero[1], Carolina Porras[1], Allan Hildesheim[1], Rebecca Ocampo[1], Bernal Cortes[1], Romain Fantin[1], Aimee Kreimer[2], Mónica Sierra[2], Mitchell Gail[2], Danping Liu[2], John Schussler[3], John Schiller[4], Douglas Lowy[5], Troy Kemp[6], Ligia Pinto[7]
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Introduction: There is increasingly high confidence in the documented protection afforded by a single dose of the HPV vaccines. Durability of this protection is necessary to control cervical cancer. The Costa Rica HPV Vaccine Trial (CVT) provided evidence that antibody levels observed more than a decade following single-dose vaccination with the bivalent HPV vaccine were sufficient to confer very high vaccine efficacy. We extended this evaluation to assess HPV16/18 antibody levels up to 16 years after initial HPV vaccination.

Methods: In the HPV-vaccinated arm of CVT, 991 women were invited to continue follow-up after the 11-year visit, including 398 women who had received three-dose, 368 who had received two-doses and 193 who had received one-dose. More than 95% of these women completed the 14- and 16-year visits and blood collections. Antibody concentration was assessed by ELISA. HPV16 and 18 seropositivity and GMTs were calculated with 95% confidence intervals (CIs) by dose group.

Results: Regardless of number of doses, HPV16 and 18 seropositivity at 14 and 16 years remained close to 100% up to 16-years after HPV vaccination (Table). Between years 11 and 16, HPV16 antibody GMT levels declined 16% for women who received 3 doses, 20% for those who received 2 doses and 7% for those who received 1 dose. A similar pattern was observed for HPV18.

Table. Distribution of ELISA antibody seropositivity and GMC (IU/mL) levels for HPV16 and 18 at years eleven, fourteen and sixteen, by dose group

		1 dose			2 doses (0/6 mo)			3 doses		
Virus Type	Year Visit	Positivity (n/N)	% (95% CI)	GMC (IU/mL)	Positivity (n/N)	% (95% CI)	GMC (IU/mL)	Positivity (n/N)	% (95% CI)	GMC (IU/mL)
HPV 16	11	185/185	100.0 (98.0-100.0)	25.6 (21.7-30.2)	78/78	100.0 (95.4-100.0)	50.1 (40.9-61.3)	475/475	100.0 (99.2-100.0)	78.2 (72.2-84.7)
	14	191/193	99.0 (96.3-99.9)	24.9 (21.1-29.3)	87/87	100.0 (95.8-100.0)	43.1 (35.3-52.7)	385/386	99.7 (98.6-100.0)	66.8 (60.8-73.3)
	16	181/182	99.5 (97.0-100.0)	23.8 (20.1-28.2)	85/85	100.0 (95.7-100.0)	39.9 (32.2-49.3)	369/369	100.0 (99.0-100.0)	65.7 (59.7-72.4)
HPV 18	11	183/184	99.5 (97.0-100.0)	16.9 (14.2-20.0)	78/78	100.0 (95.4-100.0)	35.9 (29.4-43.8)	475/475	100.0 (99.2-100.0)	40.3 (36.8-44.0)
	14	192/193	99.5 (97.1-100.0)	16.7 (14.2-19.6)	87/87	100.0 (95.8-100.0)	30.8 (25.0-37.9)	386/386	100.0 (99.0-100.0)	33.9 (30.6-37.5)
	16	180/182	98.9 (96.1-99.9)	16.2 (13.6-19.3)	85/85	100.0 (95.7-100.0)	28.6 (23.2-35.2)	369/369	100.0 (99.0-100.0)	32.1 (28.8-35.7)

*CI = confidence interval; ELISA = enzyme-linked immunosorbent assay; GMC = geometric mean concentration

Conclusions: Sixteen years after HPV vaccination, almost 100% of HPV-vaccinated women remained seropositive irrespective of the number of HPV vaccine doses received. Minimal decline in the antibody concentration was observed over time, especially for the single-dose HPV vaccine group. These data

confirm that a single dose of bivalent HPV vaccine induces durable antibodies, supporting the recent update to WHO recommendations.

O174 / #779

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: INTERVENTIONS, HEALTH ECONOMICS AND MATHEMATICAL MODELING
04-21-2023 10:00 AM - 11:30 AM

THE NEGATIVE PREDICTIVE VALUE OF A CERVICAL HPV TEST AND THE RISK OF CERVICAL INTRAEPITHELIAL NEOPLASIA AND CANCER IN YOUNG WOMEN OVER A 29-YEAR PERIOD.

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Introduction: There is a global shift in the recommended primary cervical screening method from conventional cytology towards HPV testing. Because HPV testing is more sensitive, it has been suggested to extend screening intervals to every five years. Even longer screening intervals for HPV negative women may be feasible. The aim of this study was to examine the long-term negative predictive value of a cervical high-risk human papillomavirus (hrHPV) test in a young female population in a Danish setting.

Methods: During 1991-1993, a cohort of 11 088 Danish women aged 20 to 29 years was established. They all had a gynecological examination with cervical cytology and a swab for hrHPV DNA detection and genotyping using the Hybrid Capture 2 and InnoLiPa methods. The women were followed in the national Pathology Registry for diagnoses of CIN2+, CIN3+, and cervical cancer for up to nearly 30 years.

Results: Altogether 8.756 women had a negative hrHPV test at baseline. The absolute risk of CIN2+, CIN3+ and cervical cancer within 27 years of follow-up was low, 7.3%, 5.2% and 0.4%, respectively. The risk was slightly lower for women with an additional normal cytology at baseline. After 27 years, a lower risk of developing CIN2+/CIN3+ was seen for women older than 25 years at baseline compared to women 25 or younger: CIN2+ 6.1% (95% CI: 4.9-6.6) vs. 8.7% (95% CI: 7.8-9.7) and CIN3+ 4.1% (95% CI: 3.4-4.8) vs. 6.2% (95% CI: 5.4-7.0). In contrast, we observed no significant difference between the two age groups regarding the risk of subsequent cervical cancer.

Conclusions: In a Danish cervical cancer screening context, a negative hrHPV test in young women still shows a high negative predictive value for CIN2+, CIN3+ and cervical cancer after almost 30 years of follow-up.

O175 / #791

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-21-2023 10:00 AM - 11:30 AM

PREVALENCE AND FACTORS ASSOCIATED WITH CONCORDANT ANOGENITAL HUMAN PAPILLOMAVIRUS (HPV) INFECTION FOR 9-VALENT (9V) HPV VACCINE TYPES IN MALES

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Introduction: Previous studies in males did not quantify global prevalence and risk factors of concordant HPV infection (ie, same-type infection) across multiple anogenital sites.

Methods: Baseline data from males aged 16-27 participating in a global 4-valent HPV vaccine trial (NCT00090285) were assessed for prevalent HPV infection at penile/scrotal and perineal/perianal sites (heterosexual men [HM] and men who have sex with men [MSM]) and at intra-anal sites (MSM). Categories were HPV-negative for all 9vHPV vaccine types (6/11/16/18/31/33/45/52/58) across all anogenital sites, non-concordant infection (infection at one site), or concordant infection (at two or three sites). Factors associated with concordant 9vHPV infection at ≥2 sites were assessed using an age-adjusted logistic regression model.

Results: Included were 3364 HM and 595 MSM. Among HM with prevalent 9vHPV infection, 329/455 (72.31%) had non-concordant infection at one anogenital site and 126/455 (27.69%) had concordant infection at two sites. Among MSM with prevalent 9vHPV infection (excluding intra-anal sites), 118/171 (69.01%) had non-concordant infection and 53/171 (31.00%) had concordant infection at two sites; concordant infection at any two or three sites (including intra-anal sites) was observed in 92/229 (40.17%) and 49/229 (21.40%) MSM, respectively. HPV6 and HPV16 were most likely to occur at multiple anogenital sites in HM and MSM. Factors associated with statistically significant increased odds of concordant infection ($p<0.05$) were geographic region (both HM and MSM; higher in Africa, Europe and Latin America than in North America), higher number of lifetime partners (both HM and MSM), and younger age at first intercourse (HM only). Decreased odds of concordant infection were associated with circumcision in both HM and MSM.

Conclusions: A high proportion of HM and MSM with prevalent infection at baseline had concordant 9vHPV infection, suggesting a risk of HPV-associated cancer at multiple anogenital sites.

O176 / #711

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-21-2023 10:00 AM - 11:30 AM

LONG-TERM EFFICACY, IMMUNOGENICITY, AND SAFETY OF THE QUADRIVALENT AND 9-VALENT HPV VACCINES: AN OVERVIEW OF CLINICAL TRIAL LONG-TERM FOLLOW-UP STUDIES

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Introduction: Given the lifetime risk of HPV infection, prophylactic HPV vaccine clinical programs must demonstrate durable protection against infection and disease. Pivotal baseline clinical trials of the quadrivalent (qHPV) and 9-valent (9vHPV) vaccines were extended to assess long-term effectiveness against infection and disease up to 14 years (y).

Methods: Six long-term follow-up (LTFU) extension studies were designed to evaluate long-term effectiveness of the qHPV (NCT00092534, NCT00090220, NCT00090285, NCT00092547) and 9vHPV (NCT00943722, NCT02653118) vaccines in females (aged 9-45y) and males (aged 9-26y), with follow-up periods of 10-14y. Endpoint evaluation was carried out in a rigorous fashion throughout the studies. Tissue samples collected because of lesions suspicious for HPV-related disease were analyzed. Pathology panel adjudication was performed on all tissue specimens, and HPV typing was conducted to determine endpoint attribution. In some studies, participants randomized to placebo in qHPV vaccine trials who received catch-up qHPV vaccination at the end of the base study were followed during LTFU to evaluate effects of delayed vaccination at an older age.

Results: Across all studies, the qHPV and 9vHPV vaccine demonstrated durable effectiveness; no cases of high-grade cervical, vulvar, vaginal, and anal dysplasia or condyloma related to vaccine-targeted HPV types were observed during LTFU. Vaccine effectiveness was also observed in the catch-up qHPV vaccination groups. The LTFU studies included participants vaccinated at various ages (9-45y), of both genders, of various sexual orientations (heterosexual men and men having sex with men), and various countries across five continents, which supports the generalizability of the results.

Conclusions: Over 10-14y, qHPV and 9vHPV vaccines provided sustained protection with no breakthrough disease related to HPV vaccine types across studies in males vaccinated at ages 9-26y and females vaccinated at ages 9-45y. Catch-up vaccination was effective, suggesting that vaccination of adults not previously vaccinated may be beneficial.

O177 / #862

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-21-2023 10:00 AM - 11:30 AM

MULTICENTRIC COHORT STUDY TO COMPARE LONG-TERM EFFICACY OF A SINGLE-DOSE OF 4-HPV VACCINE COMPARED TO TWO- & THREE-DOSE IN 10-18 YR OLD FEMALES IN INDIA

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Introduction: In a multi-centric Indian cohort study, unmarried girls aged 10-18 years received three doses, two doses or a single dose of the quadrivalent vaccine. We present 10-year immune responses, and 12-year follow-up findings on the efficacy of single-dose compared to other doses in preventing persistent HPV infection and high grade cervical precancers for the vaccinated and age-matched unvaccinated cohorts.

Methods: Around 17,000 vaccinated (evenly distributed across different dose groups) and 1,450 unvaccinated women are being followed up yearly. Serology samples were obtained at months 0, 7, 12, 18, 24, 36, 48, 60 and 120 after first dose from a convenient sample of vaccinated participants and at one timepoint from unvaccinated women. Cervical samples are collected initially at 18-months after marriage and yearly thereafter for at least four consecutive samples. E7-PCR multiplex genotyping is performed on the samples to detect 19 high or probable high-risk and two low-risk types. Married participants are screened for cervical cancer starting at 25 years with Hybrid Capture-II HPV test

Results: Ten years after vaccination, the antibody levels were at least two times higher in single dose recipients compared to those following natural infection. Based on evaluation of 2454 single-dose recipients in the year 2021, the vaccine efficacy against persistent HP16/18 infections was estimated to be 94% for the single-dose, which was similar to that of two-dose (95%) and three-dose (91%) recipients. No HPV16/18-related CIN2/3 detected in vaccinated women. Updated results based on evaluation of 2,730 single-dose recipients evaluable for persistent infection will be presented along with updated outcomes of cervical screening.

Conclusions: Systematic and rigorous evaluation of infection endpoints in the IARC-India study has established the robust protection offered by a single dose against persistent infection. The long-term protection is well-supported by immunogenicity data. Early data from screening outcomes is also encouraging.

O178 / #66

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-21-2023 10:00 AM - 11:30 AM

HPV VACCINATION IN WOMEN WITH CERVICAL INTRAEPITHELIAL NEOPLASIA UNDERGOING EXCISIONAL TREATMENT: INSIGHTS INTO UNSOLVED QUESTIONS

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Introduction: Several questions regarding the role of vaccination in women treated for high-grade cervical intraepithelial lesion (HSIL) have not been clarified. One of the main queries is whether the time at which the vaccine is administered (before or after treatment) influences the protection against post-treatment HSIL. A second unsolved question is whether the vaccine has any effect in women with persistent HPV after treatment. We aimed to address these questions in a series of 398 women undergoing excisional treatment from July 2016 to December 2019

Methods: Vaccination was funded and offered to all women undergoing treatment. Post-treatment follow-up controls were scheduled every six months with a Pap smear, HPV testing, and a colposcopy

Results: 306 women (76.9%) accepted HPV vaccination (vaccinated group): 113 (36.9%) received the first dose before excision and 193 (63.1%) after the procedure. 92 women (23.1%) refused the vaccine (non-vaccinated group). Women vaccinated before treatment showed a lower rate of post-treatment HSIL compared with non-vaccinated women (0.9% vs. 6.5%; p=0.047). Among women with persistent HPV infection after treatment, those who had received the vaccine showed a lower prevalence of post-treatment HSIL than non-vaccinated women (2.6% vs. 10.5%; p=0.043).

Conclusions: In conclusion, this study shows that HPV vaccination before treatment reduces the prevalence of post-treatment HSIL and suggests that vaccination might even benefit women with persistent HPV after treatment.

O179 / #689

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-21-2023 10:00 AM - 11:30 AM

LONG-TERM EFFECTIVENESS OF THE 9-VALENT HUMAN PAPILLOMAVIRUS (9VHPV) VACCINE IN SCANDINAVIAN COUNTRIES

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Introduction: A long-term follow-up (LTFU) extension (NCT02653118) of the 9-valent human papillomavirus (9vHPV) vaccine efficacy study in women aged 16–26 years (y) (NCT00543543) was initiated to assess effectiveness and immunogenicity up to 14y. We report an interim analysis conducted at 8y post-vaccination for effectiveness and 9y for immunogenicity.

Methods: Participants from Denmark, Norway, and Sweden, who received 9vHPV vaccine during base study and consented, continued into LTFU. National health registries were used to assess those screened and diagnosed with cervical (pre)cancers. Cervical tissue from biopsy and definitive therapy exams were retrieved from clinical biobanks for adjudication of pathology diagnosis and tested for HPV DNA by PCR. To assess effectiveness, observed incidence of HPV16/18/31/33/45/52/58-related cervical intraepithelial neoplasia-2 (CIN2), CIN3, adenocarcinoma in situ, or cervical cancer was compared with estimated incidence in an unvaccinated cohort (similar age/risk). A control chart method was used to detect signals of vaccine effectiveness <90%. Blood was collected at 9y from a subset of participants to assess antibody persistence by competitive Luminex immunoassay. Primary analyses were conducted in the per-protocol effectiveness (PPE) and per-protocol immunogenicity populations.

Results: Of 2223 participants who received ≥1 dose of 9vHPV vaccine at start of base study, 2029 continued into LTFU. Analyses were conducted based on median effectiveness follow-up post-Dose 1 of 6.8y (maximum 10.0y) among participants included in PPE analyses (n=1799). No new cases of HPV16/18/31/33/45/52/58-related CIN2 or worse were observed during LTFU among 1448 PPE participants (4084.2 person-years). Analyses indicated no waning of vaccine effectiveness over ≥6y post Dose 1. There were indications of continued effectiveness through 8y post Dose 1. Immunogenicity analyses (n=150) showed that anti-HPV antibodies persisted through 9y post-vaccination. Effectiveness data ≥9y are not available.

Conclusions: The 9vHPV vaccine provides continued protection through ≥6y post-vaccination with a trend toward continued effectiveness for up to 8y, and persistent anti-HPV immunogenicity through 9y.

O180 / #545

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-21-2023 10:00 AM - 11:30 AM

EFFECTIVENESS OF THE QUADRIVALENT HUMAN PAPILLOMAVIRUS VACCINE IN CHINESE WOMEN: A 13-YEAR LONG-TERM FOLLOW-UP OF A PHASE 3, DOUBLE-BLIND, RANDOMIZED CONTROL TRIAL

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Introduction: A randomized clinical trial (NCT00834106, V501-041) in Chinese women aged 20-45 years beginning in 2009 demonstrated the safety and efficacy of quadrivalent HPV (qHPV) vaccine during 78-month follow-up since Dose 1. A 13-year long-term follow-up (LTFU) study of V501-041 participants was conducted to evaluate the long-term effectiveness against cervical intraepithelial neoplasia (CIN).

Methods: During LTFU, the participants initially receiving the qHPV vaccine in V501-041 study constituted the early vaccination group (EVG). Those who initially received the placebo but were vaccinated from 2018 to 2020 were regarded as the catch-up vaccination group (CVG), while the control group (CG) comprised those remaining unvaccinated. A cytology-based cervical cancer screening was conducted. The endpoint was defined as histopathological-confirmed CIN2+ tested PCR-positive for HPV6/11/16/18. Effectiveness was computed by incidence. Incidence was compared between EVG and CG in the per-protocol (PP) population, and between EVG and CVG in the modified intention-to-treat (mITT) population.

Results: 1100 subjects in V501-041, among which 978 were followed in LTFU, were included with a median follow-up of 152.2 months (interquartile range (IQR: 150.8-154.9) from Dose 1 to the last follow-up of LTFU study. During V501-041 study and LTFU, the incidence per 10 000 person-years of HPV-6/11/16/18-related CIN2+ was numerically higher in the CG (N=273; 3.4 (95% CI: 0.1-18.8)) than in the EVG (N=493; 0 (0.0-6.6)), indicating 100% (≤ -999, 100) risk reduction between two groups. For the CVG, no cases of HPV6/11/16/18-related CIN2+ were detected from vaccination to the last follow-up of the LTFU (N=155) (0.0 per 10 000 person-years (0·0–81.2)), while the incidence before vaccination was 22.2 per 10 000 person-years (4.6-64.9). These results represent observed long-term effectiveness through 13 years.

Table 1. Baseline characteristics of participants included in this LTFU in Shanxi Province at the time of Dose 1 vaccination in V501-041 study

	Early vaccination group		Catch-up vaccination group		Control group		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Age (Years)								
20 to 26	397	72.0	163	73.4	231	70.6	791	71.9
27 to 45	154	28.0	59	26.6	96	29.4	309	28.1
Mean	27.4		26.7		28.3		27.6	
SD	5.7		4.2		6.9		5.8	
Median (min-max)	25 (20-45)		25 (21-36)		25 (20-45)		25 (20-45)	
Age at first sexual intercourse (Years)								
Mean	20.6		20.6		20.6		20.6	
SD	1.9		1.8		2.0		1.9	
Median (min-max)	21 (14-28)		21 (16-25)		21 (15-27)		21 (14-28)	
Number of sexual partners								
1	463	84.0	197	88.7	276	84.4	936	85.1
>=2	88	16.0	25	11.3	51	15.6	164	14.9
Abnormality on cervical cytology								
Yes	56	10.2	14	6.3	25	7.6	95	8.6
No	471	85.5	196	88.3	285	87.2	952	86.5
Unsatisfactory	24	4.4	12	5.4	17	5.2	53	4.8
Positive to HPV6, 11, 16, or 18								
By serology*	138	25.0	56	25.2	79	24.2	273	24.8
By PCR*	42	7.6	30	13.5	28	8.6	90	8.2
By serology or PCR*	154	27.9	66	29.7	95	29.1	315	28.6

*Combined prevalence on HPV6, 11, 16, or 18

Table 2 Reduction in the incidence of histology abnormalities in women who participated in the long-term follow-up study between early vaccination group and control group (Per-protocol population)

	Early vaccination group (n=551)			Control group (n=327)			Early vaccination group vs control group risk reduction estimate (%) (95% CI)*
	Participants	Person-years follow-up	Incidence per 10 000 person-years (95% CI)	Participants	Person-years follow-up	Incidence per 10 000 person-years (95% CI)	
HPV 6-, 11-, 16, and 18-related CIN1+							
V501-041 study	0/488	2732.4	0 (0.0-13.5)	3/272	1520.7	19.7 (4.1-57.7)	100 (-34.7, 100)
Long-term follow-up study	0/450	2327.7	0 (0.0-15.8)	0/232	1187.8	0 (0.0-31.1)	..
V501-041 study + Long-term	0/493	5549.6	0 (0.0-6.6)	3/273	2950.0	10.2 (2.1-29.7)	100 (-28.6, 100)
HPV 6-, 11-, 16, and 18-related CIN2+							
V501-041 study	0/488	2732.4	0 (0.0-13.5)	1/272	1522.2	6.6 (0.2-36.6)	100 (≤ -999, 100)
Long-term follow-up study	0/450	2327.7	0 (0.0-15.8)	0/232	1187.8	0 (0.0-31.1)	..
V501-041 study + Long-term	0/493	5549.6	0 (0.0-6.6)	1/273	2961.1	3.4 (0.1-18.8)	100 (≤ -999, 100)

Unless otherwise indicated, data are n/N, where n is the number of endpoint cases and N is number of participants in the analysis population with follow-up in the indicated study period.

*Refers to percentage reduction in incidence in the early vaccination group versus the control group during the indicated period; during the long-term follow-up study, the comparison between these two groups represents a comparison between similarly quadrivalent HPV-vaccinated populations.

HPV = Human papillomavirus; CIN 1+ = Cervical intraepithelial neoplasia 1 or worse; CIN 2+ = Cervical intraepithelial neoplasia 2 or worse.

Table 3 Reduction in the incidence of histology abnormalities in women who participated in the long-term follow-up study between early vaccination group and catch-up vaccination group

	Early vaccination group (n=551)			Catch-up vaccination group (n=222)			Early vaccination group vs catch-up vaccination group risk reduction estimate (%) (95% CI)*
	Participants	Person-years follow-up	Incidence per 10 000 person-years (95% CI)	Participants	Person-years follow-up	Incidence per 10 000 person-years (95% CI)	
HPV 6-, 11-, 16, and 18-related CIN1+							
Per-protocol population							
V501-041 study	0/488	2732.4	0 (0.0-13.5)	2/203	1155.0	17.3 (2.1-62.6)	100 (-125.1 to 100)
Long-term follow-up study	0/450	2327.7	0 (0.0-15.8)	-	-	-	-
mITT population							
V501-041 study	1/540	3265.4	3.1 (0.1-17.1)	3/218	1351.0	22.2 (4.6-64.9)	86.2 (-71.8 to 99.7)
Long-term follow-up study	0/488	2521.4	0 (0.0-14.6)	0/155	454.4	0 (0.0-81.2)	..
HPV 6-, 11-, 16, and 18-related CIN2+							
Per-protocol population							
V501-041 study	0/488	2732.4	0 (0.0-13.5)	2/203	1155.2	17.3 (2.1-62.5)	100 (-125.1 to 100)
Long-term follow-up study	0/450	2327.7	0 (0.0-15.8)	-	-	-	-
mITT population							
V501-041 study	0/540	3265.5	0 (0.0-11.3)	3/218	1351.2	22.2 (4.6-64.9)	100 (-0.1 to 100)
Long-term follow-up study	0/488	2521.4	0 (0.0-14.6)	0/155	454.4	0 (0.0-81.2)	..

Unless otherwise indicated, data are n/N, where n is the number of endpoint cases and N is number of participants in the analysis population with follow-up in the indicated study period.

*Refers to percentage reduction in incidence in the early vaccination group versus the catch-up vaccination group during the indicated period; during the long-term follow-up study, the comparison between these two groups represents a comparison between similarly quadrivalent HPV-vaccinated populations.

HPV = Human papillomavirus; mITT = Modified intention to treat; CIN 1+ = Cervical intraepithelial neoplasia 1 or worse; CIN 2+ = Cervical intraepithelial neoplasia 2 or worse.

Conclusions: Reporting the longest follow-up for qHPV vaccine effectiveness in Chinese women, this study demonstrated continued protection against cervical precancers related to HPV6/11/16/18 through 13 years post-vaccination.

O181 / #902

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-21-2023 10:00 AM - 11:30 AM

SINGLE DOSE OF NONAVALENT PROPHYLACTIC HPV VACCINE INDUCES STABLE HPV16 AND HPV18 ANTIBODY RESPONSES UP TO 24 MONTHS AMONG 9-11 YEAR-OLD GIRLS AND BOYS

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Introduction: Emerging data suggest that a single dose of the bivalent or quadrivalent HPV vaccine generates antibody responses and efficacies similar to 2-dose schedules in children. No similar data are yet available for the nonavalent vaccine (9vHPV). Such data may inform policy considerations around usage of a single dose of 9vHPV to reduce costs of vaccination worldwide.

Methods: This is a prospective, single-arm, open-label, non-randomized, Phase IIa trial to determine the stability of HPV type-specific antibody responses up to 24 months after a single dose of 9vHPV in 201 healthy 9–11-year-old girls and boys. Subjects received a single dose of the 9vHPV at baseline, a delayed 2nd dose at month 24, and an optional 3rd dose at month 30. Blood samples were collected at baseline and at 6, 12, 18, 24, and 30 months after the prime dose. Primary outcomes were serum geometric mean concentrations (GMC) of HPV-16 and HPV-18 IgG antibodies.

Results: Demographics are shown in Table 1. GMCs of HPV16 and HPV18 antibodies are shown in Table 2. Table 3 shows high GMC at 6 months that declined between months 6 to 12, and stabilized between months 12, 18, and 24 (meeting the pre-specified hypotheses of non-inferior responses). The GMC were stable (or slightly higher) among 87.7% participants between months 12 and 24; among the remaining participants none showed consistent declines declines between both 18- vs. 12- and 24- vs. 18-months timepoint comparisons. Almost all participants (97%/96%) had significantly boosted responses for HPV16/HPV18 after the 3rd dose. One participant (0.5%) did not seroconvert after the single dose.

Table 1. Participant characteristics at baseline.

	All (n=201)	Girls (n=143)	Boys (n=58)
Age, yr, Mean (SD)	10 (0.8)	10 (0.8)	10 (0.8)
Race			
American Indian or Alaskan Native (n (%))	4 (2.0)	4 (2.8)	0 (0)
Asian (n (%))	23 (11.4)	15 (10.5)	8 (13.8)
Black or African American (n (%))	7 (3.5)	5 (3.5)	2 (3.5)
Native Hawaiian or Other Pacific Islander (n (%))	1 (0.5)	1 (0.7)	0 (0)
Unknown (n (%))	8 (4.0)	7 (4.9)	1 (1.7)
White (n (%))	131 (65.2)	92 (64.3)	39 (67.2)
More than one race (n (%))	27 (13.4)	19 (13.3)	8 (13.8)
Ethnicity			
Hispanic or Latino (n (%))	100 (49.8)	75 (52.5)	25 (43.1)
Not Hispanic or Latino (n (%))	100 (49.8)	68 (47.6)	32 (55.2)
Unknown (n, %)	1 (0.5)	0 (0)	1 (1.7)
BMI, kg/m², Mean (SD)	19.7 (4.7)	19.8 (4.6)	19.6 (4.8)
Menarche, Yes (n (%))	-	9 (6.3)	-

Abbreviations: BMI: Body mass index, SD: standard deviation.

Table 2: Summary of HPV 16 and 18 antibody responses.

Time	HPV16 antibody	HPV18 antibody
	All Participants	
	GMC[a] (95% CI)[b]	GMC (95% CI)
Baseline	0.73 (0.69, 0.78) (n=179)	0.75 (0.70, 0.80) (n=178)
6 months	25.20 (22.19, 28.61) (n=179)	10.67 (9.47, 12.02) (n=179)
12 months	14.54 (12.60, 16.77) (n=179)	7.27 (6.33, 8.34) (n=179)
18 months	15.01 (12.73, 17.71) (n=179)	7.23 (6.19, 8.44) (n=179)
24 months	15.05 (12.71, 17.81) (n=180)	7.11 (6.01, 8.41) (n=180)
30 months	427.1 (362.2, 502.3) (n=178)	134.8 (114.9, 158.3) (n=178)
	GMC ratio (lower bound of one-sided 95% CI; p)[c]	GMC ratio (lower bound of one-sided 95% CI; p)[c]
12/6 month ratio	0.58 (0.54; 1.00)	0.68 (0.64; 1.00)
18/12 month ratio	1.03 (0.96; <0.0001)	1.00 (0.99; <0.0001)
24/18 months ratio	1.00 (0.92; <0.0001)	0.98 (0.91; <0.0001)
	Girls	
	GMC (95% CI)	GMC (95% CI)
Baseline	0.72 (0.68, 0.77) (n=130)	0.77 (0.71, 0.84) (n=129)
6 months	25.28 (21.66, 29.49) (n=130)	10.81 (9.32, 12.55) (n=130)
12 months	15.59 (13.25, 18.35) (n=130)	7.71 (6.53, 9.11) (n=130)
18 months	15.91 (13.36, 18.95) (n=130)	7.51 (6.32, 8.92) (n=130)
24 months	15.73 (13.08, 18.91) (n=130)	7.30 (6.01, 8.88) (n=130)
30 months	448.2 (369.4, 543.8) (n=129)	136.5 (112.8, 165.2) (n=129)
	GMC ratio (lower bound of one-sided 95% CI; p)[c]	GMC ratio (lower bound of one-sided 95% CI; p)[c]
12/6 month ratio	0.62 (0.58; 1.00)	0.71 (0.67; 1.00)
18/12 month ratio	1.02 (0.95; <0.0001)	0.97 (0.92; <0.001)
24/18 months ratio	0.99 (0.91; 0.0001)	0.97 (0.90; <0.001)
	Boys	
	GMC (95% CI)	GMC (95% CI)
Baseline	0.75 (0.65, 0.87) (n=49)	0.70 (0.63, 0.77) (n=49)
6 months	24.99 (19.91, 31.36) (n=49)	10.30 (8.51, 12.47) (n=49)
12 months	12.07 (8.96, 16.25) (n=49)	6.20 (4.81, 7.99) (n=49)
18 months	12.88 (8.67, 19.13) (n=49)	6.53 (4.63, 9.22) (n=49)
24 months	13.41 (9.16, 19.63) (n=50)	6.62 (4.72, 9.29) (n=50)
30 months	376.3 (277.6, 510.1) (n=49)	130.5 (96.00, 177.3) (n=49)
	GMC ratio (lower bound of one-sided 95% CI; p)[d]	GMC ratio (lower bound of one-sided 95% CI; p)[d]
12/6 month ratio	0.49 (0.42; 1.00)	0.60 (0.54; 1.00)
18/12 month ratio	1.07 (0.86; 0.0001)	1.05 (0.88; 0.0001)
24/18 months ratio	1.02 (0.83; <0.001)	1.01 (0.83; <0.001)

[a]GMC: geometric mean concentration (IU/mL)

[b]derived from log-normal distribution

[c]derived from one-sided pair t-test with a non-inferiority margin of -0.35 standard deviations. If the lower bound of the 95% CI is above the exp(-0.35 standard deviations of changes in log-transformed HPV16/18), it will produce a one-sided p-value <0.05 and indicates the subsequent time point had an non-inferior HPV16/HPV18 to the prior time point. To account for multiple comparisons, each individual p-value needs to be multiplied by the number of comparisons for the threshold of statistical significance. Hence a p-value of less than 0.0167 (0.0167*3=0.0501) is considered necessary for statistical significance after accounting for 3 simultaneous comparisons (12 vs. 6, 18 vs. 12, and 24 vs. 18).

[d]derived from one-sided pair t-test with a non-inferiority margin of -0.50 standard deviations. If the lower bound of the 95% CI is above the exp(-0.50 standard deviations of changes in log-transformed HPV16/18), it will produce a one-sided p-value <0.05 and indicates the subsequent time point had an non-inferior HPV16/HPV18 to the prior time point. To account for multiple comparisons, each individual p-value needs to be multiplied by the number of comparisons for the threshold of statistical significance. Hence a p-value of less than 0.0167 (0.0167*3=0.0501) is considered necessary for statistical significance after accounting for 3 simultaneous comparisons (12 vs. 6, 18 vs. 12, and 24 vs. 18).

Table 3: Summary of changes in HPV16 and HPV18 antibody concentrations.

	HPV16		HPV18	
	All Participants			
	Freq (%)	95% CI*	Freq (%)	95% CI
6-0 months				
Decrease	0	NA	0	NA
Stable	2 (1.1%)	(0.1%, 4.0%)	2 (1.1%)	(0.1%, 4.0%)
Increase	177 (98.9%)	(96.0%, 99.9%)	176 (98.9%)	(96.0%, 99.9%)
12-6 months				
Decrease	69 (38.6%)	(31.4%, 46.1%)	43 (24.0%)	(18.0%, 31.0%)
Stable	105 (58.7%)	(51.1%, 66.0%)	134 (74.9%)	(67.8%, 81.0%)
Increase	5 (2.8%)	(0.9%, 6.4%)	2 (1.1%)	(0.1%, 4.0%)
18-12 months				
Decrease	7 (3.9%)	(1.6%, 7.9%)	6 (3.4%)	(1.2%, 7.2%)
Stable	162 (90.5%)	(85.2%, 94.4%)	164 (91.6%)	(86.6%, 95.2%)
Increase	10 (5.6%)	(2.7%, 10.0%)	9 (5.0%)	(2.3%, 9.3%)
24-18 months				
Decrease	8 (4.5%)	(2.0%, 8.6%)	6 (3.4%)	(1.2%, 7.2%)
Stable	164 (91.6%)	(86.6%, 95.2%)	165 (92.2%)	(87.2%, 95.7%)
Increase	7 (3.9%)	(1.6%, 7.9%)	8 (4.5%)	(2.0%, 8.6%)
30-24 months				
Decrease	1 (0.6%)	(0.0%, 3.1%)	1 (0.6%)	(0.0%, 3.1%)
Stable	5 (2.8%)	(0.9%, 6.4%)	7 (3.9%)	(1.6%, 7.9%)
Increase	172 (96.6%)	(92.8%, 98.8%)	170 (95.5%)	(91.3%, 98.0%)
	Girls			
	Freq (%)	95% CI*	Freq (%)	95% CI
6-0 months				
Decrease	0	NA	0	NA
Stable	1 (0.8%)	(0.0%, 4.2%)	2 (1.6%)	(0.2%, 5.5%)
Increase	129 (99.2%)	(95.8%, 100%)	127 (99.0%)	(94.5%, 99.8%)
12-6 months				
Decrease	42 (32.3%)	(24.4%, 41.1%)	26 (20.0%)	(13.5%, 27.9%)
Stable	84 (64.6%)	(55.8%, 72.8%)	102 (78.5%)	(70.4%, 85.2%)
Increase	4 (3.1%)	(0.8%, 7.7%)	2 (1.5%)	(0.2%, 5.5%)
18-12 months				
Decrease	3 (2.3%)	(0.5%, 6.6%)	4 (3.08%)	(0.8%, 7.7%)
Stable	122 (93.9%)	(88.2%, 97.3%)	120 (92.3%)	(86.3%, 96.3%)
Increase	5 (3.9%)	(1.3%, 8.8%)	6 (4.6%)	(1.71%, 9.78%)
24-18 months				
Decrease	4 (3.1%)	(0.8%, 7.7%)	3 (2.3%)	(0.5%, 6.6%)
Stable	122 (93.9%)	(88.2%, 97.3%)	123 (94.6%)	(89.2%, 97.8%)
Increase	4 (3.1%)	(0.8%, 7.7%)	4 (3.1%)	(0.8%, 7.7%)
30-24 months				
Decrease	1 (0.8%)	(0.0%, 4.2%)	1 (0.8%)	(0.0%, 4.2%)
Stable	2 (1.6%)	(0.2%, 5.5%)	3 (2.3%)	(0.5%, 6.7%)
Increase	126 (97.7%)	(93.4%, 99.5%)	125 (96.9%)	(92.3%, 99.2%)
	Boys			
	Freq (%)	95% CI*	Freq (%)	95% CI
6-0 months				
Decrease	0	NA	0	NA
Stable	1 (2.0%)	(0.1%, 10.9%)	0	NA
Increase	48 (98.0%)	(89.2%, 100%)	49 (100%)	(92.8%, 100%)
12-6 months				
Decrease	27 (55.1%)	(40.2%, 69.3%)	17 (34.7%)	(21.7%, 49.6%)
Stable	21 (42.9%)	(28.8%, 57.8%)	32 (65.3%)	(50.4%, 78.3%)
Increase	1 (2.0%)	(0.1%, 10.9%)	0	NA
18-12 months				
Decrease	4 (8.2%)	(2.3%, 19.8%)	2 (4.1%)	(0.5%, 14.0%)
Stable	40 (81.6%)	(68.0%, 91.2%)	44 (89.8%)	(77.8%, 96.6%)
Increase	5 (10.2%)	(3.4%, 22.2%)	3 (6.1%)	(1.3%, 16.9%)
24-18 months				
Decrease	4 (8.2%)	(2.3%, 19.8%)	3 (6.1%)	(1.3%, 16.9%)
Stable	42 (85.7%)	(72.76%, 94.06%)	42 (85.7%)	(72.8%, 94.1%)
Increase	3 (6.1%)	(1.3%, 16.9%)	4 (8.2%)	(2.3%, 19.6%)
30-24 months				
Decrease	0	NA	0	NA
Stable	3 (6.1%)	(1.3%, 16.9%)	4 (8.2%)	(2.3%, 19.6%)
Increase	46 (93.9%)	(83.1%, 98.7%)	45 (91.8%)	(80.4%, 97.7%)

*derived from the exact 95% CI

Note: decrease is defined as more than 2 fold decrease; stable is defined as within 2 fold change; increase is defined as more than 2 fold increase

Conclusions: A single dose of 9vHPV induced persistent and stable antibody responses up to 24 months in the majority of participants, and a delayed dose at 24-months induces robust anamnestic responses. Declines and irregularities in antibody levels merit further study.

O182 / #956

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-21-2023 10:00 AM - 11:30 AM

RISK OF PROGRESSION OF CERVICAL INTRAEPITHELIAL NEOPLASIA GRADE 2 BY HPV VACCINATION STATUS

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Introduction: Risk stratification of women with CIN2 is crucial as many countries have implemented active surveillance for CIN2 due to high regression rates. However, we are lacking variables that enable identification of women with higher risk of progression to CIN3+. As HPV-vaccinated women have lower risk of cervical cancer, HPV-vaccinated women with CIN2 may have lower risk of progression. Hence, we investigated whether HPV-vaccinated women undergoing active surveillance for CIN2 are less likely to progress to CIN3+ during surveillance compared to unvaccinated women.

Methods: Using nationwide registries, we conducted a population-based cohort study on all women aged 18-40 undergoing active surveillance for CIN2 during 2007-2020 in Denmark. The primary outcome was CIN3+ during the active surveillance period of 28 months. We calculated risk ratios (RR) using modified Poisson regression to evaluate the association between vaccination status and risk of CIN3+.

Results: A total of 9,203 women underwent active surveillance for CIN2 of whom 3,876 (42.1%) had received the HPV vaccine. Median age at CIN2 diagnosis was 26 (IQR 23-30), with vaccinated women being slightly younger than those unvaccinated. Overall, HPV vaccination was not associated with a lower risk of progression to CIN3+ compared to no vaccination (RR 0.98 (95% CI 0.93-1.04)). Stratified by age at vaccination, women vaccinated before age 15 (RR 0.67 (95% CI 0.58-0.77)) and between age 15 and 17 (RR 0.83 (95% CI 0.72-0.95)) had a lower risk of progression to CIN3+ compared to no vaccination. Adjusted RRs with age, index cytology, and socioeconomic status will be presented.

Conclusions: Our preliminary results suggest that HPV vaccination at a young age may be associated with a lower risk of progression of CIN2 in 28 months. There is potential for HPV vaccination status to be used for risk stratification of women with CIN2.

O183 / #615

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-21-2023 10:00 AM - 11:30 AM

THE EFFECT OF TWO-DOSE AND THREE-DOSE VACCINATION WITH THE BIVALENT VACCINE ON TYPE-SPECIFIC HUMAN PAPILLOMAVIRUS VIRAL LOAD IN YOUNG WOMEN.

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Introduction: Persisting human papillomavirus (HPV) infections increase cervical cancer risk and are associated with increased viral load. In 2009, the Netherlands introduced a bivalent vaccine against highly oncogenic HPV16 and 18. Three-dose vaccination was provided to young women and changed to two doses in 2014, due to comparable effectiveness. Three-dose vaccination was especially effective against HPV16 and 18 infections and showed cross-protectivity against HPV31, 33, 35 and 45 infections. Here, we examined the effect of two-dose and three-dose vaccination on the viral load of type-specific HPV in clearing and persistent infections in young women.

Methods: Self-collected vaginal swabs from three-dose vaccinated and unvaccinated women participating in the HPV Among Vaccinated And Non-vaccinated Adolescents (HAVANA) study, or two-dose vaccinated and unvaccinated women participating in the HAVANA-2 study, were used. Total DNA isolation and HPV genotyping was performed with the Magna-Pure-96 and SPF10-DEIA-LiPA25 platforms, respectively. HPV viral load was measured using type-specific qPCR assays and corrected for cellular content with a β-actin qPCR assay.

Results: In the HAVANA study, HPV16, 18 and 31 viral loads in clearing infections were significantly reduced in three-dose vaccinated women compared to unvaccinated women (p=0.0020, p=0.00016 and p=0.00067, respectively), while type-specific viral load in persistent HPV infections remained similar. Two-dose vaccinated and unvaccinated HAVANA-2 women had overall low infection numbers, thereby hampering subsequent viral load analyses. Infection with HPV16 and 18 were completely absent in two-dose vaccinated women. Despite low infection numbers, pooled HPV31/33/35/45 viral loads in two-dose vaccinated women showed a lower trend compared to unvaccinated women

Conclusions: Two-dose and three-dose vaccination reduces the viral load of vaccine and cross-protective HPV types. Vaccination may counteract HPV persistency by reducing the viral load of vaccine types and several cross-protective types at infection onset.

O184 / #747

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: CARCINOGENESIS + 2 ANIMAL MODELS
04-21-2023 10:00 AM - 11:30 AM

NON-CANONICAL HPV CARCINOGENESIS DRIVES RADIO-SENSITIZATION OF HEAD AND NECK TUMORS

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Introduction: Human papillomavirus-associated (HPV+) head and neck squamous cell carcinoma (HNSCC) has surpassed cervical cancer and is now the most common HPV associated cancer and its incidence continues to increase. HPV mediated oncogenesis is generally thought to rely on integration of the viral DNA into the host genome, loss of HPV E2 expression, activating alterations of PIK3CA, and APOBEC-mediated mutagenesis. We report the identification of a novel subclass of HPV+ carcinomas comprising approximately 45% of HPV+ HNSCC that is not associated with any of these classic features of HPV oncogenesis. Patients in this subgroup have improved clinical outcomes, and that cell culture models of this class have increased sensitivity to radiation.

Methods: We analyzed novel transcriptional profiling data from 104 HPV+ HNSCC tumors in tandem with two publicly available sources. Transcriptional data was correlated with viral integration, tumor genomic features and clinical outcomes. Derived tumor subclasses were modeled with HPV+ cells in culture.

Results: We found a single transcriptional module that naturally subclassifies HPV+ HNSCC tumors based on a bimodal pattern of gene expression. The subclass-defining gene set was correlated with NF-κB target expression. Tumors with high expression of this NF-κB module, were rarely associated with activating PIK3CA alterations or viral integration, expressed higher levels of E2 and had decreased APOBEC mutagenesis. Alternatively, they harbored alterations of NF-κB regulators, TRAF3 and CYLD. HPV+ HNSCC cells in culture with experimental depletion of TRAF3 or CYLD displayed increased expression of the subclass-defining genes and robust radio-sensitization, thus recapitulating both the tumor transcriptional state and improved treatment response observed in patient data.

Conclusions: Identification of a cohesive class of HPV-driven tumors without canonical features of HPV oncogenesis challenges the accepted models of HPV carcinogenesis. Recognition of this highly identifiable, biologically distinct tumor subclass with improved response to radio-therapy may fundamentally alter how HPV+ HNSCC patients are treated.

O185 / #1152

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: CARCINOGENESIS + 2 ANIMAL MODELS
04-21-2023 10:00 AM - 11:30 AM

FUNCTIONAL SCREENS FOR MICRORNAS AND THEIR MRNA TARGETS REGULATING ANCHORAGE-INDEPENDENT GROWTH IN HUMAN CERVICAL CANCER CELLS

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Introduction: The progression of anchorage-dependent epithelial cells to anchorage-independent (AI) cells is a critical hallmark and an early event of malignant transformation. Hence, alterations in genes involved in AI growth can predict the progression of precancerous lesions to invasive cancer. Using an in vitro model of HPV-transformed cells representing cervical precancerous lesions, we previously showed that acquisition of AI growth is associated with (epi)genetic changes, including altered expression of miRNAs. Here we developed a novel high-throughput functional screening method using Ultra-Low-Attachment (ULA) plates to investigate miRNAs driving AI growth.

Methods: A proof-of-concept functional screen on cervical cancer cells SiHa was developed using 96-well ULA plates (Huseinovic, 2022). Cells were transfected with a miRNA mimic library (n=2019) and cell viability was measured to identify miRNAs affecting AI growth. The screen was further optimized on 384-well adherent and ULA plates, and performed with a comprehensive library of 2574 miRNA mimics in HPV16/18-transformed keratinocytes (FK16A/FK18B). Additionally, we performed a complementary CRISPR/Cas9 screen with a genome-wide knock-out CRISPR library with anchorage-independent FK18B cells cultured on adherent and ULA plates to search for genes affecting AI growth.

Results: We successfully performed miRNA mimic screens and, based on the validation in three cell lines, were able to identify 40 miRNAs affecting AI growth during HPV-induced transformation. CRISPR/Cas9 screen and subsequent gene ontology analysis revealed the enrichment of several relevant pathways involved in AI growth. Further functional validation and integrated data analysis of miRNA mimic and CRISPR/Cas9 screens are ongoing to identify miRNAs and their target mRNAs involved in the acquisition of anchorage independence.

Conclusions: We successfully developed and completed miRNA and CRISPR/Cas9 functional screens on ULA plates. We identified miRNAs, genes, and pathways that regulate AI growth. These findings can be used for risk stratification and treatment of precancerous lesions that are at the edge of malignant transformation.

O186 / #787

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: CARCINOGENESIS + 2 ANIMAL MODELS
04-21-2023 10:00 AM - 11:30 AM

HUMAN PAPILLOMAVIRUS ONCOGENES MAY PROMOTE CERVICAL DYSPLASIA PROGRESSION THROUGH DYSREGULATION OF MIR-4488 AND WNT SIGNALING

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Introduction: Many women are diagnosed with human papillomavirus (HPV)-associated low-grade cervical dysplasia (CIN) each year. Most women will exhibit restoration to a healthy cervix; however, a few will progress to high-grade CIN, which increases their risk of developing cancer. We have demonstrated that miRNAs, including miR-4488, are dysregulated in women with progressive CIN. Pathway analysis using miRPathDB2.0 revealed enrichment of mRNA involved in Wnt (Wingless and Int-1) signaling as targets of the miRNAs downregulated in progressive CIN. Wnt signaling, previously found to be activated in cervical cancer, promotes migration in part through the action of matrix metalloproteinases (MMPs), also previously found upregulated in cervical cancer. We hypothesize that HPV onco-proteins E6/E7 promote cervical dysplasia progression by downregulating miRNAs and promoting migratory phenotypes through Wnt signaling activation and induction of MMP expression.

Methods: MiR-4488 expression was analyzed in primary cervical cells expressing HPV-16 E6/E7 (Primary-E6/E7) compared to vector controls. Synthetic miR-4488 mimics and inhibitors were used to confirm putative mRNA target MMP15 via 3'UTR reporter assays and for increased cell migration using a wound healing assay. Expression of MMP15 was examined in cells expressing HPV-16 E6/E7 compared to vector controls by qPCR. Wnt signaling activation was measured in HPV-16 E6/E7 expressing C-33A cells (C-33A-E6/E7) compared to vector controls using a Wnt responsive reporter assay.

Results: Expression of HPV oncogenes E6/E7 led to downregulation of miR-4488 (2-fold), increased Wnt signaling activation ($p<0.01$), and increased MMP15 gene expression ($p<0.05$). Increased migration was observed in cells transfected with an inhibitor of miR-4488 ($p<0.05$).

Conclusions: Downregulation of miR-4488, expression of MMP15, and activation of Wnt signaling may be early indicators of oncogenic HPV E6/E7 overexpression and CIN progression.

O187 / #936

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: CARCINOGENESIS + 2 ANIMAL MODELS
04-21-2023 10:00 AM - 11:30 AM

DISRUPTION OF MUS MUSCULUS PAPILLOMAVIRUS 1 (MMUPV1) E8^E2 ACTIVITY INDUCES E4 PROTEIN EXPRESSION AND PREVENTS WART FORMATION

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Introduction: The E8^E2 protein is a conserved repressor of papillomavirus replication and transcription. We have recently reported that the inactivation of the E8 start codon in the MmuPV1 genome (E8-) increases viral gene expression in cultured keratinocytes, but surprisingly fails to form warts in immune deficient Foxn1$^{nu/nu}$ mice.

Methods: keratinocyte culture, mouse model

Results: To confirm that the loss of E8^E2 is responsible for the failure to form warts in vivo, we mutated the E8 splice donor (E8 SD mt) used to generate the E8^E2 RNA. This resulted in increased viral transcription in mouse keratinocytes comparable to E8-. HPV E8^E2 proteins recruit NCoR/SMRT complexes to repress transcription and replication. Co-immunoprecipitation experiments revealed that NCoR/SMRT complex components HDAC3, GPS2, and TBLR1 interact with MmuPV1 E8^E2 and that these interactions are reduced by mutation of conserved E8 residues K2R/L3P/K4R. E8 RPR mt genomes displayed increased viral transcription in mouse keratinocytes, and siRNA knock-downs confirmed that NCoR/SMRT components contribute to the inhibition of transcription and replication by E8^E2. This suggests that the E8^E2 protein functionally interacts with NCoR/SMRT corepressor complexes similar to HPV. Consistent with E8- genomes, E8 SD mt and E8 RPR mt genomes do not induce warts in Foxn1$^{nu/nu}$mice. Interestingly, MmuPV1 genomes with impaired E8^E2 activity lead to a greatly enhanced number of mouse keratinocytes expressing the late viral E4 protein despite being maintained in undifferentiated conditions.

Conclusions: The increased gene expression from MmuPV1 E8-, E8 SD mt and E8 RPR mt genomes is due to the loss of E8^E2 or preventing its interaction with NCoR/SMRT complexes, and the data confirm that E8^E2 is required for wart formation in vivo. The induction of E4 protein expression in cultured murine keratinocytes from E8^E2 mt genomes suggests that the viral late phase is aberrantly induced in undifferentiated cells which might be incompatible with tumour formation in vivo.

O188 / #1120

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: CARCINOGENESIS + 2 ANIMAL MODELS
04-21-2023 10:00 AM - 11:30 AM

DOWNREGULATION OF HSA-MIR-193A/B-3P CONTRIBUTES TO ANCHORAGE-INDEPENDENT GROWTH IN HPV-TRANSFORMED KERATINOCYTES THROUGH THE PI3K/AKT PATHWAY

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Introduction: Cervical cancer is caused by a persistent infection with high-risk types of HPV and accumulation of (epi)genetic alterations in the host cell. Acquisition of anchorage-independent growth represents a critical hallmark during HPV-induced carcinogenesis, thereby yielding most valuable biomarkers for early diagnosis and therapeutic targets. In a previous study, we found that miR-193a-3p and miR-193b-3p were involved in anchorage-independent growth. This study aimed to delineate the role of miR-193a/b-3p in HPV-induced carcinogenesis and to identify their target genes related anchorage-independent growth.

Methods: Cell viability and colony formation were assessed in SiHa cancer cells and HPV-16 and -18 immortalized keratinocytes (FK16A/FK18B) upon miR-193a/b-3p overexpression to validate their functional involvement. Online target predicting programs (StarBase and miRDB) were used to find candidate mRNAs targets of miR-193a/b-3p. mRNA targets were further selected based on publicly available expression data. Targets were validated by RT-qPCR and luciferase assays.

Results: miR-193a-3p and miR-193b-3p largely reduced cell growth of SiHa, FK16A and FK18B in anchorage-independent conditions and showed minor effect in anchorage-dependent conditions. Fifteen genes were identified as potential targets related to anchorage-independence. Seven genes showed reduced mRNA expression upon miR-193a-3p and miR-193b-3p overexpression. A direct interaction was confirmed using luciferase assays for 6 genes: LAMC1, KRAS, PPP2R5C, PTK2, SOS2 and STMN1. Both miR-193a/b-3p are downregulated in high-grade CIN lesions and miR-193b-3p also downregulated in cervical cancers. All 6 targets were overexpressed in cervical cancers and/or high-grade CIN lesions.

Conclusions: miR-193a-3p and miR-193b-3p reduce anchorage-independent growth of HPV-transformed cells through targeting LAMC1, KRAS, PPP2R5C, PTK2, SOS2 and STMN1. Target upregulation in cervical cancer underlines the biological relevance of miR-193a-3p and miR193b-3p downregulation during HPV-induced carcinogenesis.

O189 / #972

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: CARCINOGENESIS + 2 ANIMAL MODELS
04-21-2023 10:00 AM - 11:30 AM

MASTOMYS COUCHA: A UNIQUE ANIMAL MODEL FOR PAPILLOMAVIRUS-INDUCED SKIN CARCINOGENESIS

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Introduction: Animals are indispensable to provide an empirical bona fide equivalent for pathophysiological processes in humans. To act as a preclinical model, an animal has to fulfill certain criteria by reflecting face validity, complexity and predictability of a disease. Here, I will describe some properties of the rodent Mastomys coucha. Although still not yet very common in the scientific community, the model is well known in various research fields and was successfully used to study the role of cutaneous papillomaviruses in non-melanoma skin cancer (NMSC) development, in testing vaccines and in dissecting the mechanisms of viral immune escape.

Methods: The Mastomys coucha colony is naturally infected by the cutaneous MnPV. Serology, ELISAs, VLP, pseudovirion productions and neutralization assays were performed as described.

Results: MnPV acts in combination with UV via a “hit-and-run” mechanism in the development of NMSC. Moreover, monitoring seroconversion during the permissive cycle, a novel humoral escape mechanism was identified. The initial synthesis of a longer L1 isoform unable to form mature capsids only induces non-neutralizing antibodies. This strategy allows viral amplification and spread. Only after a delay of a couple of months neutralizing antibodies appear, now directed against the shorter form of L1 that forms mature viral particles necessary to encapsulate progeny viral DNA. The implication of these findings were discussed, especially in the light of our vaccination experiments where we showed that – in contrast to L1 short – immunization with the only 34 amino acid longer L1 isoform completely failed to prevent skin tumor formation.

Conclusions: Mastomys coucha is a valuable preclinical model to answer a variety of questions in the context of papillomavirus-induced carcinogenesis. In future experiments, the generation of germ-free animals and their subsequent recolonization with defined microorganisms should show the impact of the microbiome on skin cancer formation after infection with cutaneous PVs.

O190 / #1053

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: CARCINOGENESIS + 2 ANIMAL MODELS
04-21-2023 10:00 AM - 11:30 AM

MMUPV1 CAN INDUCE AN INVASIVE CANCER PHENOTYPE IN ADULT IMMUNE-COMPETENT MICE WITHIN TWO WEEKS OF OROPHARYNGEAL INFECTION

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Introduction: Development of cancer in adult mammals is thought to take months or years from the time of initiation, be it by chemical carcinogens, cancer driver mutations, or cancer-causing pathogens such as oncogenic viruses. The mouse papillomavirus MmuPV1 is a useful preclinical model for human papillomavirus (HPV)-induced cancers, causing cancers in both immune-deficient and certain immune-competent mouse strains (e.g. FVB/NTac). Prior studies on MmuPV1 have focused on cancer development 3-6 months post infection.

Methods: We have assessed lesions in inbred, immune-competent FVB/NTac mice, 1-4 weeks post infection at the base of the tongue (where in humans HPVs cause oropharyngeal cancer). We pursued parallel studies in FVB-KRT14-HPV16E5-transgenic (FVB-E5) mice that express the HPV16 E5 oncogene in stratified epithelia; these mice are more susceptible to MmuPV1-induced disease (Torres et al., Virology, 2020). MmuPV1 does not encode an E5 oncogene.

Results: We were surprised to find that invasive cancers (independently scored by two pathologists: J.P.S & R.H.) developed in FVB and FVB-E5 mice within two weeks of infection, more frequently in E5-transgenic mice than in non-transgenic mice ($p = 0.023$). Dysplasia developed within one week. Cancers arose in both sexes ($p = 0.79$). Cancers and dysplastic lesions, positive for MmuPV1 by RNAscope, mostly disappeared by four weeks post infection with ~10^9 genome equivalents of virus, but cancers persisted for at least four weeks post infection with 10^{10} genome equivalents of virus. By contrast, infection of the rostro-dorsal (anterior) tongue with 10^{10} genome equivalents resulted in mild to moderate dysplasia but no cancers ($p = 0.0040$). No neoplastic lesions arose in mock-infected mice.

Conclusions: These findings indicate MmuPV1 can induce rapid onset of neoplastic lesions including cancers, depending on the site of infection. We are currently investigating the tissue specificity and transience of these lesions and the role they play in longer-term development of MmuPV1-induced disease.

O191 / #354

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: CARCINOGENESIS + 2 ANIMAL MODELS
04-21-2023 10:00 AM - 11:30 AM

HPV8 E1 AND E2 SUPPRESS THE ACTIVATION OF THE RIG-I-LIKE RECEPTOR MDA5

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Introduction: Persistent infections of the skin with HPV of genus beta (beta-HPV) in immunocompetent individuals are asymptomatic, but in immunosuppressed patients, beta-HPV infections exhibit much higher viral loads on the skin and are associated with an increased risk of skin cancer. Unlike with HPV16, the impact of beta-HPV early genes on the innate immune sensing of viral nucleic acids has not been studied.

Methods: We used primary skin keratinocytes (PHK) expressing individual HPV8 early genes and U2OS cells expressing all HPV8 genes as well as well-defined ligands of the nucleic-acid-sensing receptors RIG-I, MDA5, TLR3, and STING to analyze a potential functional interaction using cell culture, qRT-PCR and ELISA.

Results: We found that PHK and U2OS cells express RIG-I, MDA5, TLR3, and STING, but not TLR7, TLR8, or TLR9. While HPV16-E6 downregulated the expression of RIG-I, MDA5, TLR3, and STING and, in conjunction with HPV16-E7, effectively suppressed type I IFN in response to MDA5 activation, the presence of HPV8 early genes showed little effect on the expression of these immune receptors, except for HPV8-E2, which was associated with an elevated expression of TLR3. Nevertheless, whole HPV8 genome expression, as well as the selective expression of HPV8-E1 or HPV8-E2, was found to suppress MDA5-induced type I IFN and the proinflammatory cytokine IL-6. Furthermore, RNA isolated from HPV8-E2 expressing PHK, but not control cells, stimulated a type I IFN response in peripheral blood mononuclear cells, indicating that the expression of HPV8-E2 in keratinocytes leads to the formation of stimulatory RNA ligands that require the active suppression of immune recognition.

Conclusions: These results identify E1 and E2 as viral proteins that are responsible for the immune escape of HPV8 from the innate recognition of viral nucleic acids, a mechanism that may be necessary for establishing persistent beta-HPV infections.

O192 / #370

Basic Science Oral Abstracts Session
BASIC SCIENCE ORAL: CARCINOGENESIS + 2 ANIMAL MODELS
04-21-2023 10:00 AM - 11:30 AM

POLY(I:C) TREATMENT PREVENTS SKIN TUMOR FORMATION IN THE PRECLINICAL HPV8 TRANSGENIC MOUSE MODEL

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Introduction: The development of actinic keratoses and squamous cell carcinoma of the skin is associated with infections with HPV of genus beta (betaHPV), especially in immunosuppressed patients. To date, targeted therapy against betaHPV-associated skin cancer is not available due to the large number of betaHPV without defined high-risk types. We therefore tested whether an in-situ autovaccination strategy through activation of innate antiviral immunity may represent a suitable approach to develop a personalized immunotherapy preventing the formation of betaHPV-associated skin cancer.

Methods: K14-HPV8 transgenic mice were used in which skin tumor development can be induced within 3 weeks after physical skin damage such as tattooing. We administered the following nucleic acid receptor ligands locally by tattooing into the murine skin: Y-DNA (cGAS/STING ligand), CpG1826 (TLR9 ligand), R848 (TLR7/8 ligand) and poly(I:C) (MDA5/TLR3 ligand). Mice were examined for tumor development and biopsies from tattooed skin were analysed by FACS, qRT-PCR and immunohistochemical stainings.

Results: While skin tumors were induced in control animals, tattooing TLR7/8 (R848) and TLR9 (CpG1826) ligands reduced tumor formation by 50% and the cGAS/STING ligand (Y-DNA) by 25%. Strikingly, poly(I:C) treatment completely prevented tumor growth in K14-HPV8 mice. Induction of the interferon-induced genes CXCL10 and IFIT1 by poly(I:C) depended on the activation of MDA5. FACS analysis revealed increased numbers of total as well as activated $CD4^+$and $CD8^+$ T-cells in poly(I:C) treated skin. By using immunohistochemistry, T-cells were found in the skin of poly(I:C)-treated animals but not in skin tumors of untreated control mice. T-cell depletion demonstrated a predominant role of CD4 T cells in HPV8 induced tumor development.

Conclusions: Taken together, our findings identify the MDA5 ligand poly(I:C) as a promising candidate for in situ autovaccination approaches, which might very well serve as a benchmark for the development of treatment strategies against betaHPV-related diseases.

O193 / #1213

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-21-2023 2:15 PM - 3:45 PM

EXPERIENCE FROM CERVICAL CANCER SCREENING AND TREATMENT PROGRAM IMPLEMENTATION ACROSS TEN COUNTRIES IN AFRICA AND ASIA

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Introduction: Cervical cancer is one of the most preventable types of cancer, yet too many women die of cervical cancer in low- and middle-income countries (LMICs) because prevention and treatment services are unavailable. Over 300,000 women die of cervical cancer each year; >90% of these deaths occur in LMICs. The World Health Organization is leading a global effort to scale interventions that will eliminate cervical cancer for future generations.

Methods: With support from Unitaid, CHAI has been working since 2019 to expand access to critical tools and services that will enable this expansion in access to screening and treatment for pre-cancer. CHAI operates cervical cancer programs in partnership with 10 countries in Africa and Asia.

Results: With partner governments, the project has successfully reached women with effective secondary prevention services by leveraging and scaling-up existing tools: particularly HPV tests for screening, and portable devices to treat precancerous lesions. The project has brought HPV test prices down by ~40%, cut the cost of thermal ablation devices by 45%, and cut the cost of portable LEEP devices by 20%. The project has screened >725,000 women and treated 82% of screen-positive women. The project has established hundreds of screening and treatment sites offering integrated service delivery: improving access to screening using Visual Inspection with Acetic Acid, expanding HPV testing via existing testing platforms and introduction of self-sampling, increasing awareness on screening and treatment, decentralizing treatment using portable devices, building health worker capacity, tracking patients throughout care, and generating significant learnings to further scale-up these solutions.

Conclusions: By demonstrating effective delivery models for screening, treatment, and linkages to care using existing tools, the project is supporting countries to make significant progress towards WHO's elimination targets and laying the groundwork for a multi-pronged approach with the scale-up of innovative, affordable, point-of-care screening technologies once available.

O194 / #1216

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CLINICAL SCIENCE ORAL: SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
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AFFORDABLE CANCER TECHNOLOGIES: LESSONS LEARNED FROM THE DEVELOPMENT OF TREATMENTS FOR PRECANCEROUS CERVICAL CHANGES

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Introduction: Cancer incidence and mortality are disproportionally high and on the rise in low-and-middle income countries (LMIC), contributing to wide-ranging social and economic inequalities. There is an urgent need for accessible and affordable screening, diagnostic, and treatment methods that can counteract these trends. Recognizing this crisis, in 2013 the U.S. National Cancer Institute solicited applications for academic-industry partnerships to develop emerging technologies for imaging, detection/diagnosis, prevention, and treatment of cancer in LMIC.

Methods: As part of this initiative, our two teams worked independently on cervical cancer prevention. Each team developed a new technology for treatment of precancerous cervical changes. The technologies that were developed included CryoPop, CryoPen and hand-held thermal ablation. The new products were tested in randomized clinical trials using cure rates of high-grade cervical pre-cancer. Histopathologic diagnosis was assessed both pre and post treatment.

Results: Despite our different approaches, our groups encountered similar technical, administrative, and research challenges through the development process. Both teams noted the difficulty of obtaining biopsy-based cases in low resource settngs where excision therapy is widespread. Here, our goal is to disseminate important lessons learned in order to provide a blueprint for other teams working on the development of innovative cancer technologies for LMIC.

Conclusions: Despite significant advances in screening and early detection technologies, cervical cancer remains the fourth leading cause of cancer death globally with over 90% of incidence and mortality occurring in LMIC. Our teams' projects focused on the development and validation of three alternative treatment devices for high-grade precancerous changes that can facilitate the implementation of "screen and treat" approaches in low-resource settings.

O195 / #867

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TREATMENT SUCCESS RATE AFTER THERMAL ABLATION OF CERVIX IN A RANDOMIZED CONTROL TRIAL IN SCREEN AND TREAT SETTING IN ZAMBIA STRATIFIED BY HIV STATUS

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Introduction: Low-cost ablative treatment is being evaluated and recommended for treatment of cervical precancers among women with a type 1 transformation zone. Recent studies have reported sub-optimal success rate for cryotherapy to treat cervical precancers in women living with HIV (WLHIV). A randomized control trial assessing efficacy of a battery-operated thermal ablator for treatment of precancers is ongoing in Zambia. We describe preliminary results of treatment efficacy stratified by HIV status.

Methods: VIA screen-positive women eligible for ablative treatment were randomized to receive thermal ablation, cryotherapy or LLETZ. Treatment success at 6- and/or 12-month follow-up was negative HPV status among those HPV positive at baseline. and negative VIA test among those HPV negative at baseline.

Results: A total of 3065 women with baseline HIV status information have been randomized to treatment, 1797 (59%) of whom were HIV-positive. Almost all HIV-positive women (99%) were on anti-retroviral therapy (ART). Among 1055 (83%) HIV-negative and 1508 (84%) HIV-positive women eligible for follow-up, 743 (70%) HIV-negative and 937 (62%) HIV-positive women had complete follow-up data for assessment of treatment success (TS). Overall, TS was significantly lower among HIV-infected women compared to HIV-negatives (56% [539/937] versus 84% [627/743]; p-value<0.001). Similar TS rates and rate differences were observed regardless of type of treatment received. TS among WLHIV was lower for the HPV positive women. While success rates were around 90% among HPV-negative women regardless of HIV-infection status and type of treatment, that for HPV positive women was substantially lower - 67% and 40% for the HIV-negative and HIV-positive women respectively

Conclusions: With the current WHO initiative for Cervical Cancer Elimination, these findings highlight the challenges in eliminating the disease in women living with HIV through treatment of premalignant lesions. Investigations are underway to determine the underlying causes of the low success rate.

O196 / #1161

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COMPROMISED MARGINS AFTER LARGE LOOP EXCISION OF THE TRANSFORMATION ZONE (LLETZ) AND FACTORS ASSOCIATED IN ESTAMPA

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Introduction: Compromised margins after LLETZ could be an indication of treatment failure. The International Federation of Cervical Pathology and Colposcopy (IFCPC) recommends that the type of excision should be chosen to ensure adequate treatment according to the transformation zone (TZ) type. However, additional characteristics related to the presence of compromised margins may help improve excision criteria and therefore post-treatment outcomes. We aimed to identify clinical, and sociodemographic and reproductive health characteristics that may be associated with compromised margins in treated women in ESTAMPA.

Methods: In ESTAMPA, women aged 30-64 years were screened with HPV testing and cytology and referred to colposcopy with biopsy as needed. Women without CIN2+ were recalled at ~18 months for a second HPV test with colposcopy and biopsy as needed. All CIN2+ cases were referred to LLETZ. We explored the TZ type reported on colposcopy with the excision type to understand practitioners’ adherence to IFCPC recommendations. Associations between clinical and sociodemographic and reproductive health characteristics with compromised margins were assessed using odds ratios (OR) estimated with multivariate logistic regressions.

Results:

Table 1. Type of excision according to transformation zone type overall and by compromised margins status

Table 1. Type of excision according to transformation zone type overall and by compromised margins status

	Excision type 1	Excision type 2	Excision type 3	Total
	n (%)	n (%)	n (%)	
All women				
TZ type 1	139 (36.6)	231 (60.8)	10 (2.6)	380
TZ type 2	27 (15.1)	139 (77.7)	13 (7.3)	179
TZ type 3	16 (14.3)	76 (67.9)	20 (17.9)	112
Total	**182 (27.1)**	**446 (66.5)**	**43 (6.4)**	**671**
With compromised margins				
TZ type 1	17 (28.8)	38 (64.4)	4 (6.8)	59
TZ type 2	6 (16.2)	28 (75.7)	3 (8.1)	37
TZ type 3	2 (7.4)	19 (70.4)	6 (22.2)	27
Total	**25 (20.3)**	**85 (69.1)**	**13 (10.6)**	**123**
Without compromised margins				
TZ type 1	122 (38.0)	193 (60.1)	6 (1.9)	321
TZ type 2	21 (14.8)	111 (78.2)	10 (7.0)	142
TZ type 3	14 (16.5)	57 (67.1)	14 (16.5)	85
Total	**157 (28.6)**	**361 (65.9)**	**30 (5.5)**	**548**

Row percentages are presented

673 treated women were included in the analyses.Among them,124 (18.4%,95%CI 15.7-21.5)had compromised margins.Most excisions (66.5%) were type2 even among women with TZ type3 (67.9%) (Table1). Women with HSIL+ cytology,positive major or suspicion of cancer colposcopic impression,TZtype3, CIN3+before treatment,or not have been screened within 2 years before last cytology were significantly associated with compromised margins while HPV16/18 infection was not associated (Table2). Table 1. Type of excision according to transformation zone type overall and by compromised margins statusTable 2. Characteristics associated to compromised margins in ESTAMPA participants treated with

LLETZ

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Charateristic	Uncompromised margins n (%)	Compromised margins n (%)	P†	OR[a] (95% CI) (N=673)	OR[b] (95% CI) (N=430)
Total	549 (81.6)	124 (18.4)	---	---	---
Age, y					
<40	316 (84.7)	57 (15.3)	0.025	Ref.	Ref.
≥40	233 (77.7)	67 (22.3)		1.36 (0.83-2.21)	0.73 (0.26-1.94)
Cytology					
NILM/Unsatisfactory	299 (86.2)	48 (13.8)	<0.001	Ref.	Ref.
ASC-US/LSIL	146 (79.8)	37 (20.2)		1.47 (0.87-2.47)	1.58 (0.62-3.92)
HSIL+	69 (65.7)	36 (34.3)		**2.88 (1.52-5.49)**	3.73 (0.65-20.41)
HC2 RLU					
<10	87 (85.3)	15 (14.7)	0.006	---	---
10-99.9	117 (86.0)	19 (14.0)		---	---
≥100	172 (73.8)	61 (26.2)		---	---
HPV type					
Other high-risk	212 (85.1)	37 (14.9)	0.127	---	Ref.
16/18	143 (79.0)	38 (21.0)		---	0.90 (0.37-2.16)
Diagnosis before treatment					
Unknown*	71 (85.5)	12 (14.5)	0.011	Ref.	Ref.
Negative/CIN1	40 (83.3)	8 (16.7)		0.73 (0.23-2.21)	0.25 (0.01-9.44)
CIN2	217 (86.5)	34 (13.5)		1.58 (0.67-3.91)	0.38 (0.02-13.51)
CIN3+	221 (75.9)	70 (24.1)		**2.28 (1.04-5.33)**	0.78 (0.04-25.18)
Colposcopic impression					
Negative or positive minor	350 (86.6)	54 (13.4)	<0.001	Ref.	Ref.
Positive major or worse**	198 (74.2)	69 (25.8)		**1.75 (1.08-2.83)**	1.81 (0.70-4.81)
Transformation zone type					
TZ1	321 (84.5)	59 (15.5)	0.076	Ref.	Ref.
TZ2	142 (79.3)	37 (20.7)		1.45 (0.86-2.44)	1.51 (0.56-4.15)
TZ3	85 (75.9)	27 (24.1)		**2.39 (1.20-4.71)**	0.64 (0.02-7.30)
Size of the lesion					
<30%	351 (85.6)	59 (14.4)	<0.001	Ref.	Ref.
≥30%	197 (75.2)	65 (24.8)		1.46 (0.91-2.33)	2.02 (0.83-4.92)
Type of excision					
TZ1	157 (86.3)	25 (13.7)	0.033	Ref.	Ref.
TZ2	362 (80.8)	86 (19.2)		1.11 (0.66-1.93)	0.92 (0.32-2.73)
TZ3	30 (69.8)	13 (30.2)		1.19 (0.48-2.89)	2.92 (0.20-83.05)
Age of sexual debut, y					
≥21	73 (83.9)	14 (16.1)	0.359	Ref.	Ref.
17-20	251 (79.7)	64 (20.3)		1.08 (0.53-2.30)	0.85 (0.19-4.85)
≤16	225 (84.0)	43 (16.0)		0.87 (0.40-1.95)	0.60 (0.12-3.61)
Lifetime sexual partners					
≤3	310 (79.1)	82 (20.9)	0.062	Ref.	Ref.
≥4	239 (85.1)	42 (14.9)		0.63 (0.39-1.01)	0.59 (0.23-1.45)
Tobacco consumption					
Never	377 (82.3)	81 (17.7)	0.752	Ref.	Ref.
Ever	170 (81.0)	40 (19.0)		1.27 (0.79-2.02)	0.61 (0.20-1.66)
Number of pregnancies					
0-2	260 (85.2)	45 (14.8)	0.044	Ref.	Ref.
≥3	288 (78.9)	77 (21.1)		1.51 (0.95-2.42)	1.42 (0.59-3.48)
Years since last cytology					
<2	295 (85.8)	49 (14.2)	0.005	Ref.	Ref.
≥2	253 (77.1)	75 (22.9)		**1.65 (1.06-2.60)**	1.00 (0.42-2.48)

†Chi-squared test. [a]Odds ratio of compromised margins adjusted by age, cytology result at screening, diagnosis before treatment, colposcopy impression, transformation zone type, size of the lesion, type of excision, age of sexual debut, lifetime sexual partners, tobacco consumption, number of pregnancies, and years since last cytology. [b]Odds ratio of compromised margins adjusted by age, cytology result at screening, HPV16/18 genotyping, diagnosis before treatment, colposcopy impression, transformation zone type, size of the lesion, type of excision, age of sexual debut, lifetime sexual partners, tobacco consumption, number of pregnancies, and years since last cytology. *Women without histology diagnosis (32 with TZ type 3, 36 with screening cytology HSIL+ and/or colposcopy major, and 16 with unknown reason. **Includes 4 with atrofia. ---: Not applicable.

Conclusions: Reinforcing practitioner's adherence to established cervical treatment recommendations is needed. Special considerations for choice of treatment are required for women at increased risk of incomplete treatment (HSIL+ cytology, TZ type 3, high-grade colposcopy impression, CIN3+) to improve cervical cancer prevention.

O197 / #559

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WORKING TOGETHER TO INTRODUCE AND SCALE UP HPV SCREENING AND CERVICAL PRECANCER TREATMENT IN LOW- AND MIDDLE-INCOME COUNTRIES (LMIC) TO ADVANCE CERVICAL CANCER ELIMINATION

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Introduction: Cervical cancer persists as a leading cause of women's cancer deaths in LMICs, especially among women living with HIV (WLHIV). Aiming to eliminate cervical cancer, WHO recommends countries transition to screening with a high-performance test. SUCCESS (Scale-Up Cervical Cancer Elimination with Secondary Prevention), a project funded by Unitaid and implemented by Expertise France, Jhpiego, and UICC, is supporting LMICs to introduce new technologies for cervical cancer prevention. Early results of this effort are presented here.

Methods: Since 2020, SUCCESS project is harnessing multi-stakeholders' engagement led by Ministries of Health to drive efforts to introduce and scale-up HPV testing with self-sampling and thermal ablation treatment in Burkina Faso, Côte d'Ivoire, Guatemala, and the Philippines, to reach 175,000 women including 40% WLHIV by 2023. Key interventions include civil society engagement, advocacy and resource mobilization, procurement and management of key products, updating policies and training materials, increasing awareness and demand creation, and strengthening training and health information systems using e-learning and digital health solutions.

Results: By June 2022, 42,469 women were screened with HPV test in the four countries, including 8,647 (20.4%) of WLHIV; 87.6% with self-sampling. HPV positivity rate was 11.6% (n=3,918) among HIV negative women and 23.9% (n=2,066) among WLHIV. 1,121 of HPV+ women received ablative or excisional treatment according to algorithm used. Main challenges are related to system strengthening, especially ensuring continuous availability of essential equipment and supplies, timely turnaround of test results and timely treatment, follow-up, quality and integration of services.

Conclusions: SUCCESS' project experience shows that introducing HPV testing with self-sampling in LMICs is feasible and promising. Government commitment, CSO engagement, health financing, coordination and partnership are key to advance this process. The tools and lessons learned from SUCCESS project implementation will inform efforts to scale-up HPV testing and treatment in other LMICs in the coming years.

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IMPLEMENTING NEW WHO RECOMMENDED ALGORITHMS TO STRENGTHEN CERVICAL PRECANCER SCREENING AND TREATMENT SERVICES IN BURKINA FASO

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Introduction: As part of the WHO-led global effort to eliminate cervical cancer, the government, supported by the SUCCESS project, funded by Unitaid and implemented by Expertise France, Jhpiego, and UICC, is working to screen 40,000 women with HPV testing by 2023, including 46% of WLHIV, and to treat eligible women with thermal ablation or LLETZ in Burkina Faso.

Methods: The Ministry of Health supported by SUCCESS began screening women with HPV testing in June 2021. The WHO-recommended screening-triage-treatment algorithm-1 was adopted to manage HPV-positive women, using VIA as the triage method. In 2022, a decision was made to change to the screening and treatment approach for women in the general population and for WLHIV use the screening and treatment for women positive for HPV 16, 18, and 45, and the screening-triage-treatment for women positive for the other HPV types. This change in algorithm aimed to reduce lost to follow-up as most women live in rural/remote areas with limited access to health services.

Results: In 2021, 4893 women were screened, including 1037 (21%) of WLHIV. 787 (16%) tested HPV positive. 519 (66%) HPV positive women received VIA triage and 148 (28%) resulted VIA positive. Among those VIA positive, 137 (92%) received ablative or excisional treatment according to eligibility. In the 1st semester 2022, 8805 women were screened, including 1828 (21%) of WLHIV). Of the 667 treatments performed in 2022, 562 (84.25%) were done in the general population where the systematic treatment was 89% on 631 womens recieved visual assessment for treatment (562/631). 105 WLHIV were treated out of 167 who received VAT (62.9%). Systematic treatment was 87% for HPV 16,18,18_45 (29/33). For the other genotypes 76 women were treated, including 45 VAI+ and 31 VIA-.

Conclusions: Implementing new WHO recommended algorithms for cervical precancer screening and treatment require close monitoring and can lead to services strengthening.

O199 / #767

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PREVALENCE OF HUMAN PAPILLOMAVIRUS INFECTION IN THE DEMOCRATIC REPUBLIC OF CONGO

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Introduction: Cervical cancer (CC) is the leading cause of mortality by cancer in Sub-Saharan Africa. The human papillomavirus (HPV) infection is recognized as a necessary and sufficient cause for CC. Population-specific estimates of HPV prevalence in the Democratic Republic of Congo (DRC) is unknown. This study aims at estimating the prevalence of HPV and identifying predominant genotypes circulating in Kinshasa, DRC.

Methods: Between July 2015 and July 2018, women were invited to attend a screening program at Mont-Amba Health Centre in Kinshasa. Cervical specimens were collected using the Preservcyt® medium. HPV DNA testing was performed for all the specimen using real-time polymerase chain reaction.

Results: During the 2-years period, a total of 1870 woman aged 25-82 years were screened. The mean age was 46 years (± 11.4). The overall HPV prevalence was 28.2% (95% CI: 26.1-30.3). HrHPV prevalence was 24.8% (95% CI: 22.8-26.8). Women younger than 30 years had the highest overall HPV prevalence (42.2%, 95% CI: 34.7-49.9). A second peak of prevalence was observed in women aged 60 years and older. HPV68 (5.5%, 95% CI: 4.5-6.6) was the most prevalent HPV type.

Conclusions: The distribution of HPV genotypes among women in our population was different compared to other world regions. A key finding was that HPV68 was the most prevalent HrHPV genotype. These findings highlight the need for the determination in our population of the etiologic fraction of different HPV types in invasive cervical cancers. This will guide the development of next-generation vaccines covering the most prevalent HPV types found in our region.

O200 / #1144

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HPV PREVALENCE AND GENOTYPE DISTRIBUTION AMONG WOMEN LIVING WITH HIV ATTENDING A SINGLE REFERRAL AND TREATMENT CENTER IN SEMI-RURAL TANZANIA

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Introduction: Women living with HIV (WLWH) have a 6-fold increased risk to develop cervical cancer (CC), which mostly arises from persistent infection with high-risk (HR-) human papillomavirus (HPV). Tanzania has the highest HPV prevalence in East Africa, with a HR-HPV positivity rate of 46.7% among WLWH. From 07/2021-09/2022, WLWH attending a care-and-treatment-center in Ifakara, southern-central Tanzania, were screened for HPV.

Methods: Inclusion criteria were: age 18-65 years, enrollment in Kilombero and Ulanga Antiretroviral Cohort, at least 3-months on antiretroviral therapy, non-pregnant and consent provision. Women with known invasive CC or conditions interfering with cervix visualization were excluded. After cervical self-sampling (Evalyn®Brush); with Seegene Anyplex™ II 28 HPV Detection Test, 19 HR-HPV and 9 low-risk (LR-)HPV were genotyped. The project, ethically approved (TMDA-WEB0021/CTR/002/03), is registered (ClinicalTrials.gov NCT03633643).

Results: 1494 WLWH with a median age of 45 years (18-65), median number of pregnancies of 4 (0-14) and median number of births of 4 (0-12) were enrolled. 1066 (71.5%) did not use any contraceptive methods. Median time of HIV diagnosis was 9 years ago (recent–25 years) and 38.7% (n=575) were stage-1, 22% (n=327) stage-2, 26.9% (n=400) stage-3 and 12.4% (n=184) stage-4. At baseline, HPV was undetectable in 1099 (73.8%) and detected in 462 (30.9%), specifically 35 (15.8%), 16 (15.2%), 18 (15%), 58 (13%), 53 (11.9%), 33 (10.6%), 52 (10.2%), 59 (7.81%), 68 (7.59%), 45 (6.94%), 39 (6.72%), 73 (6.51%), 51 (6.29%), 82 (5.42%), 66 (4.99%), 69 (4.34%), 56 (3.90%), 31 (3.47%) and 26 (0.65%). Infections with multiple HR-HPV types were found in 12.31% (n=184). The most prevalent LR-HPV type was 42 (27.6%).

Conclusions: This study provides valuable information about HPV prevalence in a WLWH cohort prior to the implementation of the national HPV immunization program. Furthermore, WLWH with HR-HPV have access to monitoring and treatment (VIA, thermal ablation, LEEP); which will be also evaluated.

O201 / #1315

Clinical Science Oral Abstracts Session
CLINICAL SCIENCE ORAL: SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-21-2023 2:15 PM - 3:45 PM

ADOPTION OF THERMAL ABLATION FOR TREATMENT OF CERVICAL PRECANCEROUS LESIONS IN KENYA: FINDINGS AND LESSONS

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Introduction: Cervical cancer is the leading cause of cancer deaths in Kenya. The World Health Organization recommends linkage to treatment after screening as a key intervention to achieve elimination. A ‘screen-and-treat’ approach is the most feasible approach in low and middle-income countries, where loss to follow-up is high. While cryotherapy has been previously used in Kenya for treatment of cervical pre-cancerous lesions (PCL), adoption has been limited by cost of refilling treatment gases and bulkiness. As part of the national cervical cancer screening and treatment scale-up, NCCP has adopted thermal ablation (TA) for PCL treatment. We present the findings and lessons of the roll-out of TA in primary care in Kenya.

Methods: Implementation was done through collaboration between NCCP (Ministry of Health), CHAI and the respective county departments of health between 2020-2021 in 25 counties. The implementation package consisted of training and mentorship – provided by a team of master-trainers as well as county level trainers. In addition, procurement of high quality-assured, portable TA equipment i.e., Liger© (Liger Medical LLC) and Wisap© (Wisap Medical Technologies GmbH) be used to provide treatment of PCL.

Results: Currently, 820 TA devices have been distributed and 6000 healthcare workers trained on cervical cancer screening and treatment using TA. Contribution of TA in treatment of PCL in the 25 counties increased from 0% (0/787) in January-June 2019 to 18.8% (369/1959) in January-June 2022 ($p<0.001$). Cervical PCL treatment is now possible at lower-level primary care facilities (dispensaries and health centers) even in areas with power interruptions.

Conclusions: Adoption of TA can improve cervical cancer screening and treatment at primary care. However, continuous mentorship is necessary to sustain such interventions, while maintaining quality of the screening program.

O202 / #793

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: OTHER PUBLIC HEALTH & EPIDEMIOLOGY
04-21-2023 2:15 PM - 3:45 PM

RACIAL AND ETHNIC DIFFERENCES IN CERVICAL CANCER INCIDENCE, SURVIVAL AND MORTALITY BY HISTOLOGIC SUBTYPE REVEAL PROFOUND DISPARITIES

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Introduction: We conducted an integrated population-based analysis of subtype-specific cervical cancer incidence, survival, and incidence-based mortality by race and ethnicity, with correction for hysterectomy prevalence.

Methods: Using the Surveillance, Epidemiology and End Results (SEER) 21 and 18 registries, we evaluated age-adjusted incidence rates of primary malignant cervical cancer cases among women >15 years of age between 2000- 2018 (SEER21) and incidence-based mortality rates among deaths from 2005-2018 (SEER18), per 100,000 person-years, respectively. Rates were stratified by histologic subtype and race and ethnicity (incidence and mortality), as well as by stage and age at diagnosis (incidence only). Rates were corrected for hysterectomy using data from the Behavioral Risk Factor Surveillance System. We estimated five-year relative survival by histologic subtype and stratified by stage at diagnosis.

Results: Black and Hispanic women had the highest rates of cervical squamous cell carcinoma (SCC) respectively, while rates of cervical adenocarcinoma (ADC) were highest among Hispanic and White women, respectively, particularly for localized ADC. Incidence rates of both SCC and ADC peaked at ages 35-44 years for White women; however, rates of SCC and ADC in Black and SCC in Hispanic women continued to increase with age, peaking at 65-74 years. Although Black women had the lowest incidence of ADC, they had the highest overall mortality-rates and lowest five-year relative survival, for both SCC and ADC, irrespective of stage. Disparities in survival were particularly pronounced for Black women with regional and distant ADC, compared to other racial and ethnic

Table 1. Age-adjusted incidence rates and rate ratios of cervical cancer by histologic subtype and race and ethnicity, corrected for hysterectomy prevalence

Histologic Subtype	Race/ Ethnicity	No. cases	Corrected IR (95% CI)	Corrected IRR
Overall	**Total**	**75,422**	**11.5 (11.5,11.6)**	-
	White	40,584	10.0 (10.0,10.1)	Ref
	Black	11,197	16.8 (16.5,17.2)	1.7 (1.6,1.7)
	AI/AN	502	11.9 (11.1, 13.2)	1.2 (1.2,1.2)
	API	6,508	9.7 (9.4,9.9)	1.0 (0.9,1.0)
	Hispanic	16,631	15.8 (15.7,16.1)	1.6 (1.6,1.6)
SCC	**Total**	**54,023**	**8.3 (8.2,8.3)**	-
	White	27,668	6.8 (6.7,6.9)	Ref
	Black	9,261	13.8 (13.5,14.1)	2.0 (2,0,2.1)
	AI/AN	361	8.6 (7.8,9.7)	1.3 (1.2,1.3)
	API	4,563	6.9 (6.6,7.1)	1.0 (1.0,1.0)
	Hispanic	12,170	11.8 (11.6,12.1)	1.7 (1.7,1.8)
ADC	**Total**	**16,447**	**2.5 (2.5,2.5)**	-
	White	10,222	2.5 (2.5,2.5)	Ref
	Black	1,258	2.0 (1.9,2.1)	0.8 (0.8,0.8)
	AI/AN	109	2.5 (2.1,3.1)	1.0 (1.0,1.0)
	API	1,454	2.1 (2.0,2.2)	0.8 (0.8,0.9)
	Hispanic	3,404	3.0 (2.9,3.2)	1.2 (1.1,1.2)
ADSC	**Total**	**2,963**	**0.4 (0.4,0.5)**	-
	White	1,582	0.4 (0.4,0.4)	Ref
	Black	374	0.5 (0.4,0.6)	1.4 (1.3,1.5)
	AI/AN	n/a	n/a	n/a
	API	279	0.4 (0.3,0.5)	1.0 (0.9,1.1)
	Hispanic	707	0.7 (0.7,0.7)	1.7 (1.6,1.8)
Other Subtypes	**Total**	**1,989**	**0.3 (0.3,0.3)**	-
	White	1,112	0.3 (0.3,0.3)	Ref
	Black	304	0.5 (0.5,0.5)	1.8 (1.7,2.0)
	AI/AN	n/a	n/a	n/a
	API	212	0.3 (0.2,0.4)	1.1 (1.0,1.3)
	Hispanic	350	0.4 (0.3,0.4)	1.3 (1.2,1.5)

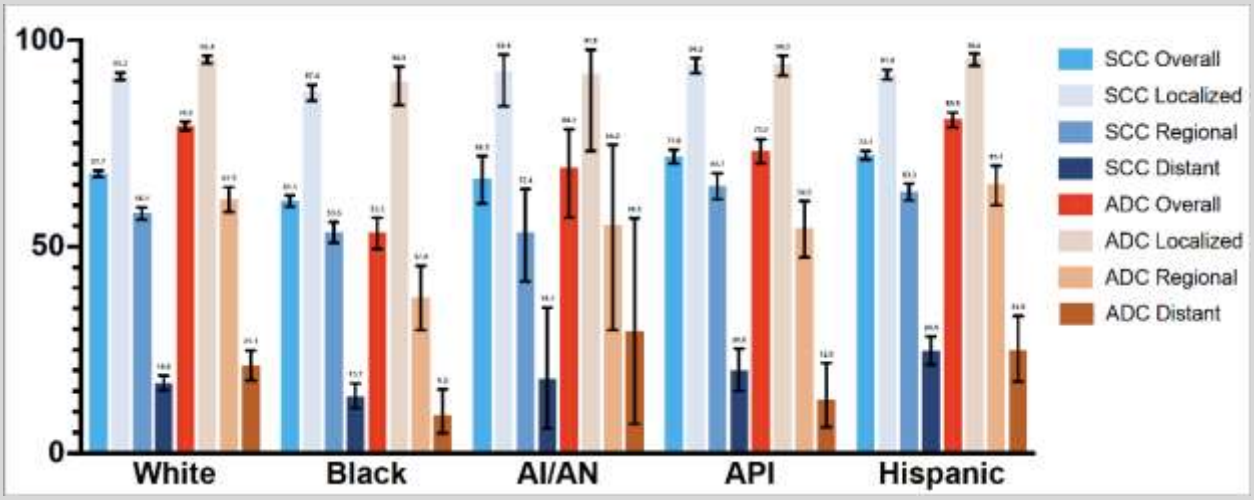
Table 1 Age-adjusted incidence rates and rate ratios expressed per 100,000 person-years of cervical cancer by histologic subtype and race and ethnicity corrected for hysterectomy prevalence among women aged 15-75+ in the U.S. in SEER21 (2000-2018). **Abbreviations:** IR, incidence rate; CI, confidence interval; IRR, incidence rate ratio; AI/AN, American Indian and Alaska Native; API, Asian or Pacific Islander; SCC, cervical squamous cell carcinoma; ADC, cervical adenocarcinoma; ADSC, cervical adenosquamous carcinoma; Ref, reference. **Note:** "n/a" indicates the statistic could not be calculated due to fewer than 25 cases being reported.

groups.

Table 2. Age-adjusted incidence-based mortality rates of cervical cancer by histologic subtype and race and ethnicity, corrected for hysterectomy prevalence

Histologic Subtype	Race/ Ethnicity	No. cases	Corrected MR (95% CI)	Corrected MRR
Overall	**Total**	**10,488**	**3.0 (2.9,3.0)**	-
	White	5,632	2.6 (2.6,2.7)	Ref
	Black	1,803	5.0 (4.7,5.2)	1.9 (1.9,2.0)
	AI/AN	102	4.0 (3.3,5.0)	1.5 (1.5,1.6)
	API	890	2.1 (1.9,2.3)	0.8 (0.8,0.8)
	Hispanic	2,061	3.5 (3.4,3.6)	1.4 (1.3,1.4)
SCC	**Total**	**7,876**	**2.2 (2.1,2.3)**	-
	White	4,172	1.9 (1.8,2.0)	Ref
	Black	1,451	4.0 (3.8,4.2)	2.1 (2.0,2.2)
	AI/AN	75	2.9 (2.3,3.7)	1.5 (1.5,1.6)
	API	610	1.4 (1.3,1.5)	0.8 (0.7,0.8)
	Hispanic	1,568	2.7 (2.5,2.8)	1.4 (1.4,1.5)
ADC	**Total**	**1,675**	**0.5 (0.5,0.5)**	-
	White	966	0.4 (0.4,0.4)	Ref
	Black	213	0.6 (0.5,0.7)	1.4 (1.3,1.5)
	AI/AN	n/a	n/a	n/a
	API	187	0.4 (0.4,0.5)	1.0 (0.9,1.1)
	Hispanic	289	0.5 (0.4,0.6)	1.1 (1.0,1.2)
ADSC	**Total**	**481**	**0.1 (0.1,0.1)**	-
	White	262	0.1 (0.1,0.1)	Ref
	Black	63	0.2 (0.2,0.2)	1.4 (1.2,1.7)
	AI/AN	n/a	n/a	n/a
	API	40	0.1 (0.1,0.1)	0.8 (0.6,0.9)
	Hispanic	110	0.2 (0.1,0.3)	1.3 (1.1,1.6)
Other Subtypes	**Total**	**456**	**0.1 (0.1,0.1)**	-
	White	232	0.1 (0.1,0.1)	Ref
	Black	76	0.2 (0.2,0.3)	2.1 (1.8,2.4)
	AI/AN	n/a	n/a	n/a
	API	53	0.1 (0.1,0.1)	1.2 (1.0,1.4)
	Hispanic	94	0.2 (0.2,0.2)	1.5 (1.2,1.7)

Table 2. Age-adjusted incidence-based mortality rates and mortality rate ratios of cervical cancer expressed per 100,000 person-years by histologic subtype and race and ethnicity corrected for hysterectomy prevalence among women aged 15-75+ in the U.S. in SEER18 (2005-2018). **Abbreviations:** MR, mortality rate; CI, confidence interval; MRR, mortality rate ratio; AI/AN, American Indian and Alaska Native; API, Asian or Pacific Islander; SCC, cervical squamous cell carcinoma; ADC, cervical adenocarcinoma; ADSC, cervical adenosquamous carcinoma; Ref, reference. **Note:** "n/a" indicates the statistic could not be calculated due to fewer than 25 cases being reported.



Conclusions: Although Black women are less likely to be diagnosed with ADC compared to all other racial and ethnic groups, they experience the highest mortality rates for this subtype, likely attributed to the poor survival observed for Black women diagnosed with regional and distant ADC.

O203 / #1473

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: OTHER PUBLIC HEALTH & EPIDEMIOLOGY
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ACCURACY OF DUAL-STAINED CYTOLOGY VS LIQUID-BASED CYTOLOGY FOR TRIAGE OF HPV-POSITIVE WOMEN IN AN HPV-VACCINATED POPULATION: RESULTS FROM THE COMPASS TRIAL IN AUSTRALIA

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Introduction: Dual-stained cytology (DS) for p16/Ki67 is potentially a more effective triage than liquid-based cytology (LBC) after primary HPV screening, but data from HPV-vaccinated populations are limited. Compass is a major RCT in Australia - primary randomization is to HPV vs LBC screening; recruitment is stratified by birth-cohort according to whether offered HPV vaccination (born</>= 1980), with vaccination coverage of 50-70%+ in catch-up cohorts vaccinated in 2007-9 to 26 years.

Methods: In the main trial, 75,875 women aged 25-74 were recruited from 2015-2019; 50,732 were randomized to HPV screening, of these 43,693 were routine screeners; 576 (1.3%) had HPV16/18 and 3,396 (7.8%) had another high-risk HPV infection (HPVOHR). Women with HPVOHR were prospectively secondarily-randomized to DS vs LBC triage; women with HPV16/18 were referred to colposcopy with concealed DS testing. Triage-negative women had 12-month follow-up with HPV and a further 6 months follow-up for colposcopy/biopsy data; DS and LBC sensitivity and specificity were estimated using worst-case histology over the period.

Results: For routine screeners, for both CIN2+ and CIN3+, DS had high absolute sensitivity (77-88%) for both vaccinated/unvaccinated populations and across type-groups (HPV16/18 and HPVOHR), but specificity was higher for HPVOHR(68-74%) vs HPV16/18(50-60%) (Table 1). Findings were similar for all primary-randomized women (including those not in routine screening). In the prospective secondary-randomized comparison for HPVOHR vs. LBC, DS had higher relative CIN2+ sensitivity (1.63[95%CI:1.38–1.92]) but lower specificity (0.75[95%CI:0.73–0.77]). For CIN3+, relative sensitivity/specificity were 1.52[95%CI:1.24-1.87] and 0.73 [95%CI:0.71-0.75], respectively (Table 2).

TABLE 1. DS absolute sensitivity and specificity in participants in routine screening

	Cohorts offered HPV vaccination (born on or after 1 July 1980)		Cohorts not offered HPV vaccination (born before 1 July 1980)		All participants	
	Sensitivity	**Specificity**	**Sensitivity**	**Specificity**	**Sensitivity**	**Specificity**
CIN2+						
HPV 16/18 (concealed testing)	80.12% (73.23% - 85.90%)	55.45% (48.47% - 62.27%)	87.50% (67.64% - 97.34%)	59.85% (50.96% - 68.28%)	81.05% (74.75% – 86.36%)	57.14% (51.72% – 62.44%)
HPVOHR (randomized to DS triage)	85.33% (78.64% - 90.57%)	71.62% (68.97% - 74.16%)	77.14% (59.86% - 89.58%)	74.82% (69.33% - 79.78%)	83.78% (77.67% - 88.78%)	72.23% (69.87% - 74.50%)
All HPV positive*	82.59% (77.96% - 86.615%)	69.20% (66.71% - 71.60%)	81.36% (69.09% - 90.31%)	70.05% (65.38% - 74.42%)	82.40% (78.16% - 86.12%)	69.39% (67.22% - 71.50%)
CIN3+						
HPV 16/18 (concealed testing)	80.77% (72.93% - 87.15%)	50.61% (44.20% - 57.00%)	82.35% (56.57% - 96.20%)	56.83% (48.17% - 65.20%)	80.95% (73.66% – 86.95%)	52.85% (47.73% - 57.92%)
HPVOHR (randomized to DS triage)	84.42% (74.36% - 91.68%)	68.29% (65.65% - 70.85%)	84.21% (60.42% - 96.62%)	72.48% (67.04% - 77.48%)	84.38% (75.54% - 90.98%)	69.09% (66.74% - 71.37%)
All HPV positive*	82.13% (76.21% - 87.09%)	65.42% (62.96% - 67.81%)	83.33% (67.19% - 93.63%)	67.51% (62.89% - 71.88%)	82.30% (76.91% - 86.89%)	65.88% (63.73% - 67.98%)

*Concealed testing for all HPV16/18+ and HPVOHR+ randomized to DS triage.

TABLE 2. Results of prospective secondary randomization: DS vs LBC in OHRHPV+ participants

	Cohorts offered HPV vaccination (born on or after 1 July 1980)		Cohorts not offered HPV vaccination (born before 1 July 1980)		All participants	
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
CIN2+						
DS	84.94% (78.58% - 90.01%)	71.92% (69.43% - 74.30%)	76.92% (60.67% - 88.87%)	74.12% (68.9% - 78.88%)	83.41% (77.60% - 88.23%)	72.33% (70.11% - 74.47%)
LBC (pHSIL threshold)*	49.62% (40.84% - 58.42%)	96.61% (95.51% - 97.50%)	63.16 (38.36% - 83.71%)	95.63% (92.89% - 97.53%)	51.32% (43.08% - 59.50%)	96.41% (95.42% - 97.24%)
Relative	1.71 (1.43 – 2.06)	0.73 (0.70 – 0.75)	1.22 (0.83 – 1.79)	0.74 (0.69 – 0.79)	1.63 (1.38 – 1.92)	0.75 (0.73 – 0.77)
CIN3+						
DS	84.71% (75.27% - 91.60%)	68.68% (66.20% - 71.08%)	81.82% (59.72% - 94.81%)	71.82% (66.63% - 76.61%)	84.11% (75.79% - 90.46%)	69.27% (67.05% - 71.42%)
LBC (pHSIL threshold)*	54.17% (42.00% - 65.98%)	94.88% (93.62% - 95.96%)	61.54% (31.58% - 86.14%)	94.56% (91.63% - 96.69%)	55.29% (44.11% - 66.09%)	94.82% (93.69% - 95.80%
Relative	1.56 (1.24 – 1.97)	0.71 (0.68 – 0.73)	1.33 (0.83 – 2.13)	0.73 (0.68 – 0.78)	1.52 (1.24 – 1.87)	0.73 (0.71 – 0.75)

* (US equivalent – ASC-H: Threshold as used in the Australian National Cervical Screening Program).

Conclusions: DS triage performance was consistent across vaccinated/unvaccinated cohorts. The specificity of DS appears higher in HPVOHR. Relative to LBC, DS has higher sensitivity for CIN3+, indicating a useful role in programs with partial genotyping where DS+ HPVOHR+ can be immediately referred alongside HPV16/18+. DS has potential for automation which should facilitate implementation at scale in high-income countries.

O204 / #1093

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: OTHER PUBLIC HEALTH & EPIDEMIOLOGY
04-21-2023 2:15 PM - 3:45 PM

RISK OF SUBSEQUENT CIN3+ IN SCREENED HPV-POSITIVE WOMEN INITIALLY DIAGNOSED WITH ≤CIN1 WITHIN ESTAMPA

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Introduction: A fraction of HPV-positive women initially diagnosed with ≤CIN1 are subsequently diagnosed with CIN3 or cancer (CIN3+). We aimed to explore the role of triage tests and women's baseline characteristics as potential markers for detection of CIN3+ during follow-up in HPV-positive women without cervical disease at entry in ESTAMPA.

Methods: In ESTAMPA, women aged 30-64 years were screened with HPV and cytology and referred to colposcopy with biopsy and treatment as needed. Those without evidence of cervical precancer (CIN1, negative biopsy, or negative colposcopy) were recalled to a follow-up visit at ~18 months for further disease ascertainment. Odds ratios adjusted by clinical and sexual and reproductive characteristics were used to estimate the risk of subsequent CIN3+ among HPV positive women initially diagnosed with ≤CIN1. The association of clinical and sexual and reproductive characteristics was also explored by triage result.

Results: 3,161 HPV-positive women with ≤CIN1 at entry were included in the analysis. 2.6% (95%CI 2.1-3.2) had CIN3+ at the follow-up visit (73 CIN3, 3 AIS, 6 cancers). Women with positive triage results had at least 3-fold the risk of subsequent CIN3+ compared to those with negative triage (Table 1). Among women with ≥ASC-US, having ≥4 sexual partners and ≥2 years since the last cytology increased the risk of subsequent CIN3+ compared to those with less sexual partners and screened within 2 years (Table 2). Among women with non-HPV16/18 infection, having ≥2 years since the last cytology was also associated

to subsequent CIN3+ (Table 2).

Table 1. Risk of CIN3+ at the follow-up visit according to reflex cytology, HC2 RLU, and partial HPV genotyping, adjusted by baseline characteristics, among ESTAMPA participants screened positive for HPV with no evidence of cervical disease at entry

Triage test / Baseline characteristics	Diagnosis at the 18-month follow-up visit		P*	OR† (95% CI) of CIN3+ in women triaged with reflex cytology	OR‡ (95% CI) of CIN3+ in women triaged with HC2 RLU	OR§ (95% CI) of CIN3+ in women triaged with HPV16/18
	<CIN2 n (%)	CIN3+ n (%)				
Total	3079 (97.4)	82 (2.6)				
Reflex cytology						
NILM/Unsatisfactory	1332 (97.7)	32 (2.3)	<0.001	Ref.	—	—
ASC-US/LSIL	226 (95.4)	11 (4.6)		2.05 (0.96-4.07)	—	—
HSIL+	143 (92.3)	12 (7.7)		**4.12 (1.84-8.80)**		
HC2 RLU						
<10	1009 (99.0)	10 (1.0)	<0.001	—	Ref.	—
10-99.9	578 (96.8)	19 (3.2)		—	**3.32 (1.56-7.50)**	—
≥100	494 (95.9)	21 (4.1)		—	**3.81 (1.79-8.64)**	—
HPV type						
Other high-risk	866 (98.1)	17 (1.9)	<0.001	—	—	Ref.
16/18	229 (93.5)	16 (6.5)		—	—	**3.35 (1.60-6.94)**
Age, y						
<40	1385 (97.5)	36 (2.5)	0.935	Ref.	Ref.	Ref.
≥40	1694 (97.4)	46 (2.6)		1.04 (0.57-1.90)	1.29 (0.70-2.42)	0.89 (0.41-1.93)
Initial diagnosis						
Negative colposcopy	833 (97.1)	25 (2.9)	0.093	Ref.	Ref.	Ref.
Negative biopsy	1224 (98.2)	23 (1.8)		0.67 (0.33-1.38)	0.66 (0.31-1.46)	0.45 (0.15-1.23)
CIN1	1022 (96.8)	34 (3.2)		1.85 (0.91-3.70)	0.97 (0.46-2.10)	1.37 (0.61-3.18)
Age of sexual debut, y						
≥21	527 (97.6)	13 (2.4)	0.577	Ref.	Ref.	Ref.
17-20	1427 (97.1)	43 (2.9)		1.25 (0.56-3.04)	2.43 (1.00-7.27)	0.79 (0.30-2.35)
≤16	1106 (97.7)	26 (2.3)		1.25 (0.52-3.22)	1.47 (0.54-4.71)	0.82 (0.28-2.59)
Lifetime sexual partners						
≤3	1934 (97.6)	47 (2.4)	0.388	Ref.	Ref.	Ref.
≥4	1084 (97.0)	33 (3.0)		1.53 (0.84-2.80)	0.99 (0.46-1.83)	2.22 (1.04-4.93)
Tobacco consumption						
Never	2255 (97.3)	63 (2.7)	0.509	Ref.	Ref.	Ref.
Ever	797 (97.8)	18 (2.2)		0.40 (0.18-0.85)	0.76 (0.34-1.56)	0.68 (0.28-1.51)
Number of pregnancies						
0-2	1328 (97.4)	36 (2.6)	1.000	Ref.	Ref.	Ref.
≥3	1737 (97.4)	46 (2.6)		0.95 (0.52-1.76)	0.93 (0.50-1.76)	0.96 (0.42-2.15)
Years since last cytology						
<2	1774 (98.0)	37 (2.0)	0.030	Ref.	Ref.	Ref.
≥2	1296 (96.6)	45 (3.4)		2.08 (1.18-3.77)	1.33 (0.74-2.38)	2.94 (1.37-6.87)

*Chi-squared test. †Odds ratio of CIN3+ at the follow-up visit adjusted by reflex cytology, age, initial diagnosis, age of sexual debut, lifetime sexual partners, tobacco consumption, number of pregnancies, and years since last cytology. ‡Odds ratio of CIN3+ at the follow-up visit adjusted by age, HC2 relative light units, initial diagnosis, age of sexual debut, lifetime sexual partners, tobacco consumption, number of pregnancies, and years since last cytology. §Odds ratio of CIN3+ at the follow-up visit adjusted by age, Cobas HPV type, initial diagnosis, age of sexual debut, lifetime sexual partners, tobacco consumption, number of pregnancies, and years since last cytology.

Table 2. Risk of CIN3+ at the follow-up visit according to baseline characteristics among ESTAMPA participants screened positive for HPV with no evidence of cervical disease at entry stratified by triage test result

Baseline characteristics	OR* (95% CI) of CIN3+ in women triaged with reflex cytology	OR† (95% CI) of CIN3+ in women triaged with HC2 RLU	OR‡ (95% CI) of CIN3+ in women triaged with HPV16/18
Women with positive triage			
Age, y			
<40	Ref.	Ref.	Ref.
≥40	0.45 (0.17-1.18)	1.03 (0.52-2.07)	1.14 (0.35-3.75)
Initial diagnosis			
Negative colposcopy	Ref.	Ref.	Ref.
Negative biopsy	0.60 (0.19-1.82)	0.75 (0.30-1.96)	0.60 (0.11-2.90)
CIN1	1.35 (0.45-4.03)	1.31 (0.56-3.30)	1.82 (0.53-7.28)
Age of sexual debut, y			
≥21	Ref.	Ref.	Ref.
17-20	1.47 (0.35-10.18)	2.12 (0.78-7.40)	0.60 (0.13-3.18)
<16	1.77 (0.39-12.51)	1.56 (0.52-5.76)	1.08 (0.24-5.83)
Lifetime sexual partners			
≤3	Ref.	Ref.	Ref.
>4	**3.47 (1.33-9.92)**	1.28 (0.60-2.63)	1.64 (0.49-5.70)
Tobacco consumption			
Never	Ref.	Ref.	Ref.
Ever	0.38 (0.13-1.00)	0.43 (0.14-1.06)	1.39 (0.42-4.42)
Number of pregnancies			
0-1	Ref.	Ref.	Ref.
≥3	1.80 (0.68-5.13)	1.13 (0.56-2.37)	0.80 (0.23-2.69)
Years since last cytology			
<2	Ref.	Ref.	Ref.
≥2	**2.76 (1.10-7.65)**	1.18 (0.60-2.28)	1.55 (0.52-4.99)
Women with negative triage			
Age, y			
<40	Ref.	Ref.	Ref.
≥40	1.79 (0.82-4.04)	3.58 (0.80-25.30)	0.75 (0.26-2.14)
Initial diagnosis			
Negative colposcopy	Ref.	Ref.	Ref.
Negative biopsy	0.54 (0.21-1.38)	0.50 (0.11-2.21)	0.42 (0.09-1.53)
CIN1	1.82 (0.74-4.61)	0.35 (0.05-1.89)	1.13 (0.37-3.44)
Age of sexual debut, y			
>21	Ref.	Ref.	Ref.
17-20	1.31 (0.52-3.78)	5.75 (0.94-111.74)	1.00 (0.27-4.75)
≤16	1.03 (0.33-3.35)	1.07 (0.04-28.79)	0.77 (0.16-4.17)
Lifetime sexual partners			
≤3	Ref.	Ref.	Ref.
≥4	1.03 (0.43-2.28)	0.22 (0.01-1.29)	2.50 (0.91-7.53)
Tobacco consumption			
Never	Ref.	Ref.	Ref.
Ever	0.45 (0.10-1.36)	2.76 (0.67-10.23)	0.35 (0.08-1.15)
Number of pregnancies			
0-1	Ref.	Ref.	Ref.
≥3	0.68 (0.31-1.52)	0.45 (0.11-1.77)	1.10 (0.37-3.27)
Years since last cytology			
<2	Ref.	Ref.	Ref.
≥2	1.80 (0.86-3.89)	2.11 (0.57-7.86)	**5.14 (1.65-22.52)**

OR: odds ratio of CIN3+ at the follow-up visit adjusted by age, initial diagnosis, age of sexual debut, lifetime sexual partners, tobacco consumption, number of pregnancies, and years since last cytology among women with negative reflex cytology (Ξ), HC2 RLU<10 (†), and non-HPV16/18 infection (‡).

Conclusions: HPV-positive women with no evidence of precancer at screening but with positive triage results, particularly HSIL+ cytology, HC2-RLU≥10, and HPV16/18 are at higher risk of subsequent detection of precancer compared to those with negative triage and should be prioritised for follow-up. Additionally, sexual behaviour characteristics and screening history may help guide the clinical management of HPV-positive women.

O205 / #1367

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: OTHER PUBLIC HEALTH & EPIDEMIOLOGY
04-21-2023 2:15 PM - 3:45 PM

INCIDENCE OF ONCOGENIC ORAL HPV AMONG MEN FROM BRAZIL, MEXICO AND USA PARTICIPATING IN THE HUMAN PAPILLOMAVIRUS INFECTION IN MEN (HIM) STUDY.

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Introduction: Oral oncogenic HPV infection is the cause of HPV-related oropharyngeal cancer. Unfortunately, little is known regarding the rate of acquisition of these infections or the natural history. The aim of this study was to estimate incidence of oncogenic oral HPV overall, and by country and age group, in the multi-national Human Papillomavirus Infection in Men (HIM) Study.

Methods: HIM Study participants (n=3,137) ages 18-70, who provided at least two oral gargle samples, every 6 months for 48 months, were included in this analysis. HPV was genotyped using the HPV SPF10 PCR-DEIA-LiPA25, (DDL Diagnostic Laboratory, Netherlands) line probe assay. Incidence rates were calculated using Poisson models and differences in oncogenic oral HPV acquisition by country and age were estimated using the Kaplan-Meier (KM) method.

Results: Among men from the USA (881), Brazil (1235), and Mexico (1021), 337 acquired an oral oncogenic HPV infection. Incidence was 2.4 per 1000 person-months with incidence significantly higher among men from the USA compared to men in Brazil and Mexico (3.8 vs 1.9 and 1.7 per 1000 person-months, respectively). HPV types 52 and 16 were the most common among all men, at 0.8 and 0.6 per 1000 person-months respectively. Men acquired new oral oncogenic HPV evenly over time (2.4, 2.8, 2.6 and 2.4 per 1000 person-months at 12, 24, 36 and 48 months respectively). Probability of new oral oncogenic infections was higher among men ages 18-24 years (HR; 95% CI 1.44 (1.01-2.05) compared to older age groups, with the effect driven by a higher incidence in younger men in Brazil.

Conclusions: Our data suggest that men are at risk of acquiring oral oncogenic HPV across the lifespan with incidence higher among men from USA than those from Mexico and Brazil. To better inform development of preventative interventions, future studies should elucidate acquisition of oncogenic oral HPV by age.

O206 / #104

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: OTHER PUBLIC HEALTH & EPIDEMIOLOGY
04-21-2023 2:15 PM - 3:45 PM

DIFFERENCES IN CERVICAL AND ANAL CANCER INCIDENCE RATES BY RACE AND VISIBLE MINORITY GROUP IN CANADA, 2006-2015: A POPULATION-BASED STUDY

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Introduction: The Canadian Cancer Registry does not collect demographic data beyond age and sex, making it hard to monitor socioeconomic inequalities in cancer incidence in Canada, a country with public healthcare and a large number of immigrants. We used data linkage to compare cervical and anal cancer incidence rates by race and visible minority group.

Methods: We used data from the CanCHEC 2006 and 2011 cohorts, which are population-based probabilistically linked datasets of 5.9 million respondents of the 2006 Canadian long-form census and 6.5 million respondents of the 2011 National Household Survey. Respondents' Indigenous identity and visible minority group identity were self-reported. Respondent data were linked with the Canadian Cancer Registry up to 2015. We calculated age-standardized incidence rate ratios (ASIRR), comparing group-specific rates to the overall population rate with bootstrapped 95% confidence intervals (95%CI). We used negative binomial regressions to adjust rates for socioeconomic variables.

Results: Age-standardized cervical cancer incidence rates were significantly lower in Chinese (ASIRR 0.64, 95%CI 0.50-0.78) and South Asian (ASIRR 0.66, 95%CI 0.49-0.86) women, and were significantly higher in women not belonging to a visible minority group (ASIRR 1.04, 95%CI 1.02-1.06) and Indigenous women (ASIRR 1.61, 95%CI 1.38-1.85) compared to the overall population. Differences in incidence rates by race and visible minority group persisted even after adjusting for household income, education, rural residence, and immigration status. Similar results were observed for anal cancer, with significantly lower incidence rates in Chinese and South Asian populations than in the overall

population.

Table. Age-standardized cervical and anal cancer incidence rates (ASIR) per 100,000 and age-standardized incidence rate ratios (ASIRR) by population group, standardized to the Canadian 2011 census population

	Cervical cancer (females)				Anal cancer			
Population	ASIR	(95%CI)	ASIRR	(95%CI)	ASIR	(95%CI)	ASIRR	(95%CI)
Overall	7.4	(7.1-7.7)	1.00	(ref)	1.8	(1.7-2.0)	1.00	(ref)
Not a visible minority	7.7	(7.4-8.1)	**1.04**	**(1.02-1.06)**	2.0	(1.9-2.2)	**1.10**	**(1.08-1.12)**
Chinese	4.8	(3.7-5.9)	**0.64**	**(0.50-0.78)**	0.3	(0.1-0.5)	**0.16**	**(0.07-0.26)**
Korean	6.3	(3.0-10.2)	0.84	(0.41-1.35)	*	*	*	*
Japanese	6.9	(2.8-12.0)	0.93	(0.38-1.61)	*	*	*	*
Filipino	8.2	(5.3-10.4)	1.10	(0.72-1.39)	1.2	(0.4-2.0)	0.64	(0.22-1.06)
Southeast Asian	11.5	(7.1-16.3)	1.54	(0.93-2.15)	*	*	*	*
South Asian	4.9	(3.6-6.4)	**0.66**	**(0.49-0.86)**	0.7	(0.3-1.2)	**0.39**	**(0.15-0.64)**
Arab	11.2	(1.1-18.6)	1.50	(0.15-2.48)	*	*	*	*
Black	6.9	(4.7-9.4)	0.93	(0.63-1.27)	1.6	(0.9-2.5)	0.88	(0.49-1.32)
Latin American	7.8	(4.6-11.9)	1.05	(0.61-1.62)	*	*	*	*
Other visible minority groups	6.1	(2.1-9.8)	0.82	(0.28-1.34)	0.7	(0.4-1.0)	**0.36**	**(0.19-0.54)**
Multiple visible minority groups	9.8	(4.1-15.9)	1.32	(0.55-2.13)	*	*	*	*
Indigenous peoples	12.0	(10.3-13.6)	**1.61**	**(1.38-1.85)**	1.9	(1.1-2.7)	1.05	(0.58-1.43)

Source: Adapted from Statistics Canada, Canadian Census Health and Environment Cohorts 2006 & 2011, 2006 long-form census, 2011 National Household Survey, Canadian Vital Statistics Death Database 2006-2015, Canadian Cancer Registry 2006-2015.

ASIR=age-standardized incidence rate; ASIRR=age-standardized incidence rate ratio; CI=confidence interval

* Number of cases under disclosure threshold, included in the "Other visible minority groups" category.

Conclusions: Although cervical cancer screening rates are known to be lower in visible minority women in Canada, many visible minority women had lower cervical cancer incidence rates than women who do not identify as visible minorities. Differences are potentially attributable to variations in human papillomavirus infection prevalence, as well as a strong healthy immigrant effect resulting from immigration selection processes.

O207 / #1126

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: OTHER PUBLIC HEALTH & EPIDEMIOLOGY
04-21-2023 2:15 PM - 3:45 PM

CERVICAL CANCER SURVEILLANCE IN SOUTH AFRICA: LESSONS FROM THE PUBLIC SECTOR OF THE WESTERN CAPE

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Introduction: The only population-level evaluation of South Africa's cervical cancer (CxCa) screening programme is a biased estimate of screening coverage based on an aggregated count of screens divided by the population eligible for screening each year. There is no routine reporting of the linkage of referrals to colposcopy clinics or to CxCa treatment.

Methods: In the public sector of the Western Cape, a unique health identifier is used in electronic record keeping in healthcare facilities. This identifier enables linkage across several databases, and we use this data to estimate screening coverage, screening intervals, and linkage to treatment, by HIV status.

Results: We estimate 10-yearly screening coverage among HIV-negative women or women with unknown HIV status to be 59.8% in 2019/20. Coverage of 3-yearly screening among women with HIV is estimated to be 53.6% in 2019/20. The screening schedule of once in 10 years for HIV-negative women and once in 3 years for women with HIV is not adhered to – 1 in 5 HIV-negative women return for another routine screen within 3 years and only half return within 10 years. The median time between screens for women with HIV is 5.1 years. Around 40% of HIV-negative women and 50% of women with HIV who were referred to treatment in 2018 had no evidence of attending colposcopy services.

Conclusions: CxCa prevention in the public sector of the Western Cape does not meet the 90-70-90 targets as proposed by the WHO's CxCa elimination strategy. Although around 90% of pre-adolescent girls who attend public schools get vaccinated, less than 60% of women get screened at the appropriate times and less than 50% of women had evidence of accessing treatment. This study shows the crucial importance of a unique health identifier to improve patient-level care and to monitor progress toward the 90-70-90 elimination targets.

O208 / #1134

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: OTHER PUBLIC HEALTH & EPIDEMIOLOGY
04-21-2023 2:15 PM - 3:45 PM

FREQUENT DISCORDANCE BETWEEN HPV DETECTION IN CYTOLOGICAL AND HISTOPATHOLOGICAL SAMPLES AMONG WOMEN LIVING WITH HIV IN ZAMBIA

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Introduction: Cervical HPV prevalence is high among women living with HIV (WLWH) and transient infections in liquid-based cytology (LBC) samples are frequent. HPV testing on cervical histopathology samples may help identify persistent genotypes. We explored HPV genotype agreement in paired LBC and histopathology samples among WLWH in Zambia.

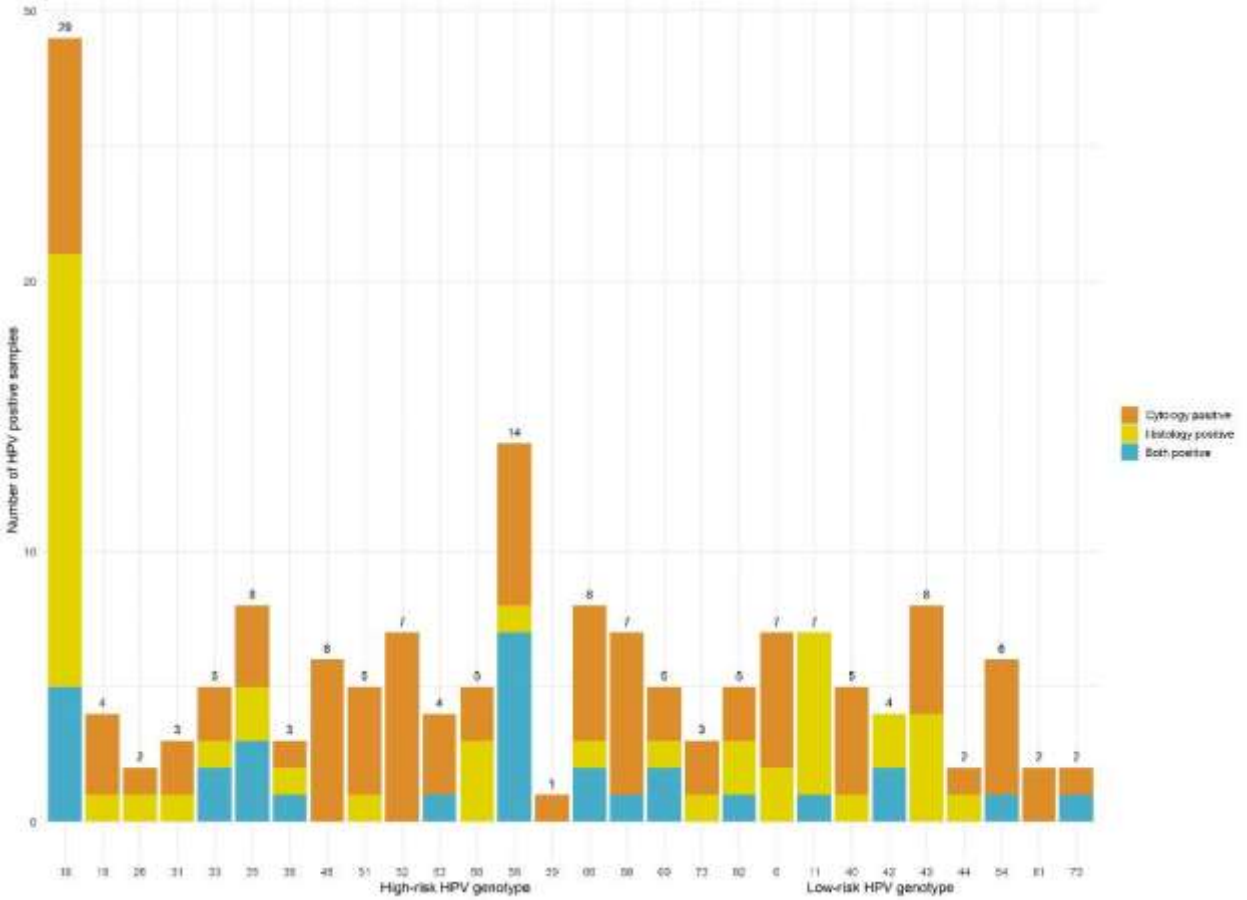
Methods: We included WLWH aged 18-65 years who participated in a cervical cancer screening test accuracy study and returned for follow-up after 30-36 months. We obtained LBC samples and ≥2 cervical biopsies, which were formalin-fixed and paraffin-embedded, from all participants. Both samples were tested for 28 HPV genotypes (Anyplex II HPV28, Seegene, Seoul). We calculated type-specific HPV prevalence and used Cohen's kappa to assess agreement beyond chance between HPV on cytology and histopathology.

Results: From February to September 2022, 146 WLWH (133 <CIN2, 13 CIN2+) had valid paired HPV results. Prevalence of any HPV was similar on LBC (46%, n=67) and histopathology (36%, n=53). Multiple-type infections were more common in LBC (19%, n=28) than histopathological samples (9%, n=13). HPV-16 was the most frequent genotype: 9% (n=13) on LBC, 14% (n=21) on histopathology. Overall agreement for any HPV was 58.9% (Kappa=0.16, 95% confidence interval [CI] 0.00-0.32), with frequent discordance between sample types (Figure). Sixteen women (15 <CIN2, 1 CIN2+) had HPV-16 detected on histopathology but not on LBC (Kappa 0.21, 95% CI 0.00-0.42), of whom four had been treated for CIN2+ diagnosed at the initial study visit; one woman had persistent CIN2+.

Conclusions: Our data from an ongoing study of WLWH with mostly low-grade cervical lesions in Zambia show more multiple-type infections on LBC than histopathology and limited HPV genotype agreement between sample types. This may be partly explained by more frequent transient HPV infections in LBC. The substantial proportion of WLWH with HPV-16 on histopathology but not on LBC warrants further

investigation.

Figure: Frequency and distribution of HPV types identified in cytological and histological samples



O209 / #1336

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: OTHER PUBLIC HEALTH & EPIDEMIOLOGY
04-21-2023 2:15 PM - 3:45 PM

EFFICACY AND SAFETY OF A CARRAGEENAN-GEL AGAINST TRANSMISSION OF CERVICAL HUMAN PAPILLOMAVIRUS (CATCH): A RANDOMIZED, PLACEBO-CONTROLLED TRIAL

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Introduction: The CATCH trial's interim analysis (June 2017, n=277) demonstrated a 36% protective effect of carrageenan. We now report the final analysis of efficacy and safety of a carrageenan-based gel in reducing incidence and prevalence of genital HPV among sexually-active young women.

Methods: The CATCH trial was conducted in Montreal, Canada. Its primary outcomes were HPV type-specific incident and clearance of prevalent infections. Women were randomized (1:1) to a carrageenan-based or placebo gel to be applied every other day for the first month and before, during, and after intercourse as needed. At each study visit (months 0, 0.5, 1, 3, 6, 9, 12), participants provided questionnaire data and a self-collected vaginal sample, which was tested for 36 HPV types (Linear Array). Intention-to-treat analyses were conducted using Cox proportional hazards regression models with participant-level and HPV-level (unit of observation being HPV type) data. Trial registration: ISRCTN96104919.

Results: 461 enrolled participants (2013-2020) were randomized to the carrageenan (n=227) or placebo (n=234) arm. The last follow-up visit occurred in October 2021. Incidence, clearance, and safety analyses included 427, 239, and 441 participants, respectively. We restricted analyses to having valid HPV results for ≥2 visits. Considering 427 participants with valid baseline HPV data, we found a 37% reduction in the risk of incident infection among participants in the carrageenan compared to those in placebo arm (hazard ratio [HR]=0.63, 95% confidence interval [CI]:0.49-0.80). Similar results were obtained with HPV-level data. Of 241 participants positive for HPV at baseline, clearance of infections (two consecutive HPV-negative visits following ≥1 positive visit) was comparable between groups (HR=1.16, 95% CI:0.73-1.84). A total of 37% (79/212, carrageenan) and 41.0% (94/229, placebo) reported an adverse event (p-value=0.42).

Incidence of any HPV and grouped infections, at the participant- and HPV-level

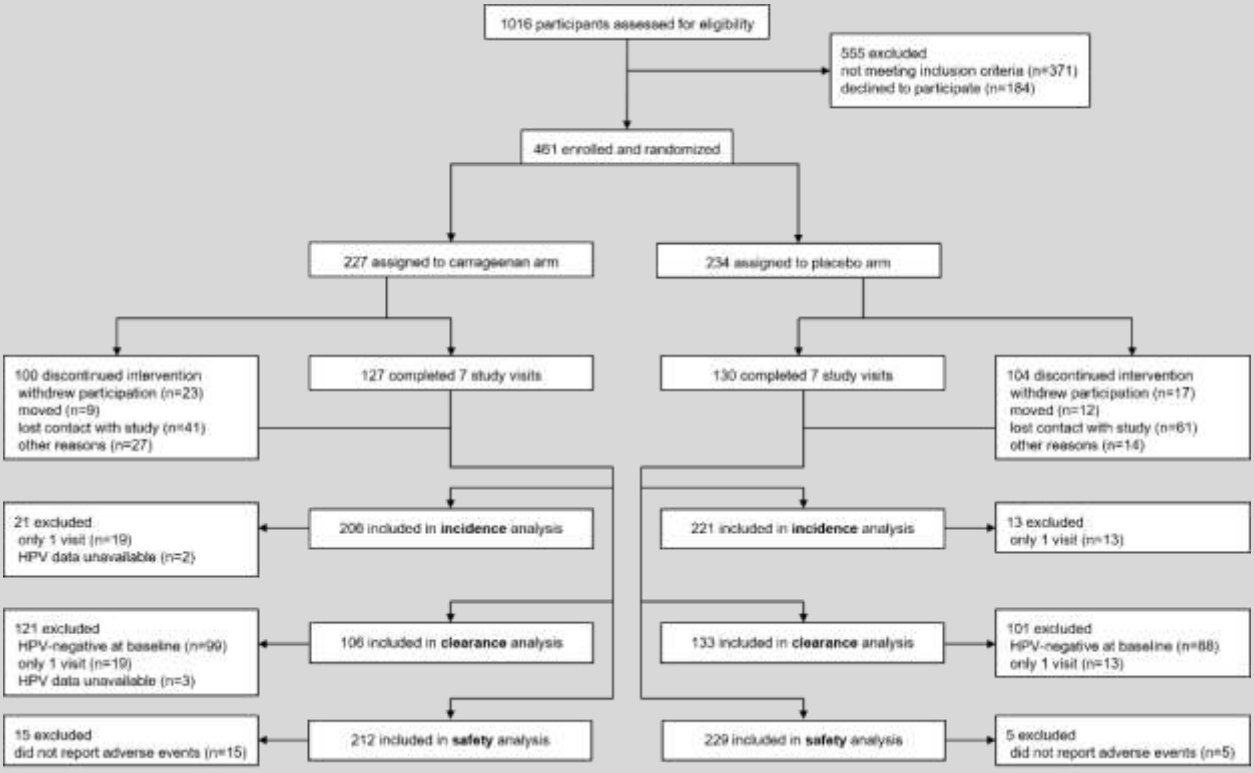
Analysis level	HPV infection grouping	Corrugenus				Placebo				Effect estimate
		N incident/ N at risk (%)	Actuarial mean[a] (95% CI)	Arithmetic mean[a] (95% CI)	Median[a] (95% CI)	N incident/ N at risk (%)	Actuarial mean[a] (95% CI)	Arithmetic mean[a] (95% CI)	Median[a] (95% CI)	Hazard ratio (95% CI)
Participant	Any HPV	106/206 (51·5)	12·7[b] (10·7–14·8)	4·2 (3·8–5·0)	11·4 (6·5–16·4)	143/221 (66·5)	8·7[b] (7·1–10·3)	3·5 (2·8–4·2)	3·7 (3·0–6·0)	0·63 (0·49–0·80)
	Subgenus 1[c]	52/206 (15·5)	24·9[b] (23·0–26·9)	6·6 (4·8–8·4)	NR	56/221 (25·3)	22·7[b] (20·5–24·8)	5·3 (4·0–6·6)	NR (17·8–)[d]	0·57 (0·37–0·87)
	Subgenus 2[e]	83/206 (40·3)	16·2[b] (13·8–18·5)	5·0 (3·8–6·1)	14·9 (12·6–)[d]	124/221 (56·1)	11·1 (9·3–12·9)	4·4 (3·6–5·3)	8·6 (6·0–12·0)	0·44 (0·46–0·80)
	Subgenus 3[f]	54/206 (26·2)	20·8[b] (18·3–23·2)	5·6 (4·0–7·2)	23·7 (20·1–)[d]	79/221 (35·8)	19·2[b] (16·8–21·6)	5·5 (4·4–6·5)	22·4 (13·6–)[d]	0·69 (0·49–0·98)
HPV	Any HPV[g]	274/7,144 (3·8)	29·1[b] (28·9–29·4)	6·6 (6·0–7·3)	NR	438/7,586 (5·8)	29·7[b] (29·4–29·9)	6·4 (5·9–6·9)	NR	0·64 (0·50–0·82)

[a]Time in months. The actuarial mean accounts for censoring, whereas the arithmetic mean excludes participants who did not acquire a new HPV type.
[b]Mean was underestimated since the largest observed analysis time was censored.
[c]Upper confidence limit was undetermined since the survival function did not fall below 0·5.
[d]Subgenus 1 consists of HPVs 6, 11, 40, 42, 44, and 54.
[e]Subgenus 2 consists of HPVs 16, 18, 26, 31, 33, 34, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 67, 68, 69, 70, 73, and 82.
[f]Subgenus 3 consists of HPVs 61, 62, 71, 72, 81, 83, 84, and 89.
[g]Proportional hazards Cox regression models account for all incident HPV infections acquired over follow-up. Participants were considered at risk for any HPV type absent at baseline. Each participant could contribute up to 36 observations, each corresponding to an HPV type. The unit of analysis was each individual HPV type.
CI: confidence interval, HPV: human papillomavirus, NR: not reached, N: number.

Clearance of any HPV infection, by outcome and clearance definition, at the participant- and HPV-level

Analysis level	Outcome	Clearance definition[1]	Carrageenan				Placebo				Effect estimate
			N cleared/ N at risk (%)	Actuarial mean[2] (95% CI)	Arithmetic mean[3] (95% CI)	Median[3] (95% CI)	N cleared/ N at risk (%)	Actuarial mean[2] (95% CI)	Arithmetic mean[3] (95% CI)	Median[3] (95% CI)	Hazard ratio (95% CI)
Participant	Time to clearance of all HPV types[4]	Liberal	62/106 (58·5)	10·0 (8·4–11·6)	5·4 (4·8–5·9)	4·3 (3·4–11·0)	66/133 (49·6)	13·0 (10·9–15·0)	5·8 (5·2–6·4)	11·1 (9·5–13·4)	1·41 (1·00–2·00)
		Conservative	34/106 (32·1)	14·8[5] (13·0–16·6)	5·7 (5·0–6·5)	16·0 (10·5–NR)	39/133 (29·3)	19·3 (16·8–21·7)	6·2 (5·4–7·0)	28·9 (13·6–NR)	1·16 (0·75–1·83)
	Time to first cleared HPV infection[4]	Liberal	85/106 (80·2)	4·7[5] (3·6–5·8)	5·0 (4·6·5·5)	3·0 (1·2–4·1)	105/133 (79·0)	4·8 (3·9–5·7)	5·4 (4·9–5·8)	3·2 (1·6–4·0)	1·04 (0·78–1·38)
		Conservative	67/106 (63·2)	6·8[5] (5·4–8·1)	5·4 (4·9·6·0)	3·8 (4·1–6·5)	83/133 (60·9)	7·6[5] (6·1–9·2)	5·7 (5·2–6·2)	5·8 (3·2–6·9)	1·04 (0·75–1·44)
HPV	Time to clearance of an individual HPV type[6]	Liberal	181/269 (67·3)	0·24 (0·21–0·27)	5·0 (4·2–5·7)	0·20 (0·13–0·23)	243/370 (65·7)	0·29 (0·26–0·32)	5·9 (5·3–6·5)	0·23 (0·21–0·25)	1·17 (0·91–1·51)
		Conservative	122/269 (45·4)	0·38[5] (0·34–0·42)	5·1 (4·4–5·9)	0·31 (0·27–0·36)	166/370 (45·7)	0·45 (0·40–0·50)	5·6 (4·8–6·3)	0·34 (0·27–0·38)	1·10 (0·84–1·43)

[1]Liberal clearance was defined as having a single HPV-negative visit following ≥ 1 HPV-positive visit(s). Conservative clearance was defined as having ≥ 2 consecutive HPV-negative visits following ≥ 1 HPV-positive visit(s).
[2]Time in months. The actuarial mean accounts for censoring, whereas the arithmetic mean excludes participants who did not acquire a new HPV type.
[3]Time to clearance of all baseline HPV infections (i.e., clearance was considered to have occurred once all baseline HPV infections cleared).
[4]Mean was underestimated since the largest observed analysis time was censored.
[5]Time to clearance of the first baseline HPV infection (i.e., clearance was considered to have occurred once the first of any baseline HPV infections cleared).
[6]Proportional hazards Cox regression models account for all baseline HPV types that cleared over follow-up. Participants were considered at risk for clearing any HPV type present at baseline. Each participant could contribute up to 36 observations, each corresponding to an HPV type. The unit of analysis was each individual HPV type.
CI: confidence interval, HPV: human papillomavirus, NR: not reached, N: number.



Conclusions: Consistent with results of its interim analysis, the CATCH trial found that use of a carrageenan-based gel reduced the risk of incident genital HPV infections in women.

O210 / #1469

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: OTHER PUBLIC HEALTH & EPIDEMIOLOGY
04-21-2023 2:15 PM - 3:45 PM

IMPACT OF COVID-19 PANDEMIC ON THE CERVICAL CANCER PREVENTION PROGRAM IN EL SALVADOR

Karla Alfaro[1], Montserrat Soler[2,3], Leticia Lopez[4], Marina Chacon[5], Gabe Conzuelo[2], Eveline Mumenthaler[2], Rachel Masch[6], Juan Felix[7], Miriam Cremer[2]
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Introduction: In El Salvador, cervical cancer prevention is a mixture of cytology and primary HPV screening. The latter consists of a first visit for HPV testing, followed by a second visit to receive results and ablation treatment for HPV positive (HPV+) women. There is a 30-day wait time between visits for test results to be ready. During the pandemic, non-emergency services were interrupted, personnel were shifted to COVID-related tasks, and fear of contagion resulted in an estimated 5,000 screen-positive women who were not able to receive follow-up care. In partnership with the Ministry of Health (MoH), we devised a rapid response approach to provide care to these women.

Methods: From April 2021 date, we used MoH records to identify women who were either HPV+ or had abnormal cytology but no follow-up. A team of 8 colposcopists and 8 nurses were contracted to provide colposcopy and biopsy to all women to determine management. Rates of cervical intraepithelial neoplasia grade 2 or higher (CIN2+) and invasive cervical cancer (ICC) were compared with available historical data from a similar population of participants in the HPV program.

Results: Out of 3,861 women identified, 2,853 (74%) underwent colposcopy and biopsy, 702 (18%) had been treated privately, 210 (5.5%) declined care, and 96 were lost to follow-up (2.5%). Median days between screening test and colposcopy/biopsy were 112 (IQR = 210.75). Biopsy results were 1,976 (69.3%) normal, 648 (22.7%) CIN2+, and 26 (.01%) ICC, while 203 (7.1%) were missing. In contrast, data from 2013-2014 show lower CIN2+ (56/385 [14.5%]) and ICC (1/385 [.003%]) rates.

Conclusions: Even a two-year interruption in cervical cancer prevention programming had noticeable effects in a vulnerable population. Efforts to strengthen such programs and to increase access to screening and treatment must be priorities in cervical cancer prevention in low and middle-income countries.

O211 / #1139

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 3
04-21-2023 2:15 PM - 3:45 PM

HIGH-GRADE CERVICAL LESIONS AT START OF SCREENING AGE IN DANISH WOMEN HPV-VACCINATED AS GIRLS

Mette Nonboe[1], George Napolitano[2], Caroline Kann[3], Berit Andersen[4], Jette Christensen[5], Sanne Christiansen[6], Niels Marcussen[7], Tonje Johansen[8], Rouzbeh Salmani[9], Jeppe Schroll[10], Elsebeth Lynge[1]
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Introduction: In Denmark, three-yearly cytology screening starts at age 23, and follow-up depends on cytology outcome. HPV-vaccination began in 2008. Optimal screening strategy for women HPV-vaccinated as girls is not straightforward, as these women have lower cervical cancer risk than previous generations. Our study (Trial 23) provides knowledge on the first screening outcome in women HPV-vaccinated as girls.

Methods: Trial23 is a method study embedded in the nationwide screening program. It included women born in 1994, living in half of the regions in Denmark, and that attended their first screening. We recruited women screened from 1 February 2017-2 July 2021. Following national guidelines, all screened women had routine cytology and clinical management was based on this test only. For a randomly selected 50% of women, their samples were also HPV-tested. Follow-up diagnosis was most severe histology/cytology outcome between baseline screening date and 795 days later. Data were retrieved from the Danish Pathology Register.

Results: In total, 11,892 women were screened. Vaccination coverage was 92%. Among the 6021 HPV-tested women, 35% were HPV-positive, of which 16 and/or 18 accounted for only 0.8%. In women, that were cytology positive/HPV-positive (Cyt+/HPV+), 610 women had been followed up, and 138 had cervical intraepithelial neoplasia (CIN)2+ diagnosed; in women Cyt+/HPV- numbers were 76 and 5, and in women Cyt-/HPV+ 182 and 8. For double positive women, Cyt+/HPV+, 4.4 women were followed up per detected CIN2+; for Cyt+/HPV- it was 15.2; and for Cyt-/HPV+ it was 22.8. For CIN3+, numbers were 8.6; 76.0; and 45.5, respectively.

Conclusions: In Danish women, HPV-vaccinated as girls and Cyt+/HPV+ at first screen around age 23, a follow-up of four women were needed to detect one CIN2+ case and nine women for one CIN3+ case. Numbers were considerably higher for women with Cyt+/HPV- and Cyt-/HPV+, suggesting that immediate follow-up should be focussed on double positive women.

O212 / #733

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 3
04-21-2023 2:15 PM - 3:45 PM

EFFECT OF SOCIAL MARKETING ON PAP SMEAR UPTAKE AMONG WOMEN RESIDING IN AN URBAN SLUM IN LAGOS, NIGERIA.

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Introduction: Globally, Nigeria is rated tenth in cervical cancer mortality. Uptake of cervical cancer screening is very low across various settings in Nigeria, especially among women residing in low resource settings. Social marketing principles can be used to design and implement interventions to promote behavior change including the practice of cervical cancer screening. This study assessed the effect of a social marketing intervention on uptake of Pap smear among women residing in an urban slum in Lagos, Nigeria.

Methods: This was a quasi-experimental study. The intervention arm consisted of 140 women from Ago-Egun Bariga community and the control arm consisted of 175 women from Oto-Ilogbo extension community. Social marketing intervention was instituted in the intervention group, applying 7 benchmarks of social marketing (Customer orientation, Behavioural focus, Exchange, Developing insight, Competition analysis, Theory, and Methods Mix) and guided by a qualitative enquiry. Data analysis was done using IBM SPSS Statistics version 20. Between groups comparisons and within groups comparisons were done using bivariate analysis with Chi-square, Students t-test and Paired t-test as appropriate.

Results: In the intervention group, the mean knowledge score of cervical cancer increased from 0.0 ± 0.3 at baseline to 15.1 ± 3.7 post-intervention ($p < 0.001$) and the mean attitude score of cervical cancer increased from 27.1±0.8 at baseline to 36.5±4.8 post-intervention ($p < 0.001$). There was a significant increase in uptake of Pap smear from 0.0% at baseline to 84.3%, post-intervention in the intervention group ($p < 0.001$). There was no statistically significant change in knowledge, attitude, or uptake of Pap smear in the control group.

Conclusions: Social marketing intervention can be successful in improving the uptake of Pap smear, even in settings where these are abysmally low. It is recommended that social marketing intervention be employed as a strategy for improving cervical cancer screening among women residing in slums.

O213 / #367

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 3
04-21-2023 2:15 PM - 3:45 PM

SCALING-UP HPV TESTING FOR CERVICAL CANCER SCREENING IN WLHIV IN ZAMBIA

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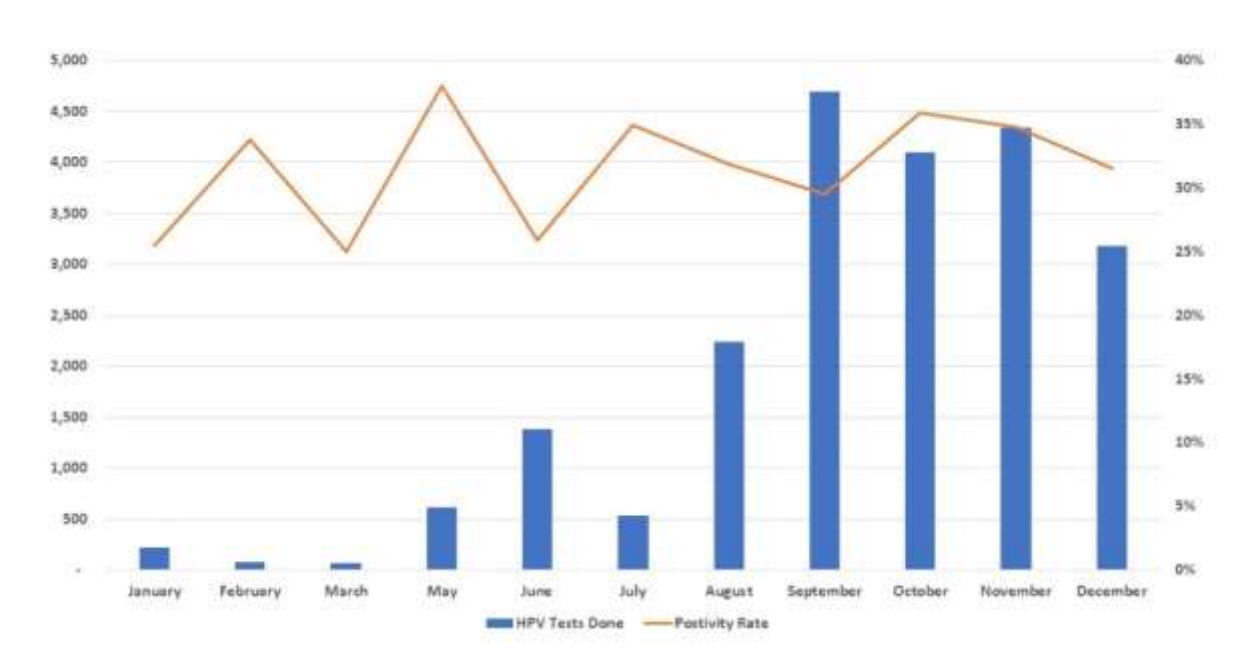
Introduction: Zambia has an estimated cervical cancer (CaCx) incidence rate of 66.4/100,0000. CaCx remains the most common cancer accounting for nearly 25% of all cancers diagnosed and causing more cancer deaths in Zambia. The Ministry of Health (MOH) established the national CaCx screening program in 2006 using Visual Inspection with Acetic Acid (VIA) enhanced with digital cervicography. Recently, WHO made a call to eliminate CaCx through the 90-70-90 approach. The 70 target demands that 70% of eligible women are screened with a high-precision test at 35 and 45 years of age. We present Zambia's progress in scaling-up HPV testing for CaCx screening in WLHIV.

Methods: Through PEPFAR funding, the Ministry of Health procured HPV test kits which were distributed across the country in 2021. Through the support of Hologic, we held a country-wide orientation in September 2021 to improve the uptake of HPV testing for CaCx screening in WLHIV.

Results: A team of 24 facilitators, distributed across 8 of the 10 Zambian provinces trained a total of 133 health care workers. This included 38 staff from the laboratory, 82 nurse providers, and 13 medical doctors. The orientation included the basics of CaCx and available screening methods and why the country was moving towards HPV testing. Other key topics included sample collection, courier systems, and testing on the Hologic Panther and other platforms. This orientation showed an immediate increase in the utilization of HPV testing from a monthly average of 641 to 4,081 before and after the training, respectively. The overall HPV positivity rate was 32% (6,966/21,451).



Conclusions: These orientations are expected to improve the utilization of HPV testing for CaCx screening. Support from PEPFAR and HPV testing kits manufacturers such as Hologic is key in the integration of HPV testing in Low- and Middle-Income Countries.

O214 / #905

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 3
04-21-2023 2:15 PM - 3:45 PM

DETERMINANTS OF INTENTION-TO-ATTEND AND CONFIRMED ATTENDANCE FOR CERVICAL SCREENING DURING COVID-19 PANDEMIC

Louiza Velentzis[1], Sam Egger[1], Caitlin Mclachlan[1], Chloe Jennett[1], Amy Pagotto[1], Deborah Bateson[1], Jo Waller[2], Julia Brotherton[3], Megan Smith[1], Rachel Skinner[4], Marion Saville[5], Karen Canfell[1]
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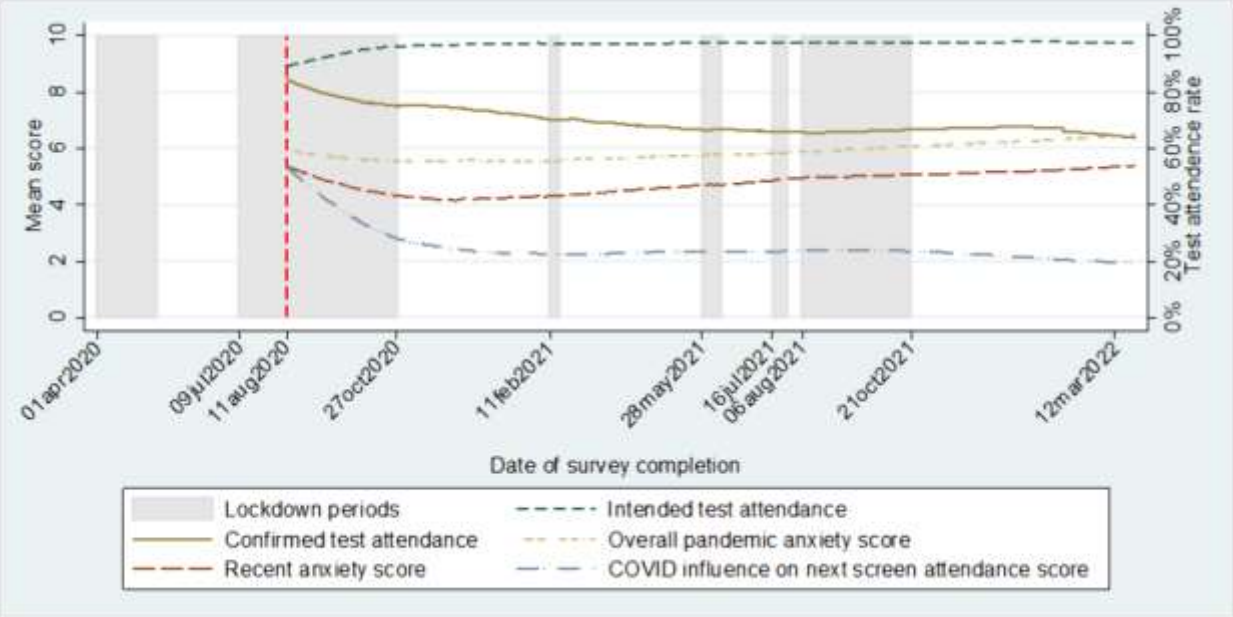
Introduction: The COVID-19 pandemic impacted participation in Australia's primary HPV-based cervical screening program. We aimed to ascertain factors associated with intention-to-attend and attendance during the pandemic.

Methods: We used data from Compass-PLUS, an ongoing sub-study of the Compass large-scale randomised controlled trial of HPV vs cytology screening predominantly conducted in the state of Victoria, Australia. Compass-PLUS focuses on psychosocial aspects and women are invited to participate after receiving an invitation to attend their Compass 5-year exit test. We analysed data from an on-line survey at Compass-PLUS recruitment (Aug'20-Mar'22) and attendance data (Aug'20-Aug'22) for women randomised to HPV screening. We investigated associations between intention-to-attend and attendance, and i) socio-demographics, ii) mean anxiety-related scores and iii) agreement with statements on other factors (e.g. screening importance, social distancing, workload).

Results: Among 3,244 participants aged 26-75 years included, there was low agreement between intention-to-attend and confirmed attendance (Kappa=0.06). Women with a cancer family history and women residing in the least populous Australian states/territories were more likely to report intention-to-screen ($p<0.05$), but not to attend. Women more likely to attend were; aged 40+ compared to aged 26-39 ($p<0.001$), and part-time employed/retired compared to full-time employed [Relative risk (RR):1.07, 95%CI1.02-1.13; RR:1.10, 95%CI 1.02-1.18; respectively]. Attendance was found to be unrelated to mean pandemic anxiety score, COVID-19 influence on screening intention or recent anxiety scores. However, attendance was significantly associated with increased agreement with statements indicating difficulty attending due to increased workload ($ptrend<0.003$) and de-prioritisation of cervical screening ($ptrend<0.001$). Decreased attendance rates during the study were also observed in Melbourne residents who experienced extended lockdowns (Fig.1).

Conclusions: Cervical screening attendance was associated with older age and part-time employment/retirement but not anxiety scores. Increased workloads and reduced priority of cervical screening during the pandemic, and annual attendance cycles, may partly explain decreasing screening attendance rates during the

study.


Mean score
0
2
4
6
8
10
Test attendance rate
0%
20%
40%
60%
80%
100%
01apr2020
09jul2020
11aug2020
27oct2020
11feb2021
28may2021
16jul2021
06aug2021
21oct2021
12mar2022
Date of survey completion
Lockdown periods
Confirmed test attendance
Recent anxiety score
Intended test attendance
Overall pandemic anxiety score
COVID influence on next screen attendance score

O215 / #339

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 3
04-21-2023 2:15 PM - 3:45 PM

HEAD-TO-HEAD COMPARISON OF 7 HIGH-SENSITIVE HUMAN PAPILLOMAVIRUS NUCLEIC ACID DETECTION TECHNOLOGIES WITH SPF10 LIPA-25 SYSTEM

Jian Yin[1], Yu-Fei Li[2]
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Introduction: To evaluate the effects of type-specific preventive or therapeutic vaccination in population, sensitive and specific HPV genotyping methods are critical for the selection and monitoring of study subjects. The SPF10 LiPA-25 system of human papillomavirus (HPV) detection with high analytical performance was widely used in HPV vaccine clinic trials. In view of more valent HPV vaccines to be developed and evaluated, other comparable methods with simpler operation could be needed.

Methods: The performance of the LiPA-25 against that of other 7 assays, including 4 systems based on reverse hybridization (Bohui-24, Yaneng-23, Tellgen-27 and Hybribio-16) and 3 real-time PCR assays (Hybribio-23, Bioperfectus-21 and Sansure-26), was evaluated in selected 1726 cervical swab and 56 biopsy samples. A total of 15 HPV genotypes (HPV6, 11, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 66) were considered for comparison for each HPV type.

Results: Among the swab samples, compared with LiPA-25, compatible genotypes in 94.1% of samples for Hybribio-23, 92.8% for Yaneng-23, 92.6% for Bioperfectus-21, 92.4% for Hybribio-16, 91.3% for Sansure-26, 89.7% for Bohui-24 and 88.0% for Tellgen-27. The highest overall agreement of 15 HPV genotypes-combined was also Hybribio-23 ($k = 0.879$, McNemar's test: $P = 0.136$), followed closely by Hybribio-16 ($k = 0.877$, $P < 0.001$), Yaneng-23 ($k = 0.871$, $P < 0.001$), Bioperfectus-21 ($k = 0.848$, $P < 0.001$), Bohui-24 ($k = 0.847$, $P < 0.001$), Tellgen-27 ($k=0.831$, $P < 0.001$), and Sansure-26 ($k = 0.826$, $P < 0.001$). Additionally, these systems were also highly consistent with LiPA-25 on biopsy specimens (all $k > 0.897$).

Conclusions: The levels of agreement for detection of 15 HPV types between other 7 assays and LiPA-25 were all good, and the hybribio-23 was most comparable with LiPA-25. The testing operation of HPV genotyping should be also considered for vaccine and epidemiological studies.

O216 / #1109

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 3
04-21-2023 2:15 PM - 3:45 PM

CERVICAL CANCER SCREENING BY VISUAL INSPECTION AND HPV TESTING IN ESWATINI

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Introduction: Eswatini has the highest incidence of cervical cancer, where approximately 6.5% of women develop cervical cancer before 75 years of age, and 35% of women aged 15–49 years are affected by the human immuno-deficiency virus. In 2009, visual inspection with acetic acid followed by cryotherapy, was introduced into the Eswatini cervical cancer prevention programme. Therefore, the study aim was to establish cervical cancer screening using visual inspection and HPV testing in Eswatini.

Methods: We present screening results of 654 women attending VIA-and-cryotherapy who participated in a sexually transmitted infections prevalence study, at which samples for HPV DNA testing and liquid-based cytology (LBC) were also collected. VIA positives (VIA+) ineligible for cryotherapy, suspected cancers and women with high-grade squamous intraepithelial or worse lesions (HSIL+) on LBC were referred for diagnosis and treatment. Women with negative VIA who were HPV positive (HPV+) and those VIA+ treated with cryotherapy were recalled for another VIA one-year later.

Results: The positivity rates of VIA, HPV, atypical squamous cells of undetermined significance or worse cytology abnormalities (LBC ASCUS+) and low-grade squamous intraepithelial or worse lesions (LBC LSIL+) were 9.7%, 42.6%, 13.2% and 5.3%, respectively. HPV testing detected 29 of 31 LSIL+ (93.6%, 95%CI: 78.6–99.2) while VIA only detected 11 (35.6%, 95%CI: 19.2–54.6). The HIV prevalence was 43% (95%CI: 39.2–46.9). HIV positives were at increased risk of being VIA+ (age-adjusted odds ratio: 2.5, 95%CI: 1.5–4.3), HPV+ (3.7, 2.6–5.3) and having LSIL+ (16.3, 4.9–54.8). The ineligibility rates for cryotherapy were 38% (24 of 63 VIA+), and 46% among HIV positives (18 of 39 VIA+).

Conclusions: HPV testing was substantially more sensitive than VIA, thus, HPV followed by ablative treatment may be more effective. However, the high ineligibility for cryotherapy highlights the need for improving the assessment of eligibility, particularly in populations with high HIV prevalence.

O217 / #859

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 3
04-21-2023 2:15 PM - 3:45 PM

SHOULD THE AGE RANGE OF THE DUTCH HPV SCREENING PROGRAMME BE BROADENED? A MODELLING STUDY

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Introduction: In the Netherlands, women are invited for HPV screening between the ages of 30 and 60 (screening at age 65 is conditional on a previous positive screen). However, an increase in cervical cancer incidence in women aged 25-40 years has been observed recently. Meanwhile HPV vaccinated cohorts are reaching the screening age of 30 in 2023. Moreover, increasing healthy life expectancy is an important consideration for screening in older age groups. Due to these developments the starting and ending ages of the HPV screening programmes should be reconsidered.

Methods: The microsimulation model MISCAN-Cervix was recalibrated using updated (increased) cervical cancer incidence data in birth cohorts 1978-1992. We used this model to calculate the cost-effectiveness of starting screening at 25 for partly-vaccinated cohorts (born in 2002-2006). Additionally, we considered screening all (unvaccinated) women in birth cohorts 1962-1992 until 65 years old. The switch from the current program to the alternative screening programs was made in 2027. For the triage in all screening strategies genotyping for HPV16/18 was used. Main outcome measures were life years (LYs) gained, QALYs gained, costs and referrals per 100,000 women simulated, compared to the current screening strategy from 2027 to end of life.

Results: The current programme prevents 337 cancers, results in 18,162 referrals and leads to 3,625 lifeyears gained. Screening at age 25 results in few extra cases prevented (+0.1%-0.7%) and LYs gained (+0.1%-0.4%), but more referrals (2.4%-7.1%), higher costs (+3.3%-8.0%) and lost QALYs (-3.3%-8.0%) (Figure 1, 2, 3). Screening at age 65 leads to 8.5% extra cancers prevented, +6.0% referrals, +5.0% LYs gained, -5.3% QALYs gained and +15.8%
costs.

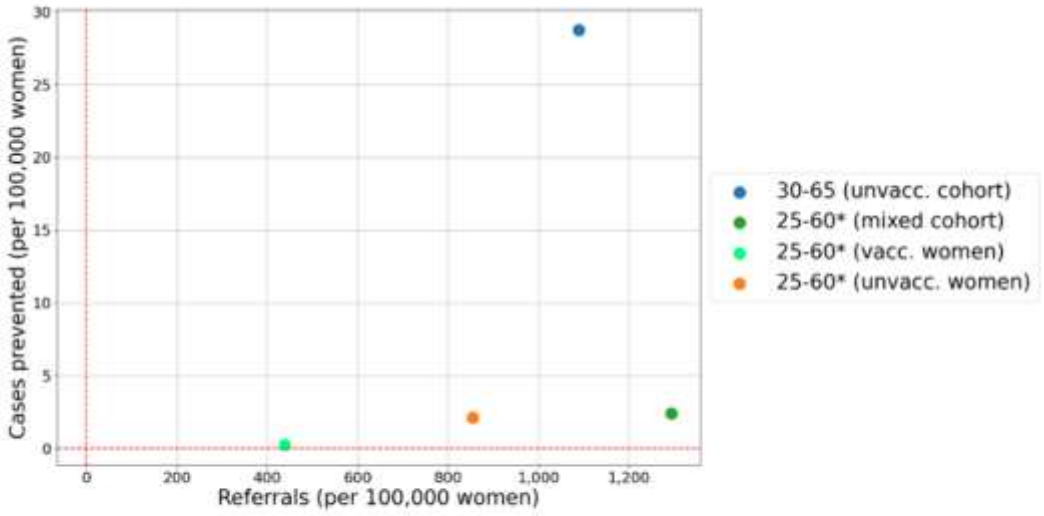

Figure 1: Prevented cancer cases and referrals as compared with the current programme (red lines). * women are screened at age 65 if they had a positive test at age 60.

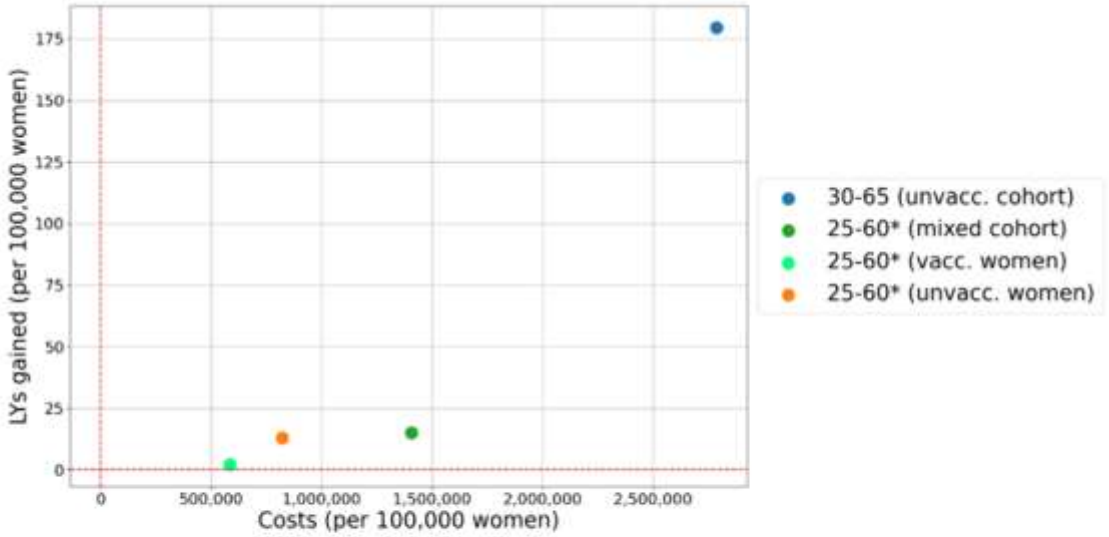

Figure 2: Life years (LY) gained and costs as compared with the current programme (red lines). * women are screened at age 65 if they had a positive test at age 60.

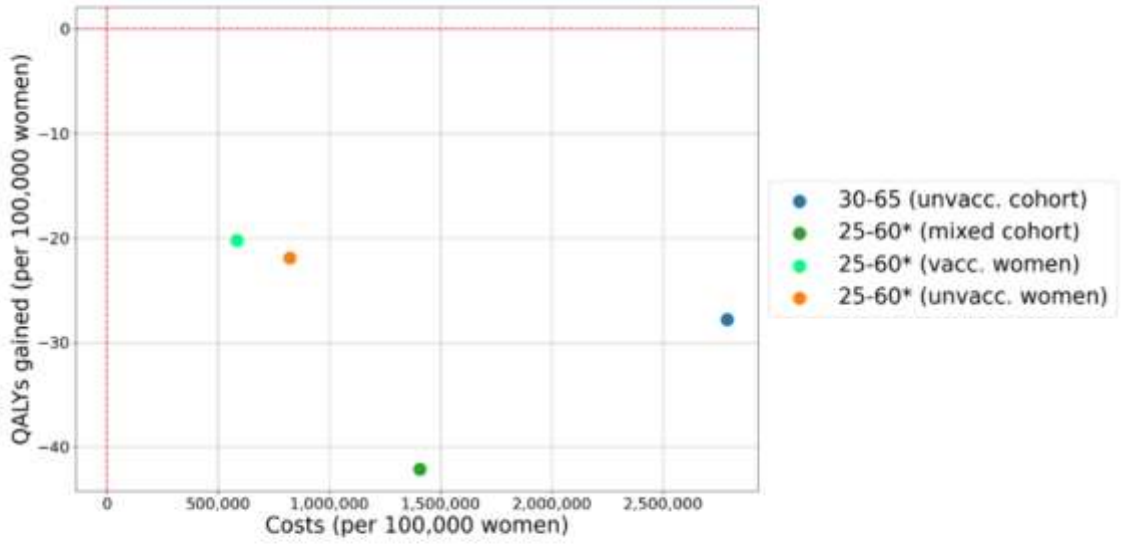

Figure 3: Quality-adjusted life years gained (QALY) and costs as compared with the current programme (red lines). * women are screened at age 65 if they had a positive test at age 60.

Conclusions: This modelling analysis has shown that with the current knowledge, it might be preferable to screen unvaccinated women at 65 years old, while it is not recommended to screen women in partly-vaccinated cohorts at age 25.

O218 / #1324

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 3
04-21-2023 2:15 PM - 3:45 PM

HPV E6/E7 ONCOPROTEINS TESTING FOR CERVICAL CANCER SCREENING IN SETTINGS WITH HIGH BURDEN OF CERVICAL CANCER

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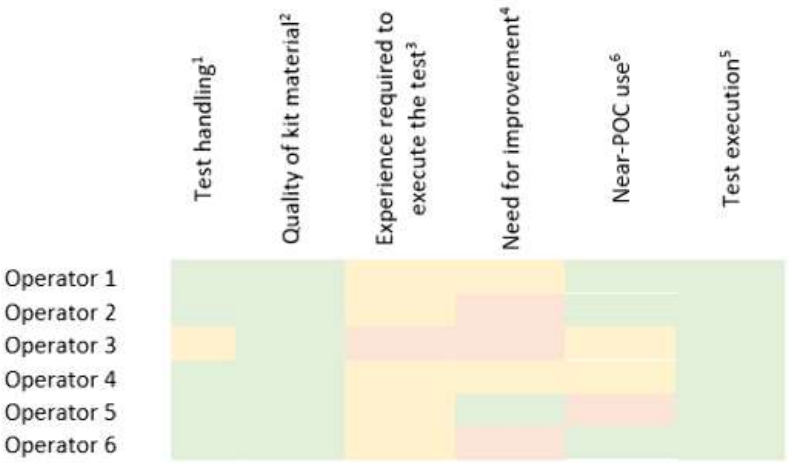
Introduction: Overexpression of HPV oncoproteins E6 and E7 is necessary for HPV driven cervical carcinogenesis. Hence, these oncoproteins are promising disease-specific biomarkers. Here, we report the first assessment of the 8-HPV type OncoE6/E7 cervical prototype test (by Arbor Vita Corp.) in HPV-positive women and women living with HIV (WLWH).

Methods: 8-HPV type OncoE6/E7 testing was done locally in 2 centres participating in a screen-triage-and-treat randomized-controlled trial. One centre in Senegal included HPV-positive/HIV-negative women and another centre in South Africa included HPV-positive WLWH, using GeneXpert for HPV testing. A feedback questionnaire was given to the laboratory technicians conducting the oncoprotein test. Results from oncoprotein testing were compared to that of GeneXpert; when multiple HPV or oncoprotein infection types were detected, a hierarchical model was applied. The oncoprotein test accuracy was also evaluated as triage in HPV-positive WLWH.

Results: Nine laboratory technicians were trained in person or online to perform the test (figure 1). Despite operators' perceived concerns about the need for experienced laboratory technicians and time-consuming procedures, they reported the test as easy to execute (figure 2). In total, 241 HPV-positive samples were tested (43 HIV negative/198 WLWH). Although the negativity of oncoprotein reduced with severity of lesions, the test missed 17/30 CIN3+ cases. The test was positive for targeted types that were negative on HPV DNA in 3, 2, and 1 of negative/CIN1, CIN2 and CIN3+ women, respectively (table 1). Among HPV-positive WLWH, sensitivity of the oncoprotein test to detect CIN3+ was 44% (95%CI=25-65) and specificity was 89% (95%CI=83-93).

Figure 1. OncoE6/E7 test training in the local study centres

Figure 2: Feedback from 6 trained laboratory technicians on the 8-HPV type OncoE6E7 cervical test



[1]Test units and tubes easy to manipulate in regards with ergonomics and format; [2]Composition, shape and size of the platforms and tubes to conduct the test; [3]Global laboratory technician experience before conducting the oncoprotein test; [4]Improvement regarding the time to conduct the test and daily throughput; [5]Globally, the ease of executing the test; [6]Whether they think oncoprotein test could be used as near-point-of-care in their laboratory

Legend figure 2:

Test handling[1]	Quality of kit material[2]	Experience required to execute the test[3]	Need for improvement[4]	Ease of execution[5]	Near-POC use[6]
Good	Good	No experience needed	Not needed	Very good/good	Yes
Medium	Medium	>2 years	Some improvement needed	Medium	Maybe
Poor	Poor	>5 years	Substantial improvement needed	Poor	No

Table 1: Comparison between GeneXpert test and the 8-HPV type OncoE6E7 cervical test in both settings (HPV+ and HIV-/+, N=241)

		GX 16+	GX 18/45+	GX other+
Neg/CIN1	OncoE6E7 16+			
(N=151)	OncoE6E7 18/45+		2	3*
	OncoE67 other+			14
	OncoE67 neg	28	30	74
CIN2	OncoE6E7 16+	1		
(N=60)	OncoE6E7 18/45+		2	2*
	OncoE67 other+			5
	OncoE67 neg	8	7	35
CIN3+	OncoE6E7 16+	4		
(N=30)	OncoE6E7 18/45+		3	1*
	OncoE67 other+			5
	OncoE67 neg	6**	3	8

Other OncoE6E7: 31,33,35,52,58; Other GeneXpert: 31,33,35,52,58,51,59,39,56,66,68;
**OncoE6E7 positives for types that were negative for HPV DNA*
***Including one cervical cancer case*

Conclusions: The OncoE6/E7 test proved to be easy to execute in resource limited settings, but the discrepancies with HPV DNA based test outcomes call for further refinements and investigations. Further evidence is needed to evaluate the role of the oncoproteins as triage, especially in screen-triage-and-treat approaches.

O219 / #1879

Public Health Oral Abstracts Session
PUBLIC HEALTH ORAL: SCREENING FOR HPV-RELATED DISEASE 3
04-21-2023 2:15 PM - 3:45 PM

A RANDOMIZED TRIAL OF SINGLE-DOSE HPV VACCINATION EFFICACY AMONG YOUNG WOMEN: FINAL EFFICACY RESULTS

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[1]Kenya Medical Research Institute, Center For Clinical Research, Nairobi, Kenya, [2]University of Washington, Department Of Global Health, Seattle, United States of America, [3]Kenya Medical Research Institute (KEMRI), Center For Clinical Research, Nairobi, Kenya, [4]Fred Hutchinson Cancer Research Center, Vaccine And Infectious Disease Division, Seattle, United States of America, [5]University of Washington, Department Of Biostatistics, Seattle, United States of America, [6]Fred Hutchinson Cancer Research Center, Public Health Sciences, Seattle, United States of America, [7]University of Washington, Department Of Epidemiology, Seattle, United States of America, [8]Fred Hutchinson Cancer Center, Human Biology, Seattle, United States of America, [9]University of Cincinnati, Department Of Obstetrics And Gynecology, Cincinnati, United States of America, [10]Massachusetts General Hospital, Division Of Infectious Diseases, Boston, United States of America, [11]University of Washington, Department Of Laboratory Medicine And Pathology, Seattle, United States of America, [12]Harvard Medical School, Department Of Medicine, Boston, United States of America, [13]Harvard School of Public Health, Department Of Epidemiology, Boston, United States of America, [14]., ., ., Kenya

Introduction: Single-dose HPV 16/18 vaccination efficacy (VE) of 97.5% at month 18 is comparable to multi-dose regimens at months 24-36. Data on single-dose durability over several years are needed.

Methods: We conducted a randomized, multicenter, double-blind, controlled, cross-over trial to estimate the efficacy of single-dose HPV vaccination at three study sites in Kenya. Healthy, 15- to 20-year-old women were randomly assigned (1:1:1) to single-dose bivalent (HPV 16/18), nonavalent (HPV 16/18/31/33/45/52/58/6/11), or control (meningococcal) vaccination. The modified intent-to-treat (mITT) HPV 16/18 and HPV 16/18/31/33/45/52/58 cohorts included HPV naïve participants (i.e., participants who tested negative for vaccine type-specific HPV DNA at enrollment and month three and HPV antibody negative at enrollment). During follow-up, clinicians collected cervical swabs every six months, which were tested for HPV DNA for endpoints. The outcome was incident persistent vaccine type-specific HPV infection. We analyzed VE up to the cross-over study visit at month 36.

Results: Between December 2018 and November 2019, we recruited and randomly assigned 2,275 participants to receive bivalent (n=760), nonavalent (n=758), or control (n=757) vaccine. From enrollment to January 2023, 2,061/2,275 (90.7%) randomized participants provided at least five swabs for HPV DNA testing before cross-over vaccination. The median follow-up up to cross-over was 35 months. Seventy-five incident persistent infections were detected in the HPV 16/18 mITT cohort: two in the bivalent group, one in the nonavalent group, and 72 in the control group; nonavalent VE was 98.8% (95%CI 91.3-99.8%, p=<0.0001); bivalent VE was 97.5% (95%CI 90.0-99.4%, p=<0.0001). Eighty-nine persistent infections were detected in the HPV 16/18/31/33/45/52/58 mITT cohort: five in the nonavalent group and 84 in the control group; nonavalent VE was 95.5% (95%CI 89.0-98.2%, p<0.0001). The rate of SAEs was 7.8-9.5% by group; none were vaccine-related.

Conclusions: In a randomized trial among young women with HPV exposure, single-dose HPV vaccination was highly efficacious (>95%) over three years.

Poster Discussion Shift 1

Shift 01-038 / #839

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 01
04-18-2023 10:00 AM - 10:30 AM

THE ASSOCIATION BETWEEN ADVERSE CHILDHOOD EXPERIENCES AND HPV VACCINATION COVERAGE IN US YOUNG ADULTS: A CROSS-SECTIONAL STUDY

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Introduction: Adverse childhood experiences (ACEs) contribute to adverse health outcomes in adulthood. Access to preventive healthcare services, including human papillomavirus (HPV) vaccinations, may mitigate the impact of ACEs on adverse health outcomes. Our objective was to assess associations between ACEs and HPV vaccination coverage among young adults in the US.

Methods: We included 3450 18–29-year-old respondents to the 2019-2020 US Behavioral Risk Factor Surveillance System (BRFSS) ACE and HPV vaccination modules. ACEs included emotional, physical and sexual abuse; household intimate partner violence, substance abuse, mental illness; and parental separation/divorce and incarcerated household member. We used log-binomial regression models to calculate prevalence ratios (PRs) with 95% confidence intervals for the associations between ACEs and self-reported HPV vaccination and completion. Secondary outcomes included influenza vaccination uptake, time since routine checkup, history of human immunodeficiency virus (HIV) testing, and HIV-related risk behavior.

Results: Several ACEs were positively associated with HPV vaccine initiation, including emotional abuse (PR:1.29,95%CI:1.17-1.43), intimate partner violence (PR:1.14,95%CI:1.01-1.30), substance abuse (PR:1.20,95%CI:1.08-1.33), and mental illness (PR:1.35,95%CI:1.22-1.50). Similar associations were observed for completion. Conversely, most ACEs were negatively associated with influenza vaccination (PRs from 0.72-1.00), and with recent checkup (PRs from 0.92-1.00). ACEs were positively associated with having had an HIV test (PRs from 1.19-1.56) and HIV-related risk behavior (PRs from 1.57-2.07).

Conclusions: The unexpected positive associations between ACEs and HPV vaccination coverage could be due to opportunities to receive HPV vaccination in late adolescence or early adulthood while accessing sexually transmitted infection (STI)/HIV prevention or treatment services. Future studies should evaluate associations between ACEs and timely HPV vaccination in early adolescence.

Shift 01-039 / #770

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 01
04-18-2023 10:00 AM - 10:30 AM

GIRLS-ONLY HPV VACCINATION – IMPACT ON THE HPV TYPE DISTRIBUTION IN YOUNG MEN

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Introduction: In Denmark, a girls-only HPV vaccination program was initiated in 2008-9. Subsequent catch-up programs for older girls/women mean that the HPV vaccination coverage in women born from 1985 until 2008 is around 70% across all birth cohorts. Since July 2019, HPV vaccination has been offered to boys aged 12 years. The objective was to assess the HPV prevalence and the type distribution in younger men before the direct effect of HPV vaccination of younger boys becomes apparent.

Methods: We invited men who attended information days regarding military service at two barracks. At random days during December 2019-December 2020, 280 men were included. They answered a questionnaire regarding risk factors for HPV infection and we collected a penile swap for subsequent HPV testing, which was performed using Inno-Lipa Extra II (Fujirebio).

Results: The median age was 18 years with 94% being 18-20 years old. Forty men (14.3%) had not had their first sexual intercourse. The median number of sexual partners in the last 6 months was one partner with 27.1% having had > 2. Altogether 129 men (46.3%) were HPV positive. Overall, 24.3% had a high-risk type, 23.9% had a low-risk type and 7.1% had an unidentifiable HPV type. No infections with HPV types 6, 11, 16, 18, 31, and 45 were detected. The most frequent type was HPV51 which was detected in 31 men (11.1%) followed by type 59 (8.2%). Analyses related to vaccination status and sexual variables will be presented as well as a comparison with a cohort of men examined before HPV vaccination in girls/women was implemented in Denmark.

Conclusions: The girls-only vaccination program in Denmark has to a large degree protected young men against the HPV types included in the licensed vaccines. The HPV prevalence is still high but consists largely of less carcinogenic HPV types.

Shift 01-040 / #1045

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 01
04-18-2023 10:00 AM - 10:30 AM

EVALUATING THE POTENTIAL PROGRAM COST SAVINGS WITH A SINGLE-DOSE HPV VACCINE SCHEDULE

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Introduction: Nearly 50% of low- and middle-income countries have not yet introduced HPV vaccination nationwide, with cost of vaccine supply and delivery cited as one concern. Implementing single-dose schedules may reduce these costs making it more affordable and sustainable compared to the current two-dose schedule. We will use data from a six-country study on HPV vaccine cost of delivery and operational context to estimate the potential programmatic impact and cost savings of switching to a single-dose schedule.

Methods: Facility staff responsible for providing HPV vaccination services in six countries (Ethiopia, Guyana, Rwanda, Senegal, Sri Lanka, and Uganda) were interviewed using structured questionnaires to understand the frequency of activities and resources used with the two-dose schedule. Stratified random sampling was used to select the health facilities included in the study (n=30 to 70 health facilities per country). Data were also collected from national and subnational administrative offices. We plan to use these data to identify the frequency of activities done with the two-dose schedule and activities that could be eliminated with a single-dose schedule and then adjust the cost estimates to estimate the potential program cost reductions with a single-dose schedule.

Results:

Table 1. Expected change in costs of HPV vaccine delivery when switching from two-dose to single-dose schedule by program activity

HPV vaccine program activity evaluated in the study	Expected change in recurrent program costs with single-dose schedule*	Explanation of the potential change in recurrent costs
Vaccine procurement	↓	Vaccine procurement costs likely reduced by half.
Program planning	≈	Minimal savings expected given that program planning is currently done for both doses concurrently.
Routine training	≈	Minimal savings expected as training is not done routinely. There may be onetime training costs for the switch.
Routine social mobilization	≈	Minimal savings expected as social mobilization is done for both doses. There may be onetime social mobilization costs for the switch.
Crisis management	↓	Activities conducted by dose, as needed; savings expected with single-dose schedule.
Vaccine distribution and storage	≈	Minimal savings expected given shared vaccine collection or delivery trips and shared storage resources with routine immunization vaccines.
Waste management	≈	Minimal cost savings expected given shared resources with routine immunization.
Human resources	↓	Expected reductions in human resource costs for service delivery and program activities with single-dose schedule.
Service delivery	↓	Costs associated with staff time and travel likely reduced by half as delivery is done for each dose.
Supportive supervision	≈ or ↓	Minimal cost savings expected in countries where HPV vaccine supervision is integrated with routine immunization; cost savings expected in countries with supervision conducted for each dose.
Record keeping	↓	Costs associated with staff time and record keeping materials likely reduced by half as record keeping is done for each dose.

*Key to symbols: ↓ reduction; ≈ no change or minimal change.

Results will be available in January 2023. Initial findings show that the largest driver of HPV vaccine program recurrent costs is vaccine procurement, so switching to a single-dose schedule could result in cost savings, if the age of eligibility is not expanded. In some countries, HPV vaccine activities are integrated with other immunization program activities or done for both doses so there may not be significant financial cost savings from the switch. The hypothesized impact is shown in Table 1.

Conclusions: Better understanding the magnitude of the expected cost savings will provide additional evidence to inform budgeting and planning as countries consider a future HPV vaccine dosing schedule change.

Shift 01-041 / #359

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 01
04-18-2023 10:00 AM - 10:30 AM

COST-EFFECTIVENESS ANALYSIS OF HPV EXTENDED GENOTYPING COMPARED TO HPV PARTIAL GENOTYPING FOR CERVICAL CANCER SCREENING IN SINGAPORE

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Introduction: Human papillomavirus (HPV) partial genotyping (PGT) identifies HPV16 and HPV18 individually, and 12 other high-risk HPV genotypes (hrHPV) collectively. In contrast, HPV extended genotyping (XGT) identifies six hrHPV individually (HPV16,18,31,45,51,52), with the remaining eight reported in three groups (HPV33/58;56/59/66;35/39/68). Hence, XGT allows for better risk stratification for patient management, and monitoring of persistent same genotype infections (PSGI) which convey higher risk for cervical cancer. This study compared the cost, quality-adjusted life years (QALY), and resource use of XGT compared to PGT as the primary cervical cancer screening method in Singapore.

Methods: A Discretely Integrated Condition Event simulation of screening 948,594 women aged 30–69 was developed. In XGT, colposcopy women with HPV35/39/51/56/59/66/68 and reflex cytology of atypical squamous cells of undetermined significance (ASCUS) were recalled for repeat screening in one year, instead of immediate colposcopy in PGT. At repeat screening, colposcopy is provided for women with PSGI in XGT, instead of all women with persistent HPV in PGT. Published data from Singapore were prioritized for inputs and supplemented with international literature. All costs and QALYs were discounted at 3% annually. Deterministic and probabilistic sensitivity analyses were conducted from the health system perspective over five years. XGT was cost-effective if the incremental cost-effectiveness ratio (ICER) versus PGT was below SG$97,798 (GDP-per-capita, 2021).

Results: XGT was cost-effective compared to PGT (ICER:SG$10,989), with 7,085 (19.1%) less colposcopies, 6,404 (7.9%) less liquid-based cytology, 10,345 (1.9%) less clinic consultations and 1,960 (0.4%) more HPV tests. The ICER was most sensitive to PGT cost, relative cost of XGT, and risk of cervical intraepithelial neoplasia grade 2 or worse for HPV35/39/51/56/59/66/68 with ASCUS. XGT remained cost-effective in one-way sensitivity analysis, and in 97% of probabilistic uncertainty simulations.

Conclusions: XGT can provide a cost-effective, risk-based approach as the primary cervical cancer screening method with lower resource utilization compared to PGT.

Shift 01-123 / #1435

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

ANAL TEST CHARACTERISTICS FOR DETECTION OF ANAL HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS AMONG HIV-NEGATIVE WOMEN: FINDINGS FROM THE COSTA RICA HPV VACCINE TRIAL STUDY

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Introduction: Most cases of anal cancer in the general population are diagnosed in HIV-negative women. High-resolution anoscopy (HRA) guided biopsy with treatment of biopsy-confirmed high-grade squamous intraepithelial lesions (hHSIL) has been shown to reduce the risk of anal cancer but access to HRA is limited. Anal cytology and HPV testing may help to prioritize individuals who would benefit from HRA but little is known about their performance for detection of anal hHSIL in HIV-negative women. We describe the performance of anal cytology and HPV testing for diagnosis of hHSIL among high-risk HIV-negative women.

Methods: Women in the Costa Rica HPV Vaccine Trial study were referred for HRA if they had abnormal anal cytology at year 7 or any annual visit, or high-risk anal HPV 16/18/45 detection (HR-HPV+;APTIMA®) at their final study visit during the anal long-term follow-up study which included 1,023 women (ages 23–35 years). We calculated the sensitivity (SE), specificity (SP), positive predictive value (PPV), and negative predictive value (NPV) of anal cytology and HPV testing for diagnosis of hHSIL at the time of first HRA.

Results: Of 56 women who were referred to and attended at least one HRA visit, 49% (95%CI=36–62%) were diagnosed with biopsy-proven hHSIL. For anal HR-HPV+ the SE was 63% (95%CI=44–78%) and PPV was 63% (95%CI=44–78%;Table 1). The sensitivity and PPV for LSIL+ on cytology were 59% (95%CI=41–75%) and PPV of 84% (95%CI=62–94%), respectively. Co-testing as HR-HPV+ with abnormal cytology (LSIL+) had the highest PPV with 92% (95%CI=65–99%) but a lower sensitivity of 41% (95%CI=25–59%).

Conclusions: HIV-negative women diagnosed with abnormal anal cytology or anal HR-HPV+ had high prevalence of hHSIL. Anal HR-HPV testing and anal cytology may be useful for prioritizing referral to HRA.

Shift 01-124 / #821

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

ACCEPTABILITY, FEASIBILITY AND APPROPRIATENESS OF INTEGRATING HPV SELF-SAMPLING FOR CERVICAL CANCER SCREENING INTO VOLUNTARY FAMILY PLANNING SERVICES IN MALAWI

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Introduction: Despite cervical cancer being preventable through screening and preventive therapy, it remains a burden for Malawi and other low income countries. The World Health Organization now recommends the use of human papillomavirus (HPV) testing for cervical cancer screening (CCS). We assessed the acceptability, feasibility and appropriateness of 2 models for integrating HPV self-sampling for CCS into family planning (FP) services in Malawi.

Methods: We randomised 16 health facilities to two models: Model 1 involved only clinic-based HPV self-sampling, whereas Model 2 included both clinic-based and community-based HPV self-sampling. We conducted a mixed-methods study through in-depth interviews (IDI), focus group discussions (FGD) and a Likert scale questionnaire. We purposely sampled 193 healthcare providers (nurses and clinicians), laboratory staff, clinic managers and community health workers (CHWs) at early, midline and final trial implementation phases. We audio-recorded IDIs and FGDs and then transcribed and analysed data using Nvivo 12 software and thematic content analysis. Quantitative data were entered directly into tablets using ODK software and analysed using Stata Version 16.

Results: We completed 171 IDIs, 22 FGDs and 272 questionnaires. Providers found both models acceptable because integrating CCS and VFP saved them time. Model 2 was acceptable due to trust the community had in CHWs. Availability of equipment and supplies, well-trained personnel, mentorship, staff commitment and teamwork made both models feasible. Workload was reduced for clinicians and nurses, but increased for CHWs and lab personnel. The models were also appropriate because HPV self-sampling was simple and ensured client privacy for those hesitant to undergo a speculum examination for screening. The integration also mitigated fears that women had about speculum exams and dispelled myths and misconceptions around family planning methods.

Conclusions: Both models of the integration of CCS into VFP were acceptable, feasible and appropriate, and provide a platform to rapidly increase the CCS uptake in Malawi.

Shift 01-125 / #1246

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

SCREENING OF PRECANCEROUS CERVICAL CANCER LESIONS BY HPV DETECTION IN THE COMMUNITY OF ASSOMIN HEALTH AREA

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Introduction: In Côte d'Ivoire, cervical cancer (CC) is the 2nd most common female cancer. 2067 new cases were recorded in 2020 with 1417 deaths, corresponding to approximately 4 deaths per day. To contribute to the elimination of CC in Côte d'Ivoire, MdM has conducted a pilot project for screening and treatment of precancerous cervical lesions through a community-based HPV detection intervention among women aged 30-49 years in Assomin, in the town of Abobo/Abidjan.

Methods: The project has experimented a community-based screening strategy : Community Health Workers (CHWs) has conducted home visits during which they raised women awareness about CC and offered them vaginal self-sampling for HPV detection . The samples have been tested by Genexpert and HPV-positive women has then been invited to health center for VIAs (Visual Inspection with Acetic acid) made by midwives. Treatment by thermocoagulation or LEEP has been offered in case of a positive VIA. The goal was to screen 70% of the female population in the implementing area allowing to reach women who wouldn’t go to health centers

Results: After 7 months of screening, 100% of women aged 30-49 years performed the HPV test with a 96.8% acceptance rate for self-sampling and 23% of HPV positivity rate. 53% of HPV+ women have come to the health center for a VIA. 10% of them were VIA positive and 93% were treated. However, 47% of women are lost to follow-up despite a positive HPV test and we must continue to work on this.

Conclusions: Through community-based CC screening, Côte d'Ivoire could reach the WHO's 2030 pre-cancer cervical screening and treatment targets. The coverage of the screening program would thus be improved, reaching 70% of the target population as recommended by the WHO. The success of this strategy depends on the quality of community mobilization and the commitment of all stakeholders.

Shift 01-126 / #1540

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

IMPACT OF EDUCATIONAL INTERVENTION ON SELF-SAMPLING FOR HPV TEST BASED CERVICAL CANCER SCREENING IN NIGERIA

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Introduction: Self-sampling for HPV test is rapidly emerging as the preferred approach to cervical cancer screening globally, including in Sub-Saharan Africa. However, there have been some concerns about the willingness and ability of women to collect these samples, and the impact of educational intervention. In this study, we evaluated the impact of educational intervention on willingness and ability to self-sample among Nigerian women.

Methods: We conducted questionnaire surveys before and after educational intervention in 220 randomly selected women participating in cervical cancer screening in Abuja, Nigeria. All participants received Evalyn® self-sampling collection device and the samples were analyzed using DEIA/LIPA HPV tests.

Results: The mean (SD) age of the study participants was 33.5 (10.1) years. Most (63.2%) were married and 33.2 were single. Most (65.5%) were in the middle class, 20.5% were in the upper class while 14.1% were in the lower class, and only 38.2% had prior knowledge of cervical cancer. Only 10.5% have ever been screened for cervical cancer. Some 43.2% of the women were concerned about their ability to collect samples properly, 25.5% were concerned about pain, 18.6% thought it might cause an infection, 35% were concerned about safety of the procedure, while 8.6% were uncomfortable with touching their genitalia. The educational intervention changed the mean attitude to self-collection score from 42.6 (SD-8.3) to 50.8 (SD-9.8), p-value < 0.001. The most important determinants of willingness to self-collect were age (OR = 0.95, 95%CI 0.90-1.00), knowledge of cervical cancer (OR = 1.42, 95%CI 1.00-1.99), socio-economic status (Upper class OR 2.81, 95%CI 0.57-13.71; Middle class OR 3.69, 95%CI 1.07-12.7) and pre-intervention attitude (OR 0.89, 95%CI 0.81-0.99)

Conclusions: In this study, we showed that educational intervention significantly influenced willingness to collect self-samples for HPV test based cervical cancer screening among Nigerian women. We also identified attitudes to cervical cancer screening which suggest additional interventions to increase uptake of cervical cancer screening

Shift 01-164 / #509

Poster Discussion
POSTER DISCUSSION - BASIC SCIENCE 01
04-18-2023 10:00 AM - 10:30 AM

IN-DEPTH INSIGHTS INTO CERVICOVAGINAL MICROBIAL COMMUNITIES AND HRHPV INFECTIONS USING HIGH-RESOLUTION MICROBIOME PROFILING

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Introduction: The cervicovaginal microbiome (CVM) correlates with women's cervical health, and variations in its structure are associated with high-risk human papillomavirus (hrHPV)-induced high-grade cervical lesions. The CVM exhibits five community state types (CSTs): I, II, III, IV, and V, based on microbial composition; however, elucidating the impact of CSTs on health and disease is challenging because current sequencing technologies have limited confident discrimination between bacterial species that shape microbial communities. This study aimed to apply high-resolution microbiome profiling to obtain in-depth and unambiguous insights into the composition of the CVM and demonstrate how CSTs associate with hrHPV status and cervical disease.

Methods: Circular probe-based RNA sequencing (ciRNAseq) was used to profile the CVM of a cohort of healthy women from the Dutch population-based screening program (n = 341) and a second cohort consisting of hrHPV positive women with known clinical outcomes (n = 200). CSTs were established and correlated to clinical outcomes.

Results: Based on unsupervised clustering analyses, we define intra-CST differences with respect to the species Lactobacillus acidophilus, Lactobacillus iners, and Megasphaera genomosp type 1, that subdivide CSTs I, III, and IV in novel A and B subgroups. These subgroups further correlate with microbial diversity and abundance. Notably, we describe associations between CST V with hrHPV negative conditions, CST I-A with the absence of cervical abnormalities, and CST IV-A with hrHPV-induced cervical disease.

Conclusions: Overall, we characterize new subdivisions of cervicovaginal CSTs and their associations with hrHPV infections and cervical disease, which will contribute to elucidating the microbiome's role in hrHPV-induced cervical cancer and have potential applications for biomarkers discovery and therapy.

Shift 01-165 / #1503

Poster Discussion
POSTER DISCUSSION - BASIC SCIENCE 01
04-18-2023 10:00 AM - 10:30 AM

ASSOCIATION OF THE CERVICOVAGINAL BACTERIOME AND VIROME WITH THE PERSISTENCE OF HIGH-RISK HUMAN PAPILLOMA VIRUS INFECTION AND REGRESSION OF CERVICAL LESIONS

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Introduction: A possible participation of the microbiota of the cervix in the immunomodulation of the cervical microenvironment throughout the natural history of cervical cancer (CC) has been reported, so the microbiota could be a co-factor in the establishment of persistent HPV infection necessary for the development of CC. The objective of this study was to analyze the cervicovaginal bacteriome and virome in cases with and without HR-HPV infection and with cervical lesions (CL) in the baseline study, and cases with HR-HPV clearance and persistence and persistence and regression of CL at the first-year cohort follow-up, (n=12 by group).

Methods: Bacterial and viral DNA was extracted from cervical swab samples taken with the COPAN eSwabTM and massive shotgun sequencing was performed with Illumina MiSeq technology. For virome analysis, samples were enriched and subsequently sequencing was carried out. Once the sequences were obtained, the bioinformatic analysis was carried out.

Results: Women with a higher abundance of Lactobacillus spp. at the baseline study had a higher probability of clearance HPV and regression of CL at 12 months. Cases with higher abundance of L. gasseri (CST II) had a faster HPV clearance rate compared to cases with higher abundance of L. iners (CST III) or Atopobium (CST IV). Regarding the virome, four viral families were found: Papillomaviridae, Anelloviridae, Genomoviridae and Herpesviridae in cases with HR-HPV persistence.

Conclusions: Women with HR-HPV persistence had a lower abundance of Lactobacillus spp and 40% CST IV: with bacterial genera such as Gardnerella vaginalis, Prevotella timonensis, Megasphoera, Atopobium compared to those who eliminated HR-HPV that were associated with persistence of CL and slow regression. A higher abundance of HPV reads was found in women with CL that was associated with carrying multiple HR-HPVs.

Shift 01-179 / #1640

Poster Discussion
POSTER DISCUSSION - BASIC SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

THE OVEREXPRESSION OF ACTIVATING TRANSCRIPTION FACTOR 3 DOWNREGULATES P16INK4A EXPRESSION IN HUMAN PAPILLOMAVIRUS TYPE 16-INFECTED CERVICAL CANCER CELLS

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Introduction: The tumor suppressor role of p16 ^{INK4A} is abolished in human papillomavirus (HPV)-transformed cervical carcinoma and it exhibits oncogenic activity in the related cancer cell lines. p16 expression is essential for the survival and proliferation of cervical carcinoma cells but not for the normal cells, a difference which creates a promising cellular susceptibility for targeting treatments. We previously suggested that activating transcription factor 3 (ATF3) induction may be a useful target for HPV16-related cervical cancer prevention and treatment. Here, we aimed to investigate the effect of ATF3 overexpression on the cellular level of p16 ^{INK4A} in HPV-infected Ca Ski cells.

Methods: Ca Ski cells were cultured and transfected with pCMV6-ATF3 recombinant plasmid. Fluorescence microscopy and flow cytometric analysis were used to evaluate the efficiency of transfection. Subsequently, cells were harvested and used for RNA extraction and cell lysate preparation. The effect of ectopic ATF3 expression on p16 ^{INK4A} gene expression in the cells was quantified by real-time qRT-PCR and normalized to GAPDH mRNA expression. Further analysis of p16 protein expression was performed via Western blotting assay.

Results: The overexpression of ATF3 in Ca Ski cells downregulated p16^{INK4A} mRNA expression 6.3-fold compared to untreated controls 24 and 48h after transfection. ($p< 0.01$). This result was additionally confirmed by the results of Western blot analysis.

Conclusions: Previous evidences confirmed that ATF3 regulates p53 function and stability in HPV-infected cells by preventing its ubiquitination and degradation. Furthermore, ATF3 suppresses E6-mediated p53 degradation by direct binding to E6, and thus restores p53 activity and accumulation in cervical cancer cells. The elevation of p53 protein promotes cell-cycle arrest at the G1 phase which occurs prior to pRB phosphorylation. It subsequently leads to the accumulation of hypophosphorylated pRB which tends to downregulate p16 ^{INK4A}. In line with these findings, our results suggest that ATF3 induction downregulates p16 ^{INK4A} expression in HPV16-infected cells, which is in favor of cervical cancer treatment.

Shift 01-180 / #1117

Poster Discussion
POSTER DISCUSSION - BASIC SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

DISSECTING THE INFLUENCE OF HIV ON HPV INFECTION, DISEASE AND IMMUNITY IN AN EAST AFRICAN COHORT

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Introduction: Cervical cancer is the most common cancer affecting women in East Africa. According to the WHO, women living with HIV are 6 times more likely to develop cervical cancer when compared to HIV- women. The HIV-HPV (2H) study was set up in 2013 in Mbeya, Tanzania to determine underlying factors associated with this increased risk for cervical cancer among HIV+ women. Having screened > 2000 women and followed-up more than 500 women for up to 7 years, makes the 2H study the largest longitudinal project addressing cervical cancer in Africa.

Methods: The study enrolled 804 HIV+ and HIV- women with and without cervical lesions. The following biological specimens were collected: Biopsies and pap smears for cytohistologic diagnosis, cervical cytobrushes for HPV genotyping and viral load quantification, and peripheral blood for HPV-specific immunology.

Results: Overall, HR-HPV prevalence was 57% (241/421); 71% (165/234) in HIV+ vs 41% (76/187) in HIV-, $p < 0.0001$. Regardless of HIV infection, HPV genotypes 16, 18 and 45 accounted for the majority of cervical cancer cases. HIV+ women were diagnosed with cervical cancer 11 years younger than HIV- women (median years: 56 vs 45, $p < 0.0001$). Half (50%) of women diagnosed with cervical cancer died within 2 years after diagnosis, regardless of HIV status. Furthermore, we analysed HPV-oncoprotein-specific T cell responses in 373 women. HIV infection, low CD4 counts were significantly associated with depletion of HPV-oncoprotein-specific T cell responses to the infecting, autologous HR-HPV type. Moreover, within women living with HIV, precancerous lesions and cancer were associated with depleted HPV-oncoprotein-specific T cell responses.

Conclusions: HIV likely contributes to increased HPV persistence and the accelerated cancerogenesis in women living with HIV. Optimized molecular diagnostic algorithms tailored to women living with HIV to detect type-specific persistence could help to pre-select women at high risk of cancer for further diagnostics and therapeutic intervention.

Shift 01-181 / #1174

Poster Discussion
POSTER DISCUSSION - BASIC SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

DEVELOPMENT OF A PROFICIENCY TESTING PROGRAM FOR HPV SEROLOGY ASSAYS USED TO EVALUATE ANTIBODY RESPONSES IN VACCINE TRIALS

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Introduction: One of the aims of the HPV Serology Standardization Initiative at the FNLCR was to develop a proficiency panel, to evaluate assay sensitivity, specificity, and inter-assay correlations. Here, we describe the sample screening process to build a proficiency panel for biennial review amongst laboratories performing routine HPV serology testing for the 9 HPV types currently included in nonavalent vaccines (HPV-6, 11, 16, 18, 31, 33, 45, 52, and 58).

Methods: 80 serum samples (seronegative and HPV vaccinated) were selected and evaluated based on HPV-type specific antibody levels of HPV-6, 11, 16, 18, 31, 33, 45, 52, and 58, which were grouped into four categories- negative, low, intermediate, and high antibody responses. These samples were tested in 11 serology laboratories to evaluate HPV neutralizing and binding antibody assays for up to nine HPV types. Sensitivity, specificity, and inter-assay correlations (concordance, accuracy, and precision) were evaluated for each HPV type.

Results: The specificity (11 serum samples collected from seronegative donors aged 9-14) for the binding antibody assays and the neutralizing antibody assays ranged from 90.9% to 100% and 83.3% to 100%, respectively across the 9 HPV types evaluated. The sensitivity for the binding antibody assays and the neutralizing antibody assays ranged from 84.9% to 98.2% and 82.4% to 98.8%, respectively across the 9 HPV types evaluated. Averaged across all assays for the 9 HPV types, concordance correlation coefficients ranged from 0.449 to 0.833, pearson correlation coefficients ranged from 0.696 to 0.925, and coefficient of accuracy ranged from 0.639 to 0.907. While HPV-45 serology assays had the weakest correlation coefficients, HPV-16 assays typically had the strongest correlation coefficients.

Conclusions: In general, the HPV serology assays evaluated performed well. The evaluated samples will provide a strong core for building a reliable proficiency panel to monitor HPV serology assay performance in the future.

Shift 01-182 / #1195

Poster Discussion
POSTER DISCUSSION - BASIC SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

FEATURES OF HUMAN PAPILLOMAVIRUS TYPE-16 SPECIFIC HUMAN MONOCLONAL ANTIBODIES FROM B-CELLS WITH CLOSELY RELATED SEQUENCES

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Introduction: Vaccination induces potent neutralizing antibodies that provide long-term protection from HPV infection. A critical step in generating strong humoral immunity is the expansion of B-cells with high affinity immunoglobin receptors for target antigens. Here we examine human antibodies from B cells that appeared to have undergone expansion.

Methods: Bloods were collected at various times after vaccination and following an additional vaccine dose two years later. B cells were singly sorted by multi-color flow cytometry. Heavy and light chains were sequenced and cloned from individual cells. Antibodies were expressed and purified for analysis in binding and pseudovirus (psV) neutralization assays. Neutralization specificity was determined using chimeric psV on which single loops were swapped with other HPV types. We considered antibodies to be clonally related if they used the same heavy and light chain, had the same length complementarity determining region 3 (CDR3), and shared at least 70% sequence identity in the CDR3 region.

Results: Of the 71 HPV-16 neutralizing antibodies cloned, 27 belonged to one of 11 families of related sequences. Seven antibody families contained two clonally related sequences, three had three related sequences, and one had four. Five different loops were required for neutralization among the six of 11 families for which specificity could be determined. Different families required different surface loops, but all members of a family required the same loops. Somatic mutations were identified in CDR regions that were important for high affinity binding and appeared to have resulted from convergent evolution.

Conclusions: Clonally expanded B-cell families produced antibodies with high affinity for HPV16. Antibody families from different subjects appeared to have followed similar evolutionary pathways indicating that these types of antibodies may possess common features of the humoral immune response to HPV16.

Shift 01-225 / #698

Poster Discussion
POSTER DISCUSSION - CLINICAL SCIENCE 01
04-18-2023 10:00 AM - 10:30 AM

SQUAMOCOLUMNAR JUNCTION VISIBILITY BY AGE IN FIVE CERVICAL CANCER STUDIES AND IMPLICATIONS FOR SCREENING.

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Introduction: The squamocolumnar junction (SCJ) is the susceptible area for cervical precancer and cancerous lesions. For effective cervical cancer screening and triage with visual methods and treatment with thermal ablation, the entire SCJ must be visualized. Cervical cancer screening guidelines recommend screening until age 65 years, however the SCJ moves into the canal throughout the life course with no clear transition

point.

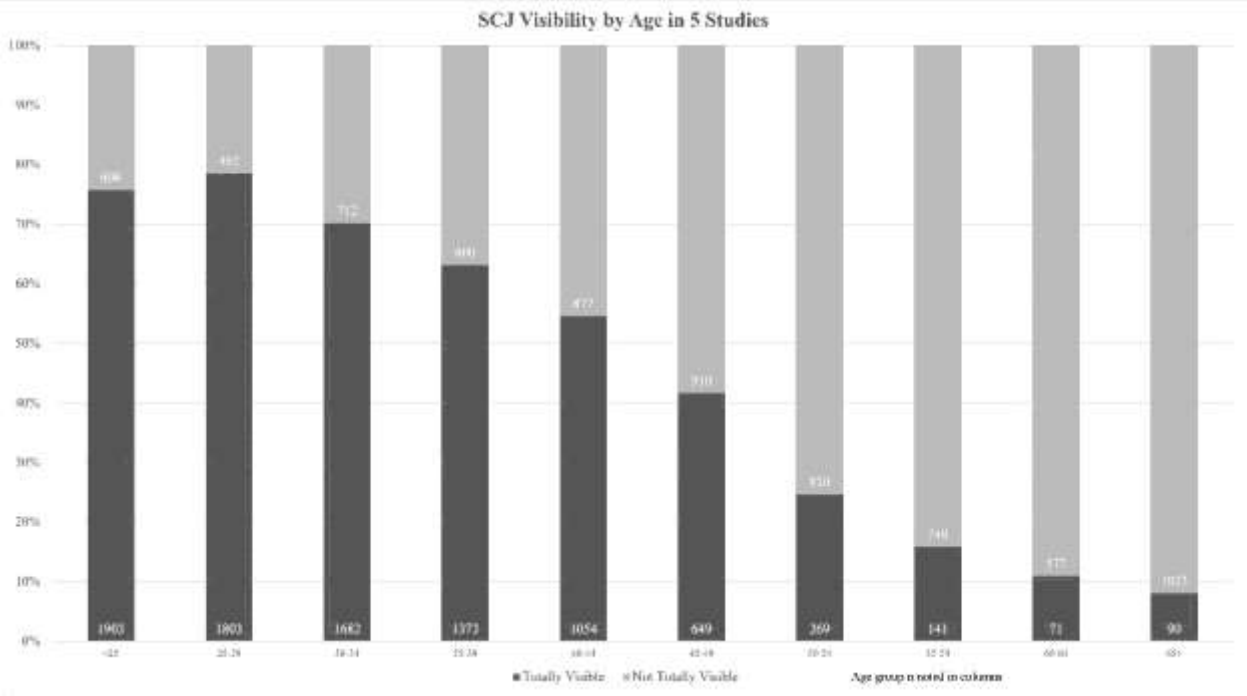
Table 1. Age by Study

	ALTS	NHS	Biopsy	Peru	Nigeria
Age	n(%)	n(%)	n(%)	n(%)	n(%)
<25	1239 (43)	756 (10)	270 (40)	246 (6)	0 (0)
25-29	585 (20)	986 (13)	203 (30)	517 (12)	4 (0)
30-34	321 (11)	1076 (14)	77 (11)	550 (13)	370 (29)
35-39	277 (10)	994 (13)	50 (7)	482 (11)	370 (29)
40-44	187 (7)	857 (11)	31 (5)	530 (12)	326 (25)
45-49	115 (4)	688 (9)	21 (3)	544 (13)	191 (15)
50-54	69 (2)	565 (7)	9 (1)	440 (10)	6 (0)
55-59	27 (1)	480 (6)	6 (1)	376 (9)	0 (0)
60-64	21 (1)	378 (5)	6 (1)	243 (6)	0 (0)
65+	23 (1)	768 (10)	2 (0)	319 (8)	1 (0)
Total	2864	7548	675	4247	1268

Methods: Age and SCJ visibility were analyzed to understand at what age-range the SCJ is no longer visible for efficient screening. The studies included screening population in the League Against Cancer in Lima, Peru (n=4,247) and the Guanacaste Natural History Study (NHS) in Costa Rica (n=7,548); participants with ASCUS and LSIL in the ASCUS/LSIL Triage Study in the United States (ALTS) (n=2,864); and participants in colposcopy in the Biopsy Study (n=684) in the United States and the project Itoju-3 in Nigeria (n=1,268). SCJ visibility was classified as totally visible or not totally visible. SCJ visibility was documented in each study during live examination or from images of the cervix.

Results: SCJ visibility decreased by age in all studies, with the SCJ being not totally visible in over 50% of participants aged 45-49. By ages 60-64, the SCJ was not totally visible in over 80% of participants across all

studies.



Conclusions: Extending cervical cancer screening programs in older age groups is likely less cost-effective because of the inability to visualize the entire SCJ in the majority of people. If the SCJ is not visible, there will be higher rates of referral and more complex diagnostic and treatment required. Because of the inability to visualize the SCJ in the majority of people after age 45-49, cervical cancer screening programs may consider reducing the upper age limit for screening.

Shift 01-226 / #1081

Poster Discussion
POSTER DISCUSSION - CLINICAL SCIENCE 01
04-18-2023 10:00 AM - 10:30 AM

COMPUTATIONAL PERFORMANCE OF AN IMAGE ADEQUACY ASSESSMENT ALGORITHM RUNNING ON SMARTPHONES

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Introduction: Cervix visualization plays a critical role in cervical cancer management. Yet capturing an adequate image of the cervix using a smartphone is not easy. Image quality varies greatly among providers. In addition to challenges with blur and brightness, there are challenges with ensuring the entire squamocolumnar junction (SCJ) is fully visible, without any blocking obstructions. Smart image capture algorithms that assist providers in both image sharpness and identifying obstructions on the SCJ have been proposed, but have yet to be developed.

Methods: An Android application was built with 3 quality assessment modules – cervix locator, auto-focus, and obstructions detector (Fig. 1). The cervix locator was implemented on an object detection network (YOLOv5). Upon detecting a cervix in the video feed, auto-focus and obstruction detection are triggered. During auto-focus, the position of the phone's lens is swept, a focus score is calculated at 10 discrete steps, and the lens position with the best score chosen. The obstructions detection module utilized a multi-task model that detects 4 potential obstructions (blood, mucus/discharge, loose vaginal walls, type III cervix) in parallel. Detected obstructions are presented in red, turning green when corrected. The computational performance of the 3 modules was compared in 2 Samsung phones – the J530 and
A52.

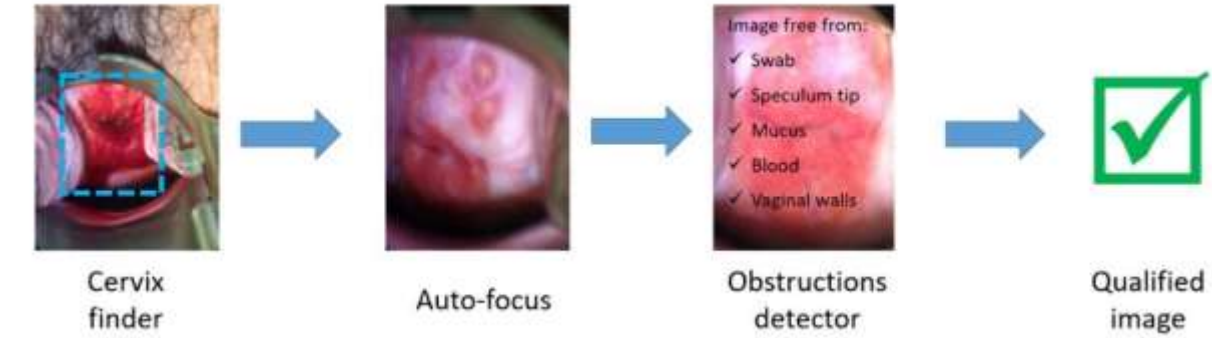

Fig. 1: Schematic of the 3 quality classifier, along with a description of each task and its output.

Results: The performance of the 3 image quality modules on the 2 phones is shown in Table 1. In the cervix locator and obstructions modules, the A52 is 5X and 3X faster, respectively. In blur computations, the A52 is 75% faster at evaluating a single frame.

Table 1: Computational and analytical performance of cervix locator, auto-focus, and obstructions detector modules. Analytical performance metrics – F1 and intersection over union (IoU) – are calculated on the pixel level. Inference time is the time it takes to run the model, the time per frame is the total time needed to process one image. Note the blur calculation is performed at each of the 10 lens positions evaluated as part of a focus-sweep.

Model	Analytical performance	Computation metric	J530	A52
Cervix Locator	F1=0.94, IoU=0.90	Inference (ms)	1,625	206
		Time per frame (ms)	1,899 (0.53 FPS)	369 (2.7 FPS)
Blur	AUC=0.86	Variance (ms)	12	4
		Total processing time (ms)	145	83
Obstructions	AUC=0.66-0.82	Inference (ms)	315	47
		Time per frame (ms)	697 (1.43 FPS)	185 (5.4 FPS)

Conclusions: To our knowledge, this is the first complete quality classifier running on an Android app. All 3 modules were validated on 2 phone models. The phone's processor plays a critical role in the speed of all quality classifier modules. Phones with processors at least as strong as the A52 are recommended.

Shift 01-227 / #1223

Poster Discussion
POSTER DISCUSSION - CLINICAL SCIENCE 01
04-18-2023 10:00 AM - 10:30 AM

PAIN AND SATISFACTION WITH THERMAL ABLATION USING BOTH SINGLE AND MULTIPLE TIPS

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Introduction: Cervical cancer disproportionally effects low and middle income countries (LMIC). Treatment of cervical cancer in LMIC has traditionally been gas-based cryotherapy however, because of its ease of use thermal ablation (TA) has reemerged as a treatment option. Questions remain regarding the ideal protocol for use. Here, we present preliminary results of a non-inferiority randomized clinical trial comparing two TA protocols (single and multiple tip) against gas-based cryotherapy.

Methods: In our study, pain was assessed at four different stages using Wonker faces scale: (1) at baseline, before any procedure was performed; (2) after the insertion of the speculum; (3) during treatment; and (4) about 5 minutes after treatment. For patients in the multiple-tip arm; pain was recorded individually for both the narrow and flat tips. Descriptive statistics for pain level are presented, and comparisons by treatment arm performed using a Kruskal-Wallis test.

Results: To date, 672 women (~60% of the expected total) have been enrolled. Most of them are from El Salvador (73%). Both TA protocols showed a median pain level of 4 (IQR=4), which is higher than cryotherapy median of 2 (IQR=2). The highest proportion of women experiencing a non-tolerable pain level (>6) was observed in the TA multiple-tip arm (8.6% [95% CI = 5.5, 13.0]), followed by TA single-tip (7.7% [95% CI = 4.8, 12.0]) and cryotherapy (3.1% [95% CI = 1.5, 6.5]). For women in the multiple-tip arm, the proportion of non-tolerable pain was similar for the narrow tip (5.4% [95% CI = 3.1, 9.3]) compared to the flat tip (5.9% [95% CI = 3.4, 9.8]). 93% of women were very satisfied with their procedure.

Conclusions: While TA is generally more painful than cryotherapy, more than 60% of women reported minimal pain (levels 0-2) 5 minutes after treatment in both TA protocols. Patient satisfaction was high.

Shift 01-228 / #1224

Poster Discussion
POSTER DISCUSSION - CLINICAL SCIENCE 01
04-18-2023 10:00 AM - 10:30 AM

HUMAN PAPILLOMA VIRUS GENOTYPE DISTRIBUTION IN VULVAR CANCER IN ZIMBABWE

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Introduction: The rise in the incidence of vulvar cancer worldwide has not spared developing countries such as Zimbabwe which saw a 26% increase in the vulvar cancer incidence between 2015 and 2018. This was mostly in women living with HIV (WLWH) and likely to have HPV dependent vulvar cancer. The specific HPV genotypes causing vulvar cancer in Zimbabwe have not been studied. This study was done to determine the HPV genotype-specific prevalence in vulvar cancer. Our results will inform preventive efforts such as vaccine strategy and development of screening protocols.

Methods: Formalin-fixed paraffin-embedded specimen blocks of vulvar cancer cases diagnosed between 1 January 2009 and 31 December 2018 were obtained from three histopathology laboratories in Harare and analyzed for the presence HPV DNA genotypes. Genotyping was performed on the AmpFIRE® ATILA multiplex PCR biosystem. The corresponding clinical data was obtained from relevant health centers. All data were analysed using Epi Info v7 and Stata v15.

Results: Ninety-eight vulvar cancer specimen blocks were obtained from women with a mean age of 44.9 years. 63 samples were from WLWH, 7 from HIV-negative women and 28 from women whose HIV status was unknown. The mean age of the women, stage of cancer and proportion of HPV-positive samples and genotype distribution are shown by HIV status in table

1.

Table 1 : Patient characteristics and HPV genotype distribution in vulvar cancer biopsies by HIV status (n=98)

Age group (years)	HIV positive women	HIV negative women	HIV status unknown	Total
15-49	49	1	17	67 (68.4%)
50-69	13	3	7	23 (23.5%)
70+	0	3	3	6 (6.1%)
Unknown	1	0	1	2 (2.0%)
Total	63	7	28	98
Mean age (years)	38.9	80.0	48.6	44.9
Vulvar cancer FIGO stage				
1-2	8	2	0	10 (10.2%)
3-4	22	3	0	25 (25.2%)
Unknown	33	2	28	63 (64.3%)
Total	63	7	28	98
HPV DNA Result				
Negative	10	4	8	22 (22.4%)
Positive	49	2	11	62 (63.3%)
Indeterminate	4	1	9	14 14.3%)
Total	63	7	28	98
Number of HPV genotypes detected				
Single	23	4	10	37
Two or more	24	0	1	25
High-risk HPV genotypes detected				
16	28	2	9	39 (41.9%)
51	9	0	2	11 (11.8%)
33	8	0	0	8 (8.6%)
68	7	0	0	7 (7.5%)
56	5	1	0	6 (6.5%)
Others	22	0	0	22 (23.7%)
Total	79	3	11	93
Low-risk HPV genotypes detected				
6	4	0	0	4 (30.8%)
11	8	1	0	9 (69.2%)
Total	12	1	0	13

Conclusions: Vulvar cancer was mainly seen in WLWH. WLWH had a higher prevalence of HPV, more multiple infections, presented at a younger age and had more advanced stage disease than the HIV-negative and HIV-indeterminate groups. HPV 16 was the commonest genotype occurring alone or in combination with other genotypes, some of which are not included in current HPV vaccines such as types

51, 68 and 56. Extensive efforts to vaccinate young girls as well as vigorous screening of WLWH will be key in curbing the noted rise in vulvar cancer.

Shift 01-250 / #1396

Poster Discussion
POSTER DISCUSSION - CLINICAL SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

HPV DNA, HPV E6*I MRNA, AND P16INK4A STATUS AMONG LATIN AMERICAN HEAD AND NECK CANCERS OF THE HEADLACE STUDY

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Introduction: HPV-driven head and neck squamous cell carcinomas (HNSCC) prevalence varies worldwide. We evaluated HPV DNA prevalence in formalin fixed paraffin embedded (FFPE) HNSCC from Argentina, Colombia, Peru and three Institutions in Brazil, included in the HEADLAcE Consortium.

Methods: HPV-driven head and neck squamous cell carcinomas (HNSCC) prevalence varies worldwide. We evaluated HPV DNA prevalence in formalin fixed paraffin embedded (FFPE) HNSCC from Argentina, Colombia, Peru and three Institutions in Brazil, included in the HEADLAcE Consortium.

Results: Overall, HPV DNA was detected in 32.2% (127/395), 11.3% (69/610) and 10.2% (57/588) oropharyngeal (OPC), oral cavity (OCC) and laryngeal/hypopharyngeal (LC/HC) cancers, respectively. HPV-16 was the most detected independently of anatomical subsite. Among HPV-16 positive cases, higher rates of concomitant detection of HPV E6*I mRNA and cellular $p16^{INK4a}$ was observed in OPC (72.3%, 34/47) in comparison to OCC (50.0%, 11/22) and LC/HC cases (50.0%, 1/2). HNSCC HPV attributable tumors varied among countries (ranging from 33.3 to 100.0%) and among the Institutions in Brazil (ranging from 33.3 to 55.6%).

Conclusions: Our results support a role for HPV-16 in a subset of HNSCC, and corroborates the heterogeneity observed in samples from different geographic regions.

Shift 01-251 / #1428

Poster Discussion
POSTER DISCUSSION - CLINICAL SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

CHARACTERISTICS OF CONFIRMED PERSISTENT AND NON-PERSISTENT ANAL HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS (HSIL) IN GAY AND BISEXUAL MEN (GBM)

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Introduction: Persistent anal HSIL is thought to precede the development of anal cancer. Factors predicting persistent HSIL are poorly understood. Laser capture microdissection (LCM) could help to identify factors associated with individual lesion-based persistent HSIL. Aims: To compare persistent and non-persistent anal LCM-HSIL with respect to causative HPV infections, histological grade, HIV status, biopsy location, and age.

Methods: Samples were from the Study of the Prevention of Anal Cancer (SPANC), a 3-year longitudinal cohort study of anal HPV natural history in GBM. Individual HSIL biopsies collected at baseline were followed-up to determine subsequent HSIL status. HSIL were classified as persistent if they: contained the same HPV genotype of the HSIL baseline, by using LCM; were again identified at consecutive visits at least 12 months after the baseline diagnosis, and were located within the same octant or up one octant on either side of the baseline lesion location. The remaining HSIL cases were classified as non-persistent, and we compared baseline characteristics of persistent versus non-persistent lesions.

Results: In total, 214 distinct HSIL among 153 men were identified at baseline, comprising 164 HSIL-AIN3 and 50 HSIL-AIN2: 96 (44.9%) were persistent and 118 (55.1%) non-persistent. Persistent HSIL were more likely than non-persistent HSIL to be caused by HPV16 (52.1% vs 22.9% respectively, $p<0.001$), be detected at 50+ age (59.4% vs 45.8%, $p=0.047$) and be located at the left lateral (LL) octant (14.6% vs 5.1%, $p=0.031$). Persistent HSIL was not associated with HIV status and histological grade. Non-persistent HSIL were more likely to be caused by possible HR types (16.9% vs 1%, $p<0.001$) and HPV51 (10.2% vs 0% respectively, $p<0.001$) Table

1.

Table 1. Comparison of persistent and non-persistent LCM-HSIL according to HPV infections in HIV positive and negative men from the SPANC study

			Any HR-HPV	HPV16	HR-HPV not 16	Nonavalent not 16	HPV51	Possible HR-HPV	HPV not detected
		N	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
All	Cases	214	191 (89.3)	77 (36.0)	114 (53.3)	79 (36.9)	12 (5.6)	21 (9.8)	2 (0.9)
	Persistent	96	95 (99.0)	50 (52.1)	45 (46.9)	37 (38.5)	0 (0.0)	1 (1.0)	0 (0.0)
	Non Persistent	118	96 (81.1)	27 (22.9)	69 (58.5)	42 (35.6)	12 (10.2)	20 (16.9)	2 (1.7)
	p-value		*<0.001*	*<0.001*	*0.091*	*0.657*	*<0.001*	*<0.001*	*0.503*
HIV Negative	Cases	104	91 (87.5)	44 (42.3)	47 (45.2)	27 (26.0)	6 (5.8)	12 (11.5)	1 (1.0)
	Persistent	46	45 (97.8)	29 (63.0)	16 (34.8)	11 (23.9)	0 (0.0)	1 (2.2)	0 (0.0)
	Non Persistent	58	46 (79.3)	15 (25.9)	31 (53.4)	16 (27.6)	6 (10.3)	11 (19.0)	1 (1.7)
	p-value		*0.006*	*<0.001*	*0.057*	*0.671*	*0.032*	*0.011*	*1*
HIV Positive	Cases	110	100 (90.9)	33 (30.0)	67 (60.9)	52 (47.3)	6 (5.5)	9 (8.2)	1 (0.9)
	Persistent	50	50 (100)	21 (42.0)	29 (58.0)	26 (52.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Non Persistent	60	50 (83.3)	12 (20.0)	38 (63.3)	26 (43.3)	6 (10.0)	9 (15.0)	1 (1.7)
	p-value		*0.002*	*0.012*	*0.568*	*0.364*	*0.031*	*0.003*	*1*

p-value performed using chi-square test unless cell count is <5 in which case Fisher exact test was used.
Any HR-HPV detected: 16,18,31,33,35,39,45,51,52,56,58,59.
Nonavalent not 16 detected: 18,31,33,45,52,58.
Possible HR-HPV detected: 66,68,26,34,53,67,69,82

Conclusions: HPV16 infections, older age, and lesions at LL octant were associated with persistent HSIL. Some HPV types were less likely to cause persistent disease. HPV typing could be useful for risk stratification before treatment.

Shift 01-252 / #348

Poster Discussion
POSTER DISCUSSION - CLINICAL SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

HPV PROPHYLACTIC VACCINES INCREASE THE RATE OF REGRESSION OF CERVICAL HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS (HSIL/CIN2) MANAGED EXPECTANTLY

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Introduction: There is a trend toward expectant management of women with cervical high-grade squamous intraepithelial lesions (HSIL/CIN2) nowadays, as about half of them will regress spontaneously. The objective of our study was to determine whether HPV prophylactic vaccines administrated in women before the age of 20 (French guidelines) and who will subsequently develop HSIL/CIN2 impact the spontaneous regression rate when managed expectantly.

Methods: This retrospective study included 210 women under 40 years (median 29, range 21-39), and HSIL/CIN2 diagnosed by biopsy between 2012 and 2022. They were followed-up every 6 months without treatment. The regression of HSIL/CIN2 was defined by the regression or the disappearance of initial colposcopic findings, cytological and/or histological results.

Results: Among 210 women, 20 (9.5%) have been vaccinated (18 quadrivalent and 2 bivalent).

Baseline characteristics	Vaccinated women (n=20)	Non-vaccinated women (n=190)	P
Age (y), mean (SD)	26.3 (1.56)	30.1 (4.16)	<0.001
Active smoking	12 (60%)	85 (45%)	NS
Quadrants 1 to 2 3 to 4	13 (65%) 7 (35%)	135 (71%) 55 (29%)	NS
Colposcopy Minor change Major change	15 (75%) 5 (25%)	105 (55%) 85 (45%)	NS
Cytology ASC-US, LSIL ASC-H, HSIL	7 (35%) 13 (65%)	114 (60%) 76 (40%)	NS
HPV genotypes HPV-HR HPV-16 HPV-LR	19 (95%) 0 (0%) 1 (5%)	181 (95%) 92 (51%) 9 (5%)	NS 0.005 NS

At baseline, vaccinated women with CIN2 were younger and not infected by HPV-16, compared to non-vaccinated women. At the end of follow-up (median 25 months, range 7–86), the lesion spontaneously regressed or disappeared in 128 (61%) patients. The regression rate was significantly higher in vaccinated women (18/20, 90%) compared to non-vaccinated women (110/190, 58%): OR=6.55 (95%IC 1.48-29.01), P=0.006.

Conclusions: HPV prophylactic vaccines increase the rate of regression of HSIL/CIN2 managed expectantly, thanks to the absence of HPV-16 at baseline in this population.

Shift 01-253 / #1176

Poster Discussion
POSTER DISCUSSION - CLINICAL SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

LONG-TERM PROTECTION OF HPV VACCINE IN WOMEN PARTICIPATING IN CERVICAL SCREENING WITHIN THE ESTAMPA STUDY, COSTA RICA

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Introduction: Between June 2004 and December 2005, the Costa Rica Vaccine Trial (CVT) was conducted in Puntarenas to evaluate the efficacy of the bivalent HPV16/18 AS04-adjuvanted vaccine in women aged 18-25 years; women in the control arm also received HPV vaccine after the 4-year follow-up. Eighteen years later, the ESTAMPA Costa Rica centre screened in the same region 9,708 women aged 30-64 years with real-time HPV testing with partial genotyping. We aimed to assess the protection of the bivalent HPV vaccine against HPV16/18 infection or CIN3+ in ESTAMPA participants aged 30-43 years, corresponding to the age-cohorts included in CVT.

Methods: ESTAMPA participants were screened with COBAS and cytology and referred to colposcopy if positive by either, with biopsy and/or treatment as needed. Women without precancer are recalled to a follow-up visit at 18 months for further disease ascertainment. Age-adjusted prevalence ratios (aPR) were used to assess the protection of the bivalent HPV vaccine against HPV16/18 infection and CIN3+ in participants aged 30-43 years who self-reported whether they had received or not the HPV vaccine.

Results: Among 3,338 participants aged 30-43 years analysed, 200 (6%) reported HPV vaccination and 3,138 did not; 2.5% (95%CI 1.1-5.7) and 5.4% (95%CI 4.5-6.3) were HPV16/18 positive, respectively, representing 54% protection of the vaccine (Table). In contrast, there was no reduction in HPV types other than HPV16/18 among vaccinated women. The prevalence of CIN3+ was 60% lower but borderline significant among vaccinated women compared with unvaccinated. Two of the 3 lesions in vaccinated women were caused by non-HPV16/18.

Table. HPV vaccination status associated to HPV16/18 infection, non-HPV16/18 infection, and CIN3+ in ESTAMPA participants aged 30-43 years

Table. HPV vaccination status associated to HPV16/18 infection, non-HPV16/18 infection, and CIN3+ in ESTAMPA participants aged 30-43 years

HPV vaccination status	HPV16/18		aPR (95% CI)	non-HPV16/18		aPR (95% CI)	Histology		aPR (95% CI)
	Negative	Positive (%)		Negative	Positive (%)		<CIN2	CIN3+ (%)	
Unvaccinated	2,968	170 (5.4)	1	2,772	366 (11.7)	1	2,973	116 (3.8)	1
Vaccinated	195	5 (2.5)	0.46 (0.16-0.98)	171	29 (14.5)	1.23 (0.85-1.71)	197	3 (1.5)	0.40 (0.10-1.04)

aPR: prevalence ratio adjusted by age

Conclusions: Women in ESTAMPA who reported receiving the HPV vaccine had significant protection against HPV16/18. This level of long-term protection is noteworthy and consistent with ITT results in CVT;

additional analysis including time since vaccination will be presented. Protection against CIN3+ is consistent with the fraction of lesions generally associated with HPV16/18.

Shift 01-254 / #719

Poster Discussion
POSTER DISCUSSION - CLINICAL SCIENCE 02
04-19-2023 9:15 AM - 9:45 AM

BIRTH OUTCOMES IN WOMEN EXPOSED TO 9-VALENT HUMAN PAPILLOMAVIRUS VACCINE DURING PREGNANCY: A 7-YEAR PREGNANCY REGISTRY

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Introduction: The 9vHPV vaccine prevents infection and disease related to HPV6/11/16/18/31/33/45/52/58; however, use in pregnant women is not recommended as there are no adequate and well-controlled studies in pregnant women. We performed an analysis of pregnancy registry data, which gathered information on exposures and pregnancy outcomes in women who received 9vHPV during pregnancy.

Methods: The pregnancy registry included spontaneous reports involving 9vHPV exposure during pregnancy originating in the US (December 2014 to March 2021). Reports were classified as prospective or retrospective, i.e., the report was received before or after the outcome of the pregnancy was known, respectively. Primary outcomes of interest were congenital anomalies and pregnancy outcomes (live births, fetal deaths, elective terminations, ectopic pregnancies and spontaneous abortions).

Results: 85 (180 prospective/5 retrospective) women and their pregnancy outcomes were included (Table 1). Among prospective reports for which length of gestation was available, 46 infants in 45 pregnancies (1 set of twins) were born at term, 1 infant at 36 weeks, and 1 infant at 43 weeks. All 3 spontaneous abortions occurred in the first trimester in women who had been vaccinated prior to detection of pregnancy. For prospective reports with known pregnancy outcomes, the estimated rate of spontaneous abortion was 4.3%. (Table 1). Three newborns (prospectively reported) had major congenital anomalies of ureterocele, hydronephrosis, and supraventricular tachycardia. The estimated rate of major congenital anomalies was 4.5%. Five retrospective cases reported live birth outcomes and no congenital
anomalies.

Table 1. Pregnancy outcomes in all enrolled reports

Report type	Total women	Lost to follow-up*	Live births	Elective abortions	Spontaneous abortions	Fetal death	Ectopic
Prospective	180	110	66†	1	3	0	0
Retrospective	5	0	5‡	0	0	0	0

*Pregnancy outcome unknown
†67 live-born infants (includes 1 set of twins)
‡6 live-born infants (includes 1 set of twins)

Conclusions: Regardless of drug or vaccine exposure, there is a background risk of major birth defects (2-4%), miscarriage (approximately 15-20%), or other adverse outcomes in all pregnancies. This analysis for 9vHPV vaccine supports other human data which have not shown evidence of a vaccine-associated increase in the risk of miscarriage or major birth defects when 9vHPV vaccine is administered during pregnancy.

Poster Discussion Shift 2

Shift 02-082 / #1696

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 03
04-20-2023 2:00 PM - 2:30 PM

DIFFERENCES IN HPV KNOWLEDGE BY RACE/ETHNICITY AND EDUCATIONAL ATTAINMENT IN THE UNITED STATES, HEALTH INFORMATION NATIONAL TRENDS SURVEY, 2017-2020

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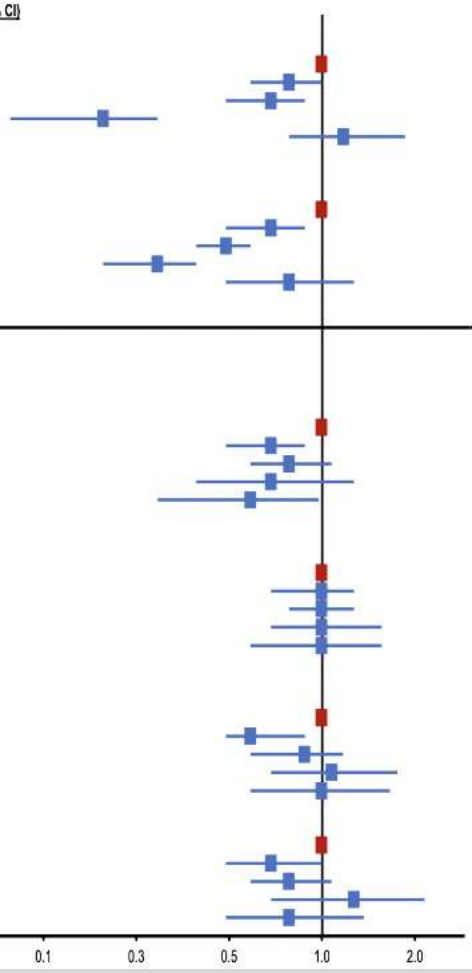
Introduction: To investigate differences in human papillomavirus (HPV) knowledge by race/ethnicity and educational attainment in the United States (U.S.), we pooled data over four survey cycles (2017-2020) from the Health Information National Trends Survey (HINTS).

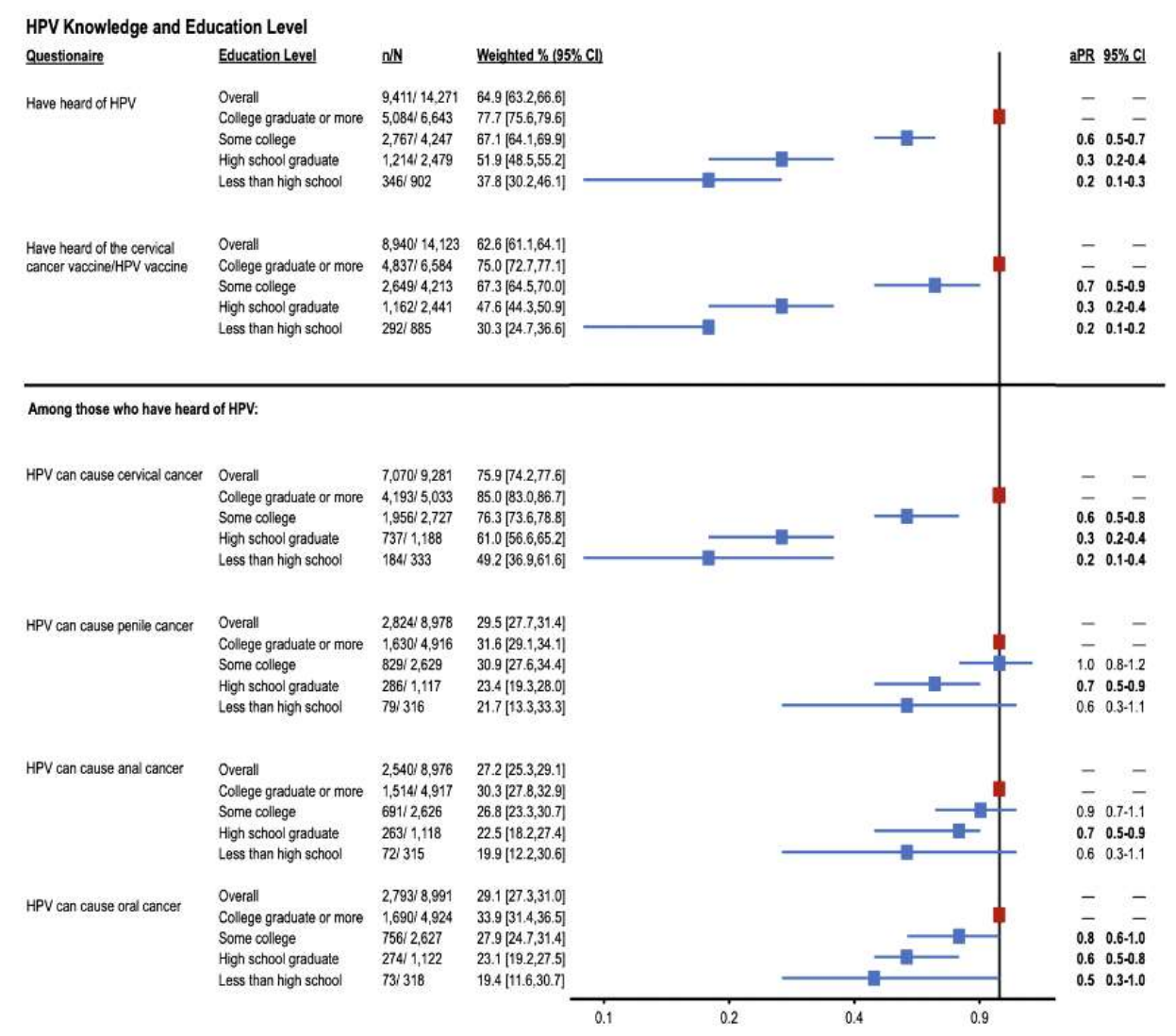
Methods: Among 14,444 U.S. adults, we calculated weighted prevalence for knowledge of HPV, the HPV vaccine, and HPV-related cancers (cervical, penile, anal, oral) overall and stratified by 1) race/ethnicity [non-Hispanic (NH)-White, NH-Black, Hispanic, NH-Asian, NH-Other] and 2) education (college graduate or higher, some college, high school graduate, less than high school). Adjusted prevalence ratios (aPRs) were calculated using logistic regression.

Results: Overall, most participants had heard of HPV (64.9%) and the HPV vaccine (62.6%); by race/ethnicity, knowledge was lowest for NH-Asian participants (43.2% and 47.8% respectively) and highest for NH-White participants (68.4% and 68.1% respectively) (Figure 1). By educational attainment, knowledge of HPV and the HPV vaccine was lowest for those with less than high school education (37.8% and 30.3% respectively) and highest for college graduates or higher (77.7% and 75.0% respectively) (Figure 2). Compared to college graduates or higher, all lower education levels had significantly less knowledge of HPV and the HPV vaccine (aPR range=0.2-0.7). Among those who had heard of HPV, 75.9% knew HPV caused cervical cancer, which was generally similar by race/ethnicity, ranging from 64.1% (NH-Other) to 78.2% (NH-White), but differed by education, ranging from 49.2% (less than high school) to 85.0% (college graduate or higher). Overall, less than 29.5% knew HPV caused penile, anal, and oral cancer; prevalance was similarly low across races/ethnicities and education levels.

HPV Knowledge and Race/Ethnicity

Questionaire	Race/Ethnicity	n/N	Weighted % (95% CI)	aPR	95% CI
Have heard of HPV	Overall	9,456/ 14,356	64.9 [63.1,66.6]	—	—
	NH White	6,245/ 8,987	68.4 [66.7,70.1]	—	—
	NH Black	1,234/ 1,983	61.4 [56.1,66.5]	0.8	0.6-1.0
	Hispanic	1,294/ 2,208	58.8 [54.1,63.3]	**0.7**	**0.5-0.9**
	NH Asian	310/ 660	43.2 [35.5,51.4]	**0.2**	**0.1-0.3**
	NH Other	373/ 518	71.2 [62.4,78.6]	1.2	0.8-1.9
Have heard of the cervical cancer vaccine/HPV vaccine	Overall	8,986/ 14,205	62.6 [61.1,64.1]	—	—
	NH White	6,086/ 8,898	68.1 [66.5,69.7]	—	—
	NH Black	1,124/ 1,965	56.1 [51.4,60.6]	**0.7**	**0.5-0.9**
	Hispanic	1,144/ 2,179	50.2 [46.1,54.4]	**0.5**	**0.4-0.6**
	NH Asian	289/ 650	47.8 [39.6,56.0]	**0.3**	**0.2-0.4**
	NH Other	343/ 513	61.5 [50.9,71.2]	0.8	0.5-1.3
Among those who have heard of HPV:					
HPV can cause cervical cancer	Overall	7,097/ 9,324	75.9 [74.2,77.5]	—	—
	NH White	4,838/ 6,174	78.2 [76.0,80.3]	—	—
	NH Black	795/ 1,204	68.5 [62.7,73.8]	**0.7**	**0.5-0.9**
	Hispanic	938/ 1,268	72.2 [66.7,77.1]	0.8	0.6-1.1
	NH Asian	237/ 307	77.9 [67.9,85.5]	0.7	0.4-1.3
	NH Other	289/ 371	64.1 [51.3,75.2]	0.6	0.3-1.0
HPV can cause penile cancer	Overall	2,835 / 9,015	29.5 [27.7,31.4]	—	—
	NH White	1,878/ 6,006	29.8 [27.6,32.0]	—	—
	NH Black	352/ 1,154	29.0 [24.5,34.1]	1.0	0.7-1.3
	Hispanic	379/ 1,204	28.6 [23.8,34.0]	1.0	0.8-1.3
	NH Asian	105/ 293	30.3 [23.0,38.6]	1.0	0.7-1.6
	NH Other	121/ 358	27.8 [19.0,38.8]	1.0	0.6-1.6
HPV can cause anal cancer	Overall	2,548/ 9,014	27.2 [25.3,29.1]	—	—
	NH White	1,725/ 6,007	28.3 [25.9,30.8]	—	—
	NH Black	286/ 1,155	20.4 [16.3,25.3]	**0.6**	**0.5-0.9**
	Hispanic	334/ 1,202	25.2 [20.0,31.3]	0.9	0.6-1.2
	NH Asian	91/ 292	31.2 [23.0,40.7]	1.1	0.7-1.8
	NH Other	112/ 358	28.2 [19.3,39.2]	1.0	0.6-1.7
HPV can cause oral cancer	Overall	2,799/ 9,028	29.1 [27.3,31.0]	—	—
	NH White	1,945/ 6,017	30.5 [28.1,33.1]	—	—
	NH Black	281/ 1,156	23.0 [18.0,28.9]	**0.7**	**0.5-1.0**
	Hispanic	355/ 1,204	25.7 [20.7,31.5]	0.8	0.6-1.1
	NH Asian	104/ 293	37.0 [26.2,49.2]	1.3	0.7-2.2
	NH Other	114/ 358	24.1 [15.8,35.1]	0.8	0.5-1.4





Conclusions: Lower levels of HPV knowledge were observed among historically marginalized individuals and those of lower educational attainment; however, heterogeneity was greater by education. This finding may present an opportunity to increase educational activities with the goal of positively impacting populations most effected by HPV knowledge gaps.

Shift 02-083 / #1257

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 03
04-20-2023 2:00 PM - 2:30 PM

UNDERSTANDING OF CERVICAL CANCER AND PREDICTORS OF CERVICAL SCREENING SEEKING BEHAVIOUR AMONG WOMEN IN GOMBE STATE, NIGERIA

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Introduction: Cervical cancer affects women worldwide. Sub-Saharan Africa bears the highest burden of the disease due to factors including poor knowledge, unavailability of services, and a high burden of HIV infection. The objective of this study was to assess the understanding of cervical cancer and cervical screening seeking behaviour of women in Gombe State, Nigeria

Methods: A community-based cross-sectional survey of 2,158 women aged 18-70 years, attending a community health facility, was carried out from October – December 2019; questionnaires drew on available evidence and underwent pre-testing and refinement. Descriptive statistics, bivariate analysis and binary logistic regression were used to analyse and summarise data. We considered statistically significant associations at $p \leq 0.025$

Results: 85% of women had no awareness of cervical cancer. Among the 15% with awareness, less than 30% had basic knowledge of cervical cancer. We examined four main outcomes affecting cervical screening seeking behaviour, and associated predictors. 1) “Having intention to screen for cervical cancer”: 27.7%; awareness of cervical screening (AOR = 94.58; 95%CI: 11.90-751.88; p=0.000) and prefer to self-screen at home (AOR = 0.23; 95%CI: 0.10-0.57; p=0.001). 2) “Needed permission to get screening”: 76.8%; Married (AOR = 2.31; 95% CI: 1.28-4.20; p=0.006), Muslim faith (AOR = 2.99; 95%CI: 1.63-5.47; p=0.000), and poor knowledge of cervical cancer (AOR = 1.89; 95%CI: 1.05-3.40; p=0.002). 3) “Prefer to be accompanied to place of screening”: 55.8%; Muslim faith (AOR = 2.37; 95%CI: 1.36-4.12; p=0.002) and unscreened due to unaware/unavailable services (AOR = 1.90; 95%CI: 1.16-3.11; p=0.011). 4) “Having gender preference for health worker”: 44.0%; Married (AOR = 2.06; 95%CI: 1.10-3.83; p=0.023), awareness of cervical screening (AOR = 2.35; 95%CI: 1.33-4.16; p=0.003), unscreened due to unaware/unavailable services (AOR = 2.33; 95%CI: 1.40-3.90; p=0.001)

Conclusions: Implementation of cervical screening services should prioritise awareness raising and integrate cultural values and practices of the community

Shift 02-084 / #1369

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 03
04-20-2023 2:00 PM - 2:30 PM

INTRODUCTION AND SCALE-UP OF HPV TESTING FOR CERVICAL CANCER SCREENING IN ZAMBIA

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Introduction: Zambia has one of the world's highest morbidity and mortality rates for cervical cancer. To reduce the burden and eliminate cervical cancer, the country introduced HPV testing, responding to the World Health Organization (WHO)'s global call to accelerate the elimination of cervical cancer.

Methods: We begun by verification of the three HPV testing platforms (Cobas, Hologic Panther and GeneXpert machines) and the testing methods (provider Vs self-collection) in August 2019. The pilot HPV testing through self-collected samples was introduced in November 2019 in 3 public health facilities in Lusaka targeting women living with HIV (WLHIV). This was later scaled up to 35 screening sites across 4 provinces of the country by September 2020. Self-collected samples were couriered to the CIDRZ Central laboratory for testing using the Hologic panther. HPV Positive women were triaged to Visual Assessment for Treatment (VAT) and same day ablative treatment for precancerous lesions provided. Women with large and complex lesions that were ineligible for thermal ablation were referred for LEEP/LLETZ.

Results: From a cohort of 18- to 59-year-old WLHIV, a total of 14,425 were included in the analysis even though more women were tested over 10 months. Positivity for HPV was noted at 45% (6,544). Women that were infected with the "other Hr HPV were 5,297 while 799 and 448 had subtypes 16 and 18 respectively.

Conclusions: Despite challenges encountered, Zambia managed to effectively introduce and scale up HPV testing. Unlike in other low resource settings, HPV positivity in Zambia was high at 45% compared to Guatemala (12.4%), Honduras and Nicaragua (14.5% and 14.2%, respectively, where testing was introduced at similar timepoint. It therefore, is possible to implement HPV testing using the self-collected vaginal specimen in resource limited settings with a high burden of cervical cancer and HIV to accelerate the elimination of cervical cancer.

Shift 02-085 / #1415

Poster Discussion
POSTER DISCUSSION - PUBLIC HEALTH SCIENCE 03
04-20-2023 2:00 PM - 2:30 PM

EVALUATION OF AN ARTIFICIAL INTELLIGENCE BASED DEVICE FOR DETECTION OF CERVICAL PRE-CANCERS-AN INDIAN STUDY

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Introduction: World Health Organization (WHO) recommends Human papillomavirus (HPV) DNA test as the primary method in cervical pre cancer screening and treatment approaches. In low and middle income countries (LMIC) there are increasing usage of visual inspection after acetic acid (VIA) or HPV detection test. To improve the selection of treatment options for screen-positives and to avoid over treatment, triaging by colposcope and analysis of images by experts may complete screening, diagnosis and treatment decisioning at one sitting. The device n-Gyn by Neo Sense Vector (NSV),USA has features of standard colposcope like autofocus facility, 3-60 X magnification and green-filter. The objective is to evaluate the accuracy of n-Gyn device in detection of CIN 2 or worse lesions.

Methods: Women between 30-59 years were screened in a hospital setting in India using Hybrid Capture 2 (HC2) test. Women positive on HPV test had evaluation by n-Gyn using IFCPC 2011 colposcopy terminology and swede score (SS). All women had biopsy irrespective of their n-Gyn findings. The agreement between histology and n-Gyn SS were estimated. Recruitment of invasive cancer cases are still on going.

Results: Total 1526 women were screened between December,2021 to September,2022. Out of which 166 (10.8%) were HPV positive. Twelve cases of CIN 2/CIN 3 and 1 case of adenocarcinoma in situ were detected. Agreement between n-Gyn SS and histology was fair with weighted kappa 0.26 (95% C.I. 0.054-0.570).The Artificial intelligence part is not yet validated.

Conclusions: There is a great need for a technically less demanding and inexpensive colposcope to be used for programs in LMICs. The portability of the device, ability to auto capture images and in-built AI software for decision making are the advantages that make n-Gyn suitable for cervical cancer screening in LMICs. The final analysis of the AI part would be presented in the conference.

Shift 02-179 / #890

Poster Discussion
POSTER DISCUSSION - BASIC SCIENCE 03
04-20-2023 2:00 PM - 2:30 PM

A NEW APPROACH TO CERVICAL CANCER CHEMOTHERAPY: INHIBITION OF PCNA

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Introduction: Despite effective vaccines, cervical cancer (CaCx) is a major source of morbidity and mortality worldwide. Incidence rates lie between 9 and 17.8 per 100000 women. Platinum-based chemotherapeutics (e.g., cisplatin) are the standard-of-care for advanced CaCx. While initially effective, they frequently show reduced therapeutic efficacy due to acquired resistance and limited patient tolerance. Thus, there is a need for new therapeutic targets. PCNA is a highly conserved protein required for critical cellular functions, including DNA replication and repair. PCNA inhibition would be lethal to CaCx cells, but also non-specific and thus toxic. Our collaborators identified a post-translational modification of PCNA that occurs with notable specificity in cancers (e.g, breast cancer, neuroblastomas and CaCx). They developed a small molecule, AOH1996, that inhibits this cancer associated form of PCNA and demonstrated its effectiveness against an in vivo neuroblastoma model. Here, we examine the efficacy of AOH1996 on CaCx.

Methods: MTT assays, immunoblots, fixed and live-cell microscopy, as well as an in vivo xenograft CaCx model were used.

Results: CaCx cells were sensitive to sub-micromolar concentrations of AOH1996. AOH1996 caused mitotic arrest, re-replication, supernumerary centrosomes, and ultimately cell death during mitosis. These effects were significantly less common in untransformed keratinocytes, suggesting specificity. AOH1996 was similarly effective at inhibiting growth of a xenograft model of CaCx, resulting in increased survival compared to saline treated mice. AOH1996 was also better tolerated than cisplatin. Approximately one third of the weekly cisplatin treatments had to be skipped due to deterioration of physical condition. In contrast, bi-daily AOH1996 treatments never had to be skipped due to signs of physical duress or weight loss. Instead, AOH1996 treated mice gained weight during the study.

Conclusions: Small molecule inhibition of cancer associated PCNA has promise as a therapeutic strategy against CaCx.

Shift 02-180 / #1791

Poster Discussion
POSTER DISCUSSION - BASIC SCIENCE 03
04-20-2023 2:00 PM - 2:30 PM

NITRIC OXIDE INHIBITS HPV16 E6 /E7 ACTIVITY AND INDUCES DNA DAMAGE IN HPV-16 INFECTED HUMAN KERATINOCYTES.

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Introduction: NVN1000 is a novel proprietary NO-releasing compound developed by Novan Inc., North Carolina. We reported that NVN1000 reduces HPV-18 E6 and E7 protein levels and their activities in HPV18 raft-cultures (PMID:31319090). Here we describe the inhibitory effect of NVN1000 in organotypic raft-cultures (RC) of primary human keratinocytes (PHK) expressing HPV16 E6/E7 and the HPV16-positive cancer cell line, CaSki.

Methods: PHKs were transfected with retroviruses expressing LTR-driven HPV16 E6/E7. RCs of untransfected PHKs, PHK-HPV16 E6/E7, and CaSki cells, were exposed topically from day-7 to vehicle or to NVN1000 (2-6 mg/ml), 1 h daily for 6 or 9 days, then harvested on day-13 or -16. Parallel cultures were harvested after 5 days of agent-free chase on day-18 or -21. RCs were analyzed by in situ methods and by immunoblots.

Results: The untreated HPV16 E6/E7 RCs were hyperprolferative, resembling CIN I/II. Daily exposure to 4 mg/ml NVN1000 significantly reduced the spinous-strata, causing rapid incomplete programmed cell-death, evidenced by the presence of residual nuclei in the cornified layers in HPV16 E6/E7 RCs, but less prominently in PHK RCs. NVN1000 abrogated HPV16 E7-induced S-phase in the suprabasal cells and slightly reduced E6-mediated p53 degradation, while triggered strong expression of γ-H2AX, the DNA damage signal, in the suprabasal layers. The condensed nuclei in the cornified strata were TUNEL-positive. Similar observations were made in RC of CaSki cells. NVN1000 partially reduced host DNA replication, induced very little change in p53 levels or DNA-damage in basal cells of normal PHK RCs. Immunoblots confirmed these observations.

Conclusions: NVN1000 down-regulates E7 activity, induces DNA-damage to replicating DNA in HPV16 E6E7 RC. In contrast, post-mitotic suprabasal cells in normal PHK RCs do not incur significant DNA damage. Thus, NVN1000 has the desirable properties for topical treatment of CIN lesions. This research was supported by NIH/NIAID award # R44AI143022.

Shift 02-181 / #982

Poster Discussion
POSTER DISCUSSION - BASIC SCIENCE 03
04-20-2023 2:00 PM - 2:30 PM

CONSTRUCTION OF A COMPLETE TRANSCRIPT MAP OF COTTONTAIL RABBIT PAPILLOMAVIRUS

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Introduction: Cottontail rabbit papillomavirus (CRPV), the first papillomavirus associated with tumor development, has been used as a powerful model to study papillomavirus pathogenesis for more than 80 years. However, the lack of a comprehensive analysis of CRPV transcriptome has impeded the full understanding of CRPV biology and molecular pathogenesis.

Methods: Here we report the construction of a complete CRPV transcription map from CRPV Hershey strain-induced skin tumor tissues using short-reads RNA-seq in combination with long-reads PacBio Iso-seq. The obtained and annotated transcripts were further experimentally confirmed by 5' and 3' RACE, primer-walking RT-PCR, and Northern blotting.

Results: We demonstrated that the CRPV genome is transcribed unidirectionally from five distinct promoters (P) and polyadenylates its transcripts at two major polyadenylation (pA) sites. We designate the P_{90}, P_{158}, and P_{906} as “early” promoters because they give rise to transcripts mainly utilizing a polyadenylation signal at nt 4368 for the expression of early genes. Transcripts from two “late” promoters, P_{7525} and P_{1225}, utilize two polyadenylation signals either at nt 4368 for expression of E1^E4 or at nt 7415 for expression of L1 and L2. The CRPV genome contains eight splice donor sites and four acceptor sites to produce more than twenty viral RNA isoforms and encode six early proteins and three late proteins. Like other low-risk HPVs, E6 and E7 transcripts are transcribed from two separate early promoters. A majority of the viral early transcripts are spliced once from nt 1371 to 3714 to express viral oncogenes E6 and E7. The late viral transcripts could be spliced either once for expression of E1^E4 and L2 or twice for L1.

Conclusions: The constructed CRPV transcription map in this study will enhance our understanding of papillomavirus gene expression and its contribution to papillomavirus pathogenesis.

Shift 02-182 / #1055

Poster Discussion
POSTER DISCUSSION - BASIC SCIENCE 03
04-20-2023 2:00 PM - 2:30 PM

HPV-16 MOLECULAR VARIANTS AMONG MEN ENROLLED IN THE HIM STUDY

Matthew Ferreira[1], Rossana Veronica Mendoza López[1], Milena Giulia Gonçalves[1], Silvaneide Ferreira[1], Bradley Sirak[2], Maria Luiza Baggio[1], Eduardo Lazcano[3], Alan Nyitray[4], Anna Giuliano[5], Luisa Villa[6], Laura Sichero[1]
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Introduction: High-risk human papillomavirus type 16 (HPV-16) variants are associated with varying carcinogenic potential as demonstrated for cervical cancer. HPV-16 causes 50% of penile cancers; however, in the male population, the natural history of specific HPV-16 variants has not been established. Our aim was to evaluate the prevalence and persistence of HPV-16 variants in the genitalia of men enrolled in the HPV Infection in Men (HIM) Study.

Methods: The HIM Study was a longitudinal, prospective study which included 4,074 men across the USA, Brazil, and Mexico followed-up for four years. Using PCR and sequencing, a fragment of the viral Long Control Region distinguished lineages and sublineages in HPV-16 positive external genital swabs and external genital lesion (EGL) swabs or biopsies. A and Non-A Lineage variants were analyzed according to prevalence and long-term persistence.

Results: 1,700 genital swabs from 753 HPV-16+ men were characterized according to HPV-16 lineages, and 22 EGL samples from 17 men. Significant differences in lineage prevalence were observed by country and marital status. Lineage A predominated among all variable categories; however, the prevalence of non-A lineages were heterogenous among the different populations. Lineage A infections were associated with a 169% increased risk of long-term genital HPV 16 persistence compared to Non-A Lineages. All penile intraepithelial neoplasia biopsies were positive for HPV 16 A-Lineage variants.

Conclusions: Conclusion: Data collected between lineages of these samples and those of comparable studies of the cervix suggest differences between the natural history of HPV-16 variant infections in external male genitalia and female genitalia.

Shift 02-204 / #677

Poster Discussion
POSTER DISCUSSION - CLINICAL SCIENCE 03
04-20-2023 2:00 PM - 2:30 PM

NONAVALENT HPV VACCINE TO INTERRUPT RECURRENT ANAL OR VULVAR HIGH-GRADE SQUAMOUS INTRA-EPITHELIAL LESIONS (VIVA TRIAL): A RANDOMIZED, DOUBLED-BLIND, PLACEBO-CONTROLLED TRIAL

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Introduction: The 9-valent human papillomavirus vaccine (9vHPV) protects against infection when administered to HPV-naïve individuals. Data suggesting a therapeutic benefit of the 9vHPV have been mixed. We investigated whether the 9vHPV reduces high-grade-squamous-intraepithelial lesion (HSIL) recurrences in unvaccinated persons previously treated for anal or vulvar HSIL.

Methods: We performed a randomized, double-blind, placebo-controlled trial in persons ages 27-69 years previously treated for anal or vulvar HSIL in Seattle, WA, and Birmingham, AL, USA. Eligible participants were HSIL-free at enrollment, confirmed by high-resolution-anoscopy (HRA) or vulvoscopy. Persons with well-controlled HIV infection were eligible to enroll. Participants received 9vHPV or placebo at 0, 2, and 6 months. Follow-up HRA/vulvoscopy was performed at months 18 and 36, and anal/vulvar swab was collected at months 0, 18, 24, and 36 for HPV DNA detection. The study's primary endpoint was histologically-confirmed HSIL recurrence in the intent-to-treat population, with secondary endpoints to assess HPV persistence (>2 consecutive positive swabs for the same 9vHPV-type) and vaccine safety.

Results: We randomized 187 participants with prior anal (104, 56%) or vulvar (83, 44%) HSIL of which 92 (45%) received 9vHPV and 95 (51%) placebo. Among the 181 participants included in the intention-to-treat analysis, the median age was 55 years, and 71 (39%) participants were living with HIV. After interim analysis, the study was halted due to futility in preventing HSIL recurrence. In 9v-HPV recipients, 15 had recurrent HSIL compared to 18 among placebo; incidence 9.1 versus 10.0/100 person-year; p=0.83. We found no differences in HSIL recurrences among vaccine versus placebo recipients by anatomical site or HIV status. HPV DNA persistence did not differ by study arm: 34% in 9vHPV versus 41% in placebo group (p=0.82). The 9vHPV was safe and well tolerated.

Conclusions: In persons with prior anal or vulvar HSIL treatment, 9vHPV vaccination failed to reduce HSIL recurrence and HPV DNA persistence.

Shift 02-205 / #734

Poster Discussion
POSTER DISCUSSION - CLINICAL SCIENCE 03
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APOLLO TRIAL: CHADOX1 AND MVA HETEROLOGOUS PRIME BOOST (VTP-200) IMMUNOTHERAPEUTIC IN LOW-GRADE HPV-RELATED CERVICAL LESIONS

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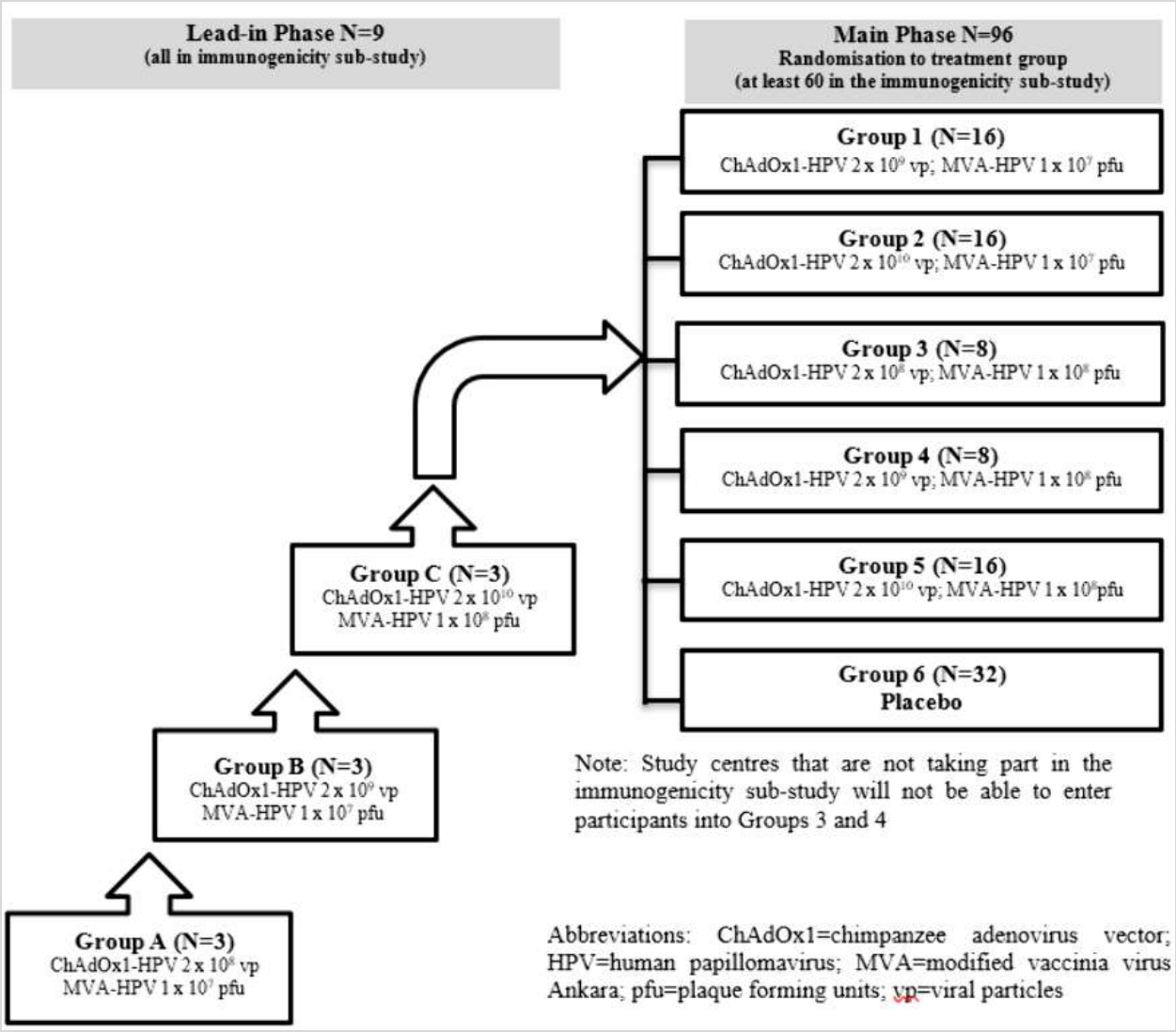
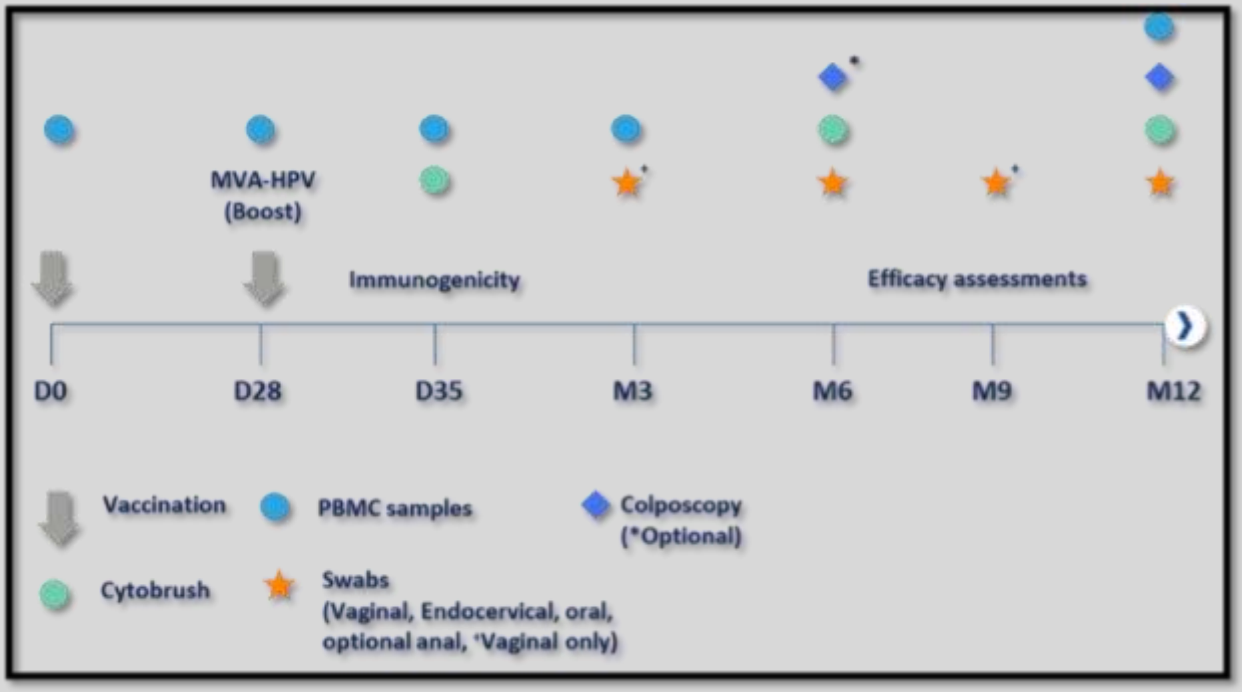
Introduction: Immunotherapeutics are a promising approach to establish the T cell immunity that appears central in clearance of persistent high-risk HPV infections. VTP-200 is a heterologous ChAdOx1-HPV prime and MVA-HPV boost regimen of two viral vectors that contain 59 conserved regions from all early proteins of 6 common high-risk HPV genotypes. The APOLLO trial is evaluating the safety, immunogenicity and efficacy of VTP-200 in participants with persistent cervical high-risk HPV (hrHPV) infection and coexisting low-grade (CIN1) cervical lesions, or HPV-related change only (LSIL/ASCUS).

Methods: The primary objective is to determine the safety and tolerability of VTP-200. The trial will also determine the effect on the hrHPV infection and lesion(s) as well as select the appropriate dose(s) for further development. Enrolment and analysis of all lead-in groups has completed (N=9), and the main phase enrolment is ongoing. The main phase is a blinded, randomised, placebo-controlled trial investigating 3 varying doses of ChAdOx1-HPV (Day 0) and 2 doses of MVA-HPV (Day 28), with a 12-month follow-up period (N=96, with 32 participants receiving placebo). The Main Phase Visit Schedule and Assessments are shown in figure 2. A protocol-specified interim analysis occurs when approximately 60 participants reach their 6-month
timepoint.


Lead-in Phase N=9
(all in immunogenicity sub-study)
Main Phase N=96
Randomisation to treatment group
(at least 60 in the immunogenicity sub-study)
Group 1 (N=16)
ChAdOx1-HPV 2 x 10^9 vp; MVA-HPV 1 x 10^7 pfu
Group 2 (N=16)
ChAdOx1-HPV 2 x 10^10 vp; MVA-HPV 1 x 10^7 pfu
Group 3 (N=8)
ChAdOx1-HPV 2 x 10^8 vp; MVA-HPV 1 x 10^8 pfu
Group 4 (N=8)
ChAdOx1-HPV 2 x 10^9 vp; MVA-HPV 1 x 10^8 pfu
Group 5 (N=16)
ChAdOx1-HPV 2 x 10^10 vp; MVA-HPV 1 x 10^8pfu
Group 6 (N=32)
Placebo
Group C (N=3)
ChAdOx1-HPV 2 x 10^10 vp
MVA-HPV 1 x 10^8 pfu
Group B (N=3)
ChAdOx1-HPV 2 x 10^9 vp
MVA-HPV 1 x 10^7 pfu
Group A (N=3)
ChAdOx1-HPV 2 x 10^8 vp
MVA-HPV 1 x 10^7 pfu
Note: Study centres that are not taking part in the immunogenicity sub-study will not be able to enter participants into Groups 3 and 4
Abbreviations: ChAdOx1=chimpanzee adenovirus vector; HPV=human papillomavirus; MVA=modified vaccinia virus Ankara; pfu=plaque forming units; vp=viral particles



Results: Safety, tolerability, and efficacy from the interim analysis of the main phase will be presented for participants who have reached the 6-month timepoint. Correlative immunogenicity (antigen-specific ELISpot to the six antigens [E1, E2, E4, E5, E6, E7] and flow cytometry ICS) will also be reviewed.

Conclusions: The success of immunotherapeutic administration is thought to depend on a T cell-inducing strategy. This clinical trial is evaluating the impact of a heterologous prime boost therapeutic vaccination strategy to induce such a response and thus to clear persistent cervical hrHPV infection and revert low-grade cervical lesions.

Shift 02-206 / #1425

Poster Discussion
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5-AZA-2'-DEOXYCYTIDINE TREATMENT IN COMBINATION WITH THE CYTIDINE DEAMINASE INHIBITOR TETRAHYDROURIDINE SIGNIFICANTLY IMPROVES SURVIVAL IN A PRECLINICAL MOUSE MODEL OF HPV-INDUCED CANCER

Lara Schlegel[1], Iris Martin[1], Hans-Jürgen Stark[1], Martin Kalteis[1], Ricarda Mehr[1], Günter Hämmerling[1], Nikolaus Von Knebel-Doeberitz[2], Yogen Saunthararajah[3], Magnus Von Knebel Doeberitz[1], Elena-Sophie Prigge[1]
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Introduction: Aberrant methylation of the HPV and the host genome is functionally associated with malignant transformation of HPV-infected cells. We are developing a novel treatment approach targeting this aberrant methylation using DNA methyltransferase inhibitors, such as 5-aza-2'-deoxycytidine (DAC). The achievement of therapeutically relevant plasma levels of DAC is challenged by the drug's instability in aqueous environments and degradation by the enzyme cytidine deaminase (CDA). Combined administration with the CDA inhibitor tetrahydrouridine (THU) can reduce degradation of DAC and may increase its therapeutic effect when applied systemically. In this study, we investigated if combinatory systemic administration of DAC and THU leads to prolonged survival in a mouse model of HPV-induced cancer.

Methods: Mice of the immune-deficient NSG strand were injected with CaSki cells and systemically treated on three consecutive days per week with PBS (control group), low-dose DAC of 0.1 mg/kg, or DAC 0.1 mg/kg+THU 10 mg/kg, until preset stopping criteria were reached. Endpoint analyses comprised survival, tumor size and biological treatment effects assessed in tumor tissue, focusing on cell death, senescence and differentiation.

Results: PBS-treated mice showed a median survival of 59 days, while mice of the DAC only-treated group survived significantly longer, demonstrating a median survival of 66 days. Mice treated with the combination of DAC+THU showed significantly prolonged survival compared to both PBS and DAC only groups, presenting a median survival of 98 days. Preliminary results from tumor tissue analyses further provided indications that DAC+THU treatment induced cell death and differentiation of tumor cells. No indications for clinical toxicity were observed in any of the DAC+THU-treated mice.

Conclusions: Our results indicate a biologically relevant treatment benefit and good tolerability of combinatory application of DAC and THU in a mouse model of HPV-induced cancer.

Shift 02-207 / #1664

Poster Discussion
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LOT-TO-LOT IMMUNOGENICITY CONSISTENCY OF RECOMBINANT HUMAN PAPILLOMAVIRUS BIVALENT (TYPES 16, 18) VACCINE (PICHIA PASTORIS) IN HEALTHY FEMALES: A PHASE III, RANDOMIZED, DOUBLE-BLIND STUDY

Min Ji[1], Ting Huang[2], Li Zhang[3], Youquan Liu[4], Linglin Zhang[2], Haiyang Qin[3], Zhijun Tan[5], Zhiwei Jiang[5], Yalin Hu[1], Qinying Lan[1], Huiyu Zhou[1], Ke Li[1], Bangwei Yu[1], Lin Yuan[6], Wei Li[7], Zhen Huang[8], Chenliang Zhou[1], Lingyun Zhou[1], Weijin Huang[3]
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Introduction: Availability of additional safe, effective, and affordable HPV vaccines would help addressing the HPV vaccine shortage. Here we aimed to demonstrate immunogenicity consistency between three industrial production lots of Walrinvax®, a new bivalent HPV Vaccine.

Methods: Participants aged 9-30 years were randomized 1:1:1:1 to receive 3 doses of the bivalent HPV vaccines of one of the three industrial lots and one clinical lot at 0, 2, and 6 months. Humoral immunogenicity was assessed pre-vaccination and 1 month post-third dose vaccination by pseudovirion-based neutralization assay. Lot-to-lot consistency was demonstrated if the 2-sided 95% confidence intervals of the geometric mean titer (GMT) ratio between all lot pairs were within [0.5, 2]. The criteria for non-inferiority of the pooled industrial lot to a clinical lot were in terms of difference in seroconversion rates (95% CI lower bound > -10%) and GMT ratios (95% CI lower bound > 0.5). Adverse events throughout the study were collected.

Results: Of the 1100 subjects enrolled, 1031 subjects (93.73%) completed the study. Humoral immune responses were robust and lot consistency among 3 industrial lots was demonstrated: GMT ratios for three pairs of industrial lots were 1.02, 0.77, and 0.76 for anti-HPV-16 antibodies and 0.99, 0.87, and 0.87 for anti-HPV-18 antibodies. The immunogenicity of the pooled industrial lot was noninferior to the clinical lot as both seroconversion rate and GMT ratio meeting the predefined immunological criteria. The incidence of solicited symptoms, unsolicited AEs and SAEs was comparable between all lots. No vaccine-associated serious adverse events were reported during the study.

Conclusions: Lot consistency between the three industrial lots and the non-inferiority of the pooled industrial lot to the clinical lot were demonstrated among healthy females aged 9-30 years with a clinically acceptable safety profile (NCT04965350).

Posters Viewing - Shift 1

Shift 01-001 / #489

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-18-2023 7:00 AM - 5:00 PM

GLOBAL EPIDEMIOLOGIC PATTERNS OF OROPHARYNGEAL CANCER INCIDENCE

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Introduction: Oropharyngeal cancer (OPC) has a complicated epidemiology due to its dependence on three primary environmental etiologic factors: tobacco, alcohol, and oral HPV infection. Given the broad international variation in trends and prevalence of these factors across the world, we examined global trends in the incidence of OPC in men and women internationally.

Methods: Cancer incidence data during the 20-year period 1993-2012 from 43 countries spanning 6 continents was obtained from the Cancer Incidence in Five Continents database Volumes V-XI. Trends in OPC were compared to head and neck cancers in sites not associated with HPV and lung squamous cell carcinoma (SCC) using age-period-cohort modeling across countries and sexes.

Results: OPC incidence significantly increased in 19 and 23 countries in men and women, respectively, compared to significant decreases in only 2 countries for men 3 countries for women. The annual rate of OPC increase was more than 3% per year in the majority of countries with increasing OPC incidence. Strong birth cohort effects were observed for men, and increased OPC incidence was observed for patients aged 45 and older in most countries. By contrast, in the 20 countries where OPC incidence increased for women that were analyzable by age-period-cohort modeling, 10 had no significant difference in OPC and lung SCC net drifts. A moderate correlation was seen with a country's Human Development Index and rate of OPC increase, somewhat weaker in men ($R=0.33$, $P = 0.05$) than in women ($R=0.58$, $P < 0.001$).

Conclusions: OPC continues to increase internationally in both sexes. In men, this increased incidence is seen throughout middle and older age and is likely driven entirely by HPV, given the incidence of lung cancer is stable or decreasing in all countries with rising OPC incidence. In women, more complex patterns were observed, suggesting varied and complex interplay of risks factors .

Shift 01-002 / #583

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
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ASSESSING THE IMPACT OF STUDENT PHARMACISTS-RUN EDUCATIONAL OUTREACH ON AWARENESS OF PAP SMEAR AND HPV VACCINES AMONG URBAN WOMEN OF KARACHI, PAKISTAN

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Introduction: Every year, half a million women are diagnosed with cervical cancer. It is third most common type of cancer among women, according to the National Cancer Institute (NCI). Human papillomavirus (HPV) is the causative agent and considered to be a health burden. We assessed the effect of educational activity regarding awareness of PAP smear and HPV vaccinations among urban women of Karachi, Pakistan.

Methods: A descriptive, cross-sectional study was conducted among 150 women. Female patients of age ≥40 years were recruited for study purpose after obtaining the informed consent. The pre-seminar data was collected on a structured questionnaire by pharmacists' student (Volunteer). After that, a two-hour seminar was conducted that focused on PAP smear and HPV vaccination and its benefits. Later, post seminar data was collected and analyzed using JMP Pro 16 software.

Results: Before, presentation, the Pre-seminar data showed that there was no awareness regarding PAP smear test and frequency of HPV vaccination and its benefits. The age range of patients was from 40 to 60 years with 2 co-morbid conditions. The response rate was 60-75% regarding fear of pain for PAP smear test. The HPV vaccination is not available and last stage of treatment was also one of pre-assessment reason. After seminar, the statistical significance was noted i.e., $p>0.001$ between age and planning PAP smear test within 6 months.

Conclusions: A positive impact was noticed with statistically significance in terms of level of knowledge regarding PAP smear test and HPV vaccination. Moreover, the awareness sessions/seminars are highly recommended educational activities that can be conducted on mass level to aware the people. We concluded that, a strong collaboration between educational health campaigns and community is the required to identify, and address the barriers i.e., knowledge, awareness and access to health resources among communities at individual level specifically for the diseases like cervical cancer.

Shift 01-003 / #584

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
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ASSESSING THE IMPACT OF STUDENT PHARMACISTS RUN EDUCATIONAL OUTREACH ON AWARENESS OF CERVICAL CANCER AMONG URBAN WOMEN OF KARACHI, PAKISTAN

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Introduction: Cervical cancer is the fourth most common cause of cancer globally, and one of major public health problems in terms of mortality in women throughout the world. In Pakistan, cervical cancer is the second most common cancer in women. Due to cervical cancer, twenty women were died each day in Pakistan, which ranks among top 10 countries in terms of mortality. We aimed to assess the effect of student pharmacists run educational outreach on awareness of cervical cancer in women of urban areas of Karachi, Pakistan.

Methods: We trained a group of 10 student pharmacists to perform awareness of cervical cancer educational sessions. A descriptive cross-sectional study was designed. We recruited 150 participants from different hospitals of Karachi, Sindh, Pakistan. The pre and post questionnaire was administered to assess the effect of educational activity by student pharmacists through presentation about cervical cancer. The data was assessed by using JMP Pro 16 software.

Results: Out of 150 participants, the mean age was 52+7.7 years. Majority of participants were either illiterate or literate up to 5th grade (percent illiterate). Before the educational intervention, 81% of women had no awareness about cervical cancer. All women were not aware about the symptoms and early treatment of cervical cancer. After education activity by student pharmacists, a drastic change was noted in awareness of cervical cancer among recruited samples. More than 70% responded that were aware about cervical cancer prevention, and its treatment options. JMP software statistical analysis showed the significant relevance of level of knowledge of cervical cancer i.e. $p<0.05$.

Conclusions: The educational activity clearly reflects the improvement of awareness of cervical cancer. Overall confidence level was also improved to discuss the signs and symptoms with female student pharmacists. These types of activities will help to diagnose cervical cancer at an early stage that can decrease rate of mortality.

Shift 01-004 / #622

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
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AWARENESS OF HUMAN PAPILLOMAVIRUS AND ACCEPTABILITY OF THE VACCINE AMONG WOMEN IN PALESTINE: IS IT TIME FOR POLICY ADJUSTMENT?

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Introduction: Progress has been made in the reduction of morbidity and mortality of cervical cancer by the implementation of HPV vaccination programs. This study aimed to assess the awareness of Palestinian women about HPV as well as their knowledge and acceptability of the HPV vaccine and to examine the factors associated with good awareness.

Methods: This was a national cross-sectional study. Adult women were recruited from hospitals, primary healthcare centers, and public spaces in 11 Palestinian governorates using convenience sampling. A structured questionnaire was used for data collection. For each correctly answered question, one point was given. The total score was calculated and categorized into poor (0 to 10) and good awareness (11 to 21).

Results: The questionnaire was completed by 7223 women out of 8086 who were approached (response rate=89.3%). A total of 7058 questionnaires were included in the final analysis; 4403 from the West Bank and Jerusalem (WBJ) and 2655 from the Gaza Strip. Only 33 women (0.5%) displayed good awareness of HPV and its vaccine with 0.7% of women from WBJ and only 0.2% of women from the Gaza Strip. Completing post-secondary education, being employed or a student, and having a higher monthly income were associated with an increase in the likelihood of good awareness. Among women who had heard of HPV, only 46 women (8.9%) reported familiarity with its vaccine. Women from the WBJ were more likely than women from the Gaza Strip to have heard about the HPV vaccine (0.9% vs. 0.2%). Most women

agreed to receive the HPV vaccine themselves or for their daughters if it was given without cost or with a co-
payment.

Table: Awareness of human papillomavirus among study participants who heard of it.

Question	Total (n= 571)	Gaza Strip (n= 232)	WBJ (n= 339)	p-value
Mode of transmission				
Airborne infection	29 (5.1)	12 (5.2)	17 (5.0)	0.99
Blood transfusion	116 (20.3)	39 (16.8)	77 (22.7)	0.09
Contaminated food	16 (2.8)	10 (4.3)	6 (1.8)	0.12
Sexually	95 (16.6)	26 (11.2)	69 (20.4)	0.004
Mother to newborn	53 (9.3)	10 (4.3)	43 (12.7)	<0.001
Others	17(2.9)	8 (3.4)	9 (2.7)	0.62
HPV can infect				
Males	9 (1.6)	3 (1.3)	6 (1.8)	0.93
Females	141 (24.7)	57 (24.6)	84 (24.8)	
Both	355 (62.1)	147 (63.3)	208 (61.3)	
Do not know	66 (11.6)	25 (10.8)	41 (12.1)	
Heard about any relation between HPV and any type of cancer	214 (37.5)	77 (33.2)	137 (40.4)	0.09
Type of cancer caused by HPV*				
Cervical cancer	107 (50.0)	23 (29.9)	84 (61.3)	<0.001
Skin cancer	3 (1.4)	0	3 (2.2)	0.55
Penile cancer	2 (0.9)	0	2 (1.5)	0.54
Incorrect answers	89 (41.6)	49 (63.6)	40 (29.2)	<0.001
Do not know	25 (11.7)	8 (10.5)	17(12.4)	0.83

n= number of participants, WBJ= West Bank and Jerusalem, HPV = human papillomavirus.

* The denominator is the number of participants who recognized a relation between human papillomavirus and any type of cancer.
Data are presented as frequencies and percentages.

Table: Awareness of human papillomavirus vaccine among study participants who heard about it.

Question	Total (n= 46)	Gaza Strip (n= 6)	WBJ (n= 40)	p-value
Age at which HPV vaccine is first given				
Correct answers	19 (41.3)	1 (17.0)	18 (45.0)	0.38
Incorrect answers	27 (58.7)	5 (83.0)	22 (55.0)	
Number of HPV vaccine doses that should be taken				
Correct answers	24 (52.1)	4 (67.0)	20 (50.0)	0.67
Incorrect answers	22 (47.9)	2 (33.0)	20 (50.0)	
HPV vaccine can be given to				
Males	0	0	0	0.050
Females	19 (41.3)	0	19 (48.0)	
Both	25 (54.3)	6 (100.0)	19 (48.0)	
Do not know	2 (4.4)	0	2 (4.0)	
HPV vaccine is a part of the Palestinian Ministry of Health vaccination program				
No	14 (30.4)	4 (66.0)	10 (25.0)	0.22
Yes	15 (32.6)	1 (17.0)	14 (35.0)	
Do not know	17 (37.0)	1 (17.0)	16 (40.0)	
HPV vaccine can help to protect against cervical cancer				
No	2 (4.4)	0	2 (5.0)	0.99
Yes	44 (95.6)	6 (100.0)	38 (95.0)	
Do not know	0	0	0	

n= number of participants, WBJ= West Bank and Jerusalem, HPV= human papillomavirus.
Data are presented as frequencies and percentages.

Table: Acceptability for the receipt of human papillomavirus vaccine among study participants who heard of it.

Question	Total (n= 46)			Gaza Strip (n= 6)			WBJ (n= 40)			p-value
	Disagree	Not sure	Agree	Disagree	Not sure	Agree	Disagree	Not sure	Agree	
Would you like to receive the HPV vaccine if given for free?	1 (2.2)	4 (8.7)	41 (89.1)	0	1 (17.0)	5 (83.0)	1 (3.0)	3 (8.0)	36 (89.0)	0.52
Would you like to receive the HPV vaccine if you will have to pay for it?	4 (8.7)	3 (6.5)	39 (84.8)	1 (17.0)	0	5 (83.0)	3 (8.0)	3 (8.0)	34 (84.0)	0.65
Would you like your (future) daughters to receive the HPV vaccine if given for free?	1 (2.2)	3 (6.5)	42 (91.3)	0	1 (17.0)	5 (83.0)	1 (3.0)	2 (5.0)	37 (92.0)	0.44
Would you like your (future) daughters to receive the HPV vaccine if you will have to pay for it?	1 (2.2)	5 (10.8)	40 (87.0)	0	1 (17.0)	5 (83.0)	1 (3.0)	4 (10)	35 (87.0)	0.59

n= number of participants, WBJ= West Bank and Jerusalem, HPV= human papillomavirus.
Data are presented as frequencies and percentages.

Conclusions: The overall awareness of HPV and its vaccine was extremely low. Inclusion of the HPV vaccine in the national immunization program could change this, especially as the HPV vaccine appeared to be acceptable.

Shift 01-005 / #671

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
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IMPLEMENTATION OF EXTREME LEARNING MACHINE ALGORITHM ON CERVICAL CANCER CLASSIFICATION

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Introduction: Cervical cancer is the second most common cancer in Indonesia after breast cancer. The number of deaths from cervical cancer in Indonesia continues to increase every year due to delays in diagnosis and examination. To detect cervical cancer, laboratory examinations can be carried out using the Visual Inspection with Acetic Acid method or a pap smear which requires the knowledge of an internal medicine specialist as well as several considerations of features to get an accurate diagnosis. Sometimes, the way doctors analyze features from one another produces different results. Therefore, it is necessary to have a classification process to make a diagnosis of cervical cancer with high accuracy results so that it is expected to be able to equalize the results of the diagnosis from medical personnel.

Methods: This study uses cervical cancer risk classification data available on the Kaggle website published by Fernandes, K., J.S. Cardoso, and J. Fernandes in 2017 with feature selection based on expert interviews. This study uses the Extreme Learning Machine algorithm in conducting the classification process and measuring the results of the algorithm's performance with the accuracy value of the confusion matrix calculation.

Results: The highest average accuracy in testing the value of many hidden neurons is with 11 hidden neurons which produce an accuracy of 91.88%. The highest average accuracy in testing the activation function is the binary sigmoid function with an accuracy value of 92.12%. The highest accuracy in testing training data and testing data with k-fold cross validation is in the first fold which produces 92% accuracy.

Conclusions: The classification of cervical cancer with the Extreme Learning Machine Algorithm can be said to be successful because it produces optimal parameters and a high enough accuracy exceeding 90%. However, further research and development are needed to produce higher accuracy.

Shift 01-006 / #749

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-18-2023 7:00 AM - 5:00 PM

THE SOCIAL AND ECONOMIC IMPACT OF A CERVICAL CANCER DIAGNOSIS ON WOMEN AND CHILDREN IN UGANDA

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Introduction: There is a need for more research on the social and economic impacts of cervical cancer in LMICs in order to provide evidence for expanded cervical cancer screening programs. The goal of this study is the understand the economic impact of cervical cancer on women and children in Uganda.

Methods: Data collection for this study began in September and will continue until December 2022. Participants were recruited by nurses at two clinics at the Uganda Cancer Institute in Kampala and Jinja. Descriptive statistics using counts and frequencies were used to describe primary outcomes which include changes in a child's education and a family's economic status.

Results: To date 19 participants have completed the survey and 17 indicated that they had children. The mean age of participants is 48 years. The majority of participants are married, have a primary school education or less, and were diagnosed with stage I or stage III cancer. In all, 35% (5/14) of women indicated that they cut down on food consumed and withdrew their child from school to help pay for cancer care. Furthermore, 69% (9/13) of women noted that they took time off work to attend the clinic today. When asked how their diagnosis impacts their children, 63% (10/16) indicated that their children had missed school this month and 60% (6/10) of children had to seek out employment.

Conclusions: We found that a cervical cancer diagnosis has an impact not only on women, but their children as well, confirming that while largely preventable, cervical cancer has far-reaching impact beyond the woman diagnosed. The results of this study can be used to provide further evidence of the urgent need to expand cervical cancer screening programs not only in Uganda, but similar countries as well. This in turn will help contribute to the eventual global elimination of cervical cancer.

Shift 01-007 / #773

Poster Viewing
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CLINICAL OUTCOMES OF PATIENTS DIAGNOSED WITH CERVICAL CANCER IN CAMEROON BAPTIST CONVENTION HEALTH SERVICES (CBCHS) BETWEEN 2013-2018

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Introduction: Cervical cancer ranks the fourth most frequently diagnosed cancer and the fourth leading cause of cancer-related deaths among women globally. In LMIC like Cameroon, patients are mostly diagnosed at an advanced stage, women have limited access to proper diagnosis and treatment, a prolonged waiting time during treatment especially due to limited radiotherapy machines and services.

Methods: Data from the Women's Health Program (WHP) , Cameroon Baptist Convention Health Services (CBCHS) database was extracted and analyzed. Cervical cancer clinical outcomes were categorized as alive with disease, alive without disease or dead . Cox regression model for survival analysis was used to determine the impact of some variables on the mean time of patient survival after diagnosis.

Results: Between 2013 and 2018, 752 women were diagnosed with cervical cancer. The average age at diagnosis was 53.33 (+/-13.822). The overall survival for women diagnosed with cervical cancer was 27.1%. 285(37.5%) of cases diagnosed did not go in for treatment while (387 (51.5%)) went in for treatment, including 205 who did not complete their treatment. Age at diagnosis was significantly associated with a lower survival hazard ratio 1.007 (95% CI(1-1.013), p value of 0.035). a positive HIV status (p value of 0.558, hazard ratio 1.032(95%CI(0.930-1.145) p value of 0.558), and histologic subtype of adenocarcinoma (, hazard ratio of 1.026(95% CI(0.705-1.493), p value 0.894) were associated with lower survival, although these associations were not statistically significant.

Conclusions: Cervical cancer remains a serious public health threat to women especially in LMIC like Cameroon where screening coverage is still extremely low. Survival from the disease is extremely poor in this country, consistent with data from other LMICs. Most cases present late with symptoms and very few can afford recommended treatment. Education, awareness creating, support and funding are necessary to strengthen cervical cancer control in Cameroon.

Shift 01-008 / #824

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
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METHIS - MODELLING TOOLS FOR HPV INFECTION-RELATED CANCERS

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Introduction: For years the International Agency for Research on Cancer (IARC) has been supporting public-health stakeholders world-wide with context-specific fieldwork and model-based projections to inform cervical cancer control policies. IARC has also played a crucial role in transferring knowledge and technology from high-resource settings, with access to cutting-edge expertise, to low-resource settings, with the largest cervical cancer burden. Among other initiatives, IARC aims at delivering an open-source modelling platform, named METHIS, which can be adopted, and further utilized, by local policy makers to inform sustainable cervical cancer control policies.

Methods: We developed, tested, and validated 5 predictive tools, 2 HPV transmission and 3 cervical cancer progression models. Since there is an intrinsic trade-off between data availability (model's inputs) and prediction flexibility (model's outputs), the platform allows for algorithms with an increasing range of complexity to match datasets available in each context. Currently, we are working on integrating and documenting these models into a modular platform flexible enough to be used in most low- and middle-income countries.

Results: Each model has been successfully used to draw predictions. For example, the HPV transmission models, RHEA (population-based model) and EPIMETHEOS (agent-based model) have been recently used to assess the impact of HPV vaccination in settings where sexual behavior is rapidly changing and the expected impact and cost-effectiveness of single-dose vaccination in India. The progression models ATLAS and PANDORA have been used to estimate the country-specific burden of expected and preventable cervical cancers among girls born between 2005 and 2014 and to predict cohort-specific cervical cancer incidence from population-based surveys of HPV prevalence. The agent-based progression model PROMETHEOS is designed to devise risk-stratified cervical cancer screening programs worldwide.

Conclusions: Based on recent publications and ongoing activities, we will illustrate the overarching design of METHIS and the specificities of each model contributing to the platform.

Shift 01-009 / #825

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
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COUNTRY-SPECIFIC IMPACT OF CERVICAL CANCER ELIMINATION ON MORTALITY: A MODELLING STUDY

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Introduction: In 2020, in its strategy to eliminate cervical cancer, the WHO set an elimination threshold at 4 cases per 100,000 women-years. Aspirational targets such as 90% HPV vaccination coverage were proposed. Here, we assessed avoidable mortality through HPV vaccination in countries aiming at cervical cancer elimination.

Methods: We used the GLOBOCAN-2020 database and ATLAS model to predict the number of country-specific cervical cancer cases and deaths expected and avoidable through vaccination in cohorts born between 2006 and 2010. Predictions were obtained assuming constant cancer incidence and mortality, and 100% vaccine effectiveness with the different valency vaccines.

Results: Adding the 2- or 4-valent vaccine to the current cervical cancer control practices would prevent 2.8 million deaths but only 78 (42%) of the 185 countries studied are expected to reach the elimination threshold by the end of the century. Switching to the 9-valent vaccine would help 68 (37%) additional countries reach the threshold, preventing 726,050 deaths. For the 39 remaining countries, even the highest possible impact of the 9-valent vaccine would not be sufficient to reach the threshold. Nevertheless, these countries would still see a reduction in mortality from 1.4 to 0.2 million (85%) expected deaths. Worldwide, the highest possible impact with the 9-valent vaccine would avoid 3.5 million deaths attributable to cervical cancer in cohorts born between 2006 and 2010.

Conclusions: Optimal impact of 2- or 4-valent vaccination is expected to substantially decrease cervical cancer mortality worldwide, despite whether countries are expected to reach the elimination threshold or not. Shifting from 2- or 4-valent to 9-valent vaccine would almost double the number of countries reaching the elimination threshold and avoid a greater number of deaths. However, as optimal vaccine coverage is difficult to achieve, an integrated approach to vaccination and screening is essential.

Shift 01-010 / #1243

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
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PERCEPTIONS OF A COMBINED STRATEGY OF HPV VACCINATION AND CERVICAL CANCER SCREENING AMONG MEXICAN WOMEN IN THE FASTER TLALPAN STUDY: A QUALITATIVE STUDY.

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Introduction: HPV-FASTER is an innovative public health intervention combining HPV vaccination and hrHPV based screening. We adapted the HPV-FASTER strategy to the urban-rural borough of Tlalpan, Mexico City and conducted a clinical trial for eligible women aged 25-45 years in primary-care clinics with the goal of mitigating the burden of cervical cancer. Here, we sought to understand women's perceptions about FASTER-Tlalpan to make recommendations for future implementation and scaling-up into routine health services.

Methods: We conducted semi-structured interviews about barriers and facilitators to potential participation in the combined strategy among 14 participants in FASTER Tlalpan. We used grounded theory analysis with the constant comparative method, as well as the socioecological model to understand perceptions and determinants of participation.

Results: Intrapersonal barriers to participation in the program included the belief that only younger women are at risk for HPV, shame about the exam, and lack of time/interest; facilitators were information, perceived time saved, peace of mind over health status, conceptions of self-esteem, perceived severity of cervical cancer, and self-efficacy in relation to HPV/cervical cancer healthcare use. Interpersonal barriers were experiences of stigma and prejudice, and lack of support from partners, facilitators were family encouragement and testimonies from peers. Institutional barriers were lack of infrastructure and inconvenient hours at the clinic, clinic distance, perceived time burden, and low quality of care from providers (e.g., uninterested, not providing information/counseling), facilitators included, good care by healthcare personnel (e.g., communicating in plain language), including partners in the program, and phone reminders. Community facilitators included openness to participate. Public policy facilitators included information campaigns, procedures available for free, and financial resources to increase program access.

Conclusions: Our findings point to significant barriers which need to be addressed and facilitators which can be leveraged for scaling up of the combined strategy in other settings in Mexico.

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Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
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INTRODUCING THERMAL ABLATION TO A PUBLIC CERVICAL CANCER SCREEN-AND-TREAT PROGRAM IN EL SALVADOR

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Introduction: El Salvador is among the first low-and-middle-income countries (LMICs) to adopt a HPV screen-and-treat program. Treatment relies on gas-based cryotherapy, but the World Health Organization endorsement of thermal ablation (TA) has increased interest in this technology. Unlike cryotherapy, TA does not require gas and there are now portable models in the market. El Salvador solicited and received a donation of 70 TA units from international agencies. Our team worked in collaboration with the Ministry of Health (MoH) to devise a TA training plan for the screen-and-treat program.

Methods: Ongoing training started in September 2022 in the metropolitan region of San Salvador where MoH providers were still naïve to the screen-and-treat program. We devised a 2-part approach consisting of 1) a “train the trainer” component where 5 MoH physicians were trained by a gynecologist with extensive experience on cryotherapy and TA, and 2) a curriculum for the MoH physicians and nurses who would implement the program. This consisted of a one-day theoretical component to introduce the equipment and allow practice on anatomical models, followed by clinical practicum where trainee physicians were required to complete 20 cryotherapy and 20 TA treatments under trainer supervision.

Results: To date, the training has reached 15 program centers, each staffed by 1 physician and 2 nurses. The theoretical component has been delivered as a group session to all 45 providers. Individual trainers were assigned to specific clinics and were able to complete the clinical practicum at each one in 3-4 days. All 15 centers have now using both cryotherapy and TA to treat patients.

Conclusions: The introduction of TA in El Salvador was made possible by collaboration between international agencies, a non-profit organization, and the Ministry of Health. Leveraging multi-actor partnerships can be instrumental in successfully increasing access to new technology in LMICs.

Shift 01-013 / #1491

Poster Viewing
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THE SENEGAL SOCIETY OF COLPOSCOPY AND PATHOLOGY RELATED TO PAPILLOMAVIRUS A SOLDIER ENGAGED IN THE FIGHT AGAINST HPV

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Introduction: Senegal, like the international community, has declared war on the papillomavirus. And our first fight is for the elimination of cancer of the cervix which constitutes the first female cancer (17.1% of cancers of all sexes combined and 26.8% of cancer cases in women) with 1917 new cases in 2020 and 1312 deaths, i.e. nearly 70%. The Senegalese Society of Colposcopy and Papillomavirus Pathology (SSCPP) was founded on May 15, 2021 with a triple vocation of research, teaching and community support. Very quickly we responded to the call of the WHO to participate in the effort to eliminate cervical cancer.

Methods: Various activities 丨 Advocacy 丨 Awareness 丨 Strengthening the skills of health personnel 丨 Care offer 丨 Scientific Meetings

Results: 丨 Officialization of the company 丨 First symposium 丨 Days of screening and treatment of precancerous lesions of the cervix 丨 International Human Papillomavirus Awareness Day Campaign 丨 press conference 丨 04 TV shows 丨 05 radio broadcasts 丨 10 Interviews 丨 10 Websites 丨 Social networks Twitter, hinstagram, facebook, whatapps 丨 100 engagement videos 丨 1000 children reached 丨 2000 T-shirts 丨 500 caps 丨 300 Gadgets

Conclusions: The SSCPP is a young, dynamic African learned society committed to achieving the WHO objectives for the elimination of cervical cancer and participating in the ideal launched in 2022 by the IPVS "ONE LESS WORRY"

Shift 01-014 / #1518

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
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DEVELOPMENT , IMPLEMENTATION, AND EVALUATION OF A DISTANCE LEARNING AND TELE-MENTORING PROGRAM FOR CERVICAL CANCER PREVENTION

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Introduction: Although Africa has the highest burden of cervical cancer in the world, educational resources to achieve the 90-70-90 targets set by the WHO in its strategy to eliminate cervical cancer are lacking in the region.

Methods: We implemented and evaluated an e-learning tool modeled on the Project ECHO (extension for community healthcare outcomes), for cervical cancer prevention in Africa. Through an online survey administered in 2021, we assessed providers' knowledge and practices regarding cervical cancer prevention and control; and compared them among respondents who had attended these ECHO sessions (prior ECHO attendees) with those who had not but were planning on attending in the near future (newcomers). We also evaluated satisfaction of prior ECHO attendees.

Results: Of the 75 survey respondents, 41 (54.7%) were prior ECHO attendees, and 46 (65.7%) were female. Overall, the rate of providers who reported performing cervical cancer screening with VIA/VILI, HPV testing, and cervical cytology in their practice was 50%, 46.3% and 30.3%, respectively. One quarter reported performing cryotherapy (25.4%), thermal ablation (27.3%) or LEEP (25.0%) for treatment of pre-invasive disease. Knowledge about cervical cancer education, prevention and management procedures was satisfactory in 36.1% of respondents; this proportion was significantly higher ($p<0.001$) among prior ECHO attendees (53.8%), compared to newcomers (4.5% (0.0 – 13.5)). Two thirds (68.8%) reported that they had applied knowledge learned in our ECHO sessions to patient care in their practice, or adopted best-practice care through their participation in this ECHO program.

Conclusions: This e-learning and tele-mentoring program contributed to improved skills for providers and enhanced quality of care for patients. In the COVID-19 era and beyond, reinforced efforts to strengthen cervical cancer knowledge and best practices through distance learning are needed.

Shift 01-015 / #1719

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
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ROADMAP FOR HPV VACCINE INTRODUCTION FOR PREVENTION OF CERVICAL CANCER WHILE CONTINUING PROVISION OF CARE IN PAKISTAN

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Introduction: Background: Pakistan has a population of 68.6 million women > 15 years who are at risk of developing cervical cancer caused by human papilloma virus. Current estimates indicate that every year almost 5000 Pakistani women are diagnosed with cervical cancer and more than 3000 women die from the disease. Cervical cancer ranks as the 3rd most frequent cancer among women in Pakistan and the 2nd most frequent cancer among women between 15 and 44 years of age. As such, Jhpiego Pakistan supported Pakistan's Expanded Programme on Immunization (EPI) to develop a roadmap for elimination of cervical cancer with an aim to introduce HPV Vaccination by 2024.

Methods: A landscape analysis was conducted by Jhpiego Pakistan in collaboration with Expanded Programme on Immunization (EPI) by interviewing group of experts, policy makers, national and sub-national consultations and literature review, to outline the process around cervical cancer elimination and introduction of HPV vaccination in Pakistan.

Results: After in-depth discussions with experts and policy makers a roadmap was developed for cervical cancer prevention which includes estimate disease burden, advocacy for national policy formulation, issues assessment, operationalization, HPV vaccine introduction, resources mobilization, strengthening health systems and national institutional capacity, community awareness and advocacy. A detailed costing analysis on vaccine introduction was also conducted by IVAC for three different scenarios; 1) vaccine introduction through campaign targeting 9-15-year girls, 2) immunizing 9-year girls through routine immunization and 3) reaching 9 year girls through campaign once a year. Cost was calculated for all the available HPV vaccines.

Conclusions: Conclusion: Pakistan is a high burden country for women cancers. As such, there is a need to institutionalize women cancer registry for cancer surveillance and plan for implementation of roadmap for cervical cancer elimination and HPV introduction.

Shift 01-016 / #537

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

RECENT CLEARANCE, PERSISTENT, AND INCIDENT HPV INFECTION INCREASES THE RISK OF HIV ACQUISTION IN WOMEN IN EASTERN AND SOUTHERN AFRICA

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Introduction: While some studies have identified an association between HPV infection and HIV acquisition, findings have been mixed. Specifically, data on HPV clearance, which is postulated to increase HIV risk by increasing the number of HIV target cells, are limited. We evaluated associations between HPV clearance, incidence, prevalence, and persistence, and HIV acquisition among women participating in MTN-020/ASPIRE, conducted in Malawi, South Africa, Uganda, and Zimbabwe.

Methods: Using a case-cohort design, we included participants aged 18-44 who acquired HIV during enrollment in the ASPIRE trial (N=125 cases) and sampled cohort participants matched by site and age group (N=335 non-cases). Cervicovaginal swabs, collected quarterly before HIV seroconversion (cases) or a proxy seroconversion visit (non-cases), were tested for HPV DNA. Logistic regression analyses accounted for sampling weights and adjusted for demographics, sexual behaviors, and a history of STIs. Participants positive for each HPV exposure (Figure 1) associated with nonavalent vaccine-containing types were compared with HPV negative participants and assessed for the odds of predicting HIV acquisition. Exploratory analyses evaluated low-risk (LR), high-risk (HR), bivalent, and any HPV types separately.

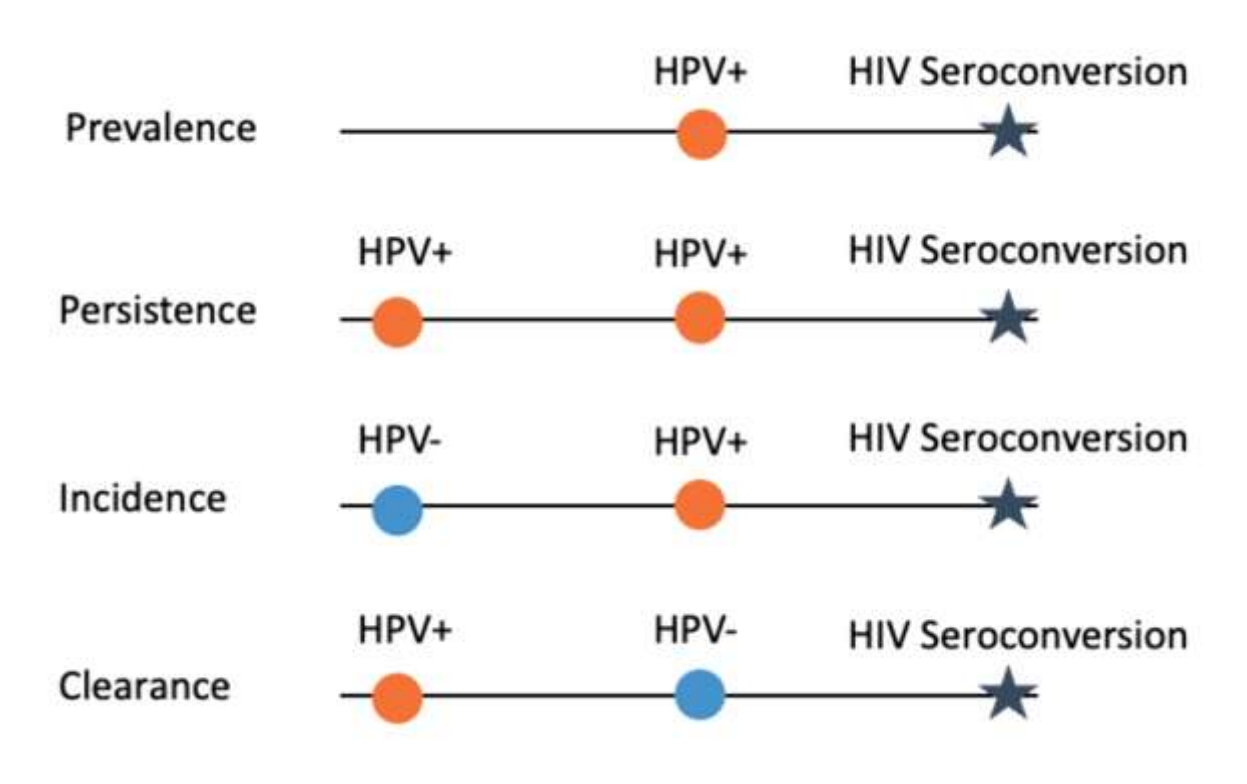

FIGURE 1. Definitions of HPV exposure. Prevalence estimates required one cervicovaginal swab before seroconversion while persistence, incidence, and clearance required two quarterly swabs.

Results: Risk of HIV acquisition increased with prevalence (aOR 1.77 [1.14-2.77]) and persistence (aOR 3.26 [1.84-5.80]) of nonavalent vaccine types. The odds of HIV acquisition was greatest for a recent clearance of HPV (aOR 3.79 [2.01-7.15]). Incident HPV infection was also significantly associated with HIV acquisition (aOR 2.49 [1.35-4.61]). Results for any, LR, HR, and bivalent vaccine HPV types showed similar associations.

Conclusions: HPV infections, including incident, persistent, prevalent, and recently cleared, are strongly associated with HIV acquisition in women in eastern and southern Africa. High-coverage prophylactic HPV vaccination has potential to decrease the burden of HPV infection and infection sequelae including HIV acquisition.

Shift 01-017 / #679

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

RELATIONSHIP BETWEEN METABOLIC SYNDROME AND CERVICAL PRECANCEROUS LESIONS IN A SOUTH KOREA NATIONAL POPULATION

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Introduction: Several epidemiologic studies have suggested an association between metabolic syndrome (MetS) and cervical cancer. Epithelial cell abnormalities proved by Pap smear suggest lesions that may progress to cervical cancer or be diagnosed as cervical cancer.

Methods: We performed a case-control study using data from the National Health Screening Programs according to the Health Insurance System of South Korea between 2009 and 2017. Among the data, women who had undergone Pap smear screening were selected, and data from women who had previously been diagnosed with cervical cancer were excluded.

Results: In women who underwent Pap smear during this period, negative results for intraepithelial lesion or malignancy were observed in 8,606,394 tests (controls), and epithelial cell abnormalities were observed in 580,012 tests (cases, 6.3% of the total tests). Among them, 21.7% of cases and 18.4% of controls met the MetS criteria (P <0.0001). In logistic regression analysis, it was analyzed that the increased odds of epithelial cell abnormalities in women with MetS was 1.23 (95% CI 1.22 – 1.24, P <0.0001).

Conclusions: In this study which analyzed through the results of the National Health Screening Programs in South Korea, women with MetS had an increased odds of developing epithelial cell abnormalities. Thus, the importance of regular Pap smear in these populations would be further encouraged.

Shift 01-018 / #723

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
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PROSPECTIVE EVIDENCE FOR REGRESSION OF UNTREATED HISTOLOGIC HSIL IN ESTAMPA

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Introduction: Histologic cervical HSIL is considered a precancerous lesion and is usually treated to prevent potential progression to invasive cancer. However, it is not possible to accurately predict which HSILs will progress, persist, or regress. We aimed to estimate the regression rate of HSIL in cervical biopsies diagnosed as ≤CIN1 by local pathology but upgraded to HSIL after central pathology review in ESTAMPA.

Methods: In ESTAMPA, women aged 30-64 years were screened with HPV and cytology and referred to colposcopy (with biopsy as appropriate) if any result was positive. Those locally diagnosed as ≤CIN1 were recalled for a second HPV test after 18 months for follow-up with colposcopy and biopsy and treatment, as needed. Cervical biopsies are centrally reviewed by pairwise independent pathologists via a three-step protocol using the LAST classification that includes a face-to-face adjudication meeting between discordant reviews (Figure 1). Diagnostic upgrades (women diagnosed locally as ≤CIN1 but centrally as HSIL) were identified; this mostly occurs after the follow-up visit so participants were not previously treated. The regression rate of untreated women whose initial biopsies were upgraded to HSIL by central review was

estimated.

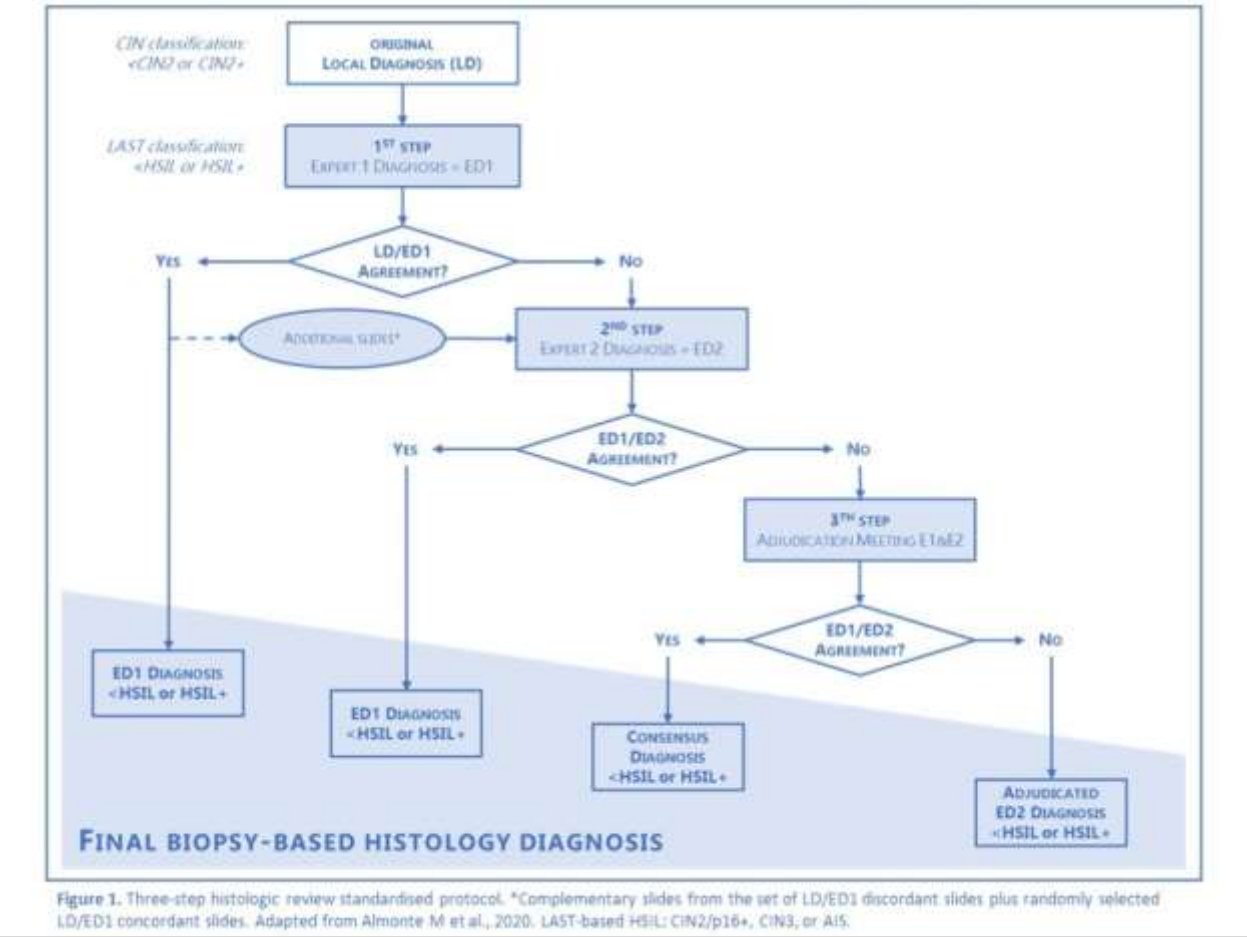

Figure 1. Three-step histologic review standardised protocol. *Complementary slides from the set of LD/ED1 discordant slides plus randomly selected LD/ED1 concordant slides. Adapted from Almonte M et al., 2020. LAST-based HSIL: CIN2/p16+, CIN3, or AIS.

Results: 55 upgraded to HSIL untreated cases followed for ~22 months (interquartile range 19-25) were analysed (Figure 2). At baseline, the average/SD age was 43/9.7 years, 54 were HPV-positive, and 32 had normal cytology; 36 were locally diagnosed with CIN1, 18 were negative, and 1 had unsatisfactory histology. At the follow-up visit, 41 (75%) had no evidence of precancer (24 HPV-negative, 3 negative colposcopy, 7 negative biopsy, 7 CIN1), 13 persisted (3 CIN2, 9 CIN3, 1 AIS), and 1 progressed to

cancer.

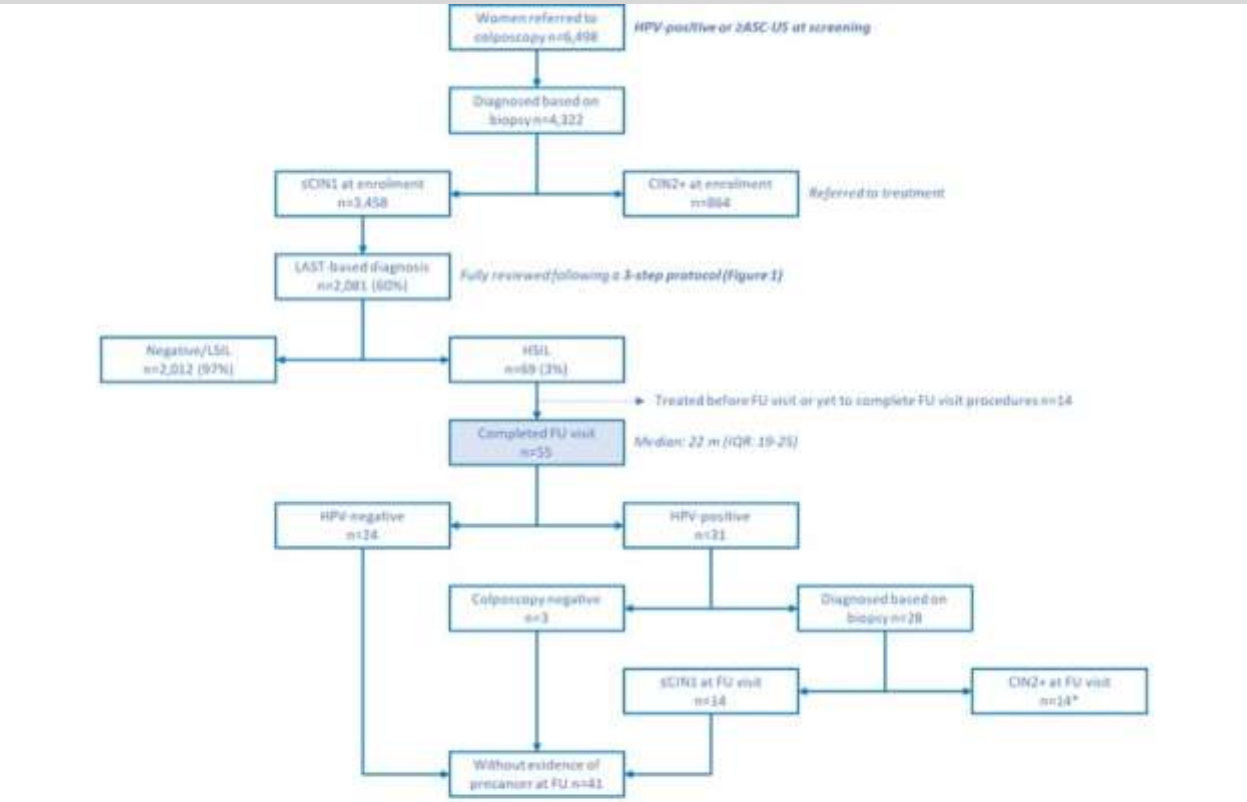

Figure 2. Flowchart of analysed participants (box blue background). Following the LAST classification, 2,081 women diagnosed by local pathologists without precancerous lesions at entry were fully centrally reviewed as per a 3-step protocol described elsewhere (Almonte M et al., 2020). Among them, 69 were upgraded to HSIL. Upgraded women were reported to local PI's; however, this occurred when cases had completed the follow-up (FU) visit so they were not treated earlier. In total, 55 upgraded and untreated women followed for about 22 months (interquartile range 19-25) until attend the FU visit for disease ascertainment, were included in the analysis. Three quarters (41/55) had no evidence of precancer at the FU visit. Similarly, among cases diagnosed based on biopsy at the FU visit (n=28), half (14/28) had no evidence of precancer either. HSIL under the LAST classification corresponded to CIN2/p16-positive, CIN3, or AIS. *Includes 1 cancer (FIGO I).

Conclusions: We noted substantial regression in a subset of lesions upgraded to histologic HSIL in untreated women ≥30 years. Further analyses including HPV typing and extended follow-up to confirm regression will be presented.

*On behalf of the ESTAMPA study group.

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Poster Viewing
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THE EPIDEMIOLOGY OF HIGH-RISK HUMAN PAPILLOMAVIRUSES AND EPITHELIAL CELL ABNORMALITIES IN KUMASI, GHANA SUGGESTS THAT A POSSIBLE USE CASE EXISTS FOR MULTIVALENT VACCINES

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Introduction: A number of vaccines are available to provide primary protection against persistent infection with high-risk human papillomaviruses (HR-HPVs) and effectively eliminate cervical cancer. However, data on the epidemiology of vaccine-preventable HPVs in Ghana is needed to inform public health measures.

Methods: In this study, 595 women were recruited in a multi-centre cross-sectional observational study in the Greater Kumasi area of Ghana to investigate the epidemiology of genital human papillomavirus (HPV) genotypes and cervical dysplasia. A nested multiplex polymerase chain reaction (NMPCR) assay using degenerate E6/E7 consensus primers and type-specific primers was used for detecting and typing eighteen (18) HPV genotypes. Exclusion criteria were a history of cervical screening prior to this study and an age less than 18.

Results: The prevalence of HR HPV was 31.4% (95% CI: 27.4–35.7) (84.4% of all 18 HPV genotypes screened were detected). Furthermore, the prevalence of epithelial cell abnormalities was 3.7% (95% CI: 2.2–5.2%). A bivalent vaccine that prevents infection from HPV-16 and -18 may potentially prevent 16.7% (95% CI: 11.3–22.0%) of HPV infections among unscreened women; a quadrivalent vaccine that prevents infection from HPV-6/11 in addition to -16 and -18 may potentially prevent 21.5% (95% CI: 15.6–27.4%) of circulating HPV infections and a multivalent vaccine that prevents infection from HPV-6/11, -16, -18, -31, -33, -45, -52, and -58 may potentially prevent 68.8% (95% CI: 62.2–75.5) of HPV burden.

Conclusions: This study strengthens the belief that prophylactic HPV vaccination for girls coupled with routine cervical screening for older women could be an effective strategy to reduce the burden of HPV infections and potentially eliminate HPV-associated cancers and epithelial cell abnormalities among health-seeking women in Kumasi. The high prevalence of epithelial cell abnormalities and vaccine-preventable HPVs show that efforts to make multivalent vaccines available to young girls in the area should be prioritized.

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Poster Viewing
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CORRELATION ANALYSIS OF LOWER GENITAL TRACT PATHOGEN INFECTION WITH HPV INFECTION AND CERVICAL PRECANCEROUS LESIONS IN WOMEN

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Introduction: To investigate the association between common lower genital tract infections in women and HPV infection and cervical precancerous lesions.

Methods: Lower genital tract pathogens were tested on cervical cytology specimens from 1158 randomly selected subjects from a cervical cancer screening population with 4 years of follow-up. Logistic regression was used to explore the association between lower genital tract infection and HPV and precancerous lesions.

Results: The prevalence of baseline HPV infection was 29.36% and pathogen infection was 64.42% in 1158 subjects, and subjects with pathogen infection had fewer pregnancies and lower age at first pregnancy; the concordance rate between lower genital tract infection with pathogen infection and baseline HPV infection was 48.01%, and a higher proportion of HPV-positive subjects developed pathogen infection compared with the HPV-negative group (P value). At the four-year follow-up, the concordance rate between persistent HPV infection and pathogen detection for lower genital tract infection was lower than for HPV infection; logistic regression showed that UU (OR=1.767), MG (OR=4.296) and MH (OR=2.413) were all risk factors for baseline HPV infection (all P values <0.05); CT (OR=3.208), and UU (OR=1.71) and MH (OR=2.466) all increased the risk of developing persistent HPV infection (all P values <0.05). Subjects were more likely to have persistent HPV infection when tested positive for baseline HPV combined with lower genital tract infection; in addition, a statistically significant difference was found in the proportion of multiple infections in those who were CIN1+ at any one time within four years compared to those who were not CIN1+ (P=0.047).

Conclusions: This study found a correlation between pathogenic infection of the lower genital tract and HPV infection and cervical precancer (CIN1), and a positive correlation between UU and MH infection and HPV infection and persistent HPV infection.

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Poster Viewing
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HPV GENOTYPING USING NEXT GENERATION SEQUENCING IN CERVICAL SAMPLES FROM THE ESTAMPA STUDY IN ARGENTINA: GENOTYPES BY HISTOLOGY AND THEIR RELATIVE PROPORTION IN MULTIPLE INFECTIONS.

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Introduction: Sensitive and specific genotyping of human papillomaviruses (HPVs) is critical for the surveillance and monitoring of the vaccine effectiveness. Next Generation Sequencing (NGS) has brought an innovative and attractive solution for detecting a larger spectrum of HPV genotypes. Here, we analysed by NGS the HPV genotypes distribution and the relative proportions for each genotype in multiple infections, in 137 cervical samples with different histology.

Methods: This ancillary study of the multicentric ESTAMPA study (NCT01881659) considered those 3,338 participants from Argentina (Figure 1), selecting by convenience 79 participants with negative or CIN1 histology or normal colposcopy without biopsies (≤CIN1) and all 58 participants detected with high-grade disease (CIN3+). A nested PGMY/GP PCR followed by NGS (amplicon about 200 bp) was performed. The presence of each genotype was measured as the proportion of reads within each sample, using a Gini index as a measure of genotypic

diversity.

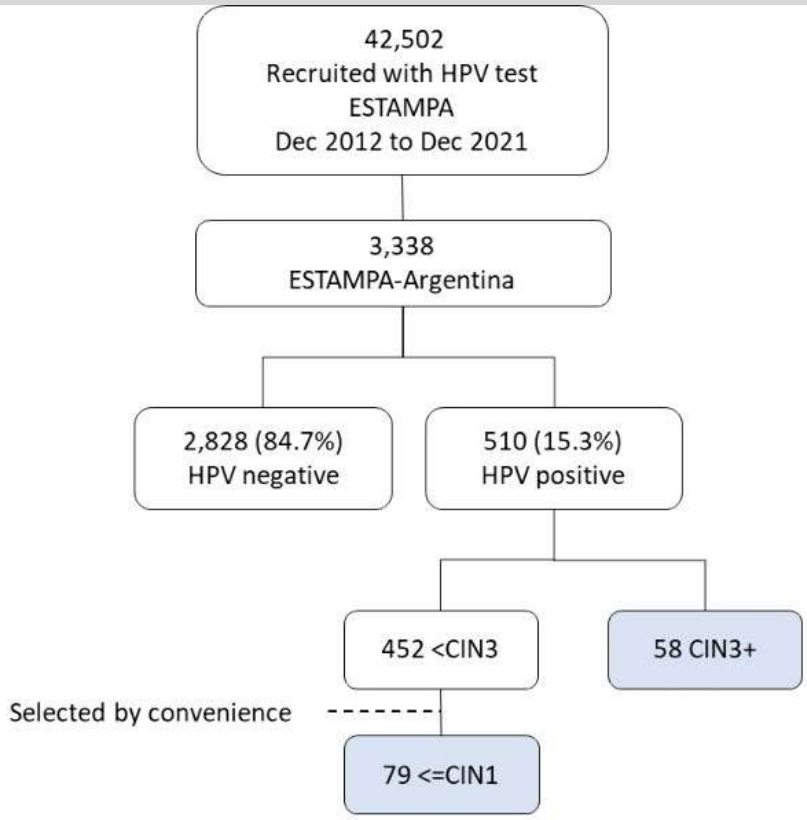

Figure 1. *Study Flowchart.* Participants from Argentina recruited at the ESTAMPA study centre Instituto Nacional de Enfermedades Infecciosas-ANLIS "Dr. Malbrán"/ Hospital Nacional "Prof. Posadas". HPV testing in this study centre was performed using COBAS test. In this study, all participants with high-grade disease (CIN3+) were selected and among those 452 <CIN3, 79 participants with negative or CIN1 histology or normal colposcopy without biopsies (≤CIN1) were selected by convenience.

Results: Multiple infections were more present in ≤CIN1 than CIN3+ cases (85% vs 41%, $p<0.01$, Figure 2). Mean Gini index was significantly higher in ≤CIN1 samples showing a 2.2 fold-increase in genotypic diversity when compared to CIN3+ samples (0.20±0.22 vs 0.09±0.17 respectively, $p<0.01$). When CIN3+ histology is compared to ≤CIN1 group in multiple infections cases, there is a strong dominance of HR-genotypes (higher proportions in the viral mix)(Figure 3).

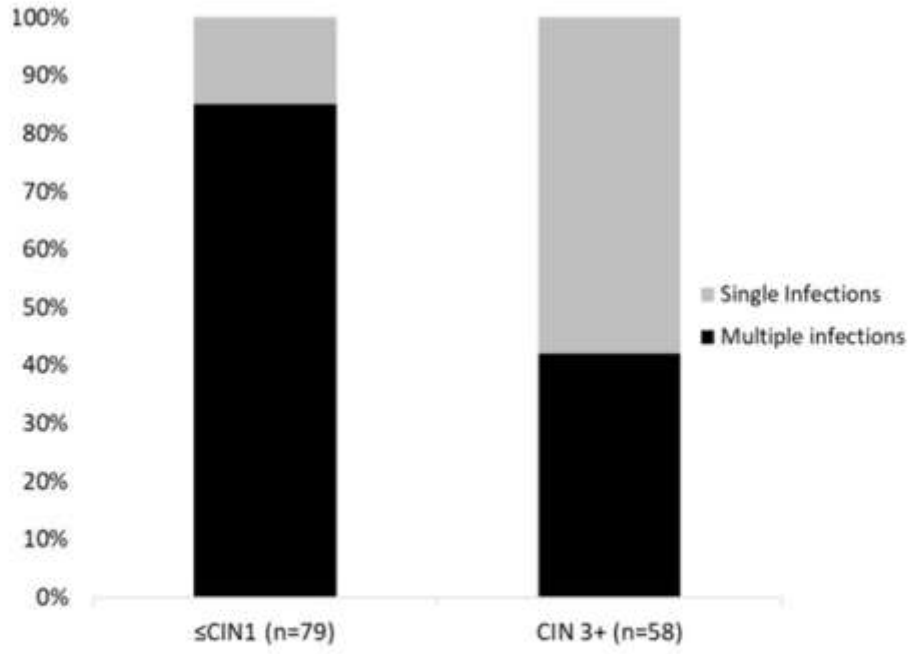

Figure 2. *Distribution of single and multiple infections by histologic group.* Percentage of samples with multiple or single infections, as detected by NGS, by histologic group shown.

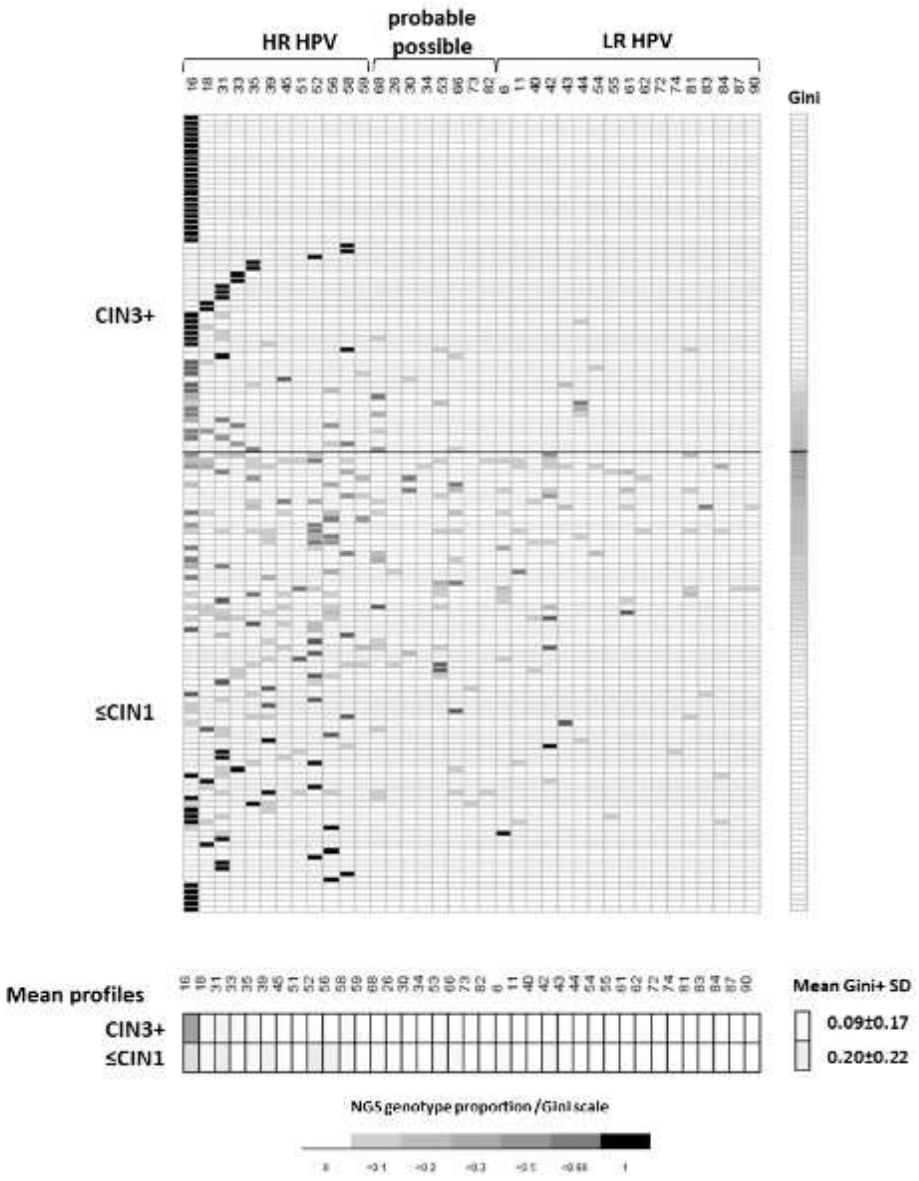

Figure 3. *HPV genotypic diversity in CIN3+ vs ≤CIN1 cervical samples.* NGS proportion profiles in 37 HPV genotypes depicted for 137 samples (79 *≤CIN1* and 58 CIN3+). Mean proportion profiles shown for each histological group. HPV genotypes ordered from high-risk (HR), probably/possibly carcinogenic to low-risk (LR). Individual and mean Gini coefficient to measure genotypic diversity shown for each sample and cytological group respectively. Samples grade ordered by Gini coefficient, from minimal to maximal genotypic diversity for CIN3+ and from maximal to minimal genotypic diversity for ≤CIN1. Overall mean ± SD Gini index by histologic group shown.

Conclusions: A reduction in genotypic diversity and/or an increase in the proportion of HR-HPV genotypes in multiple infections can be considered as a biomarker for the potential risk of progression in cervical lesions.

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Poster Viewing
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UNDERSTANDING THE ASSOCIATION BETWEEN HELMINTHS AND HPV OR CERVICAL CANCER: A SCOPING REVIEW

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Introduction: In 2018, >500,000 people globally were diagnosed with cervical cancer and >300,000 deaths were attributed to the disease. Although cervical cancer afflicts women worldwide, >85% of deaths occur in low- and middle-income countries (LMICs). Immune modulation is associated with persistent HPV infection and an increased risk of cervical cancer. Helminths remain prevalent in LMICs and have been proven to cause immune dysregulation. Although it is well-established that helminth infection regulates the host immune environment, the population-level impact of this on the persistence of common oncogenic viral co-infections like HPV, and related cervical dysplasia progression, remains unclear. Here we review the epidemiologic evidence for an association between helminth infection and an increase in HPV prevalence, persistence, or progression of dysplasia.

Methods: We searched 5 databases (Embase, Global Health, PubMed, Scopus, and Web of Science) for studies with relevance to helminth infection (schistosomes/bilharzia, hookworms, Ascaris, and Trichuris) AND cervical cancer OR HPV. We included only (1) epidemiologic studies, (2) that took place in LMICs, and (3) were published after 1990. Our search resulted in 39 papers.

Results: Of the 39 papers, ten were association studies (studies with a defined exposure, outcome, and effect measurement) and 29 were case studies. Of the ten association papers, six showed a positive relationship between helminth infection and HPV or cervical cancer prevalence. Three showed no association between helminth infection and cervical cancer. Only one small study showed a possible association between helminth infection and HPV persistence. Importantly, eight of the ten association

papers evaluated schistosomiasis, only two evaluated soil-transmitted helminth infections.

Study	Sample Size	Country	Exposure	Outcome	Effect Estimate (95% CI)	Association
Gravitt, et. al	292	Peru	Hookworm infection, *Ascaris*, *Trichuris*, *Strongyloides*	HPV prevalence	1.60 (1, 2.7)	Positive
Ameyapoh, et. al	367	Togo	Hookworm infection	HPV prevalence	2.22 (1.32, 3.75)	Positive
Kjetland, et. al	37	Zimbabwe	Schistosomiasis	HPV prevalence	1.9 (1.1, 3.6)	Positive
Rafferty, et. al	237	Zambia	Schistosomiasis	CIN	6.08 (1.58, 23.37)	Positive
Pillay, et. al	833	South Africa	Schistosomiasis	Cervical Cancer	5.6 (1.6, 21.0)	Positive
Kjetlad, et. al	37	Zimbabwe	Schistosomiasis	HSIL infection	7.1 (0.5, 92.1)	Positive
Swanepoel, et. al	1087	South Africa	Schistosomiasis	HPV prevalence	---[1]	Possible
Petry, et. al (1995)	138 cases; 35 controls	Tanzania	Schistosomiasis	Cervical Cancer	---[1]	Null
Petry, et. al (2003)	109 patients; 109 controls	Tanzania	Schistosomiasis	Cervical Cancer	---[1]	Null
Szela, et. al	48	Ghana	Schistosomiasis	Cervical Cancer	---[1]	Null

[1] Authors concluded no association - no effect estimate was provided and not enough data to estimate

Conclusions: Our data suggest a positive association between helminth infection and HPV prevalence, persistence, or disease progression. Given the high burden of helminth and HPV co-infection in LMICs, whose populations bear 85% of the global cervical cancer burden, further evaluation of this potential interaction is warranted.

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CONCORDANCE BETWEEN HPV DNA DETECTION AND TYPE-SPECIFIC SEROPOSITIVITY: AN OBSERVATIONAL STUDY IN CHINA

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Introduction: HPV DNA infections do not always lead to seroconversion. Concordance between prevalent HPV DNA and type-specific seropositivity remains controversial. This study aimed to explore cross-sectional associations between 13 high-risk (hr) HPV DNA detection and seropositivity.

Methods: Serological and genotyping data were obtained from 505 women who participated in a 1999 cervical screening study in Shanxi, China. All women were positive in Hybrid Capture II testing or with abnormal pathology. Type-specific HPV DNA and naturally acquired antibodies were respectively tested by SPF10-PCR DEIA/LiPA25 system (version 1) and a multicolor pseudovirion-based assay. Type-specific seropositivity was defined as 50 % Infectious dose equal to or above corresponding cut-off (Mean+2SD). Logistic regression model adjusting predefined covariates was used to assess associations between HPV DNA detection and seropositivity.

Results: Overall DNA detection rate of any 13 hrHPV (16/18/31/33/35/39/45/51/52/56/58/59/68) was 51.49% with an increasing trend by histopathology severity (36.57% in normal, 60.91% in CIN1, 90.70% in CIN2, and 95.35% in CIN3+) (Table 1). Seropositivity rate of any 13 hrHPV was 63.56% without statistically significant difference in histological grades (62.78%, 58.18%, 72.09%, and 74.42%, P_{trend} =0.099) (Table 2). In terms of individual HPV types, both DNA detection rates and seropositivity rates of HPV 16 and 58 increased by histopathology severity. In multivariable logistic regression analyses (Table 3), DNA detection of any 13 hrHPV were not associated with seropositivity [aOR (95%CI): 0.86 (0.58, 1.26)]. However, positive associations between type-specific DNA detection and corresponding seropositivity were observed for HPV 16 and 58 [aOR (95%CI): HPV16: 4.40 (2.45, 7.93); HPV 58: 6.14 (2.31,
16.27)].

Table 1 type-specific HPV DNA detection rate by histological grades (n[%])

Genotype	Normal (n=309)	CIN1 (n=110)	CIN2 (n=43)	CIN3+ (n=43)	Total (N=505)	P_{trend}[b]
16	47 (15.21)	21 (19.09)	28 (65.12)	33 (76.74)	129 (25.54)	**<0.001**
18	7 (2.27)	3 (2.73)	2 (4.65)	1 (2.33)	13 (2.57)	0.315
31	6 (1.94)	4 (3.64)	3 (6.98)	3 (6.98)	16 (3.17)	**0.010**
33	9 (2.91)	7 (6.36)	0 (0.00)	1 (2.33)	17 (3.37)	0.596
35	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	-
39	1 (0.32)	3 (2.73)	0 (0.00)	0 (0.00)	4 (0.79)	0.411
45	2 (0.65)	0 (0.00)	0 (0.00)	0 (0.00)	2 (0.39)	0.830
51	8 (2.59)	7 (6.36)	1 (2.33)	0 (0.00)	16 (3.17)	0.635
52	27 (8.74)	13 (11.82)	2 (4.65)	2 (4.65)	44 (8.71)	0.810
56	1 (0.32)	1 (0.91)	0 (0.00)	0 (0)	2 (0.39)	0.584
58	10 (3.24)	11 (10)	5 (11.63)	4 (9.3)	30 (5.94)	**0.004**
59	5 (1.62)	1 (0.91)	0 (0.00)	0 (0.00)	6 (1.19)	0.891
68	2 (0.65)	0 (0.00)	1 (2.33)	0 (0.00)	3 (0.59)	0.483
Any 13 hrHPV[a]	113 (36.57)	67 (60.91)	39 (90.70)	41 (95.35)	260 (51.49)	**<0.001**

CIN1, cervical intraepithelial neoplasia grade 1; CIN2, cervical intraepithelial neoplasia grade 2; CIN3, cervical intraepithelial neoplasia grade 3 or worse. [a] DNA positive for any of 13 high-risk HPV, i.e. HPV 16/18/31/33/35/39/45/51/52/56/58/59/68. [b] Cochran-Armitage trend test.

Table 2 type-specific seropositivity rate by histological grades (n[%])

Genotype	Normal (n=309)	CIN1 (n=110)	CIN2 (n=43)	CIN3+ (n=43)	Total (N=505)	P_{trend}[b]
16	29 (9.39)	13 (11.82)	9 (20.93)	17 (39.53)	68 (13.47)	**<0.001**
18	11 (3.56)	1 (0.91)	0 (0.00)	1 (2.33)	13 (2.57)	0.902
31	46 (14.89)	6 (5.45)	12 (27.91)	8 (18.60)	72 (14.26)	0.157
33	25 (8.09)	7 (6.36)	5 (11.63)	4 (9.30)	41 (8.12)	0.319
35	15 (4.85)	3 (2.73)	1 (2.33)	1 (2.33)	20 (3.96)	0.880
39	94 (30.42)	23 (20.91)	7 (16.28)	10 (23.26)	134 (26.53)	0.981
45	10 (3.24)	1 (0.91)	3 (6.98)	2 (4.65)	16 (3.17)	0.238
51	92 (29.77)	21 (19.09)	12 (27.91)	11 (25.58)	136 (26.93)	0.851
52	61 (19.74)	18 (16.36)	15 (34.88)	10 (23.26)	104 (20.59)	0.113
56	3 (0.97)	1 (0.91)	1 (2.33)	0 (0.00)	5 (0.99)	0.543
58	22 (7.12)	8 (7.27)	7 (16.28)	5 (11.63)	42 (8.32)	**0.045**
59	12 (3.88)	2 (1.82)	2 (4.65)	0 (0.00)	16 (3.17)	0.876
68	54 (17.48)	14 (12.73)	7 (16.28)	5 (11.63)	80 (15.84)	0.866
Any 13 hrHPV[a]	194 (62.78)	64 (58.18)	31 (72.09)	32 (74.42)	321 (63.56)	0.099

CIN1, cervical intraepithelial neoplasia grade 1; CIN2, cervical intraepithelial neoplasia grade 2; CIN3, cervical intraepithelial neoplasia grade 3 or worse. [a] Seropositive for any of 13 high-risk HPV, i.e. HPV 16/18/31/33/35/39/45/51/52/56/58/59/68. [b] Cochran-Armitage trend test.

Table 3 type-specific HPV seropositivity by DNA status, and associations between DNA detection and seropositivity[a]

Genotype	Seropositive among DNA+[c] n(%)	Seropositive among DNA-[d] n(%)	Crude OR for seropositivity[e] OR (95% CI)	Adjusted OR for seropositivity[f] OR (95% CI)
16	35 (27.13)	33 (8.78)	**4.07 (2.39, 6.92)**	**4.40 (2.45, 7.93)**
18	1 (7.69)	12 (2.44)	3.29 (0.40, 27.39)	4.43 (0.41, 47.57)
31	5 (31.25)	67 (13.70)	2.82 (0.95, 8.38)	2.63 (0.81, 8.50)
33	2 (11.76)	39 (7.99)	1.51 (0.33, 6.85)	1.30 (0.25, 6.66)
35	-	20 (3.96)	-	-
39	0 (0.00)	134 (26.75)	-	-
45	0 (0.00)	16 (3.18)	-	-
51	5 (31.25)	131 (26.79)	1.21 (0.41, 3.56)	1.44 (0.46, 4.53)
52	12 (27.27)	92 (19.96)	1.57 (0.78, 3.19)	1.54 (0.72, 3.30)
56	0 (0.00)	5 (0.99)	-	-
58	8 (26.67)	34 (7.16)	**4.85 (2.00, 11.77)**	**6.14 (2.31, 16.27)**
59	2 (33.33)	14 (2.81)	**17.11 (2.89, 101.31)**	**14.89 (1.85, 119.66)**
68	1 (33.33)	79 (15.74)	2.64 (0.24, 29.46)	2.79 (0.19, 40.68)
Any 13 hrHPV[b]	162 (62.31)	159 (64.90)	0.83 (0.57, 1.20)	0.86 (0.58, 1.26)

OR, odds ratio; CI, confidence. [a] Among 505 women from a population-based cervical screening study (SPOCCS I) in Shanxi, China. [b] DNA positive for any of 13 high-risk HPV, i.e. HPV 16/18/31/33/35/39/45/51/52/56/58/59/68. [c] Among number of DNA positive women of the same type. [d] Among number of DNA negative women of the same type. Univariate logistic regression. [f] Multivariate logistic regression adjusting covariates including age, marriage, ever had smoked for over six months, ever had consumed alcohol, gravidity, age at first menstration, age at sex debut, number of lifetime sexpartner, frequency of monthly sexual intercourse, common gynecological disorders (cervicitis, cervical polyp, trichomoniasis), extramarital affairs of husband and self, and hrHPV infections other than analyzed one.

Conclusions: Our study suggested the concordance between DNA detection and seropositivity in two common hrHPV types (HPV 16/58). Larger studies or pooled analyses are needed, especially for rare HPV subtypes, to explore association between type-specific infection and nature immunity induced by it.

Shift 01-024 / #1154

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

ESTIMATING HPV TYPE-SPECIFIC TRANSITION RISKS FROM ACQUISITION TO PRECANCER: DEVELOPMENT OF NEW COST-EFFECTIVENESS MODELS TO EVALUATE NOVEL SCREENING AND TRIAGE TESTS

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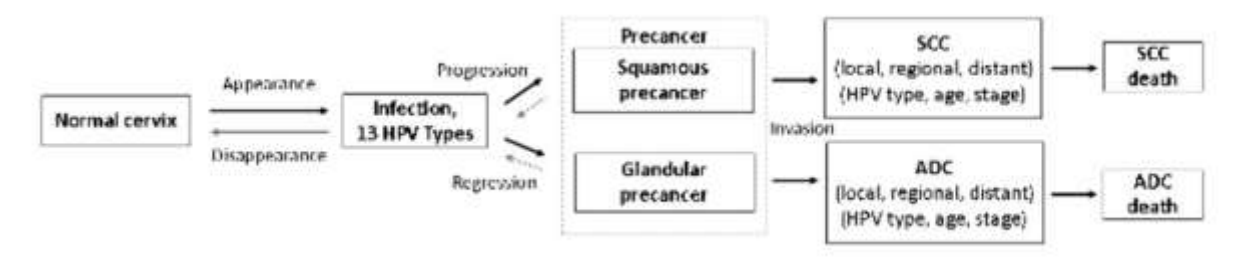
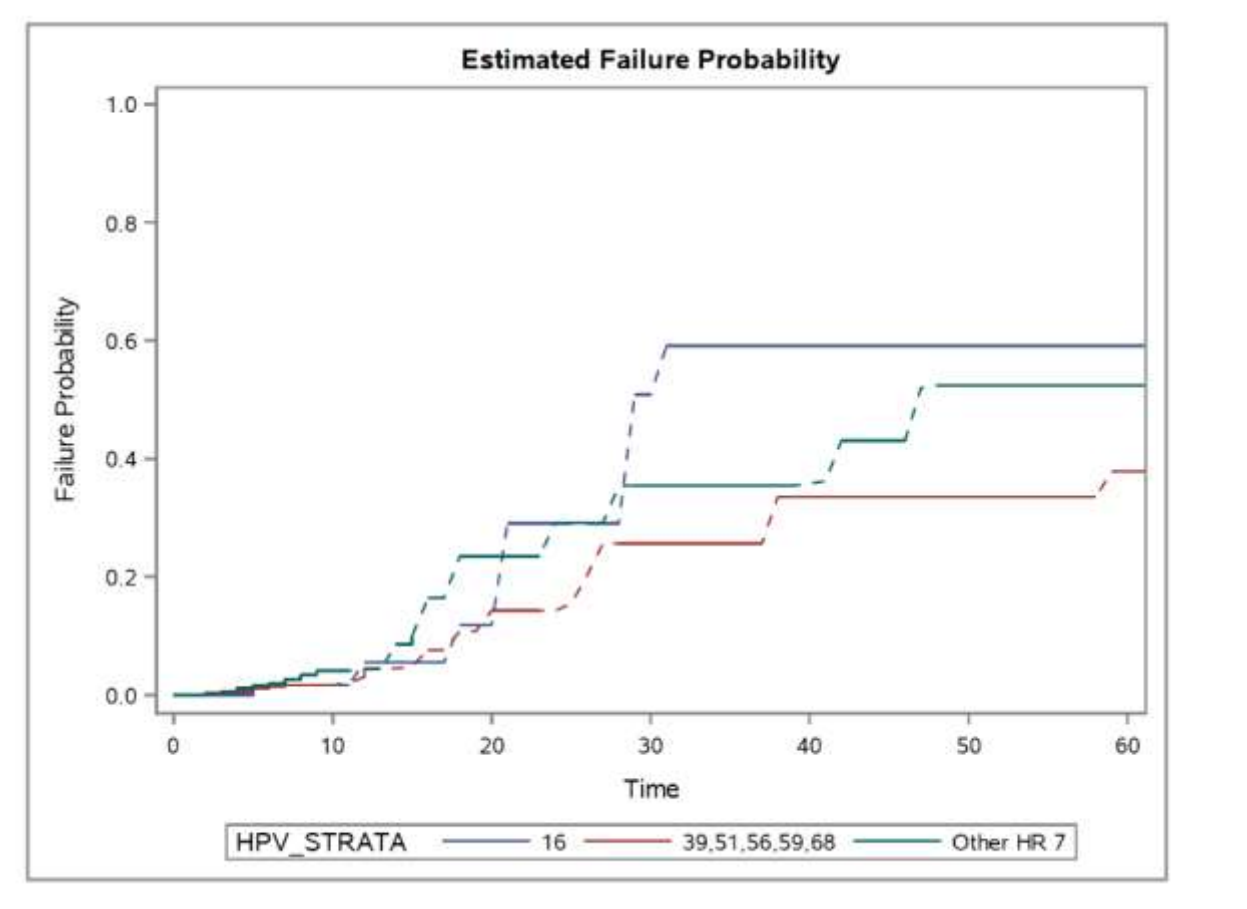
Introduction: Novel biomarkers and visual screening tools for cervical cancer screening and triage require new health decision models of HPV infection and cervical carcinogenesis to accurately assess cost-effectiveness. We are developing a microsimulation model to evaluate the cost-effectiveness of HPV testing and triage of HPV-positive women with genotyping and a deep-learning-based automated visual evaluation (AVE) of cervical images in the PAVE Validation Study, a large consortial screening project that will screen up to 100,000 women in ~10 low-resource study sites.

Methods: Individuals who acquire an HPV infection are subject to two competing transitions: clearance of the HPV infection or progression to precancer (Figure 1). We previously derived transition risks from HPV acquisition to clearance. To derive transition risks for type-specific progression to cervical precancer, we considered all incident infections with a single HPV type in the Costa Rica Vaccine Trial population of women aged 18 to 25 years at enrollment. To simplify estimation from unobserved HPV onset, we assumed infections were acquired at the midpoint between the prior HPV-negative result and HPV detection. Using the Turnbull estimator for interval-censored time-to-event data, we estimated the “pure” risk of having detectable cervical intraepithelial neoplasia grade 2 or higher (CIN2+) and CIN3+, based on rigorously adjudicated diagnoses and HPV type. Pure risk is defined as absent the competing event of HPV clearance. HPV types were grouped according to high, moderate, and lower-risk types (HPV16; HPV18/31/33/35/45/52/58; HPV39/51/56/59/68) for stability of estimates.



Results: We considered 3074 incident single-type infections (206 with HPV16; 1403 with HPV18/31/33/35/45/52/58; and 1465 with HPV39/51/56/59/68). The rate of progression was highest for HPV16, followed closely by HPV18/31/33/35/45/52/58 (Figure 2).



Conclusions: Model development continues, with data analysis underway to determine whether time to progression varies by setting-specific HPV prevalence pattern.

Shift 01-025 / #1170

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

POLYMORPHISMS IN THE NON-HOMOLOGOUS END-JOINING DNA REPAIR PATHWAY ARE ASSOCIATED WITH HPV INTEGRATION IN CERVICAL DYSPLASIA

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Introduction: Previous evidence has indicated that HPV integration status may be associated with cervical cancer development and progression. However, host genetic variation within genes that may play important roles in the viral integration process has been understudied. The aim of this study was to examine the association between HPV-16 and -18 viral integration status and single nucleotide polymorphisms (SNPs) in non-homologous end-joining (NHEJ) DNA repair pathway genes on cervical dysplasia.

Methods: Women enrolled in two existing large trials of optical technologies for cervical cancer detection and positive for HPV-16 or -18 were selected for HPV integration analysis and genotyping. Associations between SNPs and cytology (normal, low-grade, or high-grade lesions) were evaluated. Among women with cervical dysplasia, polytomous logistic regression models were used to evaluate the effect of each SNP on viral integration status.

Results: Women with high-grade lesions were significantly younger than women with low-grade or no lesions. Tag-SNPs in 13 DNA repair genes, including XRCC4, WRN, and NBN were significantly associated with cervical dysplasia. HPV16 integration status was differential across cervical cytology, but overall, most participants had a mix of both episomal and integrated HPV 16. Five tag-SNPs in the XRCC4 gene were found to be significantly associated with HPV 16 integration status.

Conclusions: Our findings indicate that host genetic variation in NHEJ DNA repair pathway genes, specifically XRCC4, are significantly associated with HPV integration and that these genes may play an important role in determining cervical cancer development and progression.

Shift 01-026 / #1172

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

DESCRIPTIVE RESULTS FROM THE HUMAN PAPILLOMAVIRUS VACCINE IMPACT MONITORING PROJECT (HPV-IMPACT) AND THE OREGON STATE CANCER REGISTRY (OSCAR) COLLABORATION

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Introduction: In 2018, the HPV-IMPACT project, which conducts population-based surveillance for cervical precancers, expanded its surveillance to include cervical cancers and conducted retrospective surveillance from 2008. Oregon's HPV-IMPACT collaborated with the Oregon State Cancer Registry (OSCaR) to obtain cervical cancer data on residents of a 28-zip-code catchment area (estimated 2020 population, 297,150).

Methods: Cases were identified in OSCaR. Complete demographics, diagnoses, risk factors, screening information, and HPV vaccinations were abstracted from medical charts, Oregon's immunization registry, and other sources. We analyzed cervical cancer data among women ≥18 years of age residing in Oregon's catchment area during 2008–2020.

Results: 300 cases were identified, yielding an average annual incidence of 8.0 per 100,000 women (Table 1). The median age at diagnosis was 44. 12% were Hispanic; of non-Hispanics, 73% were White, 3% Black, and 8% Asian—roughly reflective of the catchment-area population. 5% were immunocompromised. 43% were current or former smokers. 63% of cases had squamous-cell carcinoma and 31% adenocarcinoma. Almost 70% of cancers were diagnosed at stage 1. Two-thirds of patients presented with symptoms, 90% of them with vaginal bleeding or discharge. Almost half of all cases had barriers to prevention: 29% underinsured or uninsured, 22% with current or history of addiction disorder, 13% with current or history of serious mental conditions, 12% with current or history of BMI >39, and another 31% with other barriers. 51 (25%) of 205 women with incident cervical cancer during 2008–2016 have died from cervical cancer.

Conclusions: This collaboration expands what is known about cervical cancer in our catchment area, adding information about symptoms, barriers to prevention and natural history of disease. While most women were diagnosed at an early stage, two-thirds had symptoms at diagnosis and theoretically have

been identified sooner through pre-symptomatic screening. Many had barriers to adequate preventive care.

Table 1. Characteristics of cervical cancer cases (n=300) diagnosed among women 18 years and older in 2008–2020, Oregon Human Papillomavirus Vaccine Impact Monitoring Project (HPV-IMPACT)

Demographics	N	%
Median age at diagnosis (years)	44	
Race/Ethnicity		
Non-Hispanic White	219	73
Non-Hispanic Black	10	3.3
Hispanic	35	11.7
Asian	25	8.3
Other/Multi/Unknown	11	3.7
Factors Affecting Natural History		
Any immunocompromising condition		
Yes	15	5
No	275	92
Unknown	10	3
Smoking		
Current	62	21
No	156	55
History of	67	22
Unknown	5	2
Disease Characteristics		
Cancer Type		
Adenocarcinoma	92	30.7
Adenosquamous carcinoma	3	1.0
Squamous cell carcinoma	189	63.0
Type not specified	6	2.0
Other	10	3.3
Cancer Staging		
Stage 1	205	68.3
Stage 2	33	11.0
Stage 3	36	12.0
Stage 4	19	6.3
Unknown	7	2.3
Symptoms		
Vaginal bleeding or discharge	181	90
Pelvic pain	60	29
Pain with intercourse	16	8
Other	116	58
Unknown	1	0.5
Barriers to Treatment		
Uninsured or underinsured	87	29
Current of history of substance use disorder/addiction	22	7
Current or history of serious mental conditions	39	13
Current or history of BMI >39	35	12
Other barriers	92	31

Shift 01-027 / #1178

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

SOCIAL AND STRUCTURAL BARRIERS OF INVASIVE CERVICAL CANCER

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Introduction: Invasive cervical cancer (ICC) is a preventable disease due to vaccines, screening and treatment. ICC is now possible in many countries including the United States (US). Previous studies have identified sociodemographic disparities throughout the natural history of ICC. In this analysis we examine potential social and structural barriers to ICC prevention among women in Connecticut, US.

Methods: All cases of ICC diagnosed and/or treated at a regional academic cancer center during 2015–2020 were identified and underwent medical chart review. Eight markers of social and structural determinants of health that are potential barriers to vaccination, screening or treatment were abstracted: minority race/ethnicity status, history of alcohol use disorder, history of substance abuse, incarceration, homelessness, mental illness, health insurance status, and primary language.

Results: Charts of 143 women diagnosed with ICC were reviewed. At least one barrier was identified in 121 women (84.6%). Two or more barriers were identified in 59 women (41.2%) and 11 women (7.7%) had three+ barriers identified. The most commonly identified barriers were minority race/ethnicity status (55.9%), history of mental illness (25.1%) and no insurance coverage at the time of diagnosis and/or a gap in insurance coverage in the previous 5 years (22.4%) (Table 1).

Table 1: Social and structural barriers of ICC (not mutually exclusive)

Barrier	N=143	%
Minority race/ethnicity status	80	55.9
History of mental illness	36	25.1
No insurance/gap in coverage	32	22.4
Non-English speaking	22	15.4
Alcohol use disorder	16	11.2
History of homelessness	6	4.2
History of substance abuse disorder	6	4.2
History of incarceration	3	2.1

Conclusions: HPV vaccination and effective screening methods and treatment options make ICC a preventable disease. In this analysis we documented a high frequency of eight markers of social and structural determinants of health that may interfere with ICC prevention. Policies that address these barriers such as increasing stable health care coverage, access to mental health and substance abuse treatment services, and culturally competent healthcare to reach minority and immigrant populations are needed to improve screening and reach the goal of ICC elimination in the US.

Shift 01-028 / #1291

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

ASSOCIATION OF SEXUALLY TRANSMITTED INFECTIONS (STIS) AND CERVICAL INFLAMMATION WITH PROGRESSION OF CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN) AMONG WOMEN LIVING WITH HIV (WLHIV) IN SOUTH AFRICA

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Introduction: To evaluate the association of sexually transmitted infections (STIs) other than high-risk HPV(HR-HPV) with incidence of high-grade cervical lesions(CIN2+) in women living with HIV(WLHIV) in South Africa(SA).

Methods: Prospective cohort study of WLHIV aged 25-50 in Johannesburg, South Africa. We compared CIN2+ incidence among HR-HPV positive WLHIV with and without STIs. HPV genotyping by INNO-LiPA and histology of cervical biopsies were performed at baseline and median 16-months follow-up; lab-confirmed STI (Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, syphilis, bacterial vaginosis [BV] and Candida albicans) at baseline only. Association of STIs with CIN2+ incidence were estimated using logistic regression.

Results: Among 623 WLHIV enrolled (65% on ART), 491 (79%) were HR-HPV+ at baseline. Co-infection with any STI, including BV, was 63% (n=308/491). Among 286 women without prevalent CIN2+ and with matched histology at endline, CIN2+ incidence over 16 months was 7.3% (n=21). CIN2+ incidence was higher in women who were MG positive (MG positive vs. negative:17.4% vs. 6.5%, adjusted odds ratio [AOR]=3.88, 95% Confidence Interval [CI]:1.10-13.64; adjusted for HIV viral suppression, injectable contraception use) and in women with syphilis (66.7% vs. 6.7% AOR=36.60, 95%CI: 1.77-755.32). Cervical ectopy was marginally associated with CIN2+ incidence (18.5% vs. 6.3%; AOR=3.19, 95% CI:0.97-10.45, p=0.056).

Conclusions: STIs other than HPV are common among WLHIV in SA. Cervical lesions occur more frequently among WLHIV with Mycoplasma genitalium and syphilis. Routine STI screening and treatment is important in WLHIV.

Shift 01-029 / #1384

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

FACTORS ASSOCIATED WITH VAGINAL HPV INFECTION AMONG CISGENDER WOMEN AT HIGH RISK OF CONTRACTING SEXUALLY TRANSMITTED INFECTIONS: A CLINIC-BASED POPULATION FROM THE CONDESA STUDY

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Introduction: Some cisgender women may be more susceptible to contracting high risk (hr) HPV infection; for example, those living with HIV or do sex work. Understanding the determinants of HPV infection in this vulnerable group is need for health policies aimed at preventing HPV-associated cancers. We sought to characterize HPV infection and identify characteristics and behaviors associated with hrHPV infection in cisgender women who are healthcare users at a STI/HIV clinic in Mexico City.

Methods: This is part of the Condesa Study, an intervention for prevention of/screening for HPV-associated neoplasms in vulnerable populations. Cisgender women with a valid self-sampled vaginal HPV test result and no prior diagnosis of cervical or anal cancer were included in the analysis (n=395). Pearson's Chi-square test and Fisher's exact test were applied to find intergroup differences between women with and without a history of sex work. Statistically significant characteristics were included in logistic regression models.

Results: In female sex workers, any hrHPV prevalence was 41.1%, HPV16=9.9% and HPV18=6.3%. In non-sex workers any hrHPV=38%, HPV16=7.7% and HPV18=3.9%; differences in prevalence between women who did or did not do sex work were not statistically significant. In all cisgender women in the sample, cohabiting with a partner (OR=0.47;95%CI: 0.25-0.89) was protective against hrHPV infection. In contrast, in all women having 2-3 sexual partners (OR=4.71;95%CI: 1.77-12.56) or 4 or more sexual partners in the last three months (OR=5.57;95%CI: 1.58-19.6) was positively associated with hrHPV infection. Specifically for non-sex workers, 2-3 (OR=2.28;95%CI: 1.07-4.86) or 4+ sexual partners (OR=2.88;95%CI: 1.06-7.82) in the last three months was associated with hrHPV infection.

Conclusions: Prevalence of hrHPV in Mexico City cisgender women seeking STI/HIV care is high, regardless of whether they do sex work. HPV screening and vaccination should be strengthened in adult cisgender women, particularly for those who have several sexual partners.

Shift 01-030 / #1527

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

TYPE AND GROUP SPECIFIC PREVALENT AND PERSISTENT CERVICAL HRHPV INFECTION IN 11,000 NIGERIAN WOMEN

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Introduction: Despite the high incidence of cervical cancer in Africa and increasing use of HPV test for cervical cancer screening, little is known about type and group specific prevalent and persistent hrHPV infection in African women

Methods: We used DEIA/LiPA, Linear array and GenXpert HPV test to characterize prevalent and persistent hrHPV in cervical samples from a prospective cohort of 11,203 Nigerian women who gave samples every 6 months for 2 years.

Results: The mean (SD) age of participants was 39 (9.66) years. Some 7.4% (834/11,203) of the women had hrHPV infection at baseline while 6.5% had group persistent hrHPV infection based on tests at enrollment and 12 months later. The types and frequencies of prevalent hrHPV types detected at baseline were 16 (110, 0.98%), 18 (170, 1.52%), 31 (79, 0.71%), 33 (49, 0.44%), 35 (109, 0.97%), 39 (30, 0.27%), 45 (60, 0.54%), 51 (109, 0.97%), 52 (210, 1.87%), 53 (88, 0.79%), 56 (43, 0.38%), 58 (67, 0.60%), 59 (20, 0.18%), 66 (71, 0.63%), 68 (22, 0.20%), and 73 (2, 2.83%). The types and frequencies of persistent hrHPV infection were 16 (79, 0.71%), 18 (122, 1.09%), 31 (70, 0.62%), 33 (39, 0.34%), 35 (79, 0.71%), 39 (19, 0.17%), 45 (37, 0.33%), 51 (76, 0.67%), 52 (159, 1.42%), 53 (41, 0.37%), 56 (25, 0.22%), 58 (47, 0.41%), 59 (10, 0.09%), 66 (45, 0.40%), and 68 (12, 0.11%).

Conclusions: HPV types 52, 18, 16, 35, 51, and 31 are the commonest prevalent and persistent hrHPV infection in this large cohort of African women

Shift 01-031 / #1539

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

PERSISTENT HRHPV INFECTIONS AND COLPOSCOPIC BIOPSY FINDINGS IN NIGERIAN WOMEN

Clement Adebamowo[1], Sally Adebamowo[1], Olayinka Olaniyan[2], Amos Adebayo[3], Peter Achara[4], Bunmi Alabi[5], Ayotunde Famooto[1], Kayode Obende[6], Richard Offiong[7], Sanni Ologun[8], Yinka Owoade[9], Tolu Gbolahan[9]
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Introduction: Cervical cancer is the commonest preventable cancer in Nigerian women and the role of persistent hrHPV infection in its etiology is well established. However, the prevalence of persistent hrHPV is much higher than the incidence of cervical cancer. Nigerian women have highly heterogenous distribution of hrHPV infections and the degree of risk associated with group and type persistent hrHPV is not currently well defined. It is critical to understand the associations between hrHPV and cervical intraepithelial changes (CIN) in Nigerian women given increasing use of HPV test based cervical cancer screening in this population.

Methods: Study participants were members of the African Collaborative Center for Microbiome and Genomics Research (h3accme.com) prospective cohort study of 11,203 Nigerian women. The women were tested using either DEIA/LiPA or GenXpert HPV test at least twice with an interval of 12 months between tests. Women who were either persistently positive or persistently negative for hrHPV were invited for colposcopy and biopsy.

Results: There were 600 women in this study and their mean age (SD) was 39.6 (8.8) years. The mean age (SD) of 272 women who were CIN2+ positive was 40.4 (8.55) while that of 328 women who were CIN2+ negative was 39.0 (8.9) years and this marginally statistically significant with p-value = 0.05. The prevalence of group-specific persistent hrHPV infection among CIN2+ positive women was 0.18 while it was 0.12 among CIN2+ negative women (OR = 1.63, 95%CI = 1.03-2.57, p-value = 0.04). In multivariable logistic regression model adjusted for age and socioeconomic status, the OR was 1.70, 95%CI - 1.07-2.69, p-value 0.02. Other factors including number of sexual partners, alcohol use, tobacco use, douching, and insertion of objects into the vagina were not statistically significant.

Conclusions: Prevalence of persistent hrHPV infection among CIN2+ negative Nigerian women is high and may affect the predictive value of HPV test for cervical cancer screening in this population

Shift 01-032 / #1592

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

ASSOCIATION BETWEEN SEXUALLY TRANSMITTED INFECTIONS AND ABNORMAL CERVICAL CYTOLOGY: A PROSPECTIVE STUDY BASED ON CERVICAL CANCER SCREENING COHORT

Simiao Chen[1], Tingyuan Li[2], Yakun Wang[1], Dingkun Wu[2], Yu Dai[1], Qinjing Pan[1], Zhihui Zhang[3], Xun Zhang[4], Liao Qiong[5], Shijun Jia[5], Dongsheng Wang[6], Fangjun Liu[2], Lingling Zhu[2], Xingsheng Cai[7], Chunlin Wang[7], Lingmei Yan[7], Xiaoyan Le[7], Zeni Wu[1], Youlin Qiao[8], Yuqian Zhao[2], Wen Chen[1]
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Introduction: Sexually transmitted infection (STI) is an important public health issue worldwide, significantly impacting female health. The association between STIs and abnormal cervical cytology has been rarely evaluated.

Methods: This study was conducted within a cervical cancer screening cohort with 3 years of follow-up. A total of 8,371 women aged 21-64 years at baseline were included. Baseline cervical samples were tested by Next Generation Sequencing assay for high-risk human papillomaviruses (hrHPV), low-risk HPV (lrHPV), and non-HPV STIs including Ureaplasma parvum (UP), Mycoplasma hominis (MH), Ureaplasma urealyticum (UU), Trichomonas vaginalis (TV), Chlamydia trachomatis (CT) and Mycoplasma genitalium (MG). Logistic regression analysis was used to estimate odds ratios (ORs) and 95% confidence intervals (95% CIs) for the associations of STIs with incident atypical squamous cells of undetermined significance or worse (ASC-US+).

Results: During the 3 years of follow-up, 771 incident ASC-US+ cases were identified. Participants with infections of hrHPV, lrHPV, UP, MH, UU, TV, CT, and MG had ORs of 2.55 (95% CI: 2.14-3.04), 1.77 (95% CI: 1.41-2.23), 1.40 (95% CI: 1.18-1.65), 1.30 (95% CI: 1.09-1.55), 0.93 (95% CI: 0.76-1.14), 1.34 (95% CI: 1.01-1.78), 1.09 (95% CI: 0.68-1.75) and 2.00 (95% CI: 1.20-3.33), respectively, compared to women without infections.

Conclusions: Sexually transmitted infections, especially for HPV, UP, MH, TV, and MG, were significantly associated with incident ASC-US+ among Chinese women.

Shift 01-033 / #1616

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

STUDY ON THE CORRELATION AND RISK FACTORS OF HR-HPV INFECTION AND ABNORMAL CERVICAL CYTOLOGY WITH FEMALE LOWER GENITAL TRACT INFECTION

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Introduction: To investigate the correlation and risk factors between high-risk human papillomavirus (HR-HPV) and abnormal cervical cytology and lower genital tract infection in women.

Methods: 1240 women in cervical cancer screening were included to collect demographic and epidemiological information; cervical exfoliated cells were collected for HR-HPV testing and liquid-based cytology diagnosis; Reproductive tract secretions specimens were collected for vaginal microbiological testing for bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and trichomonas vaginitis (TV); The Logistic multivariate model was used to analyze the risk factors.

Results: The mean age of 1240 women was (47.26±8.26) years, of which 333 (26.85%) were HR-HPV positive and 218 (17.58%) had cytological diagnosis ≥ASC-US. The positivity of BV was higher in the HR-HPV positive than in the HR-HPV negative (55.26% vs. 41.90%, P<0.01), but the positivity of VVC was lower in the HR-HPV positive (6.31% vs. 14.00%, P<0.01). HR-HPV and BV positivity rates increased with cytologic severity (P< 0.01), and VVC positivity rates decreased with cytologic severity (P< 0.01). Binary logistics regression analysis showed that vaginal douching (OR=1.88, 95% CI: 1.15-3.05), menopause (OR=2.54, 95% CI: 1.63-3.95) and infection with BV (OR=1.60, 95% CI: 1.15-2.21) were independent risk factors for HR-HPV infection (P <0.05). Ordered logistic regression analysis showed that education level of high school and above (OR=0.50, 95% CI: 0.26-0.94) was a protective factor for abnormal cervical cytology, while sexual partner with redundant prepuce (OR=2.86, 95% CI: 1.58-5.19), menopause (OR=2.14, 95% CI: 1.32-3.48) and HR-HPV infection (OR=3.45, 95% CI: 2.40-4.94) were risk factors for abnormal cervical cytology (P<0.05).

Conclusions: BV was significantly associated with HR-HPV infection, and vaginal douching and menopause were important risk factors for HR-HPV infection. Compared to microecological abnormalities, HR-HPV infection was a determinant of abnormal cervical cytology, and lower level of education, sexual partner with redundant prepuce, and menopause increased the likelihood of abnormal cervical cytology.

Shift 01-034 / #1822

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-18-2023 7:00 AM - 5:00 PM

THE ASSOCIATION BETWEEN NON-HPV SEXUALLY TRANSMITTED INFECTIONS AND CERVICAL LESIONS: A MULTI-CENTER PROSPECTIVE COHORT AMONG CHINESE RURAL WOMEN

Simiao Chen[1], Tingyuan Li[2], Yakun Wang[3], Dingkun Wu[2], Yu Dai[3], Qinjing Pan[4], Zhihui Zhang[5], Xun Zhang[6], Liao Qiong[7], Shijun Jia[7], Dongsheng Wang[8], Fangjun Liu[2], Lingling Zhu[2], Xingsheng Cai[9], Chunlin Wang[9], Lingmei Yan[9], Xiaoyan Le[9], Jian Yin[10], Zeni Wu[11], Youlin Qiao[12], Yuqian Zhao[2], Wen Chen[3]
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Introduction: The impact of non-HPV sexually transmitted infections (non-HPV STIs) on cervical carcinogenesis has not been adequately validated, and the combined effect of non-HPV STIs and HR-HPV on cervical lesions remains uncertain. We explored the association of non-HPV STIs on cervical lesions and interaction between HR-HPV and non-HPV STIs in the multi-center prospective cohort study among Chinese rural women.

Methods: Data of 12121 participants were from a multi-center cervical cancer screening. Pathogens in the lower reproductive tract were detected by second generation sequencing technology. The associations of non-HPV STIs on abnormal cytology (ASC-US+ and LSIL+) and abnormal pathology (CIN1 and CIN2+) were evaluated by multivariable adjusted logistic regression models with odds ratio (OR) and 95% confidence interval (CI). The interaction between HR-HPV and non-HPV STIs was estimated based on relative excess risk due to interaction (RERI), attributable proportion (AP), synergy index (SI), and multiplicative-scale interaction.

Results: The multivariable adjusted OR of non-HPV STIs for ASC-US+ and LSIL+ in baseline were 1.34 (1.15, 1.55) and 1.38 (1.05, 1.82), respectively. The adjusted OR for incident ASC-US+ and LSIL+ in 3 years were 1.70 (1.40, 2.08) and 1.93 (1.30, 2.86), respectively. For the joint association of HR-HPV and non-HPV STIs with ASC-US+ in baseline, the joint OR was 1.15 (0.83, 1.60) with a significant additive

interaction (RERI-2.16, 95% CI 0.60-3.73; AP-0.29, 95% CI 0.09-0.48; SI-1.49, 95% CI 1.07, 2.07). Whereas, the adjusted OR for baseline and incident CIN1 and CIN2+ were not statistically significant. We found additive interaction only in incident CIN1 (RERI-5.75, 95% CI 0.24-11.25; AP-0.52, 95% CI 0.13-0.92; SI-2.37, 95% CI 0.85-6.56).

Conclusions: In this population-based multi-center cohort with 3 years follow-up, non-HPV STIs was associated with an increased risk of cervical lesions, especially abnormal cytology. The coexistence of HR-HPV and non-HPV STIs additively increased cervical lesions risk more than sum effect of individual risks.

Shift 01-035 / #1095

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-18-2023 7:00 AM - 5:00 PM

PREVALENCE AND RISK FACTORS OF HUMAN PAPILLOMAVIRUS ANAL INFECTION AMONG MSM AND TGW IN PHNOM PENH, CAMBODIA

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Introduction: Studies reported the increase of STIs among MSM and TGW, especially under HIV pre-exposure prophylaxis. In Cambodia, testing for HPV is barely performed. The objective was to estimate the prevalence of anal high-risk HPV (hrHPV) among MSM and TGW community in Phnom Penh.

Methods: A questionnaire was used to collect MSM/TGW information along with anal swab self-sampling. Analysis of hrHPV infections was performed by two methods : Cobas 4800 HPV test, Roche and AnyplexII HPV28 detection, Seegene and statistical analysis with R software.

Results: In total, 162 patients were included with a median age of 28.4 years and 56% were MSM. The majority were in open relationship (66%), reported bottom role (68%) and age at first sexual intercourse of 18.0(16 – 20) years. Seven-percent were HIV-infected and none of them received any HPV-vaccine. Overall, 97 (60%) anal samples were used for method comparison : agreement for HPV16, HPV18 and others hrHPV detection were respectively 0.91(CI95%, 0.81 – 1.00), 1.00(1.00 – 1.00) and 0.75(0.62 – 0.88) and the global performance to detect any of the 14 hrHPV was not significantly different. Fifteen samples were discordant: 3 for HPV16 positivity and 12 for others hrHPV positivity. Prevalence of all HPV types, hrHPV and other HPV were 83%, 66% and 65% with a median of 3(1-5), 1(0-3) and 1(0-3) different HPV types found, respectively. The prevalence of hrHPV included in the 9-vaccine (16, 18, 31, 33, 45, 52, 58) were 25%, 17%, 11%, 7%, 6%, 21% and 11%, respectively. Prevalence and median of hrHPV anal infections were significantly higher in HIV-positive patients.

Conclusions: Methods comparison showed a good agreement and the same performance to detect hrHPV infection in anal site. Prevalence of hrHPV infection is high, especially in HIV-population, and the implementation of HPV-vaccination in this population should be discussed to prevent anal lesions and cancers.

Shift 01-036 / #1173

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-18-2023 7:00 AM - 5:00 PM

THE PREVALENCE OF ANAL LOW RISK HPV INFECTION IN MEN WHO HAVE SEX WITH MEN IN SAINT PETERSBURG, RUSSIA

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Introduction: Low risk HPVs (lrHPVs) are known to be the cause of range of anal diseases. Our study aims to evaluate the most frequent lrHPVs prevalence in men who have sex with men (MSM) in Saint Petersburg Russia.

Methods: DNA from anal self-swabs of MSM participants was tested in Real Time PCR with the kit AmpliSens HPV6/11/44 for HPV6,11 and 44 E6 genes.

Results: 102 anal swabs were collected and tested. The median age of the participants was 32 years [IQR, 25–37 years], 35% of the participants were HIV positive. LrHPVs were detected in 37 specimens (36%; 95% CI, 28%-46%), from those 84% (95% CI, 69%-92%) were find positive with one lrHPV type, and 16% (95%CI, 8%-31%) were positive with two lrHPVs. HPV6 was the most frequent type and presented in 20%(95%CI, 13%-28%) swabs, HPV11 and HPV44 were found in 13% (95% CI, 8%-21%) and 10% (95% CI, 5%-17%) respectively. The younger group aged 18-24 tended to be less infected 25% (95% CI, 12%-45%) than others and there were no differences between 25-36 and 37-56 age groups, the average infection rate was 40% (95% CI, 30%-51%). Among those who reported constant condom usage the prevalence was 33%(95% CI, 21%-49%) and among the ones who used condom occasionally or never 38% (95% CI, 27%-50%). The prevalence of lrHPVs in groups with 0-5; 6-10 and ≥11 sex partners during recent 6 months was 31%(95% CI, 20%-43%), 32%(95% CI, 16%-53%) and 57%(95% CI, 37%-76%) respectively.

Conclusions: MSM patients are at greater risk of anal lrHPV-related diseases due to high prevalence of HPV6,11 and 44 , especially among those who are older than 26 years, have more than 10 partners per 6 months, and do not use condoms constantly.

Shift 01-037 / #1327

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-18-2023 7:00 AM - 5:00 PM

THE PREVALENCE AND ASSOCIATED FACTORS OF HUMAN PAPILLOMAVIRUS INFECTION IN DIFFERENT ANOGENITAL SITES IN CHINESE MALES

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Introduction: Human papillomavirus (HPV) infection is the main cause of anogenital cancers and genital warts. Little is known about the prevalence of anogenital HPV infections in the male population of China. This study aimed to examine the prevalence and risk factors of HPV infections in anogenital sites in Chinese males.

Methods: A total of 490 HIV-negative men aged 18-45 were recruited from January to April, 2022 in Shijiazhuang, China. Exfoliated cytological specimens from external genital (penis/glans penis/coronary sulcus, PGS) and perianal/perineum (PA) were taken from 412 participants, whereas anal cytological specimens were from 490 participants for HPV PCR genotyping testing with 25 types detected (HPV16/18/31/33/35/39/45/51/52/56/58/59/66/68/26/53/73/82/6/11/42/43/44/81/83). The demographic characteristics, sex behavior, medical history, and other individual information were collected by self-administered questionnaires.

Results: The prevalence of any HPV infection in PGS was relatively high (26.7%), followed by PA (19.4%) and anal(5.0%). The infection rates of 14 high-risk HPV (HPV16/18/31/33/35/39/45/51/52/56/58/59/66/68) in the above three sites were 21.6%, 15.1% and 4.4%, and the positivity of low-risk HPV (HPV6/11/42/43/44/81/83) were 5.1%, 4.6% and 1.0%, respectively. HPV 66 (4.1%, 4.3%) and 58(3.6%, 3.6%) were the most frequently detected HPV types in PGC and PA specimens, but HPV 66 (1%) and 31(0.8%) were the most common in anal specimens. Besides, 14%, 9.4% and 2.9% of PGS, PA and anal specimens were DNA positive for 9-valent HPV vaccine types (HPV6/11/16/18/31/33/45/52/58). Individuals with ≥4 lifetime sex partners had a statistically significant increased risk of any type HPV infection in PGS [adjusted odds ratio (aOR), 2.35; 95%CI: 1.08-5.11] and PA (aOR, 2.71; 95%CI, 1.11-6.64). No evident relationship was found between other factors and HPV infection.

Conclusions: The study indicated that the external genital more likely harbored HPV infection than the other two anogenital sites in men. Multiple lifetime sex partners might be a potential risk factor of HPV infection.

Shift 01-042 / #379

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

SCREENING AND MANAGEMENT OF PRE-CANCEROUS CERVICAL LESIONS IN BURKINA FASO,

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Introduction: Cervical cancer (CC) is common in Burkina Faso. Regarding 2020-2024 strategic plan against cancer, the screening interventions implemented are based on visual inspection of the cervix with acetic acid (VIA), and cryotherapy for treatment for precancerous lesions. This screening method is still not very effective.

Methods: To implement an innovative cervical cancer screening and precancer treatment project (DNA screening for Human Papilloma Virus (HPV) followed by VIA and thermo coagulation for treatment) ; in 9 health centres including different services (laboratory service, HIV screening and gynaecological-obstetric consultation). The project was implemented gradually from August 2018 to November 2019. A significant amount of preparatory time was required, particularly for a socio-anthropological study and time for workshops, reflection and training with the various stakeholders in order to propose a project that was best suited to the context. MdM also set up action research during the implementation of the activities to ensure that they were properly implemented. Finally, the analysis of the difficulties encountered enabled us to propose solutions to improve patient care.

Results: Training of providers was carried out (VIA, HPV testing, counselling, palliative care and loop electrosurgical excision procedure (LEEP)). These training sessions involved 103 midwives, 90 auxiliary midwives, 18 nurses, 11 laboratory technicians and 17 doctors. In addition, partnerships were set up with various structures and institutional and non-governmental actors and many tools were developed with the mobilization of the actors concerned: training modules, orientation diagram of the patient care pathway, quality protocols to ensure the traceability and quality, registers , etc. the experience was positive: 98.8% of users were satisfied.

Conclusions: Thanks to the mobilization around this innovative pilot project, many tools were developed and adjusted as the activities were implemented. The results and good practices identified in the framework of this program can thus be used to help the replication of other projects.

Shift 01-043 / #511

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

FEASIBILITY AND UTILIZATION OF COMMUNITY-BASED MOBILE CERVICAL CANCER SCREENING USING HPV SELF-SAMPLING IN RURAL INDIA: LONGITUDINAL STUDY

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Introduction: Cervical cancer is the second most common female cancers in India. Annually, there are approximately 97,000 cases and 60,000 deaths. Currently, less than a third (29.8%) of women report ever being screened for cervical cancer. HPV DNA screening has been shown to be a highly sensitive and specific cervical cancer screening method. This abstract describes the results for community-based HPV screening program in rural Mysore District in the south Indian state of Karnataka.

Methods: Between 2013 to 2019, an opportunistic sample of community-dwelling women were screened for high-risk (hr) HPV DNA using a Hybrid Capture 2 Assay (Qiagen, Gaithersburg, Maryland) and self-collected vaginal swabs. Those screening positive underwent further screening with Visual Inspection with Acetic Acid (VIA) and/or Liquid Based Cytology. Staff returned within seven days to provide results and counselling. Data were analysed using Stata version 19.0.

Results: Among 1,122 eligible women offered testing, 1,101 (98.1%) consented to screening using HPV self-sampling. The average age of participants was 35.6 (SD: 11.1), 1,018 (82.3%) had less than 7th grade education, 98% reported their religion as Hindu and 54% were housewives. Eighty-three (7.5%) women were positive for hr HPV DNA and underwent VIA. Among those, 61 (73.5%) had positive VIAs and were triaged to LBC. Five participants (8%) had precancers (3 HSIL and 2 LSIL) on LBC. About 92% of the women who underwent VIA would have been overtreated in a VIA ‘screen-and-treat’ approach.

Conclusions: Acceptability was high for self-sampling for HPV DNA. VIA appears not to be a practical strategy for cervical cancer treatment in rural India because of the large number of false positive findings, and elevated levels of overtreatment. Large scale screening with HPV DNA testing using self-sampling and triage to LBC should be considered as an alternate cervical cancer screening strategy.

Shift 01-044 / #532

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

LEVELS OF ADHERENCE TO TREATMENT AND FOLLOW-UP RECOMMENDATIONS AFTER POSITIVE SCREENING FOR CERVICAL PRECANCEROUS LESIONS IN ETHIOPIA

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Introduction: Although cervical cancer can be prevented with HPV vaccination and screening, incidences in sub-Saharan African countries remain high. In Ethiopia, visual inspection with acetic acid (VIA) screening is offered free of charge. Women with a VIA-positive screening should receive treatment with cryotherapy/thermal ablation or LEEP and a follow-up examination is recommended 1 year after treatment. While current studies are primarily investigating the reasons for the low use of screening, it is not yet known whether the women who are screened VIA positive receive treatment for (pre)cancerous lesions and follow-up care.

Methods: In our retrospective observational study, data were collected from all women screened positive with VIA between 2017 and 2020 in 14 randomly selected health facilities in two regions. We collected information on screening results, therapy, follow-up, and the patient's phone number for 701 women from logbooks and patients review. The levels of adherence to treatment and follow-up were calculated and a multivariate analysis was performed. In addition, 30 in-depth interviews were conducted with healthcare workers to explore health system related barriers.

Results: We found that 90% of all detected lesions were treated. Of those patients treated with cryotherapy, 88% received their treatment on the day of screening – adhering to the single-visit approach. Of all women who received treatment, only 45% of women adhered to the follow-up protocol. The analysis of factors influencing adherence to follow-up has not yet been completed.

Conclusions: Conclusion: Most patients received treatment for the detected lesion, but only a few came back for subsequent follow-ups after one year. Therefore, adherence to follow-up should be integral to the cervical cancer screening protocol. In our further analysis, we hope to identify key factors and develop interventions that could improve adherence to follow-up.

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Poster Viewing
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TRIAGING CHALLENGES AFTER PRIMARY HPV TESTING IN LIC: THE CASE OF ETHIOPIA

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Introduction: Self-collection-based Human Papillomavirus (HPV) testing has been found to improve the uptake of screening, including in Lower and Middle-Income Countries (LMIC). The prevalence of high-risk HPV at age >30 years in LMIC is higher compared to the countries where the efficacy trials were performed. It is a challenge for LMIC to decide to introduce HPV NAT testing for the general population and which test. No clear guidelines are given for the triaging of HPV-positive women.

Methods: A population-based cluster randomized trial was conducted among women aged 30-49 years in Butajira, south-central Ethiopia. A total of 893 samples were tested from 1020 sensitized women. A self-sampling device (Evalyn Brush, Rovers, Oss, The Netherlands) was used and HPV presence and genotype were determined using multiplexed genotyping (MPG) by BSGP5+/6+ PCR with Luminex read out. The comparison was made by standard care, screening by VIA (Visual Inspection by Acetic acid).

Results: Out of 721 samples with sufficient quality, 144 (20%) tested positive for at least one high-risk HPV genotype. Out of women positive for high-risk HPV, 122 (85%) attended VIA as a follow-up triage test. Of women attending the follow-up examination, 10(8.2%) were found positive by VIA. Of 22 VIA positives, 11(50%) were found negative during the quality check-up by the senior gynecologist.

Conclusions: Conclusion: The study demonstrated significantly higher levels of population-based uptake for self-collection HPV testing compared with VIA. Women adhered better (85%) to the follow-up test after they had received their HPV testing results. Self-collection for HPV testing may significantly improve the uptake of cervical cancer screening in Ethiopia. In LMICs such as Ethiopia, where the HPV prevalence is high there should be simple and more specific triaging tests to mitigate the health system constraints to handling high numbers of women who need subsequent follow-up.

Shift 01-046 / #548

Poster Viewing
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WORLD HEALTH ORGANIZATION (WHO) LIVING RECOMMENDATIONS AND SYSTEMATIC REVIEWS TO RAPIDLY EVALUATE EVOLVING EVIDENCE ON CERVICAL CANCER SCREENING AND TREATMENT: A NOVEL APPROACH

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Introduction: In 2021, WHO issued recommendations for cervical screening with HPV molecular tests, triage tests and treatment. The WHO recommends different approaches: 1) screen and treat or screen, triage and treat from age 30 for the general population; and 2) screen, triage and treat from age 25 for women living with HIV (WLHV). Producing these recommendations required up to three years. Rapidly evolving triage, screening and treatment technologies require a responsive evidence-based process, called living recommendations, to ensure expedient translation of research into cervical cancer screening and treatment guidance.

Methods: The WHO methodology to develop living recommendations and address evolving evidence included the following steps: 1) create a living guideline development group (LSR GDG), 2) identify recommendations that will have to be updated “living recommendations”, 3) survey the evidence, 4) conduct living systematic reviews, 5) determine whether evidence warrants a new recommendation, 6) update recommendations when warranted, 7) obtain external review, and 8) publish. Additionally, we plan to evaluate the implementation of these methods.

Results: The process will commence in December, 2022. To identify ‘living’ versus ‘static’ recommendations, the LSR GDG will review multiple inputs: an electronic platform map of current recommendations to track guidance and identify gaps; presentations to capture rapidly evolving evidence on screening, triage and treatment; and programme managers and field experts feedback on implementation of current recommendations. The LSR GDG plans to evaluate evidence from new screening and triage methods which may include artificial intelligence for aiding cervical visualization, methylation, genotyping bundles, self-sampling strategies, or other triage or screening modalities.

Figure 1: Process for Living Recommendations

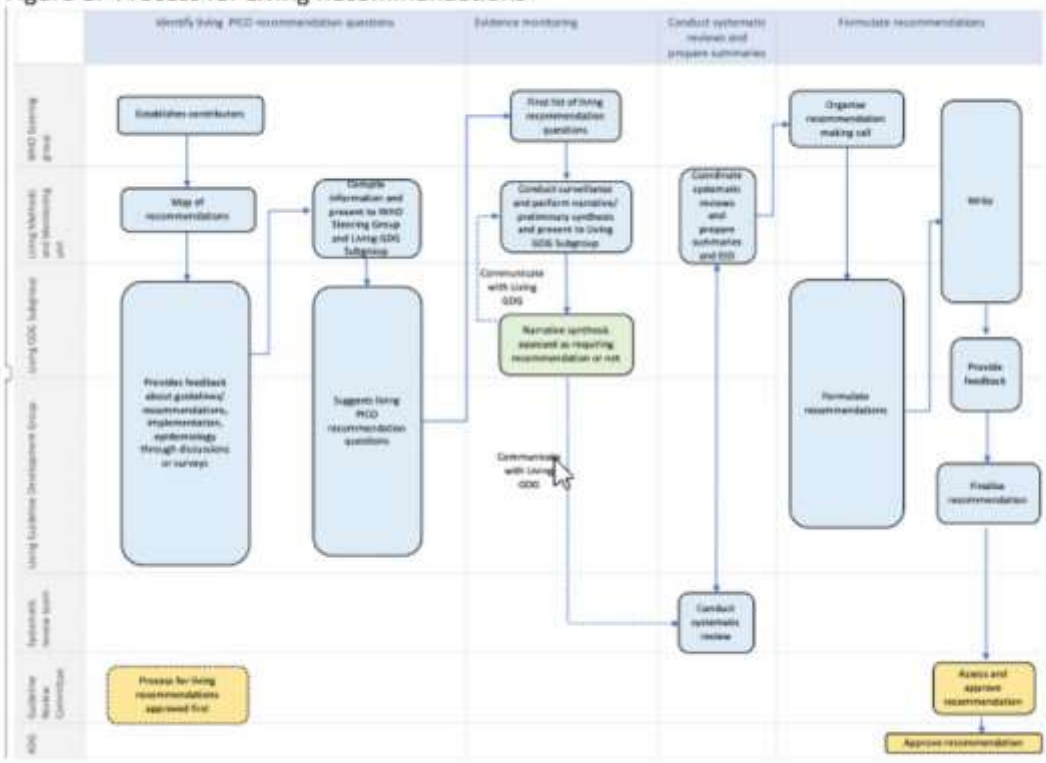

Table 1: Criteria for Living Recommendation Prioritization

Criteria contributing to recommendation that may change	Comments	Changes have occurred or will occur within a year	Potential impact
Epidemiology of 'disease' and population			
Prevalence of disease			
Burden of disease			
Context			
Perception			
Priority			
Intervention (or comparator)			
New intervention or changes to intervention			
Practice			
Resistance			
Benefits and harms of intervention			
Values and preferences			
Other criteria			
Acceptability of the intervention			
Equity			
Feasibility/implementation			
Resources (human, equipment, costs)			
Pragmatic issues in the country; in WHO			

Conclusions: This living guideline process enables end-users (policymakers, program managers, programme officers, and other health sector professionals) to receive new or rapidly evolving evidence-based recommendations with expediency and actively engages them in the process while ensuring WHO supports its member states to reach 2030 cervical cancer elimination targets.

Shift 01-047 / #712

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EVALUATING CERVICAL CANCER LITERACY AND CERVICAL SCREENING UPTAKE AMONG WOMEN IN PUEBLA, MEXICO

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Introduction: Cervical cancer is the third most common cancer among women in Mexico with 4335 deaths annually. This study assessed the relationship between cervical cancer literacy and cervical cytology (pap smear) screening uptake among women receiving care at a government hospital in Puebla, Mexico.

Methods: Women 21 years and older, eligible to receive healthcare from a government hospital were approached and recruited to participate. After consent, 200 consecutive women were administered a 20-item questionnaire assessing demographic characteristics, self-reported pap smear history, cervical screening perceptions and barriers to obtaining screening. The Cervical Cancer Literacy Assessment Tool (C-CLAT), a 21-item test validated in Spanish, evaluated their cervical cancer literacy. We compared demographic characteristics and pap smear history among women with and without adequate cervical cancer literacy using the Fisher's exact test and the Mann Whitney U test.

Results: Of women (85.5%; 171/200) who ever had a pap smear, 90% (153/170) reported receiving a pap smear within the last 3 years. Adequate cervical cancer (CC) literacy was low at 33.5% among women. Participant's occupation ($p<0.05$) and educational status ($p<0.005$) were significantly associated with cervical cancer literacy. Although not significant, a higher proportion of women with adequate CC literacy reported ever receiving a pap smear (90% vs 83%) and in the past three years (93% vs 88%) compared to women without adequate CC literacy. Additionally, 11.5% of participants did not know what a pap smear is. Participants also indicated they would like to receive information about cervical cancer screening from their doctor (37.5%) or from informational pamphlets (25%).

Conclusions: Although a high proportion of women received pap smears per Mexican guidelines, and were college-educated, their knowledge related to cervical cancer was inadequate. Enhancing cervical cancer literacy through increased resources is essential to maximize screening uptake and prevent cervical cancer disease.

Shift 01-048 / #750

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SELF-COLLECTED CERVICAL CANCER SCREENING IN RWANDA

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Introduction: Currently Rwanda has no national cervical cancer screening program. Prior research has shown that self-collection is a highly acceptable method for cervical cancer screening that can be rapidly expanded throughout communities. The goal of this study is to better understand the barriers to cervical cancer screening and preferences towards self-collection in Rwanda.

Methods: This cross-sectional study collected data in June 2022. Rwandan data collectors recruited women attending two semi-rural antenatal care clinics in Rwanda. Descriptive results were analyzed using counts and frequencies.

Results: In all 374 women completed the survey. The majority of the women were married (39.4%), had a primary school education (42.1%), and had never been screened for cervical cancer (77.0%). Approximately half the women did not know any symptoms of cervical cancer and over a quarter did not think cervical cancer could be prevented. The primary barrier to screening was knowing how or where to get tested (56.7%). Most women previously were screened at a hospital (75.0%), but their preference in the future would be at a health center (67.4%). When asked about self-collection, 88.5% were willing to self-collect at home and 71.6% said that they would not be embarrassed to do so. Finally, when asked about how they would prefer to receive results, 55.2% reported text message.

Conclusions: The results of our study demonstrate that women in Rwanda are open to self-collection for cervical cancer screening. Furthermore, our results show that many women do not get tested because they are unsure where to go for testing. As such, self-collection for cervical cancer should be considered as a method to expand cervical cancer screening in Rwanda. By expanding the cervical cancer screening program, Rwanda can reduce the number of women diagnosed with cervical cancer which in turn will contribute to the global elimination of the disease.

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IDENTIFYING MULTILEVEL STRATEGIES FOR IMPLEMENTING CERVICAL CANCER SCREENING PROGRAMS ACROSS THE GLOBE

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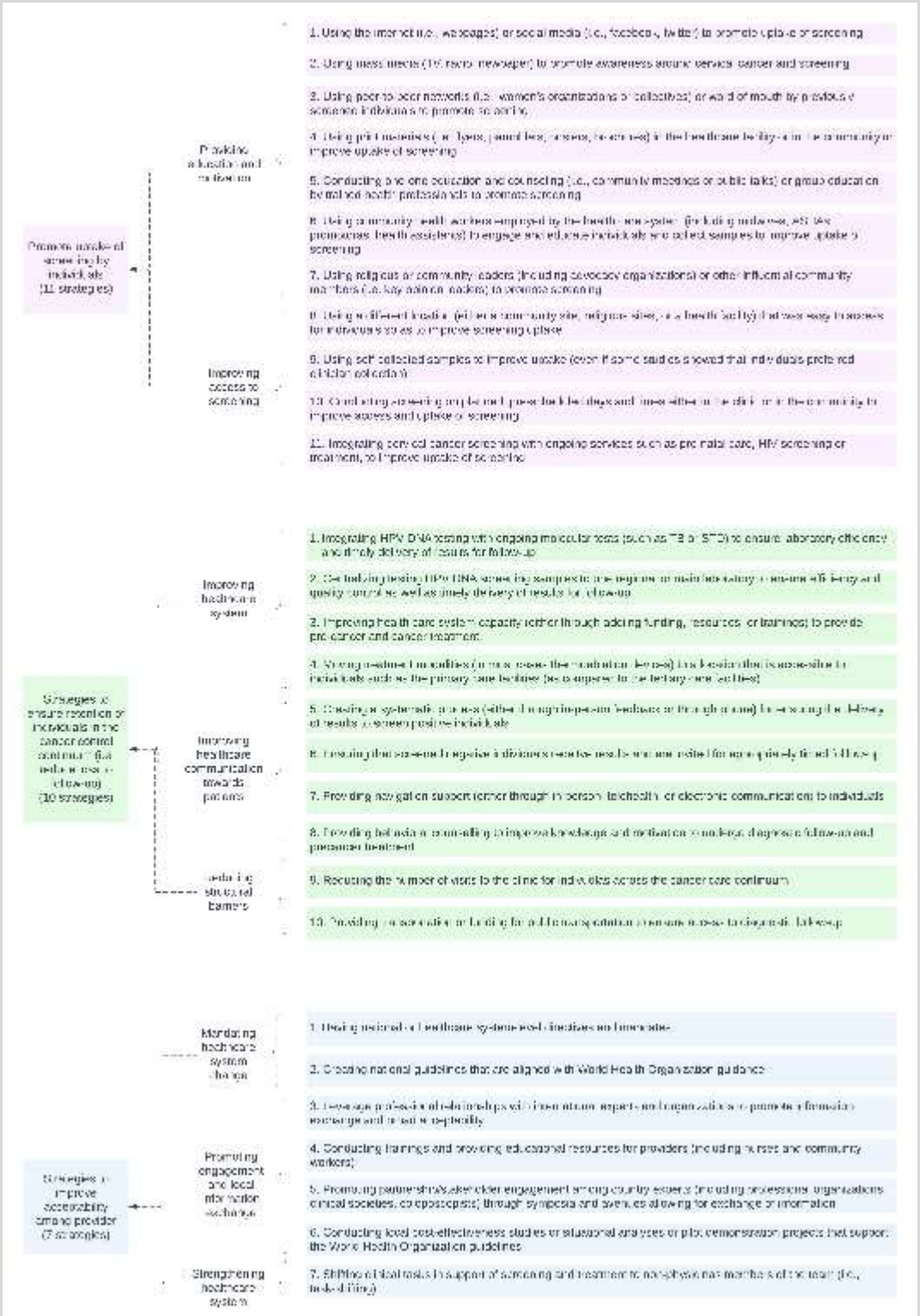
Introduction: To achieve the global targets for cervical cancer elimination, there is an immediate need to shift our research focus to adoption and implementation of national programs in alignment with the World Health Organization's (WHO) guidelines. Guided by the science of implementation, a key step is to develop a knowledge base of practice-based evidence around implementation that can inform global scale-up and sustainability of programs.

Methods: Directed by the Implementation Working Group for the updated WHO guidelines, we conducted 32 interviews with experts involved in cervical cancer screening programs from the six WHO Regions. Interviews were guided by the Exploration, Preparation, Implementation, and Sustainment Model, with visual probing techniques. Interviews were conducted on Zoom with simultaneous translation as needed, and notes and transcripts were analyzed to identify implementation strategies.

Results: For promoting uptake of screening, three common strategies emerged. First, using pre-existing community workforce was critical in building community trust for participation. Second, awareness generated by word of mouth from screened individuals was important for uptake. Third, using self-collected samples from individuals was essential in reducing the burden on logistics and was generally more acceptable. For ensuring retention of individuals, the most prominent consideration was to have a well-planned, systematic process for delivering positive results to individuals. Many respondents indicated that centralization of the laboratory process could help timely delivery of results while others preferred point of care organization, to ensure retention. Provider acceptability seemed to be highest in systems with national screening programs aligned with the WHO guidelines, especially when program planning

involved facilitated and broad stakeholder



engagement.

Conclusions: Examining existing programs allowed us to generate an in-depth practice-based taxonomy, which highlights commonly used strategies, that can guide future global and national

implementation efforts. Future studies could help determine their effectiveness in improving key implementation outcomes in different contexts.

Shift 01-050 / #796

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DISTRIBUTION OF HIGH-RISK HUMAN PAPILLOMA VIRUS TYPES AMONG WOMEN LIVING WITH HIV WITH PRECANCER AND CANCER OF THE CERVIX

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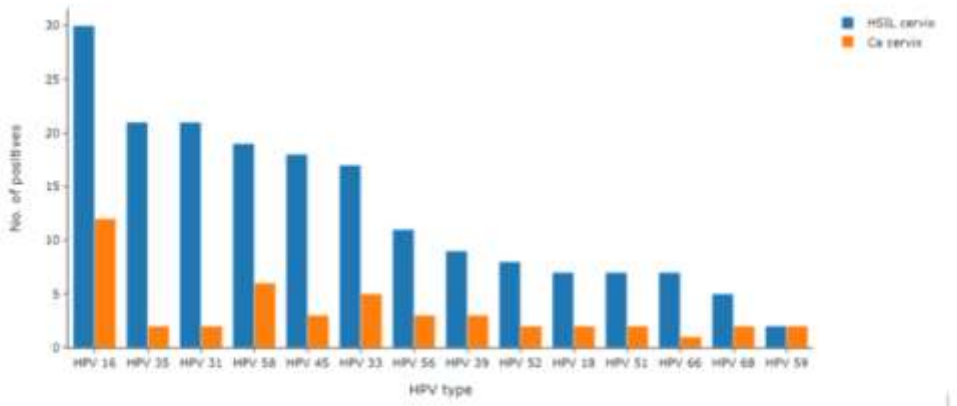
Introduction: Persistent infection with high-risk human papillomavirus (hrHPV) is associated with the development of cervical cancer (CC) and women living with HIV (WLHIV) have a 6-fold risk of developing CC. We describe the distribution of hrHPV types in WLHIV with cervical precancer and cancer at an urban clinic in Harare, Zimbabwe

Methods: A retrospective review of the case notes of 101 WLHIV with a histological diagnosis of cervical precancer (high grade squamous intraepithelial lesions - HSIL) and cancer was conducted between January 2021 and August 2022. Routinely collected demographic data, HIV viral load (VL) and antiretroviral medication (ART) was abstracted from the patient electronic medical records. Key summary statistics are presented.

Results: Cervical HSIL was found in 80 (79.2%) women, and 21 (20.8%) had CC. Median age at diagnosis of CC and cervical HSIL was 48 (IQR 44 – 51) and 45 (IQR 40 – 52) years, respectively. Median duration on ART was 10.4 (IQR 5.9-14.5) and 8.5 (IQR 4.0 – 13.0) years for those with CC and HSIL and the HIV VL suppression (< 50 cp/mL) was 73.7% (14) and 85.9% (67) for women with CC and HSIL respectively. HPV test results were available for 97 (95.1%). Of these,100% of patients with CC and 90% (72) of those with cervical HSIL were hrHPV positive. The most common hrHPV types in women with CC were 16, 58 and 33, while 16, 35 and 31 were the common in those with cervical HSIL. (Figure 1).

Two or more hrHPV types were found in 62.9% (61).

Figure 1: Distribution of HPV types among women diagnosed with cervical cancer or high-grade squamous intraepithelial lesion



Conclusions: With 95% hrHPV positivity for cervical HSIL and CC, these data support HPV testing as the primary screening modality. It highlights that HIV disease control does not completely protect against the development of CC, and that research is required to establish bivalent HPV vaccine efficacy against diverse hrHPV types.

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CHALLENGES ALONG CERVICAL CANCER SCREENING PATHWAY: HOW CAN DIGITAL SOLUTIONS ADDRESS THESE?

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Introduction: Cervical cancer (CxCa) remains a public health problem, with an estimated 342,000 deaths globally every year. World Health Organizations global strategy suggests strengthening laboratory capacity and quality assurance programs. However, there is limited literature providing statistics along the screening pathway, such as guideline adherence and patient drop-out rate. In addition, clinicians and program managers face tremendous administrative burden, and it remains unclear how these can be addressed by digital solutions.

Methods: HPV-based opportunistic CxCa screening started at Hospital del Mar in April 2018 and by September 30, 2021, more than 10.000 women between 30 and 65 y.o. had participated. The experience acquired during this period is the basis for this study. Fifty-seven semi-structured interviews (from April 2021 to August 2022) with gynecologists, pathologists, cytotechnologists, midwives and program managers were carried out to identify key challenges along the CxCa screening pathway. Interview results were taken into the development of a new digital solution that supports the CxCa screening and diagnostic process by integrating patient tracking, lab report communication improvement, clinical decision support, and population and program performance analytics.

Results: Interview results with Healthcare professionals showed that top challenges are: 1. Administrative burden due to manual tasks and partially file management in paper format; 2. Lack of program performance analytics, resulting in uncertainty and low confidence in taking necessary actions; 3. Limited visibility and efforts needed for quality assurance for colposcopy and laboratory tests.

Conclusions: CxCa pathway can be further improved by digital solutions, particularly in areas of digitizing the patient tracking and information management to reduce administrative burden, increase operational efficiency, increase visibility of key metrics for performance improvement, and empower clinicians to make more confident decisions.

Shift 01-052 / #847

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INCREASE OF CERVICAL CANCER PREVENTION IN THE CZECH REPUBLIC USING SELF-SAMPLING

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Introduction: The cervical cancer screening program is based on annual cytology with HPV triage in the Czech Republic.Screening HPV testing is covered by health insurance for all women aged 35 and 45 from 2021.The major challenge is the involvement of the women from a refractory population who do not attend the cervical cancer screening program for a long time.The objective of the study was to compare the different approaches to inviting women to the cervical cancer screening program.

Methods: The study was conducted in three arms. 6388 women from the database of dietary supplements company were included in the Arm A regardless of whether they participated in the cervical cancer screening program.Women who do not participate in the cervical cancer screening program for at least three years, and mostly had not previously reacted to several rounds of invitation, were selected from a database of a health insurance company (Arm B, 4813 women) and gynecologist database (Arm C, 653 women).EvalynBrush self-sampling devices (Rovers Medical Devices) were sent by Czech post to the women home address.All returned samples were analyzed using the Anyplex II HPV HR Detection kit (Seegene)/QIAscreen HPV PCR (Qiagen).

Results: The return rate was 7.6% (486/6388) in Arm A, 7.6 % (367/4813) in Arm B and 9.0% (59/653) in Arm C.HPV positivity was detected in 7.4% (36/486) of Arm A samples, 17.7% (59/334) of Arm B samples and 10.2% (6/59) of Arm C samples.

Conclusions: The return rate was highest in Arm C where the women were invited through their gynecologists.Based on these results, we are currently expanding Arm C to include additional 4000 invited women.The offering of self-sampling could significantly increase the attendance of Czech women in the cervical screening program. This work was supported by grants: IGA_LF_2022_012,Programme EXCELES (LX22NPO5103),LM2018133,CZ.02.1.01/0.0/0.0/16_019/0000868 and charity Cancer Research Czech Republic.

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BUSCHKE-LOWENSTEIN GIANT ANOGENITAL TUMOR IN AN HIV-INFECTED PATIENT AT THE AIDS STAGE : RURAL AREA CASE STUDIES

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Introduction: Buschke-Lowenstein tumor (TBL) is a giant condyloma acuminata that is characterized by its degenerative and invasive potential as well as its recurrent nature after treatment. Human papillomavirus (HPV) type 6 and/or 11 infection, which is primarily sexually transmitted, is associated with this tumor. This tumor is more common in immunocompromised men and grows around the genital and perineal area sometimes causing a large, grassy ulcerated lesion.

Methods: Screening for other sexually transmitted infections should be systematic in these patients. The histological appearance is benign, contrasting with the clinical significance of this tumor

Results: Here we report the case of a 21-year-old patient with a history of unprotected sex who developed perineal swelling over several months. Physical examination found multiple exophytic and budding lesions of the anal margin presenting with a butterfly wing appearance all evoking a cauliflower crowned with centrifugal circinate lesions. Multiple condylomatous lesions of the anal margin were associated with it. There was no lymph node involvement. The patient tested positive for HIV and hepatitis B, with a CD4 count of 119 cells/mm3. Real-time PCR (qPCR) revealed HPV-16 and other high-risk (HR)-HPV DNA. Histological examination of a biopsy specimen from the anal margin revealed the presence of koilocytes in a squamous epithelial mucosa and dyskeratotic and atypical cells in the basal epithelial layer, indicative of human papillomavirus (HPV) infection. . The diagnosis of TBL was made and the patient was cared for by a multidisciplinary team including an infectious disease specialist, a gastroenterologist, a dermatologist and a surgeon.

Conclusions: Conclusion TBL is a rare tumor associated with HPV infection, the transmission of which is essentially sexual. It is more common in men and should be investigated for immunosuppression by HIV as well as the presence of other sexually transmitted infections.

Shift 01-054 / #1051

Poster Viewing
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CERVIXCHECK: OUTCOMES OF A DIGITAL APPROACH TO SELF-COLLECTED CERVICAL SCREENING IN A LOW-UPTAKE REGION OF BRITISH COLUMBIA, CANADA

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Introduction: Human papillomavirus based self-collection (HPV-SC) for cervical screening is highly accurate and has the potential to increase screening coverage in under-screened populations. In British Columbia (BC), Canada, an innovative digital approach to HPV-SC, CervixCheck, was developed and piloted in a community with low uptake of cervical screening to assess the feasibility and acceptability of a digital approach to HPV-SC.

Methods: CervixCheck was piloted in partnership with eight family physicians, with a predominantly South Asian patient population, who provided input on design and implementation. Partner physicians invited patients due or overdue for cervical screening (≥ 3 years since last screen) to register through the CervixCheck website. Once registered online, patients' eligibility was checked, and they received an HPV-SC kit by mail. After collection, kits were mailed to the lab for testing, with results provided online. The number of registrations, HPV-SC uptake rates, and acceptability are presented.

Results: The pilot began in April 2019. As of Sept 2022, 313 participants have registered, with 228 (73%) eligible. Of kits sent, 150 (66%) have been returned, and 65 (29%) of participants are considered to be non-responders (kits unreturned after 3 reminders). To date, 11 (7%) participants tested HPV positive and 10 (91%) have attended follow-up care. 147 participants were invited to complete an online feedback survey, with 33 (22%) returned surveys. Overall, 97% reported the digital HPV-SC approach as acceptable. Challenges to increasing further uptake include engagement with busy primary care providers, the COVID-19 pandemic, reaching the under-screened population, and ensuring return of self-collection kits.

Conclusions: CervixCheck is an innovative digital approach for offering HPV-SC to increase the uptake of cervical screening. To date, our findings demonstrate this approach is acceptable and feasible to the under-screened and can inform future HPV-SC program planning. Further exploration of barriers to returning self-collection kits and identifying under-screened women is ongoing.

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Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
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SYSTEMATIC REVIEW OF CERVICAL SCREENING PARTICIPATION AND ACCESS BARRIERS FOR PEOPLE WITH INTELLECTUAL DISABILITY

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Introduction: Australia is on track to be the first country to eliminate cervical cancer but a current national planning process is prioritising equity in elimination timing. People with intellectual disability are significantly less likely to engage with cervical screening than the general population. Innovative co-designed solutions are required to improve screening uptake.

Methods: To inform ScreenEQUAL rollout, we commenced a systematic review of cervical screening participation and facilitators and barriers to screening for people with intellectual disability, and interventions to improve screening uptake. ScreenEQUAL is a 3-year Australian-government funded multifaceted, co-designed intervention utilising an integrated knowledge translation framework (iKT). This cluster randomised-control trial will evaluate the impact of co-produced health education materials and a training program, targeted to people with intellectual disability, their carers, and healthcare providers, aimed at improving screening uptake.

Results: We identified 31 relevant studies conducted across 7 countries (England, United States of America, Canada, Australia, New Zealand, Scotland, Taiwan). Low screening rates were reported for women with intellectual disability, (range 10 - 55%, for screening intervals up to 5-years), which compares to 2019 World Health Organisation (WHO) general population estimates of 84% (Australia), 87% (Canada) and 82% (USA) of women screened in the past 5-years. Barriers included lack of understanding of screening need, fear of the procedure, communication and consent difficulties, perceived sexual inactivity, healthcare provider discomfort and ableist healthcare. Interventions to improve screening included annual health checks, health diaries and one-on-one counselling; most were embedded within broader health interventions and had minimal impact on cervical screening outcomes.

Conclusions: People with intellectual disability experience low cervical screening rates and specific and substantial barriers to screening participation. Our systematic review will inform implementation of the ScreenEQUAL study and support policy and practice change across Australia, with implications for achieving the WHO cervical cancer elimination targets equitably.

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Poster Viewing
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EVALUATING THE CLINICAL PERFORMANCE OF P16/KI-67 DUAL-STAINING CYTOLOGY FOR CERVICAL LESION DETECTION IN PREMENOPAUSAL AND POSTMENOPAUSAL WOMEN IN CHINA

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Introduction: To evaluate the clinical effectiveness of the p16/Ki-67 dual-staining cytology in detecting cervical lesions in premenopausal and postmenopausal women in China.

Methods: This multicenter cross-sectional study enrolled 4,364 eligible women with valid p16/Ki-67, high-risk human papillomavirus (HR-HPV), and liquid-based cytology (LBC) test results, including 542 cancer and 217 CIN2/3 cases. The sensitivity (SEN), specificity (SPE), positive predictive value (PPV), and negative predictive value (NPV) of each test in different subgroups were calculated and compared.

Results: P16/Ki-67 positivity increased with histopathological severity in premenopausal and postmenopausal women ($P<0.05$), while individual expression of p16 and ki67 in postmenopausal women was disordered. In primary screening, p16/Ki-67 showed higher SPE (88.09% vs. 81.91%, $P<0.001$) and PPV (33.8% vs. 13.18%, $P<0.001$) in CIN2/3, and higher SEN (89.97% vs. 82.61%, $P=0.012$) and SPE (83.22% vs. 79.89%, $P=0.011$) in cancer in premenopausal women. For triaging the HR-HPV+ population to identify CIN2/3, p16/Ki-67 performed comparably to LBC, and showed higher PPV (51.14% vs. 23.08%, $P<0.001$) in the premenopausal subgroup. For triaging ASC-US/LSIL population, p16/Ki-67 showed higher SPE and lower colposcopy referral rate than HR-HPV in both premenopausal and postmenopausal women. Association between p16/Ki-67 positivity and HR-HPV infection was determined in SCC (Adjusted OR=5.75, 95% CI: 2.31-14.37) but not in ADC patients.

Conclusions: Expressions of p16/Ki-67 between premenopausal and postmenopausal women are varied. In primary screening, p16/Ki-67 performs better in premenopausal women. For triaging, p16/Ki-67 is suitable for HR-HPV+ women, especially premenopausal women, to identify CIN2/3 and patients with ASCUS/LSIL.

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Poster Viewing
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THE ACCEPTABILITY AND FEASIBILITY OF SELF-SAMPLING HPV TESTING DURING PREGNANCY IN MALAYSIA: PRELIMINARY FINDINGS

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Introduction: The biggest challenge to cervical cancer elimination in low-resource settings is the lack of an effective service delivery model. This study assesses the feasibility and acceptance of self-sampling HPV testing in an antenatal setting as an innovative approach to increase opportunistic screening.

Methods: This was a cross-sectional study carried out at the antenatal clinic of University Malaya Medical Centre, Malaysia. Women aged ≥ 30 years old and ≥15th week pregnant were invited to participate in the study. All participants were given options for self-sampling or healthcare- acquired low vaginal swab using the COPAN 552C FLOQSwab®. Pre- and post-sampling's acceptability was assessed using 6 indices measured using Likert scale. Sociodemographic data and cervical screening history were collected using a validated questionnaire. All samples were tested on a clinically validated HPV genotyping platform.

Results: A total of 403 eligible pregnant women were invited with 80% (321/403) of them agreeing to HPV testing. The median age of the study population was 34 years old (Interquartile range: 32 – 36). Most participants (73.2%) were non-attendees to regular cervical screening. Almost all participants (98.8%) agreed to carry out self-sampling method and were able to complete sampling procedure without any assistance. Of the 317 self-collected sample, 97.8% returned a valid HPV test result. Prior to performing self-sampling, more than half of the participants did not feel good (54.8%) about self-sampling HPV testing and were worried about discomfort (63.5%). However, most participants' perceptions changed significantly after the procedure and reported that it was easy (87.2%), not embarrassing (99.1%), comfortable (62.3%) and were confident about self-sampling (88.8%).

Conclusions: Self-sampling using the COPAN 552C FLOQSwab for HPV testing is acceptable and safe among antenatal populations and serves as a promising approach to increase screening coverage, especially the under screened populations.

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Poster Viewing
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TIME AND AGE DEPENDENT HPV CLEARANCE AFTER HPV POSITIVE SCREENING INDEX SAMPLE: HEALTH CARE POLICY IMPLICATIONS FOR RECOMMENDED FOLLOW-UP

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Introduction: In the Capital Region of Denmark, women aged 30 to 59 undergoing HPV screening are recommended a re-test 12 months later if the index sample is 1) HPV positive (any genotype) with normal cytology or 2) ASCUS or LSIL with any of HPV35, 39, 45, 52, 56, 58, 59, 66, 68. The aim is to allow viral clearance and thereby lower potential overtreatment.

Methods: Women (30-59y) undergoing HPV screening from March to August 2021 with an index screening outcome of any HPV genotypes/normal cytology and ASCUS or LSIL/any HPV35, 39, 45, 52, 58, 56, 59, 66, 68 (N=1317). All HPV testing was done with the BD Onclarity HPV test. Clearance was defined as a Ct score above the cut-off as well as a valid sample result. The association between clearance of HPV infection and age or time to follow-up was analyzed by logistic regression.

Results: Compliance to HPV re-test recommendation was 61.5% and 75.5% within 12 and 18-months after index sample, respectively. The median number of days until follow-up was 364 days.
At re-test, 57% of the women remained HPV positive. Of these 12.7% had multiple infections. Of all HPV genotypes registered at index, 46% persisted with the same genotype at re-test, 9% were new types gained, 45% was cleared. HPV clearance was significantly associated with time, the longer period until follow-up the higher chance of clearance (p=0.035). We found no association between age and HPV infection clearance.

Conclusions: The ability to clear an HPV infection was age independent, but time to HPV follow-up test was significantly associated with HPV clearance. We are leaning towards suggesting that an 18-month follow-up time may be more optimal to allow most women time to clear the index sample HPV infection thereby reducing the number of unnecessary referrals after re-test.

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ANTENATAL AND POSTNATAL CERVICAL PRECANCER SCREENING TO INCREASE COVERAGE: EXPERIENCE FROM BATTOR, GHANA

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Introduction: Cervical precancer screening in low resource settings is largely opportunistic with low coverage. Many women in these settings, where the burden of cervical cancer is highest, only visit health institutions when pregnant or after delivery. The WHO call for elimination of cervical cancer hinges on 90% vaccination, 70% screening twice in a lifetime and treatment of 90% of women with cervical (pre)cancer. We explored screening during antenatal and postnatal visits to increase coverage.

Methods: Pregnant women (any trimester) in the antenatal clinic and women in postnatal clinics (6 to 9 weeks) were screened in Catholic Hospital, Battor and at outreach clinics. Cervical swabs for hrHPV DNA testing (Sansure MA 6000 PCR platform) were taken, followed by Visual Inspection with Acetic acid.

Results: 268 pregnant and 107 postnatal women were screened. Mean age was 29.4 (95% CI: 28.8 to 30.0) years for the pregnant women and 28.4 (95% CI: 27.1 to 29.7) years for the postnatal women. Among pregnant women, hrHPV prevalence was 26.8% (95% CI: 21.5% to 32.1%) compared to 22.4% (95% CI:14.5% to 30.3%) for postnatal women. VIA was positive in 5.2% of the pregnant women and 6.5% of postnatal women. 59.3% of pregnant women (28.3% hrHPV+) and 66.4% of postnatal women (22.5% hrHPV+) only visited a health facility when pregnant or after delivery (Child Welfare Clinics).

Conclusions: Majority (61.3%) of these women have never been to a health facility except when pregnant or after delivery. A high sensitivity test like HPV DNA testing is needed for these women with hrHPV that may persist and lead to cervical cancer and may only be picked up during these clinics for follow up. A significant number of women only visit a health facility during pregnancy or after delivery. Antenatal and postnatal clinics offer opportunities to increase coverage in cervical precancer screening in low resource settings.

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Poster Viewing
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HPV DNA TESTING AND MOBILE COLPOSCOPY FOR CERVICAL PRECANCER SCREENING IN HIV POSITIVE WOMEN: A COMPARISON BETWEEN TWO SETTINGS IN GHANA AND RECOMMENDATION FOR SCREENING

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Introduction: Women Living With HIV(WLWHIV) have a higher hrHPV prevalence and persistence rate with sixfold increased risk of cervical cancer. More frequent screening is recommended in WLWHIV. We determined and compared the prevalence of hrHPV and cervical lesions in a cohort of WLWHIV in a rural and urban setting.

Methods: Through the mPharma Ten thousand (10,000) Women Initiative (TWI), WLWHIV in Catholic Hospital, Battor (rural) and Tema General Hospital (urban) were screened with hrHPV DNA testing (Sansure MA 6000 HPV PCR platform) and mobile colposcopy with the Enhanced Visual Assessment (EVA) system (MobileODT, Tel Aviv) concurrently by trained nurses.

Results: 132 WLWHIV were screened in Battor and 126 in Tema. The mean age was 46.4 in Battor and 46.3 in Tema. The hrHPV prevalence was 53.8% (95%CI: 45.3% to 62.3%) in Battor and 48.4% (95%CI: 39.7% to 57.1%) in Tema. 14 (10.6% [95%CI: 5.9% to 17.2%]) WLWHIV in Battor and 8 (6.3% [95%CI: 2.8% to 12.1%]) in Tema had cervical lesions on colposcopy. Three (3) were treated with Loop Electrosurgical Excision Procedure (LEEP), 1 in Battor and 2 in Tema. 6 WLWHIV in Battor and 3 in Tema were hrHPV negative but had lesions on colposcopy. The histopathology reports of 2 of these colposcopy positive hrHPV negative women in Tema who had LEEP were CIN III.

Conclusions: There is a high prevalence of hrHPV in WLWHIV. hrHPV negative WLWHIV can harbor precancerous lesions which may be missed if concurrent visual inspection (VIA/colposcopy) is not employed. This is compounded if hrHPV tests are not optimally sensitive. We affirm the high prevalence of hrHPV in WLWHIV. Due to the risk of precancer being missed in hrHPV negative WLWHIV, we recommend concurrent HPV DNA testing and visual inspection (VIA/mobile colposcopy) for screening in WLWHIV.

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PSYCHOMETRIC PROPERTIES OF A CULTURALLY ADAPTED ITEM POOL TO MEASURE STIGMA RELATED TO HUMAN PAPILLOMAVIRUS AND CERVICAL CANCER AMONG WOMEN LIVING IN WESTERN KENYA

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Introduction: Individual and provider-level factors, including stigma, contribute to women's decision to screen for cervical cancer. There is little information about stigma related to Human Papillomavirus (HPV) and cervical cancer, [MOU1] which are both closely associated with HIV, a highly stigmatized condition in many settings. We sought to assess the psychometric properties of a culturally adapted measure for HPV, cervical cancer and HIV-related stigma.

Methods: English and Dholuo versions of an item pool were developed, with all items scored between 0 (no stigma) and 3 (highly stigmatized). Exploratory Factor Analysis (EFA) and a Graded Partial Credit Model (GPCM) were used to assess evidence of validity regarding internal structure and items to be retained from the item pool. Confirmatory Factor Analysis (CFA) evaluated model adjustment on an independent sample.

Results: A total of 998 women completed surveys for the EFA. The model with one dimension had the best adjustment for the item pool. From the items listed, 26 of 54 (51.9%) items were retained on the HPV scale, and 14 of 32 (43.8%) on the cervical cancer stigma scale. Most items were excluded based on the EFA loadings or examining the GCPM's person-item map. A total of 480 women completed surveys for the CFA, which indicated factor loadings for each domain are in a very good range, with the average factor loading >0.7. Average stigma scores for HPV and cervical cancer were similar to scores for HIV, and all were fairly low in this population (range 0.77-0.9). Women responding in Dholuo had significantly higher scores than English respondents and items marking shame/blame scored highest.

Conclusions: This quantitative measure of stigma related to HPV, cervical cancer and HIV among women was found to have satisfactory psychometric properties. This provides a tool to assess the relationship between stigma and screening behaviors and the impact of stigma-responsive interventions.

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Poster Viewing
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IMPLEMENTATION IN ACTION: COLLABORATING ON THE TRANSITION TO PRIMARY HPV SCREENING FOR CERVICAL CANCER IN THE UNITED STATES

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Introduction: In July 2020, the American Cancer Society (ACS) released a new cervical cancer screening guideline that endorsed primary HPV screening as the preferred test modality. Due to the screening paradigm and structure of the healthcare system in the United States, transitioning screening modalities is not simple. In September 2021, the ACS established the Cervical Cancer Screening Initiative (CCSI) to support the transition to primary HPV screening in the United States.

Methods: CCSI engages nearly 100 volunteers, including physicians, healthcare providers, and patients, on six workgroups and a Steering Committee with the ACS as the coordinating organization. Over the past year, the workgroups provided insights, organized additional data on key issues to be addressed in order to support the transition to primary HPV screening, particularly related to the use of co-testing and cytology alone, insurance coverage, laboratory and IT infrastructure, and patient and provider perceptions.

Results: CCSI has created recommendations and tools that address opportunities and challenges with the national transition to primary HPV screening, thereby filling a key implementation gap in the United States cervical cancer prevention landscape. Over thirty deliverables are being produced including slide decks, one-pagers, guides, and commentaries. The initiative will support implementation in a variety of real world practice settings. Additionally, CCSI is positively contributing to growing synergistic relationships, and is a foundation for the newly formed National Roundtable on Cervical Cancer (NRTCC).

Conclusions: CCSI innovatively accelerates progress beyond guideline development to guideline implementation. This initiative is a crucial step in successful primary HPV screening adoption and guideline alignment across stakeholder organizations. Achieving the initiative's objectives and harnessing the power of these collaborative relationships over the next year will provide a critical and model infrastructure to support advancements in cervical cancer prevention and elimination in the coming years, particularly for the NRTCC.

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THE POTENTIAL ROLE OF REFLEX ANAL CYTOLOGY TESTING IN ANAL CANCER SCREENING USING HUMAN PAPILLOMAVIRUS (HPV) TESTING IN GAY AND BISEXUAL MEN (GBM)

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Introduction: GBM, particularly those living with HIV, are at markedly increased risk for anal cancer. The implementation of cytology or HPV testing-based screening programs has been hampered by high referral rates and lower specificity than that of cervical screening. We explore the reflex use of anal liquid-based cytology (LBC) in addition to HPV testing in detection of persistent anal high-grade intraepithelial lesion (HSIL) in a cohort of GBM in Sydney, Australia.

Methods: Men in the Study of the Prevention of Anal Cancer (SPANC) underwent annual HPV testing, and cytological and high-resolution anoscopy (HRA) guided histological assessments. Persistent HSIL was defined by detection of histological HSIL at both baseline and the first annual follow-up visits. We examined an HRA referral threshold of HPV16 positivity at baseline, OR persistent non-16 high-risk HPV (HRHPV) detection at both visits if HPV16 negative, WITH reflex LBC indicating any cytological abnormality.

Results: Among a total of 617 participants, 503 (81.5%) who attended at least one annual follow-up visit and had valid HPV, cytological, and histological results were included in the analysis. Median age was 49 years (IQR: 43-56), and 180 (35.8%) were HIV-positive. Among them, 170 (33.8%) tested HPV16 positive at baseline and 173(34.4%) had persistent non-16 HRHPV infection. Guided by HPV screening alone, the theoretical referral rate, sensitivity and specificity for detection of persistent HSIL (n=93, 18.5%) was 68.2%, 97.8%, and 38.5%, respectively (Table). This was compared with 58.8%, 89.2% and 48.0% using anal LBC alone. The reflex use of anal LBC in addition to HPV testing resulted in markedly lower referral (48.5%), improved specificity (60.2%) and maintained high sensitivity

(87.1%).

Table. Anal cancer screening performance using HPV testing and anal cytology in the SPANC study

	HPV16 at baseline (n=170)			HPV16 Neg (n=333)			Overall (n=503)		
	Screen+ n (%)	Sens (%)	Spec (%)	Screen+ n (%)	Sens (%)	Spec (%)	Screen+ n (%)	Sens (%)	Spec (%)
HPV testing	170[1] (100.0)	100.0	0.0	173[2] (52.0)	94.4	53.2	343 (68.2)	97.8	38.5
Cyto screening	128 (75.3)	87.7	31.0	168 (50.5)	91.7	54.5	296 (58.8)	89.2	48.0
Cyto as reflex	128 (75.3)	87.1	31.0	116 (34.8)	86.1	71.4	244 (48.5)	87.1	60.2

[1]participants who tested HPV16 positive at baseline; [2]participants who tested to have persistent type-specific non-16 HRHPV infection at both baseline and the first annual follow-up visit.

Conclusions: The reflex use of anal cytology has the potential to substantially improve the performance of HPV testing-based anal cancer screening in GBM with much reduced referral.

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EVALUATION OF CO-TESTING WITH CYTOLOGY AND HPV TESTING IN CERVICAL SCREENING

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Introduction: In many settings, the switch to HPV-based screening has involved one or several co-tests (testing using both cytology and HPV) in the screening guidelines, to ensure safety. When Sweden switched to HPV testing in 2015 the guidelines included a co-test at age 41.

Methods: To evaluate the effect of co-testing, we identified all 208,701 women resident in Sweden who in 2019 were 40–42 years old and thus eligible for co-testing. All cervical samples, the results of the test and of the subsequent biopsies were identified in the Swedish National Cervical Screening Registry.

Results: Out of the 10,643 women with co-testing in screening, there were 197 women with a subsequent biopsy with high-grade cervical neoplasia or worse (CIN2+). Among these 197 women, 189 had a screening test positive for both HPV and cytology, 6 women were HPV+/Cyt- and 2 women were HPV-/Cyt+. There were 7,115 women with a co-test outside of the screening program. Among these, 325 women had a CIN2+ in histopathology, 290 were double positive, 13 women were cyt+/HPV-, and 11 women each were HPV+/cyt- and HPV-/Cyt-. In summary, the additional yield of CIN2+ with co-testing was 2 cases per 10,643 women as compared with 195/10,643 CIN2+ cases detected with HPV screening alone. However, for cervical samples taken outside the screening program (e.g. taken on a clinical indication) there was an increased yield (314 CIN2+ cases detected with co-testing as compared to 301 cases with HPV screening).

Conclusions: The additional CIN2+ yield of the co-test in screening was <0.02%, arguing that co-testing has a minimally increased sensitivity.

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UNDERSTANDING BARRIERS TO PRE-CERVICAL CANCER CARE IN IQUITOS, PERU THROUGH QUALITATIVE INTERVIEWS WITH WOMEN LOST TO FOLLOW UP AT THE HOSPITAL LEVEL

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Introduction: Loreto, the largest Peruvian state in the Amazon, has the highest incidence of cervical cancer in Peru. Since 2016, Proyecto Precancer (PPC) has facilitated efforts to implement an HPV-based screen and treat approach for cervical cancer prevention and control in Iquitos, the capital city of Loreto. While significant increases in screening and treatment have been achieved, a subset of women are still being lost to follow up (LTFU); mostly women with lesions suspicious of cancer who are ineligible for primary-level treatment and must seek hospital-level care. The objective of this study is to examine barriers leading to LTFU amongst these women.

Methods: In-depth interviews were conducted with 20 HPV positive women requiring hospital-level care but with documented gaps in their follow up, and 7 health professionals (doctors and midwives at the hospital and primary level) to discuss key steps of the follow up process. Interviews will be coded for themes, analyzed using Dedoose software, and presented using visual models, summaries of findings, and relevant quotes.

Results: Using the socioecological model to organize the findings, preliminary patient interview results suggest a lack of accessibility, familiarity with navigating the hospital system, and understanding of next steps in care increase LTFU. Interviews with primary-care level professionals suggest that a lack of coordinated care was associated with LTFU. Interviews with hospital-level professionals suggest that fragmented care, limited patient counseling, test duplication, and a lack of standardized care were associated with LTFU.

Conclusions: Results will identify specific barriers to care for HPV-positive women; preliminary findings highlight the need for a patient-centered approach. Gaps center around women's lack of understanding of steps involved in follow-up and lack of care coordination at the primary and hospital levels. These findings will be used by the PPC and Ministry of Health to make policy and practice recommendations to address barriers to treatment.

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CLIENT PERSPECTIVES ON INTEGRATING FACILITY AND COMMUNITY-BASED HPV SELF-SAMPLING FOR CERVICAL CANCER SCREENING WITH FAMILY PLANNING IN MALAWI: A QUALITATIVE STUDY

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Introduction: Cervical cancer disease is preventable through early screening, but access to cervical cancer screening (CCS) remains a challenge in Malawi. Integration of CCS with family planning (FP) services through HPV self-sampling may increase screening coverage. We aimed to evaluate the motivations, experiences, and satisfaction of women who underwent HPV self-sampling in Malawi.

Methods: We purposively sampled and interviewed 29 women who underwent HPV self-sampling for CCS in one of two different CCS-FP models in Malawi between 2020-2021. Model 1 involved only clinic-based HPV self-sampling, whereas Model 2 included both clinic-based and community-based HPV self-sampling through community health workers. IDIs followed a semi-structured guide and were audio-recorded, transcribed and translated into English. Data were analyzed using Nvivo 12 software and thematic content analysis.

Results: Both integration models created demand for CCS and reduced costs for participants. Participants screened in the community had reduced transport costs for screening, while those screened at the clinic could access both CCS and FP services at a single visit. Participants from both models were motivated to undergo CCS due to the availability of same day treatment, gynecological symptoms, being HIV seropositive, and concern about late cancer diagnosis. Participants further expressed satisfaction with making decisions without consulting spouses, and none reported experiencing social harm following result disclosure. Most women felt that HPV self-sampling was simple and ensured privacy. Women screened in the community felt it offered more privacy since samples were collected within their homes, compared to in public toilets or consultation rooms at the clinics.

Conclusions: Participants were satisfied with HPV self-sampling, and both models were seen to have made access to CCS more convenient and cost-effective for women. Our findings suggest that from the patient perspective, CCS and FP services can be integrated in Malawi through HPV-self sampling to improve uptake for CCS.

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FRAMEWORK FOR COST-EFFECTIVENESS ANALYSIS OF NOVEL SCREENING METHOD FOR LOW-RESOURCE SETTINGS

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Introduction: Cost-effective cervical cancer prevention depends on highly accurate screening tests and subsequent navigation of high-risk females to treatment. To estimate the cost-effectiveness of HPV-based screening, triage, and treatment strategies, health decision models should reflect measurable stages and transitions on the causal pathway to cervical cancer.

Methods: The Human Papillomavirus and Automated Visual Evaluation (PAVE) Validation Study is a large consortial screening project led by the U.S. National Cancer Institute (NCI) that will screen up to 100,000 women in up to ten low-resource study sites. The protocol includes self-sampling for high-risk HPV (hrHPV) by eligible women ages 25 to 49 years, with subsequent risk stratification and management according to genotype group and a deep-learning automated visual evaluation (AVE) of cervical images. All sites are offered a training course in micro-costing methods, data collection templates, and ongoing technical assistance. Comprehensive cost-effectiveness analyses will be performed at selected sites to support site-specific health decisions.

Results: We described a health decision framework that prioritizes direct estimation of transitions between HPV-related health states. Data analysis is underway to determine whether separate frameworks are required for higher prevalence or immunodeficient populations.

Conclusions: We will assess the cost-effectiveness of the novel HPV-AVE strategy in numerous settings. The biology of HPV and cervical carcinogenesis, along with the performance of screening and triage tests, inform trustworthy cost-effectiveness analysis critical to making health decision around adoption of HPV testing.

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HUMAN PAPILLOMAVIRUS TYPES IN INVASIVE CERVICAL CANCER IN RELATION TO CERVICAL SCREENING

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Introduction: Cervical cancer is caused by oncogenic Human Papillomaviruses (HPVs) and cervical screening programs are switching to HPV-based screening. However, different HPV types differ greatly in their prevalence and their oncogenicity, and the efficiency and effectiveness of cervical screening for each HPV type is undetermined.

Methods: We compared the incidence of invasive cervical cancer during 2004-2011 in Sweden by screening attendance in the past 10 years, in a population-based cohort of 3·5 million women. The screening-related reduction of incident cervical cancer was then stratified by HPV type, using HPV typing data of invasive cervical cancer from 2850 screened and non-screened cases, respectively. By further integrating HPV genotyping data from 362,000 women in the population cohort, we calculated number of women needed to screen (NNS), and number of women needing follow-up (NNF) to detect or prevent 1 cancer case.

Results: Attending screening was associated with a more than 70% reduction of cervical cancer incidence caused by HPV16 or by oncogenic types other than 16/18, and a 54% reduction of cancer caused by HPV18. The NNS and NNF were lowest for HPV16 but up to 40-500 times higher for some other HPVs commonly screened for. For women below 30 years of age, NNS and NNF for HPV16 were 4,700 and 288, respectively, but >220,000 and >16,000 for some other HPVs.

Conclusions: Although reasonable limits for NNS and NNF may differ between settings, the present estimation of NNS and NNF by HPV type should be informative for designing optimally effective cervical screening programs.

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GENERATING DEMAND FOR CERVICAL CANCER PREVENTION SERVICES THROUGH GRASSROOTS ORGANIZING OF MARGINALIZED SECTORS

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Introduction: Decades after the Philippines' institutionalization of cervical cancer screening for women aged 25-55 years old, uptake for cervical cancer preventive services has remained low while incidence and deaths has not declined. Eleven Filipino women die of cervical daily, while half of 7,000 women diagnosed each year, die of cervical cancer. Available evidence indicates that the cervical cancer high morbidity and mortality is attributable to limited access to and awareness of optimal pre-cancer diagnosis and treatment technologies available for women. This burden is heaviest among poor and marginalized sectors of women. SUCCESS Project in the Philippines aims to increase demand for cervical cancer prevention services to reduce the burden of mortality and morbidity.

Methods: In the Philippines, the project leveraged community organizing activities among marginal sectors to generate demand for cervical cancer preventive services while also improving coverage in catchment areas of the project sites. Through the mobilization of community leaders and grassroots organizing, the project conducted numerous health education and promotion activities to introduce the benefits of HPV-DNA testing through self-sampling as a viable health practice to decrease women's risk for cervical cancer.

Results: The conduct of community-based health education and promotion activities linked to delivery of services, and integration to existing reproductive health services in some areas revealed a growing demand for screening and early treatment services in catchment areas of project sites.

Conclusions: Collaboration with grassroots organization and providing added value to already existing civil society actions can lead to quality appreciation for preventive practices and improved reproductive and sexual health seeking behaviors among poor and marginalized sectors of women.

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CERVICAL CANCER SCREENING, DIAGNOSIS AND TREATMENT OF PRECANCEROUS CELLS AT CHELSTONE CLINIC IN LUSAKA, ZAMBIA: A CLINICAL AUDIT

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Introduction: Cervical cancer is one of the most common cancers in Zambia with an incidence rate of 66.3 per 10^5 and mortality at 44.6 per 10^5 women years. HPV 16 and 18 are the most oncogenic types accounting for almost 70% of cervical cancers. Zambia's mainstay screening method is Visual inspection with acetic acid (VIA) with a few facilities piloting HPV-DNA testing. Conducting clinical audits within the screening program plays a key role in strengthening cervical cancer prevention and resonates with the World Health Organisation's elimination strategy. Therefore, we aimed to highlight the difference between actual practice and the standard set out in the diagnosis and treatment protocols.

Methods: This clinical audit was conducted at Chelstone hospital which is one of the 24 cervical cancer screening facilities within Lusaka district. Data was collected among women aged 25-49 screened between June 2019 and June 2020. Figure 1.0 shows definitions and indicators used in this clinical

audit.

Cervical Cancer Screening Core Indicators: Global and National Levels (WHO, 2013)

Screening Rate: Percentage of women aged 30–49 years who have been screened for the first time with VIA in the previous 12-month period

Positivity Rate: Percentage of screened women aged 30–49 years with a positive VIA test result in the previous 12-month period (Target: 5–10% of all women screened)

Treatment Rate: Percentage of VIA-positive women receiving treatment in the previous 12-month period (Target: at least 90% of VIA-positive women)

- **Single Visit Approach (SVA) Rate:** Percentage of VIA-positive women with lesions eligible for cryotherapy treated during the same visit (Target: at least 80% of cryotherapy-eligible VIA-positive women)
- **Referral and Advanced Treatment Rate:** Percentage of VIA-positive women with lesions not eligible for cryotherapy who are referred to higher-level facility and complete appropriate treatment (Target: ~10% of VIA-positive women will have large lesions)

Cure Rate: Percentage of VIA-positive women treated in the previous year that return for re-screening and have a VIA-negative result at second screen (Target: 95% of previously treated women)

Coverage: Percentage of women aged 30–49 years who have been screened with VIA or another test at least once between the ages of 30 and 49 years, collected through surveys

Age-specific Incidence and Mortality: Collected through surveys

Results:

TABLE 1.0 SUMMARY STATISTICS OF AUDIT

NUMBER OF PATIENTS SEEN	2580
NUMBER OF REFERRALS	16
NUMBER OF HIV+ PATIENTS	1951
NUMBER OF PATIENTS WITH ICC(INVASIVE CANCER OF CERVIX)	14
NUMBER OF VIA POSITIVE BUT NOT ELLIGIBLE FOR CRYOTHERAPY	08

TABLE 2.0 EXPECTED STANDARD Vs ACTUAL PRACTICE RATES

	EXPECTED STANDARD %	ACTUAL PRACTICE %
SINGLE VISIT APPROACH RATE	80	81
POSITIVITY RATE	10	02
REFERRAL RATE	10	18

Conclusions: The percentages for positivity and treatment rates are lower than expected standards. This could be because Chelstone hospital use HPV-DNA self-sampling more than the VIA method because it is a convenient and cost-effective method to increase screening participation among hard-to-reach women, however, results take time to be available. Further, the referral rate is high, explained by the number HIV-positive clients who require tertiary-level care. Efforts to provide timely HPV-DNA results and continued education on increased screening uptake for early diagnosis are key.

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EVALUATION OF THE CLINICAL DETECTION OF THE HUMAN PAPILLOMA VIRUS USING TWO VALIDATED PLATFORMS: SECOND INTERLABORATORY STUDY IN ARGENTINA

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Introduction: The detection of high risk HPV (HR-HPV) DNA as a primary screening test is being gradually implemented in Argentina as part of a comprehensive strategy for the prevention of cervical cancer. External quality assessment (EQA) programs allows to evaluate the performance of laboratories; the international EQA are often expensive and panels are difficult to import for some settings, therefore provide local programs is of great interest. A First interlaboratory study was done in 2019. Our aim was to analyze the performance of laboratories that use clinical validated platforms in the frame of HPV testing in Argentina

Methods: A panel of 6 vials containing cervicovaginal cells in Preservcyt medium was generated; each sample may contain either no HPV, a single or a mixture of HPV type/s at varying concentrations. The panel was tested 10 times to analyze its homogeneity. Panels were sent to 30 laboratories that routinely use the HPV COBAS 4800 test (Roche) and RealTime High Risk HPV test (Abbott). The analysis was based on: i)- Comparing the results obtained by each participant, for each vial, using the EP12-A2 (CLSI). ii)- Calculating the frequencies of each HPV genotype in each vial.

Results: All laboratories showed a degree of agreement of 100% for positive and negative results. All vials with positive results showed the presence of single or a mix of HR-HPV genotypes; however, some labs using Cobas HPV test detected some additional genotypes in some vials that were not identified by others using Cobas HPV test or Abbott high risk HPV Test.

Conclusions: An overall degree of agreement was observed for all laboratories. Different sensitivities were observed even using the same platforms, although without indicating a differential clinical approach. A local EQA program facilitates the access and allows a continuous monitoring of the performance of HPV testing in laboratories from Argentina.

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IMPLEMENTING COMMUNITY-BASED HEALTH WORKER (CBHW) ENGAGED CERVICAL CANCER SCREENING PROGRAM IN SHENZHEN, CHINA: FACTORS RELATED TO PATIENTS' TIMELY ATTENDANCE AFTER RECEIVING ABNORMAL SCREENING RESULT

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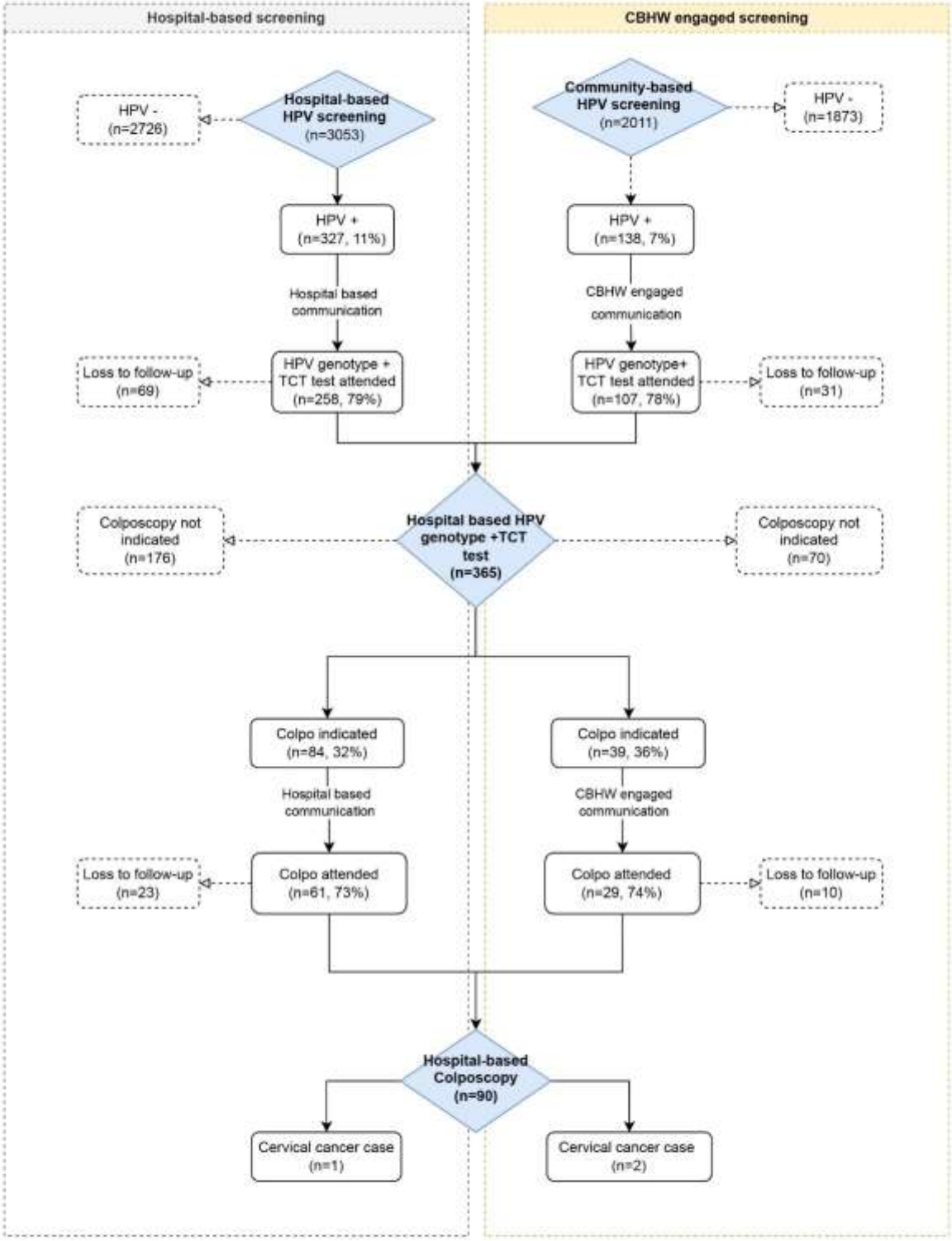
Introduction: Despite China's 10-year-old free cervical cancer (CC) screening program. The screening rate for women 35–64 is below 32%, and 30% of women with abnormal results missed colposcopy, especially for underserved women. In 2022, a community-based health workers (CBHW) CC screening program was piloted in Shenzhen, China, to reduce health disparities. We sought to investigate CC screening follow-up and underserved population coverage in CBHW-engaged and hospital-based screening scenarios.

Methods: From one hospital and thirteen community-based clinics in Shenzhen, China, which participated in the CBHW program, we reviewed the records of patients with abnormal CC screening results within the past year, focusing on demographic information, screening results, and communication with providers. Bivariate and multivariate analysis was used to identify key factors associated with patients' prompt follow-up care attendance.

Results: 365 (78.5%) of 465 women aged 30-60 with positive HPV test results had their HPV genotype and cytology test (TCT) within the recommended time interval (average 14 days). More frequent checkups ($p<0.01$) increase women's attendance. More than two attempts to communicate by the provider related to a decrease in the patient's likelihood of returning ($p<0.01$). The CBHW-engaged group covered more women aged 40-49 (52.9%, $p<0.05$) and women without adequate health insurance (58.0%, $p<0.01$). They can be more efficiently notified via text message without phone calls (71%, $p<0.01$) compared to the hospital-based group. 123 patients (33.7%) were colposcopy-indicated and 73.2% of them attended colposcopy timely (average 14 days). CBHW-engaged colposcopy-indicated patients are informed within 5 days, compared to 13 days for hospital-based patients ($p<0.05$). Ultimately, there were three women diagnosed with cervical

cancer.


Hospital-based screening
CBHW engaged screening
Hospital-based HPV screening (n=3053)
HPV - (n=2726)
HPV + (n=327, 11%)
Hospital based communication
Loss to follow-up (n=69)
HPV genotype + TCT test attended (n=258, 79%)
Community-based HPV screening (n=2011)
HPV - (n=1873)
HPV + (n=138, 7%)
CBHW engaged communication
HPV genotype+ TCT test attended (n=107, 78%)
Loss to follow-up (n=31)
Hospital based HPV genotype +TCT test (n=365)
Colposcopy not indicated (n=176)
Colposcopy not indicated (n=70)
Colpo indicated (n=84, 32%)
Hospital based communication
Loss to follow-up (n=23)
Colpo attended (n=61, 73%)
Colpo indicated (n=39, 36%)
CBHW engaged communication
Colpo attended (n=29, 74%)
Loss to follow-up (n=10)
Hospital-based Colposcopy (n=90)
Cervical cancer case (n=1)
Cervical cancer case (n=2)

Conclusions: CBHW involvement in CC screening can reach more underserved women in the community and provide timely communication of screening results. In terms of follow-up rate and patient response time, we observed no systematic differences between these two groups.

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A PILOT STUDY TO EVALUATE THE ACCEPTABILITY AND FEASIBILITY OF HPV SELF-SAMPLING TESTS FOR CERVICAL CANCER PREVENTION IN CHECA, A RURAL AREA NEAR QUITO, ECUADOR

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Introduction: Cervical cancer is the second most common cancer among Ecuadorian women despite being preventable through vaccination and screening. In rural areas, screening is a challenge due to lower access to medical care. This study assessed the acceptability and feasibility of HPV self-sampling tests in this population.

Methods: We conducted a mixed methods observational study with 102 women from the rural area of Checa, Ecuador. Women aged 25 to 60 years old were invited to participate by the healthcare center staff when they were there for an appointment. Study staff trained participants how to take an HPV self-sample. Women took the tests home and returned them within two weeks for processing. All participants were contacted to explain their results and were followed up according to guidelines. A subgroup of 21 women participated in focus groups where we inquired about their experiences and perceptions of the test.

Results: All women commented the test was feasible and acceptable for them. Many mentioned it was less painful, more private and convenient than the Papanicolaou test. 10.7% of samples were invalid. 65.6% of participants had a negative HPV test. 17.6% of participants had a negative test for HPV 16 and 18 but positive for other types of HPV. 5.8% of participants had a positive test for HPV 16.

Conclusions: This study showed that implementing an HPV self-sampling screening test in rural communities of Ecuador may be acceptable and feasible. The strengths of the study include a high level of acceptance of the test among participants and a “full-cycle” consideration from testing to communication of results and follow-up treatment. Limitations include a small sample of women from the healthcare center. Our findings, consistent with other studies of HPV self-sampling, may encourage decision-makers to implement strategies that provide self-sampling HPV tests to rural and other populations currently underserved with cervical cancer screening services.

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ACCEPTABILITY AND SUSTAINABILITY OF A POINT-OF-CARE HPV 'SELF-COLLECT, TEST-AND-TREAT' FOR CERVICAL CANCER PREVENTION IN PAPUA NEW GUINEA: A QUALITATIVE EXPLORATION OF KEY INFORMANTS' PERSPECTIVES

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Introduction: Innovative technologies over the past decade have emerged to increase uptake in cervical cancer early detection and treatment that could significantly improve screening and precancerous treatment. The changing landscape in cervical cancer screening algorithms and technologies calls for critical inquiries into their implementation in all settings, but especially in low-resource settings with the heaviest burden of disease. Papua New Guinea has among the highest estimated burden of cervical cancer globally yet has no organized national cervical screening programs. To better understand key informants' perspectives of a point-of-care HPV screen-and-treat program, we conducted key informant interviews to capture their insights into the factors impacting the acceptability and sustainability of the intervention.

Methods: We conducted 26 semi-structured interviews with a purposive sample of 20 healthcare workers and six policymakers from Well Woman Clinics in Madang and Mt. Hagen. Interviews were conducted in English, transcribed, and analyzed using thematic analysis, highlighting factors impacting the acceptability and sustainability of the program from these key informants' perspectives.

Results: The participants perceived the intervention as culturally fit and valuable. Health care workers agreed that the technological elements of the intervention were easy to use and provided the benefit of same day screen-and-treat, which helped to significantly reduce loss to follow-up. Factors such as planning for key resources (i.e., financing, and human resources) and political support were recognised as essential to ensure long-term sustainability by policymakers. The intervention was valued as 'scalable, portable and simple', emphasizing that key political support and a comprehensive national cervical cancer prevention strategy could help Papua New Guinea make considerable headway toward cervical cancer elimination.

Conclusions: In light of the burden of cervical cancer in the country, all participants agreed that a national cervical screening program, explicitly same day screen-and-treat services using self-collection, addressed an immense unmet need and salient cultural and systemic barriers.

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CERVICAL HIGH-RISK HUMAN PAPILLOMAVIRUS INFECTION, GENOTYPE SPECIFIC DISTRIBUTION AND ABNORMAL CERVICAL CYTOLOGY AMONG WOMEN RESIDING IN QUINDIO, COLOMBIA 2022

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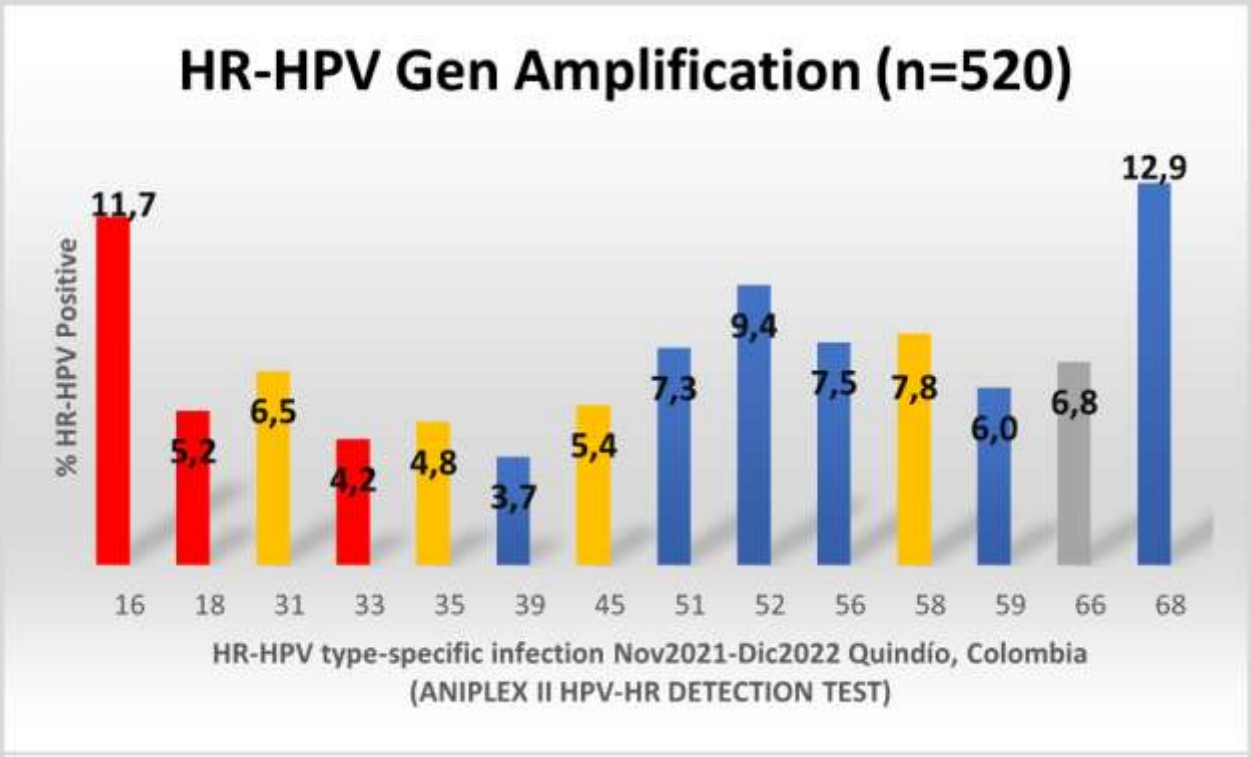
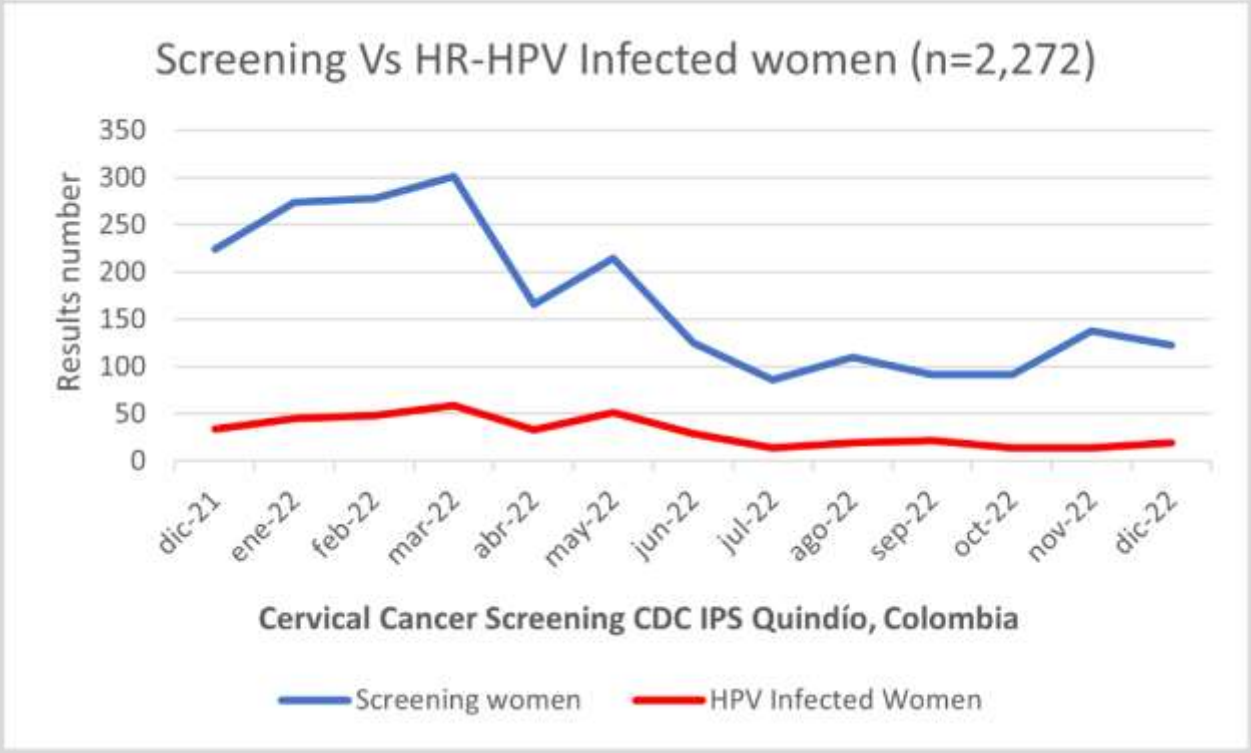
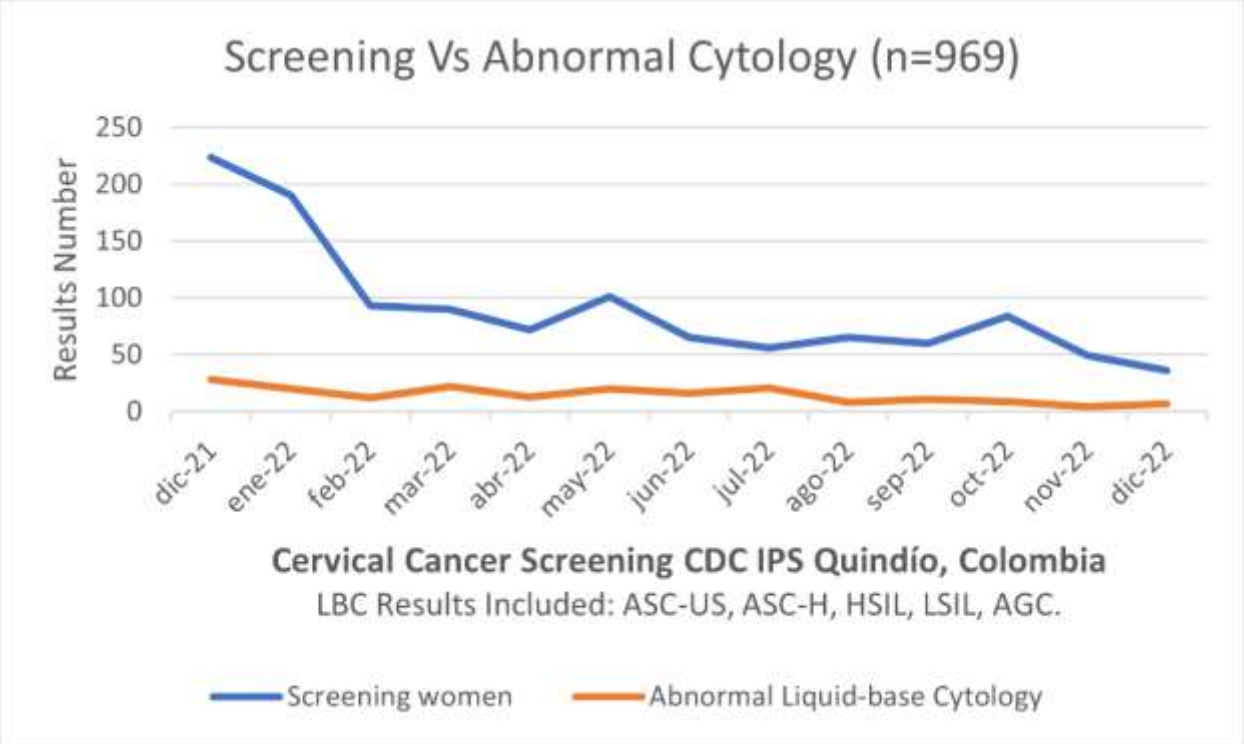
Introduction: In Colombia, according to the guidelines for Promotion and Health Maintenance (Res 3280), cervical cancer screening starts at 25 years old with cervical cytology (or 3 years after the onset of sexual activity), and between 30 to 65 years old, the screening is based on HPV detection (included since 2018). Nevertheless, cervical cancer in Colombia is uncontrolled; incidence was 12.7 new cases/100,000 women in 2018 and 14.9 new cases/100,000 women in 2020; mortality was 5.7 deaths/100,000 women in 2018 and 7.4 deaths/100,000 women in 2020 (GLOBOCAN). Besides, the data on HR-HPV infection among woman residing in Quindío are limited and unpublished. The purpose of this study was to determine the frequency of HPV infection, the High Risk (HR) genotypes distribution and abnormal cytology as baseline for local epidemiology and statistics that can support public health actions and decisions.

Methods: Retrospective study. Women´s results from CDC Laboratory´s database were analyzed in SPSS: 2,272 HR-HPV results and 969 liquid-based cytology results, from December 2021 to December 2022. The HPV detection was assessed by Aniplex II HPV HR DNA Detection and Genotyping Test, which detects 14 HR-HPV types.

Results:


HR-HPV Gen Amplification (n=520)
% HR-HPV Positive
11,7
5,2
6,5
4,2
4,8
3,7
5,4
7,3
9,4
7,5
7,8
6,0
6,8
12,9
16 18 31 33 35 39 45 51 52 56 58 59 66 68
HR-HPV type-specific infection Nov2021-Dic2022 Quindío, Colombia
(ANIPLEX II HPV-HR DETECTION TEST)


Screening Vs HR-HPV Infected women (n=2,272)
Results number
350
300
250
200
150
100
50
0
dic-21 ene-22 feb-22 mar-22 abr-22 may-22 jun-22 jul-22 ago-22 sep-22 oct-22 nov-22 dic-22
Cervical Cancer Screening CDC IPS Quindío, Colombia
Screening women
HPV Infected Women



Mean age was 46.9 years (min 18; max 74). Of the 2,272 results analyzed, 18.2% were positive for any HR-HPV type. HR-HPV types 68, 16 and 52 were the most predominant: 12.9%, 11.7%, and 9.4% respectively. Among infected women, 19.3% had coinfection up to 6 genotypes identified. HR-HPV prevalence in women with abnormal cytology (62%) was higher than in women with normal cytology (28.4%).

Conclusions: General HPV infection was 18.2%, and the most prevalent specific HR-HPV types were 68, 16, and 52. The current study provides regional statistics that can be used to monitor changes in HPV specific type infection, to improve local prevention programs and to create a cohort for future researches.

Shift 01-077 / #1789

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

THE MORE YOU KNOW… ABOUT HPV AND CERVICAL CANCER IN NATIVE AMERICAN WOMEN

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Introduction: Despite a global and nationwide decrease, Native Americans continue to experience high rates of cervical cancer morbidity and mortality. Screening and vaccination are two approaches to decrease cervical cancer incidence among women. This talk primarily focuses on cervical cancer and HPV prevalence in Native American communities along with steps to take for designing inclusive vaccines. However, the presentation will also inform the audience of ongoing HPV and cervical cancer pilot projects along with highlight factors that influence Native American choices surrounding vaccination.

Methods: We will discuss adjustments to a vaginal self-collection biospecimen protocol implemented during the COVID-19 pandemic. This includes self-collection and new clinic staff “virtual in-service training” to review all required documents. In additional, we will highlight changes to the protocol for a feasibility study starting in winter 2023. Finally, we will discuss the sample collection and HPV whole genome sequencing from previously collected vaginal biospecimens. All amendments were approved by the clinic leadership and appropriate institutional review boards (IRBs)

Results: For the first pilot, the clinic staff successfully enrolled (n=31) participants with survey data entered into REDCap. Survey data analyses are in-progress with expected completion by Spring 2023. The HPV whole genome sequencing is ongoing with a phylogenic tree for HPV-16, 18, and 51. Further discussion of the data is pending approval from the tribal IRB. We anticipate approval will be granted by the conference date.

Conclusions: In summary, the continued efforts by the clinic staff and research team resulted in successful recruitment for the first pilot study during the COVID-19 pandemic. This study set the foundation for a feasibility study to evaluate the role of the VMB and HPV-mediated cancer in Native American women from Arizona. HPV whole genome sequencing is ongoing from previous studies that is pending tribal approval to present the data.

Shift 01-078 / #1794

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
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ASSOCIATIONS OF AREA-LEVEL SOCIOECONOMIC CHARACTERISTICS AND HEALTH CARE ACCESS MEASURES WITH ADVANCED STAGE AT DIAGNOSIS BY SEX AMONG ADULTS WITH ANAL CANCER IN THE US

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Introduction: In the US, anal cancer incidence and mortality are rising in both men and women. Screening for anal cancer is not widely recommended, however, occurs among high-risk groups. Our objective was to characterize patterns in advanced stage-at-diagnosis (stage 3+) among men and women with anal cancer and evaluate associations with multi-level social determinants of health(SDoH) to gain insights into intervenable opportunities to improve access to anal cancer screening.

Methods: We used the US National Cancer Database (2004-2019), which captures 70% of US cancer cases, including patients aged 18-89 years with invasive anal cancer (ICD-O-3:C210/C211/C212/C218). Our main outcome was advanced stage-at-diagnosis, defined as stage 3 or 4. Our main exposures included area-level SDoH, specifically % of adults without a high school degree by patient's zip code and median income quartiles within patient's zip codes. We used hierarchical multivariable logistic regression models clustered by facility ID. We stratified our models by sex, patient's insurance status (uninsured, Medicare, Medicaid, and private insurance), rurality (urban/rural), and distance to care from patient to facility.

Results: We included 85,027 adults diagnosed with anal cancer, including 38% men and 62% women. Men were more likely to live in a lower income quartile (22% vs.19%, p<0.001) and lower educational attainment (24% vs.20%,p<0.001) area. Women were more likely to be diagnosed with advanced stage compared to men (39% vs.33%,p<0.001)(Figure 1). After adjustment for age, calendar year, and Charlson-comorbidity score, lower area-level education (aOR:1.15;95 CI:1.09-1.21) and lower area-level median income (aOR:1.16; 95% CI:1.10-1.23) were associated with advanced stage anal cancer(Figure 2). These associations were consistent in men and women. Further, these associations persisted across insurance status, rurality, and distance to
care.

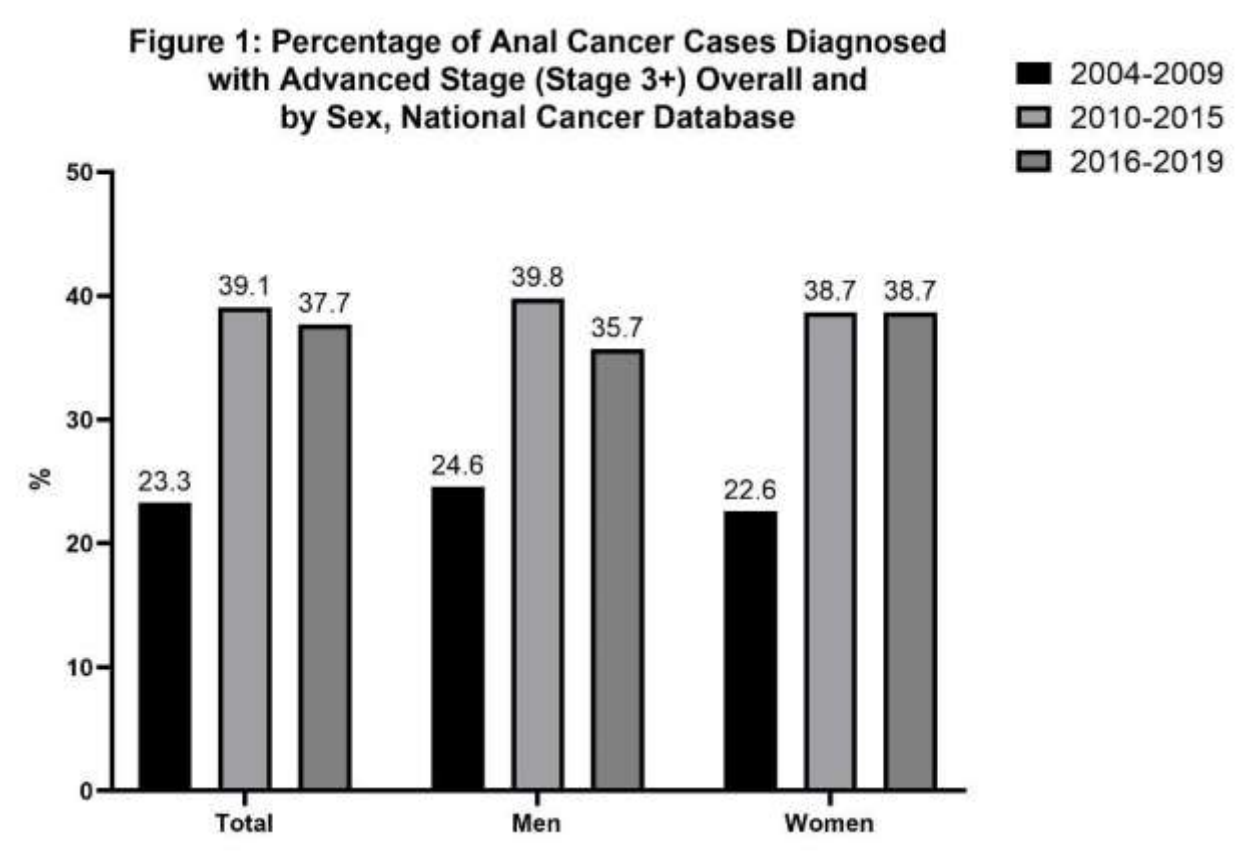
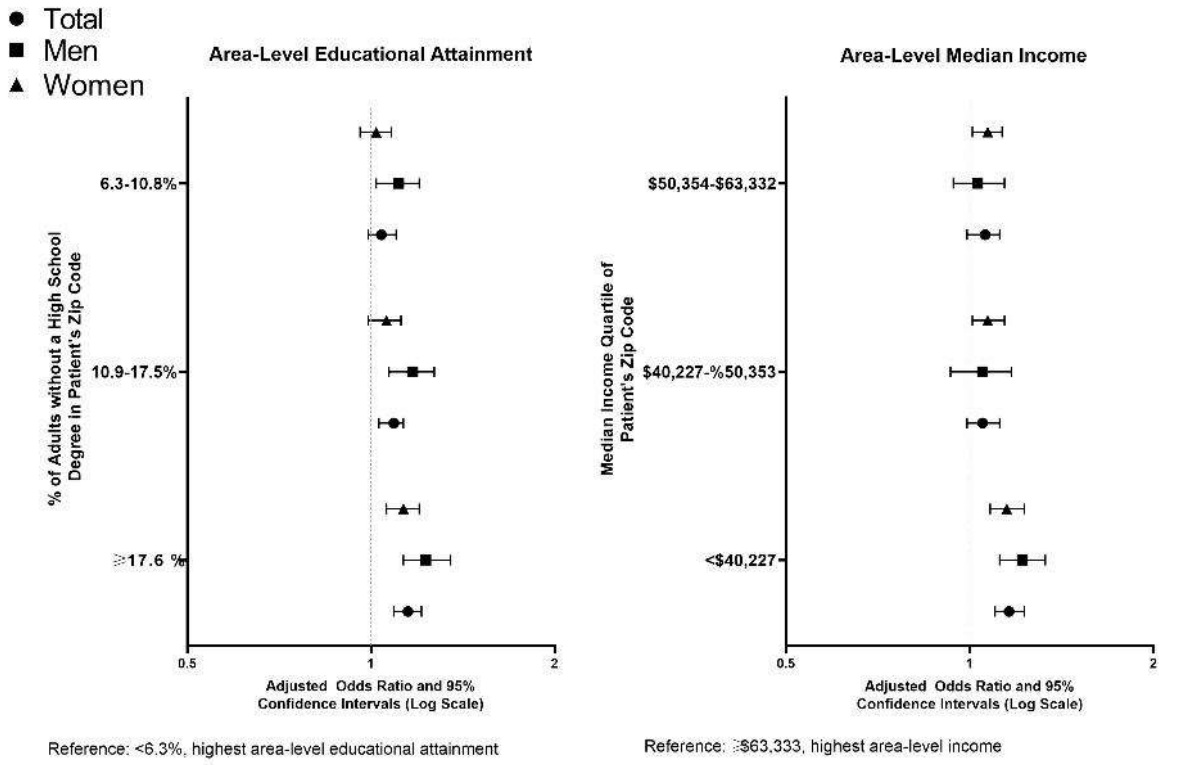


Figure 1: Percentage of Anal Cancer Cases Diagnosed with Advanced Stage (Stage 3+) Overall and by Sex, National Cancer Database
2004-2009
2010-2015
2016-2019
%
50
40
30
20
10
0
23.3
39.1
37.7
24.6
39.8
35.7
22.6
38.7
38.7
Total
Men
Women

Figure 2: Associations of Area-Level Social Determinants of Health with Advanced Stage at Anal Cancer Diagnosis, National Cancer Database (2004-2019)



Multilevel models were clustered at facility ID, and adjusted for age. calendar year, and comorbidities

Conclusions: Our findings suggest that inequalities exist in access to available anal cancer screening. SDoH characteristics should be considered to facilitate the development of tailored anal cancer screening interventions for widespread use.

Shift 01-079 / #1816

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

PERCEPTIONS OF HPV SCREENING AND VACCINATION, AND ANAL-SELF-EXPLORATION, AMONG ADULTS ENGAGED IN HIV, SEXUAL AND TRANSGENDER HEALTHCARE IN MEXICO.

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Introduction: This study explored perceptions, attitudes, knowledge and experiences related to HPV vaccination and screening as well as anal self-exploration among adults engaged in HIV, sexual or transgender affirmative healthcare in Mexico.

Methods: We conducted semi-structured interviews (12-52 minutes, average 30.9 min) with 14 transgender women, 13 cisgender women and 13 cisgender men who have sex with men engaged in healthcare at a large, public, free-of-charge clinic offering gender affirmative, HIV and sexual healthcare in Mexico City. Interviewees generally had low socioeconomic status and some were homeless, used addictive substances, and/or were living with HIV. We did thematic analysis of interview transcriptions in Spanish.

Results: All interviewees had positive attitudes towards HPV vaccination and either had already been vaccinated or wished to be vaccinated, with a few desiring vaccination but wanting to first receive a recommendation from their treating physician. Different groups of adults had different attitudes, perceptions, knowledge and experiences related to: Links between HPV and cancer; Perceived need for HPV testing and vaccination; Acceptability of and knowledge about vaginal and anal self-sampling (with a swab) and anal digital self-exploration; Provider recommendation of HPV vaccination; Experiences with healthcare services relating to HPV detection and prevention.

Conclusions: Public education campaigns which have existed in Mexico for decades targeting cisgender women seem to have positively impacted knowledge and acceptability of HPV screening, vaccination and about the HPV-cancer link. Transgender women also have positive attitudes towards HPV screening, self-sampling, anal self-exploration and HPV vaccination, possibly impacted by the existence of legislation and healthcare services that support transgender people in Mexico both nationally and in Mexico City. Cisgender men who have sex with men have positive attitudes towards HPV vaccines, perhaps related to general high acceptability of diverse vaccines in Mexico, but appear to require greater healthcare literacy promotion related to HPV.

Shift 01-080 / #99

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

ASSESSING KNOWLEDGE, ATTITUDES AND BELIEFS TOWARD HPV VACCINATION OF PARENTS WITH CHILDREN AGED 9-14 YEARS IN RURAL COMMUNITIES OF NORTH WEST CAMEROON

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Introduction: Human papilloma virus (HPV) vaccination is essential for the WHO cervical cancer elimination initiative. In Cameroon, HPV vaccine uptake is currently 5%. To assess the knowledge, beliefs and attitudes of parents of young girls aged 9 to 14 years about HPV vaccines within rural communities in the North West Region of Cameroon.

Methods: During January to May, 2022, we conducted 45 one-on-one interviews using a semi-structured interview guide in the localities of Mbingo, Njinikom and Fundong. Participants were parents of girls aged 9-14 years who speak English or Pidgin English. Health care workers were excluded. The interviews were recorded, transcribed, and analyzed using ATLAS.ti 9. Member checking was conducted presenting our findings and getting feedback from a focus group of parents.

Results: Thirty-five mothers and ten fathers were interviewed with mean age of 42 years. Ninety-one percent of parents had ever been vaccinated. Seventy seven percent had no or only primary school education. Thirty-two parents (71.12%) had daughters who had not been vaccinated against HPV. The themes identified include: Awareness of HPV related diseases, risk factors for cancer and prevention (little awareness about HPV vaccination), Access (as needed through hospitals or episodic access through mass vaccination campaigns, role of cost), Trust (in health care providers, health institutions, in contest of civil unrest) , Decision making in the home (predominantly paternalistic) and consent, and Recommendations for uptake and community engagement (how: nown and trusted community resource, by whom: endorsement of the message and where ie., churches, market place). Member checking with 30 women from two other communities confirmed our findings.

Conclusions: Lack of awareness concerning the availability and purpose of the HPV vaccination was prevalent. Use of mainstream media and top-down health education activities are not effective. Novel approaches should engage local community health workers and utilize established community social and leadership structures.

Shift 01-081 / #547

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

USING AN INTERACTIVE DIGITAL HEALTHCARE PROVIDER TO EDUCATE PATIENTS ABOUT HUMAN PAPILLOMAVIRUS VACCINATION: A PILOT STUDY

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Introduction: Available evidence suggests that armed with the correct tools, patients with human papillomavirus (HPV)-related disease can serve as health educators and advocates for HPV vaccination within their social networks. The aim of this pilot study is to use an interactive digital healthcare provider (DHP) on a tablet to educate patients with HPV-related disease or cancer about HPV vaccination and to motivate them to talk to their friends and family about HPV vaccine uptake.

Methods: We conducted a 2-institution, single-blind, randomized controlled trial to examine the DHP's preliminary efficacy. Participants (n=60) were recruited from the patient populations of Stephenson Cancer Center (Oklahoma) and Karmanos Cancer Institute (Michigan) in the United States. Participants were randomized to either the Theory of Planned Behavior (TPB)-based DHP or a standard education (SE) group, which received self-help handouts about HPV vaccination. All participants were encouraged to talk to their family/friends about HPV vaccination during a 6-week period. Outcomes of interest include positive changes in TPB measures and HPV vaccine receipt among family or friends (measured through index participants' self-report).

Results: Participants' mean age was 47 years; 48% were White and 23% were Black. Most (≥80%) participants assigned to the DHP intervention liked the DHP, were satisfied with the HPV information presented, and trusted the DHP. After receiving the interventions, DHP group were more likely to intend to talk to their family/friends about HPV vaccination (P=0.043). At the 6-week follow-up, 60% participants in DHP group and 50% in SE group (P=0.551) reported that they discussed HPV vaccination with their family or friends. Of these family members/friends, approximately one-third had subsequently discussed HPV vaccination with their healthcare providers or actually received the HPV vaccine.

Conclusions: These preliminary results indicate that DHP education program is highly acceptable, feasible, and potentially efficacious in increasing vaccine promotion.

Shift 01-082 / #604

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

PARENTS ATTITUDES TOWARD THE HUMAN PAPILLOMA VIRUS (HPV) VACCINE : A NEW CONCEPT IN THE STATE OF QATAR

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Introduction: Human papilloma virus (HPV) is one of the leading causes of cervical and genital cancer in both genders. The purpose of the study is to delineate parental attitude regarding HPV in Qatar.

Methods: A cross-sectional study using a questionnaire was conducted at Sidra Medicine, ,Qatar

Results: 334 questioners were completed . More than 60% of the parents were not aware that human papilloma virus can cause cervical and genital cancer. When asked about the level of comfort in giving their children a vaccine that would prevent them from getting genital cancer, 77% of participants answered “very comfortable”. Interestingly, less than 4 % of parents stated that their children’s primary care physicians ever mentioned that such a vaccine exist. When asked about the most preferable mode of receiving information regarding HPV vaccine, 54 % preferred the clinician’s office, followed by 34% of whom preferred social media. In terms of preferred age to receive the vaccine, 45% of participants preferred to administer the vaccine to their children before they are mature enough to understand about sexual relations, while 22 % recommended vaccination right before marriage and 15 % preferred to wait till they are grown up and decide for themselves. Furthermore, only 42 % of caregivers agreed that it is important to explain to their children the vaccine can protect against some of the sexually transmitted infections. Finally, approximately 20 % of participants were not convinced about the HPV vaccine.

Conclusions: A large proportion of parents residing in Qatar have a positive perception regarding the HPV vaccine . Parent’s attitudes and perceptions are considered indispensable targets for community health intervention. We will share the result of our study with the ministry of public health in Qatar with a goal to incorporate the HPV vaccine in the National immunization schedule

Shift 01-083 / #651

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

ACCURACY OF SELF-REPORTED HUMAN PAPILLOMAVIRUS VACCINE USING COMPUTER-ASSISTED SELF-INTERVIEW IN YOUNG MEN WHO HAVE SEX WITH MEN

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Introduction: Gay, bisexual and other men who have sex with men (MSM) are at a higher risk of acquiring human papillomavirus (HPV). In 2017-2019, a time-limited HPV catch-up program was implemented for MSM aged ≤26 years in Victoria, Australia. This study aimed to examine the accuracy of computer-assisted self-interviewer to collect HPV vaccination status among young MSM who were eligible for the HPV catch-up program.

Methods: We conducted a retrospective observational study of young MSM aged 23-30 years attending Melbourne Sexual Health Centre (MSHC), Australia, in 2020-2021. This age cohort was selected because they were eligible for the HPV catch-up program but missed the school-based HPV program. Individuals were asked to self-report their HPV vaccination status (vaccinated, unvaccinated, unsure) using computer-assisted self-interview. The primary outcome was the sensitivity and specificity of self-reported HPV vaccination status.

Results: We identified 1,786 eligible men who attended MSHC in 2020-2021 and also had at least one clinic visit in 2017-2019. The median age was 27 (IQR=25-28) and a half (49.4%, n=883) were born in Australia. There were 1,665 men who self-reported HPV vaccination status (48.8% [n=812] vaccinated, 17.4% [n=289] unvaccinated, 33.9% [n=564] unsure), and 1,159 men had had HPV vaccine administered at MSHC. The median time since the last HPV vaccine was 1.7 (IQR=1.1-2.3) years. Classifying men with unclear vaccine status as unvaccinated, self-reported HPV vaccination had a sensitivity of 61.3% (95% CI 58.9%-63.6%; 661/1079), a specificity of 74.2% (95% CI 72.1%-76.3%; 435/586), a positive predictive value of 81.4% (95% CI 79.5%-83.3%; 661/812), and a negative predictive value of 51.0% (95% CI 48.6%-53.4%; 435/853).

Conclusions: The sensitivity of self-report HPV vaccination status was low among young MSM and one-third were unsure about their HPV vaccination status. A registry that collects vaccination records and provides access to healthcare providers would be useful to clinical recommendations.

Shift 01-084 / #690

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

HUMAN PAPILLOMAVIRUS VACCINE ACCESS AND COVERAGE IN CANADA (2022)

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Introduction: Increasing HPV vaccination rates is one of three components in the Action Plan for the Elimination of Cervical Cancer in Canada, 2020-2030, which aims to set Canada on the path to eliminate the disease by 2040. Publicly available, up-to-date information on HPV vaccine access can be difficult to find and navigate. To fill this knowledge gap, the Canadian Partnership Against Cancer (the Partnership) developed a resource that describes and visually displays who can access publicly funded HPV vaccines, where they access them, and how much it costs to purchase the vaccine series privately. This resource will support partners working to implement the Action Plan by providing a current view of HPV vaccine access in Canada.

Methods: A scan of public websites was conducted to extract information on the coverage of, eligibility for and access to publicly funded HPV vaccines in each province and territory. Representatives from provincial and territorial governments, public health organizations and the pharmaceutical industry were engaged to review and validate the information.

Results: While publicly funded HPV vaccines are offered through school-based and catch-up programs throughout Canada, coverage and eligibility details vary significantly between jurisdictions. Some jurisdictions have a maximum age to access publicly funded HPV vaccines, while others have a "once eligible, always eligible" policy. Seven jurisdictions provide extended eligibility for certain groups. The cost of the HPV vaccine series—about five to six hundred Canadian dollars—is a significant access barrier to those who are ineligible for publicly funded programs.

Conclusions: Gaps in financial coverage and access to HPV vaccines create barriers in protecting the population against HPV infection and HPV-related cancers. Having a clearer picture of the current state of HPV vaccine access in Canada can help to highlight gaps and support future policy efforts to increase access to publicly funded HPV vaccines to eliminate cervical cancer in Canada.

Shift 01-085 / #923

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

EXPANDING HPV VACCINATION COVERAGE IN CAMEROON USING A MULTIFACETED APPROACH

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Introduction: Cameroon records an estimate of at least 2770 cases of cervical cancer annually. Despite these vast figures, HPV vaccination and screening coverage in the country is still relatively low, like in most Sub-Saharan African (SSA) countries which stand at less than 15%. Introducing the HPV vaccine to the Expanded Program on Immunization (EPI) has remained timid. The World Health Organization advocates 90% vaccination coverage for girls before the age of 15 by 2030 as one of the strategies to eliminate cervical cancer. A recommended one-dose regimen for HPV vaccination currently offers great hope for improving vaccination coverage in an SSA country like Cameroon.

Methods: Multiple approaches were used by the Women's Health Program (WHP) of the Cameroon Baptist Convention Health Services (CBCHS) between January to August 2022 to improve vaccination coverage among young girls (9-14) years in Cameroon. These approaches include; the school, hospital, community, Mother-Daughter and church-based approaches. Administrative protocols were duly followed prior to implementing each approach. This vaccination exercise covered 7 out of the ten regions of Cameroon. These girls got vaccinated for free with the HPV vaccines gotten from the Cameroon Ministry of Health.

Results: During this period, a total of 7505young girls aged 9 to 14 received at least one dose of the HPV vaccine. Of this number, 2967(39.5%), which constitutes more than one-third of those vaccinated, had their vaccines within the church-based vaccination approach implemented only between June and August 2022.

Conclusions: These multifaceted approaches achieved an overall increase in HPV vaccination coverage. However, the church-based approach had a more rapid turnover than the others; hence this model is worth replicating across Cameroon for a better vaccination uptake.

Shift 01-086 / #934

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

ONE SIZE DOES NOT FIT ALL: COMPARISON OF HPV VACCINE DELIVERY IN GUYANA, RWANDA, AND UGANDA, 2019

D. Scott Lamontagne[1], Kayla Betz[1], Ganesh Tatkan[2], Ertenisa Hamilton[2], Jacqueline Anena[3], Clarisse Musanabaganwa[4], Hassan Sibomana[5], Francois Uwinkindi[4], Amare Bayeh[6], Immaculate Ampaire[7], Alfred Driwale[7]
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Introduction: Since 2006, 123 World Health Organization member states and 27 territories have introduced HPV vaccine into national immunization programs. However, questions still remain about the cost of delivery and the type of delivery programs low- and lower-middle-income countries are using. Embedded in a multi-country HPV cost of delivery study, we conducted operational research to assess the delivery modalities for HPV vaccines.

Methods: This retrospective descriptive study extracted individual written vaccination session records from 2019 from a representative sample of health facilities in Guyana (n=43), Rwanda (n=42), and Uganda (n=66). Number of doses delivered by session were tabulated and stratified by location of vaccination, frequency, and vaccine dose.

Results: HPV vaccine delivery varied by country (Table 1). Facilities in Rwanda conducted 388 HPV vaccination sessions (average 9.5 sessions/facility), 99% were at schools, and delivered 24,824 doses (99% of all HPV doses). Average session size was more than 60 doses per session, and average number of doses delivered was 613 per facility. Nearly all doses were administered in March and September. * see Mvundura M., et al. for complementary abstract of full costing results from this

study.

Table 1. Key program characteristics for HPV vaccine delivery at health facilities in Guyana, Rwanda, and Uganda, 2019.

Program characteristic	Guyana	Rwanda	Uganda
Target population	9- to 16-year-old girls and boys	12-year-old girls	10-year-old girls
Delivery approach	71% of sessions at **schools** (no special funds) 25% at facilities 4% at outreach	99% of sessions at **schools** (no special funds)	78% of sessions at **schools** (special funds) 4% at facilities 18% at outreach
Frequency of HPV vaccination sessions	Continuously throughout the year, with peaks in February and March	March (dose 1) September (dose 2)	Continuously through the year with peaks in April, October, and November
Total doses delivered in sample	**6,398 doses** delivered at 216 HPV vaccination sessions conducted by 40 health facilities	**25,121 doses** delivered at 388 HPV vaccination sessions conducted by 41 health facilities	**8,438 doses** delivered at 331 HPV vaccination sessions conducted by 52 health facilities
Average number of sessions per health facility	5.4	9.5	6.4
Average number of doses per health facility	160.0	612.7	162.3
National coverage (2019)[1]	42% HPV1 20% HPVc	97% HPV1 94% HPVc	99% HPV1 64% HPVc
Financial cost per HPV vaccine dose delivered[2] (volume-weighted mean and 95% CI)	$1.26 [$0.05–$2.48]	$0.37 [$0.20–$0.54]	$3.17 [$0.45–$5.89]

Abbreviations: HPV1 = HPV vaccination program first dose; HPVc = HPV vaccination program coverage of full dose; CI = confidence interval

Conclusions: HPV vaccine delivery may not be simply categorized as school- or facility-based; implementation at the facility level is more nuanced. Pulsed, school-based delivery for HPV vaccines may also be less expensive than continuous vaccination throughout the year.

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Poster Viewing
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CLINICAL IMPACT OF HUMAN PAPILLOMAVIRUS VACCINES IN THE REDUCTION OF CERVICAL CANCER, PRECURSOR LESIONS AND INFECTIONS: A SYSTEMATIC REVIEW

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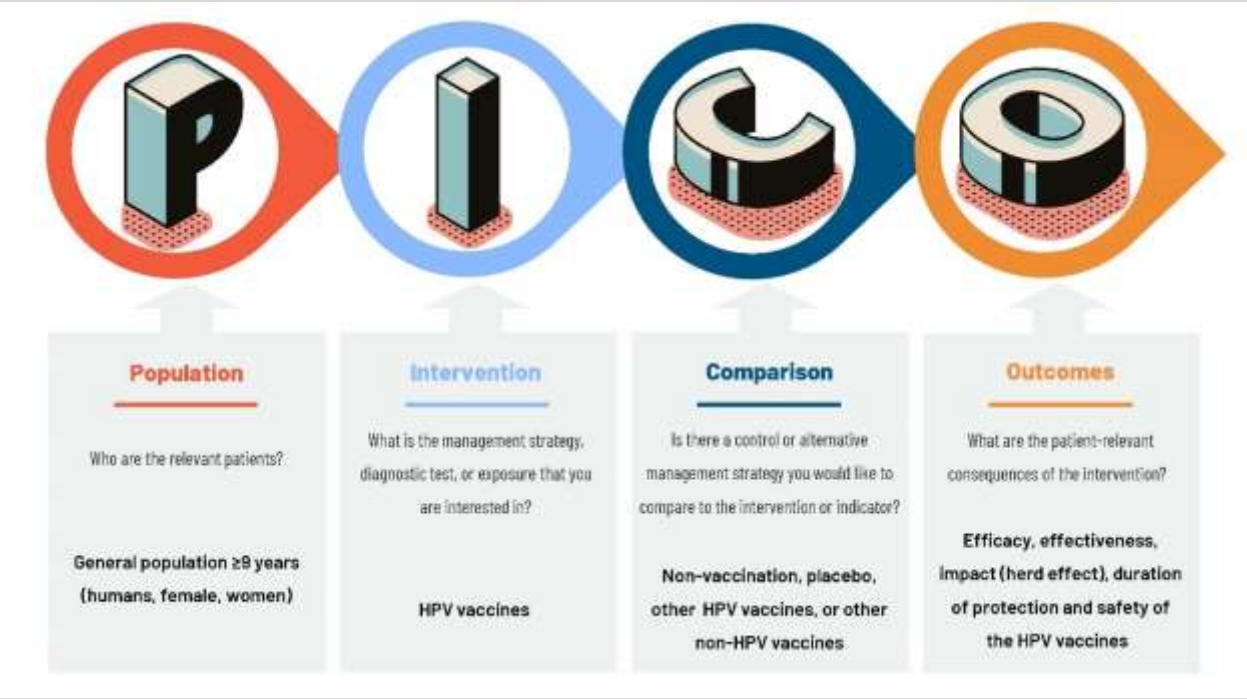
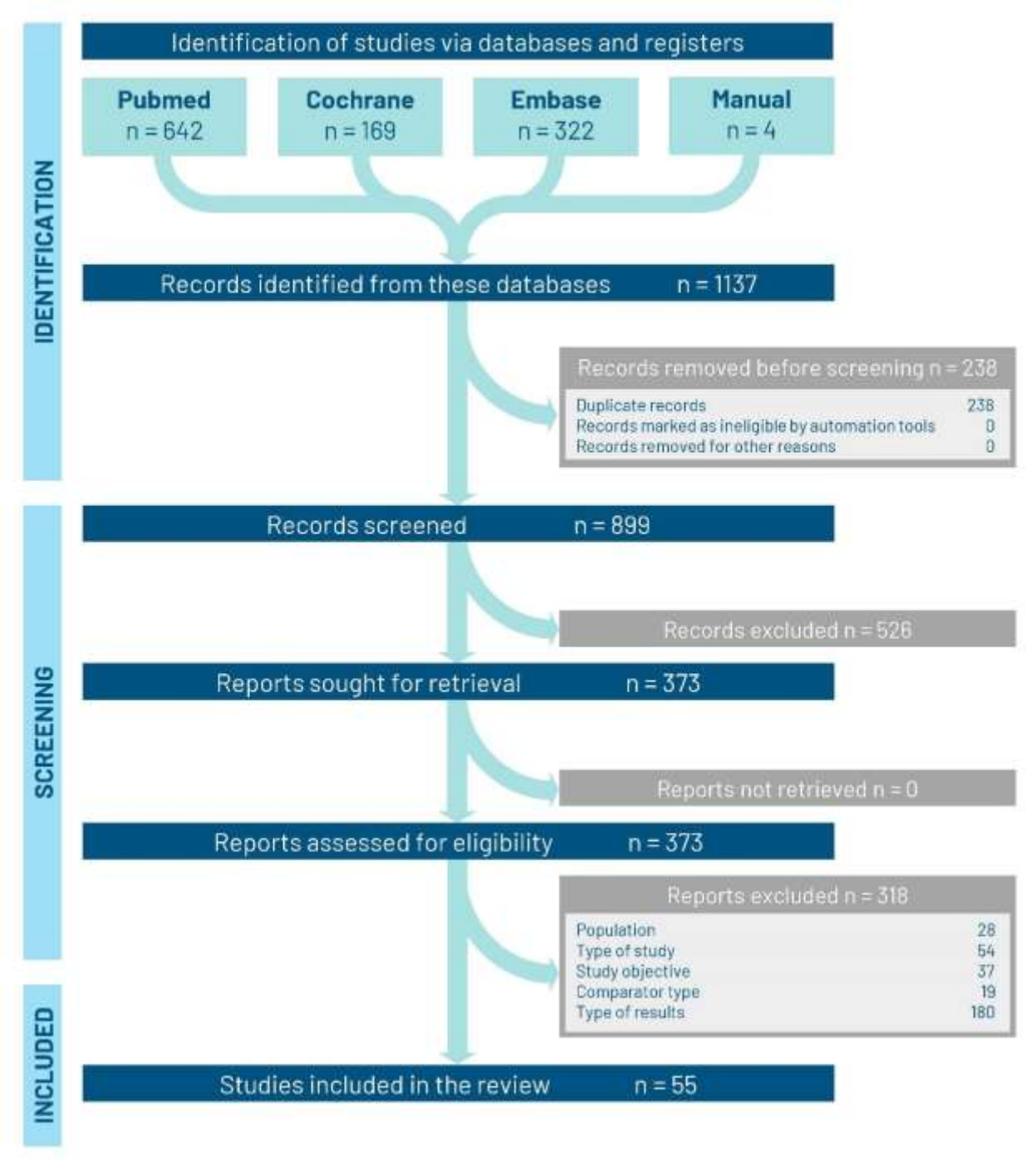
Introduction: Human papillomavirus (HPV) vaccination is a common public health strategy to reduce HPV infection and minimize cervical cancer. We performed a systematic literature review (SLR) of HPV vaccines efficacy / real-world evidence against HPV infections of cervical cancer and precursor lesions.

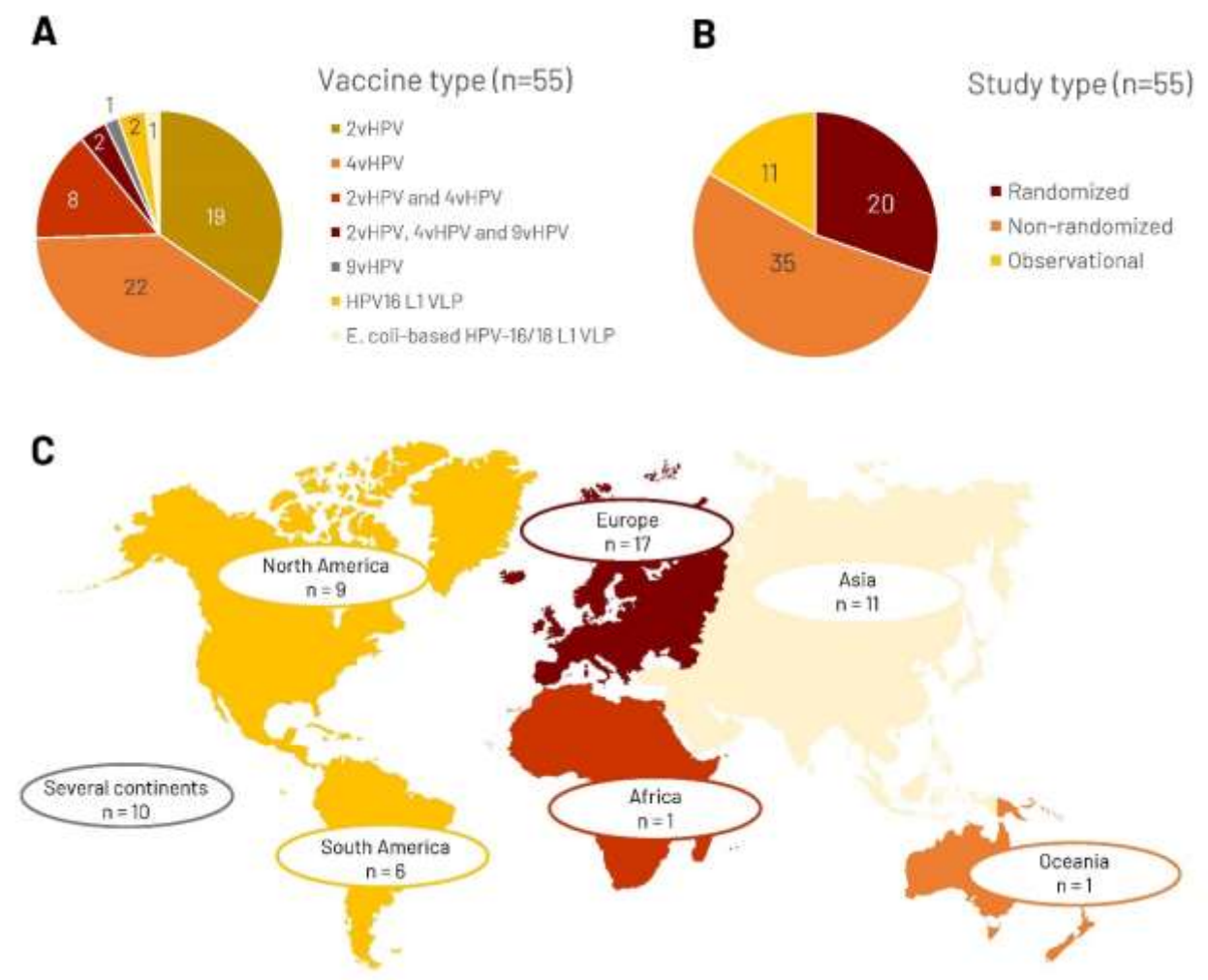
Methods: A SLR of the English language literature published between 1/01/2006 and 1/31/2022 was performed using PubMed, EMBASE, Cochrane Library databases, and grey literature searches were performed. The search was structured as PICO methodology (Figure 1). A total of 1,137 publications were retrieved, of which 55 articles were selected for full-text analysis (Figure 2).


Population
Who are the relevant patients?
General population ≥9 years (humans, female, women)
Intervention
What is the management strategy, diagnostic test, or exposure that you are interested in?
HPV vaccines
Comparison
Is there a control or alternative management strategy you would like to compare to the intervention or indicator?
Non-vaccination, placebo, other HPV vaccines, or other non-HPV vaccines
Outcomes
What are the patient-relevant consequences of the intervention?
Efficacy, effectiveness, impact (herd effect), duration of protection and safety of the HPV vaccines



Results: Twenty studies were randomised trials and thirty-five were non-randomised trials, of which eleven were observational studies. Participants' ages varied from 9–69 years, with most of the studies (31) ranging from 14-26 years of age. Studies mainly assessed the AS04-adjuvanted HPV-16/18 (2vHPV) and HPV-6/11/16/18 (4vHPV) vaccines worldwide (Figures 3A,3B,3C). Key results suggested that in real-world settings, protection duration lasts at least 10 years with 2vHPV and that its protective effect against cervical cancer was 87% to 88%, considering vaccinated and unvaccinated cohorts.[1] 4vHPV effectiveness against cervical cancer was 81% to 88% since the start of the National Immunisation Programme in Sweden.[2, 3] Both vaccines demonstrated better outcomes when administered in the youngest cohorts. Results varied depending on study settings for all HPV vaccines. Safety findings were

consistent with pre-licensure clinical studies.



Conclusions: The WHO Cervical Cancer Elimination Initiative[4] highlights the need of early protection and efficacious vaccines ensuring duration of protection. In this SLR we found that post-marketing studies in countries with routine vaccination programmes and high coverage showed decreases in the prevalence of HPV types, high-grade cervical lesions, and cervical cancer. In addition, vaccine effect is highest when administered at younger ages.

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Poster Viewing
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04-18-2023 7:00 AM - 5:00 PM

ADOPTING AND ADAPTING HEALTH BEHAVIOUR THEORIES TO IDENTIFY DETERMINANTS OF UPTAKE OF HPV PREVENTION INTERVENTIONS

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Introduction: Participation in vaccination against the Human Papilloma Virus (HPV) is essential for the prevention of cervical cancer. In addition to demographic and socio-economic factors, vaccination and screening uptake are influenced by individual beliefs, many of which are included in health behaviour theories like the Health Belief Model (HBM), the Theory of Planned Behaviour (TPB) and the Theory of care-seeking Behaviour (TCSB). A systematic review revealed that these models explain a significant proportion of the intention to participate in cervical cancer screening (CCS). This study presents the result of an investigation of the suitability of an 'adapted health behaviour model' to predict willingness to participation in HPV vaccination in India, where several challenges to vaccine acceptability like beliefs prevail.

Methods: A questionnaire integrating constructs from the HBM, TPB and TCSB along with relevant socio-demographic variables, knowledge about cervical cancer, and health literacy was applied to 606 women and 500 men aged 20-60 years in a state of South India. Logistic regression analysis was used to explore the extent to which this adapted model and related variables could predict willingness of the participants to vaccinate their children against HPV.

Results: The adapted model had a good fit (Nagelkerke's R squared=0.171, Hosmer- Lemeshow p-value>0.05). Willingness to HPV vaccination was significantly higher among males (AOR=1.31, 95%CI 1-1.72). Perceived severity of cervical cancer (AOR=1.28, 95%CI 1.16-1.41), inaccessibility to health centre (AOR=0.24, 95%CI 0.18-0.34) and routine health screening behaviour (AOR=1.63, 95%CI 1.23-2.14) significantly predicted vaccination willingness. Health literacy of individuals was significantly associated with knowledge (OR=1.15, 95%CI 1.09-1.20), perceived disease severity (OR=1.18, 95%CI 1.06-1.30) and routine screening behaviour (OR=1.8, 95%CI 1.81-1.34).

Conclusions: Integrating constructs from health behaviour theories adapted to a specific context can help identify the psychosocial and practical determinants of participation in cancer prevention interventions in countries like India where individual beliefs cause poor vaccination uptake.

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Poster Viewing
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HEALTH AND ECONOMIC EFFECTS OF INTRODUCING SINGLE-DOSE HUMAN PAPILLOMAVIRUS VACCINATION IN INDIA.

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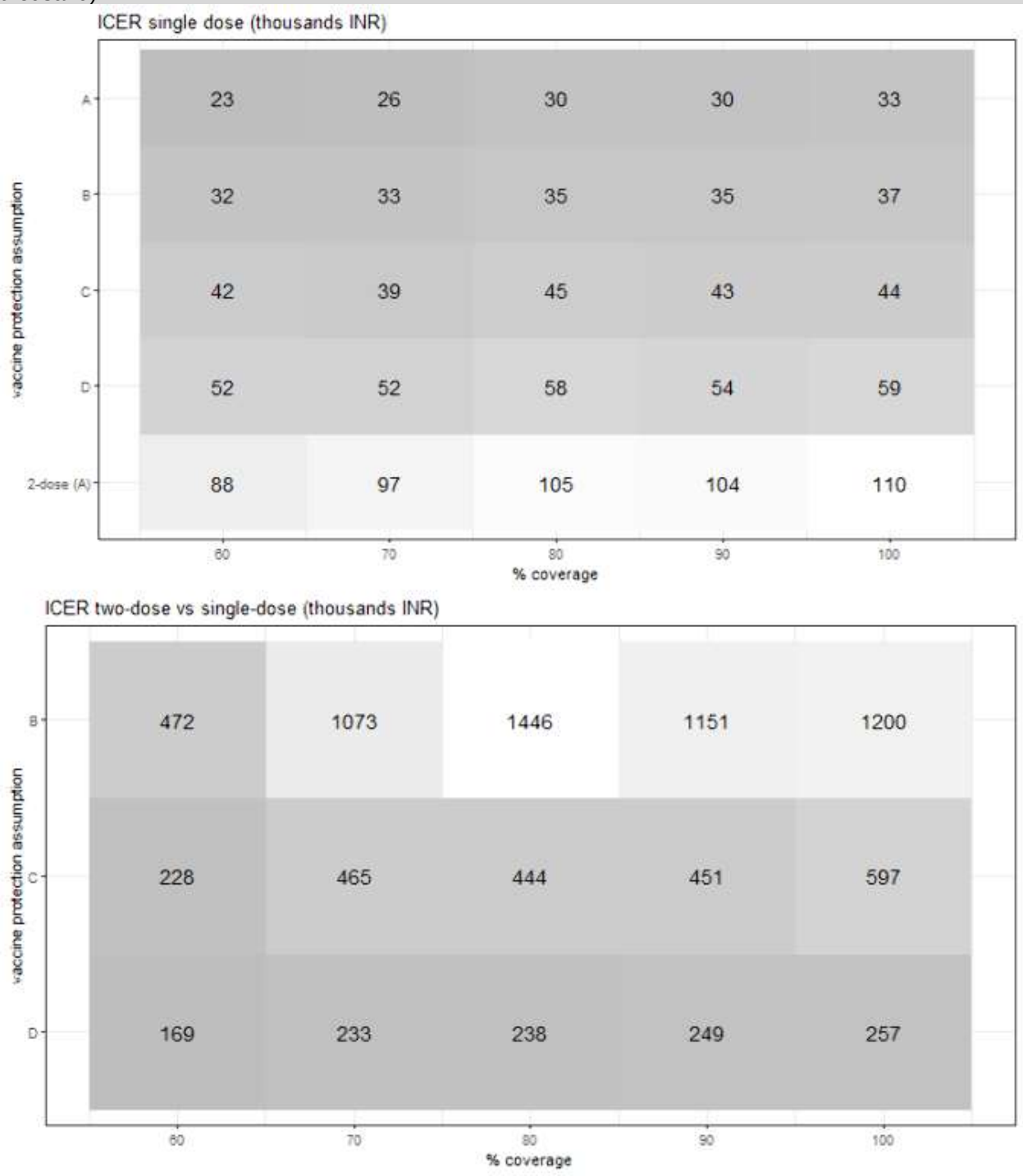
Introduction: Cervical cancer is a major public health problem in India, where access to prevention programmes is low. The World Health Organization-Strategic Advisory Group of Experts recently updated their recommendation for human papillomavirus (HPV) vaccination to include a single-dose option in addition to the two-dose option, which could make HPV vaccination programmes easier to implement and more affordable.

Methods: We combined projections from a type-specific HPV transmission model and a cancer progression model to assess the health and economic effects of HPV vaccination at national and state-level in India. The models used national and state-specific Indian demographic, epidemiological and cost data, and single-dose vaccine efficacy and immunogenicity data from the IARC India vaccine trial with 10-year follow-up. We compared single- and two-dose HPV vaccination for a range of plausible scenarios regarding single-dose vaccine protection, coverage and catch-up.

Results: Under the base-case scenario of life-long protection of single-dose vaccination in 10-year-old girls with 90% coverage, the total cost of introducing single-dose HPV vaccination was ₹INR 7.8 billion ($USD 106 million) in the first year, equivalent to 9% of the annual cost of the Indian universal childhood vaccination programme. The incremental cost-effectiveness ratio (ICER) of nationwide vaccination relative to no vaccination was ₹INR 30 thousand per DALY averted (state-specific ICER range: ₹INR 5-44 thousand,) and lay below an opportunity-cost based threshold of 30% Indian GDP per capita (₹INR 44 thousand). The ICER of two-dose vaccination versus no vaccination was ₹INR 104 thousand. The ICER of two- versus single-dose vaccination was minimum ₹INR 169 thousand, which is above the WHO threshold (₹INR 148

thousand).



Conclusions: Nationwide introduction of single-dose HPV vaccination in India is highly likely to be cost-effective whereas extending the number of doses from one to two would have a less favourable profile. These results could convey several lessons for implementation in other LMICs.

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Poster Viewing
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PREVALENCE OF ORAL HUMAN PAPILLOMAVIRUS INFECTION AMONG YOUNG URBAN GAY, BISEXUAL, AND OTHER MEN WHO HAVE SEX WITH MEN IN CANADA, 2017-2019

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Introduction: In 2015 and 2016, the HPV vaccine became publicly-funded for gay, bisexual, and other men who have sex with men (GBM) up to 26 years of age in most Canadian provinces. We estimated the prevalence of oral HPV infection among young sexually active GBM soon after the implementation of these programs.

Methods: Between February 2017 and August 2019, self-identified GBM in Montreal, Toronto, and Vancouver were recruited through respondent-driven sampling for the Engage cohort study. Participants aged 16 to 30 years were invited to self-collect oral rinse specimens for HPV testing. Specimens positive for HPV DNA were tested for 36 genotypes using the Linear Array (Roche Molecular Systems). We estimated type-specific and grouped (low-risk, high-risk, vaccine-preventable) HPV prevalence overall and compared results by HPV vaccination status (>1 dose). Vaccine effectiveness was calculated using the formula VE = (1 – [crude odds ratio]) × 100%.

Results: Among the 838/845 GBM with a valid oral specimen (median age 26 years), 36.9% reported receiving ≥1 dose of the HPV vaccine. Overall, 2.6% (95% confidence interval, CI: 1.5, 3.7) were infected with one or multiple HPV types, 1.6% (CI: 0.7, 2.4) with any low-risk type, 1.2% (CI: 0.5, 1.9) with any high-risk type, and 0.7% (CI: 0.1, 1.3) with any quadrivalent vaccine-preventable type (HPV-6/11/16/18). We detected HPV-6/11/16/18 in 1/309 (0.3%, 95% CI: 0.0, 1.0) of vaccinated individuals and 5/472 (1.1%, 95% CI: 0.1, 2.0) of unvaccinated individuals; the corresponding estimate of vaccine effectiveness for ≥1 dose against prevalent oral HPV infections was 70% (CI: -161%, 96%).

Conclusions: Oral HPV prevalence was low in a population of young urban GBM in Canada of whom 37% were vaccinated. Our findings serve as a benchmark for future research examining trends in oral HPV prevalence and the impacts of HPV vaccination among GBM.

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HUMAN PAPILLOMAVIRUS VACCINE INITIATION AND UP-TO-DATE VACCINE COVERAGE FOR ADOLESCENTS AFTER THE IMPLEMENTATION OF SCHOOL-ENTRY POLICY IN PUERTO RICO

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Introduction: The Human Papillomavirus (HPV) vaccine has been proven effective in the prevention of infection with high-risk HPV types, that lead to the development of six HPV-related cancers. In August 2018, Puerto Rico (PR) adopted a mandatory HPV vaccination school-entry policy. While school-entry requirements are generally accepted as an effective approach for increasing vaccination rates, there are few studies that have documented their impact on improving HPV vaccination rates. The objective of this study was to evaluate the impact of the HPV school-entry policy in PR on HPV vaccine coverage.

Methods: A pre-post natural experiment was used. The study population included adolescents registered in the PR Immunization Registry during 2008-2019. We calculated HPV vaccine initiation and up-to-date (UTD) vaccine coverage rates. Age-standardized rates (ASR) and standardized rate ratio with 95%CI were estimated.

Results: Vaccine data corresponding to a total of 495,327 adolescents (50.9% male and 49.1% females) were included for analysis. After policy implementation, a marked increase in raw HPV vaccine initiation among 11- to 12-year-old adolescents was observed across years 2017 (a pre-policy year), 2018, and 2019 (58.3%, 76.3%, and 89.8%, respectively). UTD coverage also showed a moderate increase after policy implementation among 11- to 12-year-old adolescents. The gap between sex in vaccine initiation and UTD coverage narrowed over time; the ASRs in 2019 showed an increase of 19% in initiation and a 7% increase in UTD relative to 2017 for males and females combined (both significant at $p<0.05$).

Conclusions: This study demonstrated evidence of improvement in HPV vaccination rates following implementation of the school-entry policy and a narrowed sex gap in vaccine rates over time in PR. Future analyses should assess how the policy continues to affect vaccine coverage in subsequent years and how the COVID-19 pandemic has impacted HPV vaccination uptake.

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OPPORTUNITIES FOR HUMAN PAPILLOMAVIRUS (HPV) VACCINE DELIVERY IN CANCER HEALTHCARE SETTINGS: A MIXED-METHODS PILOT STUDY

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Introduction: Pediatric, adolescent, and young adult (PAYA) cancer survivors are at increased risks for HPV related secondary cancers; however, their HPV vaccine uptake rates are poor. Strategies to promote routine HPV vaccine delivery have not been tested in cancer care. Therefore, we examined the perceived barriers and opportunities for HPV vaccine delivery among pediatric cancer care providers.

Methods: We disseminated a semi-structured questionnaire to a convenience sample of pediatric oncology and hematology physicians between April and July of 2022. Questionnaire measures included demographic and practice characteristics, HPV vaccine knowledge, the perceived barriers, opportunities, and roles for HPV vaccine delivery. Descriptive characteristics were generated for quantitative data, and content analysis was used to identify themes across the codes.

Results: A total of 49 providers were included in the analyses. A majority were female (67.5%) and non-Hispanic white (71.4%). Approximately 75.5% were pediatric oncology or hematology physicians, and most worked in a cancer center or children's hospital (85.7%). Nearly half had been practicing for less than 10 years, and a majority saw patients ages 11-17. Although less than half of the physicians reported discussing HPV vaccination with their patients, 69.4% were willing to become involved in HPV vaccine delivery. Findings suggest that pediatric cancer physicians described barriers to HPV vaccination delivery most often as being related to system-level factors.Other barriers to HPV vaccination delivery included lack of provider knowledge and patient/parent-related factors.Study findings also included opportunities within cancer prevention education, transitions in care, and at the system-level.

Conclusions: Although barriers to HPV vaccination persist in pediatric cancer care, most cancer care physicians perceived there to be opportunities to become involved in HPV vaccine delivery. Identifying potential strategies for cancer care physicians to adopt a stronger role in HPV vaccination remains a significant opportunity for future implementation research.

Shift 01-093 / #1097

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PARTNERING WITH SOCIAL MEDIA INFLUENCERS TO INCREASE PARENTAL ACCEPTANCE OF THE HPV VACCINE

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Introduction: Rates of adolescent human papillomavirus (HPV) vaccination remain lower than for other adolescent vaccines. Additionally, the COVID-19 pandemic led to acute decreases in vaccination. The public health community has long utilized trusted messengers to deliver messages about vaccines. As more parents receive news and information from social media, we partnered with a diverse group of social media influencers, or everyday people who are influential in their online social networks, to create and test messages specifically for communities of color about HPV vaccination.

Methods: Ten female social media influencers created posts in their own words and language about the HPV vaccine. Next, influencers recruited their followers to complete a baseline survey, view the post, and immediately complete an endpoint survey. We assessed changes in HPV vaccine knowledge, attitudes towards HPV-related cancer, and intentions to vaccinate their children. We also captured trust in the influencer, perceptions of the post, and follower demographic characteristics. Mean scores or frequencies were calculated for all variables. Changes in survey variables from baseline to endpoint were assessed with repeated measures t-tests.

Results: We recruited 10 social media influencers. Four were African American and 6 were Hispanic. Their mean age was 41 and most had 2 or 3 children. Five influencers lived in the suburbs, 4 lived in urban areas, and 1 lived in a rural area. All but one were married or with a partner. The average time as an influencer was 9.5 years. Baseline and endpoint survey data from the followers are currently being analyzed; results will be shared as part of this presentation.

Conclusions: Social media influencers can be recruited to participate in messaging about the HPV vaccine. As the public increasingly views health information on social media, partnerships with these novel trusted messengers are important for delivering timely, accurate, and culturally tailored information.

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HUMAN PAPILLOMAVIRUS (HPV) VACCINATION UPTAKE AMONG ADOLESCENT AND YOUNG ADULT (AYA) CANCER SURVIVORS IN WESTERN NEW YORK

Melany Garcia[1], Cailey Mcgillicuddy[1], Elisa Rodriguez[1], Kristopher Attwood[2], Jennifer Schweitzer[3], Scott Coley[4], Denise Rokitka[5], Nicolas Schlecht[1]
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Introduction: Although adolescent and young adult (AYA) cancer survivors are susceptible to HPV-related secondary cancers, their HPV vaccine uptake rates are low, reasons for which are unclear. We examined HPV vaccine uptake rates among AYA cancer survivors before and after diagnosis from Western New York over 13-years since introduction of HPV vaccines.

Methods: Retrospective review of patients diagnosed and treated with invasive or non-invasive cancerous conditions between ages 10-26 at Roswell Park Oishei Children's Cancer and Blood Disorder Program. We matched vaccine date information for patients between 2006 to 2020 from the New York State Immunization Information System. Demographic and cancer-related information were abstracted from electronic medical records. Cumulative vaccine uptake was assessed by Kaplan-Meier and Cox proportional hazards regression models adjusting for age and cohort effects. Treatment periods were excluded from our time-to event analyses.

Results: A total of 636 patients were included in the analyses. Most were non-Hispanic/White (83.7%) and resided in a metropolitan area (87.7%). Approximately half were diagnosed with a solid tumor (53.4%) and 73.0% presented to Roswell Park unvaccinated. Patients were 74% less likely to initiate HPV vaccination after their cancer diagnosis compared to before ($p<0.001$). Compared to females, males were less likely to initiate the HPV vaccine (HR=0.76) although this association was non-significant.

Conclusions: Although HPV vaccination is recommended for cancer survivors, we observed significantly lower uptake after diagnosis. While our findings imply a missed opportunity for HPV vaccination in cancer care, there may be potential for cancer centers to play a greater role to improve HPV vaccination rates among their patients as a component of cancer prevention and control services.

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THE IMPACT OF HPV VACCINATION ON CERVICAL PRECANCER IN THE UNITED STATES (U.S.): A STATE-WIDE POPULATION BASED EVALUATION OF CHANGES IN GENOTYPE-SPECIFIC PREVALENCE

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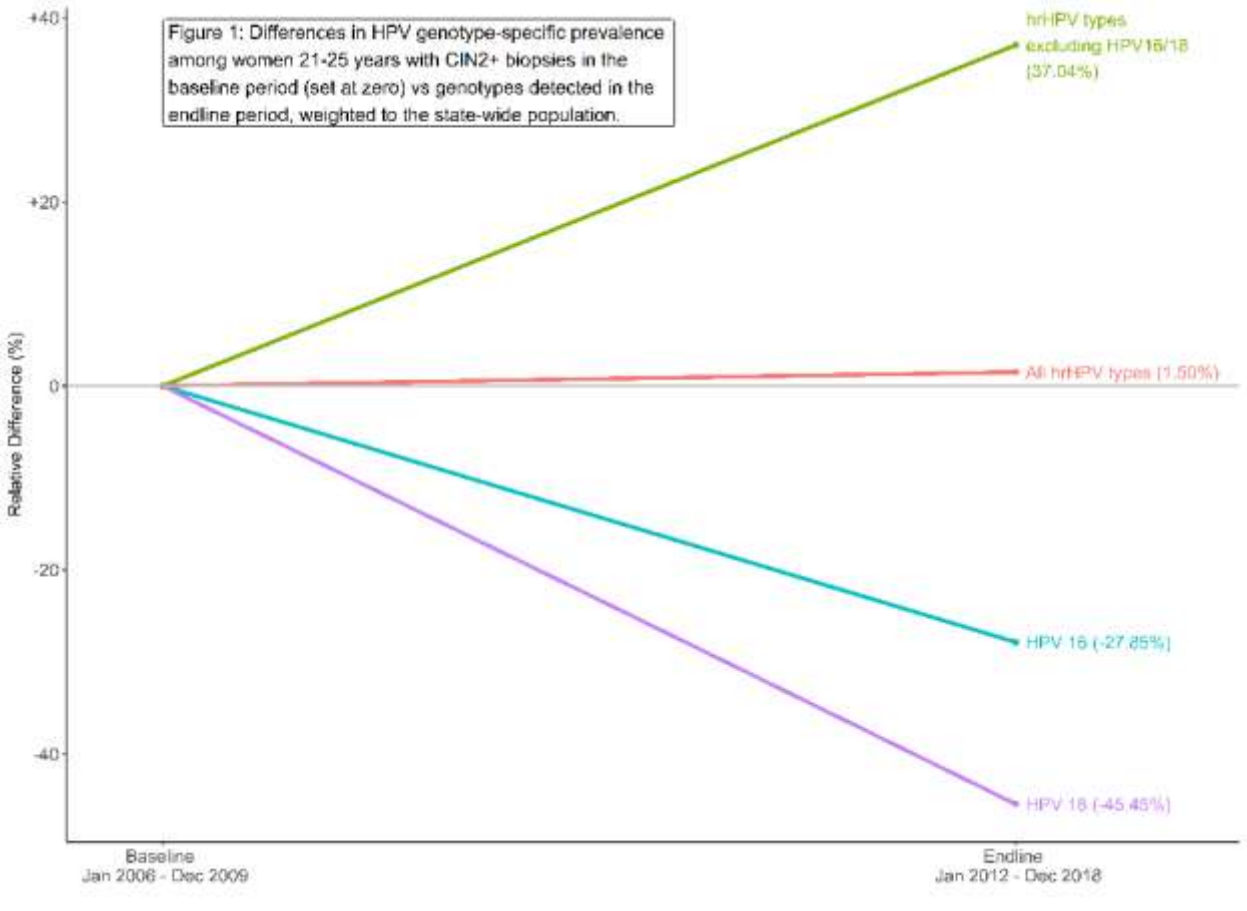
Introduction: We and others have reported declines in cervical intraepithelial neoplasia [CIN] grades 2-3 and adenocarcinoma in situ [AIS] (CIN2+), supporting that HPV vaccinations are achieving the desired impact. Here we report genotype-specific changes in CIN2+ biopsies across a decade of 4-valent HPV vaccine implementation.

Methods: Two state-wide random stratified samples of formalin-fixed paraffin-embedded tissues from women aged 15-29y undergoing diagnosis and treatment in New Mexico were genotyped by Roche Linear Array and LiPA25, version 1 assays. Weighted HPV genotype-specific relative prevalence differences (RP) and 95% confidence intervals (95%CI) were calculated for individual diagnoses in women 21-25y from 2006-2009 (n=3632) and 2012-2018 (n=3598). Weighted logistic regression models were fit to estimate changes in HPV genotype-specific positivity in CIN2+, restricted to the period of 2012-2018 and adjusted for birth cohort and age.

Results:



Among women 21-25y, overall incidence of CIN2+ decreased by 48.17%. When considering genotype-specific changes among CIN2+, significant reductions in HPV16 (RP=–27.85%, 95%CI=–33.72%, –21.98%) and HPV18 (RP=–45.45%, 95%CI=–69.54%, –21.35%) were observed. There were however increases in the overall RP of other high-risk HPV types when excluding HPV16/18 (Figure 1). For CIN2+, among women born in 1995 compared to those born in 1985, the risk of detecting any 4-valent (HPV6/11/16/18) HPV type or HPV16/18 decreased by 42.94% and 39.37%, respectively.

Conclusions: HPV vaccine impact offers the promise of significant reductions in HPV-related cancers. Overall, CIN2+ incidence has decreased significantly across 10 years of 4-valent vaccine implementation however, some attenuation of impact from clinical unmasking of non-vaccine HPV types may reduce earlier estimates of long-term reductions in high-grade cervical disease. The impact on HPV genotype distribution in invasive cervical cancer is still unknown however. Enhancement of vaccine impact and genotype-specific impact is expected to be much broader with the 9-valent vaccine. Continuing surveillance of HPV vaccine impact remains essential.

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HUMAN PAPILLOMAVIRUS VACCINATION DELIVERY SYSTEMS WITHIN NATIONAL AND REGIONAL IMMUNIZATION PROGRAMS: A SYSTEMATIC LITERATURE REVIEW

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Introduction: Human Papillomavirus (HPV) causes 4.5% of all new cancer cases. Efficient HPV vaccination programs are crucial to reduce the global burden of cancer. As of June 2020, 107/194 World Health Organization (WHO) Member States have introduced HPV vaccination, one-third of which are gender neutral whereby girls and boys receive vaccination. Globally, only 15% of girls and 4% of boys in the target age for HPV vaccination receive the full course. The objective of this systematic literature review was to describe HPV delivery strategies within national and regional immunization programs in low- middle- and high-income countries to identify strategies to increase HPV vaccination coverage globally.

Methods: We systematically reviewed studies within MEDLINE and EMBASE published between 2012-2022. Studies were included if they described immunization programs in which HPV had been included for >6 months. Key outcomes of interest were strategies utilized in the implementation of HPV delivery programs (e.g., vaccine delivery location, community awareness campaigns). Of the 2,549 articles retrieved, 168 met inclusion criteria and were included for final synthesis.

Results: Most (n=78) articles were from North America, 31 from Europe & Central Asia, 15 from East Asia and Pacific, 8 from Africa, 5 from Latin America & Caribbean, 2 from South Asia, and 29 included multiple regions. While most articles (n=121) focused on high-income countries, 19 focused on low- or middle-income countries and 28 spanned multiple income levels. The most frequently described strategies that had a positive impact on HPV vaccine coverage included selecting optimal delivery locations for the local context, such as school-based programs (n=51), multi-sectoral collaboration (n=47), community-awareness campaigns (n=42), systematic vaccine invitations and reminders (n=37), immunization information systems (n=26) and vaccine provider education and training (n=11).

Conclusions: Despite the diversity of countries included in terms of geography and income, this review identified cross-cutting strategies that may improve HPV vaccine coverage.

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ORAL HUMAN PAPILLOMAVIRUS PREVALENCE AND DETERMINANTS IN A SAMPLE OF 1610 YOUTH FROM CATALONIA, SPAIN

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Introduction: Catalonia, a region of 7.5 million inhabitants in northeast Spain, started in 2008 a school-based, single-cohort human papillomavirus (HPV) vaccination programme with the quadrivalent vaccine targeting 11-year-old girls. HPV vaccination coverages have been steadily over 80%. We aimed to determine the prevalence and determinants of oral HPV infection among young adults in Catalonia and to compare the prevalence of HPV 6/11/16/18 by sex and vaccination status.

Methods: We conducted a cross-sectional study from 2019-2022. Unvaccinated men aged 18-26 years, vaccinated women from vaccinated cohorts aged 18-24 years and unvaccinated women from unvaccinated cohorts aged 22-29 years who were university students or hold a university degree were eligible. Participants provided a 1-minute oral rinse and gargle sample to perform HPV DNA detection and completed a questionnaire to collect demographic and behavioural data. HPV DNA detection and genotyping was performed using the SPF-10/DEIA/LiPA25 system.

Results: A total of 369 men, 621 unvaccinated women and 620 vaccinated women were recruited. The prevalence of oral HPV infection in men was higher than in vaccinated and unvaccinated women (8.4% vs 3.2 and 2.6%, respectively; p=0.001 and p<0.001). Regarding vaccine-types, only one HPV16 infection and one HPV6 infection were detected, both in unvaccinated women. Prevalence of high-risk genotypes not HPV16/18 was 4.1% in men, 1.0% in vaccinated women and 0.8% in unvaccinated women, and prevalence of non-typeable genotypes was 4.1%, 1.9% and 1.3%, respectively. Main factors associated with oral HPV infection in men were ever having had sex, number of oral sex partners in the previous 12 months and history of previous sexually transmitted infections.

Conclusions: Oral HPV infection in youth from Catalonia, Spain, is more prevalent in men than in women, regardless of vaccination status. Prevalence of vaccine-types in unvaccinated youth is negligible, probably due to the herd effect of the HPV vaccination program.

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LESSONS LEARNT FROM SUB-SAHARAN AFRICAN MEETING ON HPV VACCINATION PROGRAMS – FROM PRE-INTRODUCTION PLANNING TO RESTORATION AND SUSTAINABILITY

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Introduction: More than 85% of the deaths due to HPV-related cancers occur in Low- and Middle-Income Countries (LMIC); in most sub-Saharan African (SSA) regions, cervical cancer is the leading cause of cancer deaths among women. COVID-19 and supply chain bottlenecks have severely impacted HPV immunisation programs.

Methods: For this reason, the Coalition to Strengthen HPV Immunisation Community (CHIC), with the support of the Ministry of Health in Ethiopia and the Ethiopian Society of Gynaecology and Obstetrics, convened a meeting in Addis Ababa on the 24 and 25th of September to facilitate discussion on HPV vaccination programs between key stakeholders from LMICs to engage and share their experiences with HPV vaccination programs. 109 participants, representing over 20 different SSA countries attended the meeting. Participants included members of EPI and NITAG, Ministries of Health, WHO, GAVI, UNICEF, Jhpiego and academic institutions. Live translation removed language barriers and enabled the group to share lessons learned to broader audiences, with key points highlighted below.

Results: (a)The migration to single-dose schedule requires a clear transition framework, careful stakeholder engagement and communication. (b)The engagement with the Ministry of Education from the beginning and adolescent participation were emphasised. (c)Quality training was confirmed as critical for the success of good coverage, especially the need for refresher training for healthcare professionals and continuous mentorship. (d)Training for teachers in school-based delivery mode was also stressed. (e)Countries planning to introduce HPV vaccine were very engaged in the cohort selection criteria and delivery experiences. (f)Integration of the HPV vaccine with other services and vaccines was key in the resilience and restoration of HPV vaccination programs during the COVID-19 pandemic.

Conclusions: After more than two years of online activities due to the pandemic, this face-to-face event was a reminder of how bringing together a diverse stakeholder group to the same room can accelerate collaboration, decision-making and policy.

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ABSENCE OF TOTAL AND NEUTRALIZING HPV18 L1 ANTIBODIES IN 10% OF QUADRIVALENT VACCINE RECIPIENTS: A LONG-TERM FOLLOW-UP STUDY OF TWO PHASE 3 TRIALS

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Introduction: Long-term follow-up studies of HPV vaccinated recipients have reported that variable proportions of women have no detectable total and/or neutralizing antibodies against HPV16/18 after HPV vaccination with 3-doses. We further investigated the consistency of absence or presence of vaccine-induced HPV16/18 L1 antibodies over 12 years post-vaccination.

Methods: We conducted a follow-up study of two cohorts of Finnish women receiving 3 doses of either the bivalent or quadrivalent vaccine when aged 16-17, as participants of the PATRICIA and FUTURE II randomized phase 3 trials. The vaccine recipients comprising these cohorts were followed up in the Finnish Maternity Cohort, FMC, serum bank. The FMC serum bank contains serum samples from 96% of all pregnant women in Finland from 1983-2016. During up to 12 years of follow-up post-vaccination. 2046 serum samples were identified with the shortest lag (N=648) were analyzed both for total L1 binding antibodies to HPV16 and 18 via a pseudovirion-based Luminex assay and for HPV16 and 18 neutralizing HPV L1 antibodies via pseudovirion-based neutralization assay.

Results: A total of 648 vaccinated receipts (328 quadrivalent vaccine recipients, QVR and 320 Bivalent vaccine recipients, BVRs) were eligible and included in the study. Among QVRs and BVRs, 4.0% and 0.0% respectively were seronegative for both neutralizing and total binding HPV16 antibodies, Cohen's Kappa coefficient, κ= 0.93 (95% confidence intervals, 0.83-1.03). Whilst 14% and 0.0% were seronegative for both neutralizing and total binding HPV18 antibodies respectively, κ= 0.72 (0.63-0.81).

Conclusions: Among women vaccinated in late adolescence with 3-doses of the quadrivalent vaccine, 1 in 25 recipients may have no measurable antibody response to HPV16, whilst 1 in 7 may have no response to HPV18. Observations of HPV16- or HPV18- vaccine non-response as measured via a pseudovirion-based neutralization assay were replicable when measuring total-binding antibody

response. These findings may have limited generalizability to populations vaccinated in early adolescence.

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STABILITY OF TOTAL IGG AND HPV16-ANTIBODIES IN FIRST-VOID URINE SAMPLES

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Introduction: First-void urine (FVU) samples have already proven good substitutes for clinician-collected cervical smears when testing for HPV DNA. A urine conservation medium (UCM) is required to prevent DNA degradation, but the effect on the preservation and detection of IgG has not been investigated. With this proof-of-concept experiment, we investigated the effect of UCM and different storage times at room temperature (RT) of a FVU sample on total IgG and HPV-specific antibody concentration.

Methods: FVU samples from 11 vaccinated female volunteers were collected using an empty Colli-Pee™ device. Each sample is divided into two arms, one of which has UCM added to it. The two arms were divided into three aliquots. One aliquot was frozen immediately, one was kept at RT for 7 days, and one was kept at RT for 14 days. All aliquots, after storage at -80°C for at least one week, were Amicon filtered. Total IgG (BioPlex Pro™ Human Isotyping Assay) and HPV16-antibody (DELFIA) concentrations were measured.

Results: showed that both total IgG concentrations (ng/mL) and HPV16-antibody concentrations (IU/mL) were significantly higher in samples where UCM was added (pairwise Wilcoxon rank sum test, $p \leq 0.0096$). We observed no significant difference in total IgG concentrations and HPV16-antibody concentrations when comparing the different storage times at room temperature ($p \geq 0.62$).

Conclusions: IgG and HPV-specific antibodies remain stable for at least 14 days when stored in room temperature, with no significant difference in concentration upon detection. The use of UCM is compatible with the detection of total IgG and HPV16-antibodies in first-void urine samples.

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CERVICAL HIGH-RISK HUMAN PAPILLOMAVIRUS SEROTYPES DIFFER BETWEEN CERVICAL CYTOLOGY AND VACCINATION STATUS IN WOMEN LIVING IN PUERTO RICO

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Introduction: The implementation of HPV screening and vaccination programs in the United States has been associated with a decrease in incidence of cervical cancer from 2001-2017. Despite these efforts, cervical cancer remains a significant public health problem in Puerto Rico, exemplified by the increase in incidence from 9.2 to 13.0 during the same period. We hypothesize that one of the factors influencing this disparity is a difference in the prevalence of the most common HPV serotypes infecting Hispanic women living in Puerto Rico. To test this hypothesis, we compared the seroprevalence of HPVs in women with different cytological reports and vaccination status.

Methods: For this cross-sectional study, we collected 372 samples from Hispanic women in San Juan, Puerto Rico (IRB#1050114). Genomic DNA was extracted using the DNeasy PowerSoil kit and typified HPV using the LiPA25 kit, identifying 25 different HPV genotypes. Metadata was obtained from questionnaires and included variables such as vaccination status and cervical cytology.

Results: We analyzed data from 372 participants, vaccinated n=62 and non-vaccinated n=310. HPV infection prevalence by cytology in vaccinated participants was 70.83% (NILM n=48), 80.0% (LGSIL n=5), and 88.89% (HGSIL n=9). Among non-vaccinated women 64.04% (NILM n=178), 82.76% (LGSIL n=58), and 81.08% (HGSIL n=74). There were no statistical differences between similar cytology reports differing in vaccination status. The most prevalent HPV-HR serotypes across all cytology categories in the vaccinated cohort were 52 (11.14%), 16 (8.02%), 31 (7.56%), 39 (7.52%), and 66 (7.22%), whereas in the non-vaccinated cohort were 16 (20.6%), 51 (17.55%), 33 (13.33%), 52 (12.29%), and 56 (11.94%).

Conclusions: HPV vaccination modifies the infection by HR-HPV serotypes in these cohorts of Hispanic women living in PR. The prevalence of serotypes 39, 51, 56, and 66, not covered in the nonavalent vaccine, could be a possible explanation for the rising incidence of cervical cancer in this population.

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UP-TO-DATE HUMAN PAPILLOMAVIRUS VACCINATION STATUS BY RACE/ ETHNICITY AND AGE AT INITIATION IN THE UNITED STATES ACROSS TIME AMONG 13-17 YEAR OLDS, 2016-2020

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Introduction: High rates of up-to-date (UTD) human papillomavirus (HPV) vaccination will improve prevention of HPV-related disease. Since recommendations for number of doses varies by age, UTD may differ by initiation age due to fewer recommended doses and frequency of healthcare visits.

Methods: This study was a secondary analysis of the National Immunization Survey-Teen, a repeated cross-sectional survey collected annually in the US to evaluate vaccination among 13–17-year-olds. We examined HPV vaccine series initiation and UTD vaccination status (2 HPV doses for 14 years old or younger, 3 doses for 15 years or older) between 2016 and 2020. Chi-square tests compared characteristics between initiators and non-initiators. After excluding non-initiators, multivariable binary logistic regression evaluated associations of race/ ethnicity, age at initiation, and survey year with UTD HPV vaccination.

Results: A total of 99,759 adolescents were included. Significant differences in initiation were found by: sex, race/ ethnicity, age, survey year, region, 11–12-year-old well child visit, and receipt of Meningitis, tetanus, or flu vaccines. In adjusted models, Hispanic HPV vaccine initiators (aOR: 1.42, 95% CI 1.27-1.57) had higher odds of UTD compared to whites. Black and multi-racial adolescents had marginally greater odds of UTD compared to whites. Eleven year-old initiators had higher odds of UTD (aOR: 2.53, 95% CI 2.25-2.84) compared to 12-year-olds. A well child visit at 11 or 12 years was associated with higher odds (aOR: 1.66, 95% CI: 1.37-1.94) of UTD. Initiation at 13 years or later was associated with decreasing odds of UTD. Odds of UTD were lower across time compared to 2016.

Conclusions: This study confirms previous observations of lower vaccination rates among white adolescents. Higher UTD for younger initiators could be due to the need for fewer doses but could also result from a decline in office visits at older ages.

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ASSESSING ADDITIONAL APPROACHES TO HPV VACCINE UPTAKE IN THE US

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Introduction: The HPV vaccine, approved in 2006, for the prevention of cervical cancer and now approved for several other cancers, continues to have suboptimal uptake in the US. Provider recommendation has emerged as the most salient factor in vaccine uptake. Additional strategies are needed in to increase vaccination rates. The purpose of the study was to assess additional approaches for HPV vaccine uptake.

Methods: Parents of adolescents (n=1,047) were surveyed via Qualtrics on various strategies related to HPV vaccine uptake (school entry, age 9, increasing both provider types and vaccine settings). Four parent subgroups were identified based on child's vaccination status (have vaccinated, intend to vaccinate, unsure of intention, and do not intend to vaccinate). Descriptive statistics for each vaccination strategy were obtained.

Results: The majority of the sample were female (52.1%), White (76.0%), and married (76.3%). Among participants, 68.9% have vaccinated their children, 13.7% intend to vaccinate, 11.8% are unsure of intention, and 5.6% do not intend to vaccinate. Parents that vaccinated their children were more comfortable with vaccinating at 9 years old, found requirements for school entry more acceptable, and believe it should be difficult to opt-out of school entry requirements. Most parents that intend to vaccinate and those that are unsure of intention were not comfortable vaccinating at age 9 (58.7% and 79.8%, respectively). Participants that intend to vaccinate were more accepting of school entry requirements than those that are unsure of intention and do not intend to. Parents of unvaccinated adolescents reported that pediatrician recommendations were the most highly regarded among providers; all groups of parents reported being more likely to vaccinate their child in the pediatrician's office.

Conclusions: Public health opportunities exist for education and advocacy for parents who have not yet vaccinated their children, possibly with different strategies for those who intend versus those who are unsure.

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PARENTAL PERSPECTIVES ON HPV VACCINE SCHOOL ENTRY REQUIREMENTS: EXPANDING US VACCINATION STRATEGIES

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Introduction: HPV is the causal agent for several cancers. The HPV vaccine has been available since 2006 and prevents the majority of HPV-related cancers, yet vaccination rates remain low across the US. HPV vaccine requirements for school entry have been an underutilized strategy to increase vaccine uptake. This study assessed parental perspectives on HPV vaccination for school entry.

Methods: Parents of adolescents (n=1,047) completed a Qualtrics questionnaire regarding HPV-related topics, including acceptability of an HPV vaccine requirement for school entry and parental opt-out. Four parent subgroups were identified based on their child's vaccination status (have vaccinated, intend to vaccinate, unsure of intention, and do not intend to vaccinate). One-way ANOVAs analyzed parents' mean responses to school entry questions.

Results: Most respondents were female (52.1%), White (76.0%), and mean age 40.28(±6.30). Nearly two-thirds of parents thought it would be acceptable if their state required the HPV vaccine for entry into middle school. On a five-point Likert scale (1=not at all acceptable to 5=completely acceptable) mean acceptability was highest among parents who had vaccinated their child (4.16±1.11) and lowest among parents who did not intend to vaccinate their child (1.68±1.22). Almost half (46.2%) said it should be difficult to opt-out of school entry mandates; moreover, respondents thought 48.4%(±25.48) of parents would opt-out. Mean acceptability of an HPV vaccine requirement for school entry and level of difficulty to opt-out significantly differed across parental groups ($F(3)=159.52$, $\eta^2=.315$, $p<.001$) and ($F(3)=57.63$, $\eta^2=.142$, $p<.001$), respectively. Among parents that had not yet vaccinated their child but intended to, 54.6% found a school entry mandate acceptable and a third indicated it should be difficult to opt-out.

Conclusions: In this study, 63.8% of parents were favorable about school entry policies. Among parents who intend to vaccinate their children, opportunities exist to address hesitancy through public health efforts. Further research is needed.

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UNDERSTANDING PEOPLE-SPECIFIC FACILITATORS AND BARRIERS TO HPV IMMUNIZATION UPTAKE: A CASE STUDY WITH MÉTIS NATION BRITISH COLUMBIA

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Introduction: To support the Action Plan to Eliminate Cervical Cancer in Canada by 2040, the Canadian Partnership Against Cancer (CPAC) has commissioned the Urban Public Health Network to assess the landscape of HPV immunization coverage, barriers, and opportunities at a sub-jurisdictional level. This work has involved qualitative research in partnership with First Nations, Inuit, and Métis Organizations and Communities across Canada. Specific findings from community-engaged work with Métis Nation British Columbia (MNBC) will be highlighted as a case study in this presentation.

Methods: With the understanding that Métis have distinct perspectives, priorities, and challenges in accessing HPV immunization, this project took a collaborative, community-engaged approach to data collection, analysis, and reporting. A tailored engagement plan was developed between MNBC and the Métis Chartered Communities throughout BC. Data collection methods included focus groups, key-informant interviews, and surveys with Métis Citizens across British Columbia.

Results: While Métis communities have distinct strengths, needs and priorities, many shared that barriers exist to accessing HPV immunization. These barriers included vaccine cost, inadequate availability of HPV immunization data, and a lack of access to culturally appropriate vaccine information. MNBC identified several exciting opportunities to increase access to and awareness of HPV vaccinations. Potential facilitators include: increasing access to Métis healthcare providers and health navigators, running community knowledge-sharing events, and increasing access to people-specific immunization programs led by Métis Chartered Communities. Similar programs were implemented for COVID vaccinations and saw positive uptake within communities.

Conclusions: MNBC has identified cervical cancer prevention, and specifically HPV vaccination, as a priority within their health Ministry. Findings from MNBC offer an opportunity to develop and implement community-led innovative policies and programming to increase HPV immunization rates across Canada. The right of Indigenous Peoples to determine their own health priorities and development strategies is upheld by article 23 of UNDRIP.

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THE ROLE OF NARRATIVE MESSAGING IN HPV-RELATED KNOWLEDGE AND INTENTIONS TO VACCINATE: A U.S.-BASED SAMPLE OF PARENTS

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Introduction: While the human papillomavirus (HPV) vaccine was approved in the United States more than 15 years ago, knowledge about the vaccine and virus remain suboptimal. How to best convey information to overcome the knowledge deficit remains unclear. The current study examined the association between viewing narrative versus non-narrative messages, parental knowledge, and intentions to vaccinate age-eligible adolescents against HPV.

Methods: Using an online panel, we recruited 606 U.S.-based parents whose adolescents ages 9-14 had not received the HPV vaccine. Participants viewed either 7 narrative-based HPV topics or 7 non-narrative HPV topics and answered 7 knowledge and 5 intention questions related to the topics. Bivariate and multivariate linear regression tested the associations.

Results: Parents were, on average, 41 years old. Half (49%) were female, most (76%) were married, and most (72%) completed college or post-graduate education. Eighty percent of the parents knew that the HPV vaccine protects against six types of cancer, but only 66% knew that HPV was a common virus and only 21% knew which cancers are protected by the vaccine. Knowledge scores did not significantly differ between those who viewed the narrative versus non-narrative topics ($p=0.156$). Higher knowledge led to significantly higher intentions to vaccinate adolescent(s) ($B=0.059$, $p=0.005$) and talk to their doctor about the vaccine ($B=0.042$, $p=0.023$) but led to significantly lower intentions to talk to other parents about the vaccine ($B= -0.126$, $p<0.0001$), or share the messages about the vaccine on their social media feed ($B= -0.195$, $p<0.0001$), regardless of whether they viewed narrative or non-narrative topics.

Conclusions: Higher knowledge led to increased intentions to vaccinate adolescents and talk to a physician, but lower intentions to talk with other parents or post on social media about the vaccine. The role of narrative versus non-narrative messages in conveying information continues to warrant additional study.

Shift 01-108 / #1448

Poster Viewing
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04-18-2023 7:00 AM - 5:00 PM

HIGHER LEVELS OF HPV VACCINE HESITANCY AMONG RURAL HISPANIC YOUNG ADULTS IN THE WESTERN U.S., 2020-2021

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Introduction: We assessed differences in HPV vaccine hesitancy by rurality and race and ethnicity among young adults in the western United States, during the era of COVID-19. Rural populations and Hispanics have higher cervical cancer incidence and mortality rates.

Methods: A convenience-sampled cross-sectional online survey was conducted among young adults (YAs) ages 18-26 years living in rural and urban communities across 12 western U.S. states (October 2020 - April 2021). Participants (N=2937) self-reported demographics and answered HPV vaccine hesitancy and healthcare trust questions. Factor analysis, using naïve and polychoric correlation, evaluated n=27 items to create individual coarse factor scores for three scales of HPV vaccine hesitancy, each demonstrating good internal consistency (Cronbach's alpha): HPV vaccine confidence (n=6, α=0.71[95%CI: 0.69-0.73]), HPV complacency (n=11, α=0.73[95%CI: 0.71-0.75]), and HPV vaccine complacency (n=3, α=0.81[95%CI: 0.78-0.82]). Differences were examined by race and ethnicity, rurality, and rurality among Hispanic young adults. Multivariate logistic regression estimated odds (ORs). Directed acyclic graphs (DAGs) identified scientifically meaningful and minimally sufficient covariates for estimating total effects.

Results: Compared with not-Hispanic White YAs, Hispanic YAs had significantly higher odds of HPV vaccine hesitancy across all scales: HPV confidence (OR=1.55 [95%CI:1.23-1.96]), HPV complacency (OR=1.53 [95%CI:1.22-1.93]), and HPV vaccine complacency (OR=1.28 [95%CI:1.01-1.61]). Significantly higher HPV vaccine hesitancy among rural YAs was observed in confidence (OR=1.66 [95%CI: 1.37, 2.01]) and HPV vaccine complacency (OR=1.79 [95%CI:1.48-2.17]) scales, but not in HPV complacency (OR=1.06 [95%CI:0.88-1.28]) compared to urban YAs. A similar and more pronounced difference among Hispanic YAs by rurality was observed; strong and significantly higher odds of hesitancy among rural Hispanic YAs for HPV vaccine confidence (OR=2.13 [95%CI:1.33-3.49]) and HPV vaccine complacency (OR=2.11 [95%CI:1.33-3.40]), but not HPV complacency (OR=0.84 [95%CI:0.54-1.32]) compared to urban Hispanic
YAs.

Table 1. HPV immunization (any doses) and characteristics of young adults (YAs), western U.S., 2020-2021

	All YAs HPV Vaccination[1]			Hispanic YAs HPV Vaccination[1]		
Characteristic	**No/Unsure N = 1,020[2]**	**Yes N = 1,167[2]**	**p-value[3]**	**No/Unsure N = 143[2]**	**Yes N = 202[2]**	**p-value[3]**
Age			**0.01**			**0.03**
18-19	228 (22%)	223 (19%)		35 (24%)	28 (14%)	
20-24	621 (61%)	696 (60%)		84 (59%)	129 (64%)	
25-26	171 (17%)	248 (21%)		24 (17%)	45 (22%)	
Gender			**<0.01**			0.13
Female	631 (62%)	905 (78%)		97 (68%)	152 (75%)	
Male	377 (37%)	243 (21%)		46 (32%)	50 (25%)	
Other[4]	12 (1.2%)	19 (1.6%)		--	--	
Race and Ethnicity			**0.04**			--
Not-Hispanic White/Caucasian	664 (66%)	730 (63%)		--	--	
Not-Hispanic Minority	192 (19%)	198 (17%)		--	--	
Hispanic/Latino	153 (15%)	222 (19%)		--	--	
Rurality (RUCC)[5]			0.11			0.08
Rural	345 (34%)	357 (31%)		56 (39%)	61 (30%)	
Urban	675 (66%)	810 (69%)		87 (61%)	141 (70%)	
Marital Status			**<0.01**			**<0.01**
Single/never married	757 (74%)	800 (69%)		118 (83%)	140 (69%)	
Married/living together	256 (25%)	352 (30%)		25 (17%)	62 (31%)	
Divorced/separated/widowed[4]	7 (0.7%)	15 (1.3%)		--	--	
Current Student (Yes)	647 (63%)	841 (72%)	**<0.01**	91 (64%)	144 (71%)	0.13
Health Insurance (Any)[6]			**<0.01**			**0.01**
Insured	794 (78%)	994 (85%)		104 (73%)	169 (84%)	
Uninsured/Other	226 (22%)	173 (15%)		39 (27%)	33 (16%)	
Religious Affiliation			**<0.01**			0.70
Affiliated	678 (66%)	704 (60%)		98 (69%)	135 (67%)	
Unaffiliated	342 (34%)	463 (40%)		45 (31%)	67 (33%)	
Frequency of Religious Activities			**<0.01**			0.07
At least monthly to Weekly or more	383 (38%)	342 (29%)		36 (25%)	35 (17%)	
Never to a few times each year	634 (62%)	825 (71%)		106 (75%)	167 (83%)	
COVID-19 Vaccination Intent[7]			**<0.01**			0.08
No/Unsure	392 (38%)	346 (30%)		57 (40%)	62 (31%)	
Yes	628 (62%)	821 (70%)		86 (60%)	140 (69%)	

[1] Self-report for recall of any doses for HPV vaccination.

[2] Frequency (%)

[3] Pearson's Chi-squared tests of independence used for categorical variables.

[4] Gender limited to male and female and marital status of divorced/separated/widowed excluded for examinations among Hispanic YAs due to limited numbers of observations.

[5] Rurality classified by zip code using Rural-Urban Continuum Codes (RUCC); 'urban' defined as RUCC<4; 'rural' defined as RUCC=>4; Mixed defined as zip codes containing both urban and rural counties as classified by RUCC

[6] Health Insurance categorized as a binary response as follows: Insured) Private insurance (HMO, parents' insurance), Medicaid, Medicare, Military health care (TRICARE, VA, CHAMP-VA), State sponsored health plan, or Student insurance through your university; and Uninsured) Uninsured/Self-pay, Single service (dental, vision, prescriptions), Don't know, Prefer not to answer, or Other.

[7] Survey administration began prior to availability of a COVID-19 vaccine.

Table 2. Race and Ethnicity, immunization, and dimensions of HPV vaccine trust among young adults in the western U.S., 2020-2021

	Race and Ethnicity		
Characteristic	**Not-Hispanic White/Caucasian,** N = 1,497	**Not-Hispanic Minority,** N = 442	**Hispanic/Latino,** N = 424
Trust of Health Authorities, OR (95%CI)[a]	ref	0.95 (0.77, 1.18)	**0.80 (0.64, 0.99)**
High Trust, n (%)	877 (59%)	253 (57%)	225 (53%)
Low Trust, n (%)	620 (41%)	188 (43%)	199 (47%)
HPV Vaccine Hesitancy - Confidence Dimension, OR (95%CI)[a]	ref	**1.43 (1.14, 1.80)**	**1.55 (1.23, 1.96)**
Low Hesitancy, n (%)	681 (49%)	156 (40%)	143 (38%)
High Hesitancy, n (%)	713 (51%)	234 (60%)	232 (62%)
HPV Vaccine Hesitancy - HPV Complacency Dimension, OR (95%CI)[a]	ref	1.10 (0.88, 1.38)	**1.53 (1.22, 1.93)**
Low Hesitancy, n (%)	720 (52%)	192 (49%)	154 (41%)
High Hesitancy, n (%)	674 (48%)	198 (51%)	221 (59%)
HPV Vaccine Hesitancy - HPV Vaccine Complacency Dimension, OR (95%CI)[a]	ref	1.09 (0.87, 1.37)	**1.28 (1.01, 1.61)**
Low Hesitancy, n (%)	660 (47%)	176 (45%)	155 (41%)
High Hesitancy, n (%)	734 (53%)	214 (55%)	220 (59%)
COVID-19 Vaccination Intent, OR (95%CI)[c]	ref	**1.27 (1.02, 1.60)**	0.99 (0.79, 1.24)
No/Unsure	555 (37%)	140 (32%)	158 (37%)
Yes	942 (63%)	302 (68%)	266 (63%)
HPV Vaccination Receipt (Any Doses), OR (95%CI)[c]	ref	0.94 (0.75, 1.17)	**1.32 (1.05, 1.67)**
No/Unsure	664 (48%)	192 (49%)	153 (41%)
Yes	730 (52%)	198 (51%)	222 (59%)

[a] Odds of high trust (regarding vaccination or medical information) in health authorities (providers, physicians, health authorities, and government agencies) compared with not-Hispanic White young adults, based on composite score median. Directed acyclic graph (DAG) indicated crude ORs as minimally sufficient for estimating the total effect of race and ethnicity on vaccine intent and dimensions of vaccine hesitancy.

[b] Odds of high vaccine hesitancy by race and ethnicity compared to Not-Hispanic White young adults. DAG indicated crude ORs as minimally sufficient for estimating the total effect.

[c] Odds of "yes" by race and ethnicity compared to Not-Hispanic White young adults. DAG indicated crude ORs as minimally sufficient for estimating the total effect.

Table 3. Rurality, immunization, and dimensions of HPV vaccine trust among young adults (YAs) in the western U.S., 2020-2021

	All YAs		Hispanic YAs	
Vaccine Hesitancy Dimension	**Urban[a]** N =1517	**Rural[a]** N =887	**Urban[a]** N =1517	**Rural[a]** N =887
Trust of Health Authorities, OR (95%CI)[b]	*ref*	**0.54 (0.46, 0.65)**	*ref*	0.76 (0.51, 1.13)
High Trust, n (%)	965 (64%)	402 (45%)	144 (57%)	81 (47%)
Low Trust, n (%)	551 (36%)	485 (55%)	109 (43%)	90 (53%)
HPV Confidence Dimension, OR (95%CI)[b]	*ref*	**1.66 (1.37, 2.01)**	*ref*	**2.13 (1.33, 3.49)**
Low Hesitancy, n (%)	747 (50%)	241 (34%)	111 (45%)	32 (25%)
High Hesitancy, n (%)	738 (50%)	461 (66%)	138 (55%)	94 (75%)
HPV Complacency Dimension, OR (95%CI)[b]	*ref*	1.06 (0.88, 1.28)	*ref*	0.84 (0.54, 1.32)
Low Hesitancy, n (%)	754 (51%)	328 (47%)	101 (41%)	53 (42%)
High Hesitancy, n (%)	731 (49%)	374 (53%)	148 (59%)	73 (58%)
HPV Vaccine Complacency Dimension, OR (95%CI)[b]	*ref*	**1.79 (1.48, 2.17)**	*ref*	**2.11 (1.33, 3.40)**
Low Hesitancy, n (%)	755 (51%)	246 (35%)	119 (48%)	36 (29%)
High Hesitancy, n (%)	730 (49%)	456 (65%)	130 (52%)	90 (71%)
COVID-19 Vaccination Intent, OR (95%CI)[b]	*ref*	**0.45 (0.38, 0.54)**	*ref*	**0.57 (0.38, 0.87)**
No/Unsure	439 (29%)	439 (49%)	80 (32%)	78 (46%)
Yes	1,078 (71%)	448 (51%)	173 (68%)	93 (54%)
HPV Vaccination Receipt (Any Doses), OR (95%CI)[b]	*ref*	0.98 (0.81, 1.18)	*ref*	0.69 (0.44, 1.08)
No/Unsure	675 (45%)	345 (49%)	92 (37%)	61 (48%)
Yes	810 (55%)	357 (51%)	157 (63%)	65 (52%)

[a] Rurality classified by zip code using Rural-Urban Continuum Codes (RUCC); 'urban' defined as RUCC<4; 'rural' defined as RUCC=>4; 'Mixed' rurality (defined as zip codes containing both urban and rural counties) were omitted due to number of observations.

[b] Adjusted odds of high trust, high vaccine hesitancy, and/or "Yes" answers for rural young adults compared to their urban counterparts. ORs adjusted for age and current status as a student, as indicated by directed acyclic graph (DAG). Dimension modeled as the independent variable. High versus low trust and/or high versus low vaccine hesitancy defined by median of individual composite and/or individuals coarse factor scores.

Conclusions: Interventions are needed to decrease HPV vaccine hesitancy among rural Hispanic young adults in the Mountain West to decrease risk for HPV-related cancers.

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Poster Viewing
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04-18-2023 7:00 AM - 5:00 PM

VARIATION IN HPV VACCINATION EFFECTIVENESS IN THE US BY AGE AT VACCINATION

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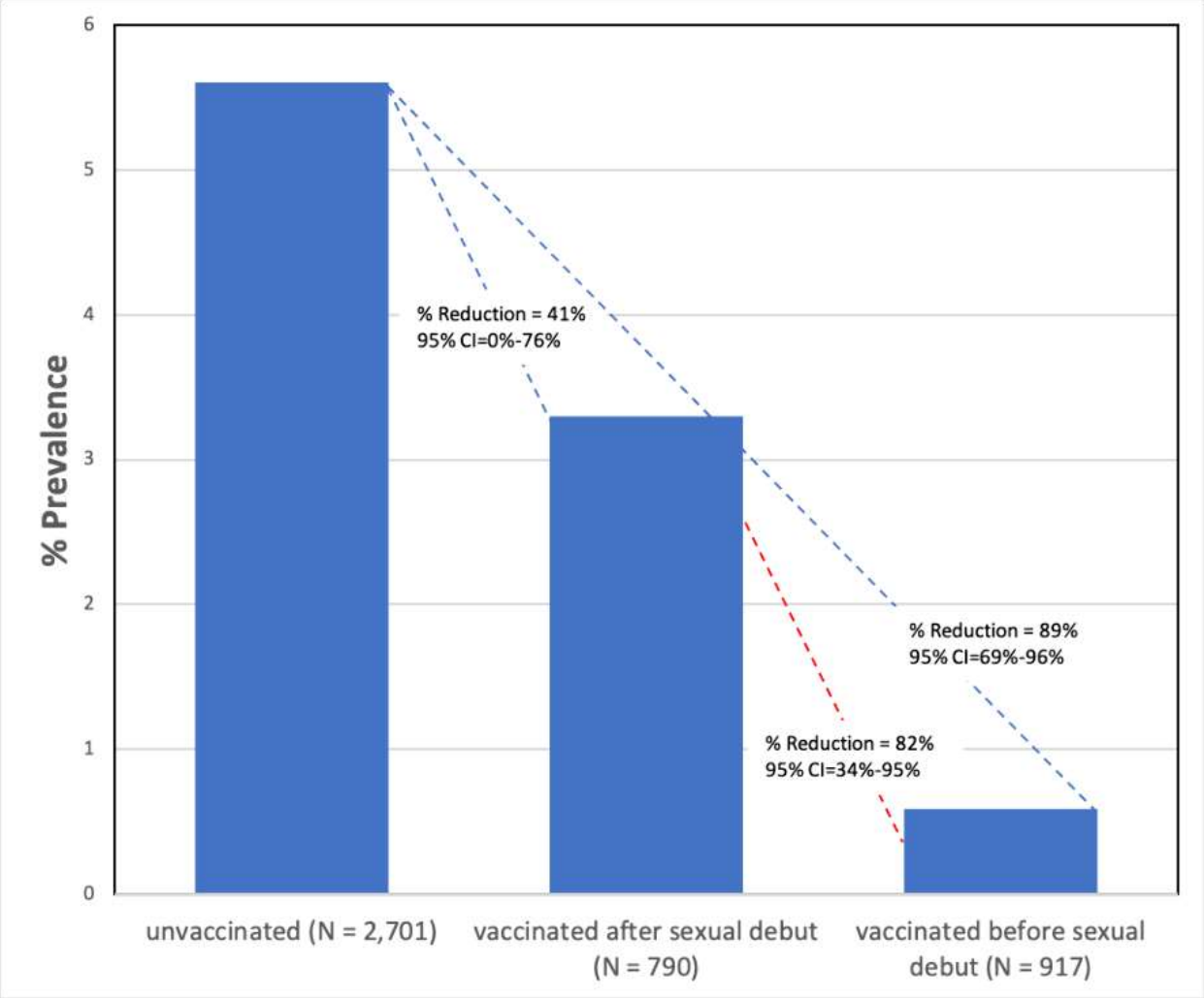
Introduction: In the US, the recommended ages for routine human papillomavirus (HPV) vaccination is from 9 to 12 years, but childhood vaccination often occurs later, after sexual initiation. In this study, we estimated the proportion of US females vaccinated before and after sexual debut and the impact of delayed vaccination on HPV 16/18 prevalence.

Methods: Using the National Health and Nutrition Examination Survey (NHANES), a representative sample of the US population, cycles 2011-2018, we identified females aged £26 years in 2006, the year the HPV vaccination was introduced, who were eligible for either routine (ages 9-12) or catch-up (ages 13-26) vaccination. We estimated the prevalence of HPV16/18 among females who were unvaccinated, vaccinated before, or vaccinated after sexual debut. This analysis required restricted-use data accessed through the Research Data Center (RDC).

Results: Among females ever-eligible for vaccination, cervical HPV16/18 prevalence decreased from 5.60% to 3.31% to 0.59% in those unvaccinated vs. vaccinated after sexual debut vs. vaccinated before sexual debut (Figure 1). Compared to unvaccinated females, prevalence of cervical HPV16/18 was 89% lower in females vaccinated before sexual debut ($p<0.0001$), but only 41% lower in females vaccinated after sexual debut ($p=0.26$). Only 38% of ever-eligible females were vaccinated, increasing to 52% when restricted to females eligible for routine vaccination (RV-eligible). Among RV-eligible adult females, 33% were vaccinated prior to sexual debut and 23% after sexual debut. Differences by race were negligible.
Figure 1: Weighted prevalence of human papillomavirus 16 or 18 infections in vaccine-eligible US

females



Conclusions: Our study highlights the importance of timely vaccination against HPV, particularly before the ages of sexual debut. To ensure maximum effectiveness from vaccination, pediatricians should stress the importance of timely vaccination.

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Poster Viewing
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EDUCATION AND LOGISTICAL STRATEGIES IMPROVE ADOLESCENT PSYCHOSOCIAL OUTCOMES AND EXPERIENCE OF HUMAN PAPILLOMAVIRUS (HPV) VACCINATION: ANALYSIS OF SECONDARY OUTCOMES OF A CLUSTER-RANDOMIZED TRIAL

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Introduction: We aimed to examine the impact of an HPV education and logistical intervention on adolescent psychosocial outcomes.

Methods: Design: Cluster-randomized controlled trial and process evaluation.
Setting: High schools in Western Australia and South Australia.
Participants: Adolescents aged 12-13 years.
Interventions: The complex intervention delivered in 2013-2014 consisted of 1) an adolescent intervention to promote knowledge and psychosocial outcomes; 2) shared decisional support tool; and 3) logistical strategies.
Main Outcomes and Measures: We used the HPV Adolescent Vaccination Intervention Questionnaire (HAVIQ) to measure changes in, fear/anxiety (6 item subscale), self-efficacy (5 item subscale), and decision-making (8 item subscale). We hypothesised that our intervention would improve adolescent involvement in vaccine decision making (measured pre-dose one only), improve vaccine related self-efficacy and reduce vaccine related fear/anxiety (measured pre doses one, two and three). Mean scores for each subscale were compared between intervention and control students. In the process evaluation we undertook focus groups with 111 adolescents in 6 intervention and 5 control schools.

Results: We recruited 40 schools (21 intervention, 19 control) across sectors with 6, 967 adolescents. The mean score for decision-making in the intervention group was 3.7, out of 5 which was 0.11 higher than for control (CI 0.06, 0.16; P: <0.0001). There was a small difference in favour of the intervention group in reduced vaccination-related anxiety (pre dose one difference: -0.11, CI -0.19,-0.02 ; pre-dose two: -0.18, CI -0.26, -0.10; pre-dose 3: -0.18, CI -0.24, -0.11) and increased vaccination self-efficacy (pre-dose one difference: 4, CI 1, 7; pre-dose two: 4, CI 2, 6; pre-dose three: 3, CI 1, 5). Focus group data revealed more confidence and less anxiety with each vaccine dose.

Conclusions: Our intervention promoted adolescent decisional involvement and vaccine-related confidence and reduced vaccination-related fear and anxiety that was maintained throughout the vaccine course.

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Poster Viewing
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IMPLEMENTATION EVALUATION OF LOGISTICAL STRATEGIES TO PROMOTE HUMAN PAPILLOMAVIRUS (HPV) VACCINE UPTAKE IN SCHOOL SETTINGS: ANALYSIS OF PRIMARY AND SECONDARY OUTCOMES OF A CLUSTER-RANDOMIZED TRIAL

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Introduction: We aimed to evaluate impact of logistical strategies as part of a complex intervention designed to increase HPV vaccination uptake.

Methods: Design: Cluster-randomized trial and process evaluation.
Setting: High schools in Western Australia and South Australia, 2013-2014.
Participants: Adolescents aged 12-13 years.
Interventions: Consent form return-strategies (e.g., direct mail-out to parents, nonmonetary rewards), additional in school catch-up of missed doses, and vaccination day organisational guidelines.
Primary outcome: Mean school vaccine coverage using the Mantel-Haenszel method, considering stratification by year, state and school sector and adjusted for clustering and potential confounders.
Secondary outcomes: Proportion of consent forms returned and mean time to vaccinate 50 students were compared between groups. Fidelity logs were used to calculate secondary outcomes.

Results: We recruited 40 schools (21 intervention, 19 control) with 6, 967 adolescents. There was no significant difference between mean vaccine coverage across groups. Differences, in favour of the intervention group, were: dose 1 0.8% (95% CI: -1.4,3.0); dose 2 0.2% (95% CI: -2.7, 3.1); Dose 3 0.5% (95% CI: -2.6, 3.7). Intervention schools had a higher consent form return rate than control: 6% difference (95% CI: 1.4, 10.7). Intervention schools had a shorter mean time to vaccinate 50 students compared to control for dose 3 only. HPV dose 1: adjusted difference 90 minutes (95% CI: -15, 196); dose 2: 28 minutes (95% CI= -71, 127); and dose 3: 110 minutes (95% CI: 42, 177). Logs revealed inconsistent implementation of logistical strategies.

Conclusions: Our intervention had no significant impact on vaccine uptake. Advisory board reluctance about strategies that may have had financial implications, and timing of consent form distribution in the first week of the school year, impacted implementation. Working with education and health stakeholders at all levels is crucial to the successful implementation of complex interventions.

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Poster Viewing
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HPV VACCINE HESITANCY AND INFORMATION NEEDS IN RACIALLY AND ETHNICALLY DIVERSE, URBAN COMMUNITIES

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Introduction: This study explored HPV vaccine hesitancy and information needs in racially/ethnically diverse urban communities to inform future communication interventions.

Methods: We used a community-engaged approach to conduct individual interviews with 17 English- and 5 Spanish-speaking mothers of adolescents aged 9-13 years. We recruited through community partners at public libraries, food pantries, schools, and health events in the greater Newark, New Jersey area. Transcripts were double-coded and thematically analyzed.

Results: Among 22 participants, 45% were Black, 41% Hispanic, 9% Asian, and 5% non-Hispanic White. Majority (54%) reported their child had not been vaccinated; 23% had initiated and 23% had completed the HPV series. Mothers trusted websites and pamphlets created by government health authorities; most did not rely on social media for credible health information. Instead, many preferred getting vaccine information from their pediatrician. However, different hesitancy determinants were noted by nationality, ethnicity, and culture, which influenced current information channels and future preferences. Foreign-born mothers relied on public services (e.g., schools, libraries, public clinics) and other community organizations (e.g., churches, grassroots organizations, and pharmacies) as important places and spaces for health information conversations and connections. Printed information in multiple languages was particularly important to foreign-born mothers. English-speaking and US-born mothers were specifically interested in videos with facts from providers and HPV vaccination testimonials from other parents who looked like them. Although attitudes about vaccination were generally positive, some mothers expressed concerns about long-term safety and side effects because of perceived novelty of the HPV vaccine. Those with 9-10 year-olds questioned the need to vaccinate because of low perceived risk due to their children's age, puberty/development, or lack of sexual activity.

Conclusions: Interventions to increase HPV vaccine confidence should be tailored to address parents' hesitancy emphasizing safety, necessity, and benefits of timely vaccination. Studies to test culturally-adapted and hesitancy-tailored interventions are underway.

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Poster Viewing
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KEY DECISION-MAKING FACTORS FOR HPV VACCINE PROGRAM INTRODUCTION IN LOW-AND-MIDDLE INCOME COUNTRIES: GLOBAL AND NATIONAL STAKEHOLDER PERSPECTIVES

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Introduction: Low-and-middle-income countries (LMICs) experience the global burden of cervical cancer. The HPV vaccine prevents against high-risk strains of HPV that cause cervical cancer, however the integration of HPV vaccines into national immunization programs within many LMICs has been suboptimal. Our study evaluated key factors that drive the decision-making process for the implementation of HPV vaccines in LMICs.

Methods: A stakeholder analysis coupled with semi-structured in-depth interviews were conducted with national stakeholders and global stakeholders. Countries in Africa and Asia were identified by conducting a mapping exercise to obtain information such as geographical region, HPV vaccine introduction status, introduction date, dosing schedule, target age cohort, delivery strategy, and coverage. Interview data were analyzed through qualitative descriptive methods.

Results: A total of 31 stakeholders participated in interviews; 18 were national stakeholders and 13 were global stakeholders. Findings from our study revealed the decision-making process for HPV vaccines required involvement of multiple institutions and stakeholders from national and global levels, with decision-making being a country-specific process. Partner considerations, locally driven processes, data for decision-making, and infrastructure and resource considerations are critical factors in decision-making that were varied based on country contexts. Ensuring that transparency was present throughout all phases of the decision-making process was essential in the implementation of HPV immunization programs.

Conclusions: Future programs should evaluate the best approaches for investing in initiatives to enhance coordination, ensure locally driven processes, increase use and access to data for decision-making, and equip countries with the necessary resources to guide country decision-making in the face of increasingly complex decision-making environments.

Shift 01-114 / #1529

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
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BARRIERS AND FACILITATORS FOR HUMAN PAPILLOMA VIRUS (HPV) VACCINE INTRODUCTION AND SCALE-UP IN LOW- AND MIDDLE-INCOME COUNTRIES: GLOBAL PERSPECTIVES

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Introduction: The HPV vaccine has been available for over a decade and protects against high-risk strains of HPV that cause approximately 91% of all cervical cancer cases. Low-and-middle-income countries (LMICs) account for 90% of cervical cancer deaths globally; yet access to HPV vaccines remains inadequate and the integration into national immunization programs is suboptimal. This study explored challenges and facilitators to HPV vaccine introduction and scale-up in LMICs through key informant interviews with global stakeholders.

Methods: A stakeholder analysis coupled with semi-structured in-depth interviews were conducted with global stakeholders. Stakeholders were categorized into academic partners and global immunization partners. A grey literature search was conducted to identify relevant non-peer reviewed literature. Interview data were analyzed through qualitative descriptive methods.

Results: A total of 61 stakeholders were identified, 13 were interviewed. Determinants were classified as upstream and downstream; with upstream determinants including financing, vaccine procurement, global supply and demand, capacity and delivery, vaccine accessibility, ethics, and equity. Strong political commitment was essential in the successful introduction and scale-up of HPV vaccines. Downstream determinants included vaccine acceptability and hesitancy, communication, and advocacy and social mobilization. These determinants were found to strongly influence the uptake of HPV vaccines within communities at-large. Efforts to enhance advocacy and communications was essential for increasing the visibility and demand for HPV vaccines and raising cervical cancer as an issue of public health importance.

Conclusions: Countries must have the best available evidence to facilitate political support in the introduction of HPV vaccines. Global stakeholders must collaborate with countries to consider mechanisms to reduce financial and capacity challenges to promote the long-term sustainability of vaccination programs. Continuous engagement between key stakeholders is needed to develop agendas to develop strategies that are evidence-driven and adolescent-centered to increase scale-up through enhancing access, equity, communications, advocacy and social mobilization while reducing vaccine hesitancy.

Shift 01-115 / #1542

Poster Viewing
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EFFECTIVENESS OF HPV VACCINE AGAINST CERVICAL PRECANCER IN JAPAN: MULTIVARIATE ANALYSES ADJUSTED FOR SEXUAL ACTIVITY

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Introduction: Japanese girls aged 12-16 years are offered free HPV vaccination and cervical cancer screening is conducted with cytology and not HPV testing from the age of 20 years. So far, no study has analyzed the effect of HPV vaccination against cervical precancers considering HPV infection status and sexual activity. We aimed to analyze the vaccine effectiveness (VE) against HPV infection and cytological abnormalities, adjusted for sexual activity.

Methods: This study was comprised of women aged 20-26 years who underwent cervical screening in Niigata. We obtained HPV vaccination status from municipal records and a questionnaire along with information concerning sexual activity. Of 5,194 women registered for this study, final analyses included 3,167 women in the vaccinated group (2,821 vaccinated women prior to sexual debut) and 1,386 women in the unvaccinated group.

Results: HPV 16/18 (0.2% vs 3.5%), 31/45/52 (3.4% vs 6.6%) and 31/33/45/52/58 (5.0% vs 9.3%) positive rates were significantly lower in the vaccinated group ($p < 0.001$). No women vaccinated before sexual debut had HPV 16/18 related cytological abnormalities. VE for HPV 16/18 infection and high-grade cytological abnormalities in women vaccinated prior to sexual debut were 95.8% (95% CI 81.9–99.0%; $p < 0.001$) and 78.3% (95% CI 11.3–94.7%; $p = 0.033$), respectively, in multivariate analyses adjusted for age and the number of sexual partners. However, analyses of all vaccinated women did not show significant effectiveness against cytological abnormalities. In addition, annual changes in the rate of cytological abnormalities with increasing or decreasing vaccination coverage were analyzed. From FY2016 to FY2018, when the vaccination rate increased to 90%, no women with abnormal cytology associated with HPV 16/18 infection were observed.

Conclusions: Our results showed the effectiveness of HPV vaccine against high-grade cervical cytological abnormalities and the importance of the vaccination before sexual debut.

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WHEN ONE SIZE DOES NOT FIT ALL: DEVELOPING INTERVENTION OF SCHOOL-BASED HPV-COUNSELLING AND -VACCINATION.

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Introduction: Human Papillomavirus (HPV)-related cancers can be prevented with vaccination, but despite free access to vaccination through a Danish Children Vaccination Program, children with ethnic minority background attend substantially less than native children (65% vs. 93%). Practical barriers such as language and insufficient understanding of prevention in terms of vaccination, as well as emotional barriers regarding sexuality and cultural taboos, needs to be accommodated in a healthcare program to achieve increased participation. Aim By offering culturally adapted school-based HPV-counselling and -vaccination, we aim to improve HPV-vaccination coverage by 10%-point for ethnic minority pupils.

Methods: The study is a non-randomized implementation study. The intervention is developed and conducted according to Complex Interventions Framework. To operationalize elements of the intervention, we have applied a Logic and Dark Logic Model. The intervention is under implementation throughout school year 2022-2023 and consists of three core-elements: 1) school-based parental HPV-counselling, 2) pupil HPV-counselling and 3) school-based HPV-vaccination of pupils. All pathways of counselling, written material, video-material as well as an animation have been developed with user-representatives. Study population is 670 9-13-year-old pupils at five schools in the Municipality of Aarhus, Denmark, with proportion of pupils with ethnic minority background varying from 26% to 91%. The control group is 2800 children comparable in age and community.

Results: Primary outcome is difference in HPV-vaccination coverage between intervention and control group. Secondary outcome is HPV-vaccination coverage for siblings to intervention-group, to investigate the effect of parental HPV-counselling alone. The intervention will be qualitatively evaluated in focus-group interviews regarding user perspectives.

Conclusions: The study has potential of increasing the attendance to HPV-vaccination by breaking down barriers to participation. It may serve as a mean to obtain equal HPV-related cancer prevention for all children regardless of ethnical background.

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IMPERATIVES FOR NATIONWIDE HPV VACCINATION PROGRAM FOR CERVICAL CANCER PREVENTION IN GHANA

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Introduction: Cervical cancer currently ranks as 2nd most prevalent cancer among women between the ages of 15 to 44 years in Ghana with about 8.57 million women in this cohort at risk of cervical cancer. While this is the case, cervical cancer prevention and control is under-prioritized by the government for intervention.

Methods: Interviews and an online survey were conducted for analysis. SPSS and NVivo were used to organize and perform statistical analysis using data from 215 online survey respondents and 8 identified key informants in Ghana. Data from the literature, news articles, and government documents were also used to support the data collection and analysis process.

Results: Only a small number of the study population debuted sex before 17 years. It is further shown that HPV, HPV vaccine, and HPV-related cervical cancer awareness is rising in Ghana; however, governmental priority setting and resource allocation for cervical cancer prevention continue to remain low.

Conclusions: Currently, there is no indication of the introduction of a nationwide HPV vaccination program in Ghana. This reflects a lack of policy accountability to foster the public good. Ghana formed a policy on cervical cancer prevention; however, implementation is constrained by under-prioritization and low resource allocation. The policy implication from the study indicates the low rate of adolescent sexual debut before 17 years presents a window of opportunity for the government to act by implementing a nationwide HPV vaccination program toward cervical cancer prevention. This consideration is a right to health.

Shift 01-118 / #1694

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INCREASING HPV VACCINATION IN COLOMBIA WITH LOW-COST BEHAVIORAL SCIENCE INTERVENTIONS

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Introduction: In 2012-2013, Colombia led Latin American with over 90% HPV vaccination coverage. However, rates dropped to 6.1% (first dose) by 2016 after an unrelated outbreak in a municipality in Carmen de Bolivar that was later found to have no association with the HPV vaccine. The vaccine uptake remains a challenge since. Aiming to increase vaccination rates, we conducted a behavioral science-based text messsage (SMS) campaign with parents in partnership with the Health Secretariat of Bogota.

Methods: The campaign targeted a total of 174,181 parents identified by health service administrative records. Of that sample, 75% received a nudge to vaccinate their daughters with the first dose. The remaining 25% were parents who received reminders about their daughters' pending second dose. The campaign was divided into six interventions. Each intervention was designed based on a different behavioral insight, including social norms, beliefs, emotions, and planning tools, and compared against a control group (no message) and policy control ("business as usual message"). The campaign took place between October and December 2021.

Results: The most impactful treatment to increase first-time vaccinations was based on the present bias using emotions to remind parents of their responsibility to care for their children. This group had an average vaccination rate of 7.6%, representing a 37% difference compared to the control group (vaccination group average of 5.5%)—this is one of many messages that had an impact. To increase series completion, a simple reminder for parents about their daughter's pending vaccine was the most impactful message. This group had an average completion rate of 20.2%, representing a 63% increase compared to the control group (vaccination group average of 12.4%).

Conclusions: Most impactful SMS messages highlighted support of doctors, communicated institutional support (helath ministry), and used modicon to indicate desired behavior. Messages lacking behavioral insights may have adverse affect on parental behavior and HPV vaccine uptake.

Shift 01-119 / #1703

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A NEAR-DECADE OF QUALITY IMPROVEMENT: DRIVING HPV RATES THROUGH HEALTH SYSTEM PARTNERSHIPS IN THE UNITED STATES

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Introduction: HPV vaccination is delivered through clinical delivery sites in the U.S. In 2015, the American Cancer Society (ACS) began partnering with health systems and using quality improvement (QI) to increase HPV vaccination. Since then, >300 systems with 2,200+ sites have participated in an HPV QI intervention project with success. This presentation will share overall vaccine rate impact including lessons learned, partner opportunities, and pandemic-related strategies.

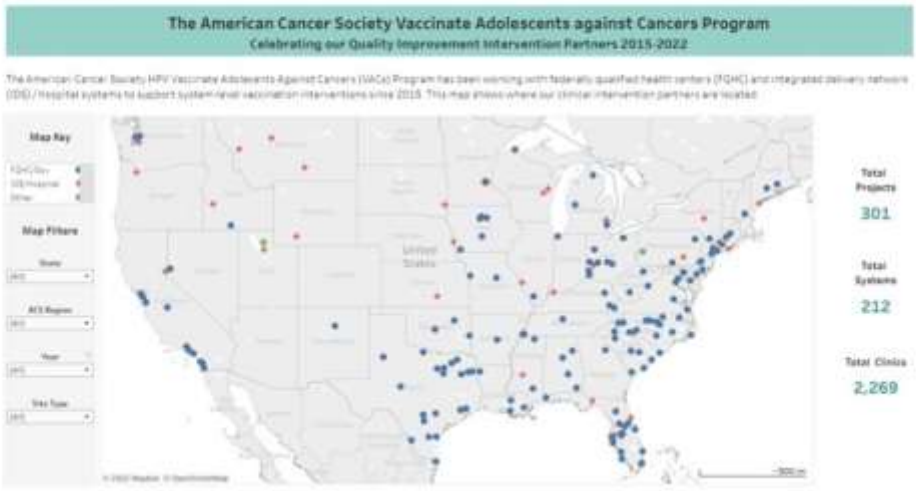
Methods: Systems agree to participate in a 12-month QI intervention to increase HPV vaccination rates for adolescents. Partners include federally qualified health centers (FQHCs) and integrated delivery systems (IDS) with HPV vaccination rates <70%. Intervention components include ongoing technical assistance (TA) and training from ACS to implement QI strategies and evidence-based interventions (EBIs). Intervention processes and outcomes vary by year, ranging from highly structured with extensive TA to more flexibility and autonomy in implementation. Health systems provide HPV initiation and completion rates for adolescents at baseline and endline.

Results: Three hundred and one projects took place over eight years. HPV initiation and completion rates increased nearly every year with an average rate increase of 10.6% and 6.2%,respectively. Partners implemented an average of three EBIs/project. Projects with more structured interventions and multi-component interventions saw greater increases in HPV vaccination rates. The pandemic decreased the number of partners in 2021 and 2022 and stifled rate gains as partners shut down, faced staff turnover, and had to prioritize COVID-19
vaccination.

ACS HPV VACS

American Cancer Society

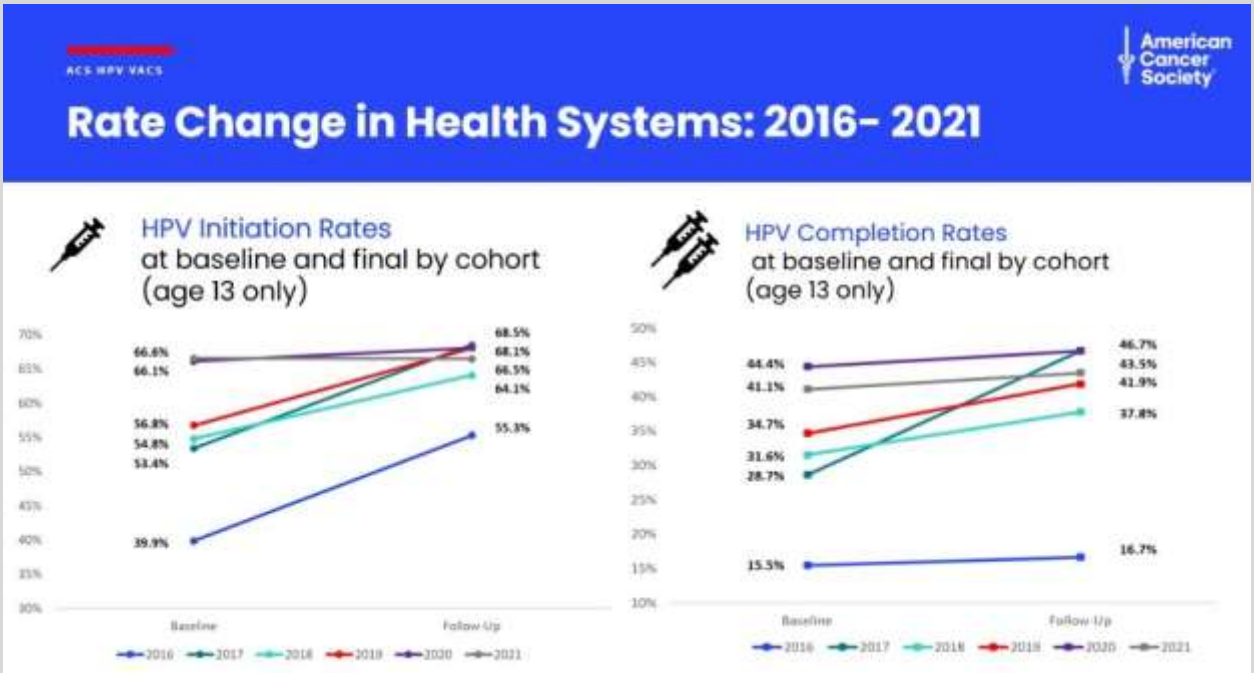
Health System Intervention Partners: 2015-2022



ACS HPV VACS

American Cancer Society

Health System Partnerships by Year & Type



Conclusions: QI is a flexible framework that can be used to support implementation of evidence-based interventions to increase HPV vaccination in U.S. health systems. With the support of ACS, partners have used QI to drive actionable change since 2015 even amidst a global pandemic. ACS continues to prioritize HPV vaccination in innovative ways and is pressing forward with an age 9 initiation strategy. Recruitment for the 2023 cohort is underway.

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HUMAN PAPILLOMAVIRUS VACCINATION UPTAKE AMONG ADULTS AFTER THE U.S. FOOD AND DRUG ADMINISTRATION'S APPROVAL FOR 27- TO 45-YEAR-OLDS

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Introduction: Previously, the human papillomavirus (HPV) vaccine was only approved for 9-26-year-olds in the United States. However, in October 2018, the U.S. Food and Drug Administration (FDA) approved expanded use of the HPV vaccination for 27- to 45-year-olds (mid-adults). This study assessed HPV vaccination prevalence among a nationally representative sample of U.S. adults aged 27-45 years following the FDA approval of the vaccine for this age group. This study also examined factors associated with HPV vaccine initiation among this age group.

Methods: The sample included adults aged 27-45 years from the 2019 National Health Interview Survey (n=8,245). The outcome variable was HPV vaccine initiation (yes/no). The odds of HPV vaccination were estimated using weighted logistic regression. The independent variables were selected from Andersen's Behavioral Model of Health Services Use framework, and included sociodemographic characteristics, health insurance coverage, regular place for healthcare services, and state of health.

Results: Overall, 13.0% of adults 27-45 had ever received the HPV vaccine, and 1.6% of adults 27-45 received their first vaccine dose when they were within the 27-45-year age range. Females had significantly higher odds of HPV vaccination (aOR=4.37; 95% CI=3.64, 5.26) than males. Hispanics (aOR=0.73; 95% CI=0.58, 0.92) and non-Hispanic Asians (aOR=0.61; 95% CI=0.43, 0.86) had significantly lower odds of receiving the vaccine than non-Hispanic Whites. Compared to those reporting excellent health, respondents who reported their state of health to be very good/good (aOR=0.83; 95% CI=0.70, 0.97) and fair/poor (aOR=0.65; 95% CI=0.46, 0.92) had lower odds of receiving the vaccine.

Conclusions: Given the low HPV vaccination rates among this population, there is a large proportion of adults eligible for shared clinical decision-making for HPV vaccination with their healthcare provider. As such, there is a need to develop tailored strategies that will assist shared decision-making in this age group.

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Poster Viewing
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STRENGTHENING COMMUNITY HEALTH WORKER CAPACITY TO REACH 90-70-90 TARGETS: LESSONS FROM THREE COUNTRIES

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Introduction: Community health workers (CHWs) are frontline, trusted health information providers across the world. The American Cancer Society (ACS) has invested in strengthening capacity of CHWs in Gurugram District of India, Nairobi County in Kenya, and in the U.S. state of Texas. CHWs are key influencers to increase HPV vaccination or cervical cancer screening uptake in communities.

Methods: ACS or partner organizations led in-person or online CHW trainings. HPV content (U.S. and Kenya) included HPV disease and vaccination science, communicating about cancer prevention, and conversation practice for the real world. Screening content (India) included cervical cancer causes, symptoms, and preventive measures. Participants were provided materials and resources specific to their program. Trainings were assessed with a mixture of quantitative surveys and qualitative interviews, focus groups, or observation

Results: Key findings across the three CHW focused programs include: - Participants demonstrated knowledge change and reacted positively and with excitement to the content - Stigma around cancer was found as a challenge in India, while vaccine hesitancy proved a salient issue in the U.S. - In an unembedded setting (Texas), it is unclear how CHWs have been able to directly impact vaccination - In embedded settings (India, Kenya), it has been difficult to ensure sustainability and long-term motivation of CHWs

Location	Lead Org	# Trained
Texas, USA	ACS	1,017 CHWs over 3 years
Gurugram District, India	Cancer Awareness, Prevention, and Early Detection (CAPED) Trust	213 AHSAs in 6 months
Westlands, Nairobi, Kenya	Women for Cancer Early Detection and Treatment	21 CHWs and nurses in a 2-day pilot session

Conclusions: CHWs as change agents are most impactful when connected to healthcare delivery systems. ACS found that: - Local partners must plan and facilitate embedding and activating CHWs within health systems - CHW incentives should be explored to meet 90-70-90 targets and address sustainability

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IDENTIFYING IMPLEMENTATION SCIENCE RESEARCH GAPS FOR INCREASING HPV VACCINATION COVERAGE

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Introduction: As part of the HPV Research Group of the St. Jude Children's Research Hospital and Washington University in St. Louis Implementation Sciences Collaborative, a series of four virtual seminars were held from January to April 2022 to explore implementation science in action and research opportunities on HPV cancer prevention in community, clinical, and policy contexts. Implementation science offers one way for us to bring what is working to improve HPV vaccination coverage to scale and adapt what is working for different contexts. The purpose of this project was to identify implementation science research gaps for increasing HPV vaccination coverage.

Methods: During the fourth virtual seminar on April 28, 2022, we used Mentimeter to generate a preliminary list of research ideas from attendees. We then developed and shared the link to a brief online survey to collect information from attendees and other key informants. Respondents answered several questions focused on ways to increase HPV vaccination through implementation science. Data were downloaded and analyzed thematically.

Results: Sixty experts from academic, clinical, public health, and non-profit settings participated. Many had worked in or studied HPV vaccination for 1-5 years (34%) or 6-10 years (20%). A majority had some experience with implementation science -- reporting they had worked in or studied implementation science for 1-5 years (41%) or 6-10 years (20%). To improve HPV vaccination coverage, respondents expressed a need for one-dose vaccine schedules, offering vaccination at non-traditional settings (e.g., schools, pharmacies), incorporating policy changes at multiple levels, and improving vaccination communication efforts. Respondents expressed how implementation science could address these needs by promoting equity informed interventions, engaging community members, and designing and implementing evidence-based intervention across multiple settings.

Conclusions: To improve HPV vaccination coverage, there is a need to better prioritize and utilize implementation science to address research and practice gaps.

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UPDATED ESTIMATE OF THE ANNUAL DIRECT MEDICAL COST OF PREVENTION AND TREATMENT OF HUMAN PAPILLOMAVIRUS ASSOCIATED DISEASE IN THE UNITED STATES

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Introduction: The annual direct medical cost attributable to human papillomavirus (HPV) in the United States over the period 2004-2007 was estimated at $10.9 billion in 2012 (updated to 2020 dollars). The purpose of this report was to update this estimate to account for the impact of HPV vaccination on HPV-attributable disease, reductions in the frequency of cervical cancer screening, and new data on the cost per case of treating HPV-attributable cancers.

Methods: Based primarily on data from the literature, we estimated the annual direct medical cost burden as the sum of the costs of cervical cancer screening and follow-up and the cost of treating HPV-attributable cancers, anogenital warts, and recurrent respiratory papillomatosis (RRP).

Results: We estimated the total annual direct medical cost of HPV to be $11.0 billion annually over the period 2014-2018 (2020 U.S. dollars). Of this total cost, 60.4% was for routine cervical cancer screening and follow-up, 37.8% was for treatment of HPV-attributable cancer, and less than 2% was for treating genital warts and RRP.

Conclusions: Although our updated estimate of the direct medical cost of HPV is slightly higher than the previous estimate, it would have been substantially lower had we not incorporated more recent, higher cancer treatment costs. The estimated annual costs we present here can be used to show the potential economic benefits of continued HPV vaccination.

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PUBLIC HEALTH AND ECONOMIC IMPACT OF INTRODUCING HPV-BASED SCREENING WITH SELF-SAMPLING TO BROADEN ACCESS TO CANADIAN CERVICAL SCREENING

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Introduction: Canada has high cervical screening coverage, but disease persists in many populations who have not traditionally accessed screening with cytology. As provinces/territories adopt HPV-based screening, self-sampling has the potential to improve screening access. Modelling the public health and economic impact of self-sampling for under-screened populations can inform updated screening policies.

Methods: An Excel-based, deterministic budget impact model was calibrated with published data for Canada's population and costs with data unavailable for Canada sourced from a large US study. The self-sampling participation rate range was based on a recent Canadian pilot and intention survey. For ages 25–69 years, the model compared HPV-based screening with and without self-sampling.

Results: The model estimates HPV-based screening with self-sampling would increase the participation of those under and never screened by 17%-61%. This would lead to a 13%-47% increase in CIN2+ detection compared to HPV-based screening alone. Although self-sampling costs are significantly less than sampling by a health care provider, the incorporation of additional screened people to the screening program would increase the screening budget between 6%-21%. However, self-sampling would lead to savings (4%-16%) in the cervical cancer treatment budget through earlier detection of cancerous and pre-cancerous lesions. Overall, self-sampling would lead to a 4%-11% overall budget increase. Sensitivity analyses demonstrate that varying the rates of disease in the under-screened population and costs do not change the budget impact implications.

Conclusions: Self-sampling is a promising method to increase cervical screening coverage. Refining program design, education and awareness building for self-sampling could further increase participation. This model considers only one screening cycle; a longer-term analysis could demonstrate costs related to missed opportunities for cancer prevention in under-screened individuals, improving the cost-effectiveness of self-sampling. Cost of cancer care would also decrease as cancers in under-screened individuals diminish over-time.

Shift 01-130 / #876

Poster Viewing
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POTENTIAL IMPACT OF ONE-DOSE HPV VACCINATION IN LOW-AND-MIDDLE-INCOME-COUNTRIES (LMIC): A MODELING ANALYSIS USING HPV-ADVISE LMIC

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Introduction: To help inform the recent 1-dose SAGE recommendations, we examined the population-level impact and efficiency of: 1) one- and two-dose multiple-age cohort (MAC) vaccination of 9-14-year-old girls and 2) one-dose routine vaccination of 9-year-old girls, both scenarios compared to two-dose routine vaccination of 9-year-old girls.

Methods: HPV-ADVISE LMIC is an individual-based, transmission-dynamic model independently calibrated to four epidemiology diverse LMICs (India, Vietnam, Uganda and Nigeria). All scenarios start in 2023 with the nonavalent vaccine and assume 80% vaccination coverage. We assumed that two doses provide 100% vaccine efficacy (VE) against vaccine-type infections and lifelong protection. We varied one-dose VE between 100% and 85% or duration of protection between 20 years, 30 years, and lifelong.

Results: For the four LMICs, our model predicts that, compared to no vaccination, two-dose routine vaccination with/without MAC would reduce cervical cancer (CC) incidence after 100 years by 79-86%. Adding MAC to two-dose routine vaccination would not impact long-term incidence but would accelerate CC incidence reductions and avert more cases. Adding two-dose MAC (or one-dose MAC with 100% lifetime VE) would avert 4-9% additional cases over 100 years. Adding one-dose MAC would provide a similar benefit (averting 2-7% additional cases) when assuming either 85% one-dose lifetime VE or 20-30-years duration. One-dose routine vaccination would reduce CC incidence after 100 years by 61-75% and avert 66-94% of the cases averted with two-dose routine vaccination under pessimistic assumptions (lifetime VE=85% or duration=30 years). One-dose in MAC and/or routine vaccination would be more efficient in terms of number needed to vaccinate than two-dose if duration is >20-30 years.

Conclusions: One-dose HPV vaccination, through MAC and/or routine vaccination, could facilitate HPV-related diseases prevention by increasing vaccine access and coverage, and potentially vaccinating more girls. Our results confirm that this strategy is likely effective and efficient if one-dose duration of protection is >20-30 years.

Shift 01-131 / #1265

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-18-2023 7:00 AM - 5:00 PM

MITIGATING COVID AND VACCINE & HPV TEST SUPPLY DELAYS TO CERVICAL CANCER ELIMINATION SCALEUP: ANALYSIS TO SUPPORT A NEW ELIMINATION PLANNING TOOL

Adam Keane[1], Michael Caruana[1], Kate Simms[1], Daniela Rivas Romero[1], Diep Nguyen[1], Rubana Islam[1], Harriet Hui[1], Elle Pearson[2], Alexander Wright[2], Natalie Varney-Hopkins[2], Franklin Mtei[3], Silvia De Sanjosé[4], Marc Brisson[5], Jane Kim[6], Morten Ervik[7], Freddie Bray[7], Isabelle Soerjomataram[7], Karen Canfell[1]
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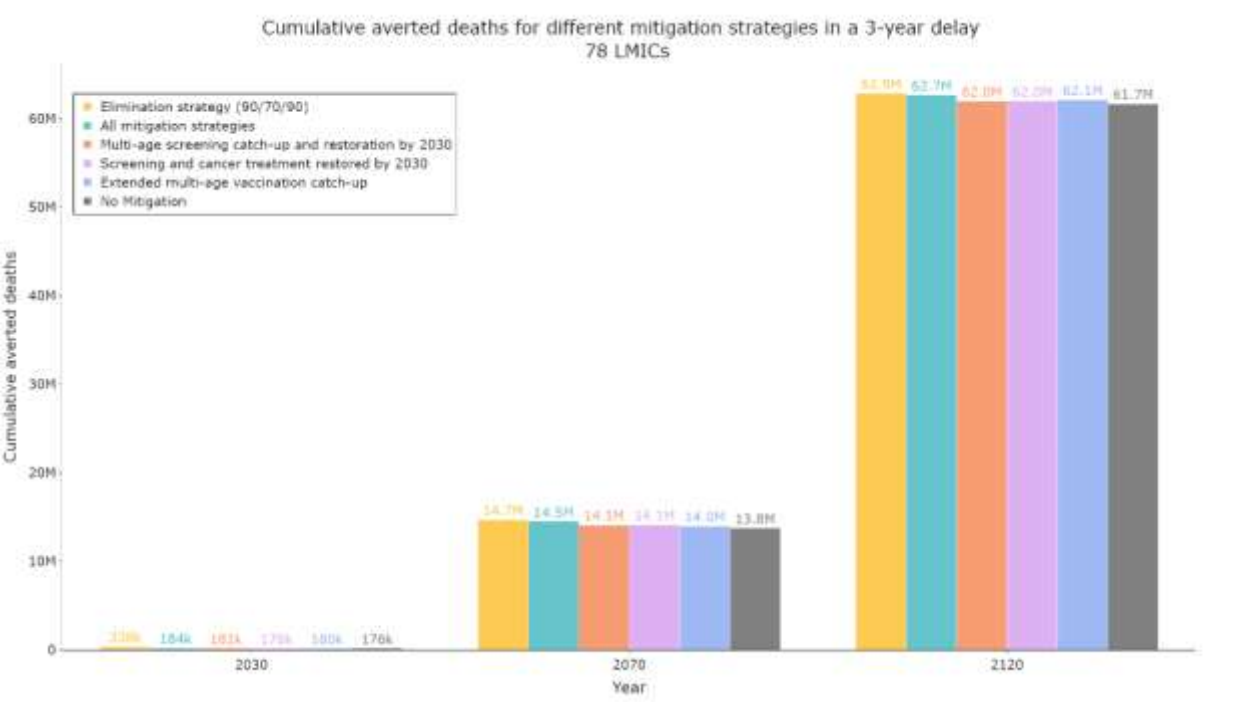
Introduction: WHO has established 90-70-90 scale-up targets for HPV vaccination, cervical screening, and precancer/cancer treatment, respectively, by 2030. Previous modelling for cervical cancer elimination planning assumed that scale-up started from 2020 (vaccination) and 2023 (screening and precancer/cancer treatment); and estimated that elimination could save over 62M lives across 78 low-and-lower-middle-income countries (78-LMICs) over the century. However, vaccine and HPV test supply/pricing and COVID-19 have delayed implementation in many countries. We evaluated the impact of resetting scale-up from 2023 and various delay mitigation strategies.

Methods: Using the well-established Policy1-Cervix platform, we evaluated the change in number of deaths averted with a 3-year delay for 78-LMICs. To assess mitigation, we examined (i) accelerated scale-up from 2023 to reach 90-70-90 targets by 2030 (‘restored scale-up’) and (ii) offering vaccination and/or screening catch-up to missed cohorts.

Results: A 3-year delay to all pillars, without mitigation, would cause 1.2M fewer deaths averted over the next century compared to no delay. Delays in vaccination, screen-and-treat and cancer treatment would cause 482,000, 314,000 and 378,000 fewer deaths averted, respectively. If the initial scale-up is delayed by 3-years but the 90-70-90 targets are still reached by 2030, 850,000 fewer deaths are averted compared to no delay. If catch-up vaccination and screening are also offered to cohorts missed during the 3-year delay, and the 90-70-90 targets are achieved between 2023-2030, 187,000 fewer deaths would be averted compared to no delay (Figure

1).



Conclusions: A 3-year delay in implementing targets implies 1.2M (of 62.9M) fewer deaths averted in 78-LMICs over the century. However, accelerated implementation from 2023 combined with catch-up vaccination and screening for missed cohorts would mitigate >84% of the adverse impact and provide a positive message for country planning. Results from this analysis will inform a new Cervical Cancer Elimination Planning Tool available on IARC's Global Cancer Observatory.

Shift 01-132 / #1445

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-18-2023 7:00 AM - 5:00 PM

OPEN-ACCESS SOFTWARE FOR MODELING HPV AND CERVICAL CANCER

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Introduction: Mathematical modeling informs many health-related targets, including cervical cancer elimination strategies. Mathematical models can project disease burden under different assumptions about the future, including the coverage and impact of interventions. Despite a robust HPV/cervical cancer modeling landscape, to date there are no open-source models. We identified a strong use case for a model that can be placed directly in the hands of decision-makers and used to support partner-led analyses of new technologies. Here, we introduce HPVsim, an HPV transmission and pathogenesis mathematical model created to meet these needs.

Methods: We began by formulating a statement of need for an open-source HPV model, which identified three essential criteria: (1) ease of use, which demands simple and customizable analysis workflows, minimal computing requirements, and transparent documentation; (2) scientific rigor, essential if the model is to be used for policy; and (3) stakeholder acceptance through active and ongoing consultation and engagement across the modeling and policy landscape. We built a team with expertise in cancer epidemiology, software development, public health, and disease modeling, and established processes for creating, sharing, evaluating, and updating the model.

Results: We created HPVsim, an agent-based model equipped with country-specific demographics, modular sexual networks on which HPV transmission occurs, default parameter values sourced from literature reviews and expert advice, genotype-specific disease progression, and built-in interventions including vaccination, screening, and treatment. It is straightforward to install and operate, and comes with extensive documentation and training materials.

Conclusions: The primary development phase of HPVsim is complete and immediate next phases will involve ongoing stakeholder engagement, peer review, training sessions, and working closely with decision-makers to ensure the model has the rigor and flexibility required to answer real-world modeling questions. We are optimistic that HPVsim, as an open-access model for HPV/cervical cancer dynamics, will be useful to inform complex decision-making around cervical cancer interventions.

Shift 01-133 / #1521

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-18-2023 7:00 AM - 5:00 PM

BENEFITS, HARMS AND COST-EFFECTIVENESS OF DUAL-STAIN CYTOLOGY AS A TRIAGE FOR HPV-POSITIVE WOMEN: MODELLING TO INFORM UPDATED WHO CERVICAL SCREENING GUIDELINES

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Introduction: The first iteration of new 2021-22 WHO guidelines for cervical screening in women in the general population recommend primary HPV screening in a screen-and-treat, or a screen-triage-and-treat approach, every 5 or 10 years. Modelling supporting these guidelines assessed triaging of HPV-positive women with 16/18 genotyping, VIA, colposcopy or cytology, and mortality reductions compared to no screening were predicted to be up to 60-63%. Dual-Stained cytology requires established laboratory infrastructure with QA/QC, and the second edition of the guidelines assessed the benefits, harms and cost-effectiveness of dual-stain cytology when used in such a setting, as an alternative triage for HPV positive women.

Methods: An updated systematic review of dual-stain cross-sectional test performance data was used to inform assumptions for the Policy1-Cervix platform (modelled CIN2+ sensitivity/specificity of 86%/64% in HPV-positive women). For LMICs, the future cost of dual-stain was assumed to be equal to cytology for this analysis. For a range of algorithms involving HPV screening every 5 or 10 years, dual-stained triage strategies were compared to the previously evaluated triage options.

Results: In settings where it could be successfully implemented, 5-yearly HPV screening with dual-stain triage could reduce cervical cancer mortality by >60%. Strategies involving dual-stain triage generated a similar number of precancer treatments and additional preterm deliveries and had similar position on the cost-effectiveness frontier when pricing similar to cytology was assumed, compared to 5-yearly primary HPV testing with the four original triage options. If pricing at current high-income-country levels is assumed, dual-stain is unlikely to be cost-effective in LMIC.

Conclusions: These findings indicate that dual-stained cytology is a promising option for triage of HPV-positive women. However, assay cost and requirements for laboratory infrastructure to ensure high-

quality testing in LMICs are important barriers. Triage HPV-positive women with partial genotyping or VIA may prove more practical options for many LMIC at the current time.

Shift 01-134 / #1666

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-18-2023 7:00 AM - 5:00 PM

COST-EFFECTIVENESS ANALYSIS OF SWITCHING FROM A BIVALENT TO A 9-VALENT HPV VACCINATION PROGRAM IN CHINA: A MODELLING STUDY

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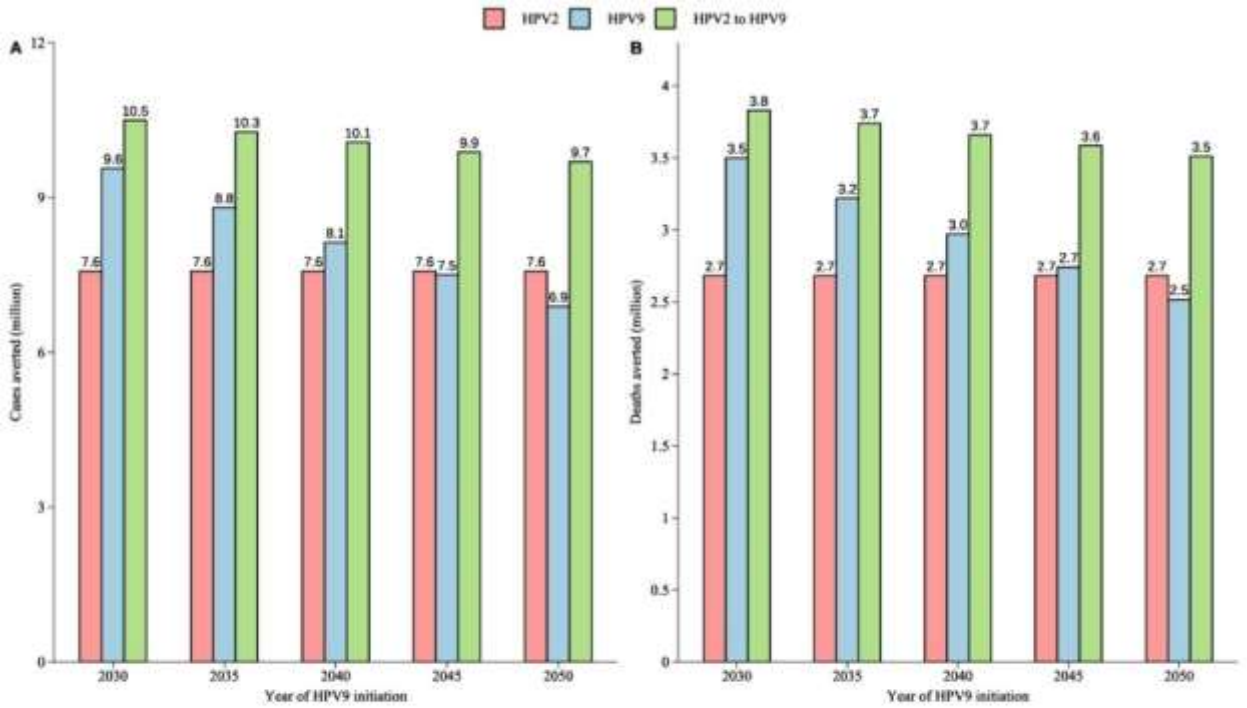
Introduction: China's domestic 9-valent HPV vaccine is expected to be available on the market in the following decade, then it could be considered for inclusion in the national immunization program. Evidence on the added health and economic benefit of the 9-valent vaccine is required for policy decisions. We compared population-level effectiveness and cost-effectiveness of domestic 9-valent and bivalent HPV vaccination in China.

Methods: A validated transmission model was used to project the lifetime costs and effectiveness of alternative strategies: (1) immediate bivalent vaccination; (2) 9-valent vaccination when it is available for large-scale vaccination; and (3) immediate bivalent vaccination with a switch to 9-valent when available. Based on the development schedule and production capacity, we assumed a domestic 9-valent vaccine would be available for large-scale vaccination between 2030 and 2050. We assumed 90% coverage of HPV vaccination for girls aged 12 years with two-dose regimens routinely. All women living or projected to be born in China during 2022-2100 were considered. We employed a societal perspective.

Results: Compared with no vaccination, bivalent HPV vaccination would avert 7.6 million cervical cancer cases and 2.7 million deaths over the lifetime of people who lived in 2022-2100. Switching from bivalent to 9-valent vaccination would avert additional 2.1-2.9 million cases and 0.8-1.1 million deaths, depending on the year when 9-valent vaccine is initiated (Figure 1). With the GDP per capita ($12,458) as the threshold, switching from bivalent to 9-valent vaccination dominated alternative strategies irrespective of the initiation year of 9-valent vaccine (Figure 2). Furthermore, this switching strategy was cost-saving compared with continuing bivalent vaccination when 9-valent vaccine is initiated before 2040 (net cost savings: $477-2,799
million).



Figures 1. Estimated (A) cervical cancer cases and (B) deaths averted compared with no vaccination under different initiation years of 9-valent vaccine
HPV2=bivalent HPV vaccine; HPV9=9-valent HPV vaccine; HPV2 to HPV9=switching from bivalent to 9-valent HPV vaccine

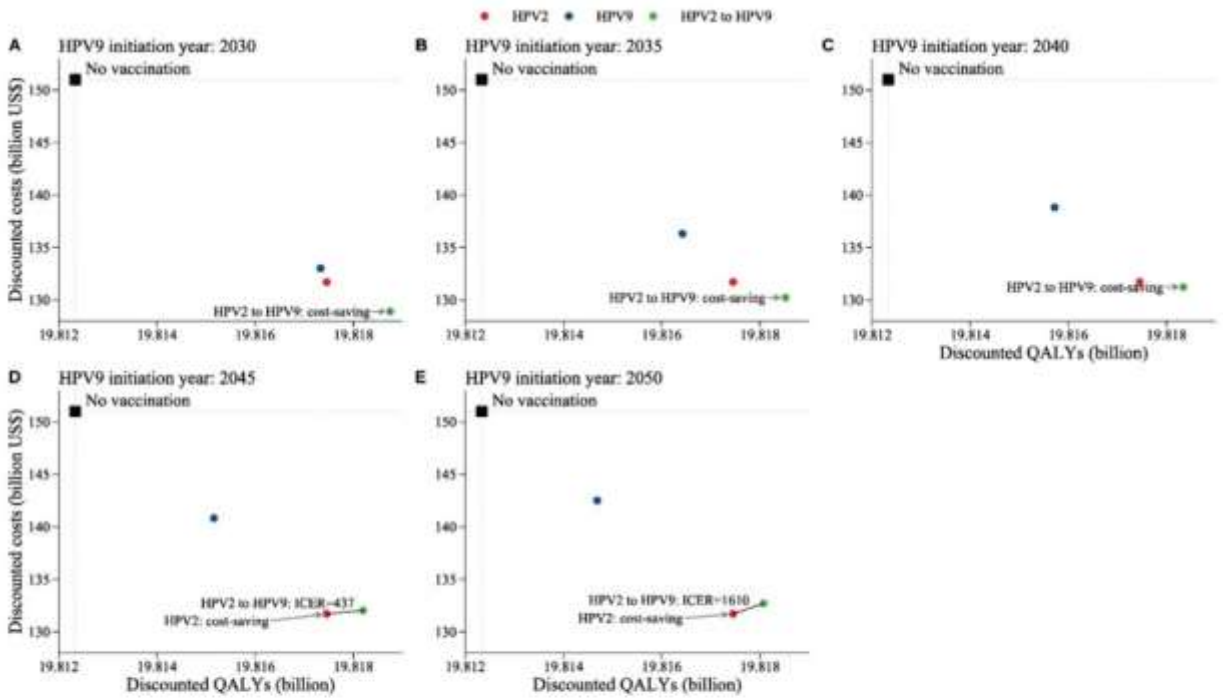


Figure 2. Cost-effectiveness for different strategies compared with no vaccination, with 3% discounting. The domestic 9-valent vaccine was initiated in (A-E) 2030-2050. The labels represent the strategies located on the cost-effectiveness frontier and their ICERs compared with the next most costly non-dominated strategy. The strategies on the upper left of the frontier are dominated by the strategies on the lower right of them. When the strategies are cost-saving, the ICERs are negative and not shown.
HPV2=bivalent HPV vaccine; HPV9=9-valent HPV vaccine; HPV2 to HPV9=switching from bivalent to 9-valent HPV vaccine; QALY=quality-adjusted life-year; ICER=incremental cost-effectiveness ratio.

Conclusions: Switching to a 9-valent HPV vaccination program was cost-effective and had a significant impact on reducing the cervical cancer burden in China.

Shift 01-135 / #385

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

CERVICAL CANCER INCIDENCE, TREATMENT AND SURVIVAL IN ELDERLY WOMEN IN GERMANY

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Introduction: Evidence suggests that the incidence of cervical cancer in elderly could be underestimated due to a lack of hysterectomy correction. Elderly cervical cancer patients are more often diagnosed with advanced-stage disease and have inferior outcomes compared to younger patients. Therefore, the aim of our study was to investigate incidence, treatment and survival of cervical cancer in elderly women in Germany.

Methods: The incidence rates of cervical cancer (ICD-10 C53) were determined using data of six federal state cancer registries obtained from the German Centre of Cancer Registry data (ZfKD). Elderly women were defined as 65 years of age and older and compared to younger women. Incidence was investigated uncorrected and corrected for hysterectomy prevalence rates. Distribution of treatment modalities (surgery, chemotherapy, radiation therapy) was assessed. 5-year relative survival was calculated using the period approach. Survival was stratified by tumor stage and histological type. Multivariable Cox proportional hazard models were calculated to compare overall survival between younger and elderly women.

Results: In total, 14 528 cervical cancer cases were included in the analyses with an age range from 20 to more than 85 years of age. Of those, nearly 30% were elderly women aged 65 years or older. Hysterectomy correction showed that incidence rates were underestimated up to 70% in the oldest age groups. A lower proportion of elderly women was treated with surgery or chemotherapy. This was found especially in more advanced tumor stages. Younger patients had a much better 5-year relative survival compared to elderly patients.

Conclusions: Cervical cancer incidence in elderly women is underestimated and survival is lower compared to younger women in Germany. Due to the high disease burden, screening strategies for elderly women need improvement.

Shift 01-136 / #883

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

IMPACT OF BEHAVIORAL FACTORS ON THE PARTICIPATION IN A CERVICAL CANCER SCREENING PROGRAMME

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Introduction: Regular participation in cervical cancer screening (CCS) is a critical factor in reducing cervical cancer-related mortality. However, a minimum of 70% participation rate is needed to keep an effective program, and reaching this threshold is still challenging in many (European) countries. Although lower socioeconomic status is related to lower attendance, little is known about other factors related to regularity in CCS participation. Therefore, this study aimed to evaluate the association between behavioral factors and regular CCS participation, adjusted for sociodemographic factors.

Methods: Lifelines population-based cohort was linked with CCS-related data from the Dutch Nationwide Pathology Databank (PALGA). Women eligible for four screening rounds from 2000 to 2019 were included and classified as regular (participated four times), irregular (participated between once and three times), and never participants. The following behavioral factors were used: smoking habits, alcohol consumption, food-based Lifelines diet score, Body Mass Index, physical activity, TV watching (as a proxy for sedentarism), sleep duration, hormonal contraception, number of children, and age at first child birth. Multinomial logistic regression was performed to evaluate the association between the behavioral factors and participation regularity adjusted by country of birth/ethnicity, educational level, income, and marital status.

Results: In total, 48,325 women were included, of which 55.9% were regular participants, 35.1% were irregular, and 9% were never participants. Being a smoker, obese, having a long duration of tv watching, and having insufficient sleep increased the likelihood of participating irregularly or never, while doing middle and high physical activity, having used hormonal contraception, and having children decreased the likelihood of participating irregularly or never.

Conclusions: These findings show that after adjustment for sociodemographic factors, behavioral factors are associated with regular participation in the CCS.

Shift 01-137 / #911

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

AVAILABILITY AND ACCESSIBILITY OF CERVICAL SCREENING IN THE BONO REGION OF GHANA: A QUALITATIVE ENQUIRY

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Introduction: The global SDGs seek to eliminate cervical cancer by 2030. The 90-70-90 strategy sets ambitious targets for vaccination, screening and treatment that will set countries on the path to elimination. To enhance elimination efforts in Ghana, the accessibility of cervical screening coverage needs to be investigated and monitored. This study explored stakeholder perspectives on the availability and accessibility of cervical screening services in the Bono Region of Ghana

Methods: An explorative descriptive qualitative design was implemented from January to July 2021 in the Region. Face-to-face in-depth interviews were conducted with nurse educators, religious leaders, market queens, health service officials and healthcare workers at sub-district, district and regional levels. Interviews were recorded and transcribed verbatim. A thematic content analysis procedure was executed.

Results: Themes embedded in the data pertained to misconceptions regarding signs and symptoms, risk factors, availability of screening options, and accessibility to screening services. Stakeholders were generally oblivious to global and national targets for cervical screening. Both positive and negative perspectives emerged about the level of public awareness of screening options. In several instances, screening services were accessible when healthcare workers partnered with non-health institutions to organize sporadic screening campaigns. Stakeholder interviews revealed that the COVID-19 pandemic had an adverse impact on these outreaches.

Conclusions: There was consensus among stakeholders that the need for both specialist and basic cervical screening services outstrips the current service delivery capacity in the Region. In order to achieve global targets, there is the need to identify gaps related to coverage, implement new services, scale up and decentralize cervical screening services in the region. This will require health planners to prioritize cervical screening services and come up with innovative and cost-effective strategies to expand same.

Shift 01-138 / #1114

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

EXPERIMENTATION OF SCREENING AND MANAGEMENT OF PRE-CANCEROUS CERVICAL LESIONS IN BURKINA

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Introduction: Since 2018, Médecins du Monde has developed a project to prevent and manage CC in 9 health centres in the Baskuy health district in Ouagadougou in Burkina Faso

Methods: The project supports the Ministry of Health in the fight against CC, by promoting early management of lesions in 9 health centers. Four of these centers have a laboratory allowing a "screen and treat" approach in one visit. The proposed algorithm is a DNA primary screening for Human Papilloma Virus (HPV) followed by visual inspection with acetic acid (VIA) and the use of the thermo-coagulation technique for the treatment of precancerous lesions (PCL).

Results: The project screened 10,975 women aged 25-55 years, from May 2019 to December 2021, of whom 79.70% were screened for the first time and 65.20% chose the self-sampling method. Approximately 20% of women were screened HPV positive. 96% of women with a positive Visual Acetic Acid Inspection and eligible for thermo-coagulation were treated. 15% of women were screened and treated in one visit at the laboratory centres. However, the number of LOSs was less than 15%, and this rate was almost the same in the centres without a laboratory We found it difficult to implement a one-visit approach without disrupting the operation of the health centre, so only 15% of women benefited from this approach; yet the number of loss of sight was less than 15%, which was equivalent in the centres offering the one-visit approach and those that could not offer it

Conclusions: "screen and treat" approach in one visit, could not be achieved but had little impact on the number of loss of sight. These results show the importance of other determinants and contextual factors on the effect of sight loss

Shift 01-139 / #1151

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

A MODEL FOR A NATIONAL CERVICAL PRECANCER SCREENING USING ALUMNI OF A TRAINING CENTRE IN GHANA.

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Introduction: Cervical cancer incidence remains high in many low -middle income countries due to inadequate capacity for screening and treating cervical precancer. The Cervical Cancer Prevention and Training Centre (CCPTC) in Catholic Hospital, Battor, Ghana, has trained 299 health workers across Ghana. Using these trainees, we screened women across Ghana, demonstrating the possibility of running a national cervical precancer program using trained health workers.

Methods: Through the mPharma 'Ten thousand (10,000) Women Initiative (TWI), across 15 regions of Ghana, CCPTC alumni screened women with hrHPV DNA testing and Visual Inspection with Acetic acid (VIA) concurrently. 205 women had self-sampling with the Evalyn brush. Samples were tested at the CCPTC using the Sansure MA 6000 HPV PCR, which was previously used for COVID-19 testing in Ghana. Women with cervical precancer on VIA were treated with thermal coagulation or Loop Electrosurgical Excision Procedure (LEEP).

Results: 5167 women have so far been screened by 106 alumni in 73 institutions in 57 metropolises, municipalities, and districts in 15 (of the 16) regions. Average age of clients was 40.0 (95%CI: 39.6 to 40.3) years. hrHPV prevalence was 27.9% (95%CI: 26.7% to 29.2%) and VIA positivity was 3.0% (95%CI: 2.5% to 3.5%), with 1 frank cancer. 7 women have been treated with thermal coagulation, and 4 have had LEEP.

Conclusions: This is the first reported cervical precancer screening with hrHPV DNA testing through a programme across Ghana. The hrHPV prevalence of 27.9% is higher than the reported estimate of 21.5% (WHO) in West Africa. Concurrent VIA with HPV testing reduced loss to follow up and cost. We demonstrate a model for national cervical precancer screening using a training centre and its alumni. With reduced COVID-19 testing, PCR platforms (e.g. MA 6000) for COVID-19 testing can be used for hrHPV DNA testing.

Shift 01-140 / #1204

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

PEER EDUCATOR RECRUITMENT AND CERVICAL PRECANCER SCREENING WITH HPV DNA TESTING AND MOBILE COLPOSCOPY IN FEMALE SEX WORKERS IN VOLTA REGION, GHANA.

Kofi Effah[1], Ethel Tekpor[1], Comfort Wormenor[1], Joseph Amuah[2], Vida Kwawukume[3], Louisa Matey[4], Seyram Kemawor[1], Stephen Danyo[1], Esu Morkli[1], Nana Essel[5], Patrick Akakpo[6]
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Introduction: Female sex workers (FSWs) are at an increased risk of sexually transmitted infections including hrHPV which cause cervical cancer. In Ghana, the prevalence of hrHPV and cervical precancer in FSWs has not been studied outside Accra. We determined the prevalence of hrHPV and cervical lesions in the Volta regional capital (Ho) and a border town (Aflao).

Methods: As part of the mPharma Ten thousand (10,000) Women Initiative (TWI), FSWs in Ho and Aflao were recruited by peer educators (FSWs trained and paid by Non-Governmental Organisations that take care of FSWs). FSWs were screened with hrHPV DNA testing (Sansure MA 6000 HPV PCR platform [partial genotyping] and full genotyping with the AmpFire HPV PCR platform (Atila BioSystems, Mountain View, CA, USA)) and mobile colposcopy with the Enhanced Visual Assessment (EVA) system (MobileODT, Tel Aviv) concurrently by trained nurses.

Results: 143 FSWs were screened (91 in Ho and 52 in Aflao). The mean age was 32.0 years (range: 19 to 63 years). The hrHPV prevalence with MA 6000 was 28.0% (95%CI: 20.6% to 35.3%) and with Ampfire 25.9% (95%CI: 18.7% to 33.1%). The top 5 hrHPV genotypes detected after full genotyping (AmpFire) were 68 (9.1%), 56 (6.3%), 52 (5.6%), 58 (4.9%) and 18 (3.5%). 14 (9.8%) FSWs had cervical lesions at colposcopy. 4 were treated on-site with thermal coagulation, 1 was scheduled for Loop Electrosurgical Excision Procedure.

Conclusions: FSWs have a higher prevalence of hrHPV (28.0% (MA 6000) and 25.9% (AmpFire)), similar to the 26% among FSWs in Accra and higher than the reported estimate of 21.5% in the general population in West Africa. FSWs are at increased risk of hrHPV infection and cervical cancer. Cervical cancer screening programmes must be tailored to cover them. Peer educators can help improve uptake of cervical cancer prevention services among FSWs.

Shift 01-141 / #1307

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

A NATIONWIDE TRIAL OF RAPID ELIMINATION OF HPV AND CERVICAL CANCER

Laila Sara Arroyo Mühr[1], Emilie Hultin[1], Emel Yilmaz[1], Camilla Lagheden[1], Malin Vikström[2], Agustín Ure[1], Roxana Merino Martinez[1], Miriam Elfström[1], Joakim Dillner[1]
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Introduction: Aim: To achieve an as rapid extinction of circulation of the major oncogenic HPV-types as possible. Setting: Sweden. School-based vaccination has a 90% coverage of girls and 85% coverage of boys. Catch-up vaccination up to age 18 has had a 60% coverage. Cervical screening uses HPV testing starting at age 23, with very high coverage (>90%) in the younger ages. Pre-vaccination HPV prevalences (14 types) in ages 23-29 were close to 30%, with 6% HPV16 and 3% HPV18.

Methods: Design: All women in the country ages 23-28 are offered no-cost nonavalent HPV vaccination and concomitant HPV screening with extended genotyping. Women positive for vaccine HPV-types are followed-up in the screening program. All women are invited for a repeat visit 3 years later. Hypotheses: At follow-up, we will assess i) whether the oncogenic HPV-types covered by the vaccine are still detectable in the Swedish population and ii) whether there has been a decline in cervical cancer.

Results: Preliminary results: The population-based HPV prevalences at enrolment (concomitantly with vaccination) were 2.1% HPV16, 0.5% HPV18, 3.9% HPV45, 11.6% HPV31/33/52/58 and 11.4% HPV35/39/51/56/59/66/68 (in this age group, these low-oncogenicity HPV-types are no longer targeted by the screening program in Sweden). The decline of HPV16 and 18 prevalences agrees with modelling predictions of a 60% quadrivalent vaccine coverage effect. The prevalence of the “other” HPV-types appears to not have been significantly affected by quadrivalent HPV vaccination. Modelling also predicts that a population-based nonavalent HPV vaccination campaign reaching at least 65% coverage will (on top of the previous 60% coverage of quadrivalent vaccine) result in an extinction of the 7 major oncogenic HPV-types.

Conclusions: Assessing whether a campaign with concomitant HPV vaccination and HPV screening of young women is followed by elimination of HPV and cervical cancer could be helpful for design of strategies for accelerated cervical cancer elimination.

Shift 01-142 / #1322

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

UNDERSTANDING HOW SECONDARY PREVENTION CAN BE SCALED UP TO ACHIEVE CERVICAL CANCER ELIMINATION: AN IMPLEMENTATION STUDY IN FOUR LOW-AND-MIDDLE INCOME COUNTRIES

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Introduction: For low-and-middle-income countries (LMICs), a cervical cancer secondary prevention approach of HPV-DNA screening and thermal ablative precancer treatment is preferred for higher efficacy and lower resource utilization, respectively. However, it is not known how it may be effectively implemented. The SUCCESS project is integrating this approach into existing women's health services in Burkina Faso, Côte d'Ivoire, Guatemala, and the Philippines. Concurrently, an implementation study is being conducted.

Methods: Over 18 months in 2022-23, we are conducting a Hybrid Effectiveness-Implementation Type III mixed-methods assessment of the feasibility, acceptability, and costs of integrated delivery. Sites (n=40, 10/country) were selected to balance considerations of urban/rural location, facility level, onsite/offsite laboratories, and health services types. Targeted recruitment is 8909 women aged 25-49 years, 15% having HIV+ status. The primary outcome is proportion of HPV+ women completing precancer treatment, if eligible, within three months. Data collection include facility and client exit surveys, key informant and client interviews, registries and project records extractions, and time-and-motion observation. Analysis includes descriptive statistics, context description, thematic analysis, and document analysis. Analyses will be stratified by HIV status. (ClinicalTrials.gov ID: NCT05133661)

Results: Recruitment started in April 2022 for Burkina Faso and Côte d'Ivoire. Preliminary results there show that 87% of participants (n=3352) prefer sample self-collection. A major barrier is long turn-around times for results (up to two months), due mainly to capacity limits at laboratories. Lagging recruitment in some facilities resulted from over-reliance on opportunistic enlistment among women presenting for other health services. Some facilitators were intensive community outreach and tailoring laboratory access.

Conclusions: In LMICs, integrating cervical cancer secondary prevention services into other health services will likely require specific rather than incidental recruitment of women for screening. Reconfiguration of laboratory infrastructure and planning for sample management must be made well in advance to meet induced demand for screening.

Shift 01-143 / #1678

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

NATIONWIDE HPV INFECTION, VACCINATION, AND CERVICAL CANCER AWARENESS PROGRAM: A ROAD MAP TOWARDS ELIMINATION OF CERVICAL CANCER FROM BANGLADESH

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Introduction: Worldwide, cervical cancer (CC) is seen as a serious issue for women's health. In Bangladesh, over 58 million women are at risk and current statistics show, it is the second most common cause of cancer death in women. Each year 12,000 women are diagnosed and 6,000 die from this disease. Due to ignorance, more than 80% of patients diagnosed with this preventable cancer are in clinically advanced, inoperable stages due to ignorance. If action is not taken WHO predicts that between 2018- 2030, there would be an increase of 400,000 fatalities. This study aimed to reduce the knowledge gap regarding HPV infection, vaccination, and cervical cancer, and estimate the prevalence of HPV infection and pre-cancerous lesions including the establishment of treatment.

Methods: A cross-sectional survey will be conducted through school-based awareness programs and population-based surveillance in two divisional districts in Bangladesh. The target population will be school girls with mothers (aged 9 and above) for awareness programs. A structured questionnaire including i) Socio-demographic information ii) Knowledge about cervical cancer and iii) Knowledge about HPV infection and vaccination will be provided. Logistic regression and a chi-square test will be used to assess the level of awareness and barriers to HPV vaccination. Women aged 35 to 45 years will be targeted for VIA tests to detect the prevalence of the disease.

Results: A previous study (2021) reported that only 13% of women knew about the association between HPV infection and cervical cancer. This ongoing study will cover approximately 1 million women in terms of raising awareness and screening. This will lead to increased acceptance of HPV vaccination and elimination of CC by 50% by 2026.

Conclusions: A better understanding in the population about the HPV vaccine and cervical cancer will ultimately increase the vaccine and screening coverage.

Shift 01-144 / #1774

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

UPDATED GUIDELINES FOR CERVICAL CANCER SCREENING AND PROGRAMM IMPLEMENTATION IN THE EU

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Introduction: The European Commission has supported the development of quality assurance and best practice recommendations for cervical screening in Europe since 1993. These efforts have had a positive impact on cervical screening quality and coverage in Europe. However, the guidelines now need updating to address the evolution of prevention methods, namely HPV vaccination, increasing diversity in socio-demographic characteristics of the population, as well as inequalities in access to screening between and within countries. The guidelines also need to move from consensus-based to evidence-based recommendations derived from systematic reviews while retaining the flexibility needed to individualise decisions.

Methods: In this project, we will update clinical guidelines on cervical cancer screening for European countries. We will make recommendations for specific sub-groups of the population (age groups, immune-compromised women, socially vulnerable populations, migrant women, LGBTQ+). The guidelines will consider risk-stratified HPV screening pathways for different demographic sub-groups and HPV vaccination status. The recommendations will be tailored to the populations they serve, considering the distribution of cervical cancer and availability of screening and triaging technologies. We will also update the recommendations on the essential components of organised cancer screening implementation, as identified by the IARC expert group. We will incorporate internationally agreed-upon indicators, benchmarks, and user-friendly tools for monitoring and evaluating cervical cancer screening in the updated guidelines. We will draw on the current IARC-led Canscreen-ECIS project to develop a voluntary quality assurance scheme for cervical cancer screening services covering the full continuum of cervical cancer control.

Results: We will provide guidance to countries for measuring and addressing inequalities in cervical cancer prevention and care using the indicator framework developed by the European Cancer Inequalities Registry.

Conclusions: The evidence-based recommendations, implementation guidelines, and quality assurance scheme will support European countries to achieve the target to provide 90% of eligible women access to population-based quality-assured cervical screening by 2025.

Shift 01-145 / #1809

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

IMPROVING HPV VACCINATION THROUGH DEFAULTER TRACKING IN THE COMMUNITY: A KENYA CASE STUDY.

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Introduction: The Human Papilloma Virus (HPV) vaccine is the primary prevention of virus-attributable cervical cancer. Although school based approach has yielded higher coverage, completion rates have been low mainly due to defaulting. In 2019, Kenya rolled out the two-dose HPV vaccine to 10-year-old girls, with the doses delivered six months apart. Despite progress made in the first year, coverage rates dropped in 2020 due to the COVID-19 pandemic that necessitated school closures leading to high defaulter rates.

Methods: Chai implemented a pilot in 35 facilities in Bungoma County between May 2021 and June 2022. Monthly defaulter tracking and awareness meetings between community members and facility staff were implemented. Healthcare workers were trained to identify defaulters in the both immunization and HPV register, and the program developed a standardized tool to monitor DT meetings. Defaulter tracking indicators were assessed at baseline, endline and routinely monitored in between

Results: The proportion of facilities using the immunization and HPV register to identify defaulters increased from 19% to 100% at endline, while engagement with community leaders increased from 67% to 100% at endline. The proportion of HFs conducting daily and weekly defaulter identification increased from 7.4% to 28.6%, and from 11.9% to 14.3%, respectively Among surveyed facility and community respondents, 100% agreed at endline they would like to continue community meetings. However, 43% of respondent do not think they can financially sustain them.

Conclusions: This pilot underscores the importance of effective DT tools and practices, supplemented by structured community engagement. Preliminary results have informed a technical working group to standardize DT in Kenya. Further investigation is needed to ensure sustainability and scalability of this approach.

Shift 01-146 / #674

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03H. VACCINE SAFETY
04-18-2023 7:00 AM - 5:00 PM

ALL VACCINES FOR ADOLESCENTS ARE NOT EQUAL IN THE MINDS OF PARENTS: HIGHLIGHTS OF RESEARCH ON VACCINE CONFIDENCE AND THE IMPORTANCE OF VACCINES

Judy Klein[1], Tamera Coyne-Beasley[2], Alexandra Garcia[1]
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Introduction: Adolescent and young adult (AYA) vaccinations plummeted during the Pandemic and have been the slowest across age-groups to return to pre-pandemic levels. Data for provider vaccine orders indicate that HPV vaccines have not recovered to pre-pandemic levels, while MenACWY and Tdap have recovered. Unity conducted two multiphase market research studies with adolescents and parents to understand the factors impacting lagging vaccination rates.

Methods: Unity conducted multiwave, online survey research on preventive health and immunizations with U.S. representative groups, adolescents aged 13-18 (n=300/wave) and parents of adolescents (n=500/wave), oversampling disproportionately impacted groups, considering income, household location and race/ethnicity. Surveys were fielded in August 2020, February and June 2021. The survey instrument was repeated across waves and updated in waves 2 and 3 with COVID-19 vaccine availability. In November/December 2021, Unity delved into vaccine confidence and social media with multiphase, mixed methods research. Starting with social media vaccine influencer interviews (n=5), then asynchronous online board group discussions with parents (n=60) of AYAs, and finishing with in-depth parent triad (n=18) discussions stratified by vaccine beliefs.

Results: Parents reported concerns about vaccine safety in general (Table 1). Influenza, COVID-19, and HPV vaccines rated lower in importance across all waves than other routine immunizations (Table 2). Focus groups highlighted vaccine safety concerns that differed significantly by vaccine type (Table 3).

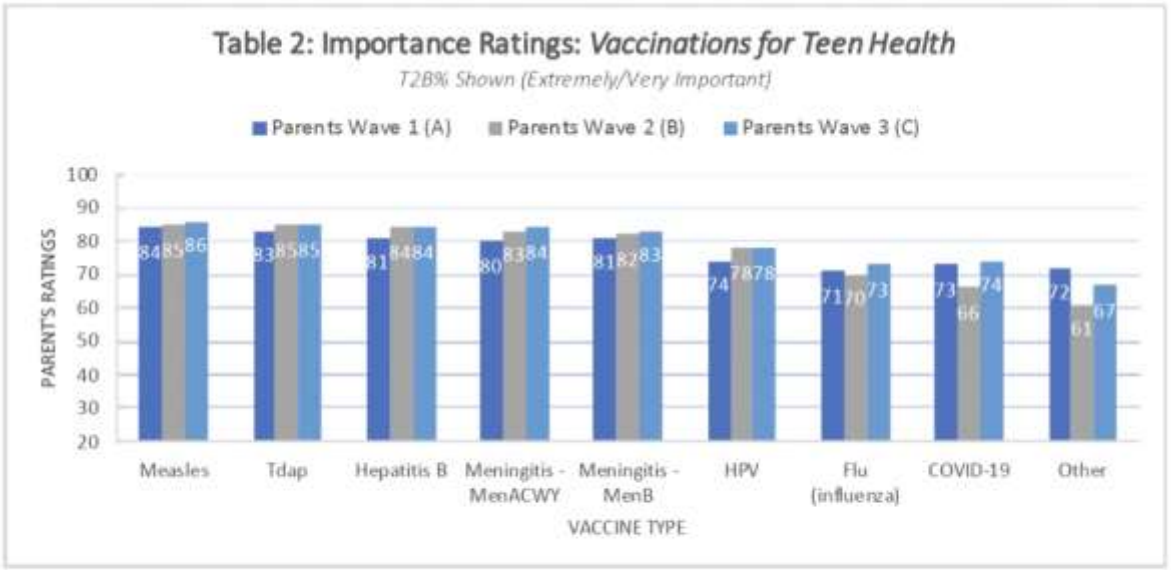
Table 1: Statement Agreement:
Vaccine Perceptions for Parents's of AYAs
To what extent do you agree or disagree...

Top 2 Box % Shown 5 - Strongly agree / 1- Strongly Disagree	Wave 1	Wave 2	Wave 3
It is important for all teens to get the vaccines recommended for them	80	78	77*
I have some concerns about the safety of vaccines	52	61	63
I have some concerns about the effectiveness of some vaccines	54	60	67

*As in wave 2, Hispanic respondents are more likely than Non-Hispanic respondents to place importance on teens getting recommended vaccinations with 75% of Hispanic respondents compared to 68% non-Hispanic respondents.
Urban and suburban respondents showed stronger agreement than rural respondents of benefits and importance of vaccinations.

Source: Unity® Survey conducted in Aug/Sept 2020, Feb 2021, June 2021, Participants by Wave: Teens 13-18 YO (n=300) for each of the 3 Waves. Parents/Guardians of Teens - Wave 1: (n=582), weighted sample, Wave 2: (n=531), Wave 3: (n=500).

Q15. To what extent do you agree or disagree with the following statements?; 5-pt scale



Source: Unity® Survey conducted in Aug/Sept 2020, Feb 2021, June 2021, Participants by Wave: Teens 13-18 YO (n=300) for each of the 3 Waves. Parents/Guardians of Teens - Wave 1: (n=582), weighted sample, Wave 2: (n=531), Wave 3: (n=500).

Q14. How important is vaccination against these diseases to your teen's health?; 5-pt scale; Parents only

Table 3: Parents' Perceptions and Voices Across Vaccines

Feelings and safety concerns change significantly across different vaccines	Focus Group Quotes
"Standard" vaccines are important - Meningitis and Tdap, older and more familiar. - Far more comfortable - Most (3/4) have little to no problem with standard vaccines	*"Meningitis is proven to be a very serious illness and the vaccine is trustworthy so it is important that my son be vaccinated. The same would be true of the TdaP vaccine."* *"There are standard vaccines that have been tested and proven successful over time, and I believe they have helped eradicate the diseases from our section of the world."*
Mixed feelings about COVID-19 vaccination - About 1/3 think that Covid-19 is as concerning as other vaccine-preventable diseases. - Many don't think the Covid-19 vaccine was tested long enough.	*"Mixed thoughts I guess. I'm actually more worried about her getting the Covid shot than me. Being my child I'm worried for her future health and long term side effects on the new vaccines that just popped out."*
Decline in vaccine confidence Some have experienced a decline in vaccine confidence over the last 2 years.	*"My child is current on all her childhood immunizations however she is not vaccinated for Covid and I am highly opposed to the vaccine."* *"My daughter has gotten all recommended vaccines throughout her life. I trust vaccines. New vaccines worry me though."*
Flu vaccine experiences - Negative side-effects - Separate category from "standard" vaccines - Less trust	*"The Flu [vaccines]... were low on my list because people still get the illnesses, even with a vaccine."* *"Flu vaccine strain is guessed every year, they never know which flu strain it will be. In addition, the vaccine has a live strain which subjects the individual to the virus."*
Mixed reactions to HPV Vaccine - Is it necessary? - What is the vaccine for? - HPV can be avoided - Applies only to females	*"We have followed the vaccine schedule for the majority of her vaccines. However, there are a few that I have not consented to based on the age of the vaccine and the side effects associated with it [HPV]".* *"We've gotten most all recommended vaccines over the years minus the Gardasil so far. That one I wanted to wait on and let them have some choice in the matter."*

Source: Unity® conducted multiphase online research, Nov-Dec 2021: Phase 1 interviews, n=5, social media healthcare influencers; Phase 2, parents of adolescents, n=60, online bulletin boards; Phase 3, Parents, n=18, triad focus groups.

Conclusions: Unity's research initiatives have uniquely assessed the shift in parental and AYA beliefs about vaccine importance and hesitancy throughout the Pandemic. Research shows that parental vaccine confidence is spread unevenly amongst AYA recommended vaccines. Flu shots are viewed as less important than routine vaccines. Mis/disinformation on social media about vaccines, including COVID-19 and HPV, have led to parental confusion and concern. Parents have more confidence in "standard" vaccines such as Tdap and MenACWY. These vaccine specific beliefs can lead to gaps in routine AYA immunization coverage.

Shift 01-147 / #784

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03H. VACCINE SAFETY
04-18-2023 7:00 AM - 5:00 PM

PARENTS' OF ADOLESCENTS PERSPECTIVES ON VACCINE INFORMATION SOURCES AND VACCINE CONFIDENCE

Judy Klein[1], Tamera Coyne-Beasley[2], Alexandra Garcia[1]
[1]Unity Consortium, Adolescent Immunizations, Newton, United States of America, [2]University of Alabama at Birmingham, Department Of Pediatrics, School Of Medicine, Birmingham, United States of America

Introduction: Throughout the Pandemic, parents broadened their sources for vaccine information including sources via social media. Access to various perspectives across social media platforms is difficult to ignore, irrespective of scientific accuracy. Concurrently, adolescent and young adult (AYA) vaccine doses plummeted and just started to return to pre-pandemic levels. To improve our understanding of the impact of vaccine information sourcing across digital/social media platforms, Unity conducted two independent market research studies that analyzed the influence of information sources on parental decisions to vaccinate their AYAs.

Methods: Unity conducted multiwave, online survey research on preventive health and immunizations with a U.S. representative group of parents of adolescents (n=500/wave), oversampling disproportionately impacted groups, considering income, household location and race/ethnicity. Surveys were fielded in August 2020, February and June 2021. The survey instrument was repeated across waves and updated in waves 2 and 3 with COVID-19 vaccine availability. In November/December 2021, Unity delved into vaccine confidence, information sourcing and social media with multiphase, mixed methods research. Unity conducted asynchronous online board group discussions with parents (n=60) of AYAs and in-depth discussions with parent triads (n=18) stratified by vaccine beliefs.

Results: Vaccine safety concerns continue to rise (1). There is confusion about trusted sources and doubt in expert opinions, even amongst previously vaccine positive parents (2). Parents seek information from their trusted sources, choosing HCPs as most credible
(3).

Table 1: Parents' Perspectives on Vaccine Safety and Vaccine Information on Social Media (% Agreement with Statements)

Parents' concerns about vaccine safety continue to rise

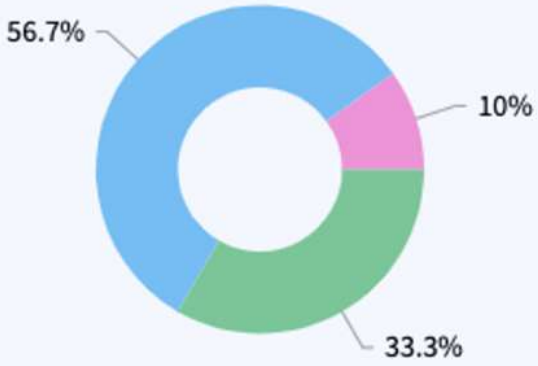
Capital letters (A,B,C,D) indicate significance at the 95 CL

Source: Unity® Survey conducted in Aug/Sept 2020, Feb 2021, June 2021, Participants by Wave: Teens 13-18 YO (n=300) for each of the 3 Waves. Parents/Guardians of Teens - Wave 1: (n=582), weighted sample, Wave 2: (n=531), Wave 3: (n=500).

Q15. To what extent do you agree or disagree with the following statements?
Statement Agreement(rating T2B: 5-Strongly Agree/ 1-Strongly Disagree)

Table 2: Parents' reported vaccine confidence over the past two years

- My confidence in vaccines has increased over the past year or two
- My confidence in vaccines has stayed the same over the past year or two
- My confidence in vaccines has decreased over the past year or two



Vaccine confidence has decreased in 1/3 of parents during the Pandemic, with Black and Hispanic parents reporting a lower rate of decrease, and rural, Caucasian parents showing a higher rate of decrease.

Source: Unity® conducted multiphase online research, Nov-Dec 2021: Phase 1 interviews, n=5, social media healthcare influencers; Phase 2, parents of adolescents, n=60, online bulletin boards; Phase 3, Parents, n=18, triad focus groups.

Table 3: Crediblity Continuum

More Credibility

Less Credibility

Sources	Participant Quotes - Online Discussion Board Posts
Health Care Provider Trust in personal doctors has decreased, though remains most important influence	*"I prefer to talk to my pediatrician and read the materials provided to make informed decisions."* *"None of those other sources have a personal loyalty to or interest in my children or my family."*
Scientific Community Many find comfort in scientific, medically backed data, especially with source links	*"I look at it all, but in the end, I trust the expert doctors and scientists."* *"I follow the advise of the medical community to make my decision on whether or not to get vaccinated."*
Personal Experiences Parents trust other parents and seek stories and experiences	*"A few things I did find helpful... were trusted medical friends sharing their opinions on vaccines."* *"I prefer to see updates from friends, family and acquantiances who have experienced the vaccine"*
Government Agencies Majority believe governmentt agencies are vaccine experts, interest is public health; while a small minority question the integrity of CDC, FDA, etc.	*"I'm not a fan of government websites in general...[they are] broad and not providing detailed information....I will consult the CDC website since I believe they are closest to what's going on with the virus and the vaccine"*
None of the above Small but vocal group do not find any credible sources, distrust government and almost all in rural areas	*"I don't think any information is relevant...because it is all one-sided."*

Source: Unity® conducted multiphase online research, Nov-Dec 2021: Phase 1 interviews, n=5, social media healthcare influencers; Phase 2, parents of adolescents, n=60, online bulletin boards; Phase 3, Parents, n=18, triad focus groups.

Conclusions: Unity's research uniquely assessed sources and their influence on parents' decisions to vaccinate their AYAs. COVID-19 heightened skepticism on vaccine information, with many sources fueling safety concerns. HCPs remained trusted messengers, however, government organizations declined in credibility. The high levels of contradictory information, the need to check multiple sources, and knowledge that their decisions impact their adolescent's future increased parental stress. HCPs should consider routine processes for actively disseminating vaccine information across digital communication channels to address vaccine concerns.

Shift 01-148 / #968

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03H. VACCINE SAFETY
04-18-2023 7:00 AM - 5:00 PM

DETERMINANTS FOR ANTI-HPV VACCINE IN THE ARAB STATES OF THE MIDDLE EAST AND NORTH AFRICA REGION: A SYSTEMATIC REVIEW.

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Introduction: Even though the HPV vaccine is the recommended prevention strategy for viruses-related cancers, its acceptability remains controversial due to social, cultural, and, ethical issues. Countries in the Middle East and North Africa are conservative and rarely discuss sexuality-related diseases and their prevention.

Methods: A systematic search was conducted across 4 electronic databases: google scholar, PubMed, Cochran, and EMBASE, to identify studies related to HPV vaccination determinants in the region between January 2012 and January 2022.

Results: Fifteen studies from 9 countries were identified. The analysis showed low to moderate HPV infection knowledge and anti-HPV vaccine awareness. Broad gaps in knowledge, willingness, Cost, vaccine safety concerns, patients' false perception of being at low risk to contract HPVand cultural issues were highlighted regarding HPV vaccine acceptability

Conclusions: The MENA region should acknowledge the changes in sexual behavior among the population by implementing comprehensive national screening programs for HPV and promoting and implementing HPV vaccine use in the universal vaccination coverage in the MENA region.

Shift 01-149 / #1011

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03I. IMPACTS OF COVID-19 PANDEMIC ON HPV VACCINATION IMPLEMENTATION
04-18-2023 7:00 AM - 5:00 PM

HPV VACCINATION DURING THE COVID-19 CONTEXT: MOZAMBIQUE HPV VACCINE INTRODUCTION EXPERIENCE

Lucy Kiarie
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Introduction: Globally, cervical cancer, caused by human papillomavirus (HPV) infection, is the fourth most frequently diagnosed cancer and the fourth leading cause of cancer deaths in women, with an estimated 604,000 new cases and 342,000 deaths in 2020 (Sunget al., 2021). In Mozambique, the annual incidence of cervical cancer is estimated at 50 cases per 100,000 women and 3,300 deaths (WHO cervical cancer country profile, 2021). It is among the highest in the world and by far the most frequent cancer in women of all age groups and with the highest mortality rate.

Methods: As a Cervical cancer prevention strategy, Mozambique implemented an HPV vaccine demonstration project in 2014-2015 in three regions (North, Center, and South), targeting girls aged ten using schools, health facilities, and communities for delivery. Lessons learned from the demonstration project informed the national scale-up in November 2021, initially scheduled for April 2021, but planning was impacted by the COVID-19 (C-19) Pandemic. The service delivery methods adopted were school campaigns, health facilities, and community-based models (mobile brigades).

Results: Competing C-19 vaccine planning and distribution led to inadequate support for HPV vaccine introduction planning sub-nationally as the inadequate staff focused on C-19 vaccination. C-19 physical distancing measures changed healthcare workers' training and introduction readiness assessment to virtual despite the lack of a stable and equitable internet nationally. The HPV vaccine was introduced while schools were closed.

Conclusions: Virtual training is not suitable for new vaccine introduction. Provinces where a physical readiness assessment was done, scored lower than those with a virtual assessment. The HPV vaccine introduction timing should align with delivery strategies, and contingency delivery plans should be developed, as demonstrated by the timing of the Mozambique HPV vaccine introduction when schools were closed despite mapping and linking schools with health facilities in anticipation of school vaccine delivery.

Shift 01-150 / #1617

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03I. IMPACTS OF COVID-19 PANDEMIC ON HPV VACCINATION IMPLEMENTATION
04-18-2023 7:00 AM - 5:00 PM

ONGOING NEED FOR HPV/CC OUTREACH TO PROMOTE ENGAGEMENT WITH CC SCREENING AND HPV VACCINATION IN MALI

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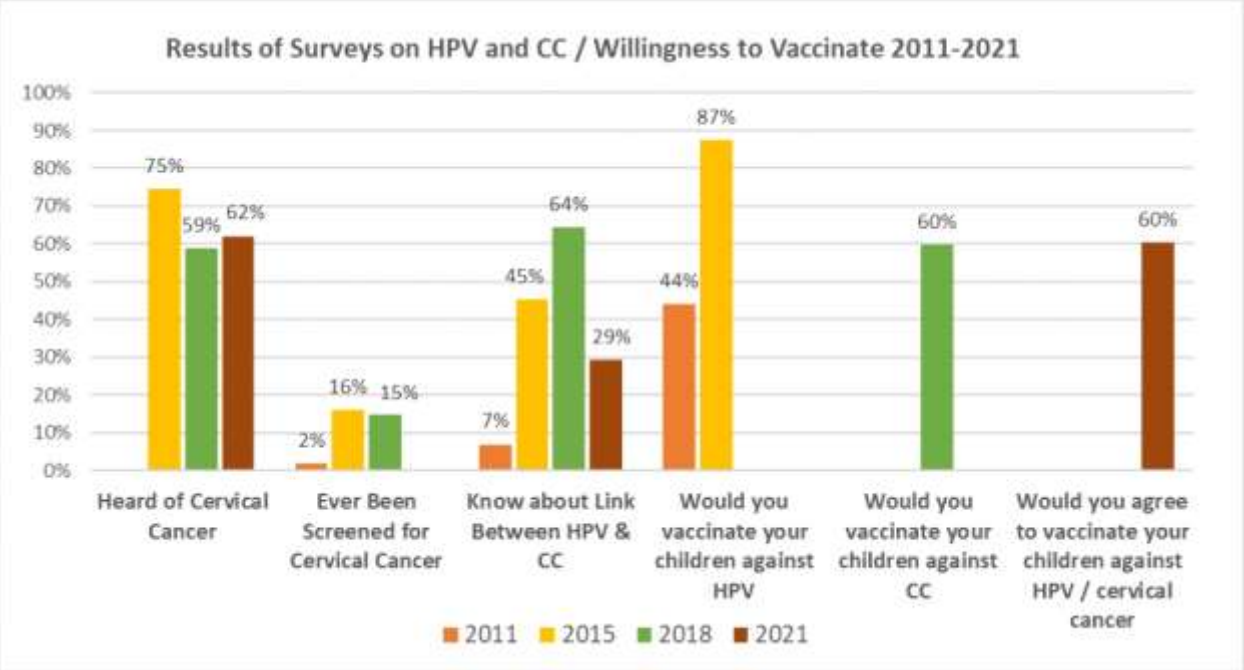
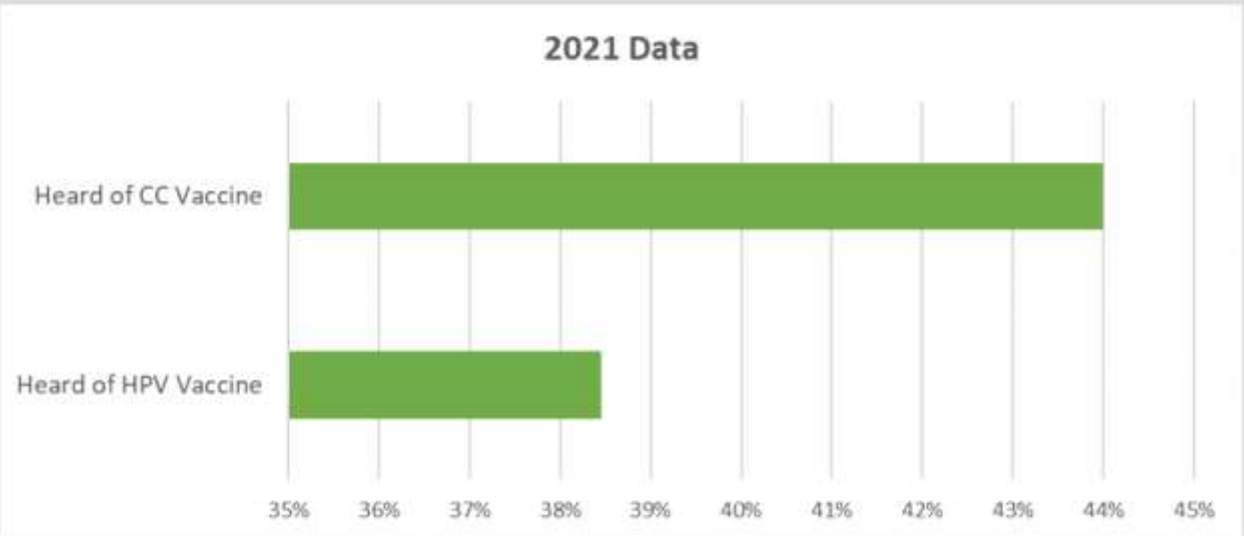
Introduction: Each year almost 2,000 Malian women are diagnosed with cervical cancer (CC) and 1,400 die from the disease. A safe, effective vaccine exists, but it is not available in Mali. In a 2011 study in Bamako, we found that 82.5% of CC biopsies were positive for HPV 16 and 18, and less than 3% of women surveyed reported ever being screened for CC. The findings from the 2011 study launched three campaigns to increase CC screening rates and HPV vaccine acceptability in Bamako.

Methods: In 2015, 2018, and 2021, GAIA Vaccine Foundation organized community-level outreach about CC and HPV in Commune I of Bamako, Mali. The 2015 project focused specifically on CC screenings and increasing HPV vaccine acceptance. The 2018 project combined healthcare-worker outreach to promote CC screenings of mothers and vaccination of their daughters during a GAVI-funded HPV vaccination pilot. The 2021 project focused on reinforcing primary care vaccination recommendations for childhood, COVID and HPV vaccines.

Results: Overall, awareness about HPV and CC increased, along with vaccine acceptability. However, there is some confusion over the terminology associated with the vaccine (in 2021, 6% more people heard of the “CC Vaccine” than the “HPV Vaccine”). A slight decrease in willingness to vaccinate may be related to increased vaccine misinformation associated with the coronavirus pandemic (67% of people reported hearing vaccine misinformation in
2021).





Have you heard these rumors about COVID-19 Vaccines					
	Vaccine contains microchips	Vaccine contains magnets	Vaccine will change my DNA	Vaccine will cause COVID-19	Vaccine will turn me into a zombie
Never heard	1167	1198	1107	873	1229
Heard and thinks it's possible	559	499	568	625	403
Heard but don't believe	1535	1594	1631	1764	1644
Heard and believe	128	98	72	108	70

Conclusions: Access to the life-saving HPV vaccine is delayed in Mali, contributing to ongoing deaths from a preventable, highly lethal, cancer. Community-level knowledge about HPV and its link with CC decreased dramatically from 2018 to 2021. Yet, once the dangers are explained, Malians remained willing to vaccinate their children. When the vaccine becomes available, widespread outreach will be necessary to remind parents of the link between HPV and CC to ensure they remain willing to vaccination their children.

Shift 01-151 / #1733

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03I. IMPACTS OF COVID-19 PANDEMIC ON HPV VACCINATION IMPLEMENTATION
04-18-2023 7:00 AM - 5:00 PM

"WHAT'S MISSING?": PUBLIC HEALTH CAMPAIGN ADDRESSING MISSED HPV AND CHILDHOOD VACCINATIONS DURING THE COVID-19 PANDEMIC

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Introduction: ~25% of children in Canada missed a routine childhood vaccine (RCV) during the COVID-19 pandemic. School-based vaccine programs were particularly affected, and the human papillomavirus (HPV) vaccine fell from 64% to <1% for students in Ontario. This study aims to understand parents' perspectives towards RCVs, and to develop a campaign to alert parents that their child may be behind on their RCVs.

Methods: A cross-sectional survey of parents from Ontario was completed in July 2022. The survey explored uptake of and attitudes towards RCVs given in schools (e.g., HPV, Hepatitis B, and Meningococcal), and their knowledge and understanding of the HPV vaccine. Based on the survey results, a campaign titled "What's Missing?" was developed and messaged tested through focus groups prior to launching on social media in the Fall 2022. The goal of the campaign was to drive parents to catch-up clinics at local public health units in Ontario to vaccinate their

child.

Results: 778 parents completed the survey. Overall, 85.6% of parents were aware that RCVs are given in schools. 69.9% of parents felt that accessing RCVs during the pandemic was challenging. However, 71.6% felt that the pandemic did not affect their attitude towards RCVs and 43.2% are likely to ensure that their child receives the HPV vaccine. Only 20.3% of Ontario parents were aware that they must pay for the HPV vaccine if their child does not receive it by Grade 12. Overall, social media metrics indicated that the "What's Missing?" campaign reached ~30 million people (non-unique users), including ~11 million impressions through earned and paid media.

Conclusions: Declines in school-based vaccinations were driven largely by lack of access due to school and health system closures during the pandemic. A public health campaign focused on increasing vaccination was effective at raising awareness about the issue of missed school-based RCVs.

Shift 01-152 / #726

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03J. IMPACTS OF COVID-19 PANDEMIC ON PUBLIC HEALTH ASPECTS OF HPV SCREENING
04-18-2023 7:00 AM - 5:00 PM

IMPACT OF COVID-19 ON CERVICAL CANCER SCREENING PROGRAMS ACROSS THE GLOBE

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Introduction: The COVID-19 pandemic disrupted many public health programs; understanding these disruptions is critical for directing future resources. In a project studying the implementation of human papilloma virus (HPV) testing-based cervical cancer screening, we queried about the pandemic and its impact on programs globally.

Methods: In consultation with World Health Organization's Regional Advisors, program managers, government officials, and clinicians involved in the implementation of HPV testing-based cervical cancer screening programs were invited to participate in semi-structured, in-depth, interviews. Interview notes and transcripts were used for inductive analysis, focusing on responses to the impact of COVID-19 pandemic on screening programs.

Results: Thirty-two interviews were conducted with participants between the age of 29 to 61 years that represented programs from 25 countries. Six key themes were noted. Regarding disruptions, (1) the entire cancer continuum was affected, leading to delays or, in some cases even cessation, of vaccination, screening, and treatment programs; (2) competing priorities led to a shift in government commitment, financing, and human resource allocation; and (3) a heightened sense of fear decreased community outreach and engagement, and trust in the healthcare system. Nonetheless, participants noted constructive ways in which programs leveraged the impact of the pandemic: (1) at the community level, participants were able to leverage an increased understanding and acceptance around the importance of preventive health behaviors; (2) many laboratories became well-equipped with molecular testing-trained technicians, increasing overall HPV-testing capacities; and (3) shutdowns gave them time to plan for scale-up of programs while the overall pandemic response provided evidence supporting the country's ability to mobilize resources when needed.

Conclusions: While disruptions were noted, the pandemic provided implementers with opportunities to strengthen screening programs. Future research should assess how the pandemic changes to the healthcare system might impact sustainability in cervical cancer prevention and control.

Shift 01-153 / #1393

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03J. IMPACTS OF COVID-19 PANDEMIC ON PUBLIC HEALTH ASPECTS OF HPV SCREENING
04-18-2023 7:00 AM - 5:00 PM

CERVICAL CANCER SCREENING IMPROVEMENTS WITH SELF-SAMPLING PRECIPITATED BY THE COVID-19 PANDEMIC

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Introduction: At the onset of the COVID-19 pandemic cervical screening in the capital region of Sweden was cancelled for several months. Several measures to preserve and improve the cervical screening under the circumstances were instituted, including a switch to screening with self-sampling to enable screening without crowding and risk for infection.

Methods: We describe the major changes implemented, which were i) nationwide implementation of HPV screening ii) switch to primary self-sampling instead of sampling by healthcare personnel iii) implementation of HPV screening in all screening ages and iv) combined HPV vaccination and HPV screening in the cervical screening program.

Results: A temporary government regulation allowed primary self-sampling with HPV screening in all ages. In the Stockholm region 330,000 self-sampling kits were sent to the home address of screening-eligible women, instead of invitation to screening by healthcare personnel. A rapid increase in population test coverage was seen. In addition, a national campaign for faster elimination of cervical cancer with concomitant screening and vaccination for women in ages 23- 28 was launched.

Conclusions: The Covid-19 pandemic necessitated major changes in the cervical cancer preventive strategies, where it can already be concluded that the strategy with organised primary self-sampling for HPV has resulted in a major improvement.

Shift 01-154 / #1427

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03J. IMPACTS OF COVID-19 PANDEMIC ON PUBLIC HEALTH ASPECTS OF HPV SCREENING
04-18-2023 7:00 AM - 5:00 PM

ASSOCIATIONS OF OBESITY WITH CERVICAL CANCER SCREENING IN THE NATIONAL HEALTH INTERVIEW SURVEY

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Introduction: Obesity is a risk factor for cervical cancer, potentially due to decreased screening and/or decreased efficacy of screening among individuals with obesity. Rates of cervical cancer screening declined substantially within the first year of _the COVID-19 pandemic. Whether these declines occurred more drastically in patients with risk factors for COVID-19, such as obesity, is unknown. We evaluated nationally representative associations of BMI with cervical cancer screening both before and after the COVID-19 pandemic in the 2019 and 2021 National Health Interview Survey (NHIS).

Methods: We estimated weighted, multivariable-adjusted odds ratios (ORs) and 95% confidence intervals (95% CI) for associations of categorical BMI (underweight/normal [<25 kg/m^2], overweight [25-29.9 kg/m^2], obese [30+ kg/m^2]) with cervical cancer screening (guideline concordant and ever/never screening) among 10,473 females ages 21-65 in the 2019 NHIS who did not have a hysterectomy. We adjusted for age, race/ethnicity, smoking, insurance, income, education, region, and urbanicity. We additionally compared prevalence and multivariable-adjusted odds of screening within the last year in 2019 and 2021.

Results: BMI was not associated with screening when accounting for covariates (Table 1; meets screening recommendations: overweight OR=0.94 (95%CI 0.79-1.11), obese OR=0.98 (95%CI 0.82-1.16); ever screened: overweight OR=0.93 (95%CI 0.77-1.12), obese OR=0.95 (95%CI 0.78-1.15)). Prevalence of screening within the last year decreased from 46.3% in 2019 to 39.9% in 2021 (Figure 1). When adjusted for covariates, BMI was not associated with screening in either year (Table

Table 1. Associations of cervical cancer screening with BMI and covariates in the 2019 NHIS

	Met Guidelines OR (95% CI)	Ever screened OR (95% CI)
BMI (kg/m²)		
Underweight/Normal (<25)	-	-
Overweight (25 to <30)	0.94 (0.79 - 1.11)	0.93 (0.77 - 1.12)
Obese (30+)	0.98 (0.82 - 1.16)	0.95 (0.78 - 1.15)
Age		
21-64	1.01 (1.00 - 1.01)	1.02 (1.01 - 1.03)
Race/Ethnicity		
Hispanic	0.95 (0.77 - 1.16)	0.70 (0.56 - 0.89)
NH White	-	-
NH Black	1.24 (0.99 - 1.56)	0.88 (0.68 - 1.12)
NH Asian	0.39 (0.30 - 0.50)	0.30 (0.23 - 0.40)
NH AIAN	0.96 (0.40 - 2.29)	0.73 (0.24 - 2.25)
Other single or multiple races	0.60 (0.36 - 0.99)	0.51 (0.30 - 0.86)
Smoking status		
Current	0.87 (0.74 - 1.04)	1.43 (1.15 - 1.78)
Former	1.20 (0.995 - 1.45)	1.52 (1.21 - 1.90)
Never	-	-
Insurance status		
Not covered	0.47 (0.39 - 0.57)	0.67 (0.55 - 0.83)
Covered	-	-
Income		
$0-$34,999	0.52 (0.41 - 0.65)	0.57 (0.44 - 0.73)
$35,000-$49,999	0.62 (0.48 - 0.79)	0.71 (0.53 - 0.94)
$50,000-$74,999	0.70 (0.57 - 0.87)	0.86 (0.67 - 1.12)
$75,000-$99,999	0.83 (0.65 - 1.06)	0.84 (0.63 - 1.12)
$100,000+	-	-
Education		
Did not graduate HS	0.40 (0.30 - 0.52)	0.34 (0.25 - 0.47)
HS graduate or GED	0.45 (0.37 - 0.55)	0.42 (0.34 - 0.53)
Some college	0.57 (0.46 - 0.70)	0.50 (0.39 - 0.64)
Associate or technical degree	0.68 (0.55 - 0.83)	0.71 (0.56 - 0.91)
Bachelor's degree or higher	-	-
Region		
Northeast	0.95 (0.77 - 1.18)	0.92 (0.72 - 1.19)
Midwest	0.90 (0.75 - 1.08)	0.99 (0.80 - 1.24)
South	-	-
West	1.07 (0.88 - 1.30)	1.11 (0.89 - 1.40)
Urban/rural classification		
Large central metro	-	-
Large fringe metro	1.00 (0.83 - 1.21)	1.02 (0.83 - 1.26)
Medium and small metro	0.95 (0.80 - 1.12)	1.00 (0.83 - 1.22)
Nonmetropolitan	0.97 (0.78 - 1.20)	1.15 (0.86 - 1.53)

*Met guidelines=21-29 years: Pap test every 3 years; 30-65 years: Pap/HPV test every 5 years, independent Pap test every 3 years, or independent HPV test every 5 years
*Guidelines model: includes hysterectomy correction; n=9,908
*Ever screened model: no hysterectomy correction; n=10,473

2).

Figure 1. Unadjusted prevalence of screening within the last year, overall and by BMI category, in the 2019 and 2021 NHIS

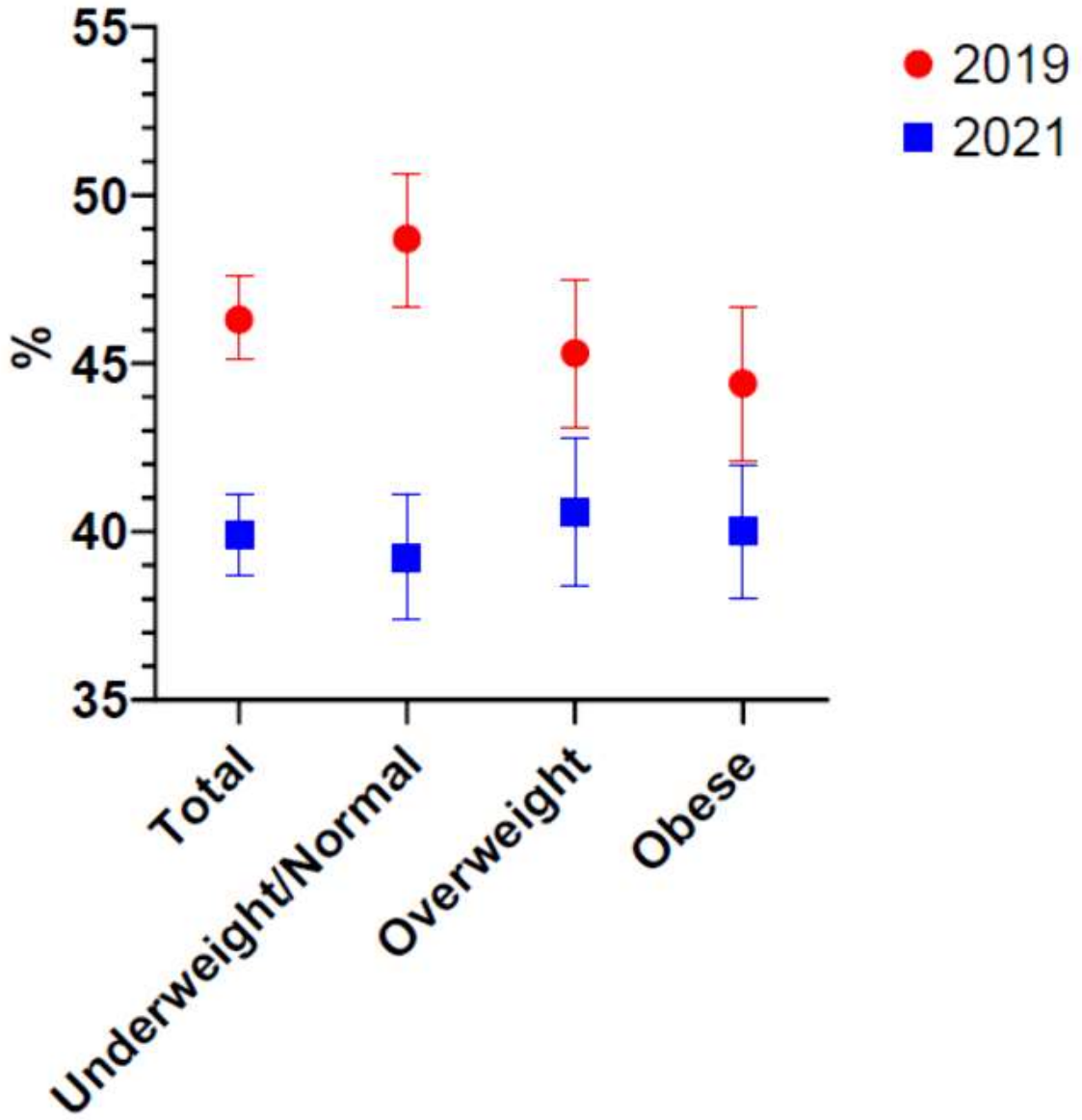

Table 2. Associations of recent cervical cancer screening with BMI and covariates in the 2019 and 2021 NHIS

	Screening <1 year OR (95% CI)	
	2019	2021
BMI (kg/m²)		
Underweight/Normal (<25)	-	-
Overweight (25 to <30)	0.90 (0.79 - 1.01)	1.10 (0.98 - 1.24)
Obese (30+)	0.90 (0.79 - 1.02)	1.04 (0.92 - 1.19)
Age		
21-64	0.99 (0.985 - 0.993)	0.99 (0.98 - 0.99)
Race/Ethnicity		
Hispanic	1.18 (1.01 - 1.36)	1.13 (0.97 - 1.31)
NH White	-	-
NH Black	1.39 (1.19 - 1.64)	1.43 (1.20 - 1.71)
NH Asian	0.73 (0.60 - 0.90)	0.71 (0.58 - 0.87)
NH AIAN	1.08 (0.72 - 1.61)	1.19 (0.83 - 1.69)
Other single or multiple races	0.98 (0.66 - 1.44)	0.99 (0.66 - 1.49)
Smoking status		
Current	0.82 (0.71 - 0.95)	0.82 (0.69 - 0.97)
Former	1.06 (0.93 - 1.21)	1.11 (0.97 - 1.27)
Never	-	-
Insurance status		
Not covered	0.47 (0.39 - 0.56)	0.47 (0.38 - 0.59)
Covered	-	-
Poverty ratio		
1st tertile	0.78 (0.67 - 0.90)	0.80 (0.69 - 0.93)
2nd tertile	0.89 (0.79 - 1.01)	0.91 (0.80 - 1.04)
3rd tertile	-	-
Education		
Did not graduate HS	0.77 (0.61 - 0.97)	0.79 (0.61 - 1.02)
HS graduate or GED	0.76 (0.66 - 0.87)	0.79 (0.67 - 0.92)
Some college	0.86 (0.74 - 1.00)	0.81 (0.68 - 0.96)
Associate or technical degree	0.98 (0.84 - 1.14)	0.93 (0.79 - 1.09)
Bachelor's degree or higher	-	-
Region		
Northeast	0.94 (0.81 - 1.09)	0.93 (0.80 - 1.08)
Midwest	0.82 (0.71 - 0.95)	0.92 (0.79 - 1.06)
South	-	-
West	0.79 (0.69 - 0.90)	0.74 (0.65 - 0.85)
Urban/rural classification		
Large central metro	-	-
Large fringe metro	0.92 (0.80 - 1.05)	1.08 (0.94 - 1.23)
Medium and small metro	0.89 (0.78 - 1.02)	1.08 (0.94 - 1.25)
Nonmetropolitan	0.92 (0.78 - 1.09)	1.03 (0.85 - 1.25)

*Recent screening models include hysterectomy correction; n=9,908

*Poverty ratio (PR) used as proxy for income; income variable was not available in 2021 NHIS. A sensitivity analysis was performed of guidelines/ever screened models using PR instead of income; results were similar.

*2019 PR tertiles=0-2, 2-4.5, 4.5-10

*2021 PR tertiles=0-2.3, 2.3-4.82, 4.82-11

Conclusions: Obesity was not associated with reduced cervical cancer screening. Prevalence of recent screening decreased during the COVID-19 pandemic; this decrease was non-differential by BMI. Our findings suggest that the association between obesity and cervical cancer is likely not driven by less

screening among females with elevated BMI. Decreases in screening rates during the COVID-19 pandemic were not differential by COVID-19 risk factors such as obesity.

Shift 01-155 / #503

Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01B. ANIMAL MODELS AND PAPILLOMAVIRUSES
04-18-2023 7:00 AM - 5:00 PM

PASSIVE IMMUNIZATION WITH A SINGLE MONOCLONAL NEUTRALIZING ANTIBODY PROTECTS AGAINST CUTANEOUS AND MUCOSAL MOUSE PAPILLOMAVIRUS INFECTIONS

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Introduction: Mouse papillomavirus (MmuPV1) induces both cutaneous and mucosal infections and cancers in numerous laboratory mouse strains. We tested a neutralizing monoclonal antibody (MPV.A4) and its ability to protect mice against infection with MmuPV1 at several clinically relevant mucosal and cutaneous sites.

Methods: Mice were inoculated with MmuPV1 following established protocols either before or after antibody infusion. Lavages were collected to monitor mucosal site infections by QPCR. Tissues were harvested at the termination of the experiments and tested for viral RNA/DNA by QPCR and tissue analyses (H&E, in situ hybridization (ISH), RNA in situ hybridization (RNA-ISH), and immunohistochemistry (IHC)).

Results: Significantly lower levels of viral signals were detected in the MPV.A4 treated female mice up to 6-hours post-viral inoculation compared to the isotype control. Males displayed partial protection when they received MPV.A4 at the time of viral inoculation, even though they were completely protected when receiving MPV.A4 at 24 hours before viral inoculation. A site differential was seen in female mice as the anus was not as protected against viral inoculation. The sex difference in males may be from the lack of antibody in the tested tissues as they may have rapidly cleared the IgG2a antibodies (MPV.A4 and the control antibody). Female mice were also partially protected when antibody was infused at 6 hours post viral inoculation. This result demonstrates that some of the virus had not entered the cells at this time point.

Conclusions: More experiments need to be conducted to determine the observed sex bias. Weight, isotype of antibodies, mouse strain, sex hormones and/or receptors could all play a role. We plan to test an isotype switch variant for MPV.A4 to determine if the males clear a different isotype. Findings from this study provide opportunities to further study the mechanisms of antibody blocking papillomavirus infections in different tissues.

Shift 01-156 / #783

Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01B. ANIMAL MODELS AND PAPILLOMAVIRUSES
04-18-2023 7:00 AM - 5:00 PM

CANNABIS SMOKING PROMOTES ORAL PAPILLOMAVIRUS INFECTIONS IN MALE MICE

Sarah Brendle[1], Jingwei Li[1], Zachary Bitzer[2], Wesley Raup-Konsavage[3], Junjia Zhu[2], Danielle Covington[4], Karla Balogh[1], Debra A. Shearer Shearer[1], Michael Kozak[1], Dongxiao Sun[3], Neil Christensen[5], Kent Vrana[3], John Richie[6], Jiafen Hu[1]
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Introduction: Human papillomavirus (HPV) -associated oropharyngeal cancer cases have surpassed invasive cervical cancer cases during the past two decades. Cannabis inhalation has been linked to HPV-associated oropharyngeal cancer. Currently, many states are legalizing various aspects of marijuana use and 1 in 16 youths in the U.S. are daily cannabis users. This forecasts a further uptick in HPV-associated cancer. We hypothesize that cannabis smoking increases HPV infections and associated oropharyngeal cancers.

Methods: C57BL/6 mice (4-6 weeks old) were exposed to either air, cannabis, or placebo cigarettes three times a week for four weeks using a customized two-port puffing exposure machine before infection with the mouse papillomavirus (MmuPV1) in the oral cavity. Following infection mice were exposed to an additional four weeks of exposure before the termination of the experiment. THC in the blood was measured by HPLC-MS-MS. Viral transcripts were detected by qPCR analysis. Antibody against viral proteins was tested by ELISA.

Results: We detected significantly lower weight gain in male but not female mice at two time points in both smoking groups when compared with the air control group ($p<0.05$, Tukey-Kramer). Low, but detectable THC levels were found in the blood of cannabis smoking mice up to 6 hours post-delivery. Viral RNA levels in males of the placebo and cannabis smoking groups were higher than those in males of the control air group (but not significant). Levels of viral RNA were also higher in males of the cannabis smoking group when compared with males of the placebo smoking group (but not significantly). All infected mice developed antibodies against MmuPV1 E4 protein. Female mice showed significantly higher levels of E4 IgG3 when compared with corresponding males in all groups ($p<0.01$, Two-way ANOVA).

Conclusions: Our findings suggest that, as documented for cigarette smoking, cannabis smoking might play a role in promoting HPV infections.

Shift 01-157 / #1676

Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01C. IMMUNOLOGY
04-18-2023 7:00 AM - 5:00 PM

CERVARIX VACCINATION SHAPES THE SIZE AND HETEROGENEITY OF HPV-SPECIFIC HUMAN MEMORY B CELL COMPARTMENT

Brian Dizon[1], Prasida Holla[2], Cynthia Thompson[3], Nicolas Cuburu[4], Mónica Sierra[5], Bernal Cortes[6], Rolando Herrero[7], Michael Zuniga[6], Carolina Porras[6], Byron Romero[6], Kate Torres[8], John Schiller[9], Susan Pierce[1]
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Introduction: The bivalent HPV vaccine Cervarix is remarkably effective in inducing neutralizing antibodies that persist for at least a decade and protect against HPV16/18 infections. Given the availability of PBMCs and serum from participants in the Costa Rica HPV Vaccine Trial (CVT) three years after a one- or three-dose vaccination regimen, we aimed to understand protective long-lived immunity in humans by first evaluating the cellular composition of B cells induced by Cervarix at three years post-vaccination.

Methods: For 10 participants in the CVT trial and five unvaccinated individuals, we assessed: 1) the levels and isotypes of HPV-specific antibodies in serum by ELISA and 2) the frequencies and phenotypes of HPV-specific B cells by flow cytometry with fluorescently-labeled HPV 16L1 virus-like particles (VLP) and an extensive panel of antibodies.

Results: The serum of vaccinated individuals contained ~56µg/mL HPV-specific IgG, 70-fold higher as compared to unvaccinated individuals. The frequency of VLP-specific B cells among total B cells was 0.005 in unvaccinated individuals, and the majority of these were IgM^+ suggesting their naïve phenotype. In contrast, the frequency of VLP-specific B cells in individuals who received one dose of vaccine was 0.012 (2.4-fold increase over unvaccinated), a frequency that did not increase following vaccination with three doses. The majority of these B cells were IgG+ memory B cells (MBCs), and their frequency correlated with the levels of VLP-specific IgG (Figure 1). Additional phenotyping showed that particular MBC subpopulations were expanded following vaccination, while others were contracted. Lastly, B cells expressing the inherently autoreactive V_H gene VH4-34 contributed to the VLP-specific MBC pool,

suggesting that Cervarix may function to recruit such cells into the VLP-specific response.

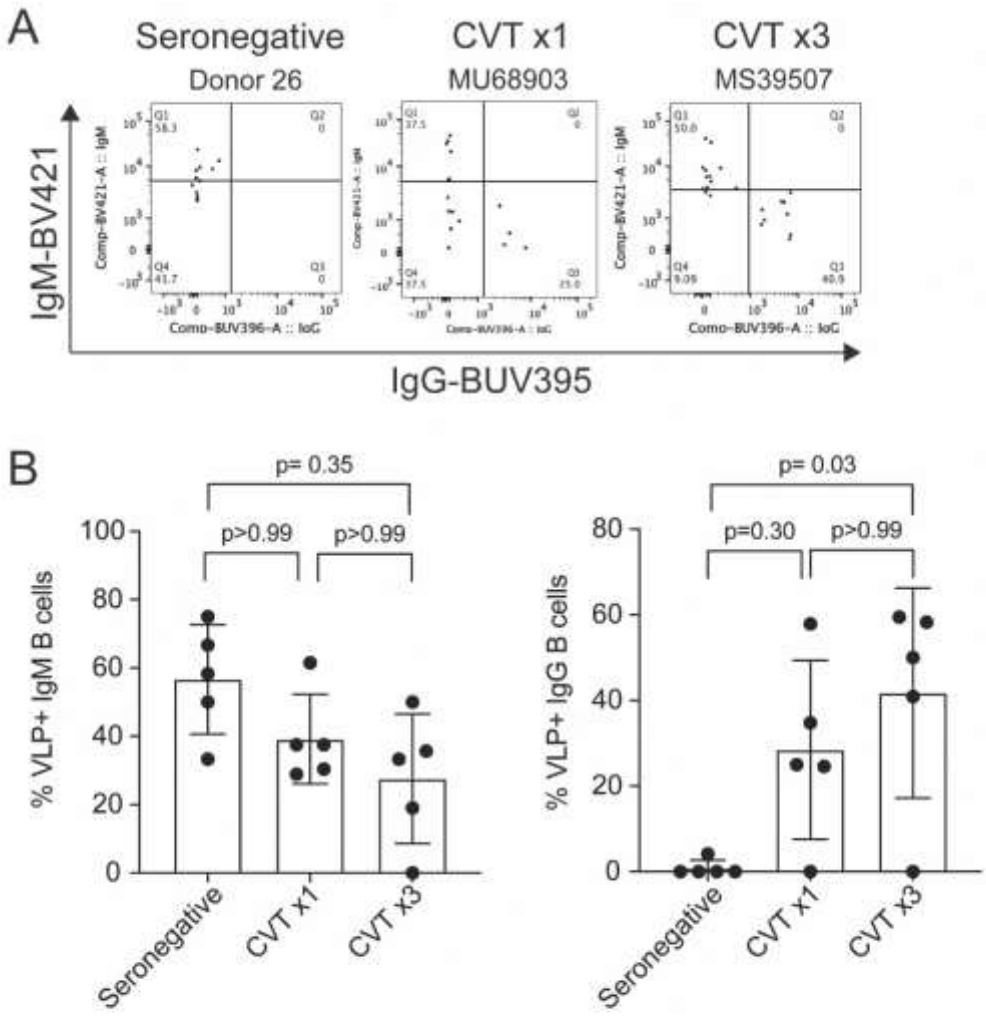

Figure 1. Analysis of class-switching to IgG in VLP16-specific B cells in participants vaccinated with Cervarix. Representative flow cytometry plots of VLP16-specific B cells in seronegative unvaccinated subjects and CVT participants receiving one dose (CVT x1) or three doses (CVT x3) of Cervarix are shown in A. Frequencies of total VLP16+ B cells of total CD19+ B cells are shown in B. The percentages of IgM$^+$ (left) and IgG$^+$ (right) B cells among VLP16+ B cells are shown in C. p-value <0.05 was considered statistically significant.

Conclusions: It will be of interest to determine if these Cervarix-induced changes in the distribution of MBC subpopulations contribute to effective long-lasting immunity to HPV.

Shift 01-158 / #873

Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01E. TRANSFORMATION AND CARCINOGENESIS
04-18-2023 7:00 AM - 5:00 PM

STEMNESS ENHANCEMENT IN HPV18-ASSOCIATED CERVICAL ADENOCARCINOMA; SINGLE CELL ANALYSIS OF HPV18-ASSOCIATED TUMORS GENERATED FROM IPS CELL-DERIVED CERVICAL RESERVE (IRC) CELLS

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Introduction: Although mechanisms of HPV-associated carcinogenesis are well-known, the difference between carcinogenesis caused by HPV16 and 18 remains unknown. We here generated HPV18 E6/E7-associated adenocarcinoma in mice model using an induced reserve cell-like cells (iRCs) derived from iPS cells. Here we examined the gene expression profile of the iRC-18 tumor.

Methods: HPV18 E6/E7-iRC (iRC18) and HPV16 E6/E7-iRC (iRC16) were generated by transfecting each E6 and E7. For comparison, HCK cells derived from the cervical squamo-columnar junction (SCJ) were also transfected with HPV16 or 18 E6/E7 (HCK-16/18). Gene expression profiles in iRC16 and iRC18 were examined by RNA sequencing. Each cell mixed with matrigel were injected into immunocompromised mice to form tumors for in vivo assay. These tumors were stained with HE and immunohistochemistry. Furthermore, iRC18 tumors were evaluated by single-cell analysis.

Results: By comparison of RNA expression of iRC, some undifferentiated markers and adenocarcinoma markers were more highly expressed in iRC18 than in iRC16. iRC-16 or -18 cells formed tumors while HCK-16/18 didn't. Tumor formation speed was faster in iRC18 than in iRC16. Adenocarcinoma in site (AIS) was observed in iRC16 and iRC18-tumors whereas barely observed in iRCcontrol-tumors. iRC18 tumor was more likely to differentiate into adenocarcinoma histologically and to grow rapidly than iRC16. Immunostaining assay revealed the AIS components had the expression of cancer stem cell (CSC) markers and adenocarcinoma (ADC) marker. Single-cell analysis showed that some gene pathway of CSC and ADC markers were enhanced in HPV18-positive cells among iRC18-tumors.

Conclusions: Our mice iRC16/18-tumor was the first model of HPV16/18-associated adenocarcinoma. iRC16/18 cells mimic the carcinogenesis of HPV-associated reserve cells residing the SCJ of the cervix. Our data demonstrated stem cell-related genes were enhanced in HPV18-positive cells with adenocarcinoma feature, indicating that HPV18-carcinogenesis is unique and has highly malignant potential.

Shift 01-159 / #1030

Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01E. TRANSFORMATION AND CARCINOGENESIS
04-18-2023 7:00 AM - 5:00 PM

MED-SEQ, A NOVEL METHOD FOR GENOME-WIDE DNA METHYLATION DETECTION, CAN BE USED TO CHARACTERIZE DIFFERENT GYNECOLOGICAL CANCERS AND ASSOCIATED HPV SUBTYPES

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Introduction: DNA methylation and the presence of HPV subtypes serves as an important markers in cancer, is applied to classify tumors and can predict disease outcome and treatment options.

Methods: We developed a novel method that generates genome-wide methylation profiles associated with pre-cancer and cancer at very low cost. The assay involves isolation and purification of DNA from formalin-fixed paraffine-embedded (FFPE) or fresh biopsies (only 10-50ng DNA is needed). This Methylated DNA sequencing (MeD-seq) assay is very robust, allowing detection of DNA methylation at more than 50% of the 30 million CpGs present in our genome as well as detection of HPV integrated DNA. With respect to costs and sequencing depth MeD-seq is superior to all available technologies and requires no DNA bisulphite treatment.

Results: We compared MeD-seq profiles of different types of cancers from vulva, cervix, endometrium, fallopian tube and ovary between cancers vs controls and cancers vs other cancers. Identification of Differentially Methylated regions (DMR's) was achieved by comparing MeD-seq profiles using genome wide statistical testing using a sliding window approach. DMR's found were used to classify gynecological cancers and determine overlap in cell type of origin. In addition to DNA methylation data, MeD-seq generates sequencing data which enables the detection of Human Papilloma Virus (HPV) DNA incorporated in the genome of HPV-infected cells. Around half of the gynecological cancer types in our study are HPV-associated and we were able to detect HPV genomic integration and call HPV subtypes based.

Conclusions: MeD-seq is a reliable low-cost technology to establish genome-wide DNA methylation profiles. DNA methylation profiles of cancers and controls can be used to characterize cell type origin of different cancers. In addition MeD-seq is able to detect HPV integration in host genomes and able to call specific HPV subtypes.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01E. TRANSFORMATION AND CARCINOGENESIS
04-18-2023 7:00 AM - 5:00 PM

THE PROOF-OF-PRINCIPLE OF MARKER DISCOVERY FOR DIFFERENT GYNECOLOGICAL CANCERS BY A NOVEL METHOD FOR GENOME-WIDE DNA METHYLATION PROFILING (MED-SEQ)

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Introduction: DNA methylation serves as an important marker for mis-regulation of gene expression in cancer, is applied to classify tumors and can predict disease outcome and treatment options.

Methods: We developed a novel method that facilitates genome-wide methylation marker discovery allowing successful identification of methylation changes associated with pre-cancer and cancer at very low cost. The assay involves isolation and purification of DNA from formalin-fixed paraffine-embedded (FFPE) or fresh biopsies (only 10-50ng DNA is needed). A DNA methylation dependent restriction enzyme digestion releases 32 base pair DNA methylated fragments that are sequenced by next generation sequencing. This Methylated DNA sequencing (MeD-seq) assay is very robust, allowing detection of DNA methylation at more than 50% of the 30 million CpGs present in our genome. With respect to costs and sequencing depth MeD-seq is superior to all available technologies and requires no DNA bisulphite treatment. MeD-seq is compatible with low amounts of DNA derived from solid tumor tissue enriched by laser capture microdissection (LCM) and liquid biopsies.

Results: We compared MeD-seq profiles of different types of cancers from vulva, cervix, endometrium, fallopian tube and ovary between cancers vs controls and cancers vs other cancers. Identification of Differentially Methylated regions (DMR) was achieved by comparing MeD-seq profiles using genome wide statistical testing using a sliding window approach, visualized through the Integrative GenomicsViewer (IGV) and subsequent identification of primer and probe regions for quantitative Methylation-specific PCRs (qMSP) to detect tumor-specific or general-tumor markers.

Conclusions: MeD-seq is a reliable low-cost technology to establish genome-wide DNA methylation profiles of FFPE treated laser dissected material of cancer and controls and can be used to call DMRs for development of PCR-based assays.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01E. TRANSFORMATION AND CARCINOGENESIS
04-18-2023 7:00 AM - 5:00 PM

FUNCTIONAL EVALUATION OF THE ROLE OF IMPORTIN KPNA2 IN CERVICAL CANCER DEVELOPMENT

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Introduction: KPNA2 belongs to the karyopherin α family which mediates the nucleocytoplasmic trafficking of
certain target proteins and RNAs. KPNA2 is overexpressed in multiple tumors associated with poor prognosis; however, its role has been poorly studied in cervical cancer (CC). The aim of this study was to investigate KPNA2 functional role and evaluate its differential expression in normal uterine cervix and cervical neoplasia.

Methods: Immunohistochemical analysis using anti-KPNA2 antibody was performed in 23 cases of cervical
intraepithelial neoplasia (CIN), 51 CC and 14 normal samples. A lentiviral vector carrying a shRNA for KPNA2 was utilized to transduce HeLa (HPV-18), SiHa (HPV-16) and C33A (HPV–) cells. Proliferation was assessed using CCK-8, while invasion and migration were evaluated using Transwell ® . Apoptosis and cell cycle were estimated using flow cytometry with Annexin V/7AAD and PI staining, respectively.

Results: All normal tissues exhibited negative KPNA2 expression, while KPNA2 increased in CIN; however, it was low in cells displaying a HPV cytopathic effect. Notably, 93.3% of adenocarcinomas, 100% of adenosquamous and squamous carcinomas displayed immunoreactivity for KPNA2 with strong staining intensity associated with the tumor stage. Knockdown of KPNA2 (>77%) led to a dramatic decrease in migration for C33A ($p = 0.048$), invasion for HeLa ($p = 0.047$) and C33A ($p = 0.016$), and proliferation for C33A ($p = 0.026$), while no difference in colony formation was observed. Moreover, wound healing assay revealed a delay in healing process. Furthermore, an increase in apoptosis for HeLa ($p = 0.033$) and C33A ($p = 0.037$) and cell cycle arrest for HeLa ($p = 0.02$), SiHa ($p = 0.051$) and C33A ($p = 0.007$) was observed following knockdown of KPNA2.

Conclusions: Overall, our results document that KPNA2 is overexpressed in CC and contributes to malignant
transformation, suggesting KPNA2 as a biomarker and promising therapeutic target for CC.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01F. STRUCTURAL BIOLOGY
04-18-2023 7:00 AM - 5:00 PM

AMINO ACID CHANGES INDUCED BY THE N29S AND H51N VARIANTS OF THE E7 PROTEIN OF HPV16 AND THEIR EFFECT ON THE INTERACTION WITH PRB.

Ciresthel Bello Rios[1], Lilian Araujo Arcos[1], Maricela Montaño Valdez[2], Olga Garibay Cerdenares[1], Marco Leyva Vázquez[1], Luz Sánchez Meza[1], Berenice Illades Aguiar[1]
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Introduction: E7 of HPV16 is an oncoprotein involved in different cellular processes that trigger cell transformation. Structurally, E7 is characterized by an intrinsically disordered region at its amino-terminal end. Through this region, E7 can interact with multiple cellular proteins responsible for regulating characteristic processes of tumorigenesis, such as the pRB protein. It has been described that the E7 gene has intragenic variants that are considered to have a differential oncogenic potential. However, there are still no reports on the difference in the oncogenic potential of these variants, so this work aims to provide evidence of these variants' role in the different processes involved in cell transformation. Objective. The main goal was to evaluate the structural changes of the E7 oncoprotein and its variants (E7-A712 and E7-G647/C789/G795) and the effect in the interaction with its target protein pRB.

Methods: Through in silico analysis, the 3D structures of the E7 protein, its variants, and the molecular target pRB were modeled and refined and molecular docking was performed to observe the differences in complex formations.

Results: Molecular docking showed that the binding energy of the E7 N29S and E7H51N variants exhibit higher affinity with ΔG -197.06 and ΔG -242.99 kcal/mol, respectively, concerning the binding energy of the reference E7, which was ΔG -161.22 kcal/mol, additionally we observed a higher number of interactions formed in the complexes formed with the genetic variants (N29S and H51N) and pRB

Conclusions: The HPV16 E7 gene variants generate significant structural changes that induce higher binding affinity and increased molecular interactions when complexed with pRB concerning the reference E7.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01F. STRUCTURAL BIOLOGY
04-18-2023 7:00 AM - 5:00 PM

THE HUMAN PAPILLOMAVIRUS 16 E6 ONCOPROTEIN E-A176/G350 VARIANT INCREMENTS ITS AFFINITY TO HDLG-1 PROTEIN: AN IN SILICO APPROACH

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Introduction: Oncogenic protein E6 from Human Papilloma Virus 16 (HPV-16) mediates the degradation of many PDZ-containing proteins. E6 has a PDZ protein-binding motif (PBM) composed of four amino acids (E148, T179, Q150, and L151) which are located at its carboxyl terminus. A generic variation of the E6 gene that translates to changes in the protein´s amino acid sequence and modifies the protein structural dynamics. These results in the increment in the interaction´s affinity of E6 with the cellular protein hDLG-1. hDLG-1 is a modular scaffolding protein located at sites of cell contact in association with adherent junctions, being part of the Scribble polarity complex, which is crucial for the establishment and maintenance of apicobasal polarity. It also supports downstream signaling networks and is known to exert control of proliferation, migration, and invasion. Loss of hDLG-1 has been related to neoplastic transformation and is associated with poor prognosis in cervical cancer. Objective. To evaluate, the interaction of the intragenic variants E-G350 (L83V), E-C188/G350 (E29Q /L83V), E-A176/G350 (D25N/L83V), E6-AAa (Q14H/H78Y/83V) and E6-AAc (Q14H/I27RH78Y/L83V) and E6-reference of HPV-16 with hDLG-1.

Methods: Through an in silico approach, employing molecular dynamics simulation and protein-protein docking we modeled and refined the 3D structures of the E6 protein, its variants, and its molecular target hDLG-1.

Results: Our molecular docking results showed that the binding energy of the E-C188/G350 and E-A176/G350 variants exhibit higher affinity with ΔG -179.03 and ΔG -230.99 kcal/mol, respectively. On the other hand, the binding energy of the E6-reference and hDLG-1 was ΔG -52.22 kcal/mol, additionally, we observed a higher number of interactions formed in the complexes formed with the genetic variants and hDLG-1.

Conclusions: We found that variants E-G350, E-C188/G350, E-A176/G350, AAa, and AAc increase their affinity to hDLG-1 compared to E6-reference.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01G. VIRUS – HOST INTERACTIONS
04-18-2023 7:00 AM - 5:00 PM

HOST TRANSCRIPTIONAL CHANGES ASSOCIATED WITH PERSISTENT INFECTIONS OF COTTONTAIL RABBIT PAPILLOMAVIRUS

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Introduction: Human papillomaviruses (HPVs) cause 5% of human cancers. Incomplete understanding of the mechanisms underlying virus/host interactions hinders studies of disease progression and has become roadblocks to developing therapeutic strategies. The cottontail rabbit papillomavirus (CRPV) model is widely used to study HPV-associated diseases and cancers. We used mutant genomes with distinguished genotypes to characterize unique changes at the molecular levels by conducting genome-wide RNA-seq analysis on tumor tissues initiated from both wild type (WT) and an E8 ATGko mutant CRPV genome that induces benign and persistent tumors.

Methods: Total RNA isolated from tumor tissues induced by either WT or E8 ATGko mutant genome was used to generate sequencing libraries. Sequencing was accomplished using Illumina TruSeq v4 chemistry, 50-bp paired-end for all tumors. Three tumors each induced by WT or mutant CRPV infection were sequenced. Viral load was determined with qPCR and further confirmed by in situ hybridization.

Results: We identified a large group of genes dysregulated (up or down) when compared with the mock control tissues in tumors of both WT and E8 ATGko mutant. In agreement with what TCGA researchers have reported in cervical cancer patients, our analysis also revealed parallel pathways and genes in both WT and E8 ATGko mutant induced tumors. When compared with E8ATGko, several genes associated with glucose metabolism [(Hexokinase 2, HK2) and uptake (Solute Carrier Family 2 Member 1, SLC2A1), growth factor (Placental Growth Factor, PGF)], and molecules in wounding-healing process [(Matrix Metallopeptidase 3, MMP3 and IL-20)] are significantly upregulated in WT CRPV induced tumors. We also found increased viral-host fusion transcripts in the tumors of WT genome than those of E8ATGko mutant genome.

Conclusions: Host gene transcriptional profiles are correlated with the disease phenotypes. Viral integration may play a role in malignancies.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01G. VIRUS – HOST INTERACTIONS
04-18-2023 7:00 AM - 5:00 PM

HISTONE H3.3 CHAPERONE HIRA: A FRIEND OR FOE TO THE HUMAN PAPILLOMAVIRUS LIFECYLE?

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Introduction: HPV genomes exist in a nucleosomal state throughout the infectious cycle, even inside the virion, and packaged HPV genomes are enriched in histone H3.3. The histone H3.3 chaperone HIRA deposits H3.3 onto transcriptionally active chromatin throughout the cell cycle in a replication-independent manner and has been implicated in pro- and anti-viral responses. We hypothesized that HIRA could either promote or restrict the HPV life cycle by H3.3 deposition. Sp100 is an interferon inducible PML nuclear body protein that restricts the HPV life cycle at early and late times of infection. Here, we examined the role of HIRA in the HPV life cycle and investigated whether Sp100 restricts HPV infection through interaction with HIRA.

Methods: The localization of HIRA, and related cellular proteins including Sp100, was examined in keratinocytes containing replicating HPV genomes using immunofluorescence and confocal microscopy. Additionally, HPV replication factories were generated by expression of the viral E1 and E2 proteins in the presence of the viral genome or origin containing plasmid. Cellular protein expression was down-regulated by siRNA transfection. Southern blotting and quantitative real-time qPCR were performed to quantitate HPV genome amplification and transcription.

Results: HIRA localized to HPV replication foci that form in differentiated keratinocytes and to those formed by expression of HPV16 E1/E2 proteins in the presence of a viral replicon. siRNA down-regulation of HIRA reduced late viral DNA replication and gene transcription, demonstrating that HIRA promotes genome amplification and viral gene expression during the late stage of the HPV life cycle. Furthermore, siRNA down-regulation of Sp100 showed that HIRA localized to viral replication foci in an Sp100-independent manner.

Conclusions: HIRA and Sp100 localize to HPV replication foci independently from one another and have opposing roles at late stages of the HPV life cycle.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01H. VIRUS LIFE CYCLE
04-18-2023 7:00 AM - 5:00 PM

HIGH EXPRESSION OF NFX1-123, BUT NOT PABPC4, AUGMENTS HTERT MRNA IN LONG-TERM CULTURES OF 16E6-EXPRESSING KERATINOCYTES

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Introduction: Human papillomavirus 16 (HPV 16) is the most common HPV type found in cervical, anogenital, and head and neck cancers. The HPV 16 protein E6 (16E6) functions to dysregulate normal cellular processes, including post-transcriptional gene regulation. 16E6 binds to NFX1-123, which partners with cytoplasmic poly(A) binding proteins (PABPCs), and hijacks those proteins' functions to post-transcriptionally regulate cellular differentiation, growth, and immortalization genes and pathways. This includes hTERT, the catalytic subunit of telomerase activated by 16E6, that drives cellular immortalization in HPV-associated cancers. In this study, we seek to understand the impact of NFX1-123 and PABPCs on the longitudinal growth of 16E6 expressing cells, and the proliferation and differentiation pathways they collaboratively affect.

Methods: We serially transduced and selected three biologically unique human foreskin keratinocytes (HFKs) with 16E6, and then either FLAG-tagged NFX1-123 (FWT), HA-tagged PABPC4, or an empty LXSN vector control. After selection, expression of the transduced genes was confirmed. Cells were plated at $5.0x10^5$ cells and serially counted and collected every 3 days. Population doublings were calculated by dividing the 3-day cell count by the original plating density. Proliferation (hTERT) and differentiation (Notch1, Keratin 1, and Keratin 10) markers were analyzed by qPCR and western blot.

Results: 16E6 expression was confirmed by qPCR and p53 protein degradation. NFX1-123 mRNA overexpression was confirmed by qPCR and FWT protein by western blot. PABPC4 mRNA overexpression was confirmed qPCR and HA-tagged PABPC4 protein by western blot. In 16E6/FWT HFKs, there was increased in hTERT expression in early passages compared to 16E6/LXSN and 16E6/HA-PABPC4 HFKs. Additional gene expression modulations are being quantified.

Conclusions: We confirmed the expression of 16E6, FWT, and HA-PABPC4 in HFK lines, and that hTERT expression increased specifically with co-expression of 16E6 and FLAG-tagged NFX1-123, and not with co-expression of 16E6 and HA-PABPC4.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01I. GENOMICS OF HPV-ASSOCIATED DISEASE
04-18-2023 7:00 AM - 5:00 PM

CORRELATION BETWEEN HPV16 VARIABILITY AND CD4+ COUNTS IN HIV CO-INFECTED WOMEN FROM ZIMBABWE.

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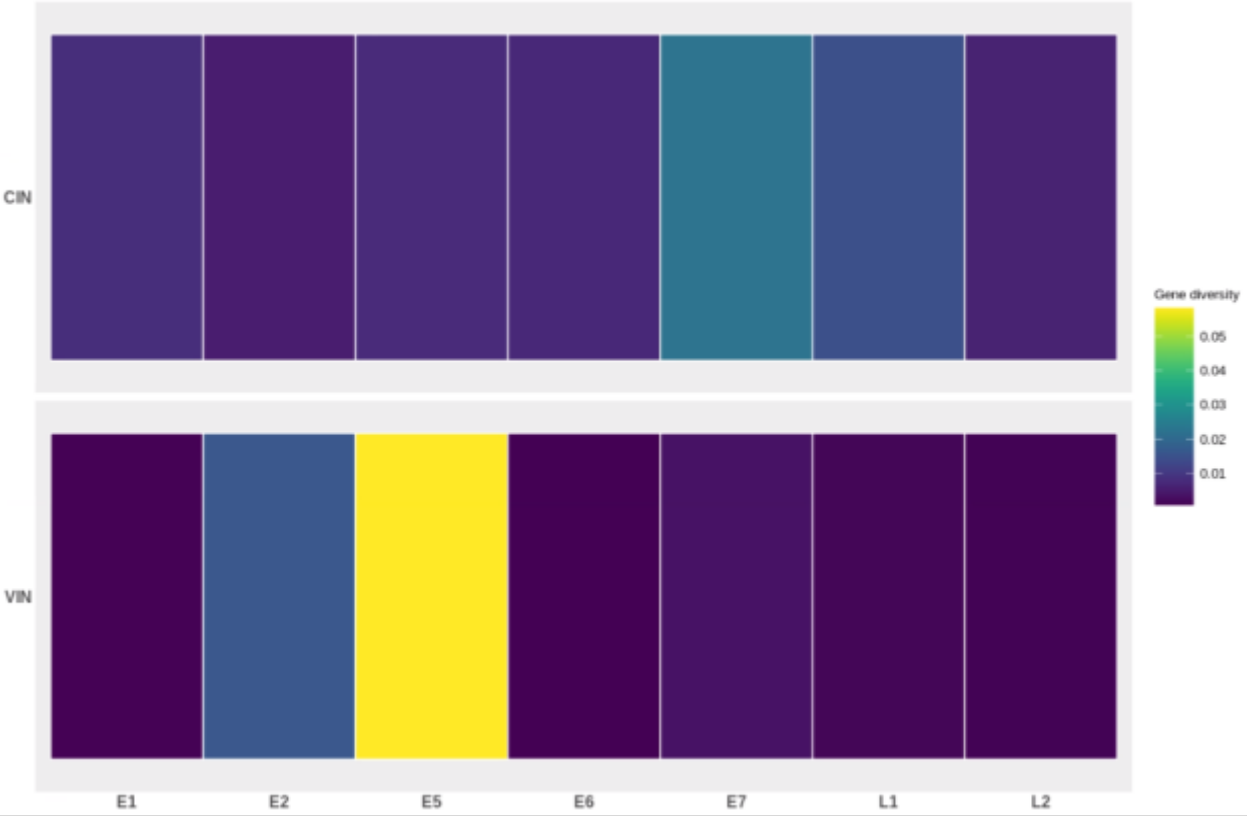
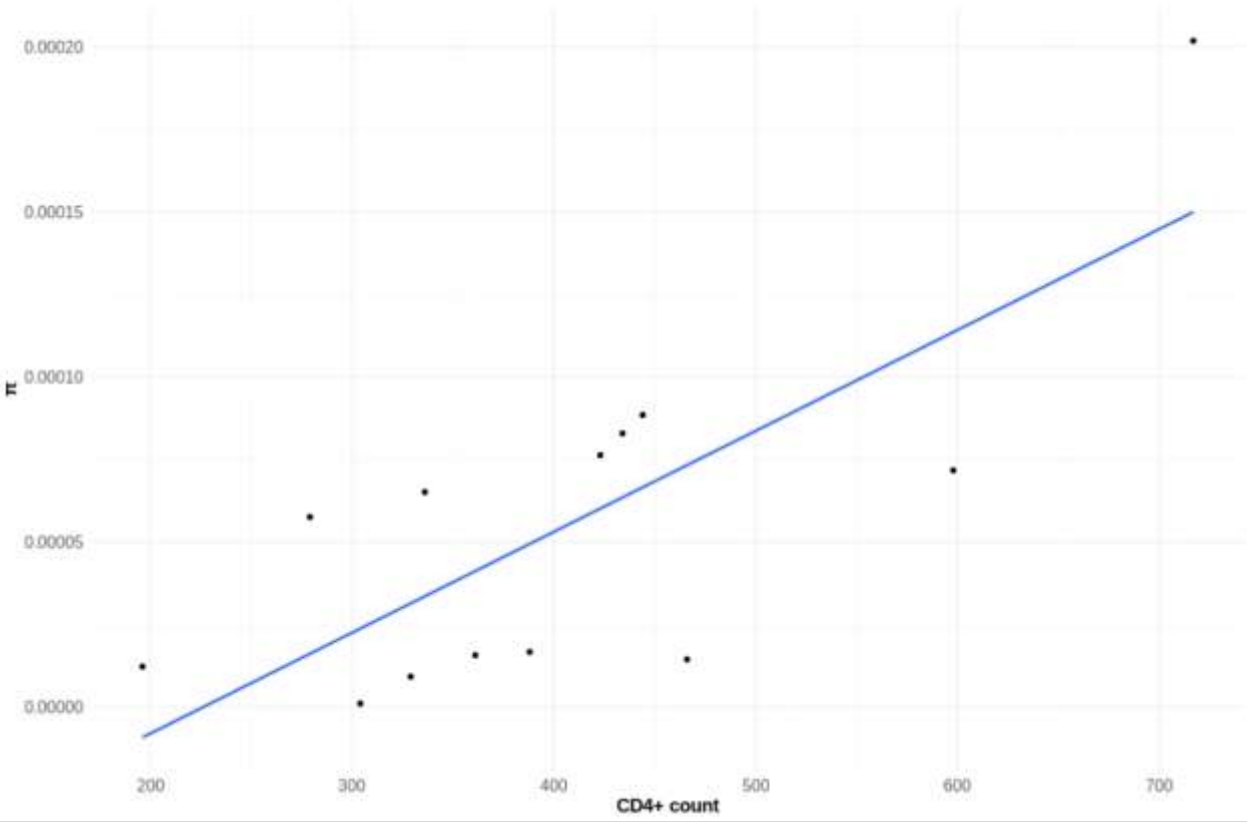
Introduction: Cervical cancer is the leading cause of cancer related death for women in Zimbabwe, a country that is also severely impacted by the HIV pandemic with a prevalence of 13.9% in adults. Moreover, it has been shown that people-living-with-HIV have an increased risk of persistent HPV infections and related cancers. However, little is known about the effect that HIV has on HPV intra-host diversity.

Methods: In this context, 29 formalin-fixed-paraffin-embedded (FFPE) tissue samples from women with HPV/HIV coinfection with histologically confirmed CIN3/VIN3 lesions or cervical/vaginal cancer diagnosis, were retrieved. The samples were analysed using the TaME-seq deep sequencing protocol, and nucleotide diversity (π) per sample and per gene (gene diversity) was calculated. To investigate the influence of HIV on HPV intra-host variation, the relationship between π and CD4+ count was calculated using a linear model.

Results: In total, 16 samples passed the conservative filtering steps and were used for the analysis. Within those samples, 120 different single nucleotide variants were observed (mean: 53.1) and CD4+ count ranged from 196 to 717 cells/mm^3 (mean: 428). The gene diversity π exhibited similar levels of diversity between the different gene regions (Figure 1). A significant relationship (p-value: 0.00239) was found between CD4+ count and nucleotide diversity (Figure 2).


CIN
VIN
E1
E2
E5
E6
E7
L1
L2
Gene diversity
0.05
0.04
0.03
0.02
0.01


0.00020
0.00015
0.00010
0.00005
0.00000
π
200
300
400
500
600
700
CD4+ count

Conclusions: From our observations, there might be a correlation between the adaptive immune system and HPV nucleotide diversity. We speculate that the adaptive immune system may be responsible for mutations in the HPV genome, in turn enhancing the clearance of the virus. More analysis is required to better understand this potential mechanism.

Shift 01-170 / #954

Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01I. GENOMICS OF HPV-ASSOCIATED DISEASE
04-18-2023 7:00 AM - 5:00 PM

PREVALENCE OF HPV IN HEAD AND NECK CANCERS IN PUERTO RICO

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Introduction: The incidence of head and neck cancers (HNC) associated to human papillomavirus (HPV) infections has increased in the last decades in the United States. In Puerto Rico, HNC are the fourth and twelfth most common cancers among Puerto Rican men and women, respectively. The aim of this retrospective study is to describe the prevalence of HPV infection, by anatomic site, among a sample of HNC tumors in Puerto Rico (PR), from 2008-2021.

Methods: Formalin-fixed paraffin embedded (FFPE) HNC tissue samples were obtained from biobanks of two pathology laboratories in PR. DNA was extracted from 145 FFPE HNC tissue samples using standard methods. Detection of the presence of HPV and HPV genotyping was performed using the RHA kit HPV SPF10-LiPA25 that detects more than 40 HPV genotypes. Covariates obtained included age, sex, location of head and neck primary tumors, smoking and alcohol consumption.

Results: Among the 145 samples analyzed, mean age of cases was 61.6 years ± 10.9 SD, 84.8% were men and 62.8% were known smokers. Among tumor types, the most commons cancers were larynx (48.3%), oral cavity (29.7%) and oropharynx (15.9%), while a smaller proportion were hypopharynx (4.1%) and nasopharynx (2.1%). Overall, 40.7% of all tumor samples were HPV-positive, 31.7% were positive to high-risk HPV types and 33.1% to HPV types included in the nonavalent vaccine. Among HPV-positive samples, 49.2% were positive to HPV-16; the second most common HPV type was HPV-52 (13.6%), followed by HPV-18 (11.9%). The prevalence of HPV positivity ranged from 100% in nasopharynx samples, 56.5% in oropharynx, 50.0% in hypopharynx, 35.7% in larynx to 34.9% in oral cavity.

Conclusions: HPV was more commonly found in oropharyngeal samples. The most common HPV types found are included in currently available nonavalent vaccine. Further analysis is underway to estimate the HPV attributable fraction of HNC in Puerto Rico.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01I. GENOMICS OF HPV-ASSOCIATED DISEASE
04-18-2023 7:00 AM - 5:00 PM

WHOLE-GENOME SEQUENCING OF 860 HPV45 CASES AND CONTROLS IDENTIFIES GENETIC VARIANTS SPECIFICALLY ASSOCIATED WITH CERVICAL GLANDULAR LESIONS

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Introduction: HPV45 causes ~6% of all cervical cancers and a greater proportion of adenocarcinomas (ADC). Little is known about how HPV45 genetic variation is related to risk of glandular and/or squamous cervical precancer and cancer. Objective: To investigate HPV45 sublineage and single nucleotide polymorphism (SNP) associations with histologic outcomes using HPV45 whole-genome sequencing of 860 women in the NCI-Kaiser HPV PaP study.

Methods: We sequenced HPV45 DNA samples from 141 CIN2, 80 CIN3, 15 AIS, 4 ADC, 7 squamous cell carcinoma (SCC), 2 cancers (unknown histology), and 611 controls (≤CIN1). To assess associations between each HPV45 sublineage and SNP with the worst outcome, we used Fisher exact tests and logistic regression to estimate the odds ratios (ORs). Analyses performed included and excluded 113 women with HPV16 coinfections.

Results: HPV45 was classified into one of seven sublineages (A1-5, B1-2), two of which (A4 and A5) we discovered in this population. Compared to the most common A1 sublineage, A2 and B2 were similarly associated with risk of CIN3+ (A2, OR=3.7, 95%CI 1.4-9.3) and glandular lesions (AIS/ADC; A2, OR 6.9, 95%CI 0.8-62.3). Women who self-reported as Asian with A2 (enriched in women of Asian origins) had greater cervical precancer/cancer risks than all other women (OR=7.2, 95%CI 1.3-38.9). At a finer level, we evaluated individual HPV45 SNPs with a minor allele frequency (MAF) ≥1% (n=262) among samples associated with histologic outcomes. We identified one SNP associated with CIN3/SCC (MAF=27.9%, URR, OR=3.40; 95%CI 1.8-6.6) and four different SNPs associated with AIS/ADC after correction for multiple tests (MAFs=1.5%-3.2%; E1, OR=32.1, 95%CI 6.8-151.6; URR, OR=27.5, 95%CI 6.0-125.9; E2, OR=21.0, 95%CI 3.7-120.4; E1, OR=13.4, 95%CI 3.2-56.0).

Conclusions: We show that HPV45 genetic variation is associated with glandular lesions. Further studies of these genetic variants may improve our understanding of glandular lesion etiology.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01J. PAPILLOMAVIRUS VACCINES (I.E NEW DEVELOPMENTS)
04-18-2023 7:00 AM - 5:00 PM

CHIMERIC L2-BASED VLP TARGETING GENUS BETA PAPILLOMAVIRUSES

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Introduction: Human betapapillomaviruses (βHPV) have been implicated in the development of cutaneous squamous cell cancer in patients with the rare genodermatosis Epidermodysplasia verruciformis and in immunosuppressed individuals like organ transplant recipients or HIV+ people. Licensed HPV vaccines that are based upon L1 virus-like particles (VLP) provide type-restricted protection only against the most common mucosal alpha HPV types causing anogenital cancer and genital warts. None of these multivalent vaccines target any of the cutaneous βHPV. A strategy to develop a broad-spectrum βHPV vaccine is based upon the minor structural protein L2. In contrast to L1, L2 can induce low titers of cross-neutralizing antibodies mediated by N-terminal epitopes.

Methods: We have generated monoclonal antibodies (mAbs) against the N-terminal L2 protein (amino acids 10-142) of five βHPV types to identify cross-neutralization B-cell epitopes. Four distinct mAbs were obtained that showed cross-neutralization against a panel of tested βHPV pseudovirion (PsV) types. In a murine genital challenge model, two of the four mAbs (cross-)protected mice against experimental challenge with tested βHPV PsV types HPV5/24/38.

Results: In order to circumvent L2's low immunogenicity in L2 peptide/protein immunizations, we have used the novel βHPV cross-neutralization epitopes to design chimeric VLP by genetic insertion into the αHPV16 L1 DE surface loop. Four chimeric VLP with the respective single epitope insertion were generated, and a chimeric VLP with a longer insert encompassing two of the epitopes. VLP assembly was confirmed by transmission electron microscopy and ELISA using conformation-dependent mAbs to HPV16 L1, and VLP were used for mouse immunizations using Freund's adjuvant. Four of the five chimeric VLP induced sera that broadly cross-neutralized eight tested βHPV types 5/8/20/24/38/76/92/96 (titers ranging from 50-3,200) and hr mucosal αHPV16 (ranging from 3,200-51,200).

Conclusions: In conclusion, unlike licensed HPV vaccines targeting αHPV, the novel βHPV-targeting chimeric VLP elicit broad immunity against βHPV involved in skin cancer development.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01J. PAPILLOMAVIRUS VACCINES (I.E NEW DEVELOPMENTS)
04-18-2023 7:00 AM - 5:00 PM

DEVELOPMENT OF HPV-35 VLP SEROLOGY ASSAYS FOR ASSESSMENT OF IMMUNE RESPONSES TO HPV-35 AFTER INFECTION AND VACCINATION

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Introduction: Human papillomavirus (HPV) is the leading cause of cervical cancer which is the fourth most prevalent cancer in women worldwide. HPV-16 and HPV-18 are the two most common HPV types leading to cervical cancer, however other HPV-16-related types, namely HPV-35, the closest related to HPV-16, accounts for 2% of invasive cervical cancers worldwide, and possibly as much as 10% in sub-Saharan Africa. This HPV type is not included in currently licensed vaccines. Further investigation into the potential cross-protection against HPV-35 by currently licensed vaccines is needed to determine whether the addition of HPV-35 to the next generation of vaccines would result in a broader coverage for women of African ancestry. Here, we focused specifically on developing serology assays to measure anti-HPV-35 antibodies using enzyme-linked immunosorbent assays (ELISA), and pseudovirion-based neutralization assays (PBNA).

Methods: The ELISA and PBNA assays used in this study have been previously used and optimized for other HPV types including HPV-16 and HPV-18, but further optimization and qualification was required for this new HPV type of interest, HPV-35. HPV-35 L1L2 virus-like particles (VLPs) were produced and characterized through electron microscopy to provide insight into VLP structure, confirming the characteristic icosahedral geometry and evaluation of the L1 structural proteins with an Agilent 2100 Bioanalyzer. The assay specificity for HPV-35 antibody binding was assessed by ELISA using various HPV type-specific monoclonal antibodies.

Results: Assay qualification is underway to determine sensitivity, lowest level of detection, and assay precision.

Conclusions: Qualified HPV-35 binding and neutralization assays will allow us to understand if current vaccines induce any neutralizing antibody responses against HPV-35 and assess next generation vaccines that may target HPV-35 and thus cervical cancer, particularly for women in those high-risk ethnic groups.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01K. BETA AND GAMMA CUTANEOUS HPV INFECTION, BIOLOGY, AND NATURAL HISTORY
04-18-2023 7:00 AM - 5:00 PM

BETA HUMAN PAPILLOMAVIRUS INCREASES ALTERNATIVE END JOINING REPAIR PATHWAY

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Introduction: Each year, Americans spend about four billion dollars treating over three million non-melanoma skin cancers. Cutaneous beta genus human papillomavirus, including β-HPV8, infections contribute to this burden in certain immunocompromised populations. β-HPV8 is hypothesized to increase the risk of cancer by making UV more mutagenic. β-HPV8 expresses a protein (β-HPV8 E6) known to disrupt DNA repair by binding and destabilizing p300, a transcription factor for multiple DNA repair genes. This makes UV exposure more likely to result in more deleterious lesions called double stranded breaks (DSBs). We previously found that β-HPV8 E6hinders two primary DSB repair pathways, non-homologous end joining and homologous recombination but does not stop DSB repair. Since the primary repair pathways are disrupted, we hypothesized that β-HPV8 E6 caused cells to use a mutagenic backup DSB repair pathway, alternative end joining (alt-EJ).

Methods: A GFP based reporter to measure alt-EJ efficiency. Immunofluorescence microscopy was used to detect H2AX foci, a standard DSB marker. Small molecule inhibitors were used to manipulate repair pathway usage. Next generation and whole genome sequencing were used to detect mutations. Computational Analysis was used to identify mutational signatures associated with alt-EJ.

Results: Consistent with our hypothesis, we found that β-HPV8 E6 increases the use of alt-EJ measured by reporter assay. Chemical inhibition of alt-EJ lead to persistent pH2AX foci following DSB induction. Sequencing demonstrated that β-HPV E6 makes DSB to be significantly more mutagenic and analysis of these data demonstrated that these mutations were associated with alt-EJ.

Conclusions: We conclude that β-HPV8 E6 cause mutations by promoting the use of alt-EJ.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01K. BETA AND GAMMA CUTANEOUS HPV INFECTION, BIOLOGY, AND NATURAL HISTORY
04-18-2023 7:00 AM - 5:00 PM

C-JUN AND P53 COOPERATION IN B-HPV-38 TRANSCRIPTIONAL REGULATION

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Introduction: While the role of mucosal high-risk HPVs (HR HPVs) in cervical carcinogenesis is well understood, less is known about the cutaneous β-HPVs transforming properties. To become transcriptionally active and express E6 and E7 oncogenes, HPVs essentially require a permissive cellular environment. Particularly, cellular transcription factors (TFs) are essential for determining the fine-tuned magnitude and temporal regulation of viral transcription. The most notable refers to the composition of TFs that directly bind to the non-coding region of the HPV genome, designated as Long Control Region (LCR). It is well known for all alpha-HPV types investigated so far that the activator protein 1 (AP-1) binding at the LCR plays a crucial role in viral transcriptional activation and therefore leads to constitutive expression of E6 and E7. c-Jun is the most extensively studied and the major transcriptional activator of the AP-1 family. The stress response of c-Jun has an important synergistic interaction with p53-regulated pathways, such as DNA repair and cell cycle checkpoints regulation. However, few studies address the role of these TFs upon cutaneous β-HPV transcription. Therefore, we investigated the cooperation of c-Jun with p53 on the regulation of the transcriptional activity of the cutaneous HPVs.

Methods: The transcriptional activity of HPV-5, -38, and -49 was measured by luciferase reporter assays. Next, we address the question of whether c-Jun and p53 directly interact with HPV-38 LCR by EMSA, DNA-pull-down, and ChIP assays.

Results: We found that the ectopic co-expression of c-Jun and p53 resulted in strong activation of the HPV-38 promoter, but not HPV-5 and -49. Furthermore, we demonstrated that c-Jun and p53 interact directly in multiple sites along the HPV-38 LCR.

Conclusions: The data presented in this study provide novel insight regarding an interplay between these important cellular players and the cutaneous β-HPV transcriptional status.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01L. MICROBIOME
04-18-2023 7:00 AM - 5:00 PM

MICROBIOME HPV-ASSOCIATED FEATURES ARE DETECTABLE IN PHYSICIAN- AND SELF-COLLECTED CERVICOVAGINAL SAMPLES

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Introduction: Growing evidence suggest that the cervicovaginal microbiota could play a significant role in HPV life cycle. Cervical cancer screening samples could be tested to determine the microbiome composition and help to identify women with an increased risk of suffering high-grade lesions or cancer. We aim to analyse how sampling methods may affect the microbiome composition comparing liquid-based cytology (LBC) physician-collected and Evalyn brush Self-collected specimens (SCS).

Methods: We analysed 20 pairs of LBC and SCS collected from 11 HR-HPV positives and 9 HPV negative samples from a screening population. Total DNA was isolated, and full-length 16S rRNA gene copies were amplified and barcoded by PCR. Amplicons were later sequenced in 12-plex groups using a MinION device (Oxford Nanopore Technologies). Samples with less than 10.000 reads and a Q-score lower than 16 were discarded (n=10). Finally, the taxonomy was assigned to 16 HPV+ and 12 HPV- samples (n=30) at the genus level using Kraken2 software.

Results: Microbiome composition alterations in HPV-positive samples were detected in both LBC and SCS[Figure1], and microbiome proportions remain constant for all the pairs (p>0.9). HPV-positive samples were associated with a higher genus diversity than negative samples with borderline significance (p=0.052). No differences were found between LCB and SCS (p=0.92)[Figure2]. HPV-positive samples showed a higher concentration of bacillus (p=0.04) and a decreased lactobacillus (p=0.09) compared to HPV-negative
samples[Figure3].

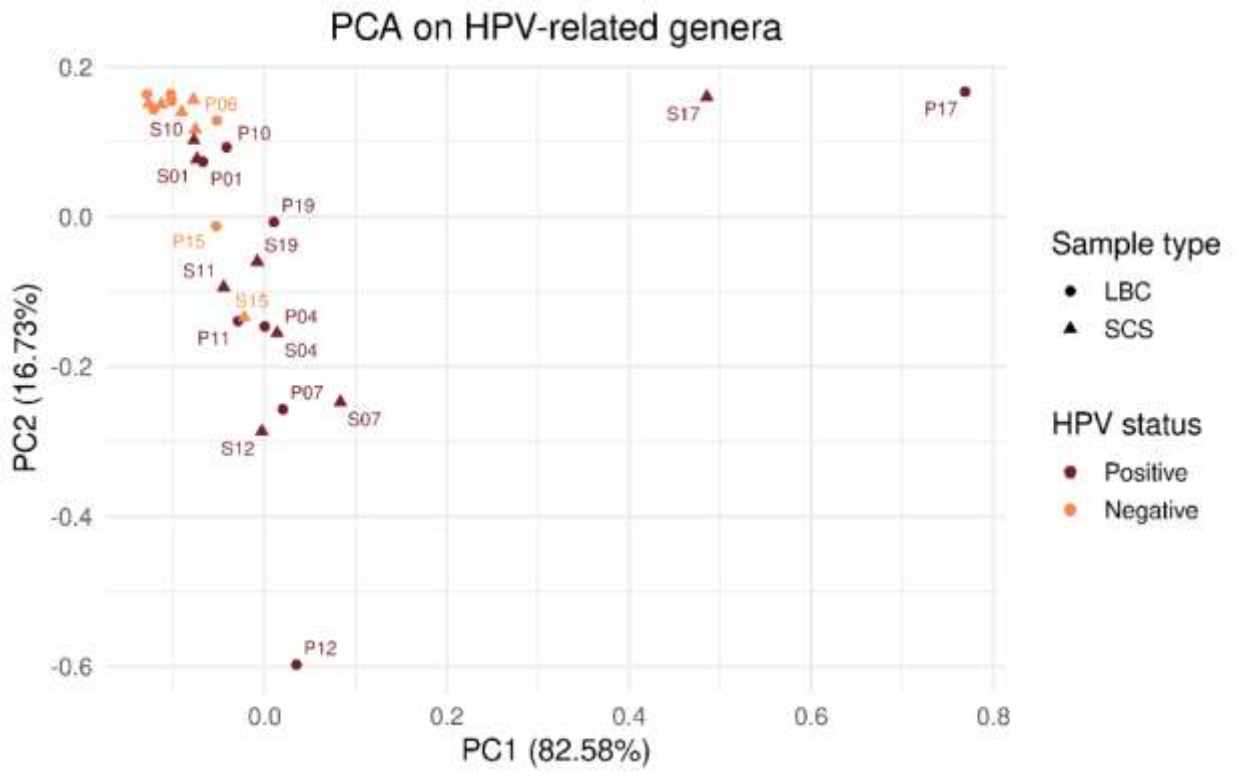

Figure1: Paired samples are found close to each other and HPV positive samples are more dispersed than
negative.

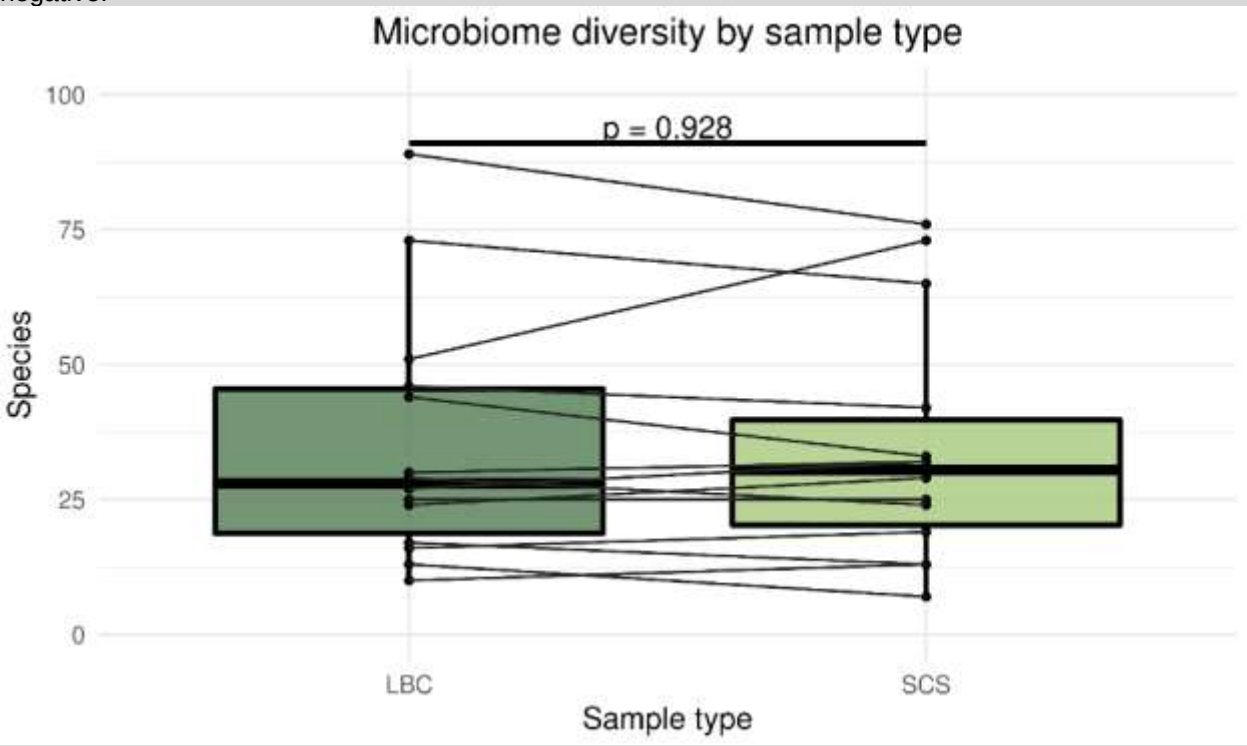

Figure2: No differences in microbiome composition were found between sample type groups (p=0.92).

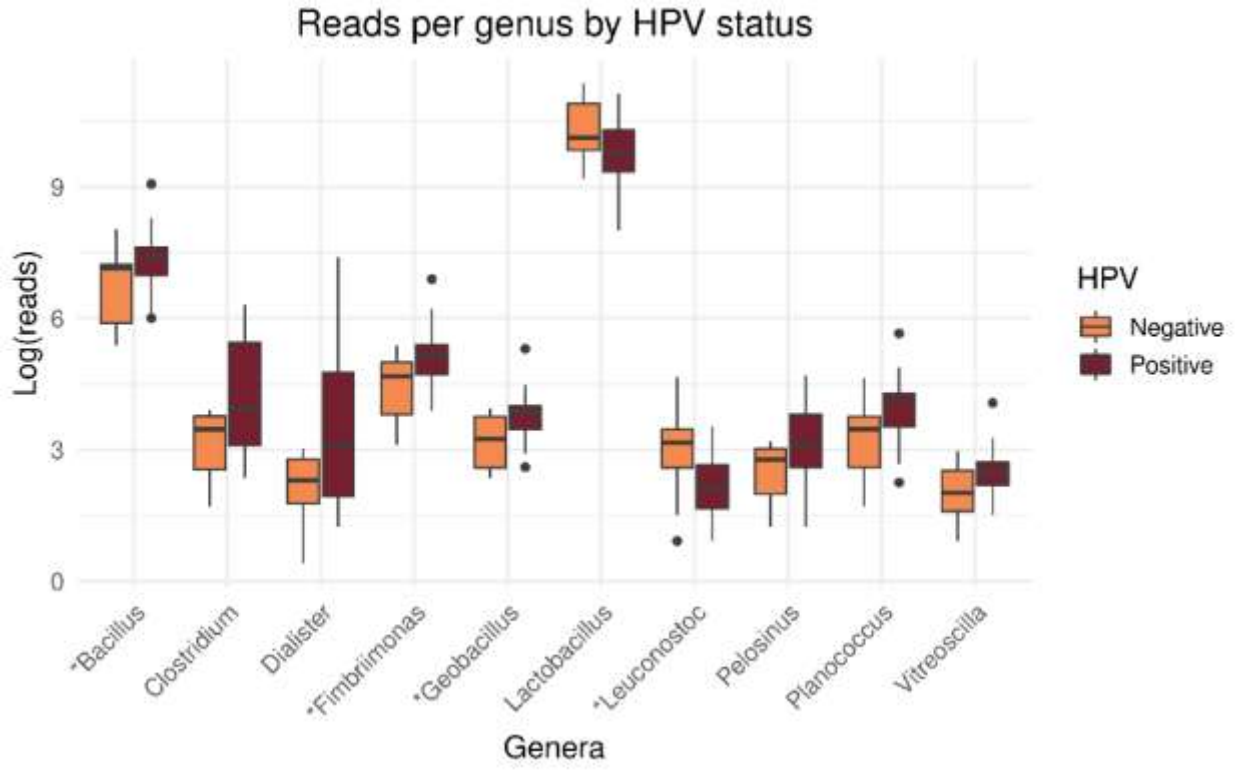

Figure3: Differences between HPV positive and negative samples groups. *Statistically significant($p<0.05$)

Conclusions: HPV status appears to be strongly associated with a distinctive microbiome. These preliminary results indicate that similar microbiome composition can be detected irrespective of the sampling approach of the vaginal-cervical specimens. Further research is warranted to confirm these results.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01L. MICROBIOME
04-18-2023 7:00 AM - 5:00 PM

METATRANSCRIPTOME ANALYSIS IN HUMAN PAPILLOMAVIRUS NEGATIVE CERVICAL CANCERS

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Introduction: Some invasive cervical cancers may test negative by HPV PCR. HPV- negative cervical cancers are associated with symptomatic detection, late-stage diagnosis, and worse prognosis. Whether infectious agents other than HPV may be associated with HPV-negative cancers is not known. We aimed to compare the metatranscriptome present in HPV PCR positive cervical cancers with the metatranscriptome present in HPV negative cancers.

Methods: We previously requested all invasive cervical cancers in Sweden during 10-year period and subjected them to HPV genotyping using HPV PCR-Luminex. FFPE specimens that were HPV negative (392/29850), together with a set of 59 HPV PCR positive specimens (used as positive controls), were further subjected to an unbiased total DNA and cDNA sequencing using Novaseq 6000 to ensure complete detection of HPVs. A total of 223/392 cervical cancers were still HPV-negative after sequencing. We now selected all 223 HPV negative specimens and compared the metatranscriptome present with the metagenomes detected in 223 HPV PCR positive cancers using the Kraken2 bioinformatic pipeline. A total of 11 blank paraffin block pools were used as negative controls.

Results: Overall, 84 bacterial genera were detected with 6/84 genera being present in all samples in both groups (HPV positive and HPV negative). No significant bacterial difference was found among HPV positive and HPV negative specimens. There were a total of 63 different viral genera, with 6/63 being positive in all samples. Except for alphapapillomaviruses that were transcribed in all HPV PCR-positive specimens, no other virus was associated with any significant difference among the HPV PCR positive and HPV negative specimens.

Conclusions: Metatranscriptome analysis of bacteria and viruses present in HPV positive and HPV negative cervical cancers shows no significant difference in bacteria or viruses present (besides HPV). Further characterization of the biologically distinct group of HPV-negative cervical cancers should probably focus on the human transcriptome.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01L. MICROBIOME
04-18-2023 7:00 AM - 5:00 PM

CERVICAL MICROBIOTA PROFILES IN PRECANCER LESIONS AND CERVICAL CANCER AMONG ETHIOPIAN WOMEN

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Introduction: Although high-risk human papillomavirus (hr-HPV) infection is a well-established risk factor for cervical cancer, other co-factors within the local microenvironment may play an important role in the development of cervical cancer. Therefore, this study aimed to characterize cervical microbiome in Ethiopian cervical cancer patients and compare the microbiota diversity and composition with dysplasia and healthy women.

Methods: This study comprised 120 Ethiopian women (60 cervical cancer patients who had not received any treatment, 25 women with dysplasia and 35 healthy women. Cervical specimens were collected with either Isohelix ™ DNA Buccal swab or an Evalyn® Brush. We characterized the 16S rDNA cervical microbiome sequencing. Shannon and Simpson diversity indices were used to evaluate alpha diversity. Beta diversity was examined using principal coordinate analysis (PCoA) of weighted Unifrac distances. Relative abundance of microbial taxa was compared between samples.

Results: Alpha diversity was significantly higher in patients with cervical cancer than in patients with cervical dysplasia and healthy women ($p<0.01$). Beta diversity was also significantly different in cervical cancer patients (weighted UniFrac Bray-Curtis, $p<0.01$). The microbiome composition was different in low-grade squamous intraepithelial lesion (LSIL), as compared to high-grade squamous intraepithelial lesion (HISL), and patients with cancer. In addition, Lactobacillus iners were particularly enriched in patients with cancer. High relative abundance of Lactobacillus was identified in dysplasia and healthy groups, while Porphyromonas, Prevotella, Bacteroides, and Anaerococcus predominated in the cervical cancer group.

Conclusions: This study has found differences in cervical microbiota diversity, composition, and relative abundance between cervical cancer patients, women with dysplasia, and healthy controls. Additional studies need to be carried out in Ethiopia or any other regions in order to control for variation in sample collection and determine if cancer enriched organisms contribute to cancer progression

Shift 01-183 / #959

Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01M. OTHER BASIC RESEARCH
04-18-2023 7:00 AM - 5:00 PM

AT11-GUIDED LIPOSOMES FOR HUMAN PAPILLOMA VIRUS CANCER: DEVELOPMENT AND CHARACTERIZATION OF A NOVEL APPROACH

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Introduction: Conventional anticancer therapies present low specificity, leading to several secondary effects. To improve these drawbacks, aptamers able to fold into G-quadruplex (G4), with higher stability, are being used to promote drugs accumulation in cancer cells. AS1411 is a G4 aptamer able to recognize nucleolin, a protein overexpressed in cancer cells' surface. This aptamer was tested in phase II clinical trials but showed low response rates and suboptimal pharmacokinetics. Nevertheless, AS1411 is being used as targeting agent. Moreover, AS1411 derivatives have been proposed, with improved toxicity and high affinity to nucleolin. In this sense, we propose to use AT11, an AS1411 derivative, to functionalized liposomes and improve the selectivity of C_8 (a potential anticancer drug) into oral cancer.

Methods: Thus, we produced liposomes (blank or C_8-associated) by ethanol injection method to, then, functionalize with 5'-Cy5-AT11-TEG-Cholesteryl-3'. The resulting liposomes were characterized by dynamic light scattering. C_8 association was determined by UV/vis spectroscopy and the AT11 functionalization was determined by SDS-PAGE. The effect of blank and C_8-associated liposomes on oral cancer positive for HPV16 (UPCI-SCC-154) and healthy (Het1A) cells' viability was determined by MTT and the internalization of AT11-liposomes in UPCI-SCC-154 cells was visualized by fluorescence microscopy.

Results: Through this production method we obtained liposomes with hydrodynamic diameters ranging from 148 to 168 nm and C_8 was efficiently associated (~100%). When UPCI-SCC1-54 and Het1A cells were treated with blank liposomes, the cell viability was almost unaffected. After treating with C_8-associated liposomes, both cell lines showed a dose-response effect. Additionally, we observed that AT11-liposomes can internalize and reach the cytoplasm of UPCI-SCC-154 cell line.

Conclusions: Overall, these findings suggest that the tested liposomes are promising drug carriers for oral cancer therapy.

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Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01M. OTHER BASIC RESEARCH
04-18-2023 7:00 AM - 5:00 PM

DEVELOPMENT OF GEL FORMULATION FOR HUMAN PAPILLOMAVIRUS-INDUCED LESIONS

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Introduction: Cervical cancer is one of the most common cancers with human papillomavirus (HPV) being responsible for most of the cases. The current standard treatments are invasive, with limited effectiveness and undesirable side-effects, namely lead to infertility and regrettably, about 50% of the cancer patients will die. Thus, improving treatment options for cervical HPV-related lesions is still a priority. The use of vaginal formulations is often indicated for local drug delivery and previous studies shown that Thymus vulgaris essential oil (TEO) can be a excipient to include in gel formulations, since it has anticancer properties. Moreover, AT11, a DNA aptamer, can act a targeting agent, and through its conjugation with liposomes it is expected to improve the anticancer selectivity of potential anticancer drugs.

Methods: The formulations were prepared based on the universal placebo formulation, combined with TEO and the AT11-guided liposomes with C_8 associated. The resulting formulations were characterized in terms of pH and buffering capacity, osmolality, and viscosity. To assess their biological effect, cell viability assays were performed using MTT in both HeLa and NHDF cell lines.

Results: We produced liposomes (blank or C_8-associated) by ethanol injection method to, then, functionalize with 5'-Cy5-AT11-TEG-Cholesteryl-3'. The resulting liposomes were characterized by dynamic light scattering. C_8 association was determined by UV/vis spectroscopy and the AT11 functionalization was determined by SDS-PAGE. After treating with C_8-associated liposomes, both cell lines showed a dose-response effect. The MTT assay revealed an increase in the cytotoxic effect of formulations loaded with AT11-guided liposomes with C_8 associated in the presence of thyme. Even though TEO presented some toxicity against the healthy cell line, it was greater in HeLa cells. Additionally, we observed that AT11-liposomes can internalize and reach the cytoplasm of these cell lines.

Conclusions: Therefore, the developed vaginal gel formulations are suitable candidates for local cervical delivery of anti-HPV drugs.

Shift 01-185 / #974

Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01M. OTHER BASIC RESEARCH
04-18-2023 7:00 AM - 5:00 PM

RNA-GUIDED NANOPARTICLES FOR ORAL CANCER THERAPY

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Introduction: Oral cancer is characterized by mouth and oropharyngeal cancer. Human papillomavirus is the most commonly associated with oral cancer, especially types 16, 18, 31, 33, 35, and 39. Currently, there are several therapeutic options, however, none is fully effective. To overcome these limitations, selective drug targeting methodologies have been employed, namely RNA functionalized nanoparticles to enhance drug delivery.

Methods: Firstly, RNA secondary structure and interaction with C_8, dexamethasone and nucleolin were evaluated through spectroscopic techniques, namely circular dichroism (CD), nuclear magnetic resonance (NMR) and fluorimetry titrations. Then, size and encapsulation efficiency of functionalized liposomes were evaluated by dynamic light scattering (DLS) and UV-visible, respectively. Finally, in vitro studies were used to assess cell viability and RNA internalization, whether or not via nucleolin. To achieve this, two different cell lines were studied, namely non-malignant (NHDF) and a HPV-positive cell line derived from a squamous cell carcinoma of the tongue (UPCI-SCC154).

Results: The biophysical results showed that RNA did not form a secondary structure and interact with nucleolin with higher affinity even when interacting with drugs C_8 and dexamethasone. The liposomes were effectively functionalized with RNA and loaded with C_8 or dexamethasone, as observed in the electrophoresis and UV-Visible spectroscopy and presented a size close to 160 nm. RNA-coated liposomes loaded with C_8 or dexamethasone showed a significant reduction in cancer cell viability and the RNA was effectively internalized in cancer cells, but not via nucleolin.

Conclusions: C_8 and dexamethasone ligands, despite the non-stabilization of the RNA structure, increase the affinity to nucleolin and present considerable cytotoxic effect in SCC-154 and NHDF cells. The developed nanosystems, namely the RNA-coated liposomes carrying C_8 and dexamethasone, displayed high cytotoxicity and selectivity for SCC-154 cells in detriment of NHDF cells. Overall, this approach could bring advantages to the therapy of HPV-positive oral cancer.

Shift 01-186 / #992

Poster Viewing
POSTER VIEWING - SHIFT 01: BASIC SCIENCE-01M. OTHER BASIC RESEARCH
04-18-2023 7:00 AM - 5:00 PM

APPLICATION OF ESTROGEN AS AN HPV THERAPEUTIC STUMBLES ON STROMA

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Introduction: Currently, there are no specific antiviral therapeutic approaches targeting Human papillomaviruses (HPVs), which cause around 5% of all human cancers. Specific antiviral reagents are particularly needed for HPV-related head and neck squamous cell carcinomas (HPV$^+$HNSCCs) whose incidence is increasing and for which there are no early diagnostic tools available for combatting this disease. HPV$^+$HNSCCs are found at 4-fold higher levels in men than in women, suggesting there are sex-related differences in the development of these cancers.

Methods: Using data from The Cancer Genome Atlas (TCGA), we and others have shown that the estrogen receptor alpha (ERα) is overexpressed in HPV$^+$HNSCC and that these elevated levels are associated with an improved disease outcome. Moreover, we have demonstrated that 17-estradiol (estrogen) attenuates the growth and cell viability of HPV$^+$ keratinocytes and HPV$^+$ cancer cells in vitro, but not HPV$^-$ keratinocytes or HPV$^-$ cancer cells.

Results: Sensitization occurs via numerous mechanisms: 1) at the level of viral transcription 2) through interactions with E6 and E7 3) through manipulation of cell survival and cell death pathways. Knockdown of ERα revealed that estrogenic viral transcriptional control is receptor-dependent. We are working to further elucidate these specific mechanisms. Our recent work has continued to focus on whether estrogen has therapeutic potential for the treatment of HPV$^+$ cancers. Expansion of this work into in vivo models revealed a lack of response to estrogen alone or in combination with CRT. In vitro co-culture studies then revealed that stromal interaction alters the response to estrogen; markedly changing cell growth and viability, in part, via p53 mediation.

Conclusions: Current investigations seek to determine the mechanism by which stromal support alters estrogenic sensitization, expand coculture studies to other chemotherapeutics, and elucidate one possible explanation for the common downfall in the leap from bench to bedside for many translational treatment paradigms.

Shift 01-187 / #502

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

HEALTHCARE PROVIDERS' PERSPECTIVE ON HPV EXTENDED GENOTYPING AND SELF-SAMPLING FOR CERVICAL CANCER SCREENING IN SINGAPORE

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Introduction: Human papillomavirus (HPV) extended genotyping (XGT) beyond HPV16/18 can provide risk-based patient management to optimize outcomes of cervical cancer screening (CCS) programs. Additionally, self-sampling for HPV can increase CCS uptake compared to conventional screening modalities. Perspectives on XGT and self-sampling remain limited in Singapore. We aimed to explore the perspectives of healthcare providers (HCPs) on both approaches in Singapore.

Methods: Physicians, nurses, program administrators and laboratory technicians involved with CCS were invited for a one-on-one semi-structured interview conducted over Zoom between May to August 2021. The interviews were transcribed and analyzed using thematic analysis.

Results: Eighteen HCPs from 12 institutions were interviewed, in which 61.1% were women and 72.2% worked in public health institutions. Four key themes were discussed: 1) value and utility of XGT, 2) considerations for advancing XGT in Singapore, 3) Value and utility of self-sampling, and 4) implementation considerations for self-sampling. XGT could play an important role in the management of persistent HPV infections, and non-HPV16/18 genotypes that pose high risk of disease, especially with a shift in HPV epidemiology due to increasing HPV vaccine uptake. More awareness and guidance are needed for a wider adoption of XGT in clinical practice. Self-sampling was viewed favorably to increase CCS uptake, as it can address key patient barriers, increase screening accessibility, and reduce time spent for clinic consultations. The reliability of patient-collected samples was raised by some participants. Lower acceptance for self-sampling may also be observed among older women. Additionally, the distribution, labelling, and submission of test kits, along with the dissemination of screening results, are critical operational considerations for self-sampling.

Conclusions: Based on the HCPs' perspective, XGT and self-sampling can play an important role in optimizing the national CCS program in Singapore. Insights from this study are directly relevant to improving the CCS program in Singapore.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

CERVICAL CANCER SELF-SCREENING OUTREACH TO UNSERVED POPULATIONS

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Introduction: Cervical cancer screening is not equally accessible to all women in the US. The un/under-screened women contribute to nearly 75% of the cervical cancers that are detected. Self-sampling for HPV testing is an option for cervical cancer screening that may alleviate the continued cancer burden. Our research aims to assess the acceptability of vaginal and urine-based HPV self-screening kits.

Methods: Women who have not been screened for at least three years volunteered to participate in our self-sampling study. The 126 women presented to us from our community partners in southeast Michigan: African American, Arab American, and rural White women between the ages of 30-65 years. The women were randomized to receive vaginal and urine self-sampling kits to use at home, followed by a semi-structured phone interview and paper questionnaire.

Results: The average age of participants was 46.5 years. The self-sampling kits returned with a 25.4% positive rate for high-risk human papillomavirus (HR HPV). 88.9% indicated a preference for self-sampling over traditional clinician-directed screening. Of the women who preferred self-sampling, 79.4% preferred to use the self-sampling kits at home versus in a clinic setting. Overall, participants reported that the kits would positively impact cervical cancer screening, with 70.6% indicating they would have a higher likelihood of being screened in the future if self-completed screening occurred.

Conclusions: Our research suggests that women believe home-based self-sampling is an acceptable screening method for cervical cancer and would positively impact their choice to screen in the future.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

PILOT STUDY: DISTRIBUTION OF SELF-SAMPLING DEVICE AMONG CZECH WOMEN TARGETED BY THE CERVICAL CANCER SCREENING PROGRAM

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Introduction: The implementation of primary HPV screening and increasing cervical screening participation are major challenges to cervical cancer screening in the Czech Republic. The offering of self-sampling to cervical screening non-attenders could significantly increase participation as was shown in several European countries. The objective of this study was to bring the pilot data about the acceptance of self-sampling by Czech women and to find out the high-risk HPV (hrHPV) prevalence in the screening population.

Methods: Evalyn® Brush self-sampling kits (Rovers Medical Devices) were distributed by mail between October 2019 and March 2020 to 6388 women aged 30-65. Women were chosen regardless of their cervical cancer attendance. After the self-sampling, samples were returned free of charge by regular mail. All samples were tested for hrHPV DNA using the Qiascreen HPV PCR Test (Qiagen). Results were delivered to women by mail or e-mail with the recommendation to schedule the check-up regardless of their HPV status.

Results: The response rate in this study was 7.61% (486/6388). All samples were suitable for analysis using Qiascreen by which hrHPVs were detected in 7.47% (36/486) self-samples. Seven HPV16 (19.4%), one HPV18 (19.4 %), and 28 other (77.7 %) high-risk HPV-positive cervical/vaginal samples were identified.

Conclusions: HrHPV was detected in 7.61% of women chosen from the cervical cancer screening population. The offering of self-sampling could significantly increase the attendance of Czech women in the cervical screening program. This work was supported by grants: IGA_LF_2022_012, CZ.02.1.01/0.0/0.0/16_019/0000868, Programme EXCELES, ID Project No. LX22NPO5103, LM2018133 and charity Cancer Research Czech Republic.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

PILOT STUDY: INVOLVEMENT OF LONG-TERM NON-ATTENDING POPULATION OF CZECH WOMEN IN CERVICAL SCREENING PROGRAM

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Introduction: Long-term non-attendance in cervical screening is a common obstacle in decreasing cervical cancer incidence and mortality. Addressed invitations for pre-scheduled check-ups or reminders of long-term non-attending in the screening represent a possible way of increasing coverage of the unscreened population. Still, the direct distribution of self-sampling kits for human papillomavirus (HPV) testing is suggested to possess a better response for the involvement of non-attenders in screening. This study aimed to bring pilot data on the response rate for the addressed distribution of self-sampling kits in the Czech Republic.

Methods: In July 2021, self-sampling kits (Evalyn® Brush, Rovers Medical Devices) were distributed. Only women aged 30-65 who hadn´t attended a regular screening check-up for more than three consecutive years were enrolled. They were asked to collect vaginal/cervical self-samples at home and send the self-samples to the laboratory free of charge by regular mail. Anyplex™ II HPV HR Detection assay (Seegene Inc.) was used for HPV testing, and results were delivered to women with the referral for scheduling the check-up regardless of their HPV status.

Results: In total, 653 self-sampling devices were distributed. The response rate among non-attenders was 9,04 % (59/653), with most samples (98 %) returned within two months since distribution. High-risk HPVs were detected in 10,2 % (6/59) self-samples. Two HPV16 (33,3 %), one HPV18 (16,6 %), and three other (50 %) high-risk HPV-positive cervical/vaginal samples were identified.

Conclusions: Direct distribution of self-sampling kits increased the participation of non-attenders in cervical screening in the Czech Republic. However, the response rate remained lower than expected. Based on that, this pilot study was extended, and additional distribution of 5,000 self-sampling kits is ongoing to reinforce the importance of cervical screening. This study was supported by the project ENOCH (CZ.02.1.01/0.0/0.0/16_019/0000868), the internal grant of Palacky University (IGA_LF_UP_2022_012), and the Cancer Research foundation Czech Republic.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

CLINICAL VALIDATION OF ONCOPREDICT SCREENING HPV ASSAY ON SELF-SAMPLES WITHIN THE VALHUDES FRAMEWORK

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Introduction: HPV testing on self-samples is an alternative method to detect cervical precancer in women who do not participate in cervical cancer screening. VALHUDES is a research framework assessing the accuracy of HPV testing on vaginal and urine self-samples compared to clinician-collected samples. In this study we evaluated the clinical accuracy of PCR-based Oncopredict Screening (SCR) assay (Hiantis).

Methods: A total of 590 (median age 38, range: 25-64) women recruited at four colposcopy centres (Brescia, Edinburgh, Milan and Sassari) (NCT04312737) with valid HPV test result and histological outcome were included in the study. Urine and vaginal self-samples were collected prior to colposcopy with Colli-Pee device (Novosanis) and FLOQSwab (Copan), respectively. Matched cervical samples were taken by gynaecologists with a Cervex-Brush (Rovers Medical Devices). Dry vaginal samples were suspended into 5ml PreservCyt or eNAT (Copan) solution, whereas cervical samples were suspended into 20 ml PresrvCyt. Colii-Pee device contained 7ml UCM allowing collection of 13 ml first-void urine. Colposcopy and histological assessment of biopsies were used as reference standard. HPV positivity was defined with cycle threshold (Ct) <=40.

Results: HPV testing with Oncopredict SCR assay was similarly sensitive to detect CIN2+ (ratio=0.95 [95%CI 0.88-1.02] and CIN3+ (ratio=0.96 [95%CI 0.88-1.05]) and specific to identify <CIN2 (ratio=1.01 [95%CI 0.94-1.08]) on urine versus cervical samples. The clinical sensitivity for CIN2+ (0.95 [95%CI 0.90-1.01]) and CIN3+ (0.96 [95%CI 0.89-1.04]) on vaginal samples was similar to cervical, whereas, the clinical specificity was 8% lower (ratio=0.92 [95%CI 0.86-0.97]). A posterior cut-off optimisation resulted in specificity improvement (ratio=0.94 [95%CI 0.89-1.002]) with no change in sensitivity (Ct<=38).

Conclusions: Clinical accuracy of the Oncopredict SCR assay on self-collected vaginal and first-void urine samples were not different from clinician-taken cervical samples. Specificity on vaginal samples was lower but could be improved with optimised Ct cut-off values.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

SELF- VERSUS CLINICIAN-COLLECTED SAMPLES FOR THE DETECTION OF HPV BY 14-TYPE DNA AND 7-TYPE MRNA TESTS

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Introduction: Cervical cancer remains a major public health problem in Mexico. Self-sampling for HPV testing increases access to screening and population coverage. E6/E7 mRNA detection has been identified as a potential biomarker for triage of DNA-positive women. The aim of this study was to compare self-sampling versus clinician-sampling for complete molecular HPV diagnostics, with respect to sample quality, positivity rates and relevance for referral to colposcopy.

Methods: 505 women aged 30–65 years at Mexico General Hospital underwent self-sampling (Mia by XytoTest) and clinician-sampling (Cervex by Rovers). Samples were tested for HR-HPV DNA (RealTime hrHPV, Abbott (14 types)) and E6/E7 mRNA (PreTect HPV-Proofer`7, genotyping 16-18-31-33-45-52-58). Follow-up was in line with national guidelines. Cytology/histology results were not accessible.

Results: HPV-DNA prevalence was 22.8% in self-collected versus 19.2% in clinician-collected samples (P=0.19). Overexpression of mRNA E6/E7 from 7 HPV types was 7.1% and 6.3%, respectively (P=0.71). Overall agreement between the two collection methods was fair, with a concordance rate of 78.2% (390/505), k=0.34 (95% CI: 0.25-0.44), P<0.001, for the HPV-DNA test and 92.5% (467/505), k=0.40 (95% CI: 0.25-0.56), P<0.001, for the mRNA test, respectively. The self-sampled aliquot contained about 3 times more cells compared to clinician taken aliquot; 1.87 million cells/ml versus 0.63 million cells/ml, respectively.

Conclusions: Self-sampling (Mia by XytoTest) is as reliable as clinician-sampling for HPV testing and allows direct HPV mRNA genotyping. Self-sampling is an effective strategy to reach under screened women. The high prevalence of DNA positive results reflects the need for reflex triage, thereby reducing unnecessary colposcopies, women’s uncertainties, and cost. A low positivity rate of concurrent DNA+/mRNA+ (6.3%) effectively discriminates women warranted for immediate colposcopy/biopsy from return to follow-up and suggests longer follow-up interval for single DNA+ women. Such a strategy will inevitably reduce over-referral for colposcopy but needs clinical and cost-benefit assessment in prospective studies.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

COLLI-PEE® DEVICE ARCHITECTURES FOR DEFINED VOLUMES OF FIRST-VOID URINE COLLECTION, COMPATIBLE WITH HIGH-THROUGHPUT CARRIERS

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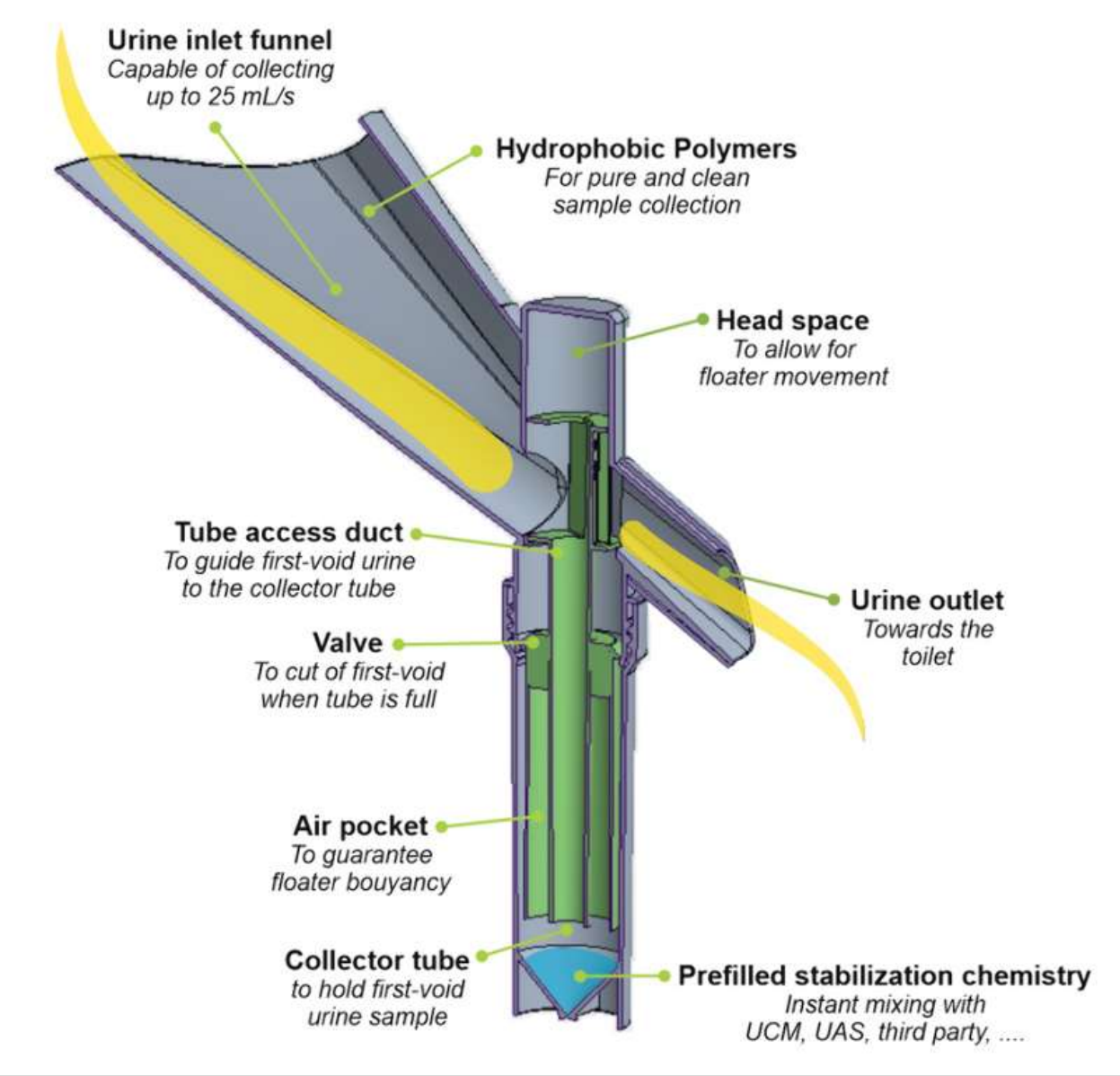
Introduction:

A properly collected first-void urine (FVU) sample can be important for accurate detection of e.g. Sexually Transmitted Infections (STI), Human Papilloma Virus (HPV) as well as cancer biomarkers. As FVU is the initial wash-out of urine, it contains a higher concentration of specific analytes, possibly improving diagnostic accuracy. Therefore, Novosanis developed and patented Colli-Pee, a FVU self-collection device. Recently, new Colli-Pee® device variants (patent pending) were developed with collection tubes in different sizes and volumes compatible with existing high-throughput machines used for detection of HPV. The aim of this study was to explore functional and dimensional requirements to ensure these compatibilities.

Methods: Both desktop and field research was executed to assess compatibility of these new Colli-Pee variants with diagnostic equipment from Roche, Hologic, Hamilton, Seegene and Abbott. Required aspects for tubes (including tube outer diameter, length, filling volume, leaking/sealing performance and head space) necessary for an optimal fit with carriers, centrifuge blocks, racks, etc. were evaluated. Additional development areas included: (i) tube interfaces that allowed push-fit or threaded neck connection, (ii) inlet funnels capable of processing a urine flow of up to 25mL/s, and (iii) different floater valve designs banking on buoyancy laws allowing access to the tube, mixing with preservatives, and instant valve switching to guarantee quality of
FVU.



Results: Development resulted in volumetric variants with different physical designs, which have similar functional performance in terms of FVU collection, as evaluated by volume, flow, mixing, and usability testing. Proprietary and selected third party tubes are compatible with a wide range of carriers and trays.

Conclusions: Current results show that Colli-Pee variants collecting small volumes (4-10mL), regular volumes (20mL), and large volumes (40mL) perform well. These variants allow for tailor-fit diagnostic

solutions, with regard to required analyte concentrations, high-throughput carrier compatibility, and telehealth applications needing postal solutions.

Shift 01-194 / #1106

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

THE ACCEPTABILITY OF URINE SELF-TESTING FOR CERVICAL SCREENING IN THE LGBTQIA+ COMMUNITY

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Introduction: The LGBTQIA+ community experiences health inequities including reduced cervical screening uptake. Unique barriers to screening, including fear of judgement from healthcare staff, gendered waiting areas and gender dysphoria, as well as the common barriers of inconvenience and speculum examination, contribute to poor uptake. Testing urine for high-risk human papillomavirus (hr-HPV) may therefore be an attractive self-sampling option for LGBTQIA+ non-attenders of routine cervical screening. The aims of the Alternative CErvical Screening (ACES) LGBTQIA+ study were to ascertain community-specific barriers to accessing cervical screening and explore the acceptability of urine self-sampling for overcoming these.

Methods: Individuals who identified as LGBTQIA+, have a cervix and were 16+ years were invited to complete a co-created, cross-sectional, Twitter-disseminated online survey. Data were collected and analysed via the Qualtrics platform. Quantitative results were analysed using descriptive statistics. Ethics approval was obtained through the University of Manchester (Ref. 2021-12901-21603).

Results: 503 fully completed surveys were included in the analysis. Sexual identity was as follows: 168 (33%) bisexual, 129 (26%) lesbian, 96 (19%) other and 3 (11%) asexual. 221 (44%) individuals identified as transgender. 405 (81%) were currently eligible for cervical screening and 284 (70%) had attended a cervical screen in the last 5 years. The speculum examination was the commonest barrier for cisgendered individuals, however, for transgender individuals the commonest barriers were gendered surroundings, being misgendered, fear of judgement from staff and lack of LGBTQIA+ inclusive language. Urine self-sampling was the preferred screening method overall n=211 (42%) with a significantly higher number of transgender individuals (n=104, 47%) choosing this as their preferred screening method. The clear preference was for postal receipt of a self-test (n=392, 78%).

Conclusions: The LGBTQIA+ community experience universal and unique barriers to cervical screening and home-based urine self-sampling could eliminate these barriers, improve uptake and the community's user experience.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

CYCLE-THRESHOLD VALUES OF THE COBAS HPV TEST AS A PREDICTOR OF HIGH-GRADE CERVICAL DISEASE IN WOMEN TESTED HIGH-RISK HPV POSITIVE ON SELF-COLLECTED VAGINAL SAMPLES.

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Introduction: The Cobas® HPV test reports cycle threshold (Ct) values, reflecting viral load. The presented analysis reviews Ct-values from high-risk (hr) HPV-DNA positive samples collected within GRECOSELF, a cross-sectional study on HPV-primary cervical cancer screening combined with self-sampling in Greece. The aim was to investigate the association between Ct-values and histopathology.

Methods: Of the 13,111 non-pregnant women, aged between 25 to 60 years old, who had been enrolled in GRECOSELF, 1,074 were found hrHPV positive, on self-collected vaginal samples tested with the cobas® HPV test. This test detects 14 hrHPVs [16 & 18 separately, and the remaining hrHPVs (31,33,35,39,45,51,52,56,58,59,66,68)] as a pooled result. HrHPV positive women were referred for colposcopy with or without biopsy. Ct-values were compared among the following groups: No-neoplasia (NN) versus cervical intraepithelial neoplasia grade 1 (CIN1), grade 2 or worse (CIN2+), grade 3 or worse (CIN3+), and NN/CIN1 versus CIN2+ and CIN3+, considering only the minimum Ct-values of the hrHPV-positive samples.

Results: Of the total 1,074 hrHPV-positive women, 774 were subjected to colposcopy. We found 603NN, 86CIN1, 28CIN2, 42CIN3, 1 Adenocarcinoma and 1 Squamous Cell Carcinoma (SCC) with valid results. The logistic model for the prediction of CIN1, CIN2+ and CIN3+ versus NN showed that higher Ct-values lead to lower risk of CIN2+ (OR=0.92, p-Value<0.001, AUC=0.64), and CIN3+ (OR=0.9, p-Value=0.002, AUC=0.64). Similar results were obtained for the prediction of histopathology NN/CIN1 versus CIN2+ or CIN3+ (OR=0.92, p< 0.001, AUC=0.64; OR=0.92, p=0.003, AUC=0.64, respectively). Using the ROC curve analysis, the optimal cutoff point, obtained by maximizing either Youden's index or the product of sensitivity and specificity, was equal to 29.8 for NN/CIN1 vs. CIN2+ and 28.9 for NN/CIN1 vs. CIN3+.

Conclusions: Ct-values can be used as a predictor of CIN2+ or CIN3+ in women tested hrHPV positive with the cobas HPV test on self-collected vaginal samples.

Shift 01-196 / #1372

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

HPV SELF SAMPLING: ENHANCING ACCESS TO CERVICAL CANCER SCREENING

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Introduction: India contributes to a huge burden of cervical cancer globally.We do not have an organized screening system and awareness of the availability of effective screening tests and the HPV vaccine is as low as 16%. Socio-cultural barriers prevent women from accessing health care services especially those that necessitate gynecological examinations.

Methods: HPV Self sampling was introduced to make cervical cancer screening more culturally acceptable. Women in rural areas were approached, the importance of cervical cancer screening explained and the technique of self sampling taught by community health care workers. Women took the self sample in the privacy of their own homes . COBAS kit was used for HPV testing.The COBAS brush was initially used and this was switched to the Copan brush. After sampling, the swab was collected from women by the HCW, placed in the collection kit and labeled.

Results: 3145 samples have been collected and results have been analysed for 2394 samples. Only 10% of women had a previous screening history. About 5.8% of women were HPV positive. Of these 16% were HPV 16 positive, 8.6% were HPV 18 positive, 66.9% were other High risk HPV positive and 7.9% had mixed infections. Of the 139 women who were HPV positive, 34% (N=48) had a colposcopy done. Majority of the colposcopies were negative (43.8%) Two women had a diagnosis of LSIL, 1with HSIL and one had a diagnosis of cervical cancer. Twenty one women were treated with cryotherapy, 2 had LLETZ and 2 women had a hysterectomy

Conclusions: HPV self sampling is an effective tool in increasing cervical cancer screening as women find it more acceptable, less embarrassing and are more likely to recommend it to others

Shift 01-197 / #1377

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

COMPARISON OF NEXT GENERATION SEQUENCING (NGS) TO ROCHE LINEAR ARRAY FOR HPV GENOTYPING IN CLINICAL SPECIMENS

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Introduction: Dot and line blot probe hybridization assays have been the mainstay of HPV genotype testing for clinical research for the past several decades. High-throughput, next-generation sequencing (NGS) is an attractive alternative to probe-based genotyping methods because it can identify a broad spectrum of HPV genotypes, including novel HPV genotypes. Studies comparing the results of probe-based and NGS data are necessary to understand NGS data in the context of the extensive literature using probe-based methods.

Methods: Cervical specimens were previously tested for HPV genotype by Linear Array (Roche). HPV-specific libraries were prepared from DNA extracts by PCR amplification with MY09/11 L1 primers. Libraries were sequenced on an Illumina Mi-Seq instrument. Sequence reads passing quality control were aligned to published HPV genotype sequences using custom Perl scripts. Linear Array genotype data was compared to data obtained by NGS.

Results: High quality reads sufficient to identify HPV genotypes were obtained from 94% of specimens undergoing NGS. Linear Array identified HPV genotypes 6, 16, 18, 31, 42, 45, 51, 53, 54, 55, 58, 61, 62, 68, 70, 71, 73, 81, 83, 84, and 89. Genotypes 6, 16, 18, 31, 33, 42, 53, 54, 61, 62, 70, 71, 81, and 83 were detected by NGS. Additionally, NGS detected HPV-44 and -85, which are not included on the Linear Array. Multi-genotype infections could be resolved by both testing methods and were commonly detected (69% of specimens). Average within-specimen genotype concordance between the two methods was 94% (range, 81-100%). Average within-genotype concordance was 94% (range, 78-100%).

Conclusions: NGS for HPV genotyping generates data that is largely comparable to Linear Array. Discordance can likely be explained by differential sensitivity of the two methods, and genotype-specific amplification efficiency that differs between MY09/11 primers (NGS) and PGMY09/11 primers (Linear Array).

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

CATCH-UP SCREEN: OFFERING AN AT-HOME URINE HPV TEST TO OLDER WOMEN

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Introduction: The NHS Cervical Screening Programme replaced primary cytology with primary HPV testing in 2019. In England, where almost half of all cervical cancer deaths are now among women aged 65 years or over, the age at stopping screening has remained at 65 since the screening programme was introduced in 1988. Women currently being discharged from the screening programme with a negative HPV test will be at extremely low risk of developing cervical cancer, but the lifelong risk will be substantially higher in women who were screened only with cytology.

Methods: “Catch-up Screen” is a two-stage research project offering a catch-up HPV test to women aged 65-79 who have not had a primary HPV test. The first stage will be a feasibility study inviting 3,000 women (stratified by their screening history) to test the methodology and determine the uptake, and the second stage will be a wider roll-out inviting about 15,000 women to estimate the rates of pre-cancer detection and cancer prevention. Over the two phases we expect to screen about 10,000 women. This single test will lead to follow-up and suitable treatment for the HPV positive minority and give those who are HPV negative the reassurance of knowing that their risk is minimal. The Colli-pee urine collection device is easy to use, less invasive than other devices and avoids the embarrassment of a speculum examination which older women often find uncomfortable. It is hoped that this will encourage women who were not screened regularly to take part. Funding: Yorkshire Cancer Research

Results: The study is due to start in April 2023, so early observations will be presented. We aim to determine uptake rates, levels of HPV and diagnoses of pre-cancer and cancer.

Conclusions: We hope to demonstrate that at-home urine tests are an effective way to reduce cancer in this older age group.

Shift 01-199 / #1413

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

VALIDATION OF DRY SELF-COLLECTED FLOQSWABS® ELUTED IN MSWAB™ MEDIUM FOR THE DETECTION OF HUMAN PAPILLOMAVIRUS (HPV) USING SIX COMMERCIAL PCR-BASED HPV ASSAYS

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Introduction: Vaginal self-collection has been advocated to improve women's participation to Human Papillomavirus (HPV) programs using molecular assays. A dedicated protocol is essential to process self-collected swabs instead of cytology alcohol-based medium. MSwab™ is a molecular medium that support HPV stability and compatibility with clinically validated PCR-based HPV assays. The aim of this validation was to examine the compatibility of the MSwab for the elution of dry self-collected vaginal FLOQSwabs® for detection of HPV using six PCR-based HPV assays.

Methods: Thirteen dual vaginal self-collected swabs, one swab, eluted in 3ml ThinPrep, tested at zero-time using the Seegene HPV28 assay, the other swab, stored dry at 20^0 to 40^0C for 7 to 84 days, were used for this validation. Dry samples and HPV16, PV18, HPV45, Negative PROCEEDx FLOQ Swab controls, (PFSC) were swirled in 3ml MSwab™ for 20 seconds and removing the swab. Samples and controls were tested for HPV genotypes using the Abbott's Alinity and Realtime, Qiagen NeuMoDx, Roche Cobas 4800 and 6800, and Seegene HPV28 assays. Testing was undertaken at VCS Pathology.

Results: In the thirteen self-collected swabs, the Abbott Realtime and two Roche assays detected 10-HPV positives and 3-HPV negative while the Abbott Alinity, Qiagen NeuMoDx and Seegene assays detected 9-HPV positives and 3-HPV negative when compared to the zero-time samples. An overall corresponding 100% sensitivity and specificity and Positive and Negative Predictive value was obtained by samples and PFSC in MSwab™ analyzed with the six HPV assays.

Conclusions: Data obtained in this evaluation, using self-collected vaginal specimens, stored dry at 20^0 to 40^0C for 7 to 84 days and PFSC, eluted in MSwab™ demonstrated an 100% concordant performance using six HPV assays, supporting the use of self-collected FLOQSwabs® eluted in MSwab™ for HPV testing with commercial clinically validated PCR-based assays for cervical cancer screening programs.

Shift 01-200 / #1534

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

HIGH ACCEPTABILITY AND ACCURACY OF SELF-COLLECTION VAGINAL VEIL COLLECTOR FOR HIGH RISK-HPV SCREENING BY MULTIPLEX REAL-TIME PCR AMONG ADULT WOMEN LIVING IN SUB-SAHARAN AFRICA

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Introduction: Cervical cancer is caused by high risk-human papillomavirus (HR-HPV) infection. Self-collection of genital specimens and HPV DNA molecular testing are methods increasing screening rates.

Methods: The practicability and acceptability of genital self-collection method with veil (Vaginal Veil Collector V-Veil Up UP2™, V-Veil-Up Production SRL, Romania; https://hpv-veil.com) were assessed in female sex workers (FSWs) in Kisangani, Republic Democratic of Congo (DRC), and adult women in N'Djamena, Chad. The accuracy of Veil-Up Gyn UP2 for HPV DNA detection was compared in subgroup of unselected women to clinician-collected endocervical swabs (as reference collection). Samples were conserved in medium Cyt-All (Alphapath, Mudaison, France). HPV DNA detection used Anyplex™ II HPV28 test (Seegene, Seoul, South Korea) or Papilloplex High Risk HPV (GeneFirst, Abingdon, United Kingdom).

Results: 415 FSWs (mean age, 28.1 years) in DRC and 253 women (mean age, 35.0 years) in Chad were enrolled. In DRC, the prevalences of HPV and HR-HPV infections were 54.2% and 29.0%; two-third of HR-HPV would be covered by Gardasil-9® vaccine. In Chad, HPV and HR-HPV prevalences were 22.9% and 15.8%, respectively; 70% of HR-HPV were targeted by Gardasil-9®. Veil-based genital self-collection showed high acceptability (96%), feasibility and satisfaction, in both DRC and Chad. Self-collection by veil was non-inferior to clinician-based collection for HR-HPV DNA testing, with "good" agreement, high sensitivity (95.0%; 95%CI: 88.3-100.0%) and specificity (88.2%; 95%CI: 83.9-92.6%). Remarkably, HPV DNA and HR-HPV DNA positivity rates were significantly higher (1.67- and 1.57- fold, respectively) when using veil-based collection method than clinician-collected endocervical swabs.

Conclusions: These observations highlight the high burden of cervical HR-HPV infection in adult women living in Central Africa. V-Veil-Up Gyn collection device would constitute a simple, highly acceptable and powerful tool for self-collection of genital secretions for molecular testing and screening of HR-HPV that could be implemented in cervical cancer prevention programs in Africa.

Shift 01-201 / #1594

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

COMPARISON OF SELF-COLLECTED VERSUS CLINICIAN COLLECTED CERVICOVAGINAL SPECIMENS FOR DETECTION OF HIGH RISK HUMAN PAPILLOMAVIRUS AMONG HIV INFECTED WOMEN IN ETHIOPIA

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Introduction: Background: In order to meet the WHO 2030 cervical cancer elimination program, evaluation and utilization of sensitive testing method, and feasible sampling technique is a paradigm for enhancing cervical cancer screening coverage. Self-sampling for screening of HPV DNA testing is one of the easiest and sensitive techniques, though the evidence was limited in the Ethiopian context. This study aimed to compare the performance of self-collected vaginal specimen versus clinician collected cervical specimen for detection of HPV among HIV positive women in Ethiopia.

Methods: We conducted a comparative cross-sectional study design to collect cervicovaginal specimens among HIV positive women of age older than 24 years. Data were collected from six government hospitals from January to October 2021. A total of 994 cervicovaginal specimens was collected by clinicians and HIV positive women themselves in the cervical cancer screening unit using Abbott Cervi-Collect Specimen Collection Kit, and molecular HPV testing was conducted. Data were entered into an Excel spreadsheet and analyzed using SPSS version 25.

Results: The prevalence of high-risk HPV was 29.4% among self-sampled specimen and 23.9% among clinician collected specimens. The overall concordance of the test result was 87.3%. Oncogenic HPV types, other than HPV16&18 were predominant in both sampling techniques, 19.9% from vaginal self-collected specimen and 16.7% of clinician collected cervical specimens. The sensitivity and specifcity of self-sampled HPV test was 84.0% and 88.4%, respectively. The level of agreement was good (k=0.68) and statistically signifcant (p<0.001).

Conclusions: The magnitude of oncogenic HPV was higher in self-collected samples than the clinician collected specimen with good agreement between the two sampling methods. Thus, we recommend the Ministry of Health in Ethiopia to expand utilization of the self-sampled technique and enhance the coverage of screening in the country.

Shift 01-202 / #1691

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-18-2023 7:00 AM - 5:00 PM

HPV GENOTYPING AGREEMENT BETWEEN SELF-COLLECTED WET, DRY AND URINE SAMPLES IN A REFERRAL POPULATION

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Introduction: We previously reported results from a study (Predictors 5.1) to compare five different self-sample devices for Human Papilloma Virus (HPV) testing. This found urine and vaginal self-samples (both dry and wet) from three different devices performed well. Here we assess agreement between these devices by HPV genotype from the BD Onclarity assay.

Methods: N=620 women referred for colposcopy to the Royal London Hospital provided informed consent and were invited to provide one urine and two vaginal self-samples. Urine samples were collected using the Colli-Pee device; women were randomised to a dry Copan FLOQswab sample (DF) and a wet Qiagen digene Dacron swab sample (WD); or a HerSwab and Qvintip device (not used in this analysis). Samples were tested for 14 HPV genotypes in 9 channels by the BD Onclarity assay. McNemar's test was used for comparisons.

Results: Analysis included n=247 women who each provided urine, DF and WD samples (median age 29y, inter-quartile range 27-33y; n=189 <CIN2, n=29 CIN2, n=29 CIN3+; n=198 HPV+ by 1+ device). HPV-positivity was slightly higher for urine (74.1%) than DF (70.9%, P_{diff}=0.14), WD (70.5%, P_{diff}=0.20). In HPV-positive women there was an exact genotype match between the vaginal devices in 78.3% women, which was greater than urine (WD/Urine 66.7% (P_{diff}=0.005), DF/Urine 63.1% (P_{diff}<0.001)). More HPV infections in urine were detected in 7/9 HPV-type channels, and the same number in the others (HPV18; HPV35,39,69). The excess was in <CIN2 (CIN2+ HPV-positivity n=51 WD, n=50 DF, n=49 Urine). Urine samples had a lower positive predictive value for CIN2+ and CIN3+ overall, and by genotype channel.

Table 1: Summary characteristics of women

	Women with WD, DF & urine samples
Total	N=247
	Median (IQR)
Age at enrolment (years)	29.0 (27.0-33.0)
	N (%)
Referral cytology (prior to enrolment)	
Borderline	114 (46.2)
Mild dyskaryosis	103 (41.7)
Moderate dyskaryosis	15 (6.1)
Severe dyskaryosis or worse	15 (6.1)
Most recent abnormal cytology result	
0-1 years	202 (81.8)
1-2 years	37 (15.0)
2-3 years	8 (3.2)
Previous treatment (more than 3 years prior to enrolment)	
No	233 (94.3)
Yes	14 (5.7)
Most recent cytology	
Within last 6 months	159 (64.4)
>6 months to 3 years	88 (35.6)
HPV positive for any self-sample	
No	49 (19.8)
Yes	198 (80.2)
Histology	
<CIN2	189 (76.5)
CIN2	29 (11.7)
CIN3+	29 (11.7)

WD = wet Dacron; DF = dry flocked; IQR = inter-quartile range; CIN = cervical intraepithelial neoplasia

Table 2: HPV positivity overall and by genotype channel, CIN grade and sample type

	hrHPV positivity		
	n (% out of CIN grade type) [% out of any hrHPV positives]		
	WD	DF	Urine
<CIN2 (n=189)			
Any hrHPV	123 (65.1) [100.0]	125 (66.1) [100.0]	134 (70.9) [100.0]
HPV16	20 (10.6) [16.3]	22 (11.6) [17.6]	23 (12.2) [17.2]
HPV18	7 (3.7) [5.7]	7 (3.7) [5.6]	7 (3.7) [5.2]
HPV31	16 (8.5) [13.0]	16 (8.5) [12.8]	21 (11.1) [15.7]
HPV45	12 (6.3) [9.8]	13 (6.9) [10.4]	16 (8.5) [11.9]
HPV51	22 (11.6) [17.9]	23 (12.2) [18.4]	26 (13.8) [19.4]
HPV52	14 (7.4) [11.4]	14 (7.4) [11.2]	19 (10.1) [14.2]
HPV33,58	22 (11.6) [17.9]	22 (11.6) [17.6]	24 (12.7) [17.9]
HPV35,39,69	26 (13.8) [21.1]	25 (13.2) [20.0]	26 (13.8) [19.4]
HPV56,59,66	39 (20.6) [31.7]	38 (20.1) [30.4]	47 (24.9) [35.1]
CIN2+ (n=58)			
Any hrHPV	51 (87.9) [100.0]	50 (86.2) [100.0]	49 (84.5) [100.0]
HPV16	31 (53.4) [60.8]	29 (50.0) [58.0]	30 (51.7) [61.2]
HPV18	2 (3.4) [3.9]	1 (1.7) [2.0]	2 (3.4) [4.1]
HPV31	13 (22.4) [25.5]	13 (22.4) [26.0]	13 (22.4) [26.5]
HPV45	0 (0.0) [0.0]	0 (0.0) [0.0]	0 (0.0) [0.0]
HPV51	1 (1.7) [2.0]	2 (3.4) [4.0]	2 (3.4) [4.1]
HPV52	6 (10.3) [11.8]	8 (13.8) [16.0]	7 (12.1) [14.3]
HPV33,58	7 (12.1) [13.7]	8 (13.8) [16.0]	6 (10.3) [12.2]
HPV35,39,69	8 (13.8) [15.7]	6 (10.3) [12.0]	7 (12.1) [14.3]
HPV56,59,66	8 (13.8) [15.7]	8 (13.8) [16.0]	9 (15.5) [18.4]
CIN3+ (n=29)			
Any hrHPV	26 (89.7) [100.0]	25 (86.2) [100.0]	24 (82.8) [100.0]
HPV16	20 (69.0) [76.9]	19 (65.5) [76.0]	18 (62.1) [75.0]
HPV18	1 (3.4) [3.8]	0 (0.0) [0.0]	1 (3.4) [4.2]
HPV31	5 (17.2) [19.2]	5 (17.2) [20.0]	5 (17.2) [20.8]
HPV45	0 (0.0) [0.0]	0 (0.0) [0.0]	0 (0.0) [0.0]
HPV51	0 (0.0) [0.0]	0 (0.0) [0.0]	0 (0.0) [0.0]
HPV52	1 (3.4) [3.8]	2 (6.9) [8.0]	3 (10.3) [12.5]
HPV33,58	3 (10.3) [11.5]	4 (13.8) [16.0]	2 (6.9) [8.3]
HPV35,39,69	2 (6.9) [7.7]	1 (3.4) [4.0]	1 (3.4) [4.2]
HPV56,59,66	3 (10.3) [11.5]	4 (13.8) [16.0]	4 (13.8) [16.7]

A positive result is defined as a C_t value ≤38.3 for HPV16 and ≤34.2 for all other genotypes. WD = wet Dacron; DF = dry flocked; CIN = cervical intraepithelial neoplasia

Table 3: Agreement of the number of matching genotypes between paired samples for women with at least one hrHPV+ self-sample

	WD vs DF	WD vs Urine	DF vs Urine
	N (% [95% CI])	N (% [95% CI])	N (% [95% CI])
hrHPV positivity (n=198)			
No match	25 (12.63 [8.34,18.07])	37 (18.69 [13.51,24.83])	40 (20.20 [14.84,26.48])
Partial match	18 (9.09 [5.48,13.99])	29 (14.65 [10.03,20.35])	33 (16.67 [11.76,22.60])
Exact match	155 (78.28 [71.88,83.81])	132 (66.67 [59.64,73.19])	125 (63.13 [56.00,69.86])
<CIN2 (n=144)			
No match	19 (13.19 [5.88,14.58])	29 (20.14 [10.03,20.35])	33 (22.92 [11.76,22.60])
Partial match	10 (6.94 [2.45,9.09])	21 (14.58 [6.69,15.75])	22 (15.28 [7.10,16.34])
Exact match	115 (79.86 [50.88,65.04])	94 (65.28 [40.35,54.68])	89 (61.81 [37.89,52.16])
CIN2+ (n=54)			
No match	6 (11.11 [1.12,6.48])	8 (14.81 [1.76,7.81])	7 (12.96 [1.43,7.15])
Partial match	8 (14.81 [1.76,7.81])	8 (14.81 [1.76,7.81])	11 (20.37 [2.81,9.72])
Exact match	40 (74.07 [14.84,26.48])	38 (70.37 [13.95,25.38])	36 (66.67 [13.07,24.27])
CIN3+ (n=27)			
No match	2 (7.41 [0.12,3.60])	5 (18.52 [0.82,5.79])	4 (14.81 [0.55,5.09])
Partial match	2 (7.41 [0.12,3.60])	5 (18.52 [0.82,5.79])	3 (11.11 [0.31,4.36])
Exact match	23 (85.19 [7.51,16.92])	17 (62.96 [5.08,13.39])	20 (74.07 [6.28,15.17])

WD = wet Dacron; DF = dry flocked; CIN = cervical intraepithelial neoplasia

Conclusions: There was good agreement in HPV genotyping results across these devices, particularly the wet and dry vaginal sampling devices. Further exploration of urine samples is needed to evaluate relative specificity to vaginal self-sampling devices; and to compare HPV genotyping in self-sample devices with clinician-taken samples.

Shift 01-203 / #1730

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
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OFFERING SELF-SAMPLING METHOD FOR HPV-DNA TESTING IN AN ORGANIZED CERVICAL SCREENING PROGRAM: UPDATE OF AN ITALIAN EXPERIENCE

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Introduction: The Local Health Authority of Bologna (the capital of the Emilia-Romagna Region–Northern Italy) launched an initiative that consisted in offering to 30–64 years-old women, overdue for screening due to COVID-19 pandemic, the availability of self-sampling method for HPV-DNA testing as an alternative to a clinician appointment. Never/intermittent attenders were mostly involved. The study aimed to assess the ease of use and the acceptability of self-sampling method as well as its feasibility in the screening programme.

Methods: Self-collection was performed with self-vaginal FLOQSwabs® (Copan SpA). Self-sampling device was available for pick-up and return by the invited women at their local pharmacy. Upon arrival at the laboratory, self-samples were eluted in 5 mL of ThinPrep PreservCyt® media (Hologic Inc) and high-risk HPV-DNA testing was performed by Cobas® 6800 System (Roche Diagnostics). The entire first-level procedure, from the self-sampling device collection to the laboratory result, can be tracked. Women were invited from November 15th 2021 to April 05th 2022. Screening attendance rates were evaluated till December 31, 2022.

Results: A total of 24228 women was invited, with an overall screening attendance of 17.5% (n=4241). Among these, 12.1% (n=2934) accepted self-sampling and 5.4% (n=1307) preferred clinician-sampling. The 15.1% (n=443) of the self-samples were HPV-DNA positive. Adherence to follow-up examinations was 92.8% and CIN2/3 was detected in 4.4% (n=11) of cases. Moreover, two <40 years-old women received a diagnosis of adenocarcinoma in situ. The 1.1% of the self-samples were unsatisfactory. Due to technical-organizational issues, samples were not investigated in 0.7% of cases.

Conclusions: Offering self-sampling method allowed to resolve the backlog due to the pandemic.This method has been positively accepted, proving to be an effective strategy to reach women who historically did not participate in the programmed clinician-based screening. The low percentage of unsatisfactory self-samples reflected ease of use.

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ELEVATE - EARLY DETECTION OF CERVICAL CANCER IN HARD-TO-REACH POPULATIONS OF WOMEN THROUGH PORTABLE AND POINT-OF-CARE HPV TESTING: PORTUGUESE COLLECTION OF CERVICAL SAMPLES

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Introduction: Early detection of cervical cancer through screening (CCS) can increase survival. A 5y project aims to create a novel test and strategy for CCS in hard-to-reach populations. The test combines self-sampling with a low-cost, portable measurement instrument that will be piloted in Belgium, Brazil, Ecuador, and Portugal. To develop a novel HPV DNA test that will detect 14 high-risk HPV types and measure the levels of protein expression, requires clinical validation based on samples from healthy women and real patients. This study focuses on the samples collection conducted in Portugal at the Gynaecology Service of the Institute of Oncology of Lisbon, in a collaboration between the NOVA School of Public Health and the IPOLFG.

Methods: The protocol consisted of recruiting n=250 women from healthcare units providing CCS. Women attending consultations were invited to participate in the study and provided a semi-cervical sample. All samples were taken by the physician to ensure its quality and preserved in Thin Prep. HPV genotyping was performed following the clinical procedures established by IPOLFG.

Results: Between November 2019 and July 2021, n=310 women were enrolled, 116 from IPOLFG and 194 from other healthcare units (one Hospital and five primary care services). The 116 women attending consultations at the Gynecology Service of the IPOLFG presented a median age of 45 years, a histologic diagnostic of 12% (n = 10) carcinoma, 13% (n = 15) high-grade lesions, and 63% (n = 73) low-grade lesions, and 16% (n=18) women had negative cytology. HPV presented in 84%, of which 49% had a single infection and 35% had co-infections with more than one type. The most prevalent type was HPV16.

Conclusions: The Portugal recruitment cohort with histological characterization and HPV status included provides technical and clinical information that supports the necessary clinical validation for the new device and requirements of the ELEVATE project.

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INTER-TEST COMPARISON OF ALINITY M HR HPV VERSUS REALTIME HIGH RISK HPV ASSAY ON CERVICAL AND VAGINAL SAMPLES WITHIN VALHUDES FRAMEWORK

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Introduction: In this study, clinical performance of the Alinity m HR HPV assay (Alinity, Abbott Molecular Inc.) was assessed relative to the RealTime High Risk HPV (RealTime, Abbott Molecular Inc.) for the detection of cervical intraepithelial neoplasia grade 2 or higher (CIN2+) and CIN3 within VALHUDES framework.

Methods: 493 matched cervical and 484 matched vaginal samples from women referred to colposcopy were included in the study (NCT03064087). Vaginal self-samples were collected with Evalyn Brush (Rovers Medical Devices) (n=233) or Qvintip (Aprovix) (n=260) and cervical samples were taken by gynaecologists with a Cervex-Brush (Rovers Medical Devices). Both, vaginal and cervical samples were suspended in 20 ml PreservCyt LBC vials. Colposcopy and histological assessment of biopsies were used as clinical outcome. HPV testing was performed with Alinity and RealTime assays.

Results: The relative sensitivity on cervical samples of Alinity versus RealTime on CIN2+ and CIN3 was 0.96 (95%CI 0.91-1.02) and 0.93 (95%CI 0.86-1.01), respectively, whereas specificity was 1.05 (95%CI 1.00-1.11). Sensitivity of Alinity on vaginal samples was similar to RealTime for CIN2+ (ratio=0.97 [95%CI 0.91-1.04]) and CIN3+ (ratio=0.97 [95%CI 0.89-1.07]), whereas specificity for <CIN2 was significantly higher (ratio=1.09 [95%CI 1.03-1.20]). Relative sensitivity included unity for Evalyn and Qvintip samples for both CIN2+ (ratio Evalyn=0.98 [95%CI 0.88-1.09]); ratio Qvintip=0.97 [95%CI 0.91-1.03]) and CIN3+ (ratio Evalyn =0.95 [95%CI 0.80-1.13]; ratio Qvintip=1.00 [95%CI 1.00 -1.00]), respectively. Specificity of Alinity for <CIN2 on Evalyn samples (ratio=1.11 [95%CI 1.01-1.21]) was significantly higher than RealTime, but on Qvintip samples (ratio=1.07 [95%CI 0.99-1.16]) 95% confidence intervals of relative specificity included unity. Kappa concordance for hrHPV, HPV16, HPV18 and others hrHPV varied from 0.84 to 0.93 on cervical samples and from 0.78 to 0.97 on vaginal samples.

Conclusions: Clinical sensitivity of Alinity HPV was similar to that of the RealTime assay on cervical and vaginal samples, whereas specificity was significantly higher on vaginal samples.

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PROGNOSTIC VALUE OF EXTENDED HIGH-RISK HUMAN PAPILLOMAVIRUS GENOTYPING IN PATIENTS WITH NEUROENDOCRINE CARCINOMA OF THE UTERINE CERVIX: A MULTICENTER LONG-TERM FOLLOW-UP STUDY

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Introduction: The objective of this long-term follow-up study was to identify the prognostic value of extended HPV genotyping in NECC. A meta-analysis of individual participant data (IPD) was also performed.

Methods: All patients diagnosed with NECC from five medical institutions in Fujian Province, China, between January 2008 and August 2016 were recruited for the study. All participants were tested for extended HR-HPV genotyping and immunohistochemical characteristics of cancer tissues. IPD was systematically reviewed in articles that showed the relationship between HPV and NECC published before 28 November 2021. The impact of risk factors on the survival of patients with NECC was evaluated using Kaplan–Meier estimations, log-rank tests and Cox proportional hazards models. Significance was set at a P value <0.05.

Results: Overall, 72 women diagnosed with NECC in China and 50 cases from the IPD meta-analysis obtained from 13 studies were included. In addition, 105 cases were available in HR-HPV genotype results, of which 83 patients (83/105, 79.0%) had HR-HPV infection, and HPV-18 was the predominant genotype (62/105, 59.0%), followed by HPV-16 (17/105, 16.2%), HPV-52 (2/105, 1.9%), HPV-59 (2/105, 1.9%), HPV-31 (1/105, 1.0%), HPV-45 (1/105, 1.0%), and HPV-68 (1/105, 1.0%). The multivariate analysis identified that HR-HPV was associated with poor overall survival of NECC, with an HR (hazard ratio) of 2.619 (95% confidence interval [CI], 1.203-5.702, P=0.015). The research showed that NECC patients with HPV-18 infection were an independent prognostic factor for overall survival (HR, 3.163; 95% CI, 1.294-7.732; P=0.012). HPV-16 infection (HR, 4.418; 95% CI, 1.058-18.457, P=0.042) presented a remarkably poorer prognosis than HPV-18 infection. Although not statistically significant, non-HPV 16/18 infection tended to adversely affect survival (HR, 1.337; 95% CI, 0.136-13.156; P=0.803).

Conclusions: HPV-16 and HPV-18 infection were confirmed as poor prognostic indicators for patients with NECC. Specifically, HPV-16 represented a remarkably poorer prognostic factor.

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EXTENDED GENOTYPING, CYTOLOGY, AND SELF-SAMPLING: RISK-BASED ILLUSTRATIONS

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Introduction: An analysis of published science was used to tabulate immediate risk of CIN3+ and 5-year cumulative incident risk of CIN3+ and then compare the risks to known thresholds for standard of care clinical actions.

Methods: MedLine was searched from 2001 through 2022 for relevant studies, supplemented by hand-searching of retrieved article reference lists. Eligible studies included prospective studies of women and retrospective studies of residual specimens from women that were tested using HPV genotyping tests. Outcomes were CIN3 or CIN3+ or invasive cervical cancer. Existing guidelines were used to establish clinical action thresholds in the USA and globally.

Results: Reporting genotyping provides stratification of both current and future CIN3+ risks. Genotyping combined with cytology improves risk stratification for Bethesda categories NILM, ASC-US, and LSIL. The risks were plotted for the general screening population, for follow-up 1-year after prior result of lesser abnormalities, for post-treatment follow-up, and for vaginal self-sample. By combining the published risks and the published guideline clinical action thresholds, extended genotyping informative illustrations were provided that support risk-based clinical action steps by the principle of equal management for equal risk.

Conclusions: Based on quality-evaluated studies that met inclusion criteria, genotyping combined with cytology stratifies risk. 20 annotated references are provided.

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PAX1/SOX1 DNA METHYLATION FOR TRIAGING HIGH-RISK HUMAN PAPILLOMAVIRUS (HPV) POSITIVE WOMEN IN CERVICAL CANCER SCREENING

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Introduction: HPV testing has been adopted as the primary cervical screening method in many countries. Because of the higher sensitivity and lower specificity of HPV testing compared to cytology, effective triage methods are critical to avoid misdiagnosis and overtreatment. DNA methylation markers have shown the diagnostic potential for triaging high-risk HPV positive women.

Methods: A total of 403 cervical cytology samples obtained from our previous randomized controlled trial were used in this study, including 113 normal cytology, 173 low-grade cervical intraepithelial neoplasia (LG-CIN), 114 high-grade CIN (HG-CIN) and 3 cervical cancers. HPV genotyping was assessed by BD Onclarity HPV assay. The methylation pattern of PAX1 and SOX1 genes was analyzed by quantitative methylation-specific PCR (qMSP) and compared between the groups.

Results: The methylation level of PAX1/SOX1 positively associated with the severity of the underlying disease in HPV positive women. Both methylation markers were significantly higher in HG-CIN and cancers compared to those in LG-CIN and control (all $p<0.001$), either alone or in combination. The sensitivity and specificity of PAX1 in differentiating HG-CIN and cancer from LG-CIN and normal were 73.5% (95%CI: 73.25-73.76) and 70.28% (95%CI: 70.11-70.45), respectively. The sensitivity and specificity of SOX1 were 41.88% (95%CI: 41.59-42.17) and 83.57% (95%CI: 83.43-83.7), respectively. On the other hand, HPV16/18+ showed lower sensitivity (36.75%, 95%CI: 36.47-37.03) and specificity (67.13%, 95%CI: 66.96-67.31) than those of either methylation markers.

Conclusions: Detection of PAX1/SOX1 methylation status has increased sensitivity and specificity for diagnosis of HG-CIN and cancer compared to HPV16/18 genotyping in high-risk HPV positive screen cohort. Using these as a triage for high-risk HPV positive women can potentially reduce the unnecessary colposcopy referrals and overtreatment.

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RISK STRATIFICATION OF CERVICAL INTRAEPITHELIAL NEOPLASIA GRADE 2 (CIN2) BY HUMAN PAPILLOMAVIRUS GENOTYPE

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Introduction: Several countries have recently switched from excisional treatment to active surveillance for CIN2 to reduce risk of overtreatment and associated harm. However repeated examinations may cause discomfort and concerns about disease progression. Thus, it is important to explore potential biomarkers for risk stratification of CIN2. Here, we aimed to describe risk of diagnostic regression in women with an index CIN2 community diagnosis by human papillomavirus (HPV) genotype.

Methods: We conducted a historical cohort study on women aged 23-40 years, who had undergone active surveillance for CIN2 in 2000-2010. Women were randomly selected through the Danish Pathology Databank at Aarhus University Hospital, Denmark. Women were excluded if they had a previous record of CIN2 or more, excisional treatment, or hysterectomy. Cervical tissue samples were tested for HPV using the SFP_{10} DEIA Lipa25-assay. Diagnostic regression was defined as a subsequent record of CIN1 or less in a biopsy or LEEP specimen. We used a Poisson model to estimate the risk of regression (RR), overall and stratified by age (cut-off 30 years).

Results: A total of 511 women were included. Median age was 26 (IQR 24-30) years. High-risk HPV (hrHPV) was detected in 91% of women, and HPV16 was most prevalent (35%). During follow-up, 50% of women had histologically verified regression. Compared to women testing positive for other hrHPV genotypes diagnostic regression was less likely in women positive for HPV16 (RR 0.84; 95% CI 0.78-0.89) and women positive for HPV16/18 (RR 0.88; 95% CI 0.82-0.93). Results did not change when stratifying by age.

Conclusions: As diagnostic regression was lower for women positive for HPV16/18, HPV genotyping might be a useful tool to support shared decision making in the clinical management of women diagnosed with CIN2. Future studies should explore the addition of other HPV-related biomarkers to improve risk stratification of CIN2.

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THE PREDICTIVE VALUE OF METHYLATION MARKERS TO DEVELOP A RECURRENCE IN WOMEN WITH HIGH-GRADE CERVICAL INTRAEPITHELIAL LESIONS

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Introduction: To prevent the burden of cervical cancer, population based cervical cancer screening has been implemented in the Netherlands. The screening consists of hrHPV testing and cytology. To identify more women with (pre)malignant disease than based on hrHPV and triage cytology, DNA methylation markers with high sensitivity and specificity to detect cervical intraepithelial neoplasia (CIN) have been identified. Lesions with CIN2/3 found at colposcopic examination are often treated with a large loop excision of the transformation zone (LLETZ). This treatment is effective, but recurrence rates are high. The aim of this study is to evaluate the correlation between DNA methylation in scrapings collected prior to LLETZ and the occurrence f recurrent CIN2/3 (rCIN2/3) lesions.

Methods: Data on treatment and follow-up of women treated for CIN2/3 lesions in the University Medical Center Groningen (UMCG) between 2004-2017 was collected through the Electronic Patient Record of the UMCG. Written informed consent was obtained for use of patient data and scraping material. To date, cervical scrapings of 18 women with a rCIN2/3 and 32 women without rCIN2/3, matched by CIN score at baseline, age and Pap score at baseline, were analysed. Methylation levels for six genes (ANKRD18CP, C13orf18, JAM3, SOX1, ZSCAN1 and EPB41L3) were determined by quantitative methylation-specific PCR (QMSP).

Results: Preliminary results show that methylation levels of EPB41L3 ($p = 0.022$) and methylation positivity of JAM3, SOX1, ZSCAN1 and EPB41L3 ($p<0.03$) were significantly related with recurrence status.

Conclusions: Our study showed that the levels and positivity of methylation markers as determined in cervical scrapings prior to LLETZ, are correlated with developing an rCIN2+. This indicates that women with methylation positive markers at baseline are more at risk to develop an rCIN2+ lesion than women that are methylation negative. When confirmed in subsequent studies, treatment and surveillance strategies should be tailored according to these findings.

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IMPACT OF HLA-DP RS4713607、EXOC1 RS13117307 AND MIR-219A1 RS213210 GENETIC POLYMORPHISMS ON THE CERVICAL CANCER SUSCEPTIBILITY IN CHINESE WOMEN

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Introduction: To investigated the association between 11 SNPs and cervical cancers among Chinese women, to identify new genetic risk factors for cervical cancer.

Methods: This study is a multi-center study in the Fujian and Shenzhen Maternity and Child Healthcare Hospital. The selected Single-Nucleotide Polymorphisms (SNPs) (rs13117307, rs2116260, rs4282438, rs3117039, rs4713607, rs3129275, rs3117008, rs9391756, rs213210, rs9277952, rs8067378) were genotyped by the Kompetitive Allele-Specific PCR (KASP) method.

Results: In all HPV (+) women, the rs213210, rs4713607 and rs13117307 were association with HPV infection ($P < 0.001$). The EXOC1 rs13117307 and MIR-219A1 rs213210 showed lower risk of HPV infection (OR=0.47, $P < 0.001$; OR=0.63, P=0.002) . The rs13117307 T/T, rs213210 T/T genotypes may be related to a lower risk of HPV infection. HLA-DP rs4713607 showed higher risk of HPV infection (OR=2.51, $P < 0.001$) and cervical cancer (OR = 1.61, P = 0.02). The rs4713607 A/G and G/G genotypes may be related to a higher risk of developing cervical lesions compared with the A/A genotype.

Conclusions: Our study determined that HLA-DP rs4713607 G/G contribute to the HPV infection and cervical cancer, while EXOC1 rs13117307 T/T and MIR-219A1 rs213210 T/T were the protective alleles of HPV infection.

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POINT-OF-CARE TESTS TO AMPLIFY AND DETECT HIGH-RISK HPV DNA AND MRNA

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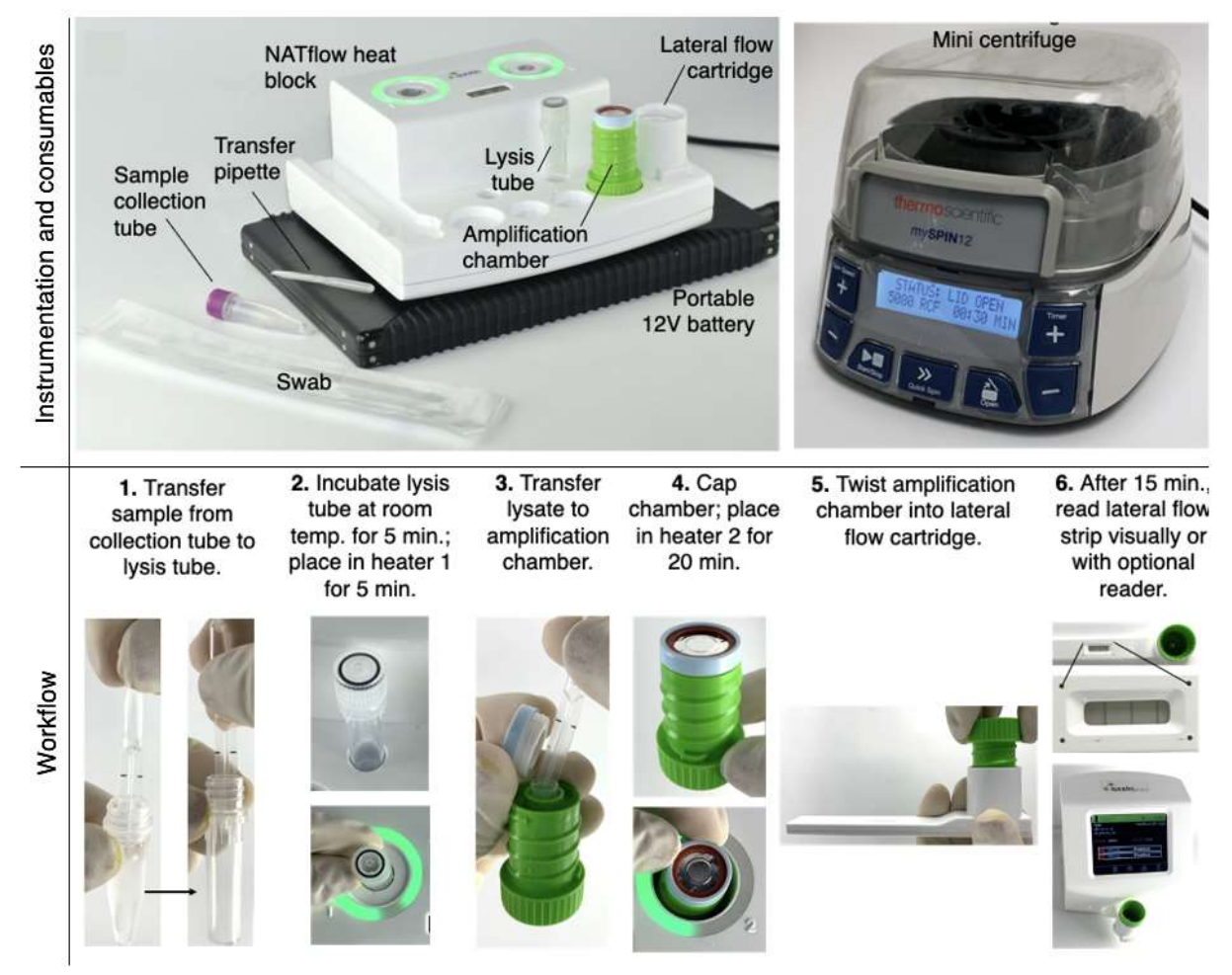
Introduction: Screening with a high-precision HPV test is an important pillar of the global cervical cancer elimination strategy. However, HPV molecular testing remains too costly and/or too complex for widespread use in resource-limited settings. Toward the development of point-of-care HPV tests, we demonstrated low-cost, low-infrastructure methods to detect HPV16 and HPV18 DNA and mRNA.

Methods: We developed Recombinase Polymerase Amplification (RPA) assays targeting the E7 gene of HPV16 and HPV18. For DNA detection, the RPA assay was incorporated into a novel sample-to-answer, cartridge-based test with a visual lateral flow readout. The DNA test was validated with 42 cellular samples collected with cervicovaginal swabs from a referral population in Houston, Texas. To detect mRNA, a custom reverse transcription RPA (RT-RPA) assay was developed with real-time fluorescence detection. The mRNA test was validated with 11 cellular samples on low-cost, affordable fluorimeters appropriate for use in resource-limited settings.

Results: The RPA DNA test, which requires six user steps and provides a qualitative result within 45 minutes (see figure), reliably detected as low as 1,000 HPV 16 and 18 DNA copies per reaction in cervicovaginal samples. The overall percent agreement between the RPA DNA test and Roche cobas HPV was 85% (n=42), and all discordant samples had fewer than 500 copies of HPV DNA per reaction. The RPA mRNA test detected as low as 1,000 copies of extracted cellular RNA per reaction, and overall percent agreement with in-house RT-qPCR was 91% (n=11). No cross-reactivity was detected with other high- and low-risk HPV

genotypes.



Conclusions: These RPA HPV DNA and mRNA tests are low-cost, rely on limited infrastructure, and demonstrate analytical sensitivities and specificities similar to those of select commercially available tests. Future work will include (1) incorporating additional HPV genotypes for maximum clinical sensitivity and specificity and (2) evaluating point-of-care sample preparation methods for improved analytical sensitivity.

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A COMPREHENSIVE AND COST-EFFICIENT NGS ASSAY FOR DETECTION OF 41 HPV AND NON-HPV SEXUALLY TRANSMITTED INFECTIONS

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Introduction: Sexually transmitted infections (STI) cannot be regarded as an isolated problem since multiple HPV-STI co-infections are rather common and these infections are often asymptomatic or may induce non-specific symptoms. A comprehensive HPV-STI diagnostic tool can prevent further spreading of STIs in a healthy population and provide an extensive overview of HPV and STI co-infections.

Methods: A set of 274 samples that were previously tested by Roche cobas HPV test were analyzed by ChapterDx comprehensive NGS-based method. ChapterDx assay amplifies and detects 28 HPVs and 13 STIs type-specifically (including Chlamydia trachomatisserotypes). The NGS assay workflow includes a single-tube and single-PCR reaction, where barcoding and amplification occur simultaneously. For HPV genotyping study, a set of 75 samples previously analyzed by Genomica Clart HPV assay were analyzed by ChapterDx HPV-STI NGS assay.

Results: ChapterDx HPV-STI assay and Roche cobas HPV test exhibited an overall agreement of 97.5% for hr-HPV, and 98.5% for both HPV16 and HPV18. The NGS assay also detected HPV-infected CIN2/3 with 100% agreement. Moreover, several co-infections with non-HPV STIs, such as C. trachomatis, T. vaginalis, M. genitalium, and HSV2 were identified. The genotyping agreement with Genomica Clart HPV assay was 98.7% and ChapterDx HPV-STI NGS assay detected other non-HPV STIs in the genotyping sample group, which included C. trachomatis, N. gonorrhea, T. vaginalis, M. hominis, and U. parvum.

Conclusions: ChapterDx HPV-STI NGS assay showed excellent concordance for HPV detection and genotyping with both Roche cobas and Genomica Clart assay. Moreover, ChapterDx assay detected non-HPV STIs in both sample groups, which shows many samples harbor other STIs that go undiagnosed in selective testing. ChapterDx NGS assay is a user-friendly and easy to automate method, which provides accurate and comprehensive results for a wide spectrum of HPVs and STIs. The assay is cost-efficient and can be applied to low, medium, and high-throughput sample scales.

Shift 01-216 / #928

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-18-2023 7:00 AM - 5:00 PM

IDENTIFICATION AND PROFILING OF HPV INDEPENDENT AND DEPENDENT CERVICAL CANCER IN LOW RESOURCE SETTINGS

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Introduction: The majority of cases of cervical cancer are caused by human papillomavirus (HPV); however, up to 5% of tumors are not associated with HPV-persistent infection and, moreover, the new WHO Female Genital Tumors classification (2020) subdivided cervical squamous and adenocarcinomas into HPV-associated and HPV-independent tumors. HPV testing is a highly sensitive technique with high negative predictive value. In the local setting, there are few accredited testing centers and the costs can be prohibitive. HPV-associated tumors show increased expression of inhibitor proteins, such as p16, which can serve as a surrogate marker of HPV infection, especially in a low resource setting. Based on this new information, the aim of this review is to provide an overview of HPV- independent and associated cervical cancer, evaluating diagnostic techniques, and clinicopathologic profiles and outcomes.

Methods: This is a retrospective cohort from 2020-September 2022 of all cervical cancer patients in a National Cancer Institute in the Philippines. 950 new cases of cervical cancer were reviewed regarding HPV status. Case note and pathologic slide review were done on the HPV independent cases. Clinicopathologic profiling of HPV-associated and independent cervical cancers were noted.

Results: Only 23 patients (2.4%) were classified based on their HPV status, and most were classified via p16 as a surrogate marker (21, 91%). There were 20 (87%) HPV dependent cases. Only 3 HPV independent cases (15%) were identified with the following histopathologies: clear cell, mesonephric type adenocarcinoma and endocervical adenocarcinoma.

Conclusions: HPV-independent and HPV-associated tumors should be classified separately and p16 could be utilized in low resource settings as a surrogate marker for HPV. Thus far, no specific therapeutic strategies have been developed based on HPV status; however, with advancing knowledge of differences in the molecular profiles it is crucial to stratify in the local setting as novel approaches may be developed in the near future.

Shift 01-218 / #1112

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-18-2023 7:00 AM - 5:00 PM

LABEL-FREE ELECTROCHEMICAL IMMUNOSENSOR FOR CERVICAL CANCER SCREENING

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Introduction: Human papillomavirus (HPV) is the leading cause of cervical cancer. Current cervical cancer screening consists of various order of cytology on Pap smear and HPV test, samples for which are collected by a doctor or a nurse. These methods, however, require skilled personnel and infrastructure, all of which limit the possibility of using this technique at the point of care or in resource-limited settings. In the Pap test, the pathologist checks the sample for cancer cells or detects precancerous changes and the presence of Ki-67 and P16ink4a which are associated with high-grade lesions via immunostaining. The simultaneous detection of the anti-proliferative P16ink4a protein and the proliferation marker Ki-67 provides a strong indicator of the presence of transforming HPV infections which suggests a higher risk of developing cervical cancer.

Methods: As part of ELEVATE (a EU funded H2020 project), we developed a label-free electrochemical sensor for Ki-67 and P16ink4a detection. The sensor was developed by immobilizing custom-made antibodies on a gold electrode surface using a specific crosslinker. The immobilized anti- P16ink4a recognizes the target protein in the sample. The coupling event between antibodies and targets hinders the charge electron transfer transduced by a decrease in the current signal which is proportional to the target concentration.

Results: The optimized sensor was found to be highly sensitive with LoD 1.6 and 1.1 ng/mL and LoQ 5 and 3.33 ng/mL for P16ink4a and Ki-67 respectively, easy to use and capable of detecting target proteins in less than one hour.

Conclusions: The developed P16ink4a and Ki-67 electrochemical sensor can be exploited in portable integrated molecular diagnostic devices, for point of care or in limited resource areas to determine cell dysplasia and cervical cancer. Using clinical samples, the results of the developed sensor would be compared with that of in-house ELISA developed specifically for these type of samples.

Shift 01-219 / #1434

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-18-2023 7:00 AM - 5:00 PM

QUANTIGENE-MOLECULAR-PROFILING-HISTOLOGY (QG-MPH) ASSAY IS A CERVICAL DYSPLASIA SEVERITY DIAGNOSING SCREENING/TRIAGING TEST USING MULTIPLEXED MESSENGER-RNA-QUANTITATION OF BIOMARKERS POTENTIALLY WITH A PROGNOSIS FOR LESION DEVELOPMENT

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Introduction: NAT-based HPV screening is WHO standard. Low specificity for true dysplasia detection by PCR-based assays poses problems. Triage by cytology, biomarker-based IHC, or methylation marker assays shall prevent over-referral to treatment. We developed and validated a multiplexed and cost-efficient HPV-oncogene and biomarker mRNA-detecting and directly quantifying assay (QG-MPH). Highly accurate risk score (RS) calculations detect and discriminate cervical dysplasia, reducing pathology services need.

Methods: QuantiGene 2.0 (ThermoFisher) platform-technology was used for highly economical multiplexed evaluation of 18 HR-HPV-oncogene and 18 cellular-biomarker mRNAs. QG-MPH RSs developed on 1400 consecutively collected smears have an AUC (accuracy=sensitivity+specificity) >80% (CIN2, CIN3) and >92% (cervical cancer, CxCa). From a triage study population morphologically-identified CIN3 (pathology result) were characterized for their biomarker expression and RS-dependent classification (≤CIN2 vs. CIN3 vs. CxCa). HPV genotype composition, viral E7 expression-strength, and methylation marker positivity by Gyntect assay (Oncgnostics, Jena, Germany) were compared.

Results: HR-HPV genotype composition differed markedly in CIN3 underrated as ≤CIN2, correctly identified as CIN3, or over-rated as CxCa by the specific RSs, with 8.8%, 53.3%, 66.7% HPV16/18 prevalence, 20.6%, 31.1%, 38.9% for 7 most carcinogenic genotypes, and 14.7%, 6.7%, 8.3% potentially carcinogenic genotypes, respectively. E7-oncogene expression was below detection cut-off in 55.9%, 8.8%, 0%, respectively. Importantly, by the methodologically RS-unrelated Gyntect-measurement of 6 methylated target genes, the positivity cut-off for CIN3+ was reached in 22.6%, 56.5%, 77.8%, respectively, for the 3 RS-classified groups. A comparable genotype difference and methylation marker increase was seen in pathology/morphology-defined dysplasia diagnoses CIN2.

Conclusions: QG-MPH assay is useful to detect and diagnose specific dysplasia severity, e.g. for LMIC settings (sparse pathology services). RS results may reflect lesion biology and prognosis for dysplasia pro-/regression. This has to be evaluated in longitudinal studies. QG-MPH may solve screening problems concerning cost, roll out, and specificity in high-risk populations like WLWH.

Shift 01-220 / #1478

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-18-2023 7:00 AM - 5:00 PM

TOPOLOGICAL ANALYSIS OF THE PROGRAMMED DEATH-LIGAND (PD-L1) ASSOCIATED IMMUNE MICROENVIRONMENT IN ANAL HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS (HSIL) AND ANAL SQUAMOUS CELL CANCER (SCC)

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Introduction: Upregulation of and direct interaction between programmed cell death protein 1 (PD-1) and programmed death-ligand 1 (PD-L1) leads to immunosuppression and may be important in the pathogenesis of HPV-associated squamous cell carcinoma (SCC). Little is known about the expression anal spatial relationship of PD-1 and PD-L1 in anal epithelial cells (EC) and immune cells (IC) in the immune microenvironment (IM) of anal SCC and high-grade squamous intraepithelial lesions (HSIL). Using multiplex immunofluorescent technology (mIF) we simultaneously visualized the expression of PD-L1, PD-1, T cells (CD4+, CD8+), macrophages (CD68) and cytokeratin (CK) in SCC and HSIL. Density and median distance (md) between cells expressing these proteins were analyzed, to characterize the IC infiltrate and cell-cell interactions that shapes the IM.

Methods:

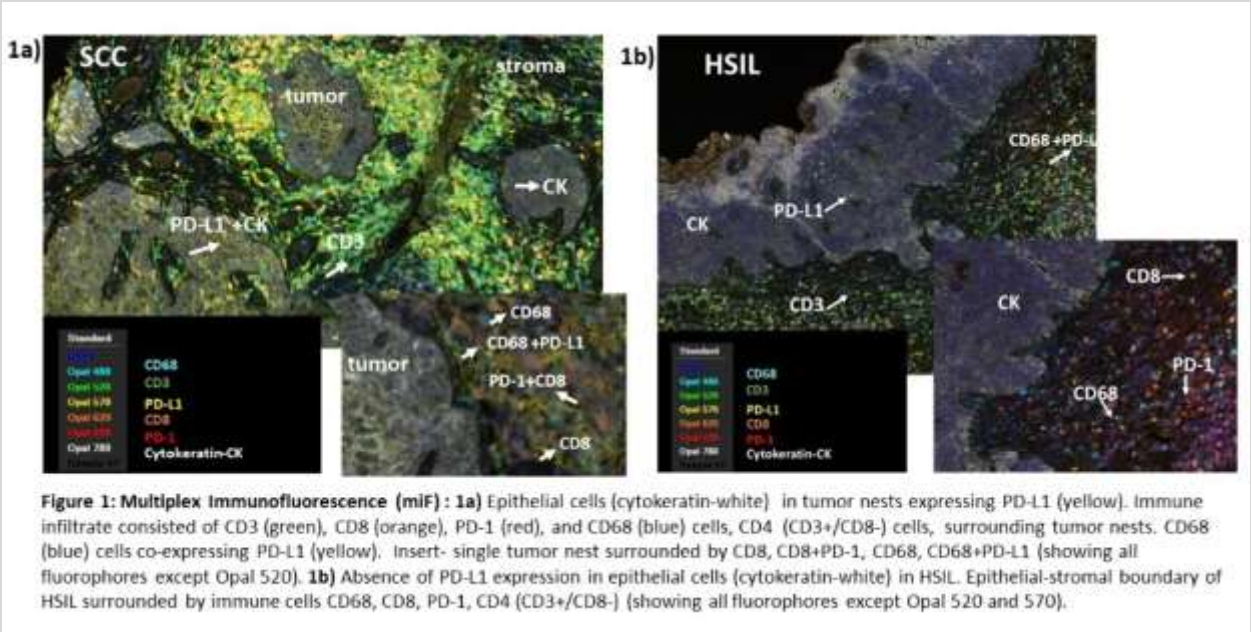

Figure 1: Multiplex Immunofluorescence (miF) : 1a) Epithelial cells (cytokeratin-white) in tumor nests expressing PD-L1 (yellow). Immune infiltrate consisted of CD3 (green), CD8 (orange), PD-1 (red), and CD68 (blue) cells, CD4 (CD3+/CD8-) cells, surrounding tumor nests. CD68 (blue) cells co-expressing PD-L1 (yellow). Insert- single tumor nest surrounded by CD8, CD8+PD-1, CD68, CD68+PD-L1 (showing all fluorophores except Opal 520). **1b)** Absence of PD-L1 expression in epithelial cells (cytokeratin-white) in HSIL. Epithelial-stromal boundary of HSIL surrounded by immune cells CD68, CD8, PD-1, CD4 (CD3+/CD8-) (showing all fluorophores except Opal 520 and 570).

Sequential staining of formalin-fixed paraffin-embedded (FFPE) tissues was performed with 7 biomarkers attached to tyramide-conjugated Opal fluorophores, including CD68-480, CD3-520, PD-L1-570, CD8-620, PD-1-690, CK-780 and DAPI. Multispectral imaging and digital image analysis was performed on 5 SCC and 2 HSIL samples.

Results:

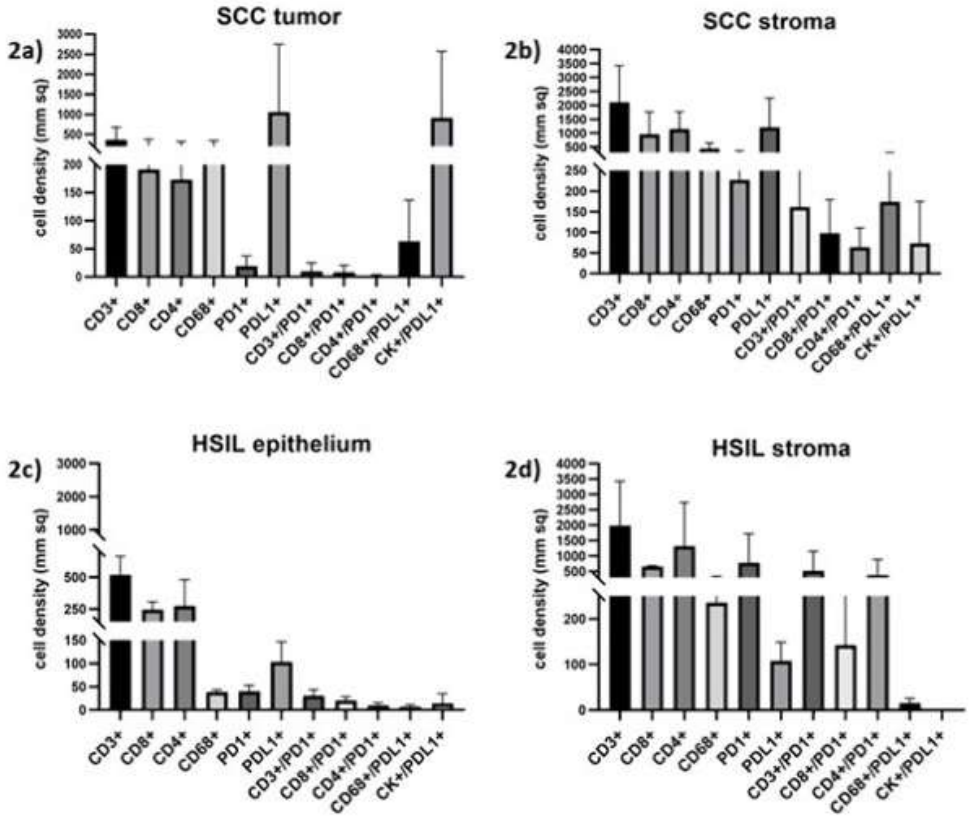

Figure 2: Density, distribution and composition of immune and non-immune cells in SCC (a,b) and HSIL (c,d). Quantification of single stained biomarkers CD3+, CD8+, CD4+ (CD3+/CD8-), PD-1+, PD-L1+ and co-localized biomarkers CD3+/PD-1+, CD8+/PD-1+, CD4+/PD-1+, CD68+/PD-L1+, CK+/PD-L1+ in stroma and epithelium. Degree of immune cell infiltration in response to PD-L1 expression in CK and CD68 cells. Average density of 5 SCC and 2HSIL has been displayed.

PD-L1 expression was seen in SCC tumor cell nests but not in EC of HSIL (Fig1 a,b). The density of CD3+ T cells was higher in the stroma of SCC than within the tumor nest. CD68+/PD-L1+ cells were found in HSIL and SCC (Fig2). The md from CK+/PD-L1+ tumor cells to the nearest CD68+/PD-L1+ was less than the md from CK+/PD-L1- to the nearest CD68+/PD-L1+ in both the stroma and within tumor nests of SCC samples (Fig3).

Conclusions:

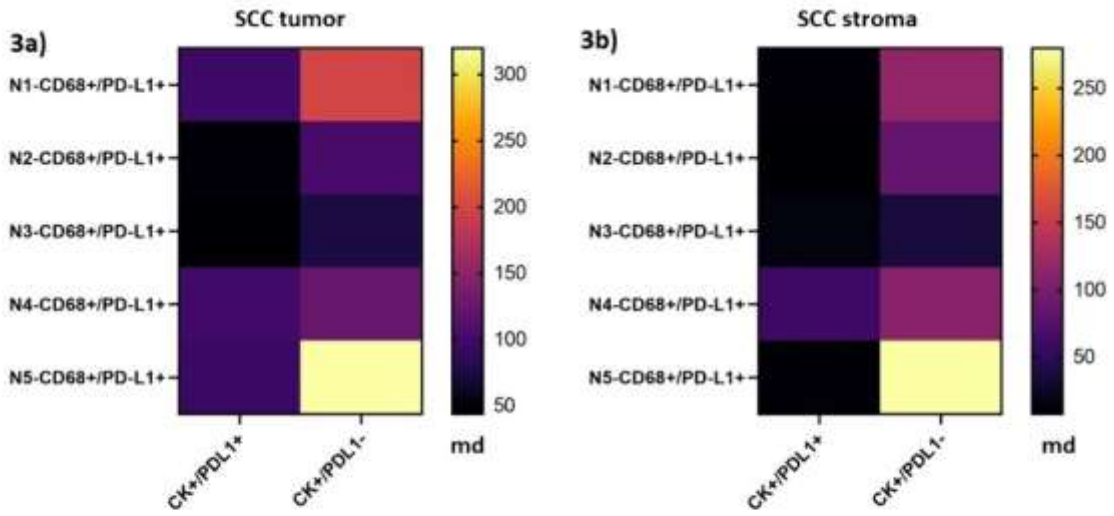

Figure 3: Spatial analysis showing the relative proximity (median distance) from CK+ cells expressing PD-L1 (first column) to CK+ cells not expressing PD-L1 (second column) to CD68+/PD-L1 cells in the tumor (a) and stroma (b) of SCC. N1-N5=patients, md=median distance in microns. CD68+/PD-L1+ cells were closer to CK+/PD-L1+ cells in comparison to CK+/PD-L1- cells both in tumor and stroma. Enrichment of CD68+/PD-L1+ cells in the vicinity of PD-L1 positive tumor cells reveals a unique topography. Heat map was generated by statistical software-GraphPad Prism 9.3.1

PD-L1 expression varied according to severity of pathology; in SCC expressed in EC and macrophages and in HSIL only in macrophages. Enrichment of CD68+/PD-L1+ cells near tumor cells expressing PD-L1 (CK+/PD-L1+) increases the total amount of PD-L1 available to bind PD-1+ T cells (CD4+, CD8+). This IM may potentiate anal tumorigenesis through T cell suppression and blocking T cell infiltration into tumor nests.

Shift 01-221 / #1511

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-18-2023 7:00 AM - 5:00 PM

HPV ANTIBODY RESPONSE AND RISK OF ANAL AND VULVAR HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESION RECURRENCE

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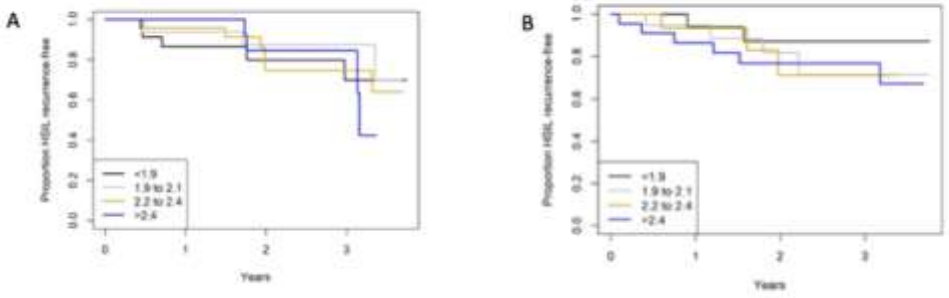
Introduction: The overwhelming antibody response elicited by the nonavalent HPV (9vHPV) vaccine is the putative mechanism for preventing HPV infection in uninfected individuals. Our understanding of the magnitude and effect of the 9vHPV vaccine-induced antibody response in reducing high-grade squamous intraepithelial lesion (HSIL) recurrences among an older cohort is limited. We assessed the immunogenicity of 9vHPV vaccineand the risk of anal or vulvar HSIL recurrence among participants in the VIVA trial.

Methods: The VIVA trial evaluated the efficacy of 9vHPV vaccine to reduce HSIL recurrence in persons with prior anal or vulvar HSIL. Participants free of anal/vulvar HSIL at screening were randomized to 9vHPV vaccine or placebo and vaccinated at 0, 2, and 6 months. High-resolution anoscopy or vulvoscopy was performed at 18 and 36 months to evaluate HSIL recurrence, and blood was collected at 0, 7, 18, and 36 months to test for vaccine-type HPV antibodies using Luminex. We evaluated the immunogenicity of 9vHPV vaccine measured by MFI and assessed whether the presence of HPV antibodies is protective against HSIL recurrence.

Results: Of 181 persons (age 27-69 years, median 55) included in the intention-to-treat analysis, 88 received 9vHPV vaccine and 93 received placebo. At baseline, 165 participants had natural antibody titers to 9vHPVvaccine-types. At 1 month after 3-dose vaccination, the HPV16 and HPV18 antibody MFI values among 9vHPV recipients had increased by a median (IQR) ratio of 52 (27 to 135) and 43 (20 to 140), respectively, relative to baseline. We found no association between vaccine-type antibody titers and reduced risk of HSIL recurrence among placebo (p=0.92) or vaccine (p=0.71) recipients. We will present updated longitudinal immunogenicity results at the

conference.

Figure 1. Kaplan-Meier curve for histologically-confirmed HSIL recurrence for A) placebo recipients, and B) nonavalent HPV vaccine recipients by quartile of HPV antibody level.



Conclusions: The 9vHPV vaccine induces a strong antibody response in persons up to age 69 years. There was no evidence that natural or vaccine-induced antibody responses influenced anal or vulvar HSIL recurrence.

Shift 01-222 / #1690

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-18-2023 7:00 AM - 5:00 PM

PERFORMANCE OF DNA METHYLATION-BASED PAX1 AND JAM3 DETECTION AMONG HPV INFECTED WOMEN WITH THE CERVICAL INTRAEPITHELIAL NEOPLASIA GRADE 3 AND INVASIVE CERVICAL CANCER

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Introduction: Primary cervical cancer screening by using HPV testing and cytology is being implemented in several countries. However, cytology as triage for colposcopy referral suffers from several shortcomings, and HPV testing overcomes some of these but lacks specificity in young women. Here, we aimed to develop and validate an automatable triage test that is highly sensitive and specific independently of age and accurate detection of CIN3+ in HPV+ patients.

Methods: This study collected 20000+ samples of cervical cancer opportunistic screening in Peking Union Medical College Hospital, and cervical exfoliated cells were collected for liquid-based cytology, hrHPV genotyping, and PAX1 and JAM3 gene methylation tests (CISCER®, Beijing Origin Poly Bio-Tec Co., China). The participants underwent colposcopy and biopsy. The final diagnosis was based on the pathology. All participants followed standard cervical cancer diagnosis, treatment, and management guidelines. The diagnostic accuracies of screening strategies for definitive pathology and CIN3 or more severe lesions (CIN3+) were compared.

Results: Satisfactory risk stratification to detect cervical intraepithelial neoplasia grade 3 or worse (CIN3+) was demonstrated by the PAX1 and JAM3 gene methylation tests with an odds ratio of 24.0 among methylation-positive women compared to -negative counterparts. As a triage method for initially screened, PAX1 and JAM3 gene methylation analysis showed >90% of clinical specificity in women with/without 16/18 hrHPV+.

Conclusions: The PAX1 and JAM3 gene methylation test alone or combined with hrHPV genotyping can stratify hrHPV+ women in the baseline risk of CIN3+ disease. It is a promising triage strategy for cervical cancer screening and can identify most women with (pre) invasive cervical cancer in an objective and scalable way.

Shift 01-223 / #1693

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-18-2023 7:00 AM - 5:00 PM

IDENTIFYING SMALL NON-CODING RNAS AS BIOMARKERS FOR CERVICAL CANCER

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Introduction: Background: Small non-coding RNAs (sncRNAs) that control post-transcriptional gene expression are attractive candidate molecular targets for cancer screening tests. We evaluated whether sncRNAs expression are markedly different in benign, precancerous, and cancerous cervical tissue.

Methods: We examined the expression of six sncRNA species: circular RNAs (circRNAs) microRNAs (miRNAs), piwi-interacting RNA (piRNAs), small nuclear RNA (snRNAs), small nucleolar RNA (snoRNAs), and transfer RNA (tRNA), from archival formalin-fixed paraffin-embedded cervical specimen obtained from 172 women (74 benign, 58 high-grade squamous intraepithelial lesion (HSIL) and 40 invasive cervical cancer). We used DESeq2 to identify differentially expressed sncRNA molecules with adjusted p-value < 0.05 and at least 2-fold up- or down-regulation.

Results: Comparing benign to HSIL samples, we found several statistically significant, differentially expressed sncRNAs: 906 circRNAs (*circ_0066810, $p=3.76x10^{-16}$), 87 miRNAs (*miR-149-5p, $p=1.30x10^{-14}$), 11 piRNAs (*piR_016945, $p=8.32x10^{-13}$), 32 snRNAs (*RNU1-17P, $p=1.90x10^{-10}$), 5 snoRNAs (*SCARNA18, $p=1.35x10^{-5}$), and 24 tRNA (*tRNA-Glu-TTC-8-1, $p=6.45x10^{-17}$). Comparing benign to invasive cervical cancer samples, we also found several statistically significant, differentially expressed sncRNAs: 3,192 circRNAs (*circ_0123115, $p=7.46x10^{-50}$), 325 miRNAs (*miR-7-5p, $p=6.72x10^{-36}$), 82 piRNAs (*piR-hsa-27513, $p=1.44x10^{-15}$), 71 snRNAs (*RNU1-20P, $p=1.37x10^{-45}$), 52snoRNAs (*SNORD95, $p=1.68x10^{-23}$), and 68 tRNA (*tRNA-Cys-GCA-9-3, $p=1.01x10^{-21}$). * Indicates the sncRNA with the smallest p-value, for each specie.

Conclusions: Our results identify sncRNAs with potential utility of as diagnostic and prognostic biomarkers, and therapeutic targets for cervical precancer and cancer.

Shift 01-224 / #1659

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02M. NOVEL DIAGNOSTIC TECHNOLOGIES FOR HPV-RELATED DISEASE
04-18-2023 7:00 AM - 5:00 PM

EVALUATE SALIVA AS A SAMPLE ON THE GENEXPERT® SYSTEM TO ELIMINATE HPV DRIVEN OROPHARYNGEAL CANCER THROUGH EARLY DETECTION

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[1]Griffith University, Gridd And Mhiq, Nathan, Australia, [2]Griffith University, Griffith Institute For Drug Discovery, Nathan, Australia, [3]RBWH, Ent, Brisbane, Australia, [4]RBWH, Cancer Care Services, brisbane, Australia

Introduction: Human Papillomavirus (HPV) is one of the most common sexually transmitted infections in young adults. Persistent HPV infection may lead to the development of oropharyngeal cancer (OPC) and is rising globally. Early detection of HPV infection in high-risk communities, and early intervention is considered as one of the most effective strategies to eliminate HPV-driven cancers. However, the lack of standardised, point-of-care tests hampers early diagnosis of HPV driven OPC, especially in rural and remote communities. Unlike other HPV-driven cancers, OPC's originate in the tonsillar crypts and access to this anatomical site is limited. GeneXpert® system is an automated PCR-based point-of-care diagnostic platform, originally developed for the detection of HPV in vaginal swab samples. We have used the GeneXpert® to detect HPV infection in salivary oral rinse samples. Quantitative real-time polymerase chain reaction (qPCR) was used as the gold standard method for comparison.

Methods: We have recruited 107 participants including at-risk groups and HPV-OPC patients. A total of 10mL of salivary oral rinse samples were collected from participants. Volume of 1mL of enriched salivary oral rinse samples were used on the GeneXpert® system, whereas extracted DNA from samples was used for qPCR.

Results: The results from the GeneXpert® system significantly corroborated with qPCR results (Kendall's W coefficient = 0.952, $p < 0.001$, $n = 107$). In addition, the GeneXpert® system showed a specificity of 100% and sensitivity of 92.86%, highlighting the detection of HPV with minimal bias.

Conclusions: GeneXpert® system can be used with saliva as a biological fluid to detect HPV in a remote setting. This may pave the way towards future screening studies targeting communities where the HPV prevalence is high. In addition, GeneXpert® can also be used in stratifying the risk of developing HPV-driven OPC, whereby providing a platform to eliminate HPV-driven OPC in the distant future.

Shift 01-229 / #781

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02D. BEHAVIOURAL SCIENCE ASPECTS OF NEW TECHNOLOGIES IN CERVICAL SCREENING INCLUDING DISSEMINATION/COMMUNICATION RESEARCH
04-18-2023 7:00 AM - 5:00 PM

HOW TO COMMUNICATE HPV SELF-COLLECTION: A LANDSCAPE ANALYSIS OF PATIENT-FACING MATERIALS

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Introduction: Self-collection of samples by women for HPV testing can overcome barriers for conventional cervical cancer screening. While not yet FDA-approved, this method has been explored for its feasibility, acceptance, and accuracy in research projects in diverse delivery settings (homes, clinics, community settings) and has been integrated successfully as part of routine cervical cancer screening programs in several countries. This project examines the landscape of patient-facing informational material that have been used to explain the process of self-collection.

Methods: Principal investigators from publicly funded projects on HPV self-collection for cervical cancer screening were contacted and requested to share their patient-facing materials and instructions for self-collecting vaginal samples. Materials were cataloged and examined for length, reading level, population specificity, and other factors.

Results: Self-collection instructions were received from 14 investigators representing 21 studies involving self-sampling (31% response rate). The instructions had between 4 and 30 steps (median 9) and all materials included at least one diagram, cartoon, or photo. For instructions in English (18/21), the Flesch-Kincaid Grade level (readability) ranged from 1.8 to 9 (median 4.9), indicating ‘very easy to read’. In 12/21 studies, the sample was self-collected at home with instructions to mail or drop off the specimen, whereas self-collection was done in the clinic setting in 5/21 studies and in either/both settings in 4/21 studies. Most studies adapted the material to cultural and language needs of the target populations, which included those living with HIV and racial and ethnic minorities.

Conclusions: Clear communication using these materials is essential to the successful collection of a sample that can be used to detect HPV in women at risk of developing cervical cancer. The US National Cancer Institute (NCI) plans to develop a publicly accessible repository of patient facing materials for community-based groups who may implement self-collection-based cervical cancer screening initiatives to reach underserved and hard-to-reach communities.

Shift 01-230 / #1085

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02D. BEHAVIOURAL SCIENCE ASPECTS OF NEW TECHNOLOGIES IN CERVICAL SCREENING INCLUDING DISSEMINATION/COMMUNICATION RESEARCH
04-18-2023 7:00 AM - 5:00 PM

STRATEGIES TO IMPROVE JAPANESE CERVICAL SCREENING COVERAGE: RESULTS OF THE FIRST SYSTEMATIC CERVICAL SCREENING TRAINING PROGRAM FOR NURSES IN JAPAN

Risa Kudo[1], Sachiko Suzuki[2], Sharon Hanley[3], Akiko Enatsu[4], Yuka Kitajima[5], Kaori Nishimura[5], Riyako Murakami[5], Eriko Kobayashi[5], Miyoko Murata[5], Tomoko Saotome[6], Hiromi Matsui[5]
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Introduction: Under-screened women are at risk for cervical cancer. This represents around 60-70% of Japanese women. Government initiatives such as free screening coupons have not increased coverage. While cervical screening has traditionally been done by gynecologists, from 2016 nurses could perform screening under physician supervision. However, physician resistance meant no training program was implemented. This study evaluates the results of the first cervical screening training program for nurses in Japan.

Methods: The program was implemented in two parts, a basic and an advances program. Between 2018-2022, 48 nurses underwent lectures on cervical cancer natural history, the anatomy of the pelvis and issues to be considered when performing screening such as explanation of the test and how to put women at ease. They practiced taking smears on dummies and then performed smears on each other under the supervision of a gynecologist. From June 2022, two of the nurses who attended the basic training attended the advanced course where they could perform smears on healthy women. To date they have performed smears on healthy women and the women were asked to complete a questionnaire to evaluate their experience.

Results: In both the basic and advanced program, no inadequate smears were recorded. Feedback from the women was positive and included comments such as: ‘I was relieved. Before the test, I was given a detailed explanation of the procedure and how to understand the results', 'I was reassured because the same person explained and took the test', 'Because I was not rushed', 'I will take the test again in the future'.

Conclusions: Nurses could perform screening well and the women being screened felt reassured. However, barriers to recruiting healthy women for nurses to perform screening remains. Efforts are needed to facilitate nurse-led screening in Japan which may help to increase coverage.

Shift 01-231 / #1188

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02D. BEHAVIOURAL SCIENCE ASPECTS OF NEW TECHNOLOGIES IN CERVICAL SCREENING INCLUDING DISSEMINATION/COMMUNICATION RESEARCH
04-18-2023 7:00 AM - 5:00 PM

PREFERENCES FOR HPV SELF-SAMPLING IMPLEMENTATION IN A SAFETY NET HEALTHCARE SYSTEM

Susan Parker[1], Trisha Amboree[2], Maria Daheri[3], Elizabeth Chiao[4], Ashish Deshmukh[5], Michael Scheurer[2], Kathleen Schmeler[6], Matthew Anderson[7], Sue Hilsenbeck[1], Shaun Bulsara[1], Mohammad Zare[8,9], Maria Jibaja-Weiss[1], Jane Montealegre[2]
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Introduction: At-home self-sample HPV testing kits have been demonstrated to improve cervical cancer screening participation among underscreened women, but patient preferences for their implementation have not been widely assessed.

Methods: We assessed patient preferences as part of the PRESTIS (Prospective Evaluation of Self-Testing to Increase Screening) randomized controlled trial. Trial participants are women enrolled in a public safety net health system, ages 30-65 years, who are underscreened for cervical cancer. We conducted a telephone survey in English and Spanish among a subgroup of trial participants randomized to self-testing.

Results: Of the 232 surveys completed, most were conducted in Spanish (61.2%). Most survey participants (65.1%) used the kit to obtain a cervicovaginal sample. Among the women who used the kit, 96.8% responded that they would be willing to use a self-sampling kit again. Over half (59.5%) stated they would prefer to collect their own sample in the future, 19.6% stated they would prefer a physician or nurse collect the sample and 20.9% were unsure. Significantly more English- versus Spanish-speaking participants preferred self-sample over clinic-based screening in the future (73.3% vs, 50.5%, $p<0.05$). Most participants (77.8%) said they would prefer to receive a kit in the mail, while 13.1% would prefer to receive the kit directly from their healthcare provider in the clinic. A higher percentage of English-speaking participants reported a preference for a mailed kit (86.7%) compared to Spanish-speaking participants (72.0%), although the difference was not statistically significant.

Conclusions: Telephone survey data from the ongoing PRESTIS trial suggest that underscreened women in safety net healthcare system would be willing to use self-sampling HPV tests in the future. Mailed, at-home sampling, is a preferred delivery strategy. Health systems should provide options for HPV testing to accommodate for differing preferences in its administration.

Shift 01-232 / #1455

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02D. BEHAVIOURAL SCIENCE ASPECTS OF NEW TECHNOLOGIES IN CERVICAL SCREENING INCLUDING DISSEMINATION/COMMUNICATION RESEARCH
04-18-2023 7:00 AM - 5:00 PM

COMMUNITY'S AWARENESS AND ATTITUDES ABOUT CERVICAL CANCER AND HPV IN ETHIOPIA: A QUALITATIVE STUDY

Demisew Amenu Sori[1], Kim Mulholland[2], Alemseged Abdisa[3], Suzanne Garland[4], Gelila Goba[5], Nigisti Mulholland[6], Nega Jibat[7], Rahma Ali[8], Wendemagegn Addisu[9], Melkamu Berhane[10]
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Introduction: Improving community's awareness and attitudes about cervical cancer requires generating strong evidence to inform context-fit policy. Therefore, this study aimed to assess community perceptions and understanding of cervical cancer and HPV in Ethiopia.

Methods: We conducted 20 interviews with 15-19 and 25-29 women, 3 interviews with health extension workers, and 8 focus group discussions with men and women from May-July 2021 in Jimma town and its surrounding suburbs, Ethiopia. Age category and marital status were used to purposively recruit the participants. All participants gave consent. Thematic analysis was used to draw findings from the interview and FGD materials.

Results: Community awareness about cervical cancer is very limited except people believe it is fatal. A few participants were aware of cervical cancer through its symptoms but most people did not know it by name and had never heard about HPV as cervical cancer-causing agent, its risk and transmission factors, vaccination, screening and treatment. They considered their participation in this study as their first chance to properly hear about the disease. However, they have shown favorable attitude about HPV vaccination, screening and treatment after they got the basic information about cervical cancer from data collectors. They were keen to share the information with others and to encourage girls and women to seek the services even based on out-of-pocket payment. Finally, they strongly suggested awareness creation programs for the wider community members.

Conclusions: There is a critical information gap about cervical cancer, its cause and risk factors, HPV transmission, screening, and treatment. The limited community's awareness implies low uptake of HPV vaccination, screening, and treatment. There are missing links between available services and potential users because of lack of information. Therefore, awareness creation programs about cervical cancer and available services would ensure massive community mobilization toward improving people's health-seeking behavior.

Shift 01-233 / #144

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02E. DIAGNOSIS AND MANAGEMENT OF ANAL CANCER AND RELATED PRECURSORS: SCREENING, DIAGNOSIS AND MANAGEMENT
04-18-2023 7:00 AM - 5:00 PM

CYTOLOGY AND HPV RESULTS FROM SELF-COLLECTED VERSUS CLINICIAN-COLLECTED ANAL SWAB SPECIMENS

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Introduction: In cervical screening programs, self-collected vaginal specimens for HPV testing have been found to be acceptable and to yield technically satisfactory results in the majority of cases. By avoiding the need for an intimate examination, self-collection improves participation and considerably improves outcomes for otherwise unscreened and under-screened women. It was postulated that similar principles would apply to anal screening programs. We therefore set out to compare cytology and HPV results of Clinician-Collected anal swabs (CC) and Self-Collected anal swabs (SC), in patients attending the Dysplasia and Anal Cancer Services.

Methods: Following consent, and education regarding the taking of self-collected specimens, patients were randomized with regards to sampling order. The Dacron swabs were eluted into ThinPrep vials and sent for standard cytopathological testing and HPV testing using the COBAS 4800 system

Results: 100 participants were recruited, 94 (94.0%) male, 58 (58.0%) HIV-positive (1 HIV status unknown), with a median age of 57 years (IQR: 50.5-63). Among them, 54 were randomised to SC first, and 46 CC first. SC anal cytology results were more likely to be technically unsatisfactory compared to CC, but this did not reach statistical significance (16.0% vs 9.0%, p=0.09). Overall, there was no difference in HPV inhibition rate between SC and CC (6.0% vs 5.0%, p=0.564). HPV16 prevalence was 35.8% in SC and 31.6% in CC (p=0.103). For non16/18 HRHPV types, the prevalence was 53.1% vs 59.4% in SC and CC- (p=0.083), respectively. Overall, there was no significant difference in any abnormality (SC vs CC 82.3% vs 86.1%, p=0.317).

Conclusions: Overall, SC and CC provided similar diagnostic information. However, a larger study is required to confirm these findings. Further work is also required to see if these results can be replicated in community settings, and to investigate their potential role in screening programs.

Shift 01-234 / #708

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02E. DIAGNOSIS AND MANAGEMENT OF ANAL CANCER AND RELATED PRECURSORS: SCREENING, DIAGNOSIS AND MANAGEMENT
04-18-2023 7:00 AM - 5:00 PM

ASSOCIATION BETWEEN HPV16/HPV18 E6 ONCOPROTEIN RESULTS AND HISTOLOGY GRADE OF ANAL BIOPSIES

Jeanne Jordan[1], Karina Rivas[1], Annette Aldous[1], Kaleigh Conners[1], Kamwing Jair[1], Liz Hoke[2], David Klein[2], Stephen Abbott (He/him)[3]
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Introduction: Upregulation of HPV oncoproteins E6 and E7 expression is a necessary event for anal cancer progression. Performance of the OncoE6™ Anal Test was evaluated for predicting high-grade anal lesions in a population of HIV-positive men with >ASCUS grade anal cytology who have sex with men (MSM).

Methods: MSM participants ages 18 years or older and living with HIV participated in this cross-sectional study. Swab-based anal samples were collected just prior to obtaining biopsies and tested for HPV16/HPV18 E6 oncoproteins and high-risk HPV (HR-HPV) genotypes. These results were compared to histology, the gold standard. Odds ratio was calculated for presence of E6 oncoproteins among those with AIN2+ lesions versus AIN1 or lower lesions and tested for association using Fisher's Exact test. Analytical performance characteristics were calculated for both tests.

Results: 219 eligible MSM living with HIV were consented and enrolled between 06/2017 and 01/2022. Total of 4.6% (10/219) of anal swabs tested positive for HPV16/HPV18 E6 oncoprotein, while 93.6% (205/219) tested positive for 1 or more HR-HPV genotypes. Of those with AIN2+ lesions, 8.6% (7/81) had positive OncoE6™ results versus 2.2% (3/138) with only AIN1 or lower grade lesions. Odds of having a positive OncoE6™ result was 4 times higher among participants with AIN2+ lesions (OR 4.26, 95% CI 1.07-16.95, p = 0.04). In this study, specificity (95% CI) of OncoE6™ was 97.83% (93.78-99.55) with sensitivity (95% CI) of 8.64% (3.55-17.0). HR-HPV genotyping demonstrated specificity (95% CI) of 10.14% (5.66-16.44) and sensitivity (95% CI) of 100% (95.55-100.0).

Conclusions: In this population at high-risk for anal cancer, OncoE6™ demonstrated excellent specificity but low sensitivity; opposite to that found for HR-HPV genotyping. Using OncoE6™ as a companion diagnostic to the anal Pap test may provide insight into predicting AIN2+ in this population.

Shift 01-235 / #863

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02E. DIAGNOSIS AND MANAGEMENT OF ANAL CANCER AND RELATED PRECURSORS: SCREENING, DIAGNOSIS AND MANAGEMENT
04-18-2023 7:00 AM - 5:00 PM

NATURAL HISTORY OF ANAL HPV INFECTION IN WOMEN TREATED FOR CERVICAL INTRAEPITHELIAL NEOPLASIA

Marta Del Pino[1], Isabel Matas[1], Cristina Martí[1], Adela Saco[2], Natalia Rakislova[3], Ariel Glickman[1], Lorena Marimon[3], Aureli Torné[4], Jaume Ordi[3]
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Introduction: Women with high grade squamous intraepithelial lesion/cervical intraepithelial neoplasia (HSIL/CIN) are at high risk of anal HPV infection, and it has also been suggested that self-inoculation of the virus from the anal canal to the cervix could explain HPV recurrence in the cervix after treatment of HSIL/CIN. We aimed to evaluate the bidirectional interactions of HPV infection between these two anatomical sites.

Methods: 68 immunocompetent women undergoing excisional treatment for HSIL/CIN were evaluated. Immediately before treatment, samples from the anus and the cervix were obtained (baseline anal and cervical HPV status). Cervical HPV clearance after treatment was defined as treatment success. The first follow-up control was scheduled 4-6 months after treatment with cervical and anal samples. High resolution anoscopy was performed to patients with persistent anal HPV infection or abnormal anal cytology in the first control.

Results: Baseline anal HPV was positive in 42/68 (61.8%) of the women. Anal HPV infection persisted after treatment in 29/68 (42.6%) women. One third of these women (10/29; 34.5%) had HSIL/anal intraepithelial neoplasia (AIN). Among women achieving treatment success, cervical HPV in the first control was positive in 34.6% and 17.6% of the patients with positive and negative baseline anal HPV infection, respectively (p=0.306).

Conclusions: In conclusion, patients with persisting anal HPV after HSIL/CIN treatment are at high risk of HSIL/AIN, suggesting that these women would benefit from anal exploration. The study also suggests that women with anal HPV infection treated for HSIL/CIN might be at higher risk of recurrent cervical HPV even after successful treatment.

Shift 01-236 / #993

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02E. DIAGNOSIS AND MANAGEMENT OF ANAL CANCER AND RELATED PRECURSORS: SCREENING, DIAGNOSIS AND MANAGEMENT
04-18-2023 7:00 AM - 5:00 PM

DETECTION OF HPV CELL FREE DNA IN PLASMA IS SPECIFIC TO TUMOR-DERIVED HPV DNA IN PERSONS WITH HIV

Grant Ellsworth[1], Roger Shen[2], Kinge-Ann Marcelin[1], Rahul Majumdar[2], Maximillian Bazil[2], Grace Moore[2], Meredith Nelson[1], Isabel Alland[1], Gustavo Sepuldeva[1], Timothy Wilkin[1], Daniel Higginson[2]
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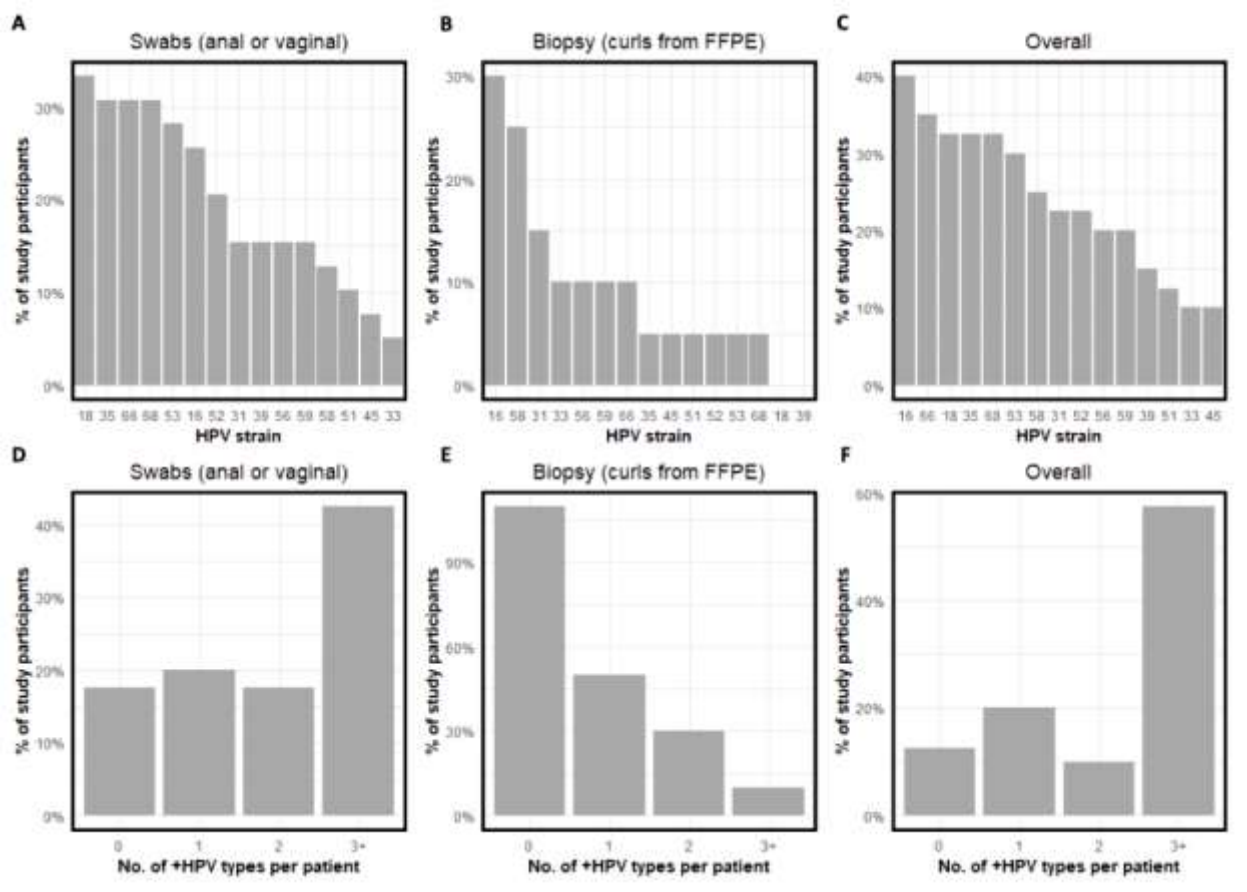
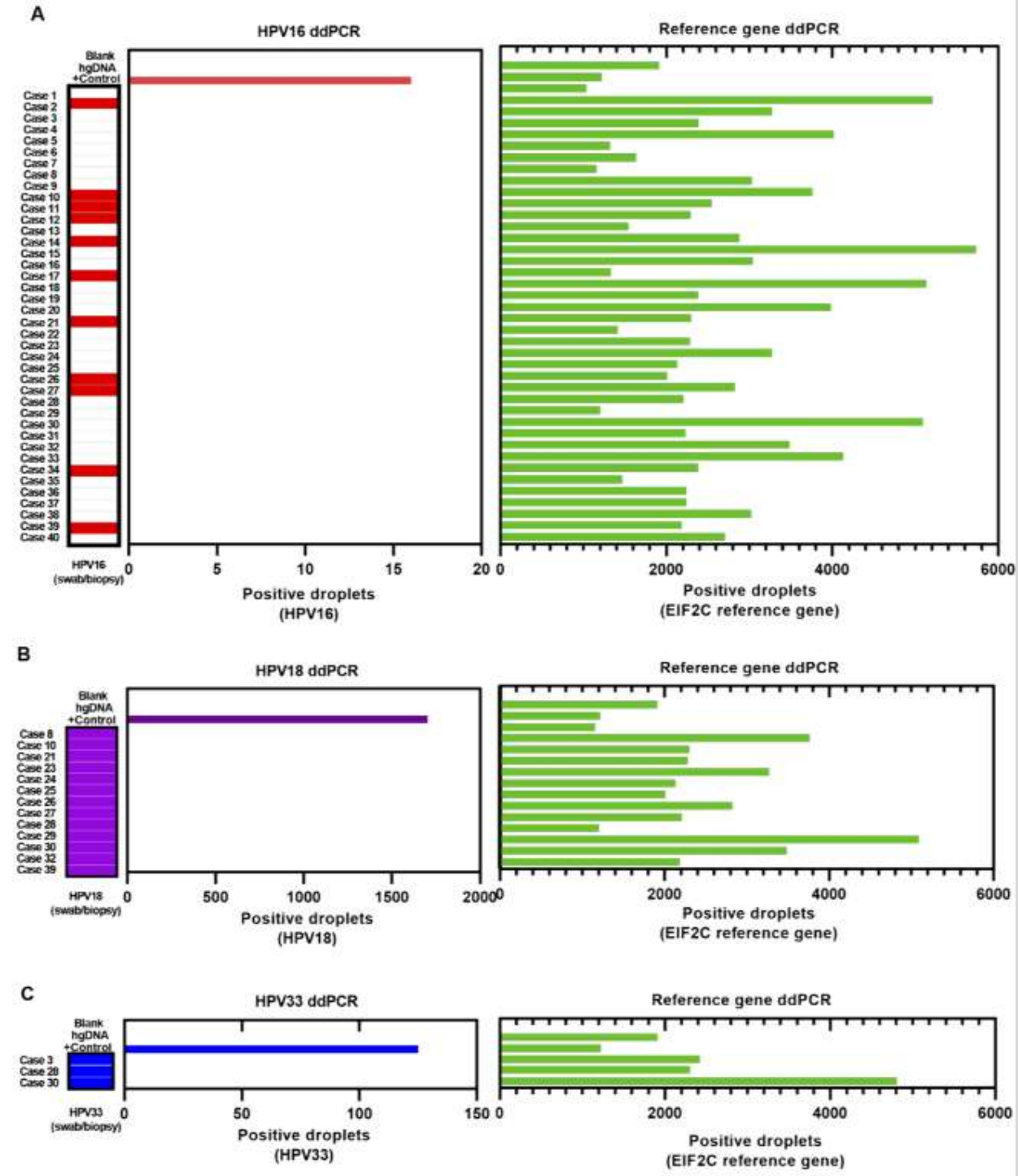
Introduction: Persons with HIV (PWH) have much higher rates of HPV-associated cancers compared to the general population. Plasma HPV cell free DNA (cfDNA) tests have been highly sensitive in patients with known HPV-associated cancers, but it is not known if these tests are feasible for cancer screening in populations with higher burdens of non-malignant HPV disease such as PWH. It was not known whether HPV infection alone or anal high grade in situ disease (HSIL) alone in this population would result in a positive HPV cfDNA signal, which would result in an unacceptably high false positive rate if used in a screening setting.

Methods: To answer this question, we conducted a prospective study of 40 PWH, including one cohort without and one cohort with anal HSIL. We tested anal and vaginal swabs for HPV infection and HPV genotyped the biopsies of anal HSIL. Finally, we performed HPV cfDNA droplet digital PCR (ddPCR) to test for HPV16/18/33 from plasma samples.

Results: 84.6% of this cohort exhibited HPV infection, including 10 participants with HPV16 infection, 13 with HPV18, and 2 with HPV33. Five and two participants had HPV16 and HPV33 positive anal HSIL, respectively (Figure 1). However, despite the high prevalence of HPV infection and anal HSIL, none of the participants had any HPV16/18/33 detectable cfDNA by ddPCR (Figure 2).


A
Swabs (anal or vaginal)
% of study participants
HPV strain
18 35 66 68 53 16 52 31 39 56 59 58 51 45 33
B
Biopsy (curls from FFPE)
% of study participants
HPV strain
16 58 31 33 56 59 66 35 45 51 52 53 68 18 39
C
Overall
% of study participants
HPV strain
16 66 18 35 68 53 58 31 52 56 59 39 51 33 45
D
Swabs (anal or vaginal)
% of study participants
No. of +HPV types per patient
0 1 2 3+
E
Biopsy (curls from FFPE)
% of study participants
No. of +HPV types per patient
0 1 2 3+
F
Overall
% of study participants
No. of +HPV types per patient
0 1 2 3+



Conclusions: These results provide a strong rationale for investigating the use of HPV cfDNA in a screening setting for suspected anal cancers in PWH.

Shift 01-237 / #1027

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02E. DIAGNOSIS AND MANAGEMENT OF ANAL CANCER AND RELATED PRECURSORS: SCREENING, DIAGNOSIS AND MANAGEMENT
04-18-2023 7:00 AM - 5:00 PM

EPIDEMIOLOGY OF ANAL HUMAN PAPILLOMAVIRUS INFECTION BY NEXT-GENERATION-SEQUENCING IN TRANSGENDER INDIVIDUALS: DECIPHERING THE CLINICAL AND IMMUNOLOGICAL DETERMINANTS OF GENUS SPECIFIC HPV COLONIZATION AND ALPHA-HPV-RELATED DISEASES

Andrea Lisco[1], Subramanian Poorani[2], Peiying Ye[1], Ornella Sortino[1], Omar Harfouch[3], Angelina Angelova[2], Henry Masur[4], Shyam Kottilil[3], Sarah Kattakuzhy[3], Elana Rosenthal[3]
[1]National Institutes of Health (NIH), Niaid-division Of Intramural Research, Bethesda, United States of America, [2]NIH, Bioinformatics And Computational Biosciences Branch, bethesda, United States of America, [3]University of Maryland, Institute For Human Virology, Baltimore, United States of America, [4]NIH Clinical Center, Critical Care Medicine Department, Bethesda, United States of America

Introduction: Men-who-have-sex-with-men, bisexual and transgender individuals (TG) are disproportionally affected by HPV infection and HPV-related diseases. We evaluated the prevalence and distribution of HPV types by next-generation sequencing (NGS) in anal swabs of TG to decipher the epidemiological, clinical, and immunological risk factors for HPV-colonization.

Methods: A longitudinal cohort of TG was established in the Washignton DC metropolitan area between 4/2021–9/2022. 47 consecutive subjects were selected for HPV-genotyping by a hybrid-capture target-enrichment NGS method allowing the identification of 210 α-, β- or γ-HPV types. Anal swabs for cytology were also collected. Unsupervised hierarchical-clustering and multivariate distance-matrix regression was utilized to test the similarity between samples and the association between prevalence of α-, β- or γ-HPV, HIV status and other epidemiological variables.

Results: The TG study population comprised mostly TG women (male sex assigned at birth, 66%), while 15% were non-binary and 8% were TG men (female sex assigned at birth). The median age was 37 years and 60% were HIV-1-infected (median CD4: 620 cells/mL; 78.5% on antiretroviral therapy). Gender-affirming hormones were used by 49% of the enrolled subjects and anal cytology was abnormal in 48%. Only 19% recalled receiving an HPV vaccine. α-HPVs largely exceeded the prevalence of β- and γ-HPV in anal swabs (Figure 1). The α-10 HPV44, α-6 HPV30, α-9 HPV16 were the most prevalent HPV types (66%, 57%, 55%, respectively). The relative abundance (RA) of α-HPV types not included in Gardasil-9® (HPV6,11,16,18,31,33,45,52,58) exceeded the RA of the latter HPV-types in 86% of TG subjects (Figure 2). HIV-1 infection was associated with higher prevalence of any α-HPV but did not affect the probability to detect β- or γ-HPV ($p<0.01$, Figure 3).

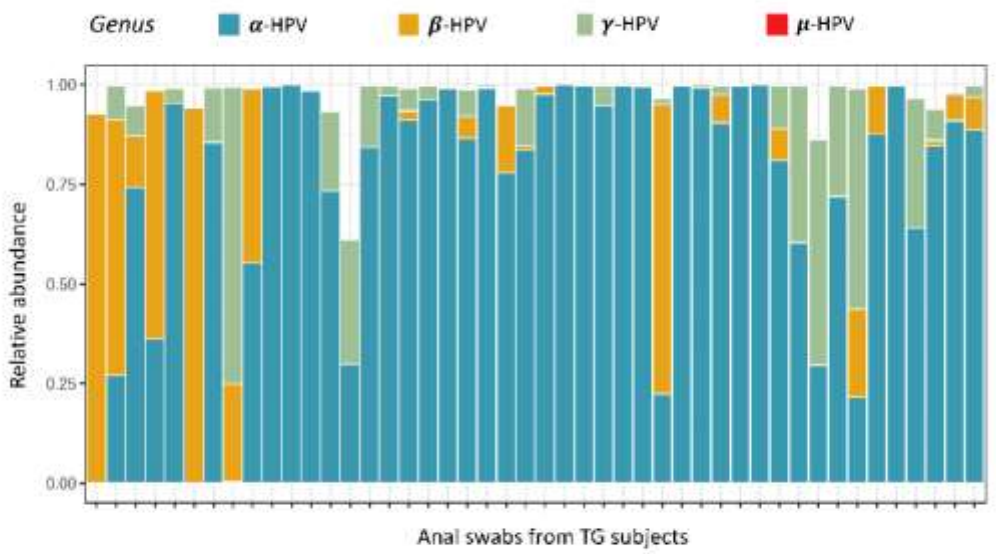

Genus
α-HPV
β-HPV
γ-HPV
μ-HPV
Relative abundance
1.00
0.75
0.50
0.25
0.00
Anal swabs from TG subjects

Figure 1

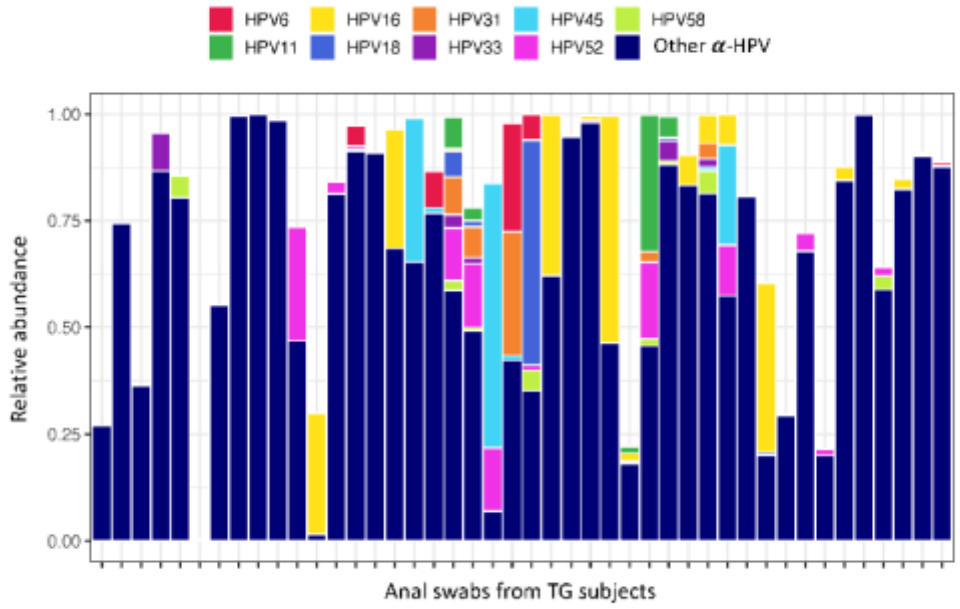

HPV6
HPV11
HPV16
HPV18
HPV31
HPV33
HPV45
HPV52
HPV58
Other α-HPV
1.00
0.75
0.50
0.25
0.00
Relative abundance
Anal swabs from TG subjects

Figure 2

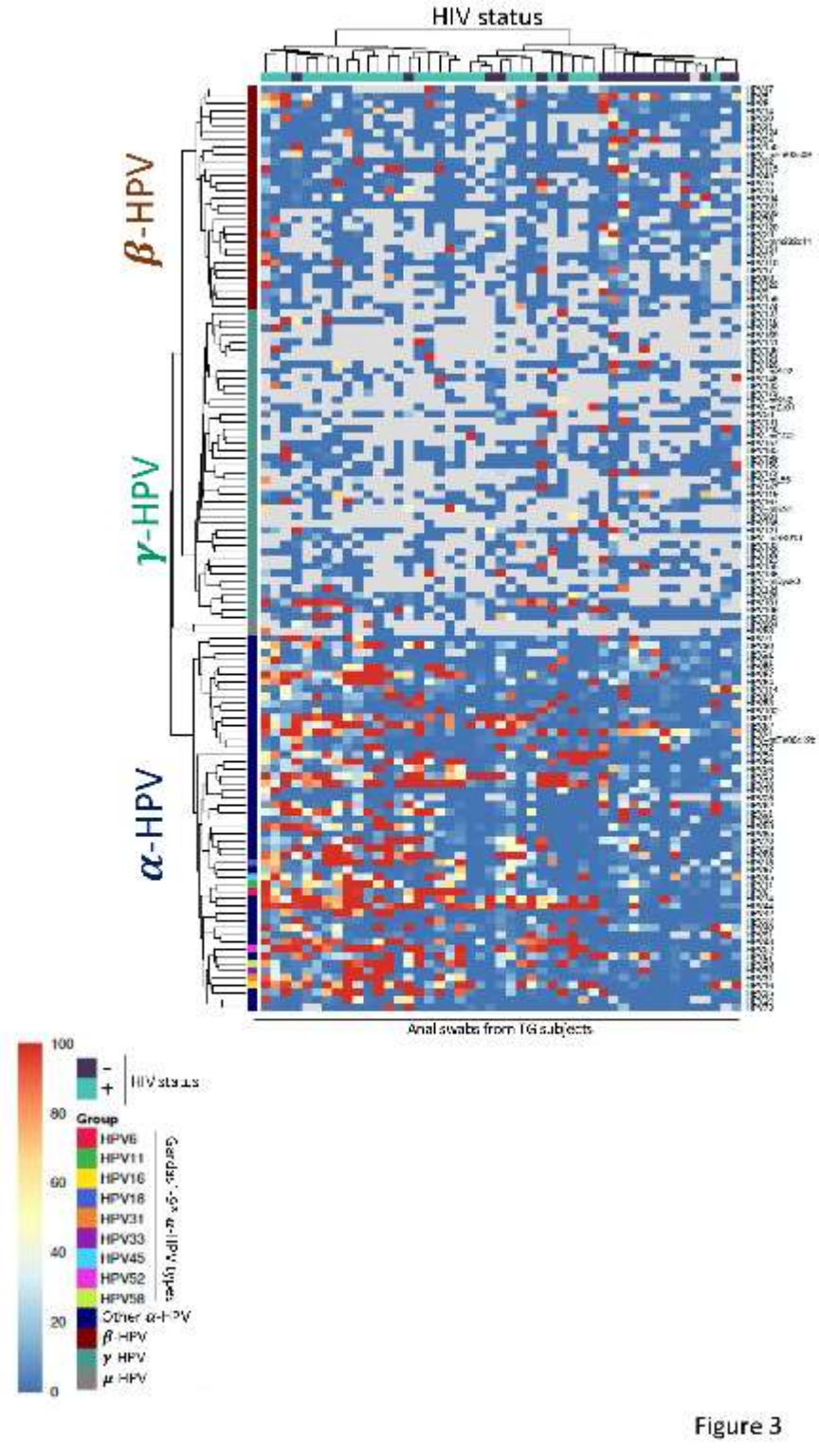


Figure 3

Conclusions: Target-enriched NGS reveals an increased prevalence of α-HPV in HIV-1-infected TG individuals emphasizing the role of specific clinical and immunological determinants of genus-specific HPV colonization and consequent α-HPV-related diseases.

Shift 01-238 / #1146

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02E. DIAGNOSIS AND MANAGEMENT OF ANAL CANCER AND RELATED PRECURSORS: SCREENING, DIAGNOSIS AND MANAGEMENT
04-18-2023 7:00 AM - 5:00 PM

RISK FACTORS FOR ANAL DYSPLASIA AND LINKAGE TO HRA IN TRANSGENDER WOMEN

Omar Harfouch[1], Andrea Lisco[2], Rahwa Eyasu[1], Amelia Cover[1], Ashley Davis[1], Emade Ebah[1], Phylis Bijole[3], Grace Garrett[4], Tina Liu[4], Michelle Spikes[3], Imani Fnu[3], Henry Masur[4], Shyam Kottilil[1], Sarah Kattakuzhy[1], Elana Rosenthal[1]
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Introduction: Studies estimate that transgender women (TGW) have a high prevalence of high-risk HPV (HR-HPV) and anal intraepithelial lesions. We examined risk factors associated with anal dysplasia (AD) and linkage to high resolution anoscopy (HRA) in a sample of TGW.

Methods: We recruited a convenience sample of TGW in DC from 4/2021–9/2022. Data collected included: demographics; serum samples; anal swabs for cytology and HPV genotyping. We defined AD as a cytology diagnosis of atypical squamous cells of undetermined significance, low-grade or high-grade intraepithelial lesions (HSIL). Current estrogen use was defined as self-report of use, and serum estradiol level higher than 60 pg/mL. Participants with AD were scheduled for off-site HRA. We used chi-square tests to compare differences between AD risk factors.

Results: Of 62 TGW with adequate anal cytology samples, most were black (87%), stably housed (55%), engaged in anal receptive sex within 12 months (77%), and not on estrogen (63%). Only 12 (19%) recalled receiving an HPV vaccine. Of 43 (69%) patients with HIV, 22 (47%) had previous anal cancer screening. AD was found in 29 (47%), while 45 (74%) tested positive for HR-HPV. AD was associated with the presence of HR-HPV (p=0.04), and with black race (p=0.03), but was not significantly associated with current GAH use or HIV status (Table 1). Of all TGW with AD, 23 (79%) had HRA scheduled, but only 6 (26%) attended, with HSIL found in 2 patients.

Table 1: Association of risk factors with abnormal anal cytology.

Risk Factor		Anal Cytology		p-value	HPV Status		p-value
		Abnormal n(%)	Normal n(%)		Positive n(%)	Negative n(%)	
Age	21-34	9 (31)	16 (49)	0.16	18 (40)	7 (44)	0.79
	35 or older	20 (69)	17 (51)		27 (60)	9 (56)	
Current estrogen use	Yes	9 (31)	19 (58)	0.64	15 (33)	7 (44)	0.46
	No	20 (69)	14 (42)		30 (67)	9 (56)	
HIV	Positive	23 (79)	20 (61)	0.11	33 (73)	9 (56)	0.2
	Negative	6 (21)	13 (39)		12 (27)	7 (44)	
High risk HPV	Positive	24 (83)	19 (59)	**0.04**	NA	NA	
	Negative	5 (17)	13 (41)		NA	NA	
Race	Black	28 (97)	26 (79)	**0.03**	39 (87)	53 (88)	0.97
	Non-Black	1 (3)	7 (21)		6 (13)	8 (12)	

Conclusions: Our findings highlight the high prevalence of HR- HPV and AD in TGW regardless of HIV status, age or use of GAH. In this high-risk population, we found low rates of prior HPV vaccination, and

limited HRA attendance despite facilitated linkage. Future studies should identify longitudinal risk factors for persistence of HR-HPV or AD, and strategies for enhancing HPV vaccination, anal cancer screening, and linkage to HRA in TGW.

Shift 01-239 / #1212

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02E. DIAGNOSIS AND MANAGEMENT OF ANAL CANCER AND RELATED PRECURSORS: SCREENING, DIAGNOSIS AND MANAGEMENT
04-18-2023 7:00 AM - 5:00 PM

FROM LOW TO HIGH GRADE ANAL LESIONS : COMPARISON OF DNA METHYLATION, CHROMOSOMAL ABERRATIONS AND HPV TYPES.

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Introduction: Men having sex with men (MSM) and people living with HIV (PLHIV) are at higher risk to develop anal squamous cell carcinoma (ASCC). Similarly to cervical cancer, ASCC is preceded by low and high-grade anal intraepithelial lesions (LGAIN, AIN1; HGAIN, AIN2-3). However the progression of normal epithelium through AINs, to ASCC is less well understood. We propose to determine if HGAIN is preceded by LGAIN or may develop directly from hrHPV infection.

Methods: Twenty-three HIV-infected MSM diagnosed with LGAIN (T0) and who progressed to HGAIN (T1) were included. Biopsies were collected at each sampling time and used to perform a comprehensive molecular analysis including: (i) host cell genome modifications (6 methylation markers and copy number aberrations (CNA)), (ii) HPV typing and HPV16 variants. Non-parametric statistical analysis were performed with R software.

Results: In total, 50 samples (25 paired-samples) issued from 22 cases were tested. HPV-typing and DNA methylation testing were effective for 98% (n=49) and 88% (n=44) of samples, respectively, and paired-samples with the same HPV-type were tested for CNA. After reviewing of the slides, 23 lesions were LGAIN and 27 lesions were HGAIN. The prevalence of hrHPV was 39% and 70% in LGAIN and HGAIN. Both the methylation level and CNA increased significantly from LGAIN to HGAIN. Fourteen (56%) paired-samples showed a persistence of HPV-infections (9 hrHPV and 5 lrHPV), associated with a progression from LGAIN to HGAIN in 6/14 cases. Five out of 6 showed a good correlation of CNA between low and high-grade lesions with similar or increased methylation level.

Conclusions: HPV persistence and molecular changes in LGAIN and subsequent HGAIN suggest that some LGAIN may progress HGAIN.

Shift 01-240 / #1219

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02E. DIAGNOSIS AND MANAGEMENT OF ANAL CANCER AND RELATED PRECURSORS: SCREENING, DIAGNOSIS AND MANAGEMENT
04-18-2023 7:00 AM - 5:00 PM

ROLE OF ANAL PAP TESTS FOR PRIMARY SCREENING IN THE PREVENTION OF ANAL CANCER

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Introduction: People living with HIV (PLWH) are at a 10-50-fold increased risk of developing anal cancer. The ANCHOR study showed that treatment of AIN2-3 lesions prevents cancer. The optimal way to initially screen PLWH for AIN2-3 lesions is not known. Anal Pap tests are easy to obtain and could be an initial screening test to prevent anal cancer. The utility of anal Pap tests as a screening tool was ascertained.

Methods: PLWH who had undergone high resolution anoscopy and at the same visit had an anal Pap test and a biopsy were identified from the EMR at University Medical Center in New Orleans. Demographic information obtained included sex, race, age, HIV status, and history of treatment for high-grade lesions. Anal Pap test and paired biopsy results were compared.

Results: A total of 245 paired specimens from 117 different patients were obtained since 12-1-2019. The population was 88% male, 60% Caucasian, 90% non-Hispanic and average age 51. There were 14% normal, 36%, ASCUS, 2% ASCUS-H, 36% LSIL and 7% HSIL Paps. There were 15% normal, 40% AIN1, and 44% AIN2-3 biopsies. There was a strong association between the severity of the Pap test and the biopsy results ($p<0.001$). AIN2-3 was seen in 88% of the HSIL Pap tests. However, 8/34 (24%) of patients with a normal Pap test had an AIN2-3 lesion.

Conclusions: In this small study from a single institution and provider, a single anal Pap test (normal) would have missed assigning 24% of the at-risk individuals to anoscopy. This raises concern that the anal Pap test may lack sensitivity as a primary screen for anal cancer. The role of sequential Pap tests is currently under investigation as is the addition of anal HPV detection. There is a need for additional biomarkers that can be utilized to identify at-risk patients.

Shift 01-241 / #1605

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02E. DIAGNOSIS AND MANAGEMENT OF ANAL CANCER AND RELATED PRECURSORS: SCREENING, DIAGNOSIS AND MANAGEMENT
04-18-2023 7:00 AM - 5:00 PM

HPV33 ANAL INFECTION AND PERSISTENCE ARE ASSOCIATED WITH HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS IN MSM LIVING WITH HIV

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Introduction: Globally, Human papillomavirus (HPV) is the most common sexually-transmitted infection. Persistent infections with high-risk HPV (HR-HPV) in immunocompromised individuals can result in more rapid disease progression; low-grade squamous intraepithelial lesions (LSIL) can progress to high-grade squamous intraepithelial lesions (HSIL). Men living with HIV, who have sex with men (MSMLWH) are at highest risk for anal cancer.

Methods: A cross-sectional population of 163 MSMLWH attending high-resolution anoscopy clinic each had an anal swab (FLOQ, Copan) collected for HR-HPV genotyping (Atilla AmpFire HPV assay) prior to biopsy. Genotyping data were grouped based on histology and analyzed to determine whether the proportion of individuals infected with specific HR-HPV genotype(s) showed an association with HSIL. Persistent HR-HPV infection was then studied in a longitudinal subset of 38 individuals, in whom anal samples and biopsies were obtained at 2 clinic visits. Here we examined whether HR-HPV persistence was associated with HSIL. Pearson's Chi-square test with continuity correction was used to assess association with HSIL in these groups.

Results: Overall prevalence of having a HR-HPV anal infection in this cross-sectional population was 91.4% (149/163). Here, the proportion of participants infected with HPV33 was higher in HSIL group (44.4%) than in LSIL group (8.3%, $p<0.0001$), as was HPV35 (HSIL; 36.7% vs. LSIL; 13.6%, $p=0.001$) and HPV56 (HSIL; 29.5% vs 11.8%, $p=0.009$). In the longitudinal subset of this population, persistent infection with HPV33 was more frequently seen within the HSIL group compared to the LSIL group (HSIL; 38.9% vs LSIL; 5.3%, $p=0.02$).

Conclusions: There was a statistically significant association with HSIL for both HPV33 anal infection and its persistence. These data highlight the importance of using an HPV assay that genotypes more than just HPV16/18, as well as for vaccinating this highest-risk population with a nine valent vaccine to prevent infection and reduce the risk of anal cancer.

Shift 01-242 / #1133

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02G. DIAGNOSIS AND MANAGEMENT OF CUTANEOUS WARTS AND OTHER SKIN LESIONS
04-18-2023 7:00 AM - 5:00 PM

DETECTION OF CUTANEOUS HPV BY PCR USING SKIN SURFACE MATERIALS: METHODOLOGICAL COMPARISON AND DIVERSITY OF VIRAL LOAD BY HPV TYPES

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Introduction: Warts present with various clinical presentations, which usually depend on the type of human papillomavirus. Sometimes plantar warts are difficult to differentiate from clavus or callus. Bowen's disease and squamous cell carcinoma may also be differential diagnosis if the lesion is on the nail apparatus or digit. Although biopsy is necessary, other non-invasive methods of definitive diagnosis are required. This study aims to analyze the accuracy of virological diagnosis by comparing swab samples and hyperkeratosis scales from warts.

Methods: The study included ninety cases of warts and related diseases. DNA was extracted from three types of specimens in each case: a surface swab, hyperkeratosis scale, and a post-shaved surface swab, and analyzed for HPV type and HPV viral load by polymerase chain reaction.

Results: Fifty-five cases were PCR-positive, seven cases for HPV1a, five cases for HPV2a, three cases for HPV4, twenty-one cases for HPV27, fourteen cases for HPV57, and five cases for HPV65. Regarding the correlation between clinical diagnosis and HPV detection, the positive agreement rate was 90.9%, the negative agreement rate was 40.0%, and the overall agreement rate was 71.1%. Notably, only half of the fourteen cases clinically diagnosed as plantar warts were PCR-positive, suggesting that it is challenging to differentiate plantar warts from clavus or callus, especially in elderly patients. The amount of HPV DNA before and after exfoliation was compared, and the amount of HPV DNA from the removed keratin was the highest for all HPV types. The amount of HPV DNA detected differed by HPV type, with HPV1a, the causative virus of myrmecia, producing about 1000 times more HPV DNA than HPV57, the least common HPV type.

Conclusions: HPV types and DNA concentrations in fifty-five cases were identified. The specimen of a surface swab from a wart appears useful for virological diagnosis and determination of cure.

Shift 01-243 / #350

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02H. PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-18-2023 7:00 AM - 5:00 PM

NEED FOR ENHANCEMENT OF HPV VACCINE EDUCATION IN MEDICAL AND DENTAL SCHOOLS

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Introduction: The HPV vaccine is highly efficacious in protecting against oral, genital, and other cancers. There is an important role for medical and dental professionals in advocating for vaccination and building their confidence in this task is crucial. The objectives of this study were to assess vaccine knowledge, personal immunization status, attitudes, and confidence in vaccine counseling among future healthcare providers – medical (MS) and dental (MS) students.

Methods: An anonymous survey was completed by students from 1 medical and 3 dental schools in the United States (US). The survey assessed knowledge about 3 vaccines: HPV vaccine as well as influenza and COVID-19 vaccines. Personal vaccination status and confidence in vaccine counseling were also assessed. The survey used was an existing tool previously published by the investigators.

Results: 453 students (232 MS and 221 DS) completed the survey. Total knowledge score for the 3 vaccines was 81% for MS and 51% for DS. HPV vaccine score was 79 % and 56 % for MS and DS, respectively (Table 1). MS had better HPV knowledge than DS, however, both groups had low knowledge of vaccine recommendations for females diagnosed with HPV (48%) and older patients (63%), skin-to-skin transmission (54%), and HPV vaccine effectiveness in preventing oral cancers (64%) (Table 2). Although 87% of respondents indicated they would recommend HPV vaccine to family/friends, only 62% felt they had adequate knowledge, and 69% felt they had evidence-based information to counsel patients. No major differences were found in knowledge scores between vaccinated and unvaccinated students.

Table 1. Knowledge Scores by Student and Vaccine Type (N=453)

	Overall Mean (sd) (N=453)	Medical Mean (sd) (N=232)	Dental Mean (sd) (N=221)	p-value*	# of Items	Overall % correct	Medical % correct	Dental % correct
HPV	5.4 (2.4)	6.3 (1.8)	4.5 (2.5)	<0.00001	8	68	79	56
COVID-19	6.5 (2.4)	7.4 (1.8)	5.5 (2.6)	<0.00001	9	72	82	61
Influenza	3.3 (1.4)	4.1 (1.1)	2.6 (1.3)	<0.00001	5	67	81	51
Total	15.2 (5.4)	17.8 (4.1)	12.6 (5.4)	<0.00001	22	69	81	57

*Based on two independent sample t-test.

Table 2. HPV Knowledge Scores by Student Type (N=453)

	Overall n (%) correct N=453	**Medical n (%) correct N=232**	**Dental n (%) correct N=221**	**OR (95% CI)***
HPV can be transmitted by skin-to-skin contact	243 (54)	161 (69)	82 (37)	3.7 (2.5-5.6)
HPV vaccination is recommended for routine vaccination at age 11 or 12	343 (76)	205 (88)	138 (62)	5.0 (2.9-8.7)
HPV vaccination leads to long lasting immunity	344 (76)	202 (87)	142 (64)	3.7 (2.2-6.3)
HPV vaccine is effective in preventing cervical cancers	378 (83)	217 (94)	161 (73)	7.9 (3.4-18.0)
HPV vaccine is effective in preventing oral cancers	288 (64)	165 (71)	123 (56)	1.8 (1.2-2.7)
HPV vaccine works best when given before any exposure to HPV	367 (81)	206 (89)	161 (73)	2.9 (1.6-5.3)
Women diagnosed with HPV should not be given HPV vaccine	216 (48)	152 (66)	64 (29)	4.6 (3.0-6.8)
Adults ages 27 through 45 years can received HPV vaccination	284 (63)	158 (68)	126 (57)	1.4 (1.0-2.2)

*Reference Group: Dental Students

Conclusions: This is the first study to evaluate HPV vaccine knowledge and attitudes among US medical and dental students and highlights the need for profession-specific curricula to educate future providers who play a critical role in disease prevention. Curricula should bridge the knowledge gaps identified and provide skills to counsel vaccine-hesitant patients.

Shift 01-244 / #780

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02H. PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-18-2023 7:00 AM - 5:00 PM

BASELINE HUMAN PAPILLOMAVIRUS (HPV) INFECTION AND THE RISK OF INCIDENT-PERSISTENT HPV INFECTION AMONG YOUNG ADULT MEN

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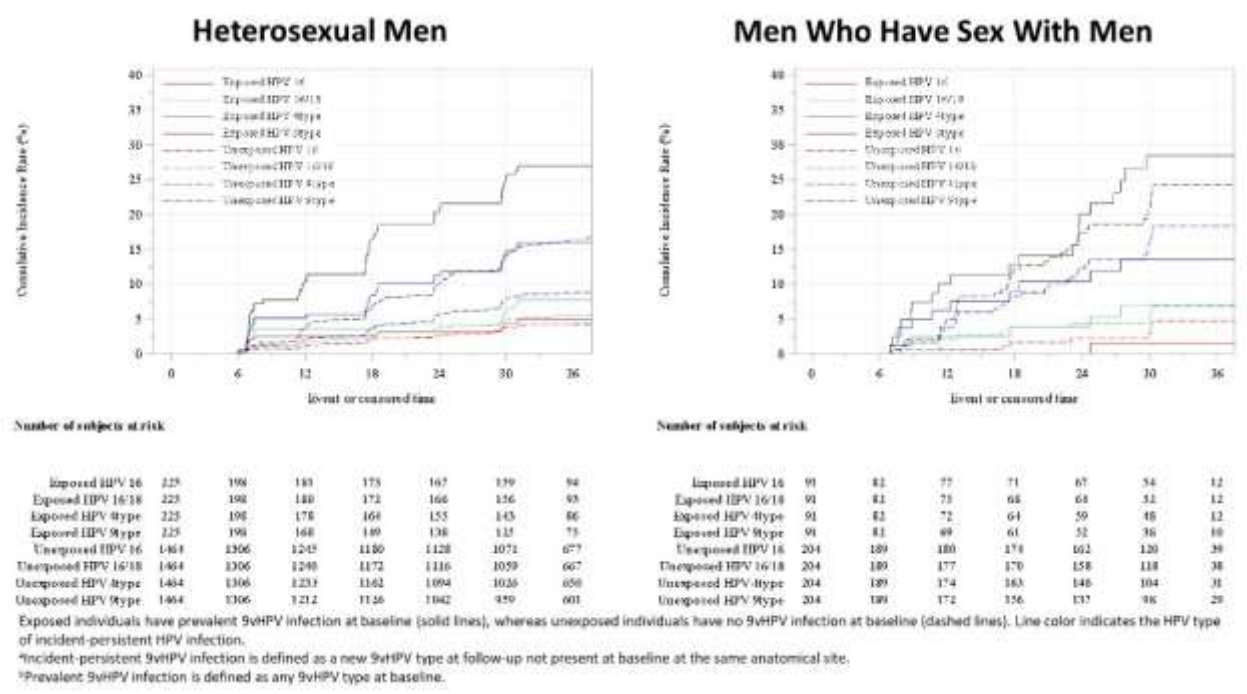
Introduction: Current vaccination programs prioritize HPV-naive individuals. Prevalent HPV infection may identify high-risk young adult men most in need of vaccination. The association between prevalent and incident-persistent HPV infection among heterosexual men (HM) and men who have sex with men (MSM) has not been evaluated.

Methods: HM and MSM aged 16-27 years in the placebo arm of a global 4-valent HPV vaccine trial (NCT00090285) were assessed for incident-persistent anogenital infection at penile/scrotal and perineal/perianal sites with 9-valent (9v) HPV (6/11/16/18/31/33/45/52/58) vaccine types by baseline prevalent 9vHPV infection status. Association between baseline prevalent infection and incident-persistent infection was estimated using incidence rate differences (IRDs) and incidence rate ratios (IRRs) adjusted for age, geographic region, and number of lifetime sex partners. Three-year cumulative incidence of incident-persistent infection at the same anatomic site was estimated using the Kaplan-Meier method, according to baseline 9vHPV infection status at enrollment.

Results: Included were 1689 HM and 295 MSM. Incidence rate (per 100 person-years) of incident-persistent HPV infection for prevalent HPV infection and no infection at baseline among HM was 11.24 and 6.38, respectively, and among MSM was 11.69 and 9.69, respectively. Baseline infection status was associated with incident-persistent infection among HM (IRD, 4.86 [95% CI, 1.59-8.13]; IRR, 1.55 [1.13-2.14]) but not MSM (IRD, 1.99 [95%CI, –3.94 to 7.93]; IRR, 1.01 [0.58-1.76]). Cumulative incidence rates of incident-persistent HPV infection were higher among HM with baseline prevalent infection versus those without baseline infection; no differences were observed among MSM (Figure

1).



Number of subjects at risk

Exposed HPV 16	225	198	183	173	167	139	94
Exposed HPV 16/18	225	198	180	172	166	136	93
Exposed HPV 4type	225	198	178	164	155	143	86
Exposed HPV 9type	225	198	168	149	138	115	73
Unexposed HPV 16	1464	1306	1245	1180	1128	1071	677
Unexposed HPV 16/18	1464	1306	1240	1172	1116	1059	667
Unexposed HPV 4type	1464	1306	1233	1162	1094	1026	650
Unexposed HPV 9type	1464	1306	1212	1136	1042	959	601

Number of subjects at risk

Exposed HPV 16	91	81	77	71	67	54	12
Exposed HPV 16/18	91	81	73	68	64	52	12
Exposed HPV 4type	91	82	72	64	59	48	12
Exposed HPV 9type	91	81	69	61	52	36	10
Unexposed HPV 16	204	189	180	170	162	120	39
Unexposed HPV 16/18	204	189	177	170	158	118	38
Unexposed HPV 4type	204	189	174	163	148	104	31
Unexposed HPV 9type	204	189	172	156	137	98	29

Exposed individuals have prevalent 9vHPV infection at baseline (solid lines), whereas unexposed individuals have no 9vHPV infection at baseline (dashed lines). Line color indicates the HPV type of incident-persistent HPV infection.
[a]Incident-persistent 9vHPV infection is defined as a new 9vHPV type at follow-up not present at baseline at the same anatomical site.
[b]Prevalent 9vHPV infection is defined as any 9vHPV type at baseline.

Conclusions: Baseline 9vHPV infection was associated with incident-persistent anogenital infection among HM, but not MSM. MSM experienced high incidence regardless of baseline infection. Young adult HM with a history of infection and MSM may benefit most from HPV prevention interventions.

Shift 01-245 / #1159

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02I. THERAPEUTIC VACCINES – CLINICAL ASPECTS
04-18-2023 7:00 AM - 5:00 PM

RECRUITMENT FOR AND RETENTION IN A PHASE II RANDOMIZED DOUBLE-BLIND CLINICAL TRIAL OF A HUMAN PAPILLOMAVIRUS THERAPEUTIC VACCINE, PEPCAN

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Introduction: A human papillomavirus therapeutic vaccine for regressing high-grade squamous intraepithelial lesion (HSIL) is being evaluated. The study aim was to understand the motivations and barriers for clinical trial recruitment and retention.

Methods: Women with an abnormal Papanicolaou smear were eligible to enroll; only those with biopsy-confirmed CIN II or III were vaccinated. Four vaccinations 3 weeks apart were followed up with two visits 6 months apart. Women who agreed to participate answered a questionnaire at enrollment. Potential subjects who met all criteria but declined participation received a different questionnaire. Recruitment efforts included clinic visits, informational letters to statewide gynecologic service providers and potentially eligible patients in-house, and advertisements (pamphlets, brochures, Facebook, Instagram, and Google).

Results: Ninety-nine women provided informed consent, and were screened. Eight-one subjects (81.8%) qualified for vaccination, and 80 received at least one vaccination. Motivations for joining the study were personal health needs (77 of 99, 77.8%), contribution to medical science (12.1%), possible free treatment (7.1%), others (2%), and reimbursement (1%). The majority first heard about the study through referrals (67 of 99, 67.7%), 23.2% through other, 6.1% through study brochure, 2% though Facebook, 1% through word of mouth. Of thirteen potential subjects who declined to participate, 10 responded. Thirty percent (3 of 10) indicated “the study duration was too long” while 20% said “not knowing whether I will receive PepCan or adjuvant only” was the main reason for not participating. Ten percent indicated “difficulty getting to study visits”, and the remaining had “other” unique reasons.

Conclusions: In-person visits to clinics by study staff seemed to be helpful in promoting recruitment. Patients were primarily motivated by their health needs to participate in the study. The long duration of the study was the most common barrier identified. Retention rate was excellent for the study with 93.8% of subjects completing the study.

Shift 01-246 / #1647

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02I. THERAPEUTIC VACCINES – CLINICAL ASPECTS
04-18-2023 7:00 AM - 5:00 PM

PHASE I/II RANDOMIZED CLINICAL TRIAL OF AN ORAL THERAPEUTIC VACCINE TARGETING HPV; ANTI-CANCER THERAPY THAT LEVERAGES MUCOSAL IMMUNITY

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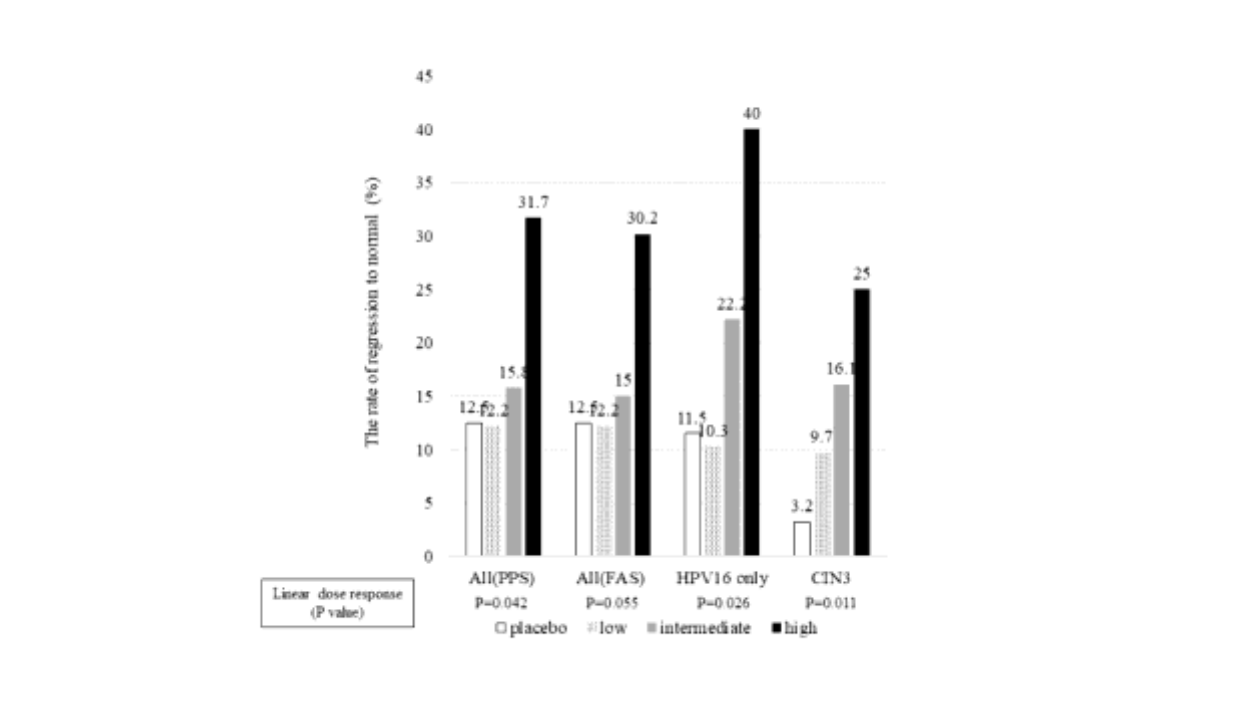
Introduction: Although many HPV-targeted therapeutic vaccines have been examined for efficacy in clinical trials, none have been translated into clinical use. These previous agents were administered by intramuscular or subcutaneous injection to induce systemic immunity. We investigated the safety and therapeutic efficacy of an HPV16 E7-expressing lacticaseibacillus-based oral vaccine.

Methods: In a double-blind, placebo-controlled, randomized trial, 165 patients with HPV16-positve high-grade cervical intraepithelial neoplasia (CIN2/3) were assigned to orally-administered placebo, or low-, intermediate-, or high-doses of IGMKK16E7 (HPV16 full-length E7-expressing lacticaseibacillus paracasei). In all four groups, IGMKK16E7 or placebo was administered orally at weeks 1, 2, 4 and 8 post-enrollment. The primary outcomes included histopathological regression and IGMKK16E7 safety.

Results: In per-protocol analyses, histopathological regression to normal (CR) occurred in 13 (31.7%) of 41 high-dose recipients and in five (12.5%) of 40 placebo recipients (rate difference 19.2: 95% CI, 0.5-37.8, P=0.06). In patients positive for HPV16 only, the clinical response rate was 40.0% (12/30) in high-dose recipients and 11.5% (3/26) in recipients of placebo (rate difference 28.5: 95%CI, 4.3-50.0, P=0.03). Linear dose responses were clearly shown in these groups (P=0.026). Adverse events occurred in 21 patients (48.8%) in the high-dose group and in 19 patients (46.3 %) in the placebo group (P=0.83). The number of HPV16E7-specific IFN-γ producing cells in peripheral blood increased with level of response (stable disease, partial, and complete responses;

P=0.004).



Conclusions: This trial demonstrates safety of IGMKK16E7 and its dose-dependent efficacy against HPV16-positive CIN2/3. IGMKK16E7 is the first immunotherapeutic mucosal immunity-based vaccine to show anti-neoplastic effects.

Shift 01-247 / #1311

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02J. DIAGNOSIS AND MANAGEMENT OF HPV DISEASE IN PEOPLE LIVING WITH HIV AND OTHER FORMS OF IMMUNOCOMPROMISE
04-18-2023 7:00 AM - 5:00 PM

PILOT STUDY ON PATTERN AND TYPES OF HPV INFECTION IN WOMEN ATTENDING HIV CLINIC IN ILE-IFE, SOUTH-WEST NIGERIA.

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Introduction: Cervical cancer being an AIDS-defining disease requires that women living with HIV should have routine screening as an integral part of their care. Screening for high-risk HPV (HrHPV), the causative agent of cervical cancer is becoming the preferred modality for cervical cancer screening.

Methods: In this pilot study, sixty-seven consenting women attending the HIV clinic of our hospital had cervical self-sampling after watching a video describing the process. Their samples were analyzed with the Atilla PCR system. All positive women were invited for colposcopy

Results: Sixty-seventy women took part in the study; the mean age and mean parity was 44years and 3 respectively. The mean duration of being on HAART treatment was 53 months. The viral load was less than 1000 copies/ml in all but one of the women. Twenty-two women tested positive for HrHPV. The commonest serotype was 45 seen in 36.4% of positive cases and this was followed by serotypes 18 and 31 which were each found in 27.3%. Multiple infections were found in 11 women (16.4%) and were more common in older women than in young women. 40-49 years (24.3%) versus 30 to 39 years 18%. Women in the age range of 40-49years (24.3%) had multiple Hr HPV infections (22) than those 30-39years (42.9%) who had only 18. Colposcopy attendance was poor as only 20 women attended. Of those that attended the colposcopic clinic, it was adequate in 17 of the women. Acetowhite lesions were only seen in 2 of them. Targeted biopsies did not reveal any cervical intraepithelial lesions.

Conclusions: The prevalence of HrHPV is higher in women living with HIV compared to the general population and HPV 45 was the commonest infection in this group followed by 18 and 31 serotypes. However, very few lesions were seen at colposcopy despite the high HPV prevalence.

Shift 01-248 / #1563

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02J. DIAGNOSIS AND MANAGEMENT OF HPV DISEASE IN PEOPLE LIVING WITH HIV AND OTHER FORMS OF IMMUNOCOMPROMISE
04-18-2023 7:00 AM - 5:00 PM

HPV BEYOND SIMPLE GENITAL WARTS, HIV ASSOCIATED HUGE GENITAL CONDYLOMA ACUMINATES CASE SERIES MANAGED WITH SKINNING VULVECTOMY FROM; ADDIS ABABA, ETHIOPIA, SPHMMC

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SPHMMC, Ob/gyn, Addis Ababa, Ethiopia

Introduction: Human papilloma virus is the commonest sexually transmitted infection among young adult, fortunately enough most of the individuals infected with human papilloma virus are asymptomatic and able to clear the virus so long as they have no innate or acquired immune deficiency. Though it is not uncommon to see genital warts of small-medium sized, it is very rare to find giant genital warts which cannot be managed with topical ablative therapy. Human immune-deficiency virus (HIV) co-infection is the most important contributor for locally aggressive vulvar condyloma acuminatas (Buschke Lowenstein tumor).

Methods: Here I report a case series of giant vulvar condyloma accuminata (vulvar wart) of three cases with all of the cases of Sero-positive for HIV on HAART (highly active anti-retroviral therapy) CD4 counts of all of them under 500 cells/ul , including a ten year old pre-menarche female who had also a giant wart which was not amenable for local ablative treatments.

Results: The cases were referred from regional hospitals for possible vulvectomy in our teaching hospital .the surgeries were skinning vulvectomy with extensivive wider vulvar skin excision ,the surgery had significant bleeding from the incision sites and we used multiple clumps. with no intra-operative complications. All of the cases had superficial wound infections and improved significantly with a local wound care and discharged and had good wound healing in their three weeks of follow up vists.

Conclusions: HPV associated vulvar genital condyloma accuminata, in HIV seropositive patents can be beyond local ablative treatments and delay in referral and care for these cases can cause significant impact in their quality of life. The surgical care of giant warts needs gynecologic oncologist surgical expertise.

Shift 01-249 / #724

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02J. DIAGNOSIS AND MANAGEMENT OF HPV DISEASE IN PEOPLE LIVING WITH HIV AND OTHER FORMS OF IMMUNOCOMPROMISE
04-18-2023 7:00 AM - 5:00 PM

SIGNIFICANCE OF HIV STATUS IN CERVICAL CANCER PATIENTS RECEIVING CURATIVE CHEMORADIATION THERAPY, DEFINITIVE RADIATION ALONE, OR PALLIATIVE RADIATION IN BOTSWANA

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Introduction: Cervical cancer associated with Human Papillomavirus (HPV) has the highest cancer incidence and mortality for women in Botswana, a middle-income country in Sub-Saharan Africa, due to a high human immunodeficiency virus (HIV) prevalence and limited early screening. This study investigates the significance of HIV on the overall survival (OS) of patients with locally advanced cervical cancer by various treatment categories (curative chemoradiation, definitive radiation alone, or palliative radiation alone).

Methods: This study included patients diagnosed with cervical cancer between 2013 and 2020, prospectively enrolled in the Botswana Prospective Cancer Cohort (BPCC) at Gaborone Private Hospital and a gynecological multidisciplinary team clinic at Princess Marina Hospital. Baseline demographics were summarized by descriptive statistics. For various treatment groups, comparisons of 2-year OS by HIV status were performed by the log-rank test, univariate Cox regression analyses, and multivariable cox analyses adjusting for cancer stage, RT dose, number of chemotherapy cycles, and baseline hemoglobin levels.

Results:

Figure 1. 1,131 Cervical Cancer Patients by HIV Status

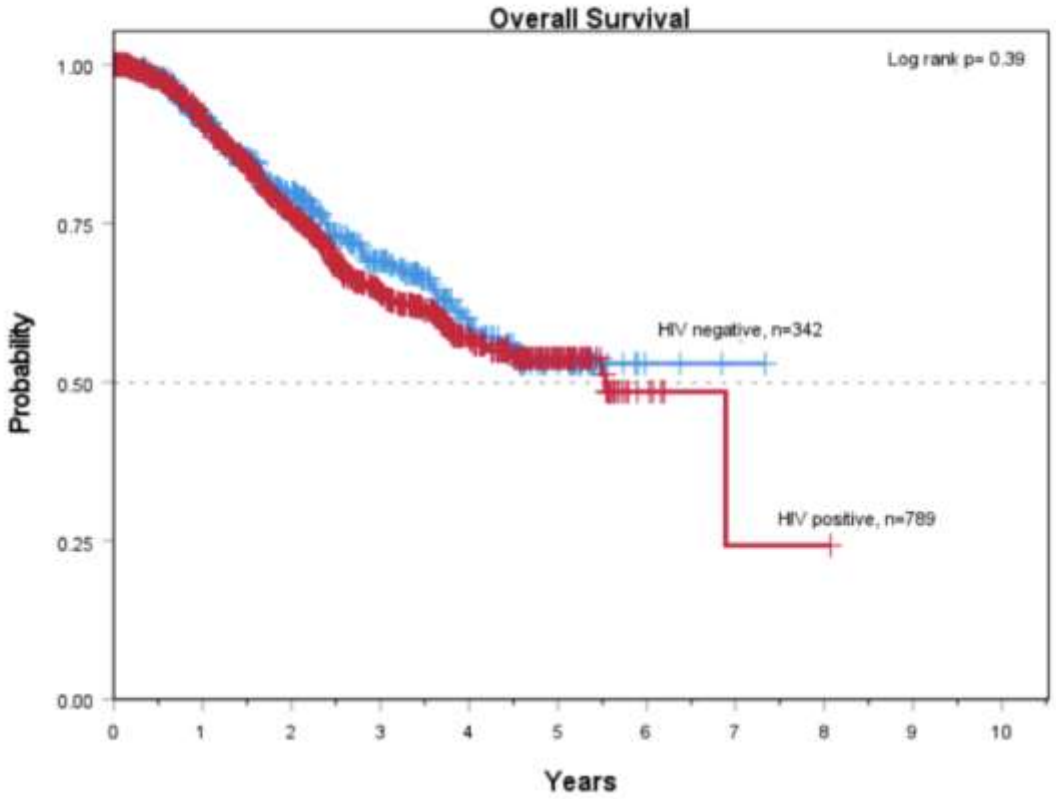


Figure 3a. Patients with Curative Treatment by HIV Status

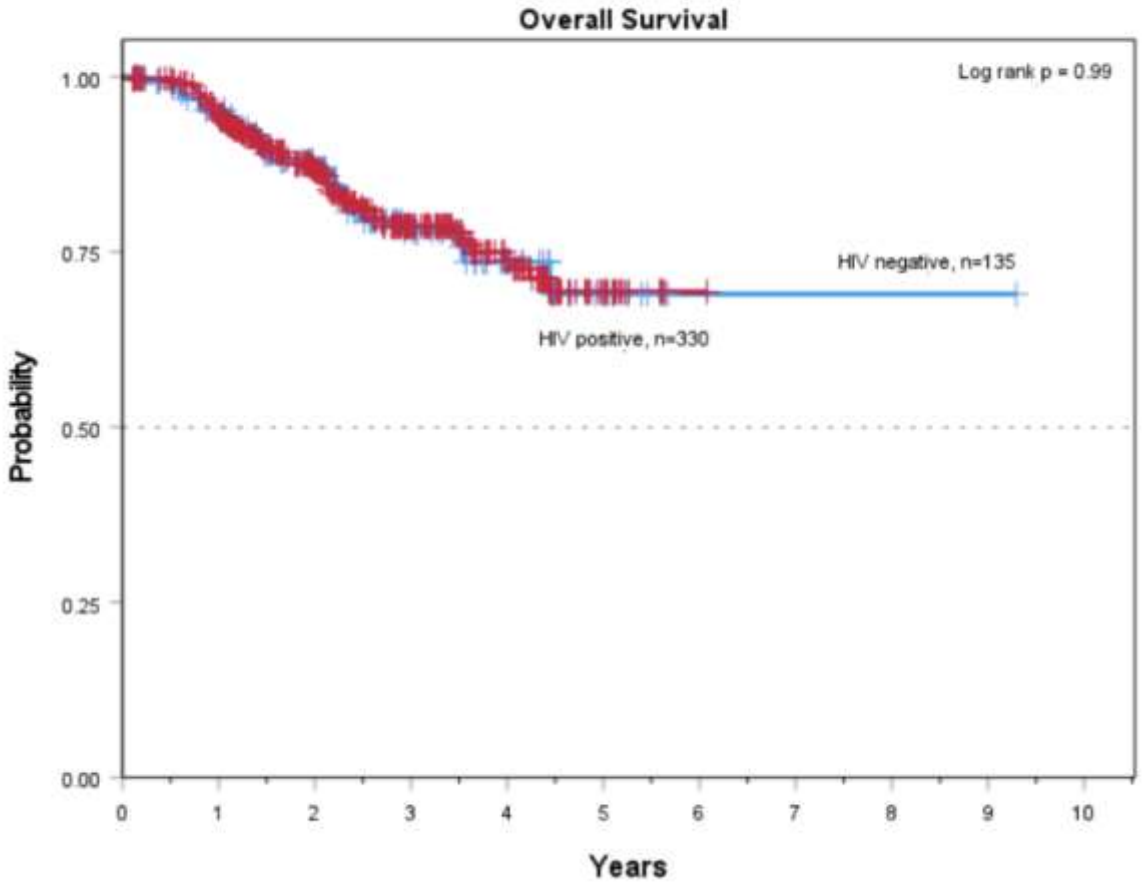
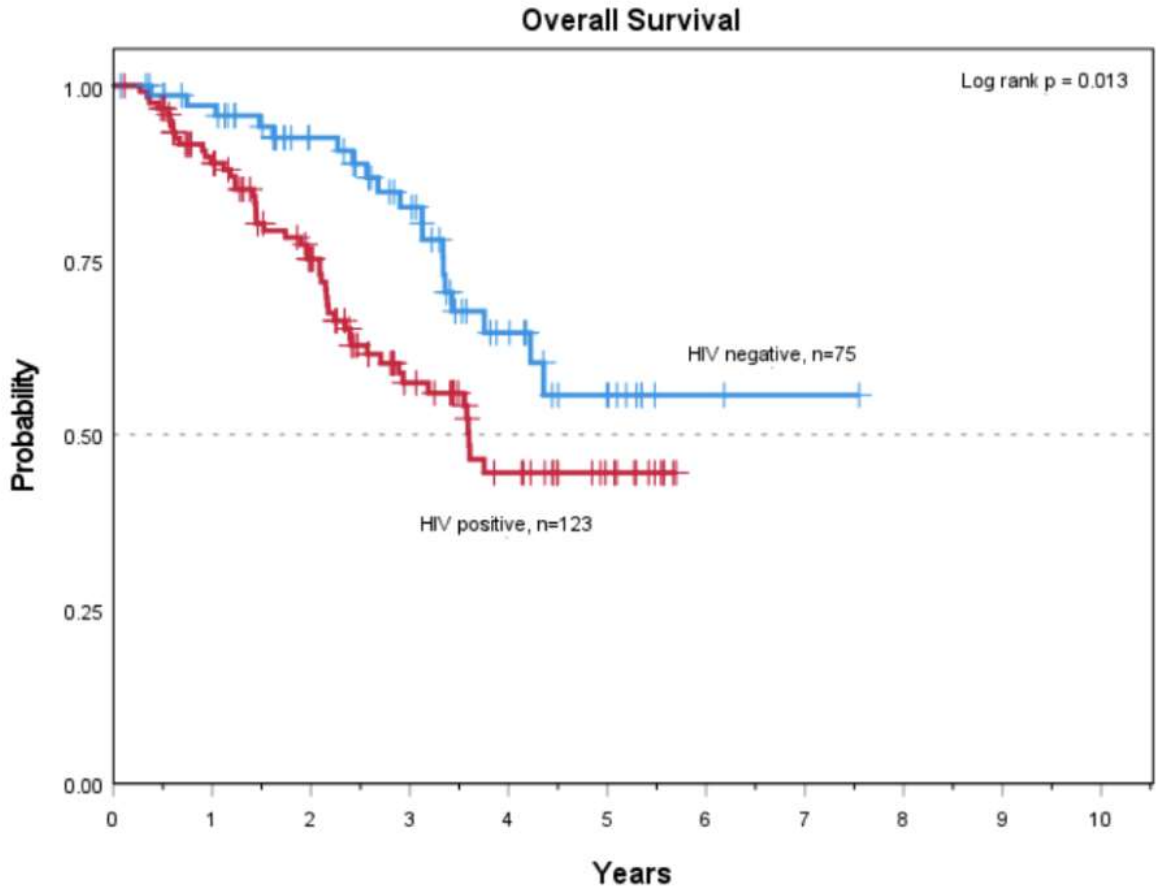


Figure 4a. Patients with High Dose RT by HIV Status



A total of 1,131 patients were diagnosed with cervical cancer in the BPCC. Among these women, 69.8% were women living with HIV (n=789). For the 465 patients who received curative chemoradiation treatment, HIV status was not significantly associated with OS in unadjusted (p=0.987) and adjusted analysis (p=0.578). For the patients who completed RT-only treatment, HIV status was significantly associated with OS in unadjusted analysis (HR=1.77, p=0.002), but not in adjusted analysis (p=0.227). HIV status was significantly associated with OS for the 198 patients receiving definitive (high dose) RT alone in unadjusted analysis (p=0.014), but not in adjusted analysis (p=0.073). For the 154 patients receiving palliative (low dose) RT, HIV status was not associated with OS in unadjusted (p=0.835) or adjusted analysis (p=0.359).

Conclusions: In Botswana, a resource-limited country, HIV status had no significant effect on 2-year OS in cervical cancer patients with well-managed HIV receiving chemoradiation, radiation alone, or palliative radiation.

Shift 01-255 / #389

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-18-2023 7:00 AM - 5:00 PM

OUTCOME OF EXCISIONAL PROCEDURES PERFORMED FOR SEVERE CERVICAL DYSPLASIA IN BOTSWANA

Lisa Bazzett-Matabele[1], Emily Macduffie[2], Manya Gupta[3], Jessica Ball[4], Jemma Hazan[5], Mohan Narashimhamurthy[6], Angela Maoto-Mokote[7], Alexander Seiphetlheng[8], Barati Monare[8], Rebecca Luckett[9], Doreen Ramogola-Masire[10], Surbhi Grover[11]
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Introduction: Cervical cancer is the leading cause of cancer and cancer-related death among women in Botswana, accounting for 32% of female cancers and 19% of cancer-related deaths in the overall population. National screening has focused on a see-and treat approach with a significant number of Loop electrosurgical excision procedures(LEEP) performed. Our objective was to determine the number of LEEPs performed with confirmed cervical intraepithelial neoplasia(CIN) 2or3, as well as rates and outcomes of follow-up among women with positive margins.

Methods: This retrospective study identified patients who underwent LEEP from January 2014-December 2015 showiing CIN 2/3 on final histology. Patients underwent LEEP for positive visual inspection with acetic acid(VIA) or biopsy proven CIN2/3. Histopathology was reviewed at a central lab in Gaborone, Botswana. Demographic and clinical data such as age, HIV status, margin status and follow up data was collected.

Results: 778 women underwent LEEP for CIN2/3 during the study. Average age was 40.2 years. 638(81.8%) had CIN3. 390(50.1%) had positive LEEP margins, 204(52.3%) had positive endocervical margins (ECM), and 186(47.7%) had positive ectocervical margins only. Women with HIV had more positive ECM than women without HIV, 73% vs.27%. Of women with positive ECM seen back within a year, 7.7%(4/52), had persistent CIN2/3 on repeat LEEP. In contrast, 48.3%(30/62) of women who underwent repeat LEEP >1year later for positive ECM had persistent/recurrent CIN2/3. 44%(90/204) of women with positive ECM had no documented re-excision procedure. Women with HIV and positive ECM were more likely to have documented follow-up(62.3%) than women without HIV(40%).

Conclusions: Most women who underwent LEEP procedures had CIN3, half had positive margins. Many with positive, particularly endocervical margins, had a recurrence of CIN2/3 requiring further treatment. Resources should be made available for women who are screen-positive and post-LEEP margin positive, requiring additional ablative or excisional procedures, to reduce the cervical cancer burden in Botswana.

Shift 01-256 / #741

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-18-2023 7:00 AM - 5:00 PM

SCREENING OF CERVICAL PRECANCER IN A TERTIARY CARE HOSPITAL IN BANGLADESH

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Introduction: Cervical cancer is the second most common cancer among women in Bangladesh. Cervical cancer is a preventable disease as it has a long precancerous stage. Routine and effective screening detects the disease at its precancerous stage and can reduce the incidence of cervical cancer by almost 80%. All the tertiary level hospitals are caring a large load of cervical cancer patients. Visual Inspection of the cervix with 5% acetic acid allows for inspection of the aceto-white area (VIA Positive). Women with VIA positive tests are referred for colposcopy. Successful screening program is one of the effective way for early diagnosis and prevention of this cancer.

Methods: This was a cross-sectional study that was conducted in the gynecology department of Sir Salimullah Medical College and Mitford Hospital, Dhaka from January 2018 to December 2019. Women who came for cervical cancer screening by VIA were included in this study. A total of 1023 women were included in this study. VIA-positive cases were evaluated in colposcopy clinics where the ‘see and treat’ policy applied. The specimen was sent for a Histopathology examination.

Results: Among 1023 women, 92 were VIA positive (8.99%). Colposcopy test among VIA positive women, 21 (22.82%) were normal, 39 (42.39%) CIN-1, CIN-2, CIN-3 29 (31.52%), 3 were unsatisfactory (3.26%). In CIN-1, cryotherapy was given to 21 patients. LEEP was done in 18 patients of CIN-1, all CIN-2 and CIN-3 patients. The histopathology Report showed chronic cervicitis with squamous metaplasia in 15 patients, CIN-1 in 20 patients, CIN-2 in 8 patients, CIN-3 in 3 patients, and invasive cancer in 1 patient.

Conclusions: VIA is safe and feasible in our country. The hopeful news is that women are eager to gather knowledge about carcinoma cervix. We will achieve the goal of reducing the mortality rates associated with cervical cancer.

Shift 01-257 / #782

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-18-2023 7:00 AM - 5:00 PM

COMMUNITIES DRIVE DEMAND FOR AND UTILIZATION OF SECONDARY PREVENTION SERVICES FOR CERVICAL CANCER IN BURKINA FASO

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Introduction: Cervical cancer is the third most common cancer among women in Burkina Faso, with an incidence of 14.6% according to GLOBOCAN 2020. To address this, "the SUCCESS (Scale-Up Cervical Cancer Elimination with Secondary Prevention) project has been implemented in six regions of Burkina Faso since 2020. Funded by Unitaid and implemented by Expertise France, Jhpiego, and UICC, the SUCCESS project supports the MOH to promote women's and men's access to information about cervical cancer secondary prevention services, adoption of health-seeking behavior in the community, and increase women's access to quality services.

Methods: A community engagement strategy was developed and implemented, including the development of advocacy and education materials, training of community health workers and media, use of social mobilization strategies, and engagement of communities and their leaders in selected sites or areas.

Results: From February 2020 to June 2022, we: Developed an outreach and demand creation plan, trained 150 community actors and actively implemented the outreach and demand creation plan, produced educational materials (picture boxes, posters, flyers, handouts) and made available to actors engaged in outreach and demand creation; 200 community leaders have been oriented to secondary prevention and are supporting community-based interventions; and nine community-based organizations providing care to people living with HIV/AIDS have signed contracts with Jhpiego and are implementing microprojects to enroll at least 9,000 women in cervical pre-cancer screening by June 2023. The combined actions of 350 community leaders and the media (radio, television, print, online) have reached 10,000 women and men, of whom 5,500 have already engaged in HPV self-screening through the organization of 20 screening campaigns.

Conclusions: The Burkina Faso experience shows that promoting community participation with the support of trained and equipped outreach and demand creation workers, supported by the Ministry of Health and Public Hygiene, stimulates demand for and use of cervical cancer prevention services.

Shift 01-258 / #1500

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-18-2023 7:00 AM - 5:00 PM

IMPLEMENTING LOW-COST HPV TESTING FOR CERVICAL CANCER SCREENING AMONG HIV POSITIVE AND HIV NEGATIVE WOMEN IN CAMEROON

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Introduction: According to the WHO global strategy to eliminate cervical cancer, HPV testing is considered the preferred test for primary test for cervical cancer. In Cameroon, cervical cancer screening rates are low (5%) with visual screening (VIA/VILI) being the most commonly used screening tool. We piloted the introduction of a new low-cost HPV test to screen HIV positive and HIV negative women in Cameroon as part of a screen and treat strategy.

Methods: Between January and December 2021, the WHP of the CBCHS organized sensitization campaigns to screen women aged between 30 and 65 years across the country. Consenting women were screened with an HPV test (Ampfire) and HPV-positive women were treated based on the result of the VIA/VILI triage, with thermal ablation or LEEP. Cases suspicious for cancer were referred for further evaluation and management. HIV status and other socio-demographics of women were collected.

Results: A total of 3,468 women were tested for high-risk HPV in CBCHS-WHP clinics in 2021, including 620 (17.9%) women living with HIV and receiving ART in HIV care units. Of these 620 women living with HIV, 320 (52.6%) were positive for HPV. Up to 2690 women were HIV negative with 792 (29.4%) testing positive for HPV. The remaining 158 women had unknown HIV status. HPV results were made available to women within one month of specimen collection, and consenting HPV positive had VIA/VILI triage and were treated per WHO guidelines.

Conclusions: In Cameroon, HPV testing for cervical cancer screening is feasible and could increase screening coverage. Given the higher HPV positivity rates among HIV positive women, integrating HPV based cervical cancer screening in HIV care units could facilitate systematic screening of women living with HIV. Follow up of screen positive women who received treatment is needed to further evaluate the effectiveness of this screening strategy.

Shift 01-259 / #1634

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-18-2023 7:00 AM - 5:00 PM

ASSOCIATION BETWEEN DYSLIPIDAEMIA AND CERVICAL INTRAEPITHELIAL NEOPLASIA: RESULTS FROM A CASE CONTROL STUDY IN SOUTH WESTERN UGANDA

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Introduction: Altered lipids have been shown to occur in development of malignancies including cervical cancer. This study aimed at determining the association between dyslipidaemia and Cervical Intraepithelial Neoplasia (CIN) at a clinic in South Western Uganda.

Methods: This was an unmatched case control study (a ratio of 1:1), involving women with CIN (cases) and those negative for intraepithelial lesions or malignancy (controls) at the cervical cancer clinic of Mbarara Regional Referral Hospital. We collected demographic data, collected venous blood into plain vacutainers, centrifuged and separated serum from cells. We measured lipid profile using Cobas 6000 Clinical Chemistry Analyzer. Dyslipidemia was defined as total cholesterol >240mg/dL, LDL >160 mg/dL, triglyceride >200 mg/Dl or HDL <40 mg/dL. Data was analysed in STATA version 17 at a statistical significance level of ≤0.05.

Results: Out of the 94 cases, 81 had low grade lesions (LSIL), 12 had high grade lesions (HSIL) while one had atypical squamous cells of undetermined significance (ASCUS). High triglycerides and high low density lipoprotein (LDL) shared an equal prevalence of 13% among the controls and 3% among cases and this difference in distribution was statistically significant (p=0.016). A reduced High Density Lipoprotein (HDL) was the most prevalent dyslipidemia among cases, with a prevalence of 41.5% (39/94). This prevalence was more in LSIL (37%) and weakly significant in cases compared to controls (p=0.086). High serum triglycerides was significantly associated with CIN (OR 0.395, 95% CI 0.084-1.851, p=0.007). High LDL was only weakly associated with CIN (OR 0.251, 95% CI 0.061-1.047, p= 0.058).

Conclusions: There was a high prevalence of HDL dyslipidaemia among women with CIN especially low grade squamous intraepithelial lesions. There was a significant association between triglyceride dyslipidaemia and CIN. This highlights the need to control other non-communicable diseases that could arise due to dyslipidaemia.

Shift 01-260 / #1635

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-18-2023 7:00 AM - 5:00 PM

METABOLIC SYNDROME COMPONENTS IN CERVICAL INTRAEPITHELIAL NEOPLASIA; A CASE OF OBESITY: RESULTS FROM A CASE CONTROL STUDY IN SOUTH WESTERN UGANDA

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Introduction: Metabolic syndrome components like obesity have been said to be associated with a number of malignancies. We set out to determining the prevalence of obesity, its association with cervical intraepithelial neoplasia (CIN) as well as factors associated with obesity.

Methods: This was an unmatched case control study, involving women with CIN (cases) and those negative for intraepithelial lesions or malignancy (controls) at the cervical cancer clinic of Mbarara Regional Referral Hospital, between April and November 2022. Cases and controls provided written informed consent and were recruited in a ratio of 1:1, basing on cytology and/or histology results. We collected demographic data, measured height, weight and waist circumference. We calculated body mass index (BMI) and defined obesity as BMI of ≥30kg/m^2. Data was analysed using STATA version 17, using proportions, chi-square and logistic regression at a statistical significance level of ≤0.05.

Results: The prevalence of general and central obesity among cases was 26% (24/94) and 97% (91/94) respectively while among controls it was 38% (36/94) and 96% (90/94) respectively. There was an increased prevalence of obesity among women with low grade squamous intraepithelial lesions (LSIL) but no statistically significant association between obesity and CIN. Factors associated with obesity included residing in Mbarara city (AOR 2.156, 95%CI 1.085-4.282, P-value 0.028), age-groups of 31-45 years (AOR 2.421, 95%CI 1.577-9.705, P-value 0.003) and ≥46 years (AOR 1.971, 95%CI 1.022-11.157, P-value 0.046).

Conclusions: We observed and increased prevalence of obesity among women with LSIL but no association between obesity and CIN. Factors associated with obesity included residing in Mbarara city, and being in the age groups of 31-40 and ≥46 years. This highlights the need to bear in mind the risk of other non-communicable diseases that could arise due to obesity.

Shift 01-261 / #1829

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-18-2023 7:00 AM - 5:00 PM

SCREENING BASED ON HR-HPV DETECTION AND CERVICAL PRECANCER: CHALLENGE TIMELY DIAGNOSIS IN LOW-MIDDLE RESOURCE SETTING, COLOMBIA 2022

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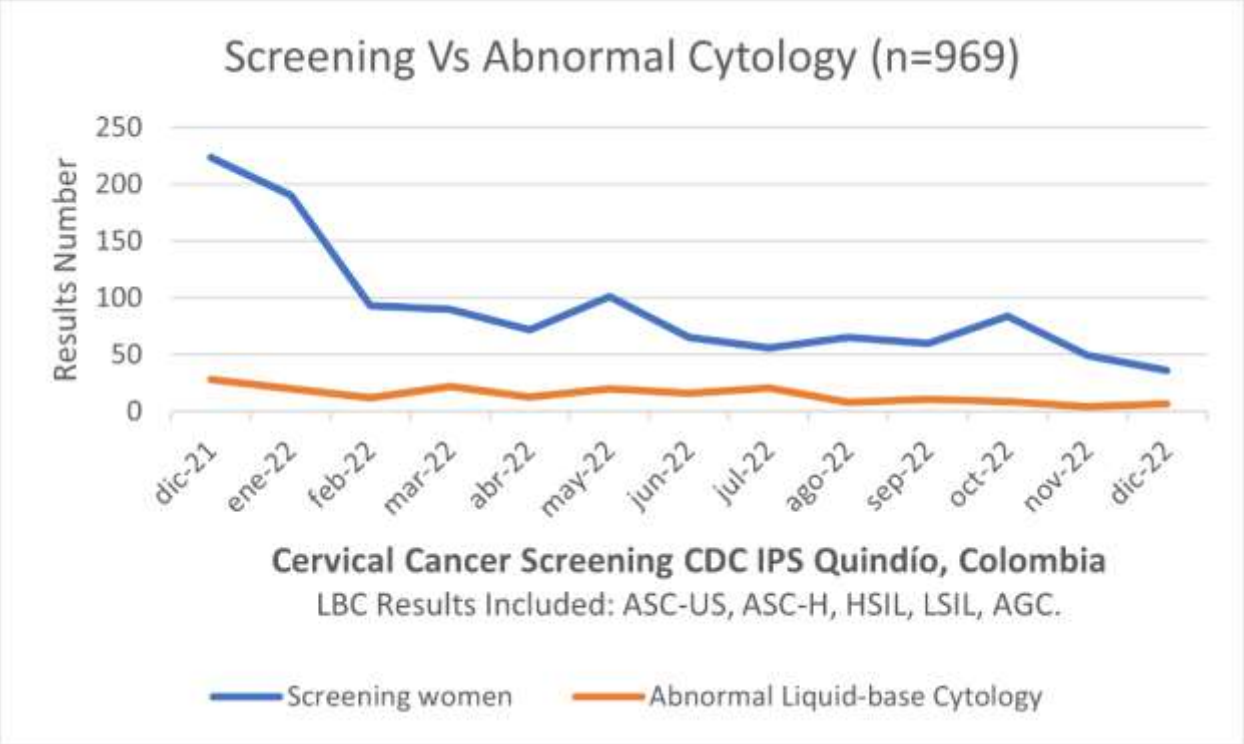
Introduction: Despite the public policy strategies implemented such as vaccination against HPV since 2012 and screening for early detection, cervical cancer in Colombia is uncontrolled; incidence was 12.7 new cases/100,000 women in 2018 and 14.9 new cases/100,000 women in 2020; mortality was 5.7 deaths/100,000 women in 2018 and 7.4 deaths/100,000 women in 2020 (GLOBOCAN). By other hand, barriers to access to timely cancer prevention services, create unprecedented pressure on health systems in low- and middle-income countries, especially post-SARS-Cov2 pandemic. To act, the CDC (Clinic Diagnostic Center), implemented the first screening program based on HPV in Armenia city, with system alarm to inform immediately (24 hours) high risk results: HPV+ 16, 18, 33, ASC-H or H-SIL which improve timely diagnosis and management. The purpose was to determine the frequency of high grade Squamous Intraepithelial Lesions (SIL) and the High Risk (HR) HPV genotypes involved.

Methods: Retrospective study. Databases analyses from CDC since December 2021 to December 2022, were excluded 216 cases with liquid-based cytology results but without HPV results and 6 unsatisfactory cytologies results; in total 969 LBC and HPV results were analyzed in SPSS v25. The HPV detection was assessed by Aniplex II HPV HR DNA Detection and Genotyping Test, which detects 14 HR-HPV types.

Results:

Age	Screening	Abnormal LBC	% HG-SIL
18-25 years	16	4	2,3
26-35 years	215	51	29,7
36-45 years	267	52	30,2
46-55 years	240	39	22,7
56-65 years	216	25	14,5
66-74 years	15	1	0,6
TOTAL	969	172	100,0



Mean age was 45 years (min 18; max 74); 17.8% (n=172) had high grade SIL (Table 1). High-SIL abnormal cytology were all HR-HPV positive (single infections), types 16, 33 and 66. Among HPV-infected and high grade SIL results, 30.2% had coinfection up to 3 genotypes identified. HR-HPV prevalence among women with abnormal cytology (61.6%) was higher than in women without SIL (28.4%).

Table 1. High Grade SIL **Vs** High Risk Human Papillomavirus Infection among women in Armenia, Quindío. CDC Database, period evaluated Nov2021 to Dec 2022. Colombia.

LIQUID-BASED CYTOLOGY RESULTS		HPV NEGATIVE		HPV POSITIVE			TOTAL	
		n	%	HR-HPV type (n)	n	%	n	%
SQUAMOUS INTRAEPITHELIAL LESIONS (SIL)	AGC	2	0,3%	16 (1)	1	0,3%	3	0,3%
	ASC-H	3	0,5%	16 (1), 31 (2), 52 (1), 58 (1), 68 (1). HPV coinfection ASC-H cases: 16-51 (2), 16-52 (1), 52-68 (1)	10	3,5%	13	1,4%
	AS-CUS	56	9,2%	16 (9), 18 (3), 31 (2), 33 (4), 35 (2), 39 (2), 45 (4), 51 (4), 52 (4), 56 (6), 58 (3), 59 (5), 66 (3), 68 (6). HPV coinfection ASC-US cases: 16-18 (1), 16-31 (1), 16-51 (1), 18-68 (1), 33-52 (1), 35, 59 (1), 35, 66 (1)	59	20,4%	115	12,8%
	H-SIL	0	0,0%	16 (2), 33 (2), 66 (1)	5	1,7%	5	0,6%
	L-SIL	6	1,0%	16 (8), 18 (1), 31(1), 33 (2), 45 (1), 51(2), 52 (2), 56 (1), 66 (2), 68 (1). HPV coinfection L-SIL cases: 16, 58, 68 (1), 31, 45 (1), 33, 59 (1), 35, 52 (1), 35, 68 (1), 39, 59 (1), 39, 59, 68 (1), 45, 66 (1), 51, 59 (1), 52, 68 (1)	31	10,7%	37	4,1%

Conclusions: High grade SIL proportion was 17.8% and the HPV genotypes most frequently involved among ASC-H and H-SIL results were 16-31-33-51-52-58-66-68. Real World Evidence from databases analyses can improve health outcomes.

Shift 01-262 / #637

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
04-18-2023 7:00 AM - 5:00 PM

A NOVEL IMMUNOTHERAPY FOR THE TREATMENT OF HPV+ TUMORS BASED ON A CHIMERIC VIRUS-LIKE DRUG CONJUGATE

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Introduction: HPV virus-like particles (VLPs) bind a wide variety of tumor types via modified heparan sulfate proteoglycans (HSPG) found on the tumor cell surface. This finding led to the development of the virus-like drug conjugate (VDC) belzupacap sarotalocan, an HPV-derived VLP conjugated to a light-activated cytotoxic payload. When activated by near-infrared light, this VDC induces rapid tumor necrosis resulting in pro-immunogenic cell death, release of tumor neoantigens and long-term anti-tumor immunity. When E6 and E7 expressing TC-1 mouse tumors are treated with the VDC, we detect E7-specific T-cells in the absence of provided tumor antigens. We are now developing a novel chimeric VDC (cVDC) in which E6 and E7 are fused to the L2 capsid protein as a means to further enhance this anti-tumor response. This cVDC could allow for the targeted cytotoxicity of HPV+ tumors in addition to the release of supplemental tumor antigens E6 and E7 within the now pro-immunogenic tumor milieu potentially leading to a long term anti-tumor response.

Methods: The detoxified sequences of E6 and E7 were engineered as one fusion polypeptide on the C-terminus of L2. Both L2/E6/E7 and L2/E7/E6 protein expression vectors were generated to determine if the order of the proteins impacted L2's ability to co-assemble with L1. The plasmids were co-expressed alongside L1 using the mammalian 293TT expression system.

Results: Both the L2/E6/E7 and L2/E7/E7 fusion proteins were expressed and co-assembled with L1 into chimeric VLPs. Fusion protein expression was validated by western blots for L2, E6 and E7, and VLPs were confirmed by electron microscopy.

Conclusions: Preliminary data indicate that chimeric VDCs containing E6 and E7 can successfully be generated using the 293TT mammalian expression system. Studies evaluating the cytotoxicity and E6 and E7 immunogenicity of the cVDC as well as the impact on tumor targeting are underway.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
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TOPICAL THERAPY FOR THE TREATMENT OF CERVICAL DYSPLASIA: A PILOT STUDY

Nerlyne Desravines[1], Chiu-Hsieh Hsu[2], Sopan Mohnat[3], Vikrant Sahasrabuddhe[4], Margaret House[4], Edward Sauter[4], Siobhan O'Connor[5], Julie Bauman[2], H-H Sherry Chow[2], Lisa Rahangdale[6]
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Introduction: Determine the feasibility of topical intravaginal 5-fluorouracil (5-FU) and imiquimod for the treatment of cervical intraepithelial neoplasia (CIN) 2/3.

Methods: This was a pilot study in women aged 18-45 with p16+ CIN 2/3. Participants underwent an 8-week alternating regimen of self-applied 5% 5-FU and physician-applied imiquimod. Feasibility was measured by tolerance, defined as the number of participants unable to apply at least 50% of the treatment doses, and safety, defined as the number of participants who experienced specified adverse events (AEs) from the study intervention. The study was feasible if the specified AEs were observed in less than 33% of participants and if more than 66% of participants tolerated the intervention. We also assessed clearance of high-risk HPV (hr-HPV). Baseline participant characteristics, AEs, and tolerability are reported using descriptive statistics.

Results: Thirteen participants were recruited. Eleven (85%) participants applied at least 50% of the treatment. All 13 participants reported grade 1 AEs; 6 (46%) reported grade 2 AEs while none had grade 3/4 events. Three (23%) participants had specified AEs. Histologic regression to normal or CIN 1 among those completing at least 50% of treatment was observed in 10 (83.3%) participants, and 7 (63.6%) tested negative for hr-HPV at the study end. These rates were 90% and 63%, respectively, in women that received 4+ doses of study

medications.

Table 1: Participants with adverse events (AE), tolerability, and treatment response (n=13)

Outcome	N (%)	95% CI[e]
Grade 1 AE	13 (100%)	NA
Grade 2 AE	6 (46.2%)	(19.2%, 74.9%)
Specified adverse events[a]	3 (23.1%)	(5.0%, 53.8%)
Tolerability[b]	11 (84.6%)	(54.5%, 98.1%)
Response	10 (76.9%)	(46.2%, 95.0%)
Histologic regression	10 (76.9%)	(46.2%, 95.0%)
Histologic regression amongst participants who tolerated treatment[c]	10 (90.9%)	(58.7%, 99.8%)
High-risk HPV clearance[d]	7 (53.9%)	(25.1%, 80.8%)
High-risk HPV clearance[d] amongst participants who tolerated treatment[c]	7 (63.6%)	(30.8%, 89.1%)

[a]Number of participants with AEs defined as Grade 2 or greater toxicity or Grade 1 genital lesion (blisters, ulcerations, or pustules) that was possibly, probably, or definitely related to treatment and lasted for more than 5 days; all had Grade 2
[b]Number participants able to apply ≥ 50% of the treatment (i.e. at least 4 weeks)
[c]11 participants who were able to apply ≥50% treatment (i.e. at least 4 weeks)
[d]Negative HPV DNA testing at end-of-study visit
[e]Clopper-Pearson ("exact") 95% CI

Conclusions: Topical therapies present a novel approach for treating cervical dysplasia and merit further investigation as adjuncts or alternatives to surgical therapy.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
04-18-2023 7:00 AM - 5:00 PM

ORAL ADMINISTRATION OF LACTOBACILLUS CRISPATUS M247 TO HPV POSITIVE WOMEN: PRELIMINARY RESULTS OF AN UNCONTROLLED OPEN TRIAL

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Introduction: Vaginal microbiota can be grouped into five different categories (CST I to V), based on their bacterial dominance. In CST I, the dominance of Lactobacillus crispatus appears to correlate with a better vaginal health and lower incidence of sine causa infertility, preterm delivery, bacterial vaginosis, and viral infections such as HPV infection. Based on this classification, CST IV (non-Lactobacillus-dominated) associated to a higher incidence of disorders.

Methods: We enrolled 35 HPV-positive women in a open non-controlled study. Twenty-four of them had a CST IV status, while the others were classified as having either CST III (N.=10) or CST II (N.=1) microbiota.

Results: After 90 days of oral administration of the probiotic L. crispatus M247, we observed a reduction of the HPV positivity of about 70% and a significant change in CST status with 94% of women classified as CST I.

Conclusions: Despite its limitations, the study shows that oral treatment with the probiotic L. crispatus can change the CST status and increase HPV clearence.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
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EFFECT OF CERVICAL ADMINISTRATION OF TRADITIONAL CHINESE MEDICINE PRESCRIPTION ON HPV E6 / E7 MRNA EXPRESSION IN PATIENTS WITH CIN

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Introduction: To explore the clinical significance of cervical administration of Paiteling (Chinese medicine prescription) on the negative conversion rate of HPV E6E7 mRNA (E6E7)

Methods: From January 2021 to July 2022, a total of 198 patients with pathological CIN3 and below were enrolled in Peking University Shenzhen Hospital. According to the treatment method, patients were divided into non-surgical and surgical groups before Paiteling administration. All patients were diagnosis with HPV E6/E7 mRNA positive before Paiteling administration in 2 groups. Inclusion criteria: ① women over 20 years old; ② no previous history of cervical physical therapy or surgery. Exclusion criteria: no follow the treatment and / or diagnosis protocol and the patients withdrew from the study. Petaline was administered according to the instructions, and the course of treatment was 6 weeks. Patients in the control group were only observed and followed up without treatment. TCT and E6E7 test were examined in one years after enrollment or treatment.

Results: 48 of 102 patients (surgical group average 41.9 years) and 46 of 96 patients (non-surgical group average 38.5 years) were treated with Paiteling, and the other patients were in the control group. The negative conversion rate of HPV E6E7 in Petaline administration / control of non-surgical group were 81.3% / 45.8%, 87.5% / 62.5%, and 89.6% / 75.0% in the 6th, 9th, and 12th months ($P<0.05$), respectively. The negative conversion rate of HPV E6E7 in Petaline/ control of surgical group were 84.8% / 71.7%, 91.3% / 80.4%, and 89.1% / 82.6%, in the 6th, 9th, and 12th months ($P<0.05$), respectively. The E6/E7 copy levels were decreased significant after Petaline administration in 2 groups ($P<0.05$).

Conclusions: The cervical administration of Petaline (Chinese medicine prescription) can reduce E6 / E7 of CIN in the surgical and non-surgical group, and reduce the risk of cervical cancer.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
04-18-2023 7:00 AM - 5:00 PM

DRUG-TARGETED ACTIVATION OF THE RIG-I PATHWAY TO DEVELOP NOVEL COMBINATORIAL THERAPEUTIC APPROACHES AGAINST HPV-ASSOCIATED CANCERS

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Introduction: Restoring pathways capable of triggering immunogenic cell death of HPV-associated cancer through production of type I interferons (IFNs) and lymphocyte-recruiting chemokines is of increasing interest. In this scenario, pattern recognition receptors (PRRs) appear to be among the most promising therapeutic targets. Our group and others recently showed that HPV + cells display marked downregulation of several PRRs. Specifically, we found that HPV persistence inhibits IFN production in response to DNA ligands, and that this effect is mainly due to irreversible suppression of the cGAS-STING pathway. By contrast, the RIG-I pathway mediates the residual IFN production triggered exogenous stimuli.

Methods: We have investigated the potential use of the RIG-I agonist M8 as an anti-cancer agent in CaSki and HeLa cells. We have also assessed whether M8 transfection could enhance the anticancer activity of the genotoxic agent cisplatin. This combinatorial treatment was also used in a murine syngeneic model of HPV16-driven cancer.

Results: We show that M8 exerts a potent antiproliferative effect in HPV + cells that is enhanced upon combined treatment with cisplatin. This effect is almost abolished in RIG-I KO cells. In addition, conditioned media from M8-treated CaSki cells, but not the RIG-I KO counterpart, significantly enhances NK cell proliferation and CaSki cell killing in vitro. Intratumoral M8 treatment also inhibits the growth of the tumors obtained by subcutaneous injection of the C3.43 cells, that harbor integrated HPV16 genome, in C57BL/6 mice when compared to vehicle-treated tumors. This inhibitory effect is strongly enhanced upon co-treatment with cisplatin when compared to cisplatin or M8 alone. The immune infiltrate in the tumors treated with M8 is significantly enriched in activated NK cells when compared to the single treatments.

Conclusions: Our findings provide good evidence that drug-targeted activation of the RIG-I pathway is an attractive and feasible option to enhance the effectiveness of existing anticancer therapies.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
04-18-2023 7:00 AM - 5:00 PM

EFFICACY OF REBACIN® NONINVASIVE CLINICAL INTERVENTION IN 3217 PATIENTS WITH HIGH-RISK PERSISTENT HPV INFECTION

Fei Chen[1], Guonan Zhang[2], Wei Lei[3], Shuguang Zhou[4], Ying Zhang[5], Lin Liu[5], Ying Jia[6], Rongkai Xie[7], Xiufang Tian[8], Jie Guo[9], Yuebo Yang[10], Xuefeng Wang[11], Xiaomei Wu[12], Qijian Sun[13], Youzhong Zhang[14], Junqi Ma[15], Yuxiu Liu[16], Yifan Cheng[17], Jiancui Chen[18], Dongmei Du[19], Guiyu Wang[19,20], Daifei Wu[21], Sheng Wang[19], Yuli Ling[19], Chunfa Zhang[21], Jinghe Lang[1]
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Introduction: Despite various prevention and control measures, the number of persistent hrHPV infection patients in China remains high. Previously, we reported that REBACIN® as a novel non-invasive clinical intervention has a significant effect on clearing persistent hrHPV infection. To further investigate the efficacy of REBACIN® in clearing persistent hrHPV infection under real-world conditions, we conducted a clinical observational study in 256 hospitals among the most parts of China.

Methods: 4539 patients with persistent hrHPV infection participated in this study and 3127 patients were enrolled and divided into REBACIN® group while 249 patients into blank control group. The patients in REBACIN® group received one course treatment of intravaginal administration of REBACIN®. After one month of drug withdrawal, the participants in both groups were checked for hrHPV using HC2, genotyping or E6/E7 mRNA assays, which the same patient has the same detection method before and after treatment.

Results: The clearance rate of patients in REBACIN® group was 60.35% (1,887/3,127), which was significantly higher than that in the blank control group of 20.08% (50/249). Specifically, the clearance rates of infection for HPV16 or HPV18 were 70.45% and 68.31%, and the clearance rates for HPV58 or HPV52 were 62.64% and 59.04%, respectively. In addition, the single, double, and triple/more subtype

infections had a clearance rate of 65.34%, 53.23%, and 38.30%, respectively. There were also big differences in the clearance rate among patients of different age after REBACIN® treatment, which 1567 patients aged less than or equal to 40 years old had a clearance rate of 64.39%, 1390 patients aged over 40 years old had a clearance rate of 55.25%.

Conclusions: This investigation confirmed that RECABIN® can effectively eliminate persistent hrHPV infection in real-word conditions, providing a guidance and technical support for the clinical application of noninvasive treatment of RECABIN® in clearing hrHPV persistent infection.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
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EFECT OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN A HPV18+ PREGNANT WOMAN WITH CIN II/III LESIONS

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Introduction: Human papillomavirus (HPV) infection is one of the most frequent sexually transmitted infections. Although most of the infections are short-lived, several factors such as pregnancy, increase the risk of persistent HPV infection, which is higher in pregnant women compared to aged-matched counterparts. HPV persistence increases the risk of cervical cancer. The current accepted approach during pregnancy consists in preventing the evolution to cervical cancer with the minimal intervention level, as surgical procedures are not recommended because they increase the risk of preterm birth and perinatal death. In this context, new conservative approaches to treat HPV lesions in the pregnant subpopulation are needed.

Methods: A clinical case of a 30 year old pregnant woman, smoker, diagnosed HPV serotype 18, colposcopy and acetowhite staining revealed HSIL lesions, biopsy confirmed extensive CIN II/III lesions and intense positivity for Ki67 and p16. Given the patients' profile, a non-invasive treatment with a Coriolus versicolor-based vaginal gel has been decided (1 cannula/day for 1 month + 1 cannula/alternate days for 5 months) and a watchful waiting approach with periodic colposcopy control.

Results: After 11 weeks of treatment with the Coriolus versicolor-based vaginal gel, colposcopy images showed a clear regression of the affected area with a transformation zone 1 (figure 2), which was confirmed by cytology (CIN I). The patient continued to be positive to HPV

18.

Figures

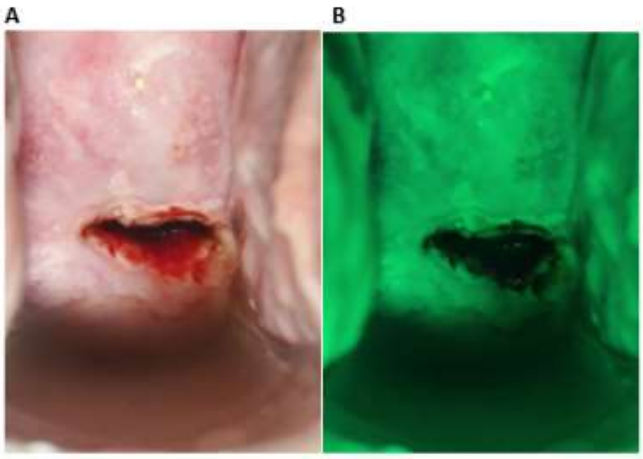

Fig. 1. Initial colposcopy. Acetic acid staining shows acetowhite areas with thick-mosaic vasculature and partial iodine staining, suggesting grade II (A). Initial colposcopy with green filter (B)

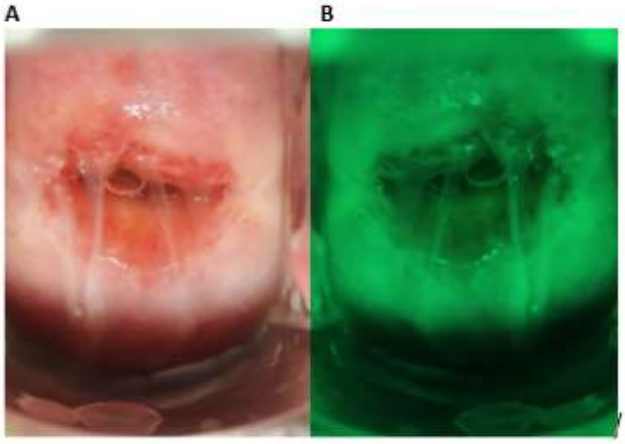

Fig. 2. Colposcopy after 11 weeks (A) Acetic acid staining shows clear regression. Colposcopy after 11 weeks with green filter (B)

Conclusions: A conservative non-invasive treatment with the Coriolus versicolor-based vaginal gel for 11 weeks has shown to be effective for HR-HPV cervical lesion regression in a pregnant 30 year old woman and no adverse events were observed in this clinical case.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
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EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV INFECTED PATIENTS: RESULTS OF 6 DIFFERENT STUDIES

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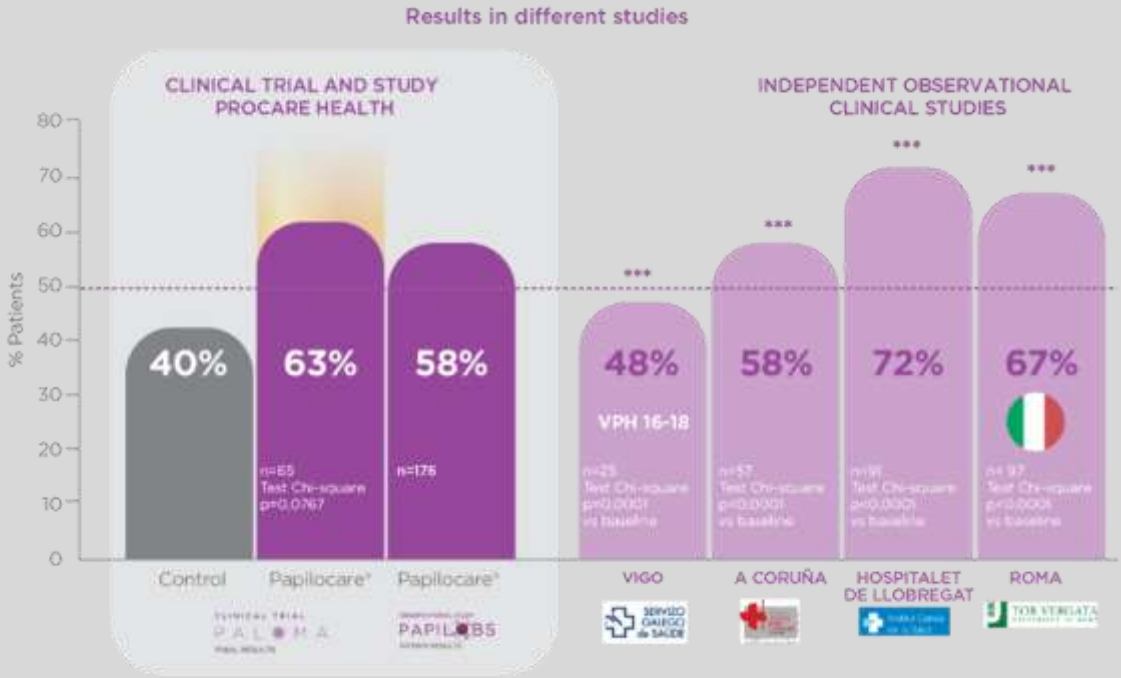
Introduction: To evaluate the consistency of the efficacy of a multi-ingredient Coriolus versicolor-based vaginal gel, on high-risk human papillomavirus (HR-HPV) clearance in 6 different studies.

Methods: Results from 4 independent observational studies (6 month-treatment period with Coriolus versicolor-based vaginal gel) were compared to results from a randomized, open, parallel, controlled trial (Paloma: NCT04002154) and an observational, multicenter, prospective, one-cohort study (PapilOBS: NCT04199260). Vigo study: Prospective one-cohort. Secondary endpoint (SE), HPV clearance in 25 patients infected by HPV 16 and/or 18. Coruña study: Retrospective one-cohort. Primary endpoint (PE), HPV clearance assessed in 57 medical patients' records. Hospitalet study: Retrospective one-cohort. PE, Composite efficacy variable (patients with normal cytology and/or HPV clearance) in 91 HR-HPV patients. Roma study: Retrospective controlled. PE, HR-HPV clearance in 183 patients. Paloma trial: SE, HR-HPV clearance in 65 patients. PapilOBS study: SE, HR-HPV clearance in 176 patients.

Results: In the Vigo study 48% of patients cleared HPV16/18, while in the Coruña study 58% of patients cleared HR-HPV. In the Hospitalet study 72.5% of patients normalized cytology and/or cleared HR-HPV. Furthermore, 67% of patients included in the Roma study cleared HR-HPV in the treated group vs 37.2% in the control group. In the Paloma trial, HR-HPV clearance reached 63% (treated group) vs 40% (control group). Finally, 57.4% HR-HPV clearance has been observed in the PapilOBS

study.



Conclusions: Coriolus versicolor-based vaginal gel has shown consistent efficacy rates across studies, with a 64% of HR-HPV clearance in average in 6 different studies involving 729 patients from which 597 represent HR-HPV cases.

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Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
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NOVEL ISO-QUINOLINE DERIVATIVES AS ORALLY AVAILABLE SELECTIVE HPV E7 DEGRADER THERAPEUTICS

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Introduction: The high-risk Human Papilloma Virus (HPV) encoded E7 proteins are generally considered addictive oncogenes for HPV induced neoplastic and malignant disease. There is strong preclinical evidence that E7 is essential for the induction, progression, and maintenance of HPV caused tumors. Loss of function of high-risk E7 can lead to senescence and eventually to apoptosis in various in vitro experiments, and to tumor regression in surrogate experimental animal models. Strikingly, high-risk E7 genes are the most stable and significantly less mutated than genes of any other HPV encoded RNA or protein. Accumulating evidence suggests loss of E7 function as a promising therapeutic strategy for HPV cancers. We posited that there is sufficient scientific confidence that a molecule able to introduce a loss of function phenotype of E7 might have a fair chance as a therapeutic option for an unmet medical need, and that the use of suitable E7 therapeutics goes far beyond cervical cancer. We elected to strive for oral applicable small-molecule-degrader drugs by their ease of use, also given the trending increase of incidences for HPV induced disease in low resource and remote areas.

Methods: A selective high-throughput screen based on in silico models and comprehensive structure-activity-relationship studies brought about robust drug candidate molecules that induce the degradation of HPV16 and 18E7 proteins in a monospecific, proteasome-dependent fashion.

Results: Lead compounds were selected with favorable drug like properties from varyingly 2,3,4-substituted isoquinolin-1-ones. Strong and fast E7 protein degrader-activities are obtained in various HPV driven tumor cells in vitro, and at low to sub µM levels in Xenograft mouse tumor models in vivo. Drug like properties, such as a favorable pharmacokinetics, and the pharmacodynamics of E7 protein degradation correlating with a dose dependent tumor growth inhibition were obtained.

Conclusions: Chemical structures of the lead-compounds with detailed structure-activity-relationship studies will be presented.

Shift 01-271 / #1351

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
04-18-2023 7:00 AM - 5:00 PM

EFFECTIVENESS OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV PATIENTS IN OVER 35- OR 40-YEAR OLD SUBGROUPS

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Introduction: HR-HPV persistence is a prerequisite for cervical cancer development, which is the fourth most common cancer in women. The aim of this study is to evaluate the effectiveness of a Coriolus versicolor-based vaginal gel- on repairing high-risk (HR) HPV-dependent low-degree cervical lesions and HR-HPV clearance in real-life practice.

Methods: Observational, multicenter, prospective, one-cohort study (NCT04199260) recruited a total population of 178 woman over >25y with an ASCUS/LSIL Pap smear and concordant colposcopy during routine clinical visits. Patients have been treated with Coriolus versicolor-based vaginal gel 1 cannula/day for 21 days the first month + 1 cannula/alternate days for 5 months. Sub-analysis of women over 35 and/or 40 years old infected with HR-HPV, data from colposcopy and concordant Pap smear results (primary endpoint) and viral clearance at 6/12 months are presented. The study was approved by the ethical committee of Public University Hospital of Puerta de Hierro (Madrid). All patients signed informed consent.

Results: Data collected from women ≤35 or ≤40 years old shown 64% and 64.5% (at 6 months), and 74.7% and 72.7% (at 12 months) Pap smear/colposcopy normalization and concordant colposcopy respectively, whilst viral clearance was 55.4% and 56% (at 6 months), and 67.6% and 68.8% (at 12 months) respectively. Additionally, data collected from women ≥35 or ≥40 years old shown 70.9% and 73.5% (at 6 months), and 76.9% and 81.2% (at 12 months) Pap smear/colposcopy normalization and concordant colposcopy respectively, whilst viral clearance was 58.8% and 59.7% (at 6 months), and 72.8% and 73.5% (at 12 months) respectively.

Conclusions: In this subpopulation analysis of HR-HPV low-degree cervical lesions normalization and clearance, women aged ≥40 years old showed similar or better ratios than the ≤40 years old group at the two studied timepoints pointing to the effectiveness of Coriolus versicolor-based vaginal gel even in that more vulnerable patients group to HR-HPV persistency.

Shift 01-272 / #648

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02M. NOVEL DIAGNOSTIC TECHNOLOGIES FOR HPV-RELATED DISEASE
04-18-2023 7:00 AM - 5:00 PM

COMPARISON BETWEEN THE ROCHE COBAS, ABBOTT REALTIME, SEEGENE ANYPLEX HPV28 AND NOVEL SEEGENE ALLPLEX HPV28 ASSAYS FOR HIGH-RISK HPV DETECTION AND GENOTYPING ON MOCKED SELF-SAMPLES

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Introduction: Infection with a high-risk (hr) human papillomavirus (HPV) is well-established as the main cause of cervical cancer. Therefore, the WHO now recommends HPV DNA testing as the first-choice screening method. The recently developed Seegene Allplex™ 28 HPV assay is a novel qPCR HPV assay, designed to separately detect and quantify 28 distinct HPV genotypes in a fully-automated and user-friendly manner. Considering the importance of self-sampling within future screening programs, our study evaluated and compared the diagnostic performance of the Seegene Allplex™ 28 HPV assay, and those of the Roche Cobas, Abbott RealTime and Seegene Anyplex™ 28 HPV assays for the use of mocked self-samples.

Methods: A total of 114 mocked self-samples, i.e. semi-cervical samples collected by gynecologists using the Viba-Brush, were analyzed with all four qPCR HPV assays. Agreement in terms of HPV detection and genotyping was assessed by mean of the Cohen's kappa (κ) coefficient. Concordance between viral HPV loads (Cq-values) detected by the different assays was examined via calculation of Pearson correlation coefficients.

Results: of all four qPCR HPV assays agreed in 85.9% of the cases when using the Abbott RealTime manufacturer's recommended Cq-cutoff for positivity (<32.00) (Table 1A) and 91.2% when using an adapted positivity range (32.00-36.00) (Table 1B). Inter-comparison of the qPCR HPV assays demonstrated an overall agreement ranging from 85.1-100.0% (κ=0.42-1.00) when using the manufacturer's guidelines (Table 2A) and 92.1-100.0% (κ=0.60-1.00) with the adapted range (Table 2B). For all assays, highly significant, strongly positive Pearson correlations were shown between Cq-values of test results (Figure
1).

Table 1. Concordance amongst the results of all qPCR HPV assays for any detectable HPV genotype (**A**) using the Abbott RealTime manufacturer's Cq cutoff for positivity (< 32.00) and (**B**) using a less stringent Abbott RealTime Cq positivity range (32.00 – 36.00)[a].

A.

Roche Cobas result	Abbott RealTime HR result	Anyplex™ 28 result[b]	Allplex™ 28 result[b]	n (%) (total = 114)		Discordance (n)
-	-	-	-	8 (7.0)	] 98 (85.9)	NA
+	+	+	+	90 (78.9)		16(12), 18(7), Other[c] hrHPV(78)
+	-	-	-	5 (4.4)		Other[c] hrHPV (5)
+	-	+	+	11 (9.7)		Other[c] hrHPV (11)

B.

Roche Cobas result	Abbott RealTime HR result	Anyplex™ 28 result[b]	Allplex™ 28 result[b]	n (%) (total = 114)		Discordance (n)
-	-	-	-	8 (7.0)	] 104 (91.2)	NA
+	+	+	+	96 (84.2)		16(12), 18(7), Other[c] hrHPV(84)
+	-	-	-	5 (4.4)		Other[c] hrHPV (5)
+	-	+	+	4 (3.5)		Other[c] hrHPV (4)
+	+	-	-	1 (0.9)		Other[c] hrHPV(1)

hr, high-risk; NA, not applicable.

[a]All +/- combinations others than the ones presented did not prevail within this sample selection.

[b]Study only includes results of the 14 hrHPV genotypes.

[c]Other hrHPV genotypes include HPV31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.

Table 2. Agreement between the results of the four qPCR HPV assays for any detectable genotype, (**A**) depending on the Abbott RealTime manufacturer's Cq cutoff for positivity (< 32.00) and (**B**) depending on a less stringent Abbott RealTime Cq positivity range (32.00 – 36.00).

A.		Abbott RealTime	Anyplex™ 28[a]	Allplex™ 28[a]
Roche Cobas	Overall agreement (%)	85.1	95.6	95.6
	Negative agreement (%)	100.0	100.0	100.0
	Positive agreement (%)	84.8	95.3	95.3
	Kappa coefficient (95% CI)	0.42 (0.21-0.63)	0.74 (0.52-0.95)	0.74 (0.52-0.95)
Abbott RealTime	Overall agreement (%)		90.4	90.4
	Negative agreement (%)		100.0	100.0
	Positive agreement (%)		89.1	89.1
	Kappa coefficient (95% CI)		0.65 (0.47-0.84)	0.65 (0.47-0.84)
Anyplex™ 28[a]	Overall agreement (%)			100.0
	Negative agreement (%)			100.0
	Positive agreement (%)			100.0
	Kappa coefficient (95% CI)			1.00 (1.0-1.0)
B.		Abbott RealTime	Anyplex™ 28[a]	Allplex™ 28[a]
Roche Cobas	Overall agreement (%)	92.1	95.6	95.6
	Negative agreement (%)	100.0	100.0	100.0
	Positive agreement (%)	92.4	95.3	95.3
	Kappa coefficient (95% CI)	0.60 (0.37-0.83)	0.74 (0.52-0.95)	0.74 (0.52-0.95)
Abbott RealTime	Overall agreement (%)		96.5	96.5
	Negative agreement (%)		100.0	100.0
	Positive agreement (%)		96.0	96.0
	Kappa coefficient (95% CI)		0.85 (0.70-0.99)	0.85 (0.70-0.99)
Anyplex™ 28[a]	Overall agreement (%)			100.0
	Negative agreement (%)			100.0
	Positive agreement (%)			100.0
	Kappa coefficient (95% CI)			1.00 (1.0-1.0)

CI, confidence interval.

[a]*Study only includes results of the 14 hrHPV genotypes.*

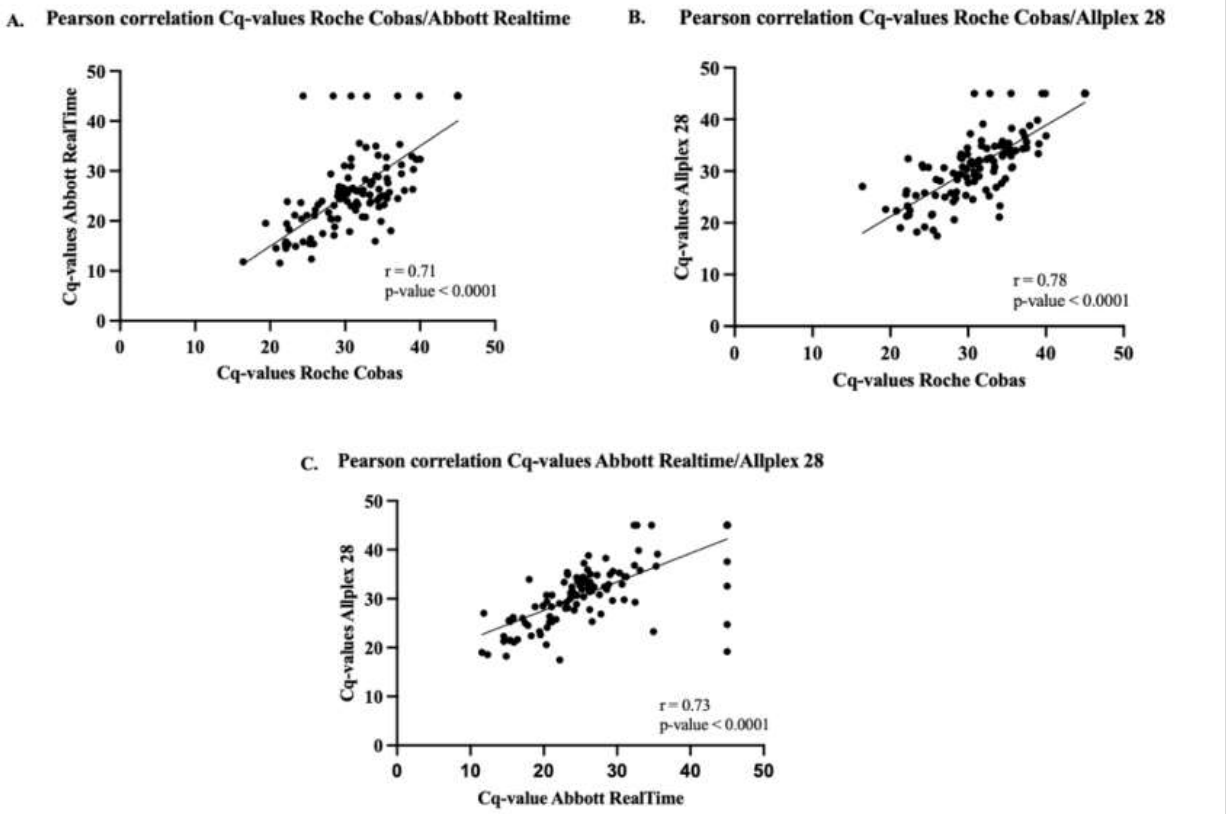

Figure 1. Correlation between the Cq-values of (**A**) the Roche Cobas and Abbott RealTime HPV assays, (**B**) the Roche Cobas and Allplex™ 28 HPV assays and (**C**) the Abbott RealTime and Allplex™ 28 HPV assays. | Graphs visualize a significant Pearson's correlation between the Cq-values of all qPCR HPV assays ($r = 0.71$, $p < 0.001$; $r = 0.78$, $p < 0.001$; 0.73, $p < 0.001$), indicating a strongly positive relationship.

Conclusions: This study shows high concordance between the included qPCR HPV assays for mocked self-samples. Based on these findings, we imply that the novel Seegene Allplex™ 28 HPV assay demonstrates comparable performance to those of currently available qPCR HPV assays, potentially providing opportunities for simplification and standardization of future large-scale testing.

Shift 01-273 / #1482

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02M. NOVEL DIAGNOSTIC TECHNOLOGIES FOR HPV-RELATED DISEASE
04-18-2023 7:00 AM - 5:00 PM

DEEP LEARNING-BASED CERVICAL CANCER VISUAL EVALUATION TEST: DESIGNING THE TEST RESULT AS 2-CLASS OR 3-CLASS

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Introduction: Cervical cancer screening visual results form a continuous spectrum starting with normal cervix and ending with severe precancer/cancer cases. In between, there is a large group of equivocal cases, and this group is a mixture of normal cervix showing HPV infections or cervicitis, and precancer cases with less severe appearance. Forcing a visual evaluation into a binary classification (control vs case) will lead to incorrect diagnoses (i.e., calling a true precancer as normal and vice versa). In this study, we present results from two versions of a deep learning-based Automated Visual Evaluation (AVE) test using a binary (normal-precancer+) and a 3-class classifier (normal-equivocal-precancer+) in terms of accuracy and repeatability.

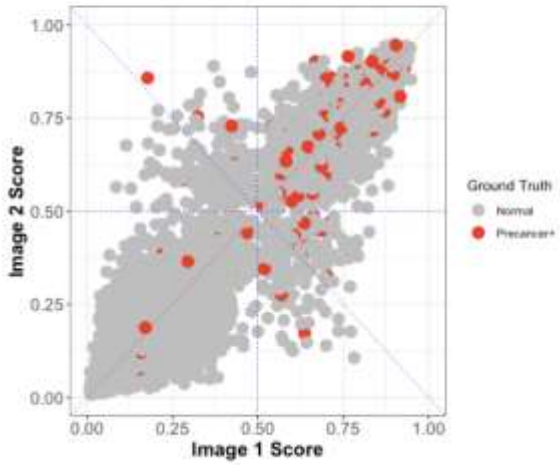
Methods: We used the Natural History Study from Guanacaste, Costa Rica, to evaluate two versions of AVE algorithm: 2-class (normal-precancer+) and 3-class (normal-indeterminate-precancer+) classification. To increase the repeatability, we incorporated the Monte Carlo drop-out method into the algorithm. These two models were evaluated based on the percentage of non-repeatable results, correct classification of each class, and extreme misclassification (incorrectly predicting a true precancer+ as normal and vice versa).

Results: In our comparisons between 2-class and 3-class classification AVE algorithms, the repeatability of the test result on 2 images captured from the same individual at the same visit increased with the 3-class classification algorithm (Figure 1). Correct classification of precancer+ cases increased from 66% to 80% with serious misclassification of true precancer+ cases as normal decreasing from 34% to 9% when

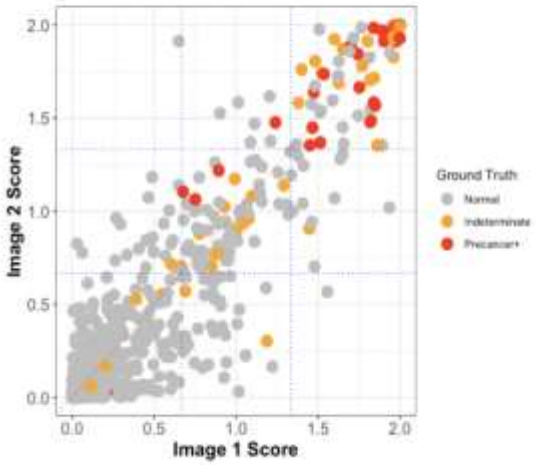
switching from the 2-class to the 3-class classification algorithm.

Figure 1: Comparison of repeatability of test results: 2 images obtained from the same patient at the same visit

1a: 2-Class (Normal-Precancer+)



1b: 3-Class (Normal-Indeterminate-Precancer+)



Conclusions: A 3-class classification model that deals explicitly with the indeterminate class considerably decreases serious errors and allows for a better clinical solution than a binary classification, as the results (especially when combined with HPV genotyping) are more reliable and repeatable.

Shift 01-274 / #768

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02P. OTHER CLINICAL RESEARCH
04-18-2023 7:00 AM - 5:00 PM

EVALUATION OF TRAINING IN COLPOSCOPY AND LARGE LOOP EXCISION OF THE TRANSFORMATION ZONE IN DENMARK

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Introduction: Colposcopy is an important tool in the diagnostic work-up of women with abnormal screening test results. In some countries, such as the United Kingdom, colposcopy is only performed by certified colposcopists, whereas in other countries, like Denmark, colposcopy may be performed by OB/Gyn residents with no or little formalized training. As clinical management depends on the colposcopic evaluation and the biopsy results, and because adequate treatment is important to reduce risk of recurrence, it is critical that the residents are adequately trained. Hence, we aimed to evaluate the level of training in colposcopy and LLETZ among Danish OB/Gyn residents.

Methods: Two questionnaires were developed: one for residents in OB/Gyn who learn colposcopy and LLETZ during their residency, and one for chief physicians who are responsible for execution of the training. Questionnaires were distributed via e-mails and social media from November to December 2021.

Results: Among 120 eligible specialty trainees, 93 completed the questionnaire (77.5%). Median age was 36 years (IQR 34-39), and most were females (90.3%). Most received training in colposcopy (84.9%), but the majority considered the training insufficient (76.3%) and had low self-efficacy in performing colposcopy (72.0%). Moreover, nearly half had < 5 supervised colposcopies before performing colposcopy without supervision (45.2%). With respect to LLETZ, most received training (84.9%), but nearly half considered the training insufficient (43.0%), and half had low self-efficacy in performing LLETZ (49.5%).

Conclusions: Most Danish specialty trainees in OB/Gyn received some training in colposcopy and LLETZ, but many consider the training insufficient and have low self-efficacy in performing the procedures. These findings suggest that a formal training program is warranted to ensure an appropriate level of training and adequate patient care.

Shift 01-275 / #967

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02P. OTHER CLINICAL RESEARCH
04-18-2023 7:00 AM - 5:00 PM

LEVELS OF ANXIETY IN WOMEN ≥45 YEARS UNDERGOING DIAGNOSTIC LOOP ELECTROSURGICAL EXCISION PROCEDURE: A LONGITUDINAL STUDY

Line Gustafson[1,2], Mette Larsen[2], Anne Hammer[3,4,5], Lone Petersen[6,7], Berit Andersen[2,8], Pinar Bor[8,9]
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Introduction: Younger women are shown to have increased levels of anxiety in relation to colposcopy. However, levels of anxiety in postmenopausal women undergoing immediate diagnostic cervical excision due to an abnormal screening test is unknown. We aimed to measure anxiety levels in women ≥ 45 years undergoing diagnostic loop electrosurgical excision procedure (LEEP) at the first colposcopy visit.

Methods: We conducted a longitudinal study based on questionnaire data from a clinical study carried out in Central Denmark Region from March 2019 - June 2021. Women were included at colposcopy if they were ≥45 years and had a transformation zone type 3. All women had an immediate LEEP performed. Women completed State Trait Anxiety Inventory (STAI) and Short Form-12 questionnaires before, immediately after, and one and six months after LEEP. STAI median score and the relative risk (RR) was calculated. Results were stratified by physical and mental health (SF-12).

Results: Of 109 eligible women, 11 were excluded leaving 98 women for final analyses. Response rates ranged from 84.7 – 100%. Overall, state anxiety levels were low, however a decrease was observed from before to immediately after LEEP (33.4 vs. 29.3, $p<0.001$) and remained stable up to six months after LEEP. Women with poor mental health were more likely to have higher anxiety levels compared to women with good mental health (before LEEP: RR 3.77 (95% confidence interval (CI): 2.12-6.70), one month after LEEP: RR 3.37 (95% CI: 1.59 – 7.15), six months after LEEP: RR 1.93 (95% CI: 1.06 – 3.51).

Conclusions: Overall, diagnostic LEEP at the first visit in women ≥45 years was not associated with high levels of anxiety. Anxiety levels were highest before colposcopy, thus the women seemed to experience an immediate relief. Women with poor mental health had the highest anxiety level throughout the study, which might warrant special attention.

Shift 01-276 / #997

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02P. OTHER CLINICAL RESEARCH
04-18-2023 7:00 AM - 5:00 PM

A MULTI-INSTITUTIONAL STUDY OF BARRIERS TO CERVICAL CANCER CARE IN SUB-SAHARAN AFRICA

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Introduction: The global rise in cancer incidence has been accompanied by disproportionately high morbidity and mortality rates in low and middle-income countries (LMICs). Despite efforts to improve outcomes, many patients diagnosed with and offered treatment for cervical cancer never return to start treatment, for reasons that are poorly documented and little understood. We investigated the interplay of sociodemographic, financial, and geographic factors among patients in Botswana and Zimbabwe for insight into the barriers to cancer care based on a country's mix of enablers and obstacles.

Methods: Patients seen in consultation between 2019-2021 who never returned for definitive cancer treatment were identified and offered the opportunity to complete a survey. Afterwards, an intervention connected patients with resources and counseling to return for treatment. Follow-up data were collected 3 months later as a measure of secondary success. Fisher's Exact tests analyzed the relationship between number and types of barriers and demographics.

Results: Forty women who initially presented for oncology care but did not return for treatment at Princess Marina Hospital in Botswana (n=20) and Parirenyatwa General Hospital in Zimbabwe (n=20) completed the survey. Overall, married women experienced more barriers than unmarried women ($p<0.001$), and unemployed women were 10 times more likely to report a financial barrier than employed women ($p=0.02$). In Zimbabwe, financial barriers and belief-associated barriers such as fear of treatment were reported. In Botswana, many patients noted scheduling obstacles associated with administrative delays and COVID. At follow-up, 16 Botswana patients and 4 Zimbabwe patients had returned for treatment.

Figure 1: Sociodemographic Factors Associated with Barriers to Care by Country

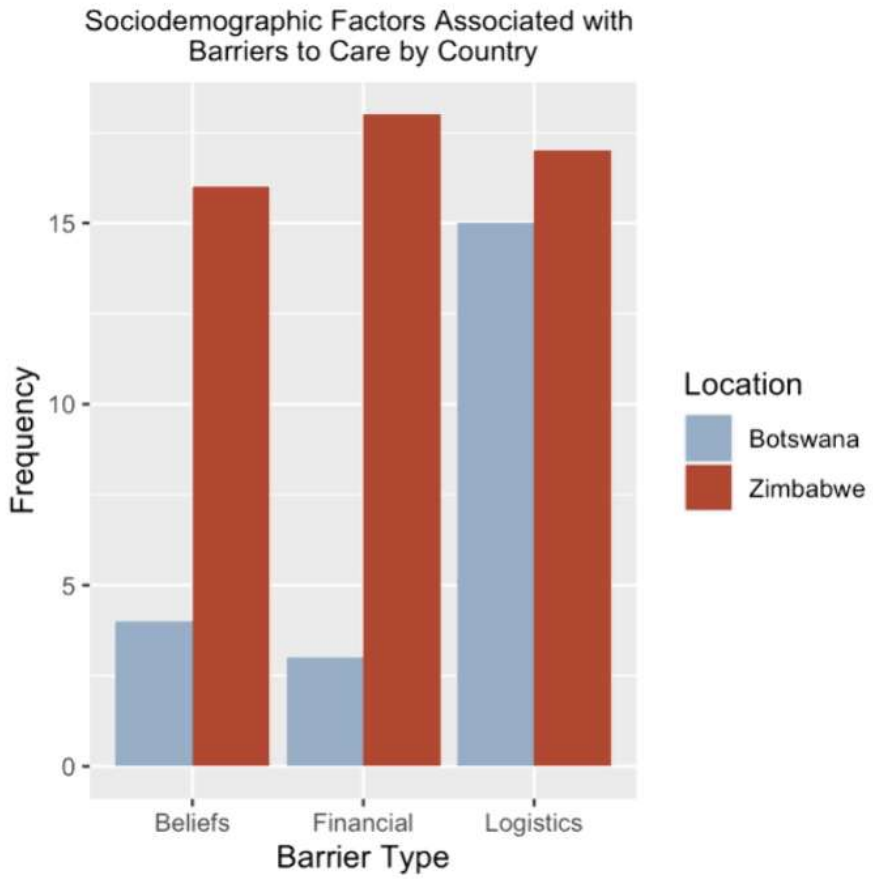

Table 1: Sociodemographic Factors Associated with Barriers to Care by Country

	Zimbabwe (n=20)	Botswana (n=20)	Total (n=40)
***Financial Burden**			
Treatment Cost	15(75.0%)	1(5.0%)	16(40.0%)
Transportation Cost	4(20.0%)	1(5.0%)	5(12.5%)
No Health Insurance	16(80.0%)	1(5.0%)	17(42.5%)
***Logistics**			
Delays due to COVID	9(45.0%)	2(10.0%)	11(27.5%)
Waiting for hospital call	1(0.0%)	15(75.0%)	16(40.0%)
Hospital Delays	4(20.0%)	1(5.0%)	5(12.5%)
Need to care for family member	8(40.0%)	0(0.0%)	8(20.0%)
***Beliefs**			
Afraid of side-effects	3(15.0%)	3(15.0%)	6(15.0%)
Believe treatment ineffective	2(10.0%)	0(0.0%)	2(5.0%)
Prefer alternative treatment/provider	14(70.0%)	1(5.0%)	15(37.5%)
Do not understand treatment	2(10.0%)	0(0.0%)	2(5.0%)
Don't trust doctors can cure cancer	1(5.0%)	0(0.0%)	1(2.5%)

Conclusions: Financial and belief barriers identified in Zimbabwe showcase the importance of targeting cost and health literacy to reduce apprehensions. In Botswana, administrative challenges could be addressed with patient navigation. Improving our understanding of the multifactorial barriers to cancer care can enable us to help patients who might otherwise default.

Shift 01-278 / #1354

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02P. OTHER CLINICAL RESEARCH
04-18-2023 7:00 AM - 5:00 PM

HPV CLEARANCE AFTER LOOP ELECTROSURGICAL EXCISION PROCEDURE IN WOMEN AGED ≥ 45 YEARS: A PROSPECTIVE COHORT STUDY.

Line Gustafson[1,2], Louise Krog[3,4,5], Mette Tranberg[6], Lone Petersen[7,8], Bayan Sardini[1,5], Berit Andersen[1,9], Pinar Bor[9,10], Anne Hammer[4,9,11]
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Introduction: Clinical management of postmenopausal women with incomplete visualization of the transformation zone (TZ3) is challenging as lesions may be located in the cervical canal, thereby increasing the risk of missing disease. Due to these issues, some women with TZ3 undergo a diagnostic loop electrosurgical excision procedure (LEEP). However, knowledge about the HPV clearance after treatment in postmenopausal women is sparse. In this study, we aimed to determine HPV clearance rates, overall and stratified by histology result, in women with a TZ3 who had a diagnostic LEEP.

Methods: We conducted a prospective cohort study including women ≥45 years with TZ3 who had a diagnostic LEEP performed at their first colposcopy visit during March 2019 – June 2021. From the Danish Pathology Databank, we collected the date and results on all cervical samples collected post-treatment. Women contributed time at risk until date of HPV negative test, immigration, death, hysterectomy, or on August 31, 2022 whichever occurred first. Hence, all included women had at least 1 year of follow-up. We illustrated cumulative HPV clearance rates stratified by histology results (<CIN2 versus CIN2 or worse) using Kaplan Meier curve.

Results: In total 107 women was included and had a LEEP performed. Of these six (5.6%) were lost to follow-up, leaving 101 (94.4%) women for analyses. The median age was 67.5 years (IQR: 62.5 – 70.3). Thirty-four (33.7%) women had CIN2+ detected in the LEEP specimen. Analyses on clearance rate are ongoing and these results will be presented at the conference.

Conclusions: will be drawn when the results are ready and presented at the conference.

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Poster Viewing
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TWO-DOSE HPV VACCINE SERIES COMPLETION ACROSS INDIANA'S 92 COUNTIES: CORRELATES OF GEOGRAPHIC VARIABILITY

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Introduction: HPV vaccine series completion in the U.S. and in state of Indiana (61.7% and 55.2%, respectively) lag behind the Healthy People 2030 goal of 80% coverage. The purpose of this study was to document variability in series completion across Indiana's 92 counties and identify county-level correlates of series completion.

Methods: The Indiana Immunization Information System provided county-level data on 2-dose completion for all individuals ages 9-14 years who received their first dose of HPV vaccine in 2017 or 2018. CountyHealthRankings.org and other data sources provided county-specific socio-demographic and health data. Pearson correlations and multiple linear regression (MLR) with backward selection determined correlates of county-level series completion.

Results: HPV vaccine series completion across the 92 counties for Indiana 1st dose recipients ranged from 55.7% to 90.4% (M=73%). Higher series completion was associated with lower: % uninsured (r = -.37;p<.001), % children living in poverty (r = -.36;p<.001), % unemployed (r = -.40;p<.001), % aged 65 years and older (r = -.22;p=.034), % rural population (r = -.26;p=.012), and % of adults who smoke (r = -.38;p < .001). Completion was associated with higher: primary care providers per capita (r = .31;p<.01), participation in mammography screening among Medicare enrollees (r = .48;p<.001), Flu vaccine coverage among Medicare enrollees (r = .37;p<.001), and % with some college (r = .50;p<.001). MLR identified % uninsured (Beta = -0.96;95%CI=-1.47,-0.44), % unemployed (Beta = -3.32;95%CI=-5.33,-1.30), and participation in mammography screening (Beta = 0.34;95%CI=0.08,0.59) as significant independent predictors of series completion (R-squared=.38).

Conclusions: There was wide variability in series completion across Indiana counties. Variations were associated with county-level socio-demographic and health measures, particularly variables reflecting difficulties with access to care and lack of financial resources. Development of programming that addresses these issues may help to improve HPV vaccine series completion in counties with particularly poor completion rates.

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Poster Viewing
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04-18-2023 7:00 AM - 5:00 PM

SYSTEMATIC COMMUNITY-BASED CERVICAL CANCER SCREENING FOR HUMAN PAPILLOMAVIRUS USING SELF-COLLECTION OF VAGINAL SWABS AMONG RURAL SOUTH INDIAN WOMEN: A DEMONSTRATION PROJECT

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Introduction: Understanding the feasibility and acceptability of community-based cervical cancer screening using self-collection of vaginal swabs in India is crucial for the implementation of national screening program. However, there is limited data available in India. This study describes the implementation challenges of rolling out a systematic screening program using self-collected vaginal swabs during cervical cancer screening in rural Mysore, India.

Methods: Between November 2021 to April 2022, systematic screening using self-collection of vaginal swab for HPV-DNA testing was conducted in eight rural communities, Mysore. All positives on HPV-DNA were followed-up with Visual Inspection of Acetic Acid(VIA) or Liquid Based Cytology(LBC). HPV-DNA testing was done using digene HC2 HPV-DNA test method. Data were analyzed using stata 16.1

Results: Total 344 women were screened using HPV-DNA testing. The average age was 41.4 years(SD: 8.84), 85% were married and 46.8% had primary or no education. Positive HPV-DNA tests were found in 22 women(6.4%) of who 18(81.8%) followed-up for additional testing using LBC. All 18 LBC results were normal. The attrition rate for the program was 18.2% and the reasons women were not able to follow-up for additional testing included lack of family support and fear of undergoing hysterectomy. Although women liked self-sampling, main challenges was collecting the samples at home when women lived in joint families with limited privacy. They felt uncomfortable in the presence of elders(in-laws) at home. Several women in the community were not comfortable with vaginal brush used for self-sampling as they felt it would be painful. Furthermore, menopausal women experience bleeding in vagina after using swab.

Conclusions: Self-collection of vaginal samples is promising as a primary screening strategy for cervical cancer prevention in conservative cultures. Self-collection was generally acceptable among women who were otherwise reluctant to undergo a pelvic examination. Self-collection reduces the need for an invasive, potentially painful, and embarrassing pelvic exam.

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TRENDS IN HYSTERECTOMY-CORRECTED SQUAMOUS AND ADENOCARCINOMA CERVICAL CANCERS AMONG WOMEN AGED 30 YEARS AND OLDER IN THE UNITED STATES.

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Introduction: Previous studies report that cervical adenocarcinoma (AC) incidence increased among younger non-Hispanic White women in the U.S. To assess whether these trends are sustained, we examined hysterectomy-corrected incidence trends for cervical AC and squamous cell carcinoma (SCC) from 1999 to 2018.

Methods: Using population-based cancer registries covering 97% of the U.S. population, we report age-adjusted incidence rates per 100,000 women for cervical SCC and AC by race and region among women aged 30 years and older in the U.S. after correcting for hysterectomy prevalence. Hysterectomy prevalence obtained from the Behavioral Risk Factor Surveillance System was used to correct the number of women at risk for cervical cancer. We examined incidence trends using joinpoint regression and quantified change using average annual percentage change (AAPC).

Results: An average of 7,758 cases (corrected rate: 11.7) of SCC and 2,985 cases of AC (corrected rate: 4.5) were diagnosed annually over 20 years. Corrected rates were highest among non-Hispanic Black women for SCC (19.3) and Hispanic women for AC (5.4). From 1999 to 2018, the incidence of SCC declined in all age groups. However, the incidence for AC was stable among women aged 30-39 years (AAPC: 1.17; 95% CI: -0.09, 2.45) and 40-49 years (AAPC: 0.99; 95% CI: -0.37, 2.37), and declined among women in all older age groups (50-59, 60-69, 70-79, 80+ years). Incidence declined for SCC and AC among non-Hispanic Black and Hispanic women but was stable for AC among non-Hispanic White women (AAPC: 0.04; 95% CI: -0.87, 0.96).

Conclusions: The changes from increasing incidence rates to stable rates for cervical AC among non-Hispanic White women and decreasing trends in older women could be due to myriad factors, including the temporal changes in the approach to screening, diagnostic testing, and treatment of precancerous lesions over the last 20 years.

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GEORGIA CANCER CONTROL CONSORTIUM'S HPV FREE WORKGROUP: COMING TOGETHER THROUGH STATE-WIDE EFFORTS FOR HPV ELIMINATION

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Introduction: Oropharyngeal and cervical cancers are increasing in the USA. HPV vaccination rates in the state of Georgia (GA) lag behind those in the USA, which in turn are lower than other high-income countries. Many Georgians lack access to healthcare and education about HPV-associated cancers. New approaches that involve multiple stakeholders are needed to reduce these cancers, and the Georgia Cancer Control Consortium (GC3) HPV Free Workgroup has worked to increase HPV awareness, vaccination and education through concerted state-wide efforts.

Methods: Two virtual events were organized and advertised through all communication channels of the GC3 HPV Free Workgroup. The target audience for these events included healthcare professionals, community members, health advocates and survivors, and state/federal legislators. We also included pharmacists and dentists, and we incentivized participation with CE credits. Polling questions were utilized throughout the webinar, and post-event surveys were distributed and collected to determine impact.

Results: There were 146 participants in the Annual Cervical Cancer Awareness Day, and 272 participants in HPV Awareness Day. Nearly 50% of the participants were medical professionals (physicians, nurses, dentists and pharmacists), and participation was mapped to counties across the entire state. 61% of participants completed the post-event survey, and 98% stated the webinar objectives were met. 100% affirmed the overall quality of the webinar was very good/excellent, and that "the information learned will result in improved patient outcomes, effective in improving provider skills/strategy, and provider performance."

Conclusions: The GC3 HPV Free Workgroup expanded HPV-associated cancer education by offering CE credits and using a virtual platform to reach over 400 stakeholders across the state of GA. These events promoted HPV awareness across a broad range of healthcare disciplines and represented an 8-fold increase in participation over prior years, which is likely to result in improved health outcomes for Georgians.

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Poster Viewing
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GLOBAL TYPE-SPECIFIC GENITAL HUMAN PAPILLOMAVIRUS PREVALENCE IN MEN, BY SEXUAL ORIENTATION: A SYSTEMATIC REVIEW AND META-ANALYSIS

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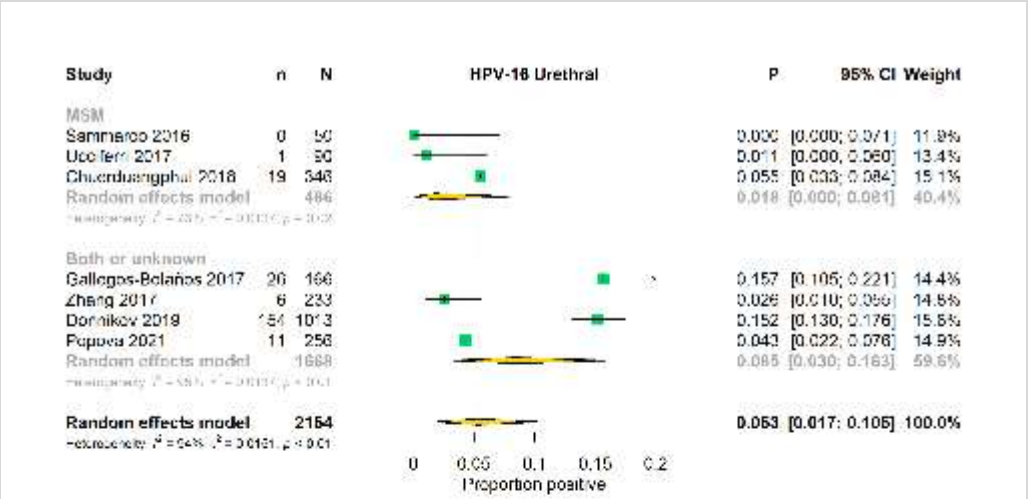
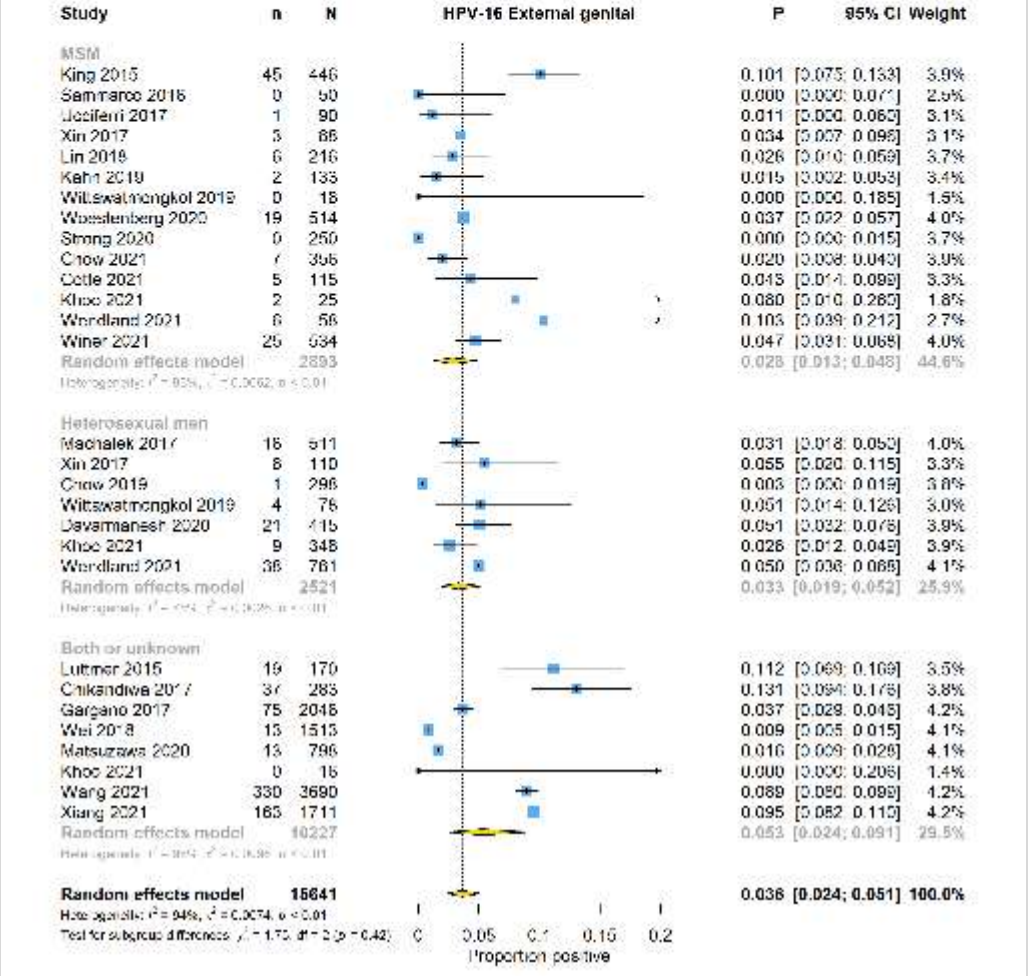
Introduction: Genital type-specific HPV infection in men is less well studied than in women, but such prevalence data are important for monitoring prevention of HPV-related diseases in men. Few systematic reviews and meta-analyses included type-specific genital HPV data. The introduction of HPV vaccination in several countries may affect genital HPV prevalence in men. Therefore, we conducted a systematic review and meta-analysis with recent publications of type-specific genital HPV prevalence among men, and assessed differences by sexual orientation.

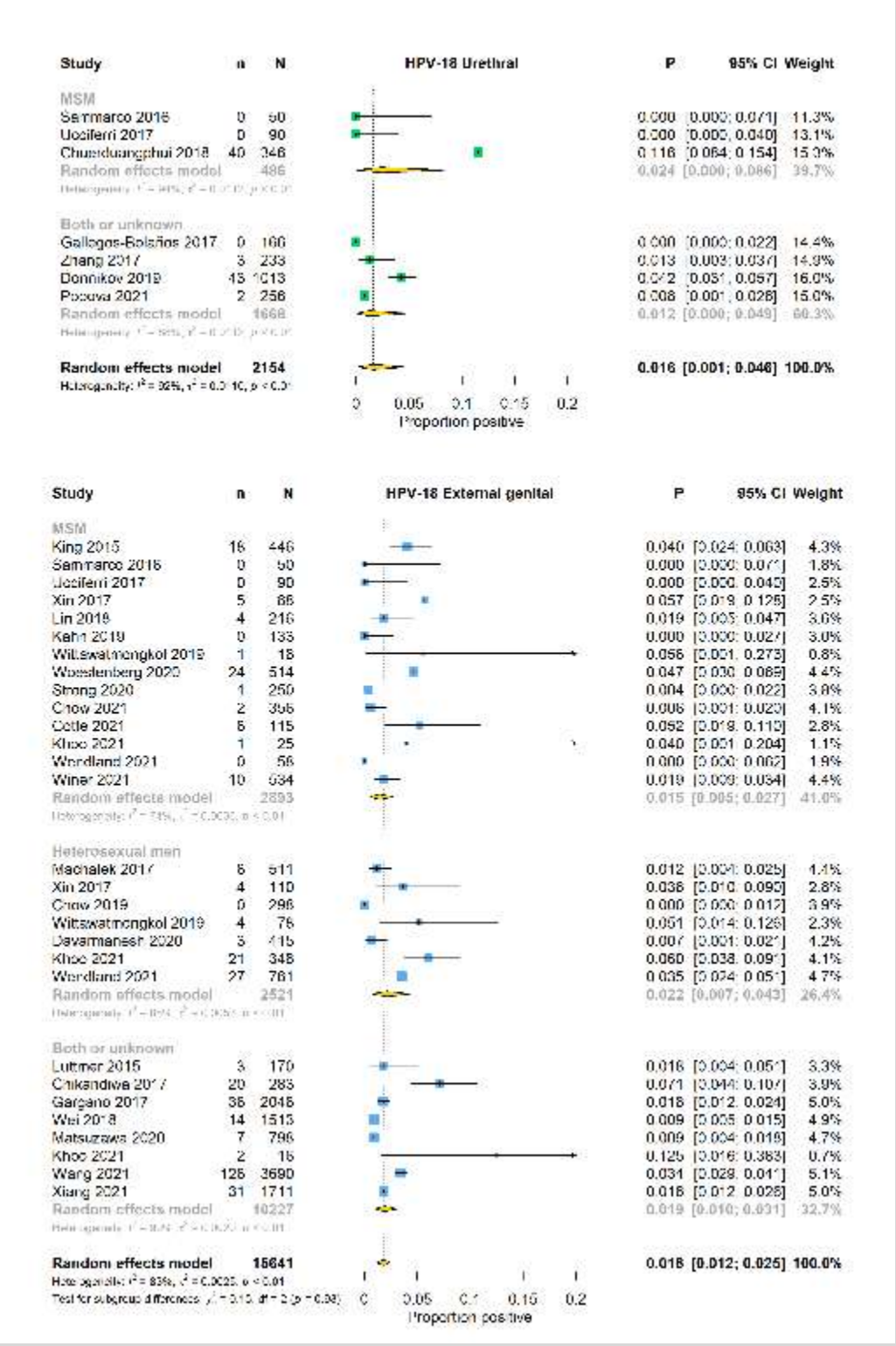
Methods: MEDLINE and Embase were searched for studies reporting on male genital HPV prevalence with data from November 2011 onwards. The final search was conducted on 25 October 2021. A random-effects meta-analysis was conducted to estimate type-specific and grouped external genital and urethral HPV prevalence. Subgroup analyses were conducted for sexual orientation.

Results: Twenty-nine studies were eligible, of which 22 reported external genital HPV prevalence, 5 urethral HPV prevalence, and 2 both. Prevalence among men who have sex with men (MSM) was reported by 20 studies and among heterosexual men (HM) by 12 studies; 6 studies did not state sexual orientation. The most common genotypes were HPV-6 (5.6% genital and 5.5% urethral) and HPV-16 (3.6% and 5.3%), although with high heterogeneity. The grouped estimates for any HPV was 25.9% for the urethra and 35.8% for external genital. In all but one HPV-type, no significant difference in pooled type-specific prevalences between HM and MSM were observed. The forest plots of HPV-16 and HPV-18 are presented in Figures 1 and


Study
n
N
HPV-16 Urethral
P
95% CI
Weight
MSM
Sammarco 2016 0 50 0.000 [0.000; 0.071] 11.8%
Ucciferri 2017 1 90 0.011 [0.000, 0.060] 13.4%
Chuenduangphai 2018 19 346 0.055 [0.033; 0.084] 15.1%
Random effects model 486 0.018 [0.000; 0.081] 40.4%
Both or unknown
Gallegos-Bolaños 2017 26 166 0.157 [0.105; 0.221] 14.4%
Zhang 2017 6 233 0.026 [0.010; 0.056] 14.8%
Dorniklov 2019 154 1013 0.152 [0.130; 0.176] 15.5%
Popova 2021 11 256 0.043 [0.022; 0.076] 14.9%
Random effects model 1668 0.085 [0.030; 0.163] 59.6%
Random effects model 2154 0.053 [0.017; 0.105] 100.0%
0
0.05
0.1
0.15
0.2
Proportion positive


Study
n
N
HPV-16 External genital
P
95% CI
Weight
MSM
King 2015 45 446 0.101 [0.075; 0.133] 3.9%
Sammarco 2016 0 50 0.000 [0.000; 0.071] 2.5%
Ucciferri 2017 1 90 0.011 [0.000; 0.060] 3.1%
Xin 2017 3 86 0.034 [0.007; 0.098] 3.1%
Lin 2019 6 216 0.026 [0.010; 0.059] 3.7%
Kahn 2019 2 133 0.015 [0.002; 0.053] 3.4%
Witswatmongkol 2019 0 18 0.000 [0.000; 0.185] 1.5%
Woestenberg 2020 19 514 0.037 [0.022; 0.057] 4.0%
Strang 2020 0 250 0.000 [0.000; 0.015] 3.7%
Chow 2021 7 356 0.020 [0.008; 0.040] 3.9%
Cotte 2021 5 115 0.043 [0.014; 0.099] 3.3%
Khoo 2021 2 25 0.080 [0.010; 0.260] 1.8%
Wrendland 2021 6 56 0.103 [0.039; 0.212] 2.7%
Winer 2021 25 534 0.047 [0.031; 0.068] 4.0%
Random effects model 2893 0.028 [0.013; 0.048] 44.6%
Heterosexual men
Machalek 2017 16 511 0.031 [0.018; 0.050] 4.0%
Xin 2017 8 110 0.055 [0.020; 0.115] 3.3%
Chow 2019 1 296 0.003 [0.000; 0.019] 3.8%
Witswatmongkol 2019 4 76 0.051 [0.014; 0.126] 3.0%
Devarmanesh 2020 21 415 0.051 [0.032; 0.076] 3.9%
Khoo 2021 9 348 0.026 [0.012; 0.049] 3.9%
Wrendland 2021 36 761 0.050 [0.036; 0.066] 4.1%
Random effects model 2521 0.033 [0.019; 0.052] 25.9%
Both or unknown
Luttmer 2015 19 170 0.112 [0.069; 0.169] 3.5%
Chikandiwa 2017 37 285 0.131 [0.094; 0.176] 3.8%
Gargano 2017 75 2046 0.037 [0.029; 0.045] 4.2%
Wei 2018 13 1513 0.009 [0.005; 0.015] 4.1%
Matsuzawa 2020 13 796 0.016 [0.009; 0.028] 4.1%
Khoo 2021 0 16 0.000 [0.000; 0.206] 1.4%
Wang 2021 330 3690 0.089 [0.080; 0.099] 4.2%
Xiang 2021 163 1711 0.095 [0.082; 0.110] 4.2%
Random effects model 10227 0.053 [0.024; 0.091] 29.5%
Random effects model 15641 0.036 [0.024; 0.051] 100.0%
0
0.05
0.1
0.15
0.2
Proportion positive

2.



Conclusions: Genital HPV is common among men, and HPV-6 and HPV-16 were the most common genotypes. Other meta-analyses have demonstrated consistently higher anal HPV prevalence in MSM compared to HM; in contrast, genital type-specific HPV prevalence appears to be similar among MSM and HM.

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Poster Viewing
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ORAL HPV INFECTION AND HPV VACCINATION

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Introduction: HPV-related oropharyngeal cancer (OPC) is increasing in incidence. Despite this increase in OPC very little is known about oral HPV infection in the general population. In this Australian-based study we wanted to analyse oral HPV prevalence stratified by Gardasil® vaccination status, and also identify factors associated with infection and the dynamics of HPV types included or not included in the Gardasil® vaccine.

Methods: To be eligible to take part in the Oral Diversity Study, participants had to be Australian residents and aged between 18 and 70 years. Participants were asked to fill out a questionnaire (about lifestyle and sexual behaviour) and donate a saliva sample, we also asked for permission to confirm HPV vaccination through record linkage with the Australian Immunisation Registry. Saliva samples were DNA quality checked, analysed for HPV, and HPV-positive samples were typed.

Results: We recruited participants to the Oral Diversity Study (2020-2021). 921 returned a saliva sample for analysis, 911 passed the DNA quality check and were included in the study. 8% had an oral HPV infection and almost half of them (48%) were high-risk HPV types. 233 participants (26%) were Gardasil®-vaccinated. Of the vaccinated participants 22% tested positive for oral HPV, compared to 26% of the unvaccinated (p=0.497). In the vaccinated group 44% of the HPV types were high-risk HPV types, compared to 48% in the unvaccinated group (p=0.752). Sixteen people were positive to one of the four Gardasil® HPV types. We found HPV-6 (n=2), HPV-11 (n=3) and HPV-18 (n=1) in non-vaccinated participants. HPV-16 was the common HPV type in this study (n=10), and identified in one Gardasil®-vaccinated participant.

Conclusions: We found no significant difference in prevalence of oral HPV infection or high-risk HPV types in participants Gardasil®-vaccinated or not. One Gardasil®-vaccinee tested positive to one of the HPV types included in Gardasil® (6%).

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SEXUAL DEBUT AND ASSOCIATION WITH ORAL HUMAN PAPILLOMAVIRUS INFECTION, PERSISTENCE AND OROPHARYNGEAL CANCER - AN ANALYSIS OF TWO AUSTRALIAN COHORTS

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Introduction: Oropharyngeal cancer is increasingly caused by human papillomavirus (HPV), and this increase is believed to be caused by changing sexual behaviour. It has been hypothesised that an immune response to HPV through sexual intercourse is much stronger than an immune response elicited from oral sex. Therefore, people who have their debut of oral sex before or at the same time as sexual intercourse would have a weaker immune response to HPV and hence be more likely to develop a persistent oral HPV infection and oropharyngeal cancer. Drake et al (Cancer. 2021;127[7]:1029-1038) found some evidence that supported this hypothesis.

Methods: We have reanalysed two of our Australian cohorts with similar data in order to provide a perspective of Drake and colleagues' publication, as sexual behaviour varies depending on culture and geographical location.

Results: We found that engaging in oral sex (OR 4.46, 95% CI [1.88-10.62]) and being younger than 20 years at oral sex debut (OR 9.46, 95% CI [3.53-25.31]) were both very strong risk factors for oropharyngeal cancer. Participants in the general population cohort who had their sexual intercourse debut before the age of 18 were more likely to be oral HPV positive (OR 2.69, 95% CI [1.50-4.83]). Oral sex debut before sexual intercourse debut was quite uncommon in our two Australian cohorts.

Conclusions: However, timing of or sexual debuts may further add to risks of oropharyngeal cancer, and future studies should be designed to investigate timing and order of sexual debuts to help clarify the roles of these potential causal factors.

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CORRELATION BETWEEN SELF-REPORTED GARDASIL® VACCINATION AND VACCINATION RECORD

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Introduction: Australia has a school-based HPV vaccination scheme (vaccinating year 7 students; 12-13 year olds) in place, with girls vaccinated from 2007 and boys included in the vaccine program in 2013. Here we wanted to confirm self-reported Gardasil® vaccination through record linkage with the Australian Immunisation Registry (AIR), as it has previously been reported that people often forget about vaccinations received in school.

Methods: We recruited 1,023 participants to the Oral Diversity Study. To be eligible, participants had to be Australian residents and aged between 18 and 70 years. Participants were asked for permission to confirm through record linkage with the Australian Immunisation Registry if they had received any Gardasil® injections, type of vaccine (Gardasil® or Gardasil9®), date of injection(s) and how many injections they have had.

Results: We received permission from 911 participants for HPV vaccination record linkage. Of those 233 (26%) were confirmed to be HPV vaccinated Most participants had received Gardasil® (226; 97%, and only seven Gardasil9®). Ninety-one percent of the vaccinated were females (n=212), 19 males and two non-binary. The highest HPV vaccine uptake was seen in the youngest age group (18-29 years; 80%), followed by 66% in 30-39 year olds, 2% in 40-49 year olds and then dropped significantly to 0.7% for people 50 to 70 years old. We had 587 who self-reported no HPV vaccination, AIR confirmed 585 of them as “no”; 238 self-reported HPV vaccination, and AIR confirmed 204 of them to be HPV vaccinated. Of the 25 who were unsure about their HPV vaccination status, 11 were vaccinated and 14 not.

Conclusions: We found that the correlation between self-reported Gardasil® vaccination and the AIR records were very good, with 96% of people answering yes or no remembered correctly if they were Gardasil vaccinated or not.

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EVALUATING THE ASSOCIATION OF CAREGIVING ON CERVICAL CANCER SCREENING IN THE UNITED STATES

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Introduction: Preventive health and screening behaviors among caregivers is an understudied component of caregiver health and well-being. We evaluated whether caregiving affects likelihood of receiving cervical cancer screening, and whether employment or insurance status modifies this relationship.

Methods: We used 2018 U.S. population-based Behavioral Risk Factor Surveillance System data to identify female caregivers (n=3,127) and non-caregivers (n=11,543) aged 25-64 years. We used Mantel-Haenszel stratified analysis to estimate adjusted prevalence ratios (PRs) and 95% confidence intervals (CIs) for associations between caregiving status and self-reported receipt of Pap testing <=3 years prior. Further, we assessed weekly hours of caregiving (<=8, 9-19, 20-39, 40+) to evaluate dose-response effects on cervical cancer screening. We assessed age, income, and education as potential confounders, and employment and insurance status as effect modifiers.

Results: Caregivers (80.4%) were less likely than non-caregivers (82.9%) to have had a Pap within <=3 years (PR=0.88; 95%CI:0.79-0.97). Compared to non-caregivers, those who provided 20-39 or >=40 hours weekly care were less likely to have had a Pap (20-39: PR=0.71; 95%CI:0.52-0.98, >=40: PR=0.76; 95%CI:0.61-0.96). No significant association was found with caregiving for <20 hours. Adjusting for age and education, employed caregivers were less likely than employed non-caregivers to have had a Pap within <=3 years (adjusted PR=0.85; 95%CI:0.74-0.97). Adjusting for age and income, insured caregivers were less likely than insured non-caregivers to have had a Pap (adjusted PR=0.89; 95%CI:0.79-1.00). No significant associations were observed among uninsured or unemployed groups.

Conclusions: Caregiving was associated with lower adherence to cervical cancer screening guidelines; the effect was amplified by increased weekly care hours and varied by employment and insurance status. As the prevalence of informal caregivers is projected to rise, public health policies must prioritize measures to promote screening behaviors among caregivers.

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Poster Viewing
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THE PROGNOSTIC IMPACT OF HPV STATUS AND THE TUMOR MICROENVIRONMENT IN VULVAR SQUAMOUS CELL CARCINOMAS – A POPULATION-BASED DANISH STUDY INCLUDING ~1,300 CANCERS

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Introduction: Identification of prognostic markers for vulvar squamous cell carcinomas (VSCCs) is needed to stratify patients into groups with different needs for treatment and follow-up. Approximately 40% of VSCCs are associated with human papillomavirus (HPV) and they seem to have a better prognosis compared with HPV-independent cases. In other solid tumors, the tumor microenvironment has been identified as an independent prognostic parameter, but only few studies have evaluated its role in VSCC. The aim of this study is to examine the prognostic role of high-risk (hr) HPV status, tumor-infiltrating lymphocytes (TILs) and tumor-stroma ratio (TSR) in VSCC.

Methods: We have established a cohort of 1544 VSCC cases (1990–2017) identified in the national Danish Pathology Register. Archived formalin-fixed, paraffin-embedded tumor tissue blocks have been retrieved from clinical biobanks, and diagnoses have been reviewed by a gynecopathologist. HrHPV status has been determined using the INNO LiPA Genotyping Extra test and p16 immunohistochemical staining (N=1278). In a subsample of our cohort, immunohistochemical staining for CD3 and CD8 will be performed and TILs and TSR will be assessed by use of digital image analysis. Information on vital status has been retrieved from nationwide registries to investigate 5-year overall survival (OS) according to hrHPV status and the tumor microenvironment. Hazard ratios (HRs) of death, adjusting for age, year of diagnosis, and stage, are also estimated.

Results: Preliminary results based on the first 950 cases show that 31.0% (95% CI: 28.4–33.5) of cases were positive for both hrHPV and p16. These women had better survival than women who were negative for both markers (5-year OS: 63.5% versus 47.4%, $HR_{adjusted}$=0.68, 95% CI: 0.52–0.90).

Conclusions: HrHPV positive status is a beneficial prognostic marker in VSCC. Data on the prognostic value of the tumor microenvironment in VSCC according to HPV status will be presented at the conference.

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Poster Viewing
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PROPORTION OF ADENOCARCINOMA AND THE DISTRIBUTION OF HPV GENOTYPES IN CERVICAL CANCER IN CHINA：A META ANALYSIS

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Introduction: There are two main types of pathology in invasive cervical cancer (ICC), squamous cell carcinoma (SCC) and adenocarcinoma (ADC), with SCC accounting for approximately 90% of ICC. In many developed countries, the incidence of SCC of the cervix has been falling for some time, while that of ADC of the cervix is now rising. Meanwhile, Global multicenter studies have shown that approximately 90.0% of SCCs are attributable to HR-HPV infection which only leads to 62.0% of ADCs. As the proportion of ADC in ICC increases, the risk of cervical cancer attributed to HPV will be reduced.

Methods: Systematically reviewed in Medline, Embase, Cochrane Library databases, and CNKI between 1997 and 2022. And we applied the random-effects models to estimate the combined effect values due to the high heterogeneity.

Results: Twenty-three studies included 49498 cases of cervical cancer were extracted. The relative incidence of ADC was 9.0% (95% confidence interval (CI): 7.7%~10.3%) and increased slowly from 1979-2006 to 2012-2018 (6.0% for 1979-2006, 8.1% for 2006-2012, and 9.5% for 2012-2018; $P < 0.05$ (1979-2006 vs 2012-2018)). Meanwhile, the ratio of ADC also varies by regions, highest in South China (15.8%; 95%CI: 9.5%~22.1%), followed by North China (10.1%; 95%CI: 5.2%-15.1%). And the remaining regions varied between 8.5% and 7.0%. The overall prevalence of HPV infection in ADC (69.4%) was significantly lower than that in SCC (88.4%) ($P < 0.05$). Top three HPV types prevalent in ADC were HPV18 (45.0%), HPV16 (22.0%), and HPV52 (7.3%), and those prevalent in the SCC were HPV16 (64.2%), HPV52 (5.6%), HPV18 (5.4%).

Conclusions: The proportion of ADC in ICC was slightly growing in the last few decades in China, which differs from the results of some international studies. And the proportion of ADC also varies by region. In ADC the predominant type is HPV18 and in SCC, HPV16.

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HIGH PREVALENCE OF HPV, OTHER STI AND ANAL LESIONS AMONG MSM IN TOGO

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Introduction: STI are a critical issue in Africa, especially in key populations such as MSM. Here, we present the baseline results of a 2-years longitudinal cohort study (ANRS DEPIST-H 12400) enrolling both HIV-positive and negative MSM.

Methods: MSM were included in Lomé (Togo) between June and December 2021, half of them living with HIV. High-risk HPV (hrHPV) and HSV-1/2 detection was performed on anal smears. Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) were tested from urine, pharyngeal and anal swabs. A clinical genital examination was carried out by trained physicians.

Results: 200 MSM with a median age of 23 years (IQR=21-29) were enrolled. Only 1.5% of participants were positive for HBs antigen, while no HCV nor syphilis infection was detected. The prevalence of CT and NG was 6.5% and 3.0% in urine, 26.0% and 22.0% in anal swab, and 5.0% and 19.0% in oropharyngeal area, respectively. Anal herpes simplex virus (HSV) infection were detected in 9 (4.5%).Overall, a high prevalence of anal hrHPV was detected (75.9%),significantly higher among HIV-positive MSM (84.0% vs 67.7%, p=0.008). HPV35 and HPV52 were the most prevalent types (24%) among HIV-infected MSM. Two-thirds of hrHPV-positive MSM were infected with at least one hrHPV covered by the nonavalent vaccine. More than a third of MSM (36.2%) presented an HPV-6 or -11. Anal lesions were detected at examination in 43.0% of MSM, with 19.5% of condylomas, 17.5% of marisks, 3.0% of anal fissures. No anal cancer was diagnosed.

Conclusions: These first data of the ANRS DEPIST-H emphasize the high prevalence of STIs among MSM. It also confirms the unusual distribution of HPV types in western Africa, with HPV35 being a highly prevalent hrHPV type non-covered by the nonavalent vaccine. A national strategy regarding STI screening and HPV vaccination in this key population is needed.

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DIFFERENCES IN CERVICAL CANCER MORTALITY RATES BY RACE AND VISIBLE MINORITY GROUP IN CANADA FROM 2006 TO 2019

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Introduction: Despite Canada's diverse population and universal health care model, differences in cancer mortality due to socioeconomic inequalities are not well known due to data limitations. We used the Canadian Census Health and Environment Cohorts (CanCHECs) datasets to evaluate disparities in cervical cancer mortality rates by race and visible minority group.

Methods: We used data from the 2006 and 2011 CanCHECs series, which are population-based probabilistically linked datasets of 5.9 million and 6.5 million respondents of the 2006 Long-Form Census and 2011 National Household Survey, respectively. Subjects in the cohorts were linked to the Canadian Vital Statistics Death Database, with follow-up to 2019. Subjects self-reported their race and visible minority group, with an optional write-in response. We estimated age-standardized mortality rate ratios (ASMRR) and bootstrapped 95% confidence intervals (95%CI) to compare race- and visible minority group-specific rates with the overall population rate. Negative binomial regressions were used to adjust rates for year, province of residence, rural residence, household income, educational level, and immigration status.

Results: Age-standardized cervical cancer mortality rates were significantly lower in Chinese (ASMRR=0.52, 95%CI: 0.37-0.73) and South Asian (ASMRR=0.62, 95%CI: 0.38-0.87) women (Table 1). They were significantly higher in Black (ASMRR=1.44, 95%CI: 1.02-2.02) and Indigenous women (ASMRR=1.85, 95%CI: 1.45-2.26), compared to the overall population. Differences in mortality rates by race and visible minority group remained even following adjustment for socioeconomic

variables.

Table 1. Age-standardized cervical cancer mortality rates per 100,000 and age-standardized mortality rate ratios by population group, standardized to the Canadian 2011 census population.

	Cervical cancer (females)			
Population	**ASMR**	**(95%CI)**	**ASMRR**	**(95%CI)**
Overall	1.9	(1.8-2.1)	1.00	(ref)
Not a visible minority	2.0	(1.9-2.1)	1.03	(1.00-1.05)
Chinese	1.0	(0.7-1.4)	**0.52**	**(0.37-0.73)**
Korean	1.9	(0.6-3.5)	0.99	(0.33-1.82)
Japanese	1.9	(0.4-3.7)	0.99	(0.20-1.89)
Filipino	1.9	(1.1-2.8)	0.97	(0.56-1.44)
Southeast Asian	1.4	(0.3-2.5)	0.70	(0.17-1.29)
South Asian	1.2	(0.7-1.7)	**0.62**	**(0.38-0.87)**
Arab	*	*	*	*
Black	2.8	(1.9-3.9)	**1.44**	**(1.02-2.02)**
Latin American	1.0	(0.2-2.2)	0.53	(0.09-1.11)
Other visible minority groups	0.9	(0.3-2.4)	0.44	(0.15-1.23)
Multiple visible minority groups	*	*	*	*
Indigenous peoples	3.6	(2.8-4.4)	**1.85**	**(1.45-2.26)**

ASMR=age-standardized mortality rate; ASMRR=age-standardized mortality rate ratio; CI=confidence interval

* Number of cases under disclosure threshold, included in the "Other visible minority groups" category.

Conclusions: Routine screening is an effective way to reduce the burden of cervical cancer at the population level, yet screening coverage is known to be lower in visible minority women in Canada, particularly Indigenous peoples who frequently present with more advanced cancer. Further, even in a publicly funded healthcare system, visible minorities may experience barriers to quality treatment, including delays in or lack of access to standard of care treatments.

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SEROLOGIC RESPONSE TO HUMAN PAPILLOMAVIRUS GENOTYPES AMONG UNVACCINATED AND VACCINATED WOMEN IN THE HPV INFECTION AND TRANSMISSION AMONG COUPLES THROUGH HETEROSEXUAL ACTIVITY (HITCH) COHORT STUDY

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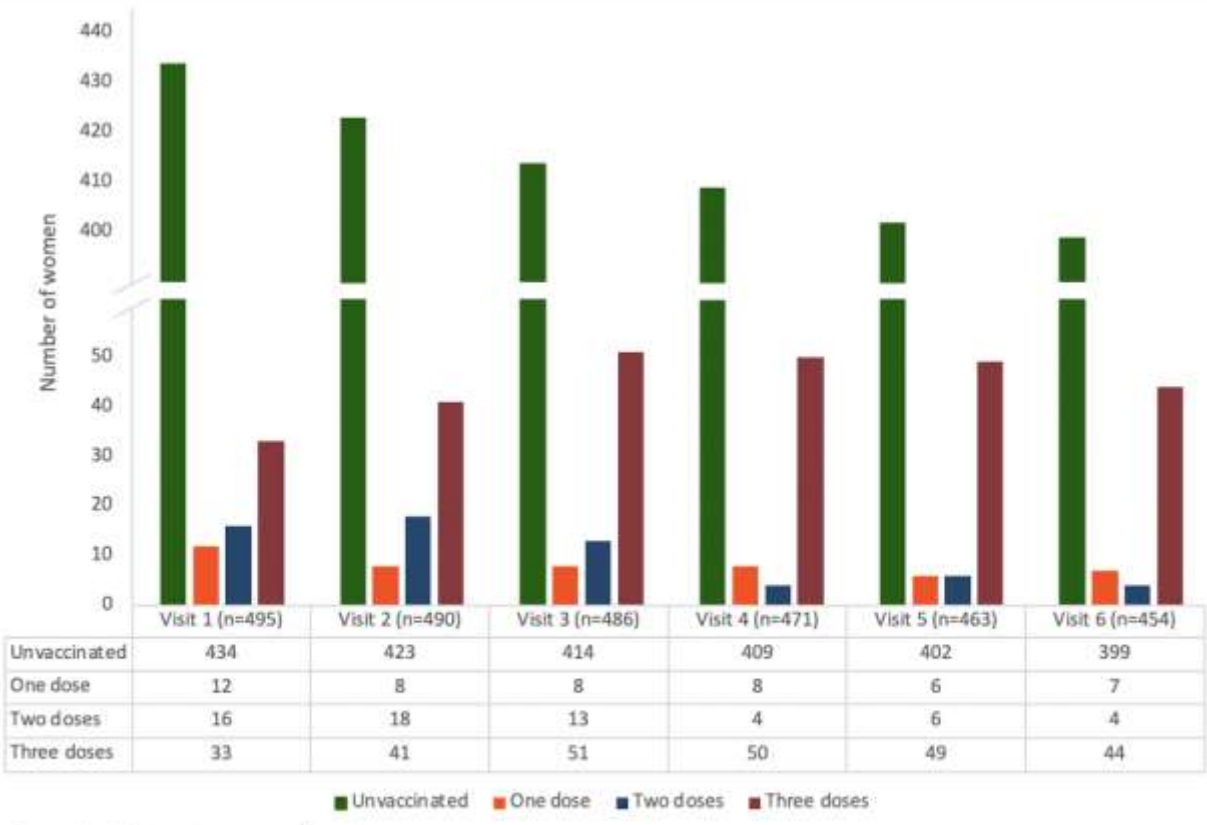
Introduction: Human papillomavirus (HPV) infections contribute to approximately 5% of the worldwide cancer burden. Humoral responses due to natural infection or vaccination may be critical for preventing, controlling, and/or eliminating HPV infection. Using data from the HITCH cohort study, we analyzed 1) humoral response to natural infection among unvaccinated women and 2) immunogenicity to vaccination among vaccinated women in relation to the phylogenetic relatedness of HPV genotypes.

Methods: We enrolled 495 women aged 18-24 years attending college or university in Montreal, Canada (2005-2011). Participants provided blood samples at enrollment and up to five follow-up visits. Antibody response to bacterially expressed L1 and E6 glutathione S-transferase fusion proteins of multiple Alphapapillomavirus types and to virus-like particles (VLP-L1) of HPV16 and HPV18 were measured using multiplex serology. We assessed correlations between antibody seroreactivities at enrollment using Pearson correlations (r).

Results: At enrollment, 87.7% of participants were unvaccinated, 2.4% had received one, 3.2% two, and 6.7% three doses of HPV vaccine (Fig.1). The corresponding L1 seropositivity to any HPV was 41.2%, 83.3%, 100%, and 97.0%. Among unvaccinated women (Fig.2A), strong correlations were observed for L1 seroreactivity between α9 HPV types: 58–52 (r=0.86), 58–33 (r=0.75), and 33–52 (r=0.72), as well as for E6 seroreactivity: 52–11 (r=0.84), 52–18 (r=0.78), 35–11 (r=0.77), and 18–33 (r=0.76). Weaker correlations were observed for VLP-L1 seroreactivity compared to L1 and E6. Between-type correlations for L1 seroreactivities increased as the number of vaccine doses increased from one (Fig.2B) to three (Fig.2C). Among the latter, the strongest correlations were observed for 58–33 (r=0.96) within α9-species, 11–6 (r=0.96) within α10-species, and 45–18 (r=0.95) and 68–59 (r=0.95) within α7-species.



	Visit 1 (n=495)	Visit 2 (n=490)	Visit 3 (n=486)	Visit 4 (n=471)	Visit 5 (n=463)	Visit 6 (n=454)
Unvaccinated	434	423	414	409	402	399
One dose	12	8	8	8	6	7
Two doses	16	18	13	4	6	4
Three doses	33	41	51	50	49	44

Figure 1. HPV vaccine status by visit.

Figure 1 legend: The bar graph presents the number of participants evaluated at each visit (visits one through six) considering their vaccination status (unvaccinated, one dose to three doses) at each point.

HPV – human papillomavirus.

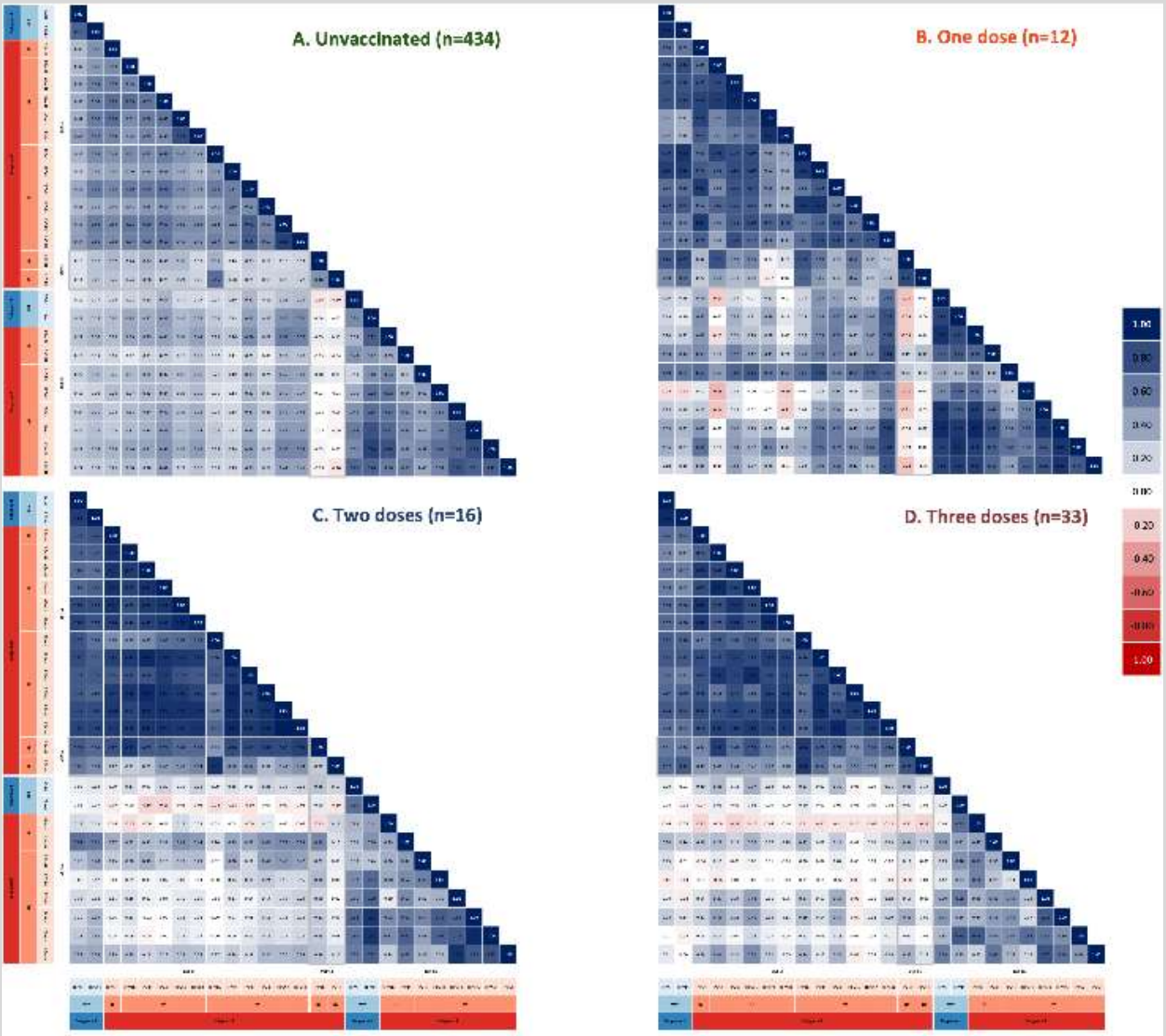


Figure 2. Correlation matrix between HPV antibody titers at baseline expressed as log median fluorescence intensity by antigen and stratified by level of phylogenetic relatedness and vaccine status.

Figure 2 legend: Correlation matrix between HPV antibody titers (GST-L1, VLP-L1 and GST-E6) measured by HPV multiplex serology for HPV types 6, 11, 51, 18, 31, 33, 35, 52, 58, 16, 39, 45, 59 and 68 and expressed as median fluorescence intensity (log transformed) at visit 1. Correlation coefficients are provided in each box. Positive correlations are displayed in blue and negative correlations are displayed in red. Colour intensity is proportional to the correlation coefficients. The legend colour on the top right shows the correlation coefficients, ranging from -1.00, a perfect negative correlation, to +1.00, a perfect positive correlation, and the corresponding colours.

E6 – oncoprotein E6; GST – glutathione S-transferase; HPV – human papillomavirus; L1 – papillomavirus major capsid protein; VLP – virus-like particle.

Conclusions: Correlations between HPV-specific antibody seroreactivities are affected by phylogenetic relatedness, with anti-L1 correlations becoming stronger with the number of vaccine doses received.

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IMPLEMENTATION OF A SELF-SAMPLING STRATEGY TO IMPROVE ACCESS TO CERVICAL SCREENING SERVICES FOR FEMALE SEX WORKERS IN GHANA

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Introduction: The 2030 WHO agenda for the elimination of cervical cancer depends on expanding screening coverage to at least 70% of all eligible women in LMICs where the greatest burden of disease exists. In Ghana, there is a threat that sex workers are a high-risk group that may be missed by existing screening strategies.

Methods: The present study investigated the acceptability of home-based genital self-sampling for hr-HPV screening among female sex workers. Non-pregnant, female sex workers aged 18-35 (N=304) were recruited to participate in the study by trusted intermediaries from 2020 to 2022. Experienced midwives provided cervicovaginal screening for consenting participants at a designated “drop-in-centre” offering reproductive health services in Ghana. Participants were trained by peer counsellors using anatomical models to provide vaginal and cervical self-swabs at a later date. Information was collected from participants on the acceptability and feasibility of home-based genital self-sampling versus clinician sampling in a “safe space”

Results: Most participants rated self-sampling to be very easy or easy (74.3%), and painless (84.2%) and were confident that the sample was collected as they had been directed (85.9%). In addition, most women were willing to take another sample for HPV screening in future (91.1%) and were willing to recommend self-sampling to a close friend or family member by sending a customized text message (94.1%). Most participants (64.8%) preferred clinician sampling in a “safe space” or “drop-in centre” to self-collection at home (35.2%).

Conclusions: The use of the self-sampling strategy for HPV testing can be successfully implemented for commercial sex workers in Ghana. Strategies to integrate genital self-sampling strategies into reproductive health services for sex workers should be explored.

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COMING TOGETHER FOR HPV ELIMINATION: EXPANDING CAPACITY OF EXTENSION AGENTS TO REDUCE GEORGIA'S CANCER BURDEN

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Introduction: HPV vaccination rates in Georgia (GA) are below rates for the United States of America (USA), which are lower than other high-income countries, and disparities in vaccination and health care access exist. Oropharyngeal cancer incidence is increasing, and many Georgians lack education about HPV-associated cancer, vaccination, and access to healthcare. New community-engaged approaches are needed to increase education and reduce HPV-associated cancers. Cooperative Extension agents are trusted community leaders who provide health education, including cancer prevention, to citizens across the USA. This project aims to expand the capacity of extension agents in Georgia to educate communities on HPV prevention to reduce the incidence of HPV-associated cancers.

Methods: To determine attitudes, knowledge, and new approaches to HPV-associated disease prevention, five focus sessions were conducted with 50 University of Georgia (UGA) Family and Consumer Sciences (FACS) extension agents. Consent was obtained, sessions were recorded, transcribed, and thematic analysis was performed.

Results: Emerging major themes include vaccine hesitancy, stigma, lack of HPV awareness and education, and vaccine promotion. Barriers to receiving the HPV vaccine include inadequate understanding of the HPV vaccine and the cancers it can prevent, belief the vaccine is needed only if sexually active, and a negative connotation of being promiscuous if receiving the HPV vaccine. Barriers at the organization level include lack of providers in rural areas, differences in provider recommendation approaches, and lack of needed educational materials. Suggestions for improving community cancer education include community fairs and school collaborations.

Conclusions: Focused listening sessions with UGA FACS extension agents revealed key themes around knowledge and attitudes toward HPV vaccination and cancer prevention in Georgia, as well as the need for educational outreach. FACS extension agents are eager to learn more about HPV-associated cancers and prevention, and they are committed to helping provide needed education to their communities.

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ECONOMIC BURDEN FOR PATIENTS WITH CERVICAL INTRAEPITHELIAL NEOPLASIA AND CERVICAL CANCER IN CHINA: A CROSS-SECTIONAL STUDY

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Introduction: Cervical intraepithelial neoplasia (CIN) and cervical cancer pose a major threat to women's health, life, and property. We aimed to estimate the economic burden of CIN and cervical cancer in China and further facilitate the implementation of comprehensive prevention and control strategies.

Methods: A nationwide multicenter cross-sectional, hospital-based survey was conducted in 26 qualified hospitals in seven administrative regions of China. Women pathologically diagnosed with CIN and cervical cancer were investigated via questionnaire. We included five disease courses (ie, "diagnosis", "initial treatment", "chemoradiotherapy", "follow-up", and "recurrence/progression/matastasis") to estimate the costs (ie, direct medical costs, direct non-medical costs, and indirect costs) of full process of the disease. As such, total costs, out-of-pocket expenses in the direct medical costs, and catastrophic health expenditures in every clinical stage were calculated.

Results: We included 3,469 patients in our analysis, including low-grade squamous intraepithelial lesion (LSIL)(n=551), high-grade squamous intraepithelial lesion (HSIL)(n=795), stage IA(n=222), IB(n=620), IIA(n=490), IIB(n=283), III(n=448) and IV(n=60). The estimated total costs of LSIL and HSIL in urban areas were $1,662.6(IQR $933.2-$2,694.6) and $2,449.5(IQR $1,542.7-$3,791.8), while $410.7(IQR $146.0-$1,328.6) and $1,155.9(IQR $475.8-$1,949.6) in rural areas. For stage IA, IB, IIA, IIB and III-IV, the total costs were $15,047.3(IQR $11,078.0-$21,598.9), $19,708.8(IQR $14,195.1-$27,075.9), $23,057.4(IQR $16,088.8-$34,984.3), $26,959.9(IQR $18,202.0-$42,055.9) and $27,356.9(IQR $17,655.8-$44,948.1), respectively. Specifically, direct medical costs accounted for 88%-96% of total expenses among various stages. 43%-55% of direct medical costs in cervical cancers were covered by medical insurance, which was 21%-46% in CIN. The expense was catastrophic for most cervical cancer patients, except for the urban population with stage IA. For rural cervical cancer patients, the extent of catastrophic health expenditure was larger than urban residents in each stage.

Conclusions: Medical insurance could partially reduce the extent of catastrophic health expenditures, but the total costs of CIN and cervical cancer are substantial, especially for rural residents without medical insurance.

Shift 01-297 / #1290

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
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ACCURACY OF E6/E7 ONCOPROTEIN-BASED HPV TESTS TO DETECT CIN3+ FOR CERVICAL CANCER SCREENING: A SYSTEMATIC LITERATURE REVIEW AND META-ANALYSIS

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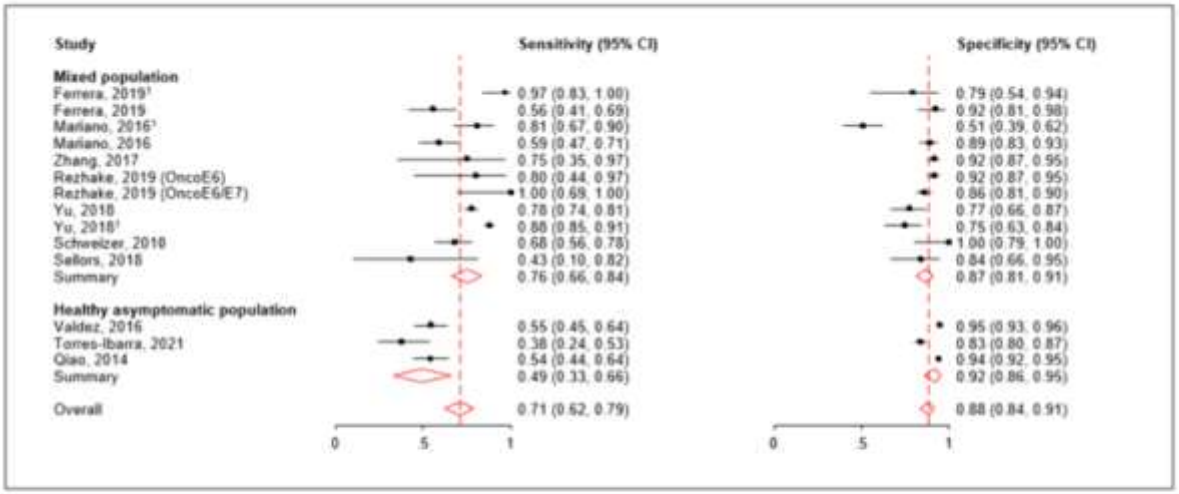
Introduction: The WHO recommends using HPV DNA and mRNA detection in primary screening for cervical cancer. HPV testing has high sensitivity but moderate specificity to detect cervical precancer and cancer (CIN3+). HPV E6 and E7 oncoproteins are necessary for oncogenic transformation and overexpressed during cervical carcinogenesis, thus promising disease-specific biomarkers. Results from a systematic review and meta-analysis on the accuracy of HPV E6/E7 oncoproteins tests to detect CIN3+ are presented.

Methods: A systematic literature search of PubMed, Embase and Web-of-Science was conducted. Studies reporting original data on the sensitivity and specificity of oncoprotein-based HPV tests to detect histologically confirmed CIN3+ were included. A meta-analysis using mixed effects logistic regression models was performed to obtain heterogeneity-adjusted (absolute and relative to other screening tests) pooled performance estimates.

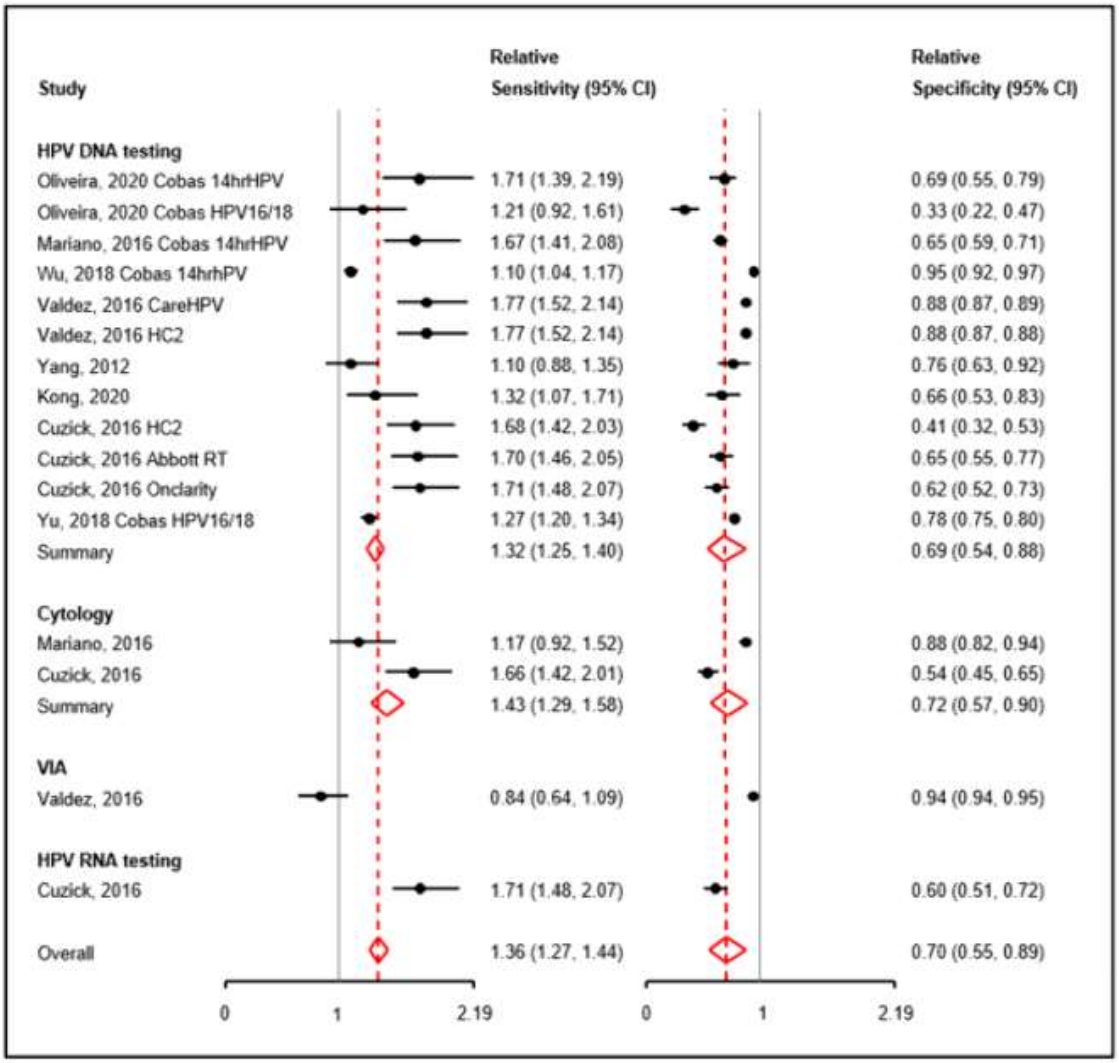
Results: Twenty-two studies were considered in the analysis, the majority conducted in Asia (45%) and including 16428 women in total with a mean age of 46 years old. Pooled estimates for CIN3+ detection were 65% (95%CI=58-71) for sensitivity and 94% (95%CI=85-98) for specificity (n=11, figure 1). Higher sensitivity (71%, 95%CI=62-79) and lower specificity (88%, 95%CI=84-91) were observed in studies including only HPV+ women (n=10, figure 2). Two studies on WLHIV reported 58% and 40% sensitivity with 98% specificity both. When compared to HPV DNA testing (figure 3), oncoprotein testing was less sensitive (relative sensitivity: 1.32, 95%CI=1.25-1.40) but more specific (relative specificity: 0.69,95%CI=0.54-
0.88).

Figure 2: Accuracy of oncoprotein test for CIN3+ detection in hrHPV+ women



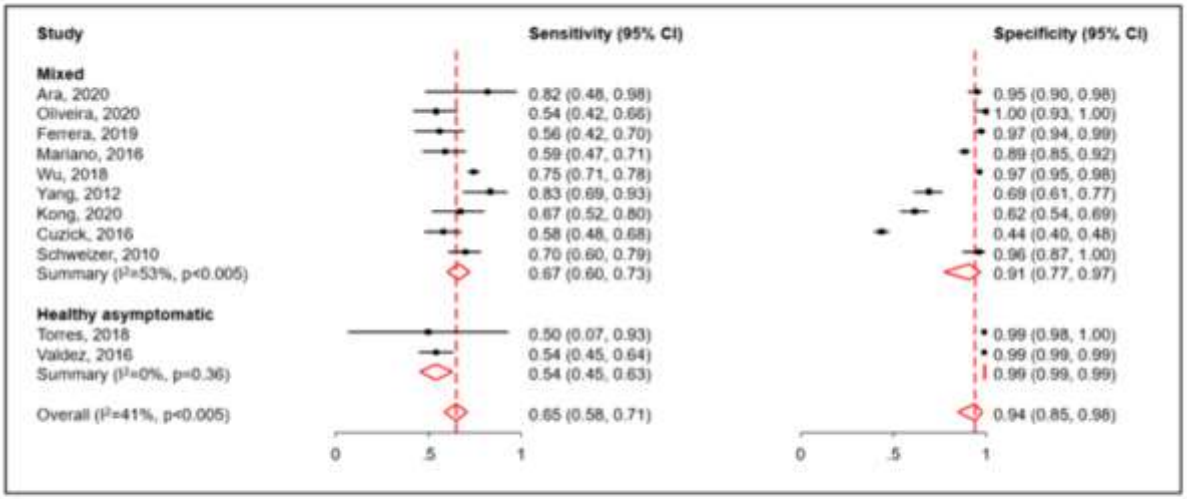
Legend: Healthy asymptomatic population refers to a primary screening population; [1]Restricted to HPV16/18+. Results from a meta-regression using as a covariate the type of included population (p-value for relative sensitivity= 0.02; p-value for relative specificity= 0.15). Mixed population includes referral population, both screening and referral population, and convenience sample.

Figure 3: Relative accuracy of oncoprotein test with HPV DNA and RNA testing, cytology, and VIA for CIN3+



Legend: Results from a meta-regression using as a covariate the type of screening test.

Figure 1: Accuracy of oncoprotein test for CIN3+ detection



Legend: Mixed population includes referral population, both screening and referral population, and convenience sample. Healthy asymptomatic population refers to a primary screening population. Stratified analysis by type of included population (results from the covariate analysis showed no significant difference between mixed and healthy asymptomatic populations (p-value for relative sensitivity=0.20; p-value for relative specificity=0.06).

Conclusions: Up to our knowledge, this is the first meta-analysis on oncoproteins tests accuracy. The higher specificity of oncoprotein tests compared to HPV DNA may be useful to improve clinical management of HPV positive women, particularly within HPV screen, triage and treat algorithms. Large scale and longitudinal studies are needed to further investigate the role of E6/E7 oncoprotein detection in predicting the risk of developing cervical cancer in general and high-risk populations.

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Poster Viewing
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04-18-2023 7:00 AM - 5:00 PM

PERSISTENCE OF AN ORAL HPV INFECTION IN MEN FROM THE US AND LATIN AMERICA

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Introduction: Oropharyngeal cancer (OPC) caused by oral human papillomavirus (HPV) is increasing globally, disproportionately affecting men. Whereas other HPV-associated cancers (i.e. cervical) have a pre-cancerous lesion that facilitates prevention, HPV-OPC does not. However, persistent HPV infection is considered the obligate precursor to HPV-OPC. Unfortunately, little is known regarding the duration of these infections and factors associated with persistence. The aim of this study was to investigate the time to oral HPV infection clearance in men in the US and Latin America.

Methods: The HPV Infection in Men (HIM) study longitudinally followed 3,137 men every 6 months for up to 8 years. At each study visit men aged 18-70 completed a computer-assisted questionnaire collecting demographic and risk factor history and provided an oral gargle sample for HPV genotyping using HPV SPF PCR-DEIA-LiPA25 (DDL Diagnostics, Netherlands). Men with at least 2 oral HPV results were assessed for a prevalent oral HPV infection (present at baseline) or an incident infection (acquired throughout follow-up. Kaplan-Meier curves assessed duration of type-specific oral HPV persistence of an oncogenic type (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) or HPV 16.

Results: There were 616 incident oncogenic infections in 337 men and 206 prevalent oncogenic infections in 185 men. Among the incident infections, 117 (19%) persisted 6 months or more and 31 (5%) persisted more than 24 months. Among prevalent oncogenic infections, 109 (53%) persisted at least 6 months and 43 (21%) persisted more than 24 months. When investigating HPV16 specifically, 11 (10%) incident infections persisted more than 24 months and 11 (22%) prevalent infections persisted more than 24 months.

Conclusions: While our study observed different proportions of persisting infections between newly acquired and prevalently detected infections, better characterization of oral HPV persistence is still needed to guide vaccination and early OPC screening efforts.

Shift 01-300 / #1438

Poster Viewing
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KNOWLEDGE, TRAINING SATISFACTION AND ATTITUDES CONCERNING CERVICAL CANCER, HUMAN PAPILLOMAVIRUS INFECTION AND VACCINE AMONG MOROCCAN MEDICAL STUDENTS

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Introduction: In Morocco, cervical cancer is the second most frequent cancer among women and the third in terms of mortality. Following the 90-70-90 rule of the “global strategy to accelerate the elimination of cervical cancer”, launched by the World Health Organization in 2020, the Moroccan Health Ministry is introducing the Human Papillomavirus vaccine to the national immunization program starting from October 2022. Medical students as future physicians are playing a key role in the management of this public health issue. The study aims to evaluate the knowledge, the satisfaction level, and acceptability of cervical cancer, HPV infection and vaccine among Moroccan medical students.

Methods: We conducted a cross-sectional study from September 2021 to July 2022 among medical students above 5th year across the nine Moroccan medical universities. General physicians, residents, foreign universities and those who did not give consent were excluded. We shared our questionnaire through Google Forms.

Results: We collected 636 answers. The mean age was 24.2 years old with a sex ratio (M/F) of 0.5. 3,3% (N=21) were vaccinated against HPV. The cervical cancer knowledge mean score was 14.4/20 (72% of good answers), with a training satisfaction rate of 9,9/20 (49,5%). The HPV infection knowledge mean score was 6.3/11 (57.2% of good answers) and the vaccine knowledge mean score was 2.0/5 (40% of good answers), with a training satisfaction rate of 7.3/20 (36.5%). 85.8% of the participants (N= 546) were in favor of including the vaccine to the national immunization program.

Conclusions: In conclusion, overall Moroccan medical students have a good knowledge of cervical cancer but an average knowledge of HPV infection and vaccine; the majority of them agree to make the vaccine mandatory. The gap in HPV training should be filled especially in the era of the vaccine introduction.

Shift 01-301 / #1463

Poster Viewing
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MANAGEMENT OF HPV INFECTIONS AND NEOPLASIAS REQUIRES SMALL MOLECULE VIRAL INHIBITORS

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Introduction: HPV infection, disease and death will not be eliminated by vaccines in most LMIC, especially with population growth vastly exceeding vaccine uptake. Based on essential pathways on which HPV infection programs and neoplastic mechanisms depend, we identify and repurpose small molecule inhibitors using highly informative 3-dimensional tissue culture models.

Methods: GloboCAN data on HPV-associated cancers document that HPV is responsible for 860,000 incident cancers, 2,300,000 (potentially treatable) prevalent cases, and 450,000 deaths annually. In one-half of countries worldwide, HPV-associated cancer deaths account for more lost years of women's life expectancy compared to breast cancer.

Results: For 37 years our lab has investigated low- and high-risk HPV genotype interactions with host keratinocytes in benign and neoplastic patient tumors and in 3-dimensional model tissues to assess protein interactions and pathways on which viral replication, virion production, and neoplastic progression depend. We identify promising targets for antiviral testing, with the goal of repurposing known pharmacologic agents to shorten time/effort toward clinical trials. Evaluation is in organotypic rafts of primary keratinocytes harboring whole-genomic HPV replicons capable of complete infection programs, in naive keratinocytes or CxCa cells expressing E6-E7 oncoproteins, in patient-tumor explants as organoids grown on rafts or in multiwell plates, and as patient-derived xenografts in mice. Transfer of tissues between experimental platforms enables optimization of doses, scheduling and combinatorial drug testing. Diverse and synergistic inhibitors have been characterized and several are in clinical trials. (See Abstract by N.S. Banerjee.)

Conclusions: Realistic long-term approaches to HPV disease management require considering HPV as an STI as well as precursor to cancers, where reduction of transmission is an optimal outcome. Early/regular screening is essential to intercept disease progression. Treatment requires topical, self-administered inhibitors, the safety-net for the 5-billion people who aged out before vaccination. Molecular and immunological antiviral therapies are priorities because vaccination cannot eliminate HPV neoplasias and deaths.

Shift 01-302 / #1465

Poster Viewing
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ORGANIZED COMMUNITY-BASED GENITAL HPV/HIV CO-INFECTION SCREENING OF WOMEN AGED 30-49 YEARS IN ABOBO, CÔTE D'IVOIRE

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Introduction: In Côte d'Ivoire, the incidence of HIV is 0,4% per year. HIV-positive women are 5 times more likely to develop cervical cancer. It is therefore essential to implement strategies for screening of pre-cancerous cervical lesions that include both HPV and HIV detection. This experiment has been conducted at community level in Abobo, Abidjan, Côte d'Ivoire, where incidences of UCC and HIV are still very high

Methods: This community-based organized screening strategy focused on self-care to empower women on their own health. A home vaginal self-sampling has been offered to women aged from 30 to 49 years for HPV detection with genexpert testing. HPV positive women has been received at the community health center for VIA (Visual Inspection with Acetic acid) during which, they have also been tested for HIV after counseling by midwifes. All HIV-positive women were integrated into the health center's active file, and those who were VIA-positive were also treated with thermocoagulation or LEEP, depending on the extent of the pre-cancerous lesions discovered.

Results: During 7 months of community-based screening, 100% of women aged 30-49 years performed the HPV test with a 96.8% acceptance rate for self-sampling and 23% of HPV positivity rate . 411 women who came to the health center for VIA agreed to be tested for HIV after counseling by the midwives. 39 of these women were HIV positive (9.5%). They were included in the health center's HIV active file for their care. Precancerous cervical lesions were found in 10% of cases, of which 93% were treated.

Conclusions: Community-based organized screening for pre-cancerous cervical lesions is a real opportunity to screen for vaginal HPV/HIV co-infection. It is an effective way to fight against UCC but also against HIV, which are fatal diseases when screening is late.

Shift 01-303 / #1484

Poster Viewing
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ADDRESSING CANCER-RELATED STIGMA IN SURVIVORSHIP AS A LINK TO PREVENTION

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Introduction: In Kenya, 80% of patients present late, contributing to low survival rates. Research in developed countries suggest that stigma discourage cancer screening attendance. We aimed to explore the prevalence of stigma towards cancer survivors, and the role survivors can play to improve cancer prevention.

Methods: In 2022, 42 cancer survivors aged above 18 years took part in key informant interviews in Kenya. We assessed demographics, type of cancer survived, and personal experiences with stigma. Open ended questions evaluated perceived stigma, and suggestion to improve community uptake of prevention. Stigma was measured with the validated Cancer Stigma Scale (CASS) which assesses six subdomains (Severity, Personal Responsibility, Awkwardness, Avoidance, Policy opposition, and Financial Discrimination), from which a mean score was calculated.

Results: Community reported perceptions recorded very high scores on cancer stigma. 100% reported that people viewed cancer as a death sentence, and cancer survivors as the walking dead (100%). Lack of information (100%) misinformation (98%) and misconceptions (95%) were key contributors to cancer related stigma.

In contrast, levels of stigma varied across the six CASS subdomains. Participants agreed strongly on policy opposition (5.1), indicating a strong believe that government policies or spending should prioritise cancer control. This was markedly above other CASS measures such as severity (3.2), financial discrimination (2.7), awkwardness around persons with cancer (2.5) and personal responsibility (2.0). Avoidance reported the lowest score (1.4), with survivors indicating they do not feel uncomfortable around people with cancer.

Conclusions: Cancer stigma is generally perceived to be very high in the general population but low among survivors themselves. Lack of information contributes to low uptake of cancer prevention. Perceptions of fatality in cancer may be reduced through awareness raising, by equipping cancer survivors as change agents to encourage prevention, while reducing cancer stigma.

Shift 01-304 / #1501

Poster Viewing
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LOGISTICAL ISSUES IN IMPLEMENTING A CLINICAL TRIAL ON ORAL CANCER PREVENTION THROUGH HPV VACCINATION: IMPLEMENTATION OF ULACNET201 IN MEXICO

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Introduction: There are many logistical issues related to implementing a randomized, Phase III interventional trial on the nine-valent HPV vaccine (9vHPV). The logistics described relate to implementation at the Mexico site.

Methods: The team invites potential participants through local community organizations and public HIV clinics. People are invited when waiting in line in the morning to get laboratory testing done, before an appointment for HIV care, through their treating physician or a community organizer. Participants are prescreened when initially invited or by phone to prevent unnecessary trips for those ineligible. Study visit appointment reminders are sent by text message 2-3 times. Participants are provided with financial compensation in cash at each visit. Clinics sometimes decide to move the study team to a smaller workspace, reduce hours the study team can work and control where participants can be recruited, which can, evidently, create barriers to recruitment. Maintaining good relationships with participants, clinic personnel who work day-to-day with patients (who may prioritize participant needs more than upper-level administrators) and community organizers is key to recruitment and retention.

Results: We have implemented both study-wide mechanisms and additional locally-designed strategies and forms to guarantee quality control. For example, registering participant issues, study agent trail and persons invited, pre-screened and enrolled (including reasons for exclusion). Data is registered on paper forms and in a bespoke data base program (DatStat, designed at Moffitt Cancer Center). DatStat carries out the randomization and requires a wireless internet connection, which can sometimes fail and then solutions must be sought..

Conclusions: Vaccine and syringe importation can be time consuming and cause enrollment delays, given the need to acquire permissions for importation or problems getting the shipment out of Customs. Making sure shipments go through an airport with better functioning Customs offices and are sent by an efficient courier or shipment service is important

Shift 01-305 / #1537

Poster Viewing
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ANALYSIS OF PUBLIC POLICY DECISIONS AND FACTORS DRIVING HPV VACCINATION COVERAGE IN THE UNITED STATES

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Introduction: Every year, millions of individuals in the United States (U.S.) are exposed to HPV, a virus that is linked to six different types of cancer affecting everyone. Too many vaccine-eligible individuals are not getting vaccinated as recommended. As a result, a diverse group of partners, providers, advocates, policymakers, and interest groups have been seeking innovative policy solutions to increase HPV vaccination coverage in the U.S.

Methods: St. Jude partnered with FTI Consulting to examine public policy decisions and related factors that drive HPV vaccination coverage across the U.S. Results are intended to educate and inform allies, partners, and advocates about public policy strategies, approaches, and opportunities that might have a meaningful impact on national, state, and local HPV vaccination coverage efforts. The research examined the relationship between HPV vaccination initiation and completion with regard to nine factors: Medicaid expansion, Insurance coverage, Parents' educational level, Access to pediatricians/primary care physicians, Access to Vaccines for Children (VFC) providers, Coverage of other adolescent vaccinations, Vaccination exemptions, Vaccination requirements, and Rurality. Cost analysis was conducted.

Results: revealed factors with positive relationships to HPV vaccinationto leverage to increase HPV vaccination coverage. Existing and new policies and regulations could address negative relationships to HPV vaccination coverage. Five policy recommendations to improve HPV vaccination coverage were developed: (1) Leverage meningococcal conjugate vaccination; (2) Expand health care provider training to strengthen HPV vaccination recommendations for parents and caregivers; (3) Improve recruitment in the U.S. VFC program; (4) Expand the resources available to improve HPV vaccination data collection and reporting through state immunization information systems (IISs); and (5) Engage in efforts to preserve and expand eligibility for Medicaid.

Conclusions: To increase HPV vaccination initiation and series completion significantly, policymakers, interest groups, and health systems should consider a combination of existing and new policies, specifically those discussed in this report.

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SEASONAL VARIATION OF GENITAL WART FROM 2010 TO 2021 : ANALYSIS OF KOREAN HIRA-NPS DATA

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Introduction: Many viral diseases, such as COVID-19 and the influenza virus, have seasonal characteristics. The purpose of this study was to investigate the seasonal characteristics of genital warts caused by human papillomavirus, a representative viral sexually transmitted disease.

Methods: From 2009 to October 2021, this study was conducted using data registered in the National Health Insurance-Health and Medical Big Data Hub. The subjects were patients with ICD-10 A63 genital wart or condyloma accuminata disease. A year was classified as “spring” in March-May, “summer” in June-August, “autumn” in September-November, and “winter” in December-February. By continuously checking the number of patients by period, trends in the prevalence of patients and seasonal differences in the same year were compared.

Results: The number of patients showed a steady increase, but after peaking in winter 2019 and spring 2020, it showed a decreasing pattern. Except for 2020, winter had the lowest number of patients (including both men and women) during the entire study period, and surgical treatment showed the same pattern. Non-surgical treatment had the lowest number of patients (including females) in the fall of 2013 and 2020, and males showed a relatively diverse distribution. In the monthly analysis, the highest number of patients and the highest surgical treatment showed various patterns, but for non-surgical treatment, July had the most, followed by August. Since the start of the COVID-19 pandemic in the spring of 2020, it has also affected the number of patients with genital warts and the number of treated patients, showing a continuous decreasing trend from the spring of 2020 to 2021.

Conclusions: Genital wart is increasing feature and like “j” shape curve until COVID-19 . Summer is more frequent and winter is less frequent than other seasons. HPV has seasonal characteristics. It is thought that analysis of more factors for the cause is necessary.

Shift 01-307 / #1662

Poster Viewing
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04-18-2023 7:00 AM - 5:00 PM

COMPARISON OF HPV SELFY, A SUSTAINABLE MOLECULAR HPV TEST, AND VIA/VILI FOR CERVICAL CANCER SCREENING IN NIGERIA

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Introduction: In low- and middle-income countries (LMICs) there are no widespread population-based cervical cancer screening programs. Approaches like visual inspection with acetic acid (VIA) or Lugol's Iodine (VILI) enable screen-and-treat screening approaches, however their lack of specificity causes high levels of unnecessary thermocoagulation treatments. A cost-effective and rapid high-risk HPV DNA test that requires minimal infrastructure and training, which can be combined with self-sampling, may be useful for screen-and-treat, and be more predictive than VIA/VILI in LMICs. In this study, we compared the performance of HPV SELFY, a CE-IVD HPV assay validated for screening purposes, both on clinician-collected (according to Meijer's guidelines) and self-collected samples (according to VALHUDES protocol), with VIA/VILI in a Nigerian screening population.

Methods: We tested with HPV SELFY samples from 367 women who participated in VIA/VILI-based cervical cancer screening in Abuja, Nigeria, from 2010 to 2014.

Results: 10 samples out of 118 VIA/VILI-negative women (8.5%) were HPV SELFY-positive, while out of 238 VIA/VILI-positive women only 102 (43.8%) were HPV SELFY-positive. Compared to HPV SELFY, VIA/VILI had specificity of 44.3% (108/244 | 95% CI 37.9% to 50.7%) and sensitivity of 91.1% (102/112 | 95% CI 84.19% to 95.64%). This implies that more than half of women that were VIA/VILI-positive and treated with thermocoagulation (136/238, 57.1%) could have avoided unnecessary treatment if tested with HPV SELFY.

Conclusions: HPV SELFY is a real-time PCR based molecular assay able to detect and genotype 14 high-risk HPV types in a single reaction; it requires only one fluorescence channel; therefore, it can be used on any real-time PCR machine, including low-cost ones. DNA extraction step can be avoided if the test is combined with Ulisse Faster DNA reagent, thereby saving time and cost for analysis. Our results suggest that HPV SELFY could be used for cervical cancer screening in LMICs.

Shift 01-308 / #1701

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-18-2023 7:00 AM - 5:00 PM

WHERE WE ARE AND WHAT NEEDS TO BE DONE TO IMPROVE HPV VACCINATION AMONG LGBTQIA+ PEOPLE

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Introduction: HPV vaccination is highly effective in preventing six types of cancer and genital warts among all genders. However, HPV vaccination is often contextualized around preventing cervical cancer and promoting women's health, leading to confusion about the benefits of vaccination for people of other genders and different sexual orientations. Several resources have been directed towards improving HPV vaccination awareness and rates in the United States (US). However, little is known about how to better promote HPV awareness and vaccination among LGBTQIA+ people. For example, gay and bisexual men in the US have higher rates of HPV-associated anal cancer compared to heterosexual men, yet few resources are available to promote HPV vaccination among this group. The goal of this study is to review and evaluate online resources and publications related to HPV vaccination among LGBTQIA+ people.

Methods: We used online search strategies to identify HPV vaccination education and awareness promotion materials and programs focused on LGTBQIA+ people in the US. We searched Google and peer-reviewed publications indexed in PubMed.

Results: Of websites that promoted HPV vaccination, the majority focused on cervical cancer prevention. Additionally, of those that promoted HPV vaccination among LGBTQIA+ people, there was a focus on gay and bisexual men. This was observed when reviewing information websites and academic articles that resulted from online searches. Of the limited information available, few included information for trans people or where to get vaccinated in a safe and gender affirming space.

Conclusions: Limited resources and research exist to promote HPV vaccination among LGBTQIA+ people. Of available information, little is specifically focused on trans people. More research is needed to better understand the needs of LGBTQIA+ people concerning HPV awareness and vaccination promotion programs that is inclusive of all sexual orientations and gender identities.

Shift 01-309 / #1747

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-18-2023 7:00 AM - 5:00 PM

INTERNATIONAL HPV AWARENESS DAY CAMPAIGN IN CHINA

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Introduction: Awareness and education are important first step toward mobilizing action to stop HPV. China has participated in International HPV Awareness Day (IHAD) for five consecutive years to raise HPV awareness and promote cervical cancer elimination.

Methods: Activities regarding improving HPV awareness were carried out across China on March 4th each year from 2018 to 2022. These activities were led by Peking Union Medical College (PUMC) and carried out in local cities. All cities were required to use the same theme and materials but were free to have unique activity styles.

Results: The number of participating cities increased from 4 in 2018 to 14 in 2022. More and more health-related government agencies, civil society organizations, hospitals, and universities were involved in IHAD, both as organizers and as audiences. Lectures were the main form of activities. Experts provided information about new guidance, resources, ongoing research and efforts to support expanded access to HPV vaccination, and enhance screening and early treatment of HPV cancers. Innovative activities were designed to attract more young people to pay attention to HPV, such as HPV knowledge forest planting, HPV-related artwork collection, HPV knowledge contest, and fun sports meeting, etc. Cutting-edge information and communication technologies were utilized to increase accessibility to information, facilitate widespread distribution, and keep up with frequent content updates. The number of people participating in the IHAD increased from 1,000 to more than 5 million in China.

Conclusions: The coverage and influence of IHAD in China are increasing after five years of efforts. Public health education is an effective way to stimulate society to discuss HPV. All organizers, under standard guidance, should organize different activities that are attractive to their targeted populations.

Shift 01-310 / #1767

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-18-2023 7:00 AM - 5:00 PM

A FACILITATION STRATEGY FOR RAPID, EMBEDDED ENGAGEMENT IN HPV-BASED SCREENING IMPLEMENTATION PLANNING IN LOW- AND MIDDLE-INCOME COUNTRIES (LMICS)

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Introduction: Globally, LMICs are moving towards cervical cancer elimination, investing valuable resources in HPV-based screening programs. However, in many LMIC countries, their complex health systems face widespread fragmentation and bottlenecks, evidenced by low adoption, scale-up, and sustainability. Time constraints challenge planning, monitoring, and evaluation of the continuum of care. We hypothesized that a short series of participatory ‘design workshops’, co-designed by implementation science (IS) researchers and local health system leadership and actors, would enable rapid engagement and collective learning.

Methods: From July-November 2022, the US NCI Center for Global Health (NCI-CGH) assembled a team of facilitators, IS researchers, cervical cancer prevention content experts and system dynamics (SD) experts to prototype rapid, embedded implementation research. The Peruvian Ministry of Health and NCI-CGH team co-designed one week of workshops to reflect on initial experiences implementing HPV-based screening in DIRIS Lima Norte (DLN) region in 2022. Facilitation used rapid adaptation of INSPIRE methodology phases 1-2. The NCI-CGH team observed facilitated discussions, using inductive approaches to describe the screening system and identify implementation processes and determinants contributing to performance.

Results: Through real-time participatory reflection, process mapping, and shared decision-making, context-specific challenges and strategies for change were rapidly identified and mapped to IS frameworks (Figures 1a and 1b). A System Dynamics model representing dynamic interactions between actors across system levels was developed (Figure 2), identifying potential leverage points for system improvement. Despite local doubts that meaningful trust and dialogue would be feasible in a short time, by workshops’ end, participants demonstrated unique shared understanding of their complex screening system and their role in the decision-making and problem-solving processes. Already, DLN demonstrates new willingness to implement process
improvements.

Figure 1a. Mapping of priority implementation context, barriers and facilitators to CFIR framework

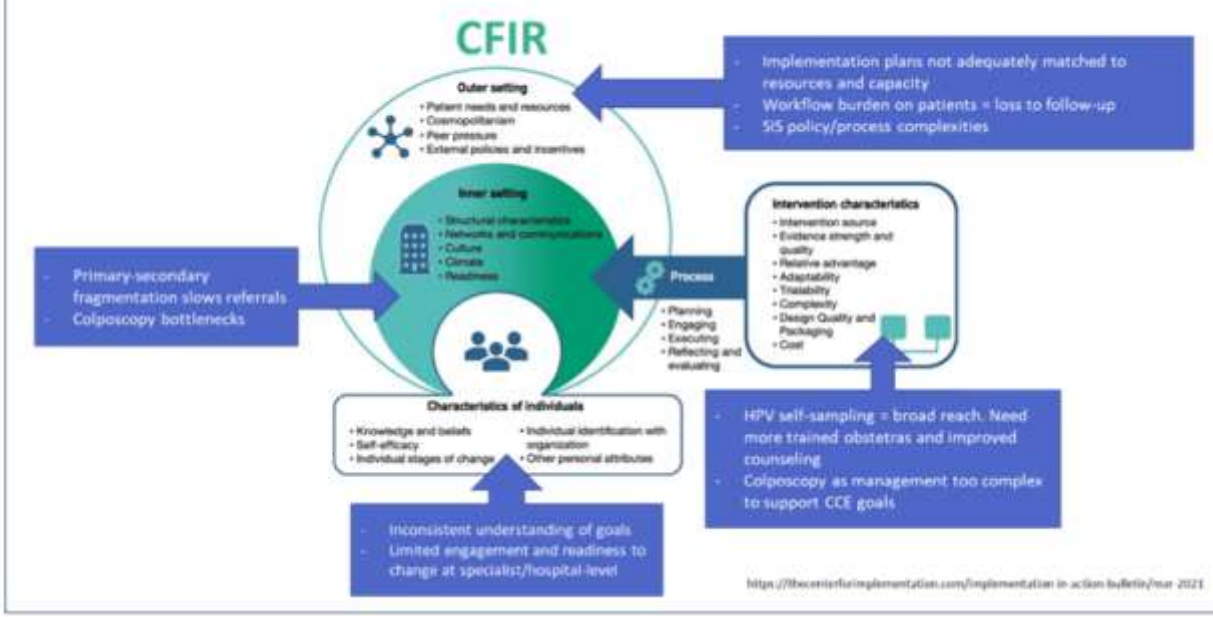
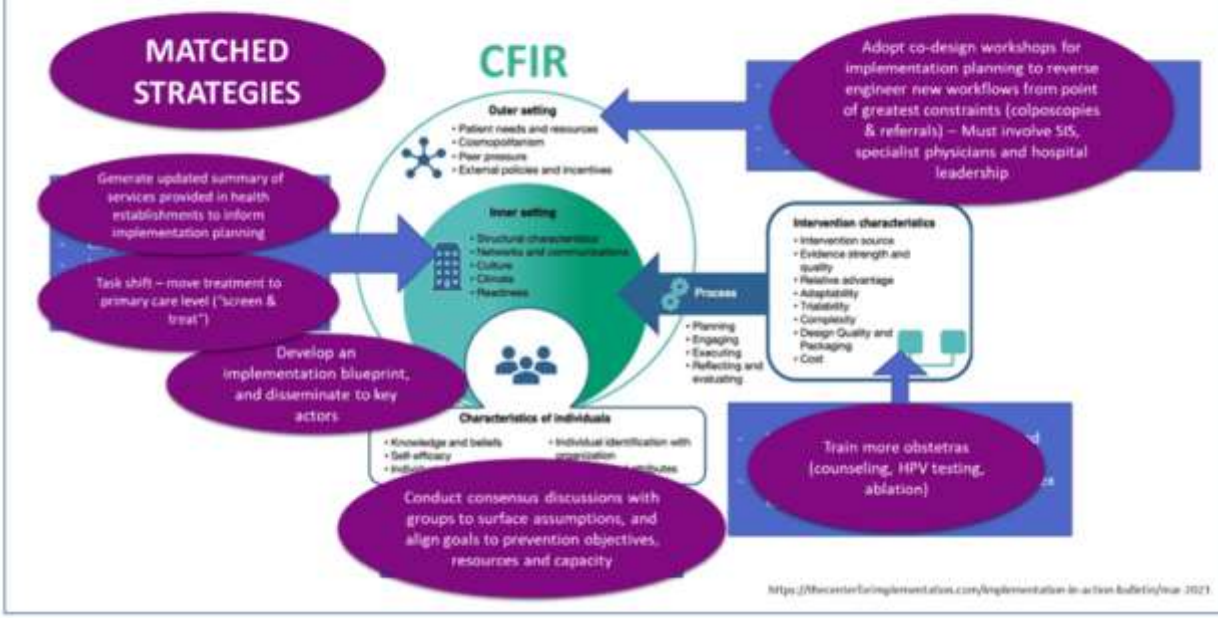
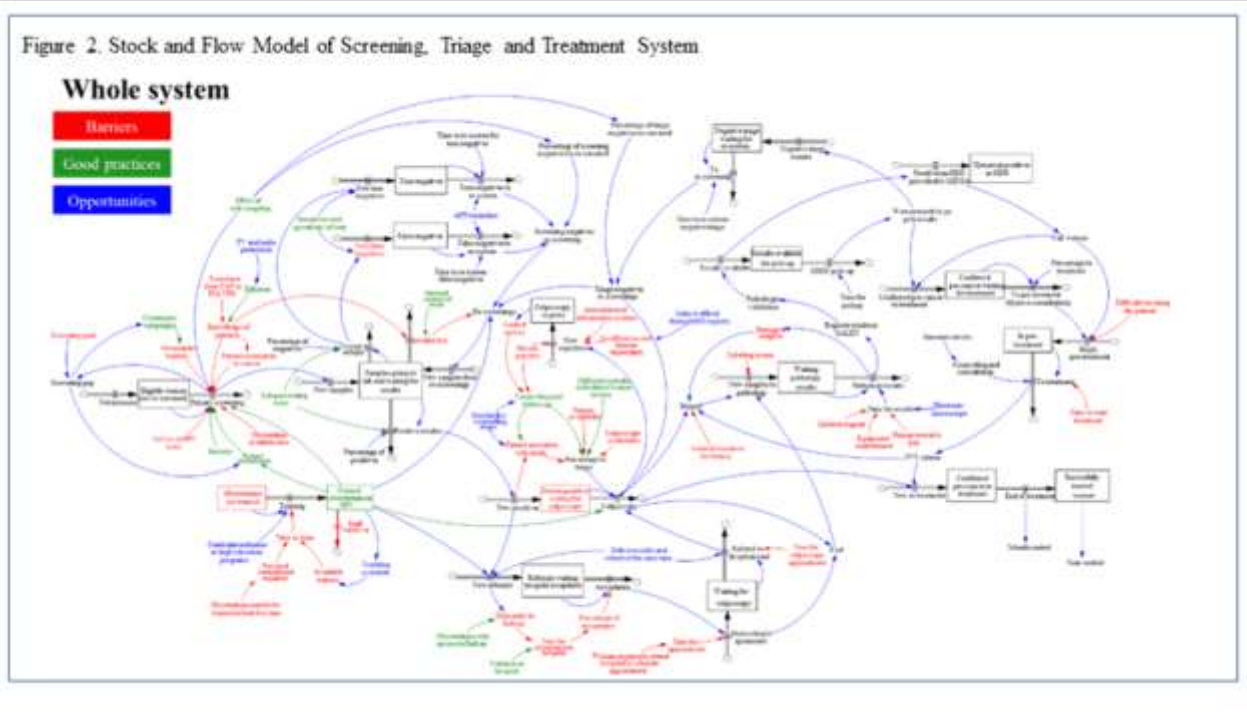


Figure 1b. Matched strategies for change according to CFIR framework





Conclusions: A rapid-cycle co-design workshop identifying context-specific priorities and implementation strategy interventions can be incorporated into an embedded Learning Health System approach with ongoing engagement to accelerate adoption, scale-up, and program adaptation.

Shift 01-311 / #1785

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-18-2023 7:00 AM - 5:00 PM

NATIONWIDE ANALYSIS OF THE STATE-LEVEL CERVICAL CANCER SCREENING COVERAGE AMONG 7,466,884 WOMEN SERVED BY THE FEDERALLY QUALIFIED HEALTH CENTERS IN THE UNITED STATES

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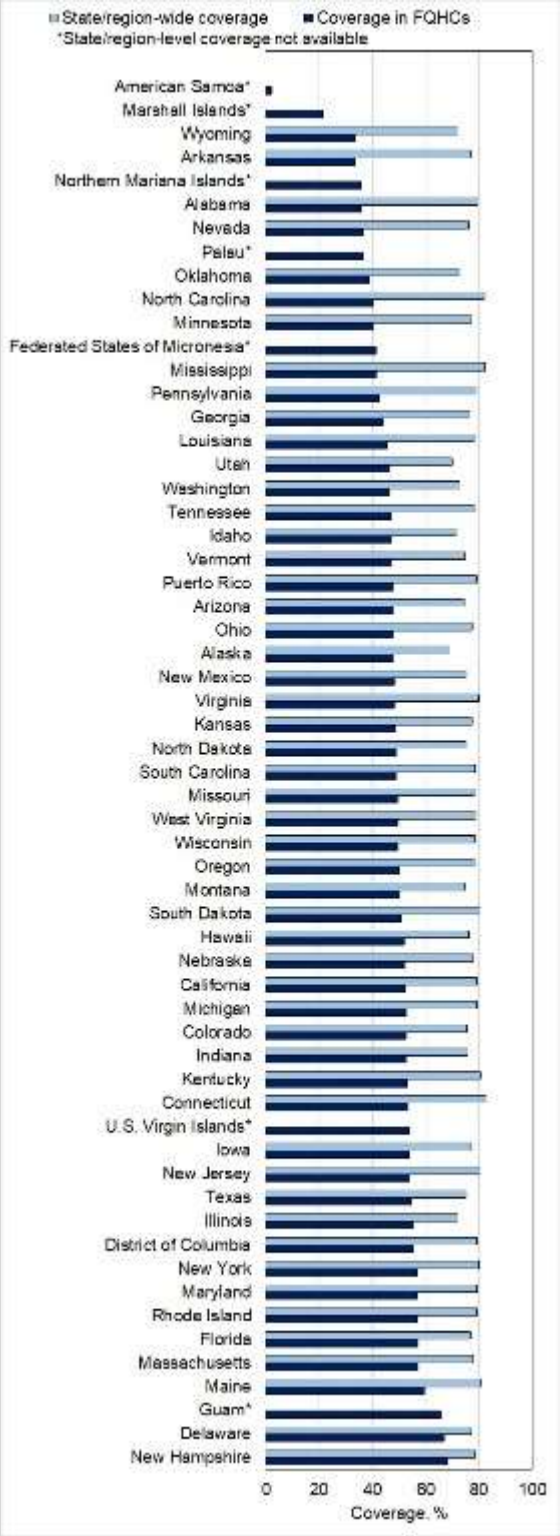
Introduction: Rising number of individuals with a cervix, particularly racial/ethnic minorities, uninsured, and low-income groups remain vulnerable to cervical cancer in the US. These populations often receive clinical services at Federally Qualified Health Centers (FQHCs), a designation made by the federal government based on health centers' provision of comprehensive services on a sliding fee scale to medically underserved populations. Nearly 1,400 FQHCs serve approximately 30 million people across the US. Here we compare state-level screening coverage in FQHCs versus population estimates from Behavioral Risk Factor Surveillance System (BRFSS) data, which often guides health policy decision-making, to elucidate possible disparities in cervical cancer screening coverage.

Methods: For 2020, guideline-concordant cervical cancer screening data from all US FQHCs were obtained from the Health Resources and Services Administration (HRSA) Uniform Data System. Weighted averages across all FQHCs in each state or territory were used to calculate state-level screening coverage. The 2020 BRFSS data were used to estimate state-level screening coverage. Chi-square tests were used to assess the difference between state-level FQHC and BRFSS screening coverage. Statistical significance was assessed at $p<0.05$.



Results: In 2020, a reported 7,466,884 persons with a cervix were eligible to receive cervical cancer screening across 1,376 FQHCs. FQHCs in New Hampshire had the highest (67.9%) screening coverage but 10.5% lower than BRFSS state-level coverage, while FQHCs in Wyoming had the lowest (33.7%) coverage, which was 38.3% lower than the BRFSS state-level coverage. Coverage in FQHCs in all 50 states, the District of Columbia, and Puerto Rico was significantly lower ($p<0.0001$) compared to the respective BRFSS state/region-level screening coverage.

Conclusions: Our study is the first to provide a comprehensive view of cervical cancer screening coverage in FQHCs that serve medically underserved populations in the US. Implementing strategies in FQHCs that circumvent prevalent barriers, such as self-sampling, could reduce disparities.

Shift 01-312 / #1795

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-18-2023 7:00 AM - 5:00 PM

INCIDENCE OF HPV-POSITIVE OROPHARYNGEAL CANCERS AMONG EVER AND NEVER SMOKERS IN KENTUCKY, UNITED STATES

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Introduction: As the association between human papillomavirus (HPV)-positive oropharyngeal cancers and smoking status is unclear, we assessed this association and estimated the incidence of HPV-positive oropharyngeal cancers among persons who ever smoked and persons who never smoked in Kentucky.

Methods: Invasive, microscopically confirmed cases of oropharyngeal cancers (with ICD-O-3 site codes C01.0-C14.8) diagnosed from 1993-2004 and 2014-2015 were identified from the Kentucky Cancer Registry (KCR). Data were analyzed for a random sample of previously collected tissue blocks that underwent HPV testing. The presence of any HPV type was used to examine HPV prevalence. Individual-level demographic, clinical, and smoking status (ever vs. never) data from cases were analyzed from KCR, which is one of the few registries in the US that collects data on smoking history. The denominator data for the same time periods and stratification variables were derived from the Kentucky Behavioral Risk Factor Surveillance System survey. Weighted odds ratios examining the association between smoking status and HPV-positive oropharyngeal cancers were estimated using regression models.

Results: Overall, HPV was found in 80.5% of the sampled oropharyngeal cancers in Kentucky. HPV prevalence was higher among persons under 50 years (85.7%) and males (82.5%). The incidence of oropharyngeal cancers during the study period (per 100,000) was approximately 3 times higher among HPV-positive persons who ever smoked (8.6) compared to HPV-positive persons who never smoked (2.8). Similarly, the odds of developing HPV-positive oropharyngeal cancer were 3.1 (95% CI: 1.8, 5.6) times higher for persons who ever smoked compared to persons who never smoked.

Conclusions: The population-level incidence of HPV-positive oropharyngeal cancers in Kentucky was higher among persons who ever smoked compared to persons who never smoked. This finding adds to the evidence that smoking increases the risk of HPV-positive oropharyngeal cancers and has potential implications for cancer prevention.

Shift 01-313 / #1832

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-18-2023 7:00 AM - 5:00 PM

CERVICAL CANCER AND HUMAN PAPILLOMA VIRUS: FACTORS IMPACTING KNOWLEDGE, ATTITUDE, AND PRACTICES AMONG STUDENTS AND PHYSICIANS IN KAZAKHSTAN

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Introduction: Human Papillomavirus (HPV) is the most prevalent sexually transmitted infection worldwide especially among women in Central Asian countries including Kazakhstan. This study aimed to assess the level of knowledge on HPV among two different populations in Kazakhstan on topics related to cervical cancer and HPV and to find their associations with socio-demographic variables. The two different groups surveyed at different time periods are university students and Physicians.

Methods: The first phase was a cross-sectional study among students from the universities in Kazakhstan's capital city, Astana. In this study, a paper-based questionnaire investigating attitudes, believes, and practices about HPV infection and HPV vaccination were administered. For the second phase of the study, a 41-item questionnaire was distributed online via the method of snowballing, targeting any physician who practiced or was practicing in Kazakhstan. The Poisson test with robust error variances was used for statistical model building.

Results: Our study found 41 percent of students had high level of knowledge of HPV infection and HPV vaccine, and 49% of students had positive attitudes towards HPV vaccination and intention to receive the vaccine. Approximately half of the physicians had appropriate knowledge (score > 70%) on topics of cervical cancer and HPV. Less than half (44.41%) have recommended HPV vaccine to their patients previously. Younger physicians, pediatricians and general practitioners had lower prevalence of appropriate knowledge, supportive attitude towards HPV vaccine and actively recommending HPV vaccine.

Conclusions: This study found that less than half of participants had high knowledge about HPV, while more than half express intention to receive HPV vaccination. Improvement in the attitudes and practices of physicians could positively influence the uptake of cervical cancer screening and HPV vaccination. The results of this study could further develop educational intervention that should precede HPV vaccination campaign implementation in Kazakhstan.

Shift 01-BOARD ONSITE01 / #1477

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-18-2023 7:00 AM - 5:00 PM

ECHO ELIMINATION OF CERVICAL CANCER IN LATIN AMERICA (ECHO ELA): LESSONS LEARNED FROM PROMOTING WHO'S CERVICAL CANCER ELIMINATION GOALS '90-70-90' IN THE AMERICAS.

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Introduction: Cervical cancer is one of the leading causes of cancer deaths among women in some countries in the Region of the Americas. Cervical cancer is preventable through HPV vaccination, screening and treatment of precancerous lesions, and can be effectively treated if diagnosed early. Telementoring is an evidence-based strategy used to disseminate knowledge and to increase collaboration among ECHO participants.

Methods: Under the framework of the Global Strategy to Accelerate the Elimination of Cervical Cancer as a Public Health Problem, the US National Cancer Institute (NCI), the University of Texas MD Anderson Cancer Center (MD Anderson) and the Pan American Health Organization/World Health Organization (PAHO/WHO) partnered to develop ECHO Elimination of Cervical Cancer in Latin America (ECHO ELA). ECHO ELA is modeled on Project ECHO® (Extension of Community Healthcare Outcomes) a knowledge-sharing approach where experts lead virtual didactic lectures and case discussions, amplifying the capacity for participants to deliver best practice programs to their regions. ECHO ELA consists of monthly, Spanish telementoring conferences whose goal is to assist countries in Latin America (LA) reaching their WHO cervical cancer elimination goals "90-70-90". Program targets Ministries of Health, Immunization Program Managers and key cervical cancer stakeholders in LA.

Results: In the first iteration of this program, 294 participants from 22 countries were registered. Fourteen sessions were held including 50% providers, 40% Ministries of Health and 27% working in hospitals and clinics. Participants completed the post survey addressing priorities, capacity, and desired outcomes, and 2 focus groups were conducted. Survey, focus group results, and learned lessons will be presented.

Conclusions: ECHO ELA has the potential to serve as an effective tool to convene participants from multiple countries to enhance collaboration and support countries' progress towards the elimination of cervical cancer in the Americas.

Shift 01-BOARD ONSITE02 / #1475

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

SCOPE2: A CLINICAL VALIDATION OF SELF-COLLECTION USING COPAN FLOQSWAB AND ROVERS VIBA-BRUSH ELUTED IN COPAN MSWAB MEDIA

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Introduction: The World Health Organization's Elimination Strategy includes the 2030 scale-up target of 70% of eligible people to be screened twice with a high -precision test. HPV-based cervical screening has created the opportunity for self-collection as a tool to increase access.

Methods: The Self-Collection or Practitioner-collection Evaluation 2 (SCoPE2) study recruited 400 participants attending for colposcopy. Participants who gave informed consent self-collected two samples, using a Copan FLOQSwab and a Rovers Viba-brush in random order, before a cervical specimen was practitioner-collected at colposcopy and eluted into a ThinPrep vial. The self-collected samples were shipped dry, stored for seven days then eluted in 5 ml of Copan MSwab media. All three specimens were tested on a range of clinically validated PCR-based HPV assays. Histological outcomes were available through to 6 months after recruitment.

Results: HPV positivity rates for the first 200 samples sets were 64.1% (mean across five HPV assays), 72.6% and 70.0% for the practitioner-collected, FLOQSwab and Viba-brush self-collected specimens. Preliminary data show the sensitivity for CIN2+ (n = 31) of HPV testing was 96%, 96% and 90% on clinician-collected cervical and on self-collected FLOQSwabs and Viba-brushes; respectively. The average relative sensitivity estimates (self- vs clinician samples) were 1.00 and 0.939, for FLOQSwab and Viba-brush, respectively.

Conclusions: Self-collection using cheap high-quality devices which can be transported dry are needed to increase accessibility both in low and middle-income countries and support screening in traditionally under- and never-screened populations in high-income countries. MSwab medium is cheap, non-toxic, does not contain alcohol and can be transported easily as it is not classified as a dangerous good. This validation demonstrates the clinical utility of two self-collection devices in combination with a non-toxic medium using a wide range of HPV assays.

Shift 01-BOARD ONSITE03 / #567

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-18-2023 7:00 AM - 5:00 PM

HPV VACCINATION TRENDS AMONG COMMERCIALLY INSURED ADULTS AGED 27-45 BEFORE AND AFTER ACIP RECOMMENDATION CHANGE IN THE US, 2007-2020

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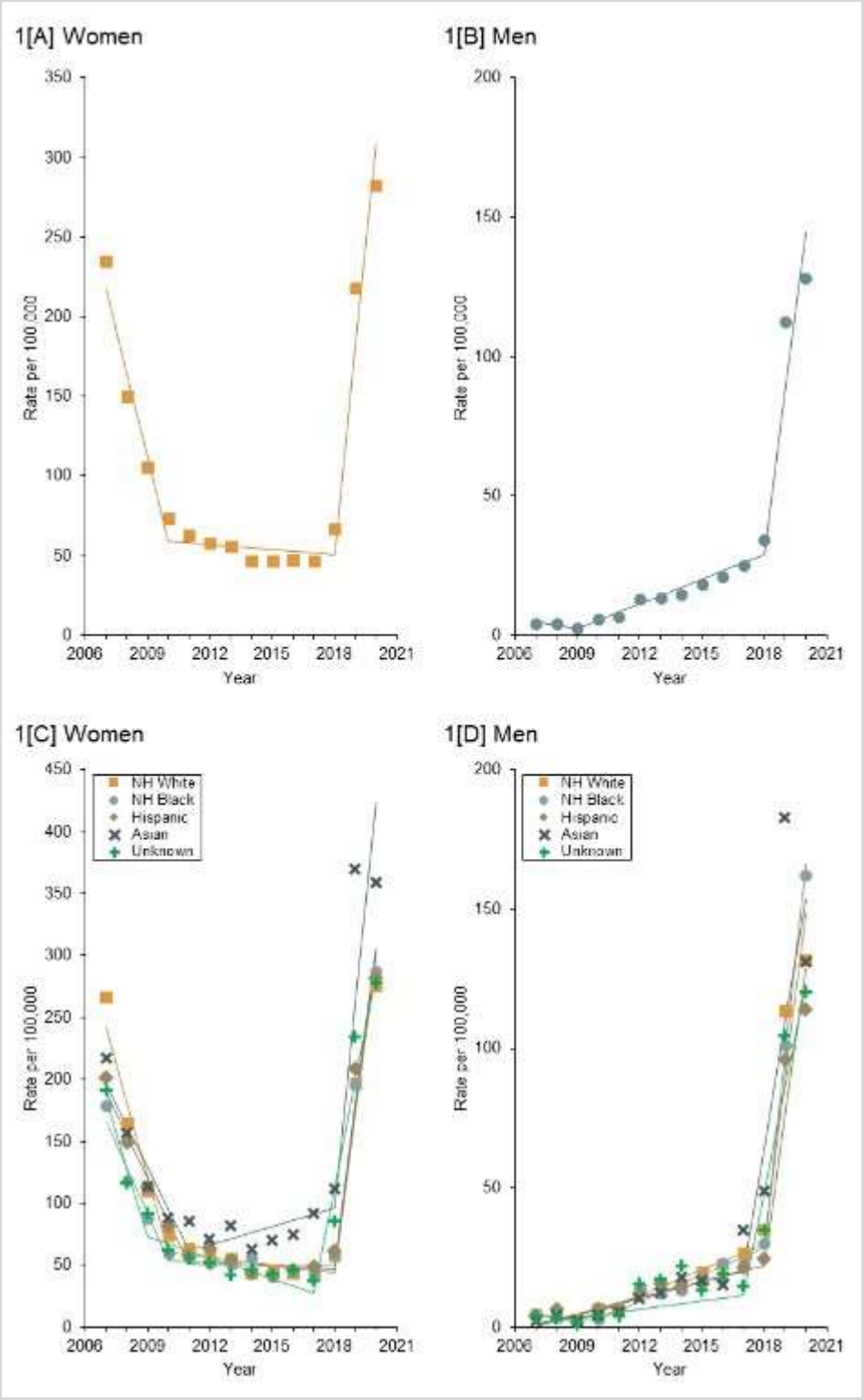
Introduction: After the US Food and Drug Administration (FDA)'s approval, the Advisory Committee on Immunization Practices (ACIP) recommended patient-provider shared decision-making for HPV vaccination in adults aged 27-45 in 2019. Less is known about the HPV vaccination administration trend in this age group before and after this recommendation update in the US. We sought to examine the temporal trend of the HPV vaccination rate among US adults aged 27-45 enrolled in commercial insurance.

Methods: We conducted a retrospective study using the 2007-2020 Optum® Clinformatics database. Among the enrolled adults aged 27-45 without previous HPV vaccination claims during the study and enrollment period, the first appearing HPV vaccination claim per individual was defined as HPV vaccination. We used joinpoint regressions to quantify annual vaccination rates (per 100,000 persons), calculate slopes (annual rate change per 100,000) for each segment, and determine the trend change (i.e., joinpoint). We also calculated the proportions of sub-age groups (27-30, 31-34, 35-39, and 40-45) by year among the vaccination cases. All analyses were stratified by sex.

Results: Among 22.6 million adults (65.0 million person-years) in the study, the majority were men (50.9%) and non-Hispanic White (53.4%). The HPV vaccination rates in both women (slope=129.3; $p<.01$) and men (slope=57.7; $p<.01$) significantly increased after 2018. This trend held true for all race/ethnicity groups (Figure 1). In both women and men, ages 27-30 comprised the majority of the HPV vaccination cases before the ACIP recommendation change (until 2018), then ages 31-45 accounted for the majority of the HPV vaccination cases during 2019-2020 (>60%) (Figure

2).


1[A] Women
Rate per 100,000
Year
1[B] Men
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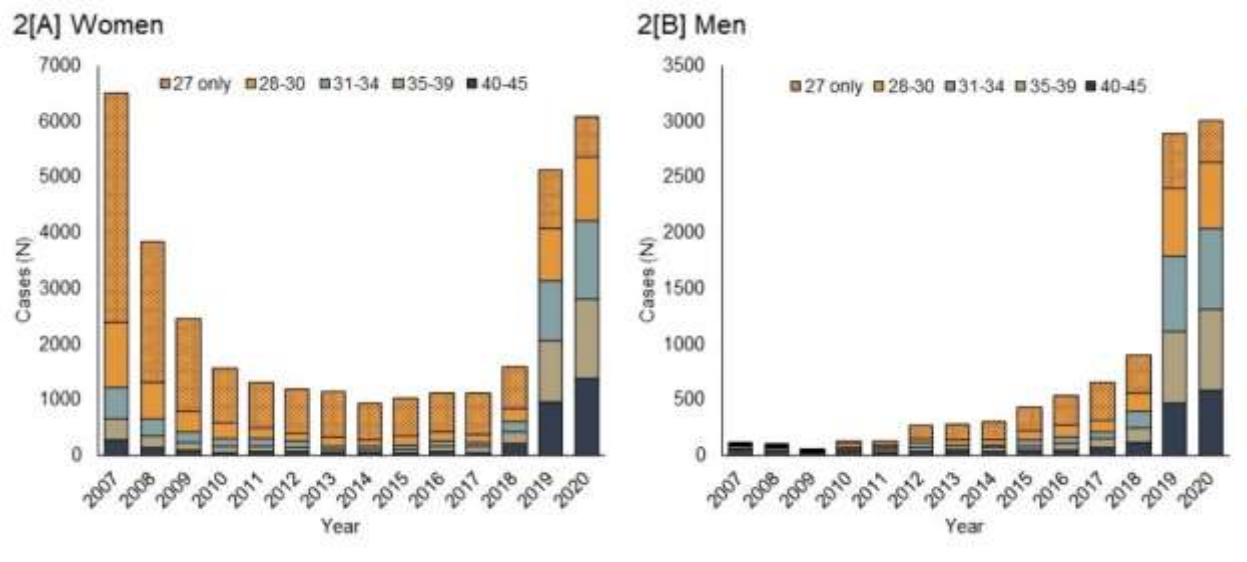
Rate per 100,000
Year
1[D] Men
NH White
NH Black
Hispanic
Asian
Unknown
Rate per 100,000
Year



Conclusions: There were significant increases in HPV vaccination in ages 27-45 after the FDA approval and the ACIP recommendation update. Further research is warranted to explore their decision-making process in receiving HPV vaccination and develop effective decision aids to maximize the cancer prevention benefit in this age group.

Shift 01-BOARD ONSITE04 / #1720

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-18-2023 7:00 AM - 5:00 PM

A SURVEY OF POLICIES TOWARDS BROADENING COVERAGE OF CERVICAL CANCER SCREENING AMONGST VULNERABLE POPULATION SUBGROUPS IN 22 EUROPEAN COUNTRIES IN 2022

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Introduction: This study aimed to investigate the status of Cervical Cancer (CC) screening implementation in Europe by investigating national or regional policies towards broadening coverage of CC screening (CCS) amongst vulnerable subgroups of the population at high-risk for CC.

Methods: A web-based survey was conducted between September 2021 and February 2022 with CCS programme managers and experts to identify and rank six population subgroups at high-risk considered most vulnerable to CC and to map existing policies that addressed the coverage of CCS towards population sub-groups at risk.

Results: A total of 31 responses were received from experts covering 22 European countries. The results of this survey suggest that whilst many countries identify lower coverage of CCS amongst population subgroups at high risk of CC as a public health problem, few countries have developed dedicated policies towards broadening coverage among these subgroups. The six countries who reported having done so were concentrated in the Northern or Western European regions, suggesting the existence of geographical disparities within the continent. A key challenge in this respect is the difficulty to categorise subgroups of the target population; many individuals are burdened by intersectionality thereby resting in multiple categories, which may hinder the effectiveness of interventions targeted to reach specific subgroups.

Conclusions: Therefore, greater clarity on the conceptualisation of vulnerability can help countries to develop and subsequently implement strategies to increase coverage to subgroups of the target population currently underserved with regards to CCS.

Shift 01-BOARD ONSITE05 / #386

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-18-2023 7:00 AM - 5:00 PM

HPV NEGATIVE ADENOCARCINOMA IN SITU IN VIETNAM – IMPLICATIONS FOR SCREENING

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Introduction: Cervical cancer remains a major cause of preventable morbidity and mortality. The number of patients with a diagnosis of cervical adenocarcinoma has increased worldwide. Adenocarcinoma in situ (AIS) remains a therapeutic challenge because it may be missed with conventional cytology and many patients want to retain their fertility. We assessed the impact of HPV testing in detecting adenocarcinoma in situ of the cervix in southern Vietnam.

Methods: A retrospective study of all women treated at Tu Du Hospital from 2007 to 2017, with adenocarcinoma in situ of the cervix, was performed. Data were collated on the high-risk HPV status, cervical cytology, histological findings from loop excisions, and results of completion procedures.

Results: The average age of cervical adenocarcinoma in situ of all 74 AIS patients was 43.0 (+/- 7.7) years. Nine of 55 patients (16.4%) with AIS were high-risk HPV negative. The methodology of HPV testing in Vietnam is, however, variable, making interpretation of data within and between institutions difficult. A median follow-up of 23.7 months (range: 0.9-151 months) in 72/74 AIS patients showed that there was no case of recurrent glandular or squamous abnormality of the vagina after LLETZ and subsequent hysterectomy, were
performed.

TABLE 1: Types of HPV testing

	Type of HPV test	Number of cases
HPV Cobas Testing	HPV-16, HPV- 18, and a group of 12 other high-risk subtypes of HPV,	19
HPV Sacace	14 high-risk subtypes tested separately	21
In-house developed high-risk HPV testing (separately)	14 high-risk subtypes tested separately	9
In-house developed high-risk HPV testing (grouped)	Group A9 (HPV-16, HPV-31, HPV-33, HPV-35, HPV-52, HPV-58), Group A7 (HPV-18, HPV-39, HPV-45, HPV-59, HPV-68) or Group A5/A6 (HPV-51, HPV-56, HPV-66)	6
Total with HPV Testing		55

TABLE 2: HPV Subtypes and Final Histology

	HPV negative	HPV 16 only	HPV 18 only	HPV Non-16 / Non-18	Co-infection	Total
AIS only	5	7	18	1	6	37
AIS with CIN 2/3	4	3	8	0	3	18
Total	9	10	26	1	9	55

TABLE 3: Cytology Results in 74 Patients with AIS on Final Histology

Cervical Cytology (Papanicolaou Smear)	Number (%)
Normal Cytology	2 (2.7%)
ASCUS	5 (6.7%)
AGC/AIS	27 (36.5%)
LSIL	11 (14.9%)
pHSIL	1 (1.4%)
HSIL	5 (6.7%)
Adenocarcinoma	9 (12.2%)
Squamous Cell Carcinoma (SCC)	2 (2.7%)
No Cervical Cytology Performed	12 (16.2%)

ASCUS : atyptical squamous cells of uncertain significance

AGC : atypical glandular cells

AIS : adenocarcinoma in situ

LSIL : low grade squamous intraepethelial lesion

pHSIL : possible high grade squamous intraepithelial lesion

Conclusions: Clinicians need to be aware of HPV negative glandular lesions when assessing symptomatic and asymptomatic patients.

Shift 01-BOARD ONSITE06 / #1041

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02C. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED ANOGENITAL CANCERS OTHER THAN CERVIX: PENILE, VAGINAL, VULVAR AND UROLOGICAL CANCER AND RELATED PRECURSORS
04-18-2023 7:00 AM - 5:00 PM

EXPLORATION OF BIOMARKERS IN MULTIZONAL INTRAEPITHELIAL NEOPLASIA: UNDERSTANDING EPITHELIAL TRANSFORMATION (MINUET)

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Introduction: Rates of lower anogenital tract (LAGT) squamous cell carcinoma (SCC), such as vulval and anal cancer, have risen steadily in women over recent years. All LAGT zones are susceptible to HPV-related dysplasia, and certain high-risk groups of women are vulnerable to persistent LAGT neoplasia and cancer. In some women, high-grade squamous intraepithelial lesions (HSIL) occur in more than one LAGT zone concurrently, designated multizonal intraepithelial neoplasia (MZN). Because all HSIL have the potential to progress to SCC without treatment, timely risk assessment and management of MZN is a clinical challenge. Although DNA methylation analysis has been useful in prognosing other LAGT HSIL, few studies have assessed this approach in MZN. Elucidation of the molecular nature of MZN is needed to determine if biomarkers can assist in MZN triage.

Methods: We conducted a study on 12 women with MZN where at least one LAGT HSIL progressed to SCC. DNA methylation of host gene EPB41L3 and late regions of HPV16, 18, 31, and 33 was assessed in biopsies: from the cancer zone prior to progression to SCC; from the cancer zone at the time of SCC; and from other LAGT zones that did not progress to invasive disease.

Results: 123 multi-timepoint samples from 12 women were analysed in total, including 15 invasive SCCs in the anal canal (n=4), peri-anus (n=6), vulva (n=2) and vagina (n=3). DNA methylation profiling of SCC with respect to time and zone is currently in progress.

Conclusions: Multizonal disease is under-researched yet complex to manage clinically. DNA methylation has previously been useful to predict oncological transformation and disease progression, suggesting its usefulness in triaging cases of MZN. Future studies will conduct a full methylome analysis on qualifying samples. Identification of biomarkers and their application in the triage of HSIL may improve the objectivity of MZN treatment.

Shift 01-BOARD ONSITE08 / #387

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-18-2023 7:00 AM - 5:00 PM

RELATIONSHIP BETWEEN SURGICAL MARGINS AFTER LOOP ELECTROSURGICAL EXCISION PROCEDURE (LEEP) AND THE RESIDUAL RATES OF CIN 2 AND CIN 3

Le-Quyen Nguyen, Hoa Ho, Thuy-Ai Pham
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Introduction: At Tu Du hospital, the histopathological results of the tissue sample after the thermoelectric loop apex, if there is a CIN lesion, will be answered by the pathologist as to how many millimeters from the surgical edge measured on all three sections. : outside, inside, and deep. From that result, we will have the next treatment direction for the patient to follow up or treat thoroughly. Evaluating the relationship between surgical margin after cervicectomy and the survival rate of CIN 2 - CIN 3 lesions is significant. It will help clinicians have data to predict the possibility of remaining pre-cancer lesions to advise the patient on the next treatment direction.

Methods: Cross-sectional study on 390 patients

Results: Cross-sectional study on 390 patients with cervical intraepithelial neoplasia grade 2 and 3 (CIN 2 - CIN 3) treated with loop electrosurgical excision procedure (LEEP) and hysterectomy after LEEP to evaluate the relationship between surgical margins after LEEP and the rate of residual CIN 2- CIN 3 after LEEP was assessed on cervical tissue after LEEP. Results: There was no residual CIN 2 - CIN 3 after LEEP if all surgical margins of LEEP > = 4 mm. We developed a model to help predict the residual probability of CIN 2 - CIN 3 after LEEP based on 3 variables: age, and minimum value of all surgical margins after LEEP with AUC 77.8
Model: m = - 4,50693 – 0,86194 x minimum surgical margin + 0,07363 x age

Conclusions: There was strong relationship between the age of patients and minimum surgical margin after the LEEP and the residual rates of CIN 2 and CIN 3 after LEEP.

Shift 01-BOARD ONSITE09 / #832

Poster Viewing
POSTER VIEWING - SHIFT 01: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
04-18-2023 7:00 AM - 5:00 PM

INITIAL REPORT OF CLINICAL RESPONSE AND TOLERABILITY TO ARTESUNATE TOPICAL OINTMENT FOR THE TREATMENT OF MODERATE AND SEVERE VULVAR INTRAEPITHELIAL NEOPLASIA.

Chad Michener[1], Stephanie Ricci[2], Mariam Al Hilli[1], Lindsey Beffa[1], Robert Debernardo[1], Jennifer Brainard[3], Mihaela Plesa[4], Jerome Belinson[4,5], Cornelia Trimble[6]
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Introduction: The aim of this study was to evaluate the safety, tolerability, and efficacy of topical artesunate ointment (ART) for treatment of biopsy-confirmed Human Papillomavirus (HPV)-associated vulvar intraepithelial neoplasia 2/3 (VIN 2/3).

Methods: Participants were enrolled on a prospective, IRB-approved, dose-escalation phase I trial testing either 1, 2 or 3 treatment cycles (5 days, every 2 weeks), as applicable. Clinical follow-up included HPV testing at 6 weeks and HPV testing with colposcopy at 15 and 28 weeks. Overall response rate (ORR) was evaluated. Complete responders (CR) had confirmatory biopsy at 28 weeks. Patients with at least 30% reduction in lesion size or resolution of at least one of their multi-focal lesions were considered partial responders (PR). PR and non-responders (NR) were schedule for definitive ablation or excision. Toxicities were assessed using CTCAE 4.0 criteria.

Results: Altogether, 18 patients were enrolled and 3 withdrew consent. Per-protocol 15-week and 28-week assessments were completed in 100% and 86.7%, respectively. The ORR was 80%; 7 CR (53.3%), 5 PR (26.7%) and 3 NR (20%). ORR was highest in the 3-cycles group (88.9%). 25% (2/8) with CR had resolution of VIN 2/3 between 15 and 28 week visits. HPV-16 was detected alone (46.7%) or with other subtypes (33.3%) in 80% of lesions including 100% of PR and NR. Complete HPV clearance occured in 80% of CR, frequently preceding lesion clearance. No grade 3 or 4 toxicities were reported. Two patients had grade 2 fungal dermatitis. The most common grade 1 toxicities were vulvovaginal burning (93.3%), pruritus (86.7%) and swelling (40%), and these rates did not differ between groups.

Conclusions: Topical ART treatment of VIN 2/3 shows a high ORR and favorable toxicity profile, especially after 3 cycles. These findings are clinically significant. While long-term follow-up for durability of response is needed, our data supports a Phase IIb study of ART for VIN2/3.

Shift 01-BOARD ONSITE10 / #1801

Poster Viewing
POSTER VIEWING - SHIFT 01: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-18-2023 7:00 AM - 5:00 PM

HPV VACCINE ADVOCACY IN THE DENTAL ENVIRONMENT: WHAT ARE WE WAITING FOR?

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Introduction: Numerous agencies and professional organizations have called for dentists and other oral health professionals to routinely educate, recommend and administer the human papillomavirus (HPV) vaccine to their patients. Covid-19 led to a delay in vaccinations that the Centers for Disease Control and Prevention (CDC) warns will impact future population health. Currently, two states allow dentists to administer the HPV vaccine in non-emergency situations. Numerous state policies allow other health professionals to educate about the vaccine. Yet, studies report the reluctance of oral health providers to recommend the HPV vaccine because they lack knowledge and skills to do so. Given these conditions, the time is ripe for professional development in the oral health community regarding HPV vaccination. What are we waiting for?

Methods: To support uptake of HPV education and recommendation in the dental environment, we designed a pilot project. Staff in two urban dental clinics were taught basic HPV information and practiced recommending the HPV vaccine using adult learning principles and youth actors as simulated patients. Following training, we implemented a qualitative study. In-depth, open-ended interviews lasting approximately 30 minutes were offered to all participants one year after the professional development seminar. Of the 61 staff trained, three dentists and nine dental assistants or dental hygienists participated in the interviews. Saturation was reached at 12. All participants answered questions related to their HPV knowledge, their comfort with recommending the HPV vaccine, and their intention to recommend the vaccine.

Results: Among all participants, we documented increased knowledge and comfort addressing HPV with patients and parents. Most endorsed increased willingness to recommend the HPV vaccine.

Conclusions: Education and practice increases oral health professionals' knowledge, comfort and intention to recommend the HPV vaccine. Professional development for oral health providers is urgently needed address low HPV vaccine uptake in the USA. The time for that is now.

Posters Viewing - Shift 2

Shift 02- / #1772

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-20-2023 7:00 AM - 4:00 PM

EVALUATION OF UCM PRESERVATIVE ROBUSTNESS – ENABLING HPV DNA PRESERVATION IN FIRST-VOID URINE COLLECTED WITH VARIOUS COLLI-PEE DEVICE FORMATS

Kyle Macdonald[1], Cameron Wood[1], Melissa Richer[1], Nette Meers[2], Koen Beyers[2], Tara Crawford Parks[1]
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Introduction: The ability to detect Human Papilloma Virus (HPV) in first-void urine (FVU) offers exciting opportunities to expand cervical cancer screening and diagnosis programs, but is dependent on proper collection. The Novosanis Colli-Pee® device enables convenient, user-friendly self-collection of a volumetric FVU sample. In addition, prefilled Colli-Pee® devices with liquid UCM® preservative (1:3 preservative-to-sample ratio) are available to stabilize urine samples post-collection and prevent degradation of HPV DNA. Understanding the effective preservative-to-sample ratio range of UCM for HPV DNA preservation is important to support multiple volume variants of the Colli-Pee® device.

Methods: FVU samples were collected from healthy female and male donors (n=9) using the Colli-Pee® device without preservative (FV-5020), then mixed post-collection with UCM® at various ratios (from 1:4 – 1:1), or left unpreserved. Samples were spiked with HPV16 plasmid DNA (~500,000 cps/mL) and then held at room temperature (20°C-26°C) for 8 days. At baseline and endpoint, DNA was extracted (Qiagen QIAamp DNA Mini kit) from each sample, which underwent in-house HPV-specific qPCR to evaluate HPV DNA preservation.

Results: After room temperature storage, HPV DNA was detected in all UCM® preserved FVU samples. There were no significant differences (paired t-test) in HPV DNA preservation (average qPCR ΔCt) between UCM® at the nominal ratio (-0.41 ± 0.25 SD) and any of the evaluated UCM®-to-sample ratios (1:4; 0.00 ± 0.25 SD, 1:1; -0.35 ± 0.32 SD). In contrast, unpreserved FVU samples experienced significant ($p < 0.001$) HPV DNA loss (9.83 ± 3.54 SD).

Conclusions: These results demonstrate the robustness of UCM® to preserve HPV DNA in FVU samples across a wide range of UCM®-to-sample ratios. Importantly, this permits UCM® incorporation in multiple Colli-Pee® volumetric variants, including FV-5004 (~4 mL), FV-5010 (~10mL), FV-5020 (~20 mL) formats, allowing device selection based on sample volume, high-throughput processing, and/or postal delivery needs.

Shift 02- / #710

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01J. PAPILLOMAVIRUS VACCINES (I.E NEW DEVELOPMENTS)
04-20-2023 7:00 AM - 4:00 PM

SYNTHETICALLY DERIVED BECC COMPOUNDS EXHIBIT COMPARABLE ADJUVANT PERFORMANCE TO BIOLOGICALLY DERIVED COUNTERPARTS WHEN COMBINED WITH THE RG1-VLP HPV VACCINE IN MICE

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Introduction: The RG1-VLP vaccine is a chimeric virus-like particle (VLP)-based vaccine composed of HPV16-L1 capsid subunits engineered to express a conserved HPV16-L2 (RG1) epitope. The cross-neutralization activity added by the RG1 epitope is designed to prevent infections and cancers caused by a range of HPV types including some that are not targeted by the current FDA-approved vaccines. Previous work has demonstrated that in vivo mouse immune responses to RG1-VLPs can be substantially enhanced by the addition of a novel TLR4 agonist, or BECC (bacterial enzymatic combinatorial chemistry) compound, to the Alhydrogel formulation. As the production and purification of BECC compounds from biologically engineered bacterial strains is cumbersome and expensive, a process for production of synthetic BECC compounds has been developed.

Methods: RG1-VLPs + Alhydrogel combined or not with synthetic or biologically derived BECC compounds were used to vaccinate BALB/c mice. Antigen-specific antibody and T cell responses were measured and the scale of vaccine-mediated resistance to infection with HPV pseudovirions was determined.

Results: Both types of BECC compounds were able to enhance the levels of HPV16-L1- and -L2-binding Abs, titers of HPV18- and HPV39-neutralizing Abs, and induction of HPV16-L1-specific T cell responses to similar magnitudes. Additionally, virtually complete protection from vaginal challenge with HPV39 pseudovirions was achieved when alum was supplemented with either version of BECC compound.

Conclusions: These data demonstrate that the adjuvant activity of the synthetic version is compellingly similar to the original biologically-sourced compound. Advantages of developing synthetically produced BECC compounds include a cheaper manufacturing process, higher batch-to-batch consistency, and improved suitability for clinical evaluation.

Shift 02-001 / #374

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-20-2023 7:00 AM - 4:00 PM

UNDERSTANDING COMMUNITY AND CLINIC PERSPECTIVES OF COVID-19 PANDEMIC IMPACT ON HPV VACCINATION IN SAFETY-NET SETTINGS IN THE UNITED STATES: DISRUPTIONS, INNOVATIONS, AND OPPORTUNITIES MOVING FORWARD

Jennifer Tsui[1], Michelle Shin[1], Kylie Sloan[1], Bibiana Martinez[1], Lawrence Palinkas[2], Lourdes Baezconde-Garbanati[1], Joel Cantor[3], Shawna Hudson[4], Benjamin Crabtree[4]
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Introduction: The COVID-19 pandemic severely disrupted routine care delivery, potentially reversing advancements in HPV vaccination in the United States. As priorities shift towards catch-up vaccination, community and clinic perspectives on pandemic disruptions to uptake and strategies to overcome them are needed, particularly within healthcare safety-net settings serving high-risk communities.

Methods: We conducted qualitative interviews and focus groups, guided by the Practice Change Model, with community and clinic members between December 2020 and January 2022, bi-coastally in Los Angeles and New Jersey, to understand adolescent HPV vaccination strategies used in safety-net primary care settings. Participants included members internal (physicians, clinic leaders, clinic staff) and external (parents, advocates, payers, policy) to safety-net clinics. We performed thematic analysis and examined themes across groups.

Results: Participants (n=65) discussed how the pandemic challenged making HPV vaccination a priority but also created opportunities for change. Clinic members highlighted the severe disruptions to deliver missed doses, as parents delayed routine adolescent clinic visits. Clinic and policy members mentioned innovative population-level COVID-19 vaccination efforts (mobile vans, paid leave, use of social media) that could be applied to future HPV vaccination strategies. Local policy members indicated new awareness of resource needs (use of immunization registries, importance of partnerships with clinics serving target communities). Policy and advocacy members noted heightened challenges of vaccine misinformation, the anti-vax movement, and school mandate exemption laws. Clinic leaders expressed concerns about staffing shortages and turnover, which will require renewed training in HPV vaccine communication and messaging.

Conclusions: The COVID-19 pandemic created a major disruption in efforts to improve HPV vaccination rates in the United States, and safety-net organizations may face disproportionate barriers to catching-up on missed vaccinations among adolescents. However, innovative partnerships and strategies from the pandemic can translate to new implementation pathways to better integrate HPV vaccination strategies within local contexts.

Shift 02-002 / #549

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-20-2023 7:00 AM - 4:00 PM

THE ACCEPTABILITY OF PHARMACY-BASED HPV VACCINATION IN WESTERN KENYA AMONG PHARMACY CLIENTS AND PROVIDERS

Shengruo Zhang[1], Benn Kwach[2], Victor Omollo[2], Stephanie Roche[3], Magdaline Asewe[2], Kendall Harkey[3], Parth Shah[3], Josephine Odoyo[2], Nelly Mugo[4,5], Kenneth Ngure[6], Elizabeth Bukusi[2,5,7], Katrina Ortblad[3]
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Introduction: In sub-Saharan Africa, HPV vaccine coverage remains low, and differentiated models that expand HPV vaccine delivery outside of healthcare facilities and schools are needed. In Kenya, private pharmacies are a promising option, as they already deliver a variety of sexual and reproductive health services. We assessed the potential acceptability of pharmacy-delivered HPV vaccination among Kenyan pharmacy providers and clients.

Methods: We surveyed clients and providers at 20 private pharmacies in Kisumu County. Eligible clients were ≥18 years and self-reported behaviors associated with sexually transmitted infection risk (e.g., condomless sex). To inform our assessment of clients' and providers' anticipated acceptability of pharmacy-delivered HPV vaccination, we used the Theoretical Framework of Acceptability (TFA), which defines acceptability as a multi-faceted construct. We measured select acceptability component constructs (e.g., affective attitude, burden) using 5-point Likert items and descriptive statistics.

Results: From March to June 2022, we surveyed 1500 clients (64% females; median age 26 years, IQR 22-31) and 40 providers (42% pharmacy owners; median time in profession: 6 years, IQR 4-10), Table 1. A quarter of clients (26%, n=390) had previously heard of the HPV vaccine and 4% (n=15) had received at least one dose, Fig. 1. Most clients (96%, n=1435) liked the idea of pharmacy-delivered HPV vaccination and did not think it would be hard to get the HPV vaccine at a pharmacy, Fig. 2. All pharmacy providers (100%) agreed that pharmacy-delivery HPV vaccination could reduce HPV infection and reported self-efficacy to counsel and administer HPV vaccine if trained.

Table 1. Characteristics of the enrolled clients and pharmacy providers

Clients	**All clients (N=1500)**
Age, med (IQR)[1]	26 (22, 31)
Age <25 years	642 (43%)
Sex: female	954 (64%)
Sex: male	546 (36%)
Years in school, med (IQR)[1]	14 (11, 16)
Monthly household income (KES), med (IQR)	10,000 (5000, 20,000)[4]
Relationship status: >1 primary partner	627 (42%)
Travel distance to the pharmacy: ≥15 minutes	687 (46%)
Age of first sexual debut, med (IQR)[1]	17 (15, 18)
Have used EC more than twice (females only, n=954)	393 (41%)
Sexual behaviors associated with STI risk	
Multiple sexual partners[2]	510 (34%)
Inconsistent condom use[3]	1310 (87%)
Exchanged sex for money/gift[3]	285 (19%)
Diagnosed with or treated for a STI[3]	149 (10%)
Providers	**N=40**
Demographics	
Age, med (IQR)[1]	31 (27, 37)
Sex: female	16 (40%)
Pharmacist/Pharmaceutical technologist	31 (78%)
Level of training: college/university	39 (98%)
Owns the pharmacy	17 (42%)
Length of time in profession (in years), med (IQR)[1]	6 (4, 10)

Abbreviations: interquartile range (IQR); Kenyan Shillings (KES); emergency contraception (EC); sexually transmitted infections (STIs)

[1] Median (Interquartile range); [2] In the past 3 months, have sex with more than 1 individual; [3] In the past 6 months; [4] 10,000 KES ≈ 83 USD

Fig. 1. Knowledge of HPV, cervical cancer, and the HPV vaccine

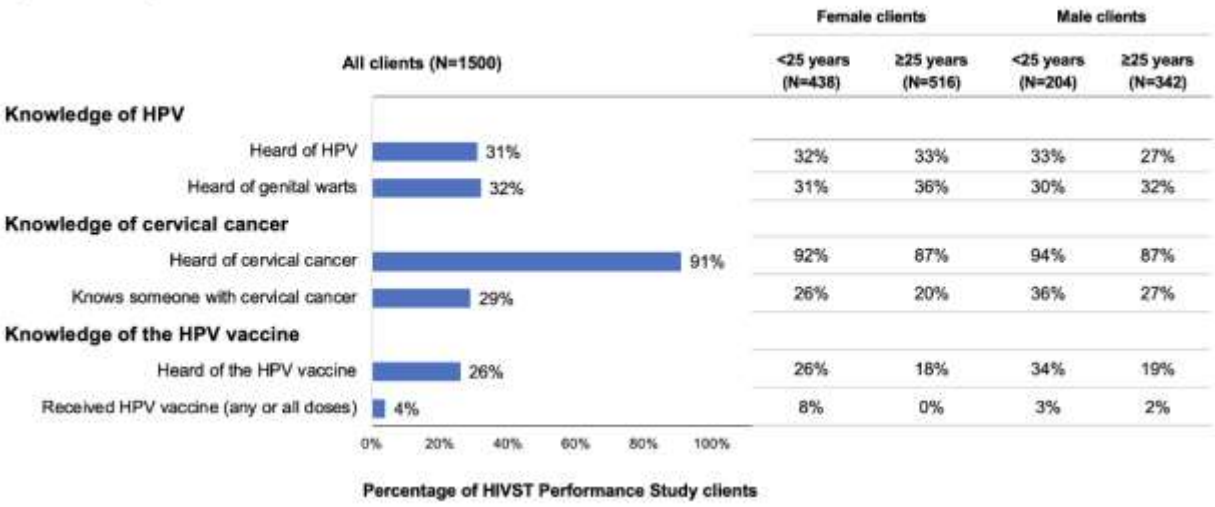
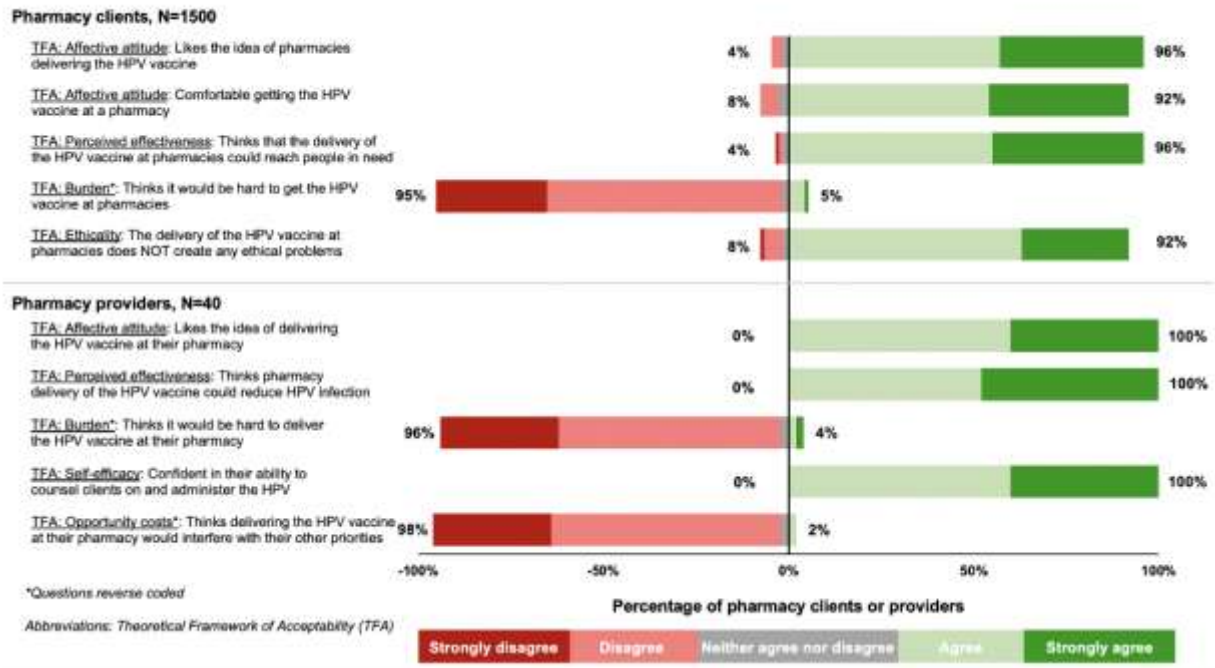


Fig. 2. The acceptability of private pharmacies delivering the HPV vaccine among clients and providers



Conclusions: The large majority Kenyan pharmacy clients and providers in this study found the idea of pharmacy-delivered HPV vaccination highly acceptable. More research is needed to test this model and assess both effectiveness (e.g., uptake) and implementation (e.g., feasibility) outcomes to better understand its potential to expand vaccination coverage and reduce the burden of HPV-associated preventable diseases.

Shift 02-003 / #649

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-20-2023 7:00 AM - 4:00 PM

THE EAST AFRICA CONSORTIUM FOR HUMAN PAPILLOMAVIRUS AND CERVICAL CANCER RESEARCH IN WOMEN LIVING WITH HIV/AIDS

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Introduction: The East Africa Consortium (EAC) was formed to study HPV infections and cervical cancer in Kenya and Uganda, and to encourage collaborations between researchers in these countries. Studies within the Consortium, beginning in 2014 have led to a better understanding of HPV detection and persistence among HIV-infected and HIV-uninfected women, associations of HPV with aflatoxin and antiretroviral therapy, and HPV type distributuion among women undergoing treatment for cervical dysplasia by either cryotherapy or LEEP.

Methods: The EAC has three aims: 1) Establish a sustainable research infrastructure for an international partnership to conduct research in HPV and cervical cancer in women living with HIV/AIDS, 2) Design and execute three integrated projects that advance the knowledge of the environmental and biologic factors leading to cervical cancer in East Africa, and 3) Increase the research workforce capacity in East Africa through mentoring, training programs and pilot projects.

Results: Project 1 enrollment has been completed (N=243, approximately 50% of women are HIV-infected). Preliminary results of participant demographics, HPV detection, VIA, cervical biopsy, HIV parameters, and aflatoxin detection will be reported. Project 2 enrollment is on-going; preliminary results of participant demographics, HPV detection, cervical biopsy, HIV parameters, and immunohistochemical studies will be presented. Project 3 will begin as serial participant samples are available; preliminary results be presented.

Conclusions: The EAC has facilitated the training of scientists and collaborative research between countries from sub-Saharan Africa and North America. While there have been challenges in performing this research, with time, this collaboration will contribute solutions towards the elimination of cervical cancer and other cancers related to HIV infection in women living in sub-Saharan Africa, as well as optimizing the processes to better facilitate research.

Shift 02-004 / #705

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-20-2023 7:00 AM - 4:00 PM

THE "GERMAN ROUNDTABLE ON HPV PREVENTION" – AN INTERDISCIPLINARY CIRCLE TO ACHIEVE THE WHO STANDARD FOR CERVICAL CANCER ELIMINATION

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Introduction: HPV vaccination is an effective strategy to prevent HPV-related cancers. Thus, one pillar of the WHO goal to eliminate cervical cancer is to achieve worldwide a 90% vaccination rate among 15-year-old girls by 2030. Given the current low HPV vaccination rate (47%) in Germany, the country will unlikely meet the WHO standard without additional efforts.

Methods: The "German Roundtable on HPV prevention" aims to contribute to an effective prevention of HPV-related cancers by information exchange, discussing achievement of national and global targets, identifying gaps, catalysing efforts and advocating for the implementation of effective measures to increase HPV vaccination coverage in Germany.

Results: Since its launch in 2019, the "Roundtable" every year brings together 40-50 stakeholders working mostly in research (30%), in public health services (24%) and associations (24%). It has initiated, among others, the following activities: - Definition of priority topics in 2019 for the elaboration of strategies to increase HPV vaccination coverage. - Call for a uniform nationwide prescription procedure for HPV vaccines in 2019, which support HPV vaccine uptake. - A statement in 2021 endorsed by relevant institutions in Germany advocating for the implementation of key policies: reminder systems, school-based HPV-vaccination, target groups (adolescents, parents) specific awareness campaigns. - Mailing of the above statement in 2022 to more than 500 relevant decision makers of federal and state parliaments in order to influence policy-making.

Conclusions: Partnerships, collaborations and advocacy are essential to promote HPV vaccination uptake. The "German Roundtable on HPV Vaccination" as a network of relevant actors is a valuable political and social instrument to increase of HPV vaccination coverage and, finally, to reach the WHO recommendation.

Shift 02-005 / #764

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-20-2023 7:00 AM - 4:00 PM

A "STORYTELLING CLOTH" APPROACH TO MOTIVATING CERVICAL CANCER SCREENING IN WEST AFRICA

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Introduction: Ninety percent of deaths from Cervical cancer (CC) caused by Human Papilloma Virus (HPV) occur in low- and middle-income countries. CC is the 2nd most common cause of cancer in women in West Africa, where 12,000 women develop cervical cancer and more than 6,000 die from the disease, annually. While HPV vaccination and CC screening have dramatically reduced the incidence of CC and mortality from CC in developed countries, prevention of CC in West Africa is often limited to visual inspection of the cervix and surgical intervention.

Methods: We piloted a novel approach to educating women in West Africa about the risk of cervical cancer and the importance of screening using a 'story-telling cloth' that can be used as a starting point for educational sessions run by community healthworkers. A total of 15 nurses and midwives at all five sites were re-trained on CC screening protocols. Women with normal screening were provided with a screening card and appointment for next year. Women with abnormal results on the first screening were referred to the regional health center. A survey questionnaire was proposed to the first 100 women seeking screening at each of the 5 health centers (total number of women: 500, all aged 18 years old or more).

Results: This program resulted in a 5-fold uptake of cervical cancer screening and increased women's knowledge of HPV and CC.

Conclusions: The story-telling cloth approach used in this campaign was effective because it allowed a predominately illiterate group to access information both visually and verbally. Further, the results of our survey also show that the use of the story-telling cloth as a visual aid during education sessions proved more effective than prevailing outreach methods. This style of community-led education through story-telling cloth may serve as a model for other disease awareness campaigns in this region.

Shift 02-006 / #788

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-20-2023 7:00 AM - 4:00 PM

GENOTYPIC DIVERSITY OF HUMAN PAPILLOMAVIRUS INFECTION IN WOMEN IN CAMEROON AND IMPLICATIONS FOR VACCINATION STRATEGY

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Introduction: High-risk human papillomavirus (HR-HPV) infections are responsible for 7.7% of cancers in developing countries, mainly cervical cancer. Several studies reveal the presence of numerous oncogenic HR-HPV genotypes worldwide, but the presence and distribution of these genotypes remains poorly known in Cameroon. The overall objective of this study was to ascertain HR-HPV genotypes circulating in Cameroon.

Methods: A cross-sectional study was conducted among non-vaccinated women in Cameroon. Detection of HR-HPV was performed by real-time PCR on cervico-vaginal swabs. Predictors of HR-HPV were determined following logistic regression analysis, with $p<0.05$ considered statistically significant.

Results: we enrolled 364 women with a median age of 41 (34-50) years. The HR-HPV positivity rate was 21.43% (95%CI: 17.21-25.64). Compared with the negatives, the positives were younger (37 [30-47] vs. 42 [34-50], P=0.002) and had a higher proportion of smokers (54.5% vs. 45.5%, P=0.005) and of those who had had ≥2 sexual partners at a time in their lifetime (27.0% vs. 11.3%, P=0.001). Overall, 12 HR-HPV genotypes were identified. 26.98% women were co-infected with at least 2 HR-HPVs, including one case of a triple co-infection. As per circulating genotypes, potential vaccine effectiveness was 47% for the 4-valent and 70% for the 9-valent vaccine. Predictors of HR-HPV were young age (i.e >41years; aOR [95%CI]: 0.408[0.194-0.862]; p=0.018); smoking (aOR: 5.199 [1.314-20.575]; p=0.018) and having >3 sex partners (aOR: 2.335[1.133-4.811]; p=0.022).

Conclusions: Within the Cameroonian context, at least one out of five women is likely to be a HR-HPV carrier, especially among youth, smokers and those with multi-sexual partners. Importantly, HR-HPV infection is highly diversified, with vaccine efficacy ranging from about 47% (4-valent) to 70% (9-valent).

Shift 02-007 / #889

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-20-2023 7:00 AM - 4:00 PM

GENETIC DIVERSITY OF HIGH-RISK HUMAN PAPILLOMAVIRUS AND ASSOCIATED FACTORS AMONG WOMEN IN SUB SAHARAN AFRICA: A SYSTEMATIC REVIEW AND META-ANALYSIS

Michel Carlos Tommo Tchouaket, Aude Christelle Ka'E, Ezechiel Ngoufack Jagni Semengue, Samuel Martin Sosso, Rachel Kamgaing Simo, Bouba Yagai, Nka Alex Durand, Collins Chenwi, Aissatou Abba, Nadine Fainguem, Vittorio Colizzi, Carlo-Federicco Perno, Joseph Fokam
CIRCB, Lam, Yaoundé, Cameroon

Introduction: Sub-Saharan Africa carries the highest burdens of HR-HPV globally, favoured by HIV-infection and other undefined factors. This systematic review aimed at identifying HR-HPV genotypes and their associated factors among women in sub-Saharan Africa.

Methods: A systematic review and meta-analysis was conducted on studies in sub-Saharan African countries that reported data on complete HR-HPV genotyping. We searched electronic databases: PubMed/Medline, Science Direct, African journals Online, academic medical education and Google scholar to retrieve articles. Association analysis was performed between HR-HPV and HIV-status, age, number of sexual partners, smoking and women who use contraceptives. R software version 3.6.0 was used to perform all meta-analyses, with p 0.05 considered statistically significant. Prospero registration number: CRD42021226708.

Results: We included twenty-eight articles with a total of 22 652 participants in this review. The overall pooled prevalence of HR-HPV genotypes was 55.13% (95% CI) with high heterogeneity between studies [x^2= 0.0719 (NS= 28); p value = 0 and I^2= 99%]. The overall pooled prevalence of HR-HPV genotypes in HIV+ participants was 75.51% with high heterogeneity between studies [x^2= 0.1313 (NS= 8); p-value <0.01 and I^2= 99%]. The overall pooled prevalence of HR-HPV genotypes in HIV- participants was 52.97% with high heterogeneity between studies [x^2= 0.0426 (NS=5); p-value <0.01 and I^2= 99%]. HPV-genotype 16 was the most prevalent (18%), followed by 35 (10.12%) and 52 (9.98%), 18(9.7%), 45(6.82%). HIV infection (8/12), multiple sexual partners (5/12); and age (5/12) were the most frequently reported risk factors associated with HR-HPV.

Conclusions: The combined prevalence of HR-HPV genotypes among women in general and HIV-infected women in particular remains high in sub-Saharan Africa. Genotypes 16, 35, 52 and 18 are the most predominant, suggesting the need for vaccination policies against HR-HPV genotypes, which can prevent a large number of HR-HPV genotypes.

Shift 02-008 / #1145

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-20-2023 7:00 AM - 4:00 PM

INCIDENCE TRENDS OF HPV-RELATED CANCERS IN THE NETHERLANDS, 2000-2019

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Introduction: Since the 1990s, cervical cancer (CC) incidence rates decreased in the Netherlands. However, since 2015 an increase in CC incidence is observed. It is unclear whether this increase is related to changes in the screening programme, such as the introduction of hrHPV-based screening in 2017, or an increase in HPV-prevalence in the population. We explored trends in incidence of HPV-related cancers, to give information on underlying changes in HPV infections, or on changes in the effectiveness of screening.

Methods: Data from the National Cancer Registry and the Dutch nationwide pathology databank were used. HPV-related cancer diagnoses (cervix, and (subtypes of) oropharynx, anus, vulva, vagina and penis) in the period 2000-2019 were included. European age-standardized incidence rates were calculated per 100,000 person years. (Average) Annual Percentage Change (A)APC) analyses using joinpoint regression were performed to analyze incidence trends. CC incidence trends were evaluated by mode of detection (clinically- or screen-detected), FIGO-stage and age.

Results: Incidence of cervical (AAPC 1.2%, CI:0.2%-2.2%), anal (AAPC 5.6%, CI:3.6%-7.7%), vulvar (AAPC 2.6%, CI:1.8%-3.4%) and penile cancer (AAPC 2.3%, CI:0.6%-4.1%) significantly increased over the period 2000-2019 while oropharyngeal and vaginal cancer showed no significant increase. Both the incidence of screen-detected and clinically-detected CC increased by 3.3% (CI:2.4%-4.1%) and 2.0% (CI:1.4%-2.7%), respectively. CC incidence increased in all FIGO-stages (except in stage III), and age groups targeted by screening (30-65 years).

Conclusions: Increasing incidence trends are observed for almost every HPV-related cancer. Increasing CC incidence was observed in most FIGO stages and in both screen-detected and clinically-detected cancers, but increased more in screen-detected cancers. Also, the increased incidence was observed between ages 30-65, which compromises the ages eligible for screening. Our results can be explained by an increase in HPV prevalence in the population, which might be exposed by the introduction of primary HPV screening.

Shift 02-009 / #1471

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-20-2023 7:00 AM - 4:00 PM

KNOWLEDGE ABOUT CERVICAL CANCER AND AWARENESS OF HUMAN PAPILLOMA VIRUS (HPV) INFECTION AND HPV VACCINE AMONG FEMALE MEDICAL STUDENTS FROM SOUTHEASTERN SERBIA

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Introduction: . The persistent infection with human oncogenic papilloma viruses (HPVs) is one of most important cause of cervical cancer. The objective of the study was to evaluate knowledge about cervical cancer, as well as awareness of HPV infection and HPV vaccination among first-year female students from Nis, Southestern Serbia.

Methods: . The retrospective questionnaire-based cohort study was conducted. Participants were 1616 female, first year college students at the University of Nis. All statistical analyses were performed using R software, version 3.0.3. The t-test or Mann-Whitney test was calculated depending on data distribution, while the mean values between three groups were compared using either ANOVA or Kruskal–Wallis test. The Chi-squared test was used for comparison of categorical variables. The p-value was set at $p<0.05$.

Results: The response rate was 81.0%. The average age of the study population was 19.13±0.73 years (Min 17, Max 29) with majority of the students coming from urban area (75.7%). The average cervical cancer knowledge score was 16.35±7.92 (Min 0, Max 30) with medical professions education, parents' education level, place of residence and relationship status having significant effect on the score. Total number of participants that have heard of HPV infection was 788 (48.8%) with medical students being aware of this infection in significantly higher percentage ($p<0.001$). Students that have finished medical high school had significantly higher knowledge compared to those from grammar school ($p<0.001$) and non-medical high schools ($p<0.001$). Students that were in relationship ($p=0.005$) and that were sexually active ($p=0.001$) knew about HPV infection significantly more often. The awareness about HPV infection and HPV vaccine was low with only 14.2% of students having heard about both HPV infection and its vaccine.

Conclusions: Conclusion: In order to reduce cervical cancer burden the health promotion and educational programs are necessary.

Shift 02-011 / #1561

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-20-2023 7:00 AM - 4:00 PM

PREVALENCE OF MULTIPLE HIGH RISK HUMAN PAPILLOMA VIRUS (HR HPV) INFECTIONS IN CERVICAL CANCER SCREENING IN LAZIO REGION, ITALY

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Introduction: Co-infection with multiple HR HPV genotypes are possible and frequent. The detection of a co-infection with two or more different HPV genotypes identifies patients at a higher risk of progression to high-grade squamous intraepithelial lesion (HSIL) and Squamous Cervical Carcinoma. The purpose of this study is to evaluate the prevalence of co-infections in women tested for HR HPV in the national cervical cancer screening program of Lazio (Italy).

Methods: From June to November 2022 a total of 30.447 females, (30 to 64 years old), were enrolled in the national cervical cancer screening in Lazio in our laboratory. Samples from the patients were tested using the Anyplex TM II HPV HR Detection test by Seegene (Arrow), a Real Time PCR method based on DPODM technology (Dual Priming Oligonucleotides) and TOCEMT (Tagging Oligonucleotide Cleavage) identifying 14 HR-HPV genotypes: 16,18,31,33,35,39,45,51,52,56,58,59,66,68.

Results: 4,244 (14%)samples tested positive for HR-HPV . Among these 3,290 (77.52%) presented a single genotype infection and 954 (22.48%) a 2 to 5 genotypes co-infection. 2 HR HPV genotypes were present in 721 (75.6%) cases, 3 in 191 (20.0%) cases, 4 in 41 (4.3%) cases and 5 (0,1%) in one case. HPV 16/31 co-infection was showed in 26 cases (2.7%), 16/68 in 25 cases (2,6%) 16/58 in 23 cases (2,4%), 31/68 in 18 cases, (1,9%) 31/52 and 58/68 in 17 cases (1,8%); 270 different combination of the 14 HR HPV genotypes tested in various percentage have been found.

Conclusions: In our study the most frequent HR HPV co-infection was 16/31 (26 cases, 2.7%), 16/68 (25 cases, 2,6%) 16/58 (23 cases, 2,4%) 31/68 (18 cases, 1,9%) 31/52 and 58/68 (17 cases 1,8%, respectively). Co-infection by multiple HPV genotypes carries a 4.1 fold increased risk of developing cervical cancer.

Shift 02-012 / #1769

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03A. GLOBAL IMPACT OF HPV AND CERVICAL CANCER PREVENTION
04-20-2023 7:00 AM - 4:00 PM

DEVELOPMENT OF A POLICY ROADMAP TO OPTIMIZE THE ADOPTION AND SCALE OF IMPROVED TECHNOLOGIES FOR CERVICAL CANCER PREVENTION IN KENYA

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Introduction: Kenya's cervical cancer burden remains among the highest worldwide, despite having a published national cancer control plan which highlights cervical cancer as a priority. As improved diagnostic and treatment options become more widely available, national programs and associated health policies should provide clear guidance for practitioners to test, adopt and scale these technologies, as warranted, to facilitate improved health outcomes.

Methods: In October 2022, program partners conducted a desk review of all published national and subnational policies related cervical cancer prevention and control. The team designed a qualitative survey to identify opportunities and barriers for adoption and scale of improved technology for cervical cancer prevention. Leaders were recruited from across government, civil society and academic sectors to complete the survey and participate in a series of workshops to identify key drivers of change needed and design a national policy roadmap to facilitate the adoption and scale of improved technologies for cervical cancer prevention in Kenya.

Results: Multiple factors were identified as key drivers necessary to accelerate cervical cancer prevention in Kenya. First, cervical cancer must be identified as a priority within the cancer community, with clear objectives and targets established at all levels of the health system. Routine data monitoring must be established to effectively monitor health outcomes. Policy makers have the opportunity to promote primary care services and financially support via Kenya's national health insurance scheme. Engaging patients and care providers is crucial to establishing trust with new services and tools in the program.

Conclusions: Kenya has identified cervical cancer as a national priority. Policy makers have an opportunity to emphasize primary health care and the role of national insurance to support preventive services. Data monitoring systems are necessary to track outcomes associated with the use of improved technologies.

Shift 02-013 / #608

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

INCIDENCE AND MORTALITY TRENDS FOR HPV-ASSOCIATED CANCERS AMONG DIVERSE POPULATIONS IN LOS ANGELES, CALIFORNIA 2000-2019: IMPLICATIONS FOR TARGETED APPROACHES IN VACCINATION AND SCREENING IMPROVEMENT

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Introduction: HPV-associated cancers are preventable through vaccination. However, inequities in access to cervical cancer prevention and treatment continue in the United States (US). Examining trends in incidence and mortality of HPV-associated cancers at the local level is critical to developing effective, targeted approaches for prevention.

Methods: Using 2000-2019 Los Angeles Cancer Surveillance Program (LACSP) data we examined the burden of HPV-associated cancers (cervix [CC] and oropharynx [OPC] separately; vagina, vulva, penis, anus combined) and estimated age-adjusted incidence (AAIR) and mortality rates. We compared trends across race/ethnicity (disaggregating by Asian/Pacific Islanders [APIs] and Hispanic/Latinos groups), socioeconomic status (SES), and disease stage.

Results: Of the 20,868 HPV-associated cancers that were identified (6,947 males 13,921 females), a higher proportion of cases were observed among low-SES (46% vs. 36%) and non-US born (59% vs. 35%) relative to higher-SES and US-born cases, respectively. CC incidence rates declined over time ($p<0.01$) and racial and ethnic disparities in incidence narrowed. Incidence among Hispanic women remained highest relative to other groups (AAIR:11.6, 95% CI: 11.2-11.9) and increased between 2013-2019. The burden of regional-stage CC differed by within Hispanic and API groups, with a higher burden of regional-stage CC disease observed among Mexican (40.1%), Filipino (38.3%), and Korean women (40.3%). CC mortality rates were higher among NHB (RR:4.0; 95% CI: 3.6-4.4) and Hispanic women (RR:3.7; 95% CI: 3.5-3.9) compared to NHW women. While OPC burden was highest among males and NHWs overall, racial differences were observed by sex: higher burden in NHB females (RR:3.0; 95% CI: 2.0-4.0) than NHW females, and higher burden in NHB males (RR:1.5; 95% CI: 1.3-2.0) than NHW males.

Conclusions: HPV-associated cancer burden is declining in the US overall. However, we highlight the importance of monitoring trends by disaggregating population groups, and cancer sites and stage to optimize strategies for cancer control targeting high-risk communities.

Shift 02-014 / #610

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

ASSESSING CERVICAL CANCER INCIDENCE IN 517,574 WOMEN LIVING WITH AND WITHOUT HIV IN SOUTH AFRICA

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Introduction: HIV infection increases the risk of developing invasive cervical cancer (CC), yet longitudinal studies directly comparing CC rates between women with and without HIV are scarce, particularly in sub-Saharan Africa. Therefore, little information is available on age-specific CC rates by HIV status.

Methods: We used reimbursement claims data from a South African medical insurance scheme (01/2011-06/2020) to examine CC rates among insured women aged ≥18 years. CC diagnoses were defined as ≥2 ICD-10 codes for CC (C53.0-9). We used Cox models to evaluate the association between HIV and CC incidence, adjusting for age, ethnicity, and calendar year. Using flexible parametric survival models, we estimated CC incidence rates and adjusted hazard ratios for HIV status as a function of age.

Results: We included 517,574 women, of whom 590 developed CC. About 8% of women were living with HIV (n=38,992), including 34,193 (88%) who initiated antiretroviral therapy during follow-up. Half of the included women were of Black ethnicity (n=256,814). The risk of incident CC was over three times higher in women with HIV than without HIV (adjusted hazard ratio 3.12, 95% CI 2.52-3.85). Other risk factors for incident CC included older age and Black ethnicity (Table). The strength of the association between HIV status and incident CC decreased with age (Figure 1). In women living with HIV, CC incidence rates increased at early ages and peaked at 49 years (122/100,000 person-years), whereas in women without HIV, CC rates remained below 50/100,000 person-years across all ages (Figure 2).

Table: Risk factors for developing cervical cancer.

Characteristic	Woman-years	Women with cervical cancer	Univariable Hazard Ratio (95% CI)	Multivariable Hazard Ratio (95% CI)
HIV status				
Negative (ref)	1,773,725	452	1	1
Positive	156,296	138	3.45 (2.85-4.18)	3.12 (2.52-3.85)
Age (time-updated)				
18-29 years	348,695	16	0.09 (0.05-0.15)	0.07 (0.04-0.12)
30-39 years	451,185	92	0.43 (0.33-0.56)	0.29 (0.22-0.38)
40-49 years	401,874	177	0.99 (0.79-1.23)	0.69 (0.54-0.86)
50-59 years	360,079	154	1.00 (0.80-1.25)	0.80 (0.64-1.01)
>=60 years (ref)	368,349	151	1	1
Ethnicity				
Black (ref)	917,839	340	1	1
Other	656,800	161	0.68 (0.56-0.82)	0.74 (0.60-0.90)
Missing	355,381	89	0.68 (0.54-0.86)	0.59 (0.46-0.76)
Calendar year (time-updated)				
2011-2013 (ref)	533,387	197	1	1
2014-2016	593,590	176	1.05 (0.83-1.34)	1.15 (0.90-1.47)
2017-2020	803,044	217	0.98 (0.78-1.22)	1.07 (0.85-1.35)

Figure 1: Adjusted hazard ratio for the association of HIV status with cervical cancer incidence by age.

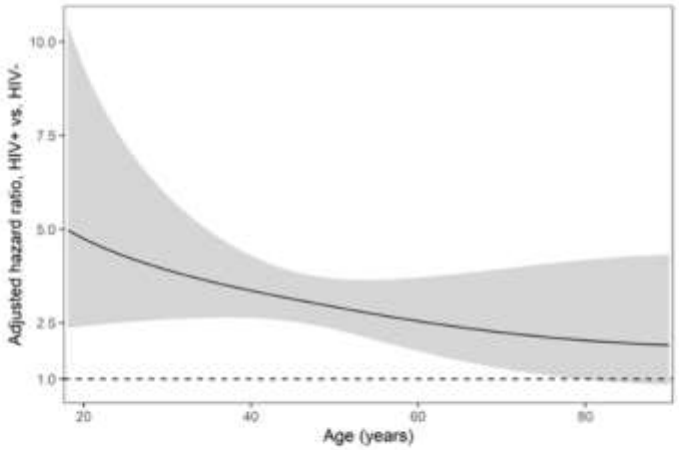
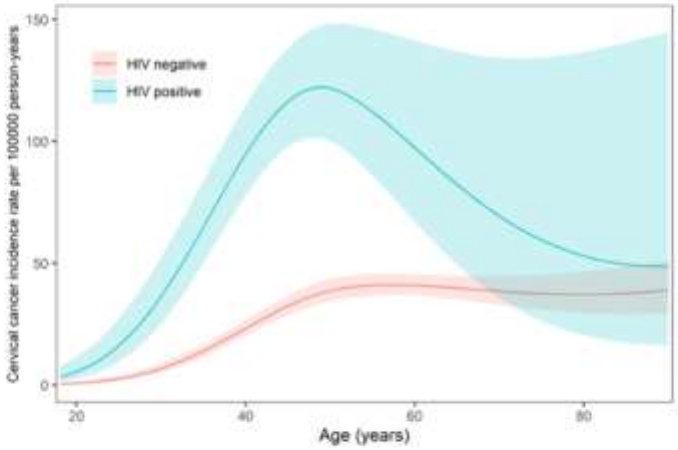


Figure 2: Cervical cancer incidence rates by age and HIV status.



Conclusions: Young women living with HIV had a much higher risk of developing CC than their HIV-negative peers. However, in absolute terms, CC rates were highest among middle-aged women living with HIV. A more in-depth understanding of CC burden by HIV status and age is essential to inform cervical cancer prevention efforts.

Shift 02-015 / #633

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

CO-DETECTION OF CERVICAL ALPHAPAPILLOMAVIRUS AND BETAPAPILLOMAVIRUS TYPES: POSSIBLE EVIDENCE OF COMPETITIVE CROSS-GENUS INTERACTIONS?

Talía Malagón[1], Emily Montosa Nunes[2], Mariam El-Zein[3], Luisa Villa[2,4], Eduardo Franco[5], Laura Sichero[2]
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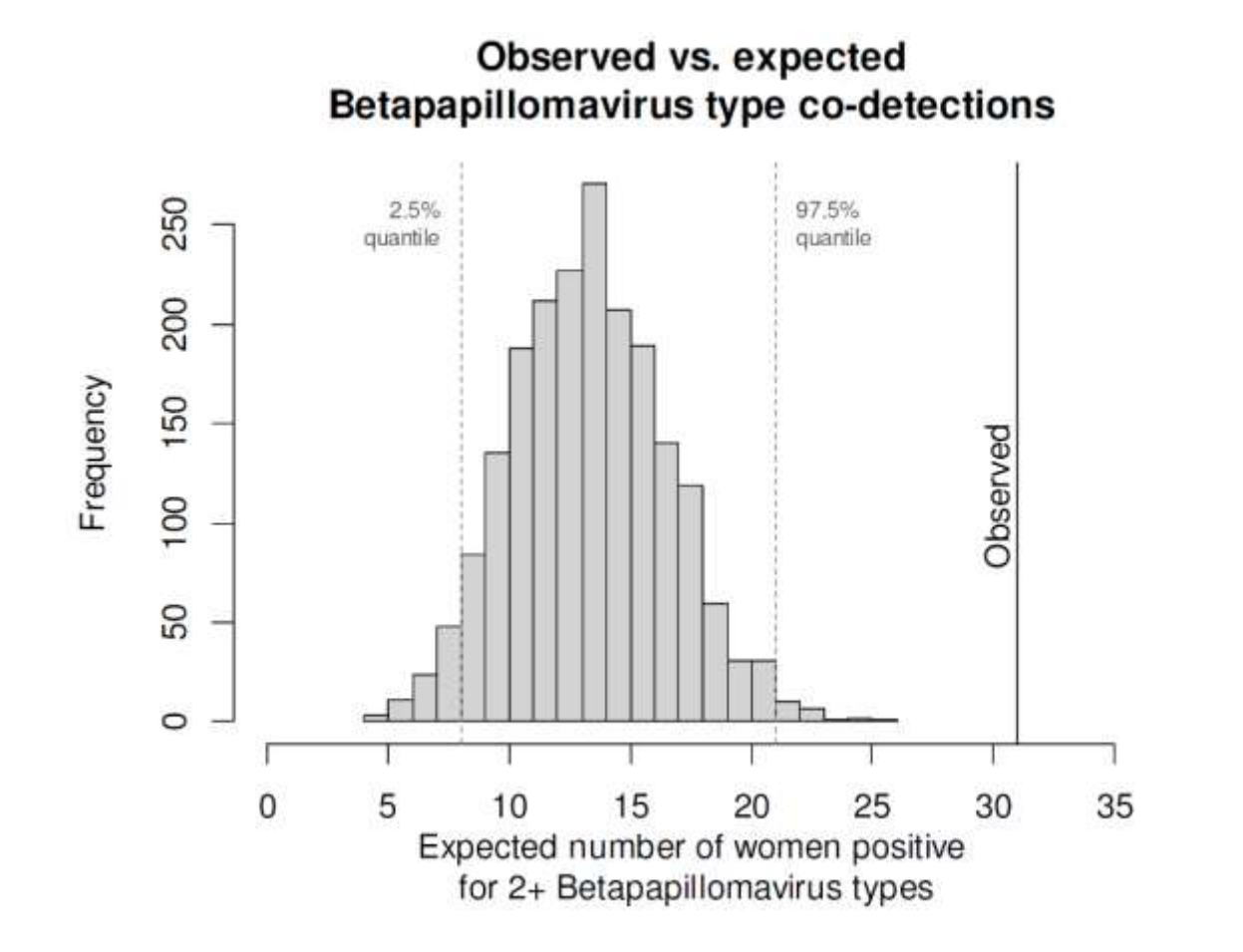
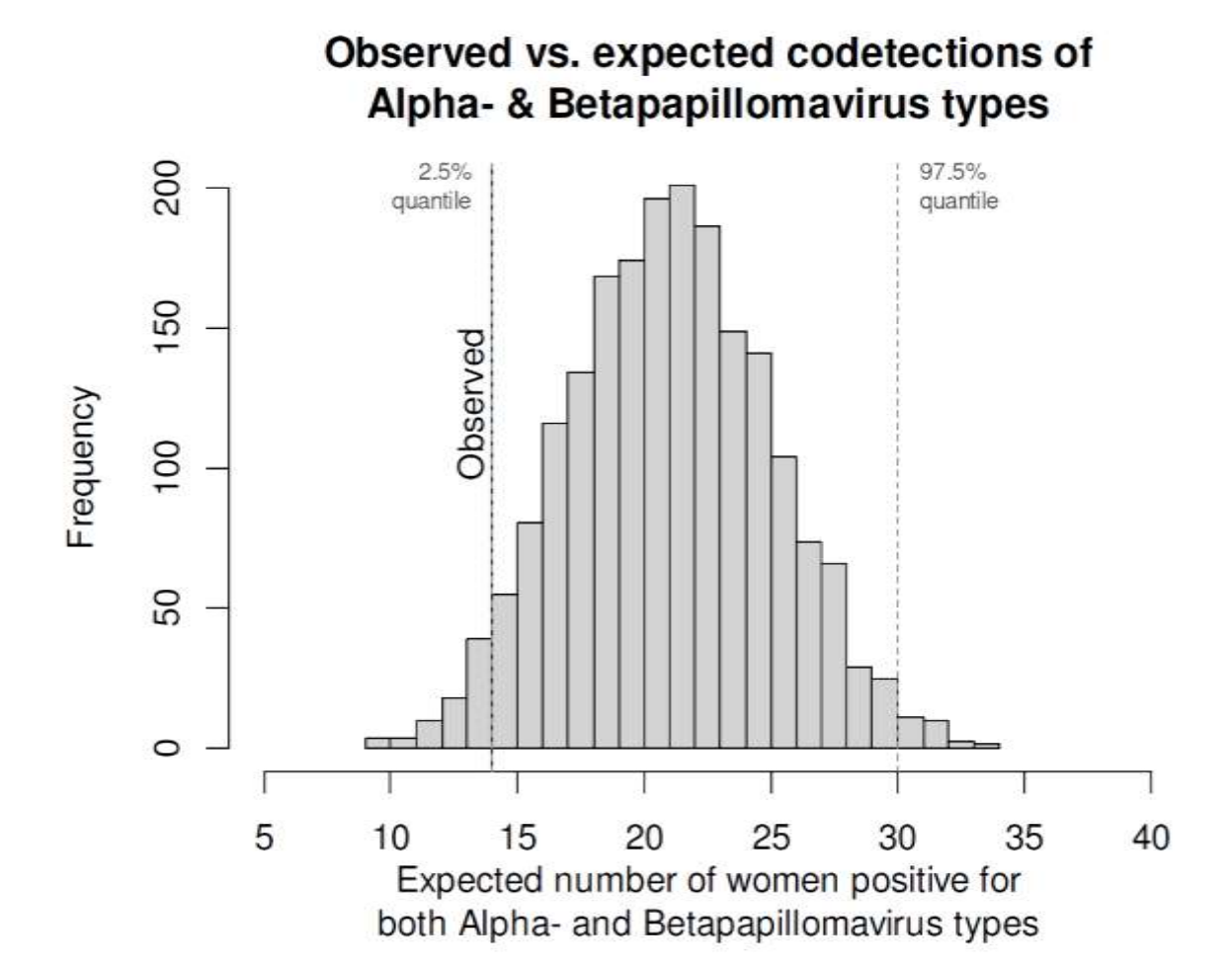
Introduction: Human papillomavirus (HPV) types of the Alphapapillomavirus genus tend to be detected together in cervical samples more often than expected assuming independence due to shared common sexual risk factors. Little research has examined co-detection patterns of Betapapillomaviruses.

Methods: We assessed a subset of 505 women with cervical samples at baseline and 1-year follow-up of the Ludwig-McGill cohort study from São Paulo, Brazil. The samples were tested for DNA of over 40 Alphapapillomavirus types using PCR amplification with MY09/11 and PGMY09/11 primers followed by genotyping via hybridization with type-specific oligonucleotide probes and restriction fragment length polymorphism; and 43 Betapapillomavirus types using a type-specific multiplex genotyping PCR assay using a mixture of specific biotinylated primers, followed by genotyping via a bead-based Luminex technology. We assessed whether types occurred more frequently together than expected assuming independence of types using permutation tests and logistic regressions.

Results: We observed significant cross-sectional within-genus clustering. Multiple Alphapapillomavirus types were co-detected in the same sample 1.88 (95%CI: 1.16-3.14) times more frequently than expected, and multiple Betapapillomavirus types were co-detected in the same sample 2.38 (95%CI: 1.48-3.88) times more frequently than expected. Conversely, co-detections of Alpha-and Beta-papillomavirus types in the same sample occurred only 0.68 (95%CI: 0.47-1.00) times as often as expected. In prospective analyses, women who tested positive for Betapapillomavirus types at baseline had 1.36 (95%CI: 0.70-2.62) times higher odds of incident detections with Alphapapillomavirus types compared with Betapapillomavirus-negative women, whereas women who tested positive for Alphapapillomavirus types at baseline had 0.32 (95%CI: 0.12-0.88) times the odds of incident detection with Betapapillomavirus types compared with Alphapapillomavirus-negative women.


Observed vs. expected
Betapapillomavirus type co-detections
2.5% quantile
97.5% quantile
Observed
Frequency
0
50
100
150
200
250
0
5
10
15
20
25
30
35
Expected number of women positive for 2+ Betapapillomavirus types



Conclusions: Alpha- and Beta-papillomaviruses appeared together less often in cervical samples than would be expected if they were independently distributed. This lower co-detection appeared to be mostly attributable to a lower Betapapillomavirus detection incidence in women who are Alphapapillomavirus positive.

Shift 02-016 / #635

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

PLASMA AFLATOXIN DETECTION IS ASSOCIATED WITH PERSISTENT DETECTION OF ONCOGENIC HPV TYPES IN KENYAN WOMEN

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Introduction: Cervical cancer is common among Kenyan women. Although oncogenic HPV (HR-HPV) is the major risk factor, cofactors that increase the presence and persistence of HR-HPV are also important. Many Kenyan women are exposed to dietary aflatoxin, a potent carcinogen and immunosuppressive agent. We previously showed that plasma aflatoxin biomarkers were associated with cervical detection of A9 HPV types in Kenyan women. An additional analysis was performed to examine associations between detectable aflatoxin and persistent HPV detection using longitudinal data from these women.

Methods: Kenyan women (N=211) were enrolled in a 2-year prospective study. The analytical cohort for this post-hoc analysis included 67 HIV-uninfected women who completed at least two of the three study visits and had an enrollment blood sample available. Aflatoxin was detected in plasma using ultra-high pressure liquid chromatography (UHPLC)-isotope dilution mass spectrometry. Cervical swabs (enrollment and annually) were tested for HPV using the Roche Linear Array. Ordinal logistic regression models were fitted to examine associations of aflatoxin and HPV persistence controlling for demographic/behavioral variables.

Results: The mean age (SD) of participants at enrollment was 34.0 (5.9) years. Aflatoxin was detected in 40 women (59.7%); 27 women (40.3%) had no aflatoxin detected. There were 10 episodes of HR-HPV persistence among 9 women (9/40, 22.5%) with detectable aflatoxin vs. 2 episodes among women (2/27, 7.4%) without aflatoxin. HPV 18 was the most frequently detected persistent type, all in women with detectable aflatoxin. Regression analysis revealed that aflatoxin detection was associated with greater probability of persistent detection of any HPV type (OR=3.03, 95%CI=1.08-8.55, P=0.036) and HR-HPV types (OR=3.63, 95%CI=1.30-10.13, P=0.014).

Conclusions: Detection of aflatoxin was associated with increased risk of HR-HPV persistence in Kenyan women. Further studies are needed to determine if aflatoxin synergistically interacts with HR-HPV to increase cervical cancer risk in Kenyan women, including those who are HIV-infected.

Shift 02-017 / #769

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

RATES OF REGRESSION AND PROGRESSION OF CIN2 - A REGISTER-BASED STUDY OF 11,056 WOMEN WITH INCIDENT CIN2

Kathrine Lycke[1,2,3], Johnny Kahlert[4], Rikke Damgaard[1,2,3], Dina Overgaard Eriksen[1,2,3], Mary Bennetsen[5], Lone Petersen[6,7], Patti Gravitt[8], Anne Hammer[1,2,3]
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Introduction: Several studies have shown high regression rates of CIN2 (50-60%), however most studies are small. The high regression rates have resulted in the implementation of active surveillance, which is often restricted to women aged <25-30. Here we aimed to estimate the rates of regression and progression of women diagnosed with CIN2 using Danish nationwide registers.

Methods: We conducted a register-based cohort study on all women with incident CIN2 from 1998-2020 who underwent active surveillance. We excluded women aged 40+ years at diagnosis and women with prior CIN2+ or LLETZ. Using the cumulative incidence function, we estimated the rates of regression (histologic ≤CIN1) and progression (histologic CIN3+) at 6, 12, 18, and 24 months after CIN2 diagnosis. Additionally, using modified Poisson regression, we estimated the relative risk (RR) of progression within 24 months stratified by index cytology (normal, low-grade, high-grade) and age (18-22, 23-29, 30-40), including adjustment for age and index cytology.

Results: We included 11,056 women with CIN2. The majority were aged 23-29 (60.8%) and nearly half had high-grade index cytology (46.4%). The regression rate after 24 months was 62.9% (95% CI 61.9-63.8), while the progression rate was 33.3% (95% CI 32.4-34.2). Women with high-grade index cytology had considerable higher risk of CIN3+ compared to women with normal index cytology (adjusted RR 1.60 (95% CI 1.44-1.77)). Of note, we found no difference in risk of progression between women aged 30-40 and 23-29 (adjusted RR 0.98 (95% CI 0.87-1.09)).

Conclusions: Our findings support the use of active surveillance for CIN2, particularly in women with ≤low-grade index cytology. As age had limited impact on risk of progression, active surveillance could be offered to women >30 years of age. However, studies are needed to explore the potential long-term consequences of active surveillance for CIN2.

Shift 02-018 / #804

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

DIFFERENCES IN HPV GENOTYPES DISTRIBUTION AMONG YOUNG WOMEN IN TWO BIGGEST CROATIAN COUNTIES

Jasmina Vranes[1], Tatjana Marijan[1], Suncanica Ljubin-Sternak[1], Ines Krivak[2]
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Introduction: The aim of this study was to compare the prevalence of high-risk HPV (hrHPV) infection between young women from two biggest Croatian counties: the City of Zagreb (CZ) and the Split-Dalmatia County (SDC), considering severity of cervical lesions and distribution of the most important hrHPV types.

Methods: The study included young women (< 30 years), who were on their gynecologist's request tested on hrHPV infection with molecular Cobas 4800 HPV Test. Liquid based cytology (LBC) were performed from hrHPV-positive cervical samples. The cytology was reported using Bethesda system, and Linear Array was used for further HPV genotype determination of 37 low and high-risk genotypes.

Results: During the research period, a total of 158 hrHPV-positive cervical samples collected from Pap positive young women from both counties were detected. HPV16 was detected in 20 and HPV18 in 13 out of 72 samples collected in CZ, while in SDC significant difference in prevalence of HPV 16 and HPV18 infection was observed with 37 HPV16 and only six HPV18 genotypes detected out of 86 samples tested ($p<0.05$). HPV 31 was detected in 15/72 and in 16/86 in CZ and SDC, respectively ($p>0.05$), and statistically significant difference was not observed for HPV33, 45, 52 and 58 as well. HPV 51 infection was significantly more prevalent among young women in CZ than in SDS ($p<0.05$). HPV coinfection with two or more HPV types was detected in 118 (74.7 %) samples with similar distribution of hrHPV monoinfection in both counties. LBC detected ASCUS in 60, LSIL in 77 and HSIL in 21 cervical samples without observed statistically significant differences between counties.

Conclusions: The observed differences in hrHPV genotypes distribution among adolescent and young women with positive cervical cytology in two Croatian counties reflects different prevalence of HPV genotypes in those regions and required further studies.

Shift 02-019 / #1058

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

NATURALLY ACQUIRED HPV16 ANTIBODIES AND RISK OF RECURRENT HPV INFECTIONS AND PRECANCEROUS CERVICAL LESIONS

Andrea Trevisan[1,2], João Candeias[3], Patrícia Thomann[4], Luisa Villa[5,6], Eduardo Franco[7], Helen Trottier[1,2]
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Introduction: Cervical HPV infections are very common, but little is known about the role of naturally acquired antibodies against HPV16 on recurrent infections and on the development of cervical lesions. Our objectives were to evaluate the association between HPV16 seropositivity and (i) recurrent infections; (ii) clearance of incident infections; and (iii) detection of cervical lesions.

Methods: We analyzed data from 2,462 Brazilian women who participated in the Ludwig-McGill cohort study on the natural history of cervical HPV infection. Seropositivity to HPV16 IgG and neutralizing antibodies at baseline were assessed in subsets of women by an enzyme-linked immunosorbent assay (n=1,975) and by an in vitro neutralization test (n=487), respectively. Detection, genotyping, and viral load of HPV DNA were assessed by polymerase chain reaction methods. Temporal associations were assessed by Cox proportional hazard models.

Results: We observed a positive association between IgG antibodies to HPV16 measured at baseline and re-detection of HPV16 DNA during follow-up. Age-adjusted hazard ratios (HR) with 95% confidence intervals (CI) ranged from 2.45 (CI: 1.04-5.74) to 5.10 (CI: 1.37-19.00) for new episodes of HPV16 DNA detection defined as preceded by two or three HPV negative tests in intervals of 4-6 months, respectively. Neutralizing antibody seroreactivity to HPV16 was not associated with HPV16 re-detection. HPV16 seropositivity was not statistically associated with HPV16 viral load at the follow-up visit when re-detection happened. Naturally acquired HPV16 antibodies were not statistically associated with incident infections, clearance of HPV infections, or detection of cervical lesions.

Conclusions: Naturally acquired antibodies to HPV16 do not seem to protect from HPV infections during follow-up. Our results suggested that overall anti-HPV16 IgG and neutralizing antibodies are serological markers for latent or past infections.

Shift 02-020 / #1101

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

PREVALENCE OF HPV INFECTION AMONG THAI SCHOOLGIRLS IN NORTH-EASTERN PROVINCES IN 2018; IMPLICATION FOR HPV IMMUNIZATION POLICY

Chulwoo Rhee[1], Pornjarim Nilyanimit[2], Nimesh Poudyal[3], Sompong Vongpunsawad[2], Suchada Jiamsiri[4], Hyeon Seon Ahn[5], Worrawan Klinsupa[4], Sunju Park[6], Jinae Lee[5], Hyeong-Won Seo[5], Nakorn Premsri[7], Chawetsan Namwat[4], Patummal Silaporn[4], Jean-Louis Excler[8], Deok-Ryun Kim[5], Lauri Markowitz[9], Supachai Rerks-Ngarm[4], Elizabeth Unger[10], Yong Poovorawan[2], Julia Lynch[11]
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Introduction: Human papillomavirus (HPV) vaccination for 9-14 years old girls and prioritization of multi-age cohort (MAC) catch-up immunization for girls up to 18 years of age are currently recommended. To inform HPV immunization policy in Thailand, we aimed to describe high-risk (HR) and vaccine-type HPV epidemiology among Thai high schoolgirls who were older than the targeted age (Grade 5, 10-11 years) for the national HPV immunization program.

Methods: Cross-sectional surveys were conducted among Grade 10 (15-16 years old) and Grade 12 (17-18 years old) schoolgirls in two north-eastern provinces of Thailand in 2018. After obtaining applicable consent or assent, urine samples were self-collected using Colli-Pee device from participating schoolgirls. All urine samples were tested by high throughput qualitative PCR assay, Cobas 4800 which reports individual HPV16, 18, and aggregated results of other 12 HR HPV types. Subsequently, all Cobas-positive samples and 1:1 matched adjacent Cobas-negative samples were tested by Anyplex PCR assay which identifies 28 individual HPV types. Prevalence of any HPV, any HR HPV, vaccine-type HPV, and individual HR HPV type infections were calculated for each school grade.

Results: In total, 4,914 Grade 10 schoolgirls and 3,660 Grade 12 schoolgirls were enrolled and analyzed. Prevalence of any HPV and any HR HPV infection was estimated at 11.6% and 8.6% for Grade 10 respectively and 12.4% and 18.5% for Grade 12 schoolgirls. Prevalence of bivalent vaccine-type HPV infection in Grade 10/12 was 3.4%/4.5% but increased to 4.0%/6.6% and 6.4%/10.4% respectively for quadrivalent and nonavalent vaccine-type HPV infection. HPV 16 was the most common type in both school grades, followed by HPV 58, 51, and 52. Distribution of circulating HPV types were similar between the grades.

Conclusions: We found substantial burden of HPV infections among unvaccinated high schoolgirls. HPV prevalence was higher in Grade 12 than Grade 10, however circulating types were similar.

Shift 02-021 / #1338

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

ASSESSMENT OF RELATIVE CONTRIBUTIONS OF LIFESTYLE, BEHAVIORAL AND BIOLOGICAL RISK FACTORS FOR CERVICAL HUMAN PAPILLOMAVIRUS INFECTION IN FEMALE SEX WORKERS

Imran Morhason-Bello[1], Kyeezu Kim[2], Yinan Zheng[2,3], Isaac Adewole[4], Miquel Angel Pavon Ribas[5], Kathy Baisley[6], Mamoudou Maiga[2,3], Musa Jonah[3,7], Elizabeth Christian[3], Jane Holl[8], Lifang Hou[2,3], Suzanna Francis[9], Deborah Watson-Jones[10,11]
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Introduction: The persistence of human papillomavirus (HPV) is a necessary cause of cervical cancer. Socioeconomic, lifestyle, behavioral, and biological risk factors associated with cervical HPV infection are sometime correlated. It is important to know the contribution of each factor to better design public health promotional messages.

Methods: This was a cross-sectional study among female sex workers (FSW) in Ibadan, Nigeria. We used the following variables for analysis: Income, duration of sex work, years of education, the total number of vaginal sex partners, age at first vaginal sex, age of first vaginal sex partner, number of weekly transactional sex, alcohol consumption, and number of other sites with HPV infection (anal, oral, and vulva). We used quantile-based g-computation (QGC) to investigate the relative contribution of each factor to the overall association with any HPV, multiple HPV or high-risk HPV in the cervix. We performed multivariable logistic regression to compare independent risk factors for the four outcomes.

Results: In total 218 FSWs had complete data on HPV genotypes, lifestyle, behavioral and biological factors. Of the nine potential risk factors considered, the number of other anatomic sites positive for HPV contributed highest (62%) to the overall positive association of having multiple cervical HPV (QGC weight=0.616). The relative contributions of the number of HPV infections in other anatomic sites were highest for having any HPV (59%), multiple hrHPV (58%), and any hrHPV (40%). The number of other anatomic sites with HPV infection also showed the strongest association with having cervical HPV infections in multivariable logistic regression models (odds ratios ranged from 2.4-4.6, p-values <0.001 for models with the four outcomes).

Conclusions: HPV infection in multiple anatomic sites relative to lifestyle and behavioral factors showed the highest contribution to having cervical HPV. We recommend screening for cervical HPV in women that have HPV in other sites.

Shift 02-022 / #1497

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

RISK FACTORS ASSOCIATED WITH PRECANCEROUS LESIONS IN HPV-POSITIVE WOMEN OF THE ESTAMPA STUDY IN BOLIVIA

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Introduction: In Bolivia, cervical cancer (CC) is the most common cancer with the highest incidence and mortality rates of Latin America: 36.6 and 18.8 per 100,000 respectively. Our aim was to examine risk factors for high-grade cervical lesions (CIN2+) among HPV positive women within the ESTAMPA study in Sucre, Bolivia.

Methods: ESTAMPA is a cross-sectional screening study at which women aged 30-64 years are screened with HPV testing and cytology and those who screened positive are referred to colposcopy, biopsy and treatment as needed. Structured questionnaires on sociodemographic characteristics and risk factors for CIN2+ were administered to participants. Women with negative colposcopy (and no biopsy) and those with negative histology were considered free of disease. Univariate and multivariate logistic regression analyses were used to examine factors associated with CIN2+, using R and Stata/BE 17.0

Results: Between 2018-2021, 3069 women were screened and 347 were HPV-positive. Among them, the prevalence of cervical intraepithelial neoplasia CIN1, CIN2, CIN3+ was 12.4% (95%CI 8.8;16.0), 7.5% (95%CI4.6;10.4) and 7.8% (95CI%4.8;10.7) respectively, while 49 women (14.1%,95%CI 10.3;17.9) had negative biopsies and 202 (58.2%,95%CI 52.9;63.5) had negative colposcopy and no biopsies were collected. Multivariate logistic regression analysis showed that non-professional or temporary work compared to professional or regular employment (aOR=2.3, 95%CI1.2;4.2) and ever use of hormonal contraceptive implant ever compared to never use (aOR=2.4, 95%CI1.1;5.0) were associated with risk of CIN2+, on the contrary ever using IUD was protective (aOR=0.4, 95%CI0.2;0.9). No associations were observed for tobacco consumption or
parity.

Table 1. Association of characteristics with HSIL

Characteristic	Total	CIN2+	<CIN2	cOR [95%CI]*	P-value†	age aOR‡	P-value‡
	N=347 (100.0%)	n=53 (15.3%)	n=294 (84.7%)				
District of residence							
Periferic	194 (55.9%)	35 (66.0%)	159 (54.1%)	Ref.		Ref.	
Central	153 (44.1%)	18 (34.0%)	135 (45.9%)	1.6 [0.9;3.0]	0.103	1.6 [0.9;3.0]	0.068
Age							
30 to 39	178 (51.3%)	33 (62.3%)	145 (49.3%)	Ref.			
40 to 64	169 (48.7%)	20 (37.7%)	149 (50.7%)	1.7 [0.9;3.1]	0.081	--	--
Education level							
Incomplete secondary or less	107 (30.8%)	20 (37.7%)	87 (29.6%)	Ref.		Ref.	
Complete secondary or more	240 (69.2%)	33 (62.3%)	207 (70.4%)	1.4 [0.8;2.6]	0.244	1.6 [0.9;3.0]	0.073
Activity head of family							
Unemployed/retired/home	17 (4.9%)	3 (5.66%)	14 (4.76%)	Ref.		Ref.	
Work	330 (95.1%)	50 (94.3%)	280 (95.2%)	1.2 [0.3;4.3]	0.784	1.2 [0.3;4.5]	0.208
Occupation of head of family							
Non-professional and temp work	157 (45.2%)	33 (62.3%)	124 (42.2%)	Ref.		Ref.	
Professional or regular employment	190 (54.8%)	20 (37.7%)	170 (57.8%)	**2.3 [1.2;4.1]**	**0.007**	**2.5 [1.4;4.6]**	**0.003**
Basic sanitation §							
Inadequate	65 (18.7%)	12 (22.6%)	53 (18.0%)	Ref.		Ref.	
Adequate	282 (81.3%)	41 (77.4%)	241 (82.0%)	1.3 [0.6;2.7]	0.437	1.3 [0.6;2.6]	0.170
Economic condition§							
Poor	52 (15.0%)	11 (20.8%)	41 (13.9%)	Ref.		Ref.	
Average and good	295 (85.0%)	42 (79.2%)	253 (86.1%)	1.6 [0.8;3.4]	0.218	1.8 [0.8;3.8]	0.073
Time since last PAP test							
≥2 y	146 (42.1%)	26 (49.1%)	120 (40.8%)	Ref.		Ref.	
<2 y	201 (57.9%)	27 (50.9%)	174 (59.2%)	1.4 [0.8;2.5]	0.266	1.4 [0.8;2.6]	0.106
Age of intercourse							
a) ≤16 y	80 (23.0%)	16 (30.2%)	64 (21.8%)	Ref.		Ref.	
b) ≥17 y	267 (77.0%)	37 (69.8%)	230 (78.2%)	1.6 [0.8;3.0]	0.192	1.6 [0.8;3.1]	0.083

Number of sexual partners in life							
2 or more	256 (73.8%)	38 (71.7%)	218 (74.1%)	Ref.		Ref.	
1 or less	91 (26.2%)	15 (28.3%)	76 (25.9%)	0.9 [0.5;1.7]	0.711	0.8 [0.4;1.6]	0.590
Number of pregnancies							
2 or more	265 (76.4%)	40 (75.5%)	225 (76.5%)	Ref.		Ref.	
1 or less	82 (23.6%)	13 (24.5%)	69 (23.5%)	0.9 [0.5;1.9]	0.868	1.1 [0.5;2.7]	0.210
Condom use							
Yes	167 (48.1%)	25 (47.2%)	142 (48.3%)	Ref.		Ref.	
No	180 (51.9%)	28 (52.8%)	152 (51.7%)	1.0 [0.5;1.7]	0.880	0.9 [0.5;1.6]	0.200
Tobacco consumption							
Ever	120 (34.6%)	20 (37.7%)	100 (34.0%)	Ref.		Ref.	
Never	227 (65.4%)	33 (62.3%)	194 (66.0%)	1.2 [0.6;2.7]	0.602	1.2 [0.6;2.7]	0.191
Hormonal contraceptive pills use							
Ever	72 (20.8%)	13 (24.5%)	59 (20.1%)	Ref.		Ref.	
Never	275 (79.2%)	40 (75.5%)	235 (79.9%)	1.3 [0.6;2.6]	0.469	1.2 [0.6;2.4]	0.187
Hormonal contraceptive injections use							
Ever	112 (32.3%)	22 (41.5%)	90 (30.6%)	Ref.		Ref.	
Never	235 (67.7%)	31 (58.5%)	204 (69.4%)	1.6 [0.9;2.9]	0.125	1.5 [0.8;2.8]	0.093
Hormonal contraceptive implant use							
Ever	46 (22.6%)	12 (22.6%)	34 (11.6%)	Ref.		Ref.	
Never	301 (77.4%)	41 (77.4%)	260 (88.4%)	**2.2 [1.1;4.7]**	**0.040**	**1.9 [0.9;4.2]**	**0.059**
IUD use							
Ever	108 (31.1%)	9 (17.0%)	99 (33.7%)	Ref.		Ref.	
Never	239 (68.9%)	44 (83.0%)	195 (66.3%)	**0.4 [0.2;0.8]**	**0.011**	**0.4 [0.2;0.9]**	**0.015**

*Chi squared test. †Crude odds ratio of CIN2+. ‡Odds ratio of CIN2+ adjusted by age. §Basic Sanitation: inadequate (no water or bathroom inside house or no flushing toilet), adequate (water and bathroom inside house and flushing toilet. ||Economic condition: poor (no possession of electrical and electronic equipment), average & good (possession of electrical and electronic equipment). ¶Intrauterine Device

TABLE 2. Multivariate analysis of associated factors with HSIL

Characteristic	OR [95%CI]*	P value
Occupation of head of family		
Non-professional and temporary work	Ref.	
Professional or regular employment	2.3 [1.2;4.2]	**0.008**
Hormonal contraceptive implant use		
Ever	Ref.	
Never	2.4 [1.1;5.0]	**0.026**
IUD use		
Ever	Ref.	
Never	0.4 [0.2;0.9]	**0.027**

*Odds ratio of occupation of head family, hormonal contraceptive implant use, and IUD use.

Conclusions: Our data suggest that women with low socioeconomic status as reflected in the type of occupation and those who ever used contraceptive implants are at higher risk of having CIN2+. As reported by others, use of IUDs appears protective against disease. Important efforts for adequate screening and early diagnosis of precancerous lesions should be prioritised in Bolivia.

Shift 02-023 / #1532

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

PREVALENCE AND RISK FACTORS OF CERVICAL NON-16/18 HR-HPV INFECTION: BASELINE FINDINGS FROM AN HPV PERSISTENCE COHORT STUDY

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Introduction: Human papillomavirus (HPV) is the most common sexually transmitted virus worldwide. Most studies that report factors associated with the prevalence of cervical HPV infection are in cases related with HPV 16 and 18, and little is known about the sociodemographic and gynecological-obstetric cofactors associated with infection by other HR-HPV genotypes. The objective of this study was to analyze the prevalence of single and multiple Non-16/18 HR-HPV infection, and the associated risk factors within the baseline study of a cohort of HPV persistence.

Methods: Cross-sectional study nested to the baseline study of the dynamic cohort study of HPV persistence in women seen at clinic of dysplasia's of the Health Services of the State of Morelos, Mexico. Data collection consisted of a questionnaire in which sociodemographic, lifestyle and sexual behavior variables were assessed, in addition to a gynecological examination in which a colposcopic and HPV test was performed. Data were analyzed by bivariate and multivariate analysis to determine the association between lifestyle variables and non-16/18 HR-HPV infection status.

Results: A total of 373 women were recruited in the baseline study, the overall prevalence of general HR-HPV, single and coinfection non-16/18 HR-HPV infection was 69.97%, 27.6%, and 24.4%, respectively. The most prevalence HR-HPV genotypes in both single infections and coinfections were HPV-53(13.4%), HPV-58(10.9%), HPV-31(10.9%), HPV-66 (10.7%) and HPV-56 (6.9%). Statistical association was found between multiple non-16/18 HR-HPV infection with marital status, number of lifetime number of sexual partners, number of full–term pregnancies and history of smoking. In single non-16/18 HR-HPV infection was not found associations with the analyzed variables.

Conclusions: The prevalence of multiple non-16/18 HR-HPV infection and associated risk factors in the Mexican population analyzed were similar to those already reported in the literature for any high-risk HPV cervical infection.

Shift 02-024 / #1695

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03B. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (CERVIX)
04-20-2023 7:00 AM - 4:00 PM

TARGETED LITERATURE REVIEW: RISKS OF HPV INFECTION AND DISEASES IN INDIVIDUALS WITH AUTOIMMUNE DISEASES

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Introduction: HPV vaccination and screening programs in France are currently offered to the population according to their age. The immune status of individuals is currently not accounted for recommendations.

Methods: Literature (PubMed) was screened for English or French worldwide publications from January 2010 to December 2020 to identify and describe the burden and data gaps of HPV infections and diseases in individuals with autoimmune conditions. Focus was given to the six most prevalent autoimmune diseases in France: Hashimoto thyroiditis, Graves' disease, celiac disease, rheumatoid arthritis, type 1 diabetes mellitus and multiple sclerosis.

Results: A total of 501 records were identified following 66 PubMed database searches. In addition, 23 records were identified through other sources. Following review of all articles, 19 records were included in this targeted literature review. Only 3 out of the 6 autoimmune conditions studied had publications of interest: 1 for Celiac Disease, 12 for rheumatoid arthritis, 6 for type 1 diabetes mellitus and no records for Hashimoto thyroiditis, Graves' disease, or multiple sclerosis. This review identified populations potentially at risk for ano-genital and cervical precancerous lesions and cervical cancer, including patients with rheumatoid arthritis on biologic DMARDs (especially anti-TNF therapy) and patients with type 1 diabetes. For all the studied populations with autoimmune diseases, additional data are needed to determine with certainty their risk for HPV infection and related diseases including cancers.

Conclusions: This initial review shows data gaps that still need to be addressed and provide evidence for patient groups with trends of increased risk in HPV precancerous lesions and cancers. Additional studies are needed to confirm these trends, that could inform HPV vaccination and screening guidelines for these patients, which are currently age based.

Shift 02-025 / #646

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-20-2023 7:00 AM - 4:00 PM

ANAL CANCER, INFLAMMATION AND ACCELERATED AGING AMONG MEN WITH HIV

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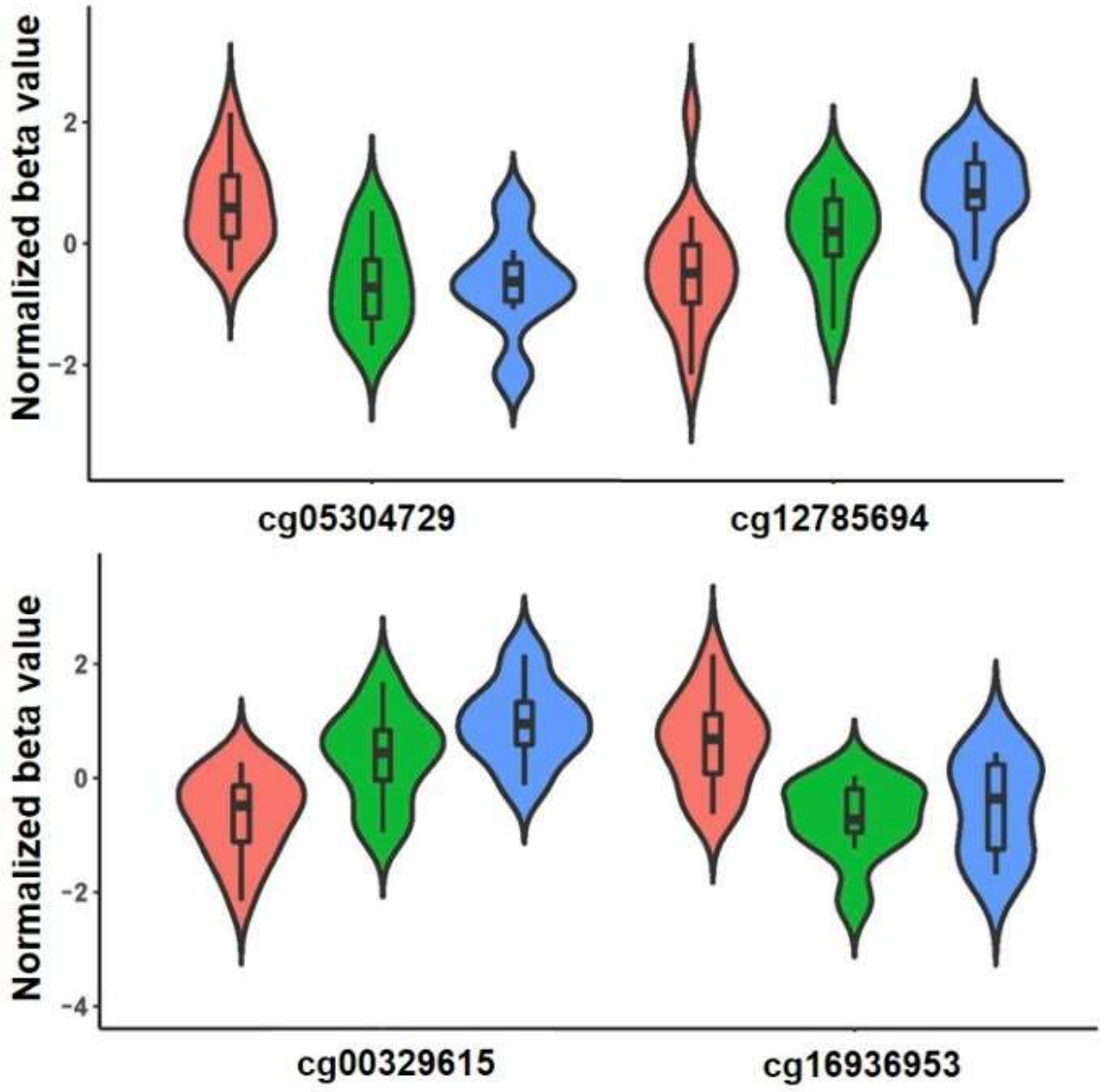
Introduction: HIV is associated with an increased risk for age-related conditions, including cancer. DNA methylation-based age (DNAmAge) is the most promising molecular estimator of biological age. We measured DNAmAge and inflammation-related CpGs and their associations with anal cancer and HSIL among men living with HIV.

Methods: Among men with HIV, we selected 16 anal cancers, 9 anal HSIL and 7 normal anal epithelium (controls) with pre-diagnostic PBMC biospecimens. DNA methylation was assessed using the MethylationEPIC BeadChip array. We investigated nine CpG sites that were previously reported to be associated with inflammation and assessed whether these CpG sites were associated with anal cancer and HSIL. We estimated the biological age, DNAmAge, using four algorithms, Hannum, PhenoAgeClock, Elastic Net and Best Linear Unbiased Prediction. We assessed age acceleration through regressing DNAmAge on chronological age and compared age acceleration between anal cancer, HSIL, and controls.

Results: For two inflammation-linked CpG sites, cg05304729 ($p=0.03$) and cg16936953 ($p=0.02$), higher methylation levels were significantly associated with an increased odds of anal cancer compared to controls (Figure 1). While for two other inflammation-linked CpG sites, cg12785694 ($p=0.02$) and cg00329615 ($p=0.05$), higher methylation levers were associated with a decreased odds of anal cancer compared to controls. Several inflammation-linked CpG methylation levels were marginally associated with HSIL. When we assessed differences in age acceleration between cancer cases and controls using Elastic Net, we found a significantly increased odds of age acceleration among cancer compared to controls ($p<0.05$). HSIL also had an increased odds of age acceleration compared to controls using PhenoAgeClock, but this was only marginally significant

(p=0.08).

Figure 1. Inflammation-linked CpGs comparing anal cancer (red), HSIL (green) and controls (blue)



Conclusions: We report accelerated aging and inflammation-related CpGs that may play a role in increased odds of anal cancer although we were limited by a small sample size. Further research in a larger cohort is underway to confirm these finds.

Shift 02-026 / #1158

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-20-2023 7:00 AM - 4:00 PM

NATURAL HISTORY OF HPV-ASSOCIATED HIGH-GRADE ANAL LESIONS IN MEN WHO HAVE SEX WITH MEN LIVING WITH HIV RECRUITED IN BARCELONA

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Introduction: Human Papiloma Virus (HPV) infection and the development of anal cancer is increasing in HIV-positive men who have sex with men (MSM). Most subjects who screen positive by HPV-DNA testing or cytology do not have concurrent precancer. We aim to estimate the anal HPV prevalence, indicence, clearance and progression of anal high-grade squamous intraepithelial lesions (HSIL) and predictors of HSIL in this cohort.

Methods: The ELAVI67-project, a prospective longitudinal study, includes samples from 354 MSM living with HIV recruited at baseline in Barcelona. The ELAVI67 cohort underwent anal cytology and high-resolution anoscopy with biopsy of suspected dysplasia areas every 6 (if HSIL) or 12 months. Composite cytological and histological results were used. HPV-DNA detection was performed by Linear Array® and Hybrid Capture®2 (HC2), and E6/E7-mRNA was tested using Aptima®.

Results: 354 participants were recruited with median follow-up (FU) of 33.7 months (IR: 25-42.3), mean age 45.2, mean CD4 801 cells/mm3 and 96.4% undetectable HIV-1 RNA viral load (VL). At baseline, 90/354 (25.4%) had HSIL, 1 progressed to superficially invasive squamous cell carcinoma within the first year. 289/354 had ≥ 2 years FU; 217/289 (75.1%) had no HSIL at baseline, progressing 62 to incident HSIL (iHSIL) (28.6%, 11 per 100 person-year (PY)). Of 103 participants with HSIL and ≥2 years FU, 49 had clearance of HSIL (cHSIL) (47.6%, 18 per 100 PY) and 54 persistent HSIL (pHSIL) (52.4%, 19 per 100 PY). HIV-1 RNA VL and several HPV biomarkers were associated with iHSIL (Table1), whereas only

HPV detected by HC2 HPV-DNA-test was associated with pHSIL (Table2).

Table 1. Participants with no HSIL at baseline (≥2 years FU)

	iHSIL (n=62)	Persistents no HSIL (n=155)	p-value
Undetectable HIV-RNA VL	77.42%	91.61%	**0.006**
LA HPV-DNA-test (14 HR-HPV genotypes)	75.81%	58.71%	**0.027**
LA HPV-DNA-test for HPV16	24.19%	10.97%	**0.02**
E6/7 mRNA-test	59.68%	30.32%	**<0.001**
E6/7 mRNA-test HPV16	17.74%	4.52%	**0.004**
E6/7 mRNA-test HPV16 and/or HPV18/45	24.19%	7.1%	**0.001**
HC2 HPV-DNA-test	48.39%	23.87%	**0.001**

Table 2. Participants with HSIL (≥2 years FU)

	cHSIL (n=49)	pHSIL (n=54)	p-value
Undetectable HIV-RNA VL	87.76%	77.78%	0.205
LA HPV-DNA-test (14 HR-HPV genotypes)	85.71%	90.74%	0.543
LA HPV-DNA-test for HPV16	32.65%	46.3%	0.226
E6/7 mRNA-test	67.35%	77.78%	0.334
E6/7 mRNA-test HPV16	30.61%	35.19%	0.777
E6/7 mRNA-test HPV16 and/or HPV18/45	32.65%	38.89%	0.65
HC2 HPV-DNA-test	51.02%	75.93%	**0.015**

Conclusions: Progression to iHSIL occurs in 11 per 100 PY and is associated with HIV-1 RNA VL and HPV-biomarkers, particularly E6/7-mRNA-test, an interesting biomarker for HSIL screening. Almost half of HSIL cleared during FU, therefore, finding biomarkers associated with cHSIL would help to select those HSILs requiring treatment.

Shift 02-027 / #1280

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-20-2023 7:00 AM - 4:00 PM

NATURAL HISTORY AND DETERMINANTS OF HUMAN PAPILLOMAVIRUS IN TRANSGENDER WOMEN AND MALE SEX WORKERS IN CATALONIA: SEXCOHORT STUDY

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Introduction: Trans women and cis-men sex workers (TWSW and MSW) are a vulnerable population for sexually transmitted infections. Historically, their sexual health has been little investigated; therefore, we aimed to study the anal and oral Human Papillomavirus (HPV) natural history and risk factors in TWSW and MSW.

Methods: The longitudinal Sexcohort project includes samples at baseline from 271 TWSW and MSW recruited between 2019-2020 in two community-based centres in Barcelona and 157 follow-up (FU) visits after 12 months. Biological samples were collected from different anatomical locations based on STIs screened infections. Anal (AC) and oral (OC) samples were HPV tested by AnyplexII-HPV28. Prevalence, clearance and incidence of non-type-specific (nts) HPV were calculated.

Results: HPV and High-Risk-HPV prevalence in the AC at baseline (85.9% and 73.0%) and FU visit (86.6% and 73.9%) was higher than in the OC (18.0% and 14.2% baseline and 13.4% and 8.8% FU). At baseline, participants HIV+ showed a higher HPV prevalence in the AC (97.1% vs. 82.9%) and OC (28.6% vs. 12.7%). Differences on HPV types were detected at both visits and sites. ntsAC-HPV was more persistent (92.6%) than ntsOC-HPV (53.8%), consequently, clearance was lower in ntsAC-HPV (7.4%) than in ntsOC-HPV (46.2%). ntsHPV incidence was also higher in the AC (47.6%) than in the OC (5.3%). Types included in the three HPV vaccines are more prevalent in the AC than in the OC at both time points. However, the vaccine-type specific relative contribution amongst HPV-positive cases in both locations is similar, except for nonavalent vaccine-type. Yet, only 3.7% declared having been immunized with HPV-vaccines.

Conclusions: High HPV prevalence, particularly in the anal canal, indicates that TWSW and MSW should be a priority population for prevention strategies. Undoubtedly, it is necessary to intensify primary prevention strategies and improve dissemination channels to facilitate access to free vaccination and information related to it.

Shift 02-028 / #1359

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-20-2023 7:00 AM - 4:00 PM

ANAL HUMAN PAPILLOMAVIRUS-RELATED DISEASE IN A CLINIC-BASED SAMPLE OF MEN LIVING WITH HIV

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Introduction: Prevalence of anal human papillomavirus (HPV) infection among immunosuppressed people is high compared to immunocompetent people and persistent infections, mainly with oncogenic types (HPV-16/18), can lead to low-grade squamous intraepithelial lesions and some may progress to high-grade lesions. High-grade anal intraepithelial neoplasia is driven by HPV infection and is considered a precursor lesion to invasive anal cancer. Anal cancer prevention strategies are not well defined, although it has been shown that adults benefit from vaccination if they have no preexisting infection with HPV-types included in the vaccine. We describe prevalence of anal high-risk HPV infection and presence of anal squamous intraepithelial lesions in men living with HIV.

Methods: Participants (18-60 years) were recruited from the Ambulatory Care Center for Prevention and Treatment of AIDS and Sexually Transmitted Infections in the central state of Morelos, Mexico, from November 2015 to December 2016. They were offered the bivalent HPV vaccine in a three-dose schedule (M0, M2 and M6). Before vaccination, a trained nurse collected a sample from the anal canal with a swab. DNA was extracted from the samples using the Cobas 4800 HPV test, for 14 hrHPV genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. After HPV determination, the remaining sample was sent to the pathology unit for cytological evaluation.

Results: A total of 178 men were included. Prevalence of any anal hrHPV was 80.9%, HPV16 prevalence was 24.16%, HPV18 prevalence was 22.47%. Prevalence of low-grade squamous intraepithelial lesions was 30.8% while for high-grade squamous intraepithelial lesion prevalence was 3.27%, both in HPV positive

men.

Table 1. Prevalence of HPV infection, warts and cytologic diagnosis of anal samples in men living with HIV.

Characteristics	Men (n=178)
Age, mean (SD)[a]	35±10.86
Anogenital condylomas (physical examination)	
No	123 (69.10)
Yes	55 (30.90)
hrHPV[b] detection	
Any hrHPV	
Negative	34 (19.10)
Positive	144 (80.90)
HPV-16[c]	
Negative	135 (75.84)
Positive	43 (24.16)
HPV-18[d]	
Negative	138 (77.53)
Positive	40 (22.47)
Other hrHPV	
Negative	44 (24.72)
Positive	134 (75.28)
Cytological diagnosis	
Cells within normal limits	65 (42.48)
Atypical squamous cells	22 (14.38)
Low grade intraepithelial lesion	61 (39.87)
High-grade intraepithelial lesion	5 (3.27)

a: SD: Standard deviation.

b: hrHPV: high-risk.

c: In 3 participants only the HPV-16 genotype was detected, the rest were accompanied by other high-risk HPV genotypes.

d: In 4 participants only the HPV-18 genotype was detected, the rest were accompanied by other high-risk HPV genotypes.

Conclusions: Prevalence of anal hrHPV infection in Mexican men living with HIV was high. A key strategy for anal cancer prevention is to implement HPV vaccination in a gender-neutral manner, and also vaccinate vulnerable adults.

Shift 02-029 / #1499

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-20-2023 7:00 AM - 4:00 PM

FACTORS ASSOCIATED WITH HUMAN PAPILLOMA VIRUS (HPV) INFECTION IN VULNERABLE GROUPS IN MEXICO

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Introduction: Human papillomavirus (HPV) infection is associated with various types of cancer in men and women. HPV-associated diseases such as cancer and genital warts have been linked to sexual behaviors and immunosuppression due to HIV. Incidence of some HPV-associated cancers, including anal cancer, is increasing in both sexes in many countries and particularly vulnerable groups have been identified. We explore factors associated with high-risk (hr) HPV infection in vulnerable groups in Mexico and the clinical utility of results.

Methods: The study included three populations: cisgender men who have sex with men (MSM, n=1850), cisgender women (CGW, n=395) and transgender women (TGW, n=178), 18-60 years, engaged in care in two HIV/STI clinics in Mexico City. Participants completed a questionnaire on sociodemographic characteristics and sexual risk behaviors. They self-collected vaginal (CW) or anal canal (MSM and TGW) samples for hrHPV detection. Risk factors and prevalence among TGW, CGW and MSM was compared using odds ratios (ORs) and 95% confidence intervals (CIs). Additionally, groups of participants were categorized according to living with HIV or history of sex work, and we built models based on previously identified characteristics to discriminate between groups with and without hrHPV infection, using ROC curves.

Results: For MSM characteristics indicative of hrHPV risk are: HIV+, age, doing sex work, lower education, age of first anal intercourse, STI symptoms/infection, receptive anal sex without condoms; accuracy=66.76%, sensitivity=84.31% and positive predictive value (PPV)=68.64. For TGW characteristics indicative of hrHPV risk are: age, occupation, age of hormonal treatment; accuracy=69.61%, sensitivity=87.5% and PPV=67.12%. For CGW, characteristics indicative of hrHPV risk are: age, marital status, occupation, drug use, number of recent sexual partners, casual sexual partners, sexual relations in exchange for something; precision=68.68%, specificity=79.75% and PPV=71.19%.

Conclusions: These characteristics can help identify the need for HPV screening or vaccination in specific healthcare users.

Shift 02-030 / #1513

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-20-2023 7:00 AM - 4:00 PM

TRANSGENDER WOMEN AND MEN WHO HAVE SEX WITH MEN: POPULATIONS WITH DIFFERENT RISK BEHAVIORS FOR ONCOGENIC GENOTYPES OF HUMAN PAPILLOMAVIRUS.

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Introduction: Prevalence of high-risk human papillomavirus (hrHPV), which can cause anogenital and oropharyngeal cancers, appears to be higher among transgender women (TGW) compared to men who have sex with men (MSM). However, little is known about differences in risk behaviors for hrHPV infection between these populations as they are often consolidated into a single group. We evaluated prevalence of anal oncogenic HPV genotypes and associated risk behaviors among TGW compared to MSM and present data stratified by sexual orientation and gender identity (cisgender MSM vs transgender women, who are heterosexual or attracted to men).

Methods: We enrolled TGW and MSM aged 18 to 60 years from two HIV/STI/transgender care clinics in Mexico City, 2018-2019. Participants self-reported sexual orientation, gender identity, HIV status, HPV knowledge and sexual risk behaviors. Self-collected anal samples were tested for hrHPV DNA (14 types. Prevalence among TGW and MSM was compared using odds ratios (ORs) and 95% confidence intervals (CIs).

Results: Of 1645 participants with valid samples, 122 were TGW and 1523 MSM. Any hrHPV DNA was detected in anal specimens from 67 (54.9%) TGW and 927 (60.9%) MSM. Factors associated with anal hrHPV among transgender women compared with MSM were age greater than 45 years (odds ratio [OR] = 6.7 95% CI = 2.2–20.0), HIV status (OR = 2.75, 95% CI = 2.12, 3.51) and frequency of receptive anal sex (OR = 2.24, 95% CI = 1.12, 3.61)

Conclusions: Among MSM and TGW, HPV prevalence was high, although it was slightly higher in MSM than TGW, and there were differences in related risk factors between each group, future research results should be disaggregated to allow optimal recommendations for each population according to your health needs.

Shift 02-031 / #1684

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-20-2023 7:00 AM - 4:00 PM

HIV PRE-EXPOSURE PROPHYLAXIS HAS NO IMPACT ON HPV TRANSMISSION AMONG MEN WHO HAVE SEX WITH MEN IN CHINA

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Introduction: There have been concerns that HIV preexposure prophylaxis (PrEP) may be associated with increases in HPV transmission because of subsequent reductions in increases in sexual partners. We aimed to assess the effects of PrEP on the HPV epidemic among men who have sex with men (MSM) in China.

Methods: Sexually active HIV-uninfected MSM aged≥18 years have been administered in an open ongoing observational cohort study of HPV since September 1, 2016 in China. Participants were followed up every 6 months for anal HPV testing and questionnaires about sexual behaviors. MSM who were willing to use PrEP were enrolled in an open-label intervention study of PrEP since November 2019. Based on the overlapped participants of these two studies, we compared the HPV prevalence, incidence and clearance between MSM using and not using PrEP. Prevalence ratios (PRs) incidence rate ratios (IRRs) and clearance rate ratios (CRRs) of MSM using and not using PrEP were calculated.

Results: A total of 859 HIV-negative MSM with a median age of 32 years (interquartile range [IQR]: 26 to 38) were included: of whom 429 initiated PrEP and 430 did not. Compared with MSM not using PrEP, the prevalence, incidence and clearance of individual HPV genotype did not differ significantly from MSM using PrEP. In particular, PRs for HPV 6, 11, 16, and 18 were 0.69 (95% confidence interval [CI]: 0.43-1.11), 1.12 (0.67-1.89), 0.97 (0.62-1.53), and 0.82 (0.45-1.51), respectively. IRRs for HPV 6, 11, 16, and 18 were 1.53 (0.41-5.66), 0.51 (0.16-1.57), 1.35 (0.52-3.47), and 0.64 (0.24-1.73), respectively. CRRs for HPV 6, 11, 16, and 18 were 1.38 (0.27-7.11), 0.91 (0.34-2.41), 0.31 (0.10-0.91), and 1.70 (0.63-4.60).

Conclusions: PrEP use may have no impact on HPV transmission among MSM. Our findings further extend the knowledge of the impact of PrEP on sexually transmitted infections.

Shift 02-032 / #1770

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-20-2023 7:00 AM - 4:00 PM

UNCOMMON HIGH-RISK HPV TYPES ASSOCIATED WITH CERVICAL LESIONS IN THE INDIGENOUS AND MARGINALIZED COMMUNITIES IN BOTSWANA.

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Introduction: Cervical cancer remains a public health problem with economies investing heavily to curb this global challenge that is threatening to collapse health systems, especially in LMICs. It is considered preventable with HPV vaccines and adequate screening. Prophylactic vaccines against most commonly detected hrHPV types are available. Despite efforts to improve access for nationwide screening, reports indicate that uptake by indigenous communities remains low. The study aim was to determine the burden of cervical lesions and associated risk factors in the indigenous and marginalized communities in Botswana.

Methods: This prospective study enrolled 220 consenting non-HPV vaccinated women aged 21 years and above for Pap smear screening, HPV & HIV testing and face-to-face interviews. Conventional pap smears were collected, and brushes preserved in PBS for hrHPV testing at the University of Botswana and Botswana Harvard Partnership research laboratories using the Ampfire Multiplex HR-HPV protocol.

Results: 98.6% of the participants consented to HIV testing and 31% were HIV+ve on ART program, higher than the national (24%) adult population prevalence. 10% of the women had cervical lesions with most women presenting with AGUS, ASC-H, ASCUS and LSIL. No SCC was detected. HR-HPV prevalence was 54% and the following types detected; HPV types 16, 18, 31, 35, 39, 45, 51, 52, 53, 56, 58, 59 and 68. In cervical lesions, HPV 52 (20%), HPV 53(10%) and HPV 56 (7%) were commonly detected. HPV 16 &18 were not detected in women with cervical lesions in this cohort.

Conclusions: This study reports types 52, 53, and 56 as commonly detected in women with cervical pre-malignant lesions in the marginalized and indigenous populations in Botswana. The significance of this epidemiologic shift needs to be established as these hrHPV types may increase the burden of non-vaccine HPV-associated cervical carcinogenesis in this region. These findings have direct policy implications on the current vaccine strategy.

Shift 02-033 / #1771

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-20-2023 7:00 AM - 4:00 PM

U.S. PREVALENCE OF ANAL CANCER SCREENING AMONG PERSONS WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV) AND AVAILABILITY OF HIGH RESOLUTION ANOSCOPY ONSITE AND BY ESTABLISHED REFERRAL

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Introduction: People with HIV (PWH) have elevated risk of anal cancer. Highly-affected groups of PWH include gay, bisexual, and other men who have sex with men, transgender women aged ≥35 years, and other PWH aged ≥45 years. Screening of highly-affected groups followed by treatment of precancerous lesions can reduce anal cancer incidence. We report prevalence of anal Pap testing and availability of high-resolution anoscopy (HRA) among PWH, overall and among highly-affected groups.

Methods: Data were obtained from CDC's 2019 Medical Monitoring Project, a population-based survey of PWH and a supplemental survey of HIV care facilities characteristics where participants received HIV care. We report weighted percentages of PWH receiving anal Pap testing during the past 24 months and access to HRA.

Results: Overall, 8% of PWH (age ≥18 years) had an anal Pap test in the prior 24 months. Only 16% of highly-affected groups were tested: 12% of gay, bisexual, and other men who have sex with men and transgender women aged ≥35 years and 4% of PWH aged ≥45 years. The prevalence of testing was low among PWH with the following characteristics: Non-Hispanic/Latino Black/African American, <high school education, unemployed/unable to work, public insurance only, heterosexual or straight, and <5 sexual partners in the past 12 months (range 3.9%-7.0%). About 22% received HIV care at a facility providing onsite HRA; 45% at a facility providing HRA by referral; and 33% at a facility not providing HRA onsite or by referral. High percentages of facilities receiving Ryan White HIV/AIDS Program funding, and those having higher HIV caseloads and providing onsite colposcopy and gynecologic care, provided HRA onsite/through referral (range 71%-77%).

Conclusions: Improving anal screening and access to HRA —particularly among highly-affected groups—could improve detection and treatment outcomes of anal cancer among PWH. Our data may inform large-scale implementation of anal cancer screening.

Shift 02-034 / #1824

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03C. EPIDEMIOLOGY: NATURAL HISTORY/RISK FACTORS (ANAL)
04-20-2023 7:00 AM - 4:00 PM

INTERNATIONAL TRENDS IN HPV RELATED ANAL CANCER INCIDENCE, 2000-2012

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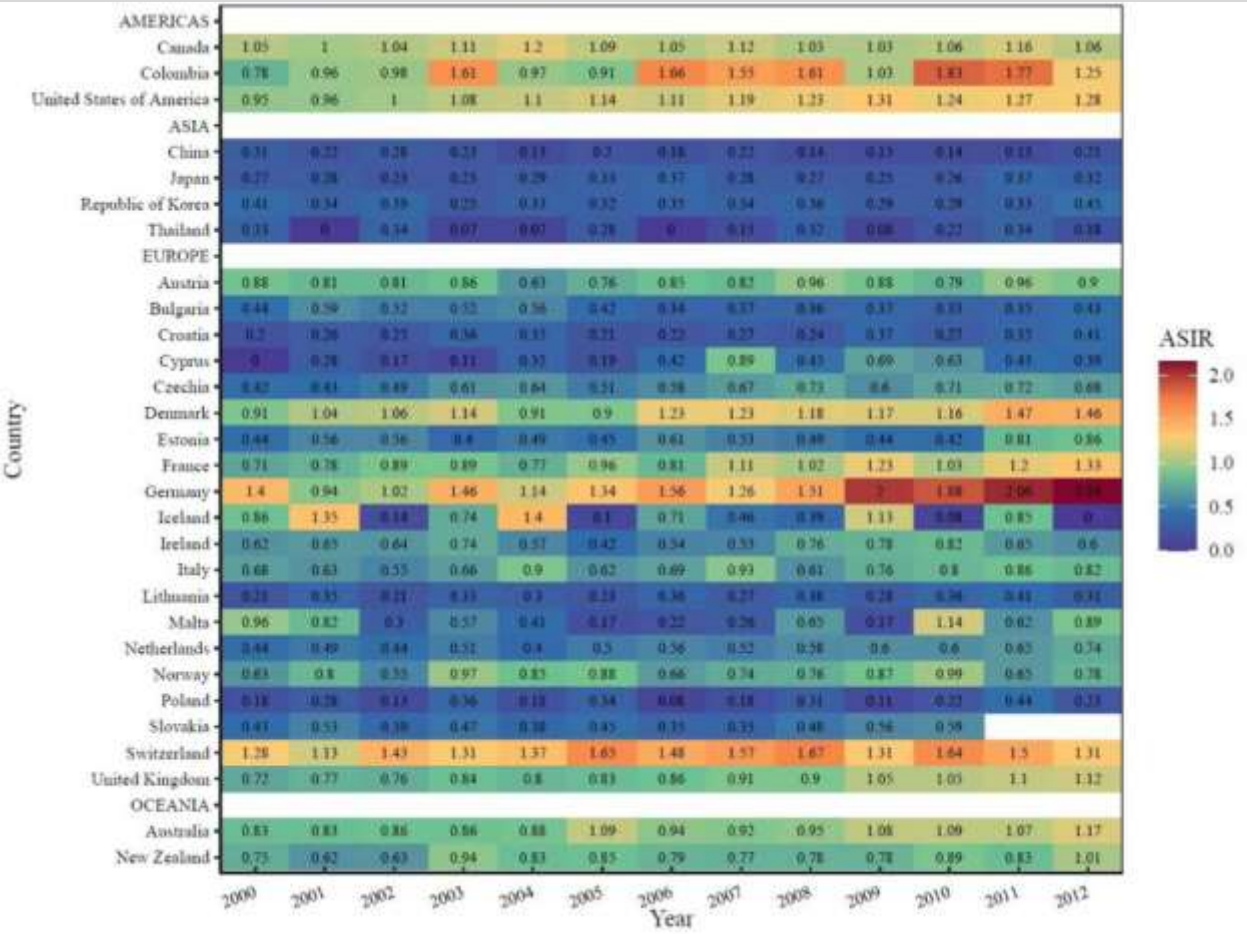
Introduction: Carcinogenic human papillomavirus（HPV）causes not only cervical cancer but also other tumors, so we aim to update the trends of HPV related anal cancer incidence in 31 countries between 2000 to 2012.

Methods: We gathered data from Cancer Incidence in Five Continents Volume XI and calculated the number of new cases and age-standardized incidence rates (ASIR) for anal cancer (AC) and its two main histological subtypes, anal squamous cell carcinoma (ASCC) and anal adenocarcinoma (AAC). The average annual percentage change (AAPC) with its 95% confidence interval was calculated to quantify the temporal trends by joinpoint regression models.

Results: In 2012, the ASIRs for AC (per 100 000 persons) ranged from 0.18 in Thailand to 2.1 in Germany, ranged from 0.01 in China to 1.39 in Germany for ASCC, and ranged from 0.06 in Lithuania to 0.66 in Malta for AAC. The incidence of ASCC was generally higher than that of AAC. From 2000 to 2012, the increase in ASIR for AC in both men and women was largely concentrated in several high-income countries, such as Germany (female:5.3; male:5.9), Denmark (female: 3.5; male: 3.3), and France (female: 4.7; male: 4.7), Netherlands (female: 4.2; male: 3.8), UK (female: 5.1; male: 2.1), and USA (female: 3.0; male: 1.9),whereas the incidence of AC increased only in women in Australia (female: 4.1), Canada (female: 1.8), and Czechia (female: 4.4). However, the incidence of AC has shown a significant downward trend in China (female: -5.4; male: -4.1), Bulgaria (male: -7.5) and Republic of Korea (male: -2.9). Meanwhile, the incidence of ASCC generally increased in most countries, except the Republic of Korea (male: -4.1). Conversely, the incidence of AAC decreased or was stable in most populations except Germany (female:
9.0).


AMERICAS
Canada 1.05 1 1.04 1.11 1.2 1.09 1.05 1.12 1.03 1.03 1.06 1.16 1.06
Colombia 0.78 0.96 0.98 1.61 0.97 0.91 1.06 1.55 1.61 1.03 1.83 1.77 1.25
United States of America 0.95 0.96 1 1.08 1.1 1.14 1.11 1.19 1.23 1.31 1.24 1.27 1.28
ASIA
China 0.31 0.22 0.28 0.23 0.13 0.2 0.18 0.22 0.14 0.13 0.14 0.13 0.23
Japan 0.27 0.28 0.23 0.25 0.29 0.13 0.17 0.28 0.27 0.25 0.26 0.37 0.32
Republic of Korea 0.41 0.34 0.39 0.23 0.33 0.32 0.35 0.34 0.36 0.29 0.29 0.33 0.43
Thailand 0.13 0 0.14 0.07 0.07 0.28 0 0.13 0.32 0.08 0.22 0.34 0.38
EUROPE
Austria 0.88 0.81 0.81 0.86 0.63 0.78 0.85 0.82 0.96 0.88 0.79 0.96 0.9
Bulgaria 0.44 0.59 0.52 0.52 0.56 0.42 0.34 0.37 0.36 0.37 0.33 0.33 0.43
Croatia 0.2 0.26 0.25 0.36 0.33 0.21 0.22 0.27 0.24 0.37 0.27 0.33 0.41
Cyprus 0 0.28 0.17 0.31 0.22 0.19 0.42 0.89 0.43 0.69 0.63 0.41 0.39
Czechia 0.42 0.41 0.49 0.61 0.64 0.21 0.58 0.67 0.73 0.6 0.71 0.72 0.68
Denmark 0.91 1.04 1.06 1.14 0.91 0.9 1.23 1.23 1.18 1.17 1.16 1.47 1.46
Estonia 0.44 0.56 0.56 0.8 0.49 0.45 0.61 0.53 0.89 0.44 0.42 0.81 0.86
France 0.71 0.78 0.89 0.89 0.77 0.96 0.81 1.11 1.02 1.23 1.03 1.2 1.33
Germany 1.4 0.94 1.02 1.46 1.14 1.34 1.56 1.26 1.51 2 1.88 2.06 2.19
Iceland 0.86 1.35 0.18 0.74 1.4 0.1 0.71 0.46 0.39 1.13 0.88 0.85 0
Ireland 0.62 0.65 0.64 0.74 0.57 0.42 0.54 0.53 0.76 0.78 0.82 0.85 0.6
Italy 0.68 0.63 0.55 0.66 0.9 0.62 0.69 0.93 0.61 0.76 0.8 0.86 0.82
Lithuania 0.23 0.35 0.21 0.33 0.3 0.23 0.36 0.27 0.18 0.28 0.36 0.41 0.31
Malta 0.96 0.82 0.3 0.57 0.43 0.17 0.22 0.26 0.65 0.17 1.14 0.62 0.89
Netherlands 0.44 0.49 0.44 0.51 0.4 0.5 0.56 0.52 0.58 0.6 0.6 0.65 0.74
Norway 0.63 0.8 0.55 0.97 0.85 0.88 0.66 0.74 0.76 0.87 0.99 0.65 0.78
Poland 0.18 0.28 0.13 0.36 0.18 0.34 0.08 0.18 0.31 0.31 0.32 0.44 0.33
Slovakia 0.43 0.53 0.38 0.47 0.38 0.45 0.35 0.35 0.48 0.56 0.58
Switzerland 1.28 1.13 1.43 1.31 1.37 1.65 1.48 1.57 1.67 1.31 1.64 1.5 1.31
United Kingdom 0.72 0.77 0.76 0.84 0.8 0.83 0.86 0.91 0.9 1.05 1.05 1.1 1.12
OCEANIA
Australia 0.83 0.83 0.88 0.86 0.88 1.09 0.94 0.92 0.95 1.08 1.09 1.07 1.17
New Zealand 0.73 0.92 0.63 0.94 0.83 0.85 0.79 0.77 0.78 0.78 0.89 0.83 1.01
Country
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012
Year
ASIR
2.0
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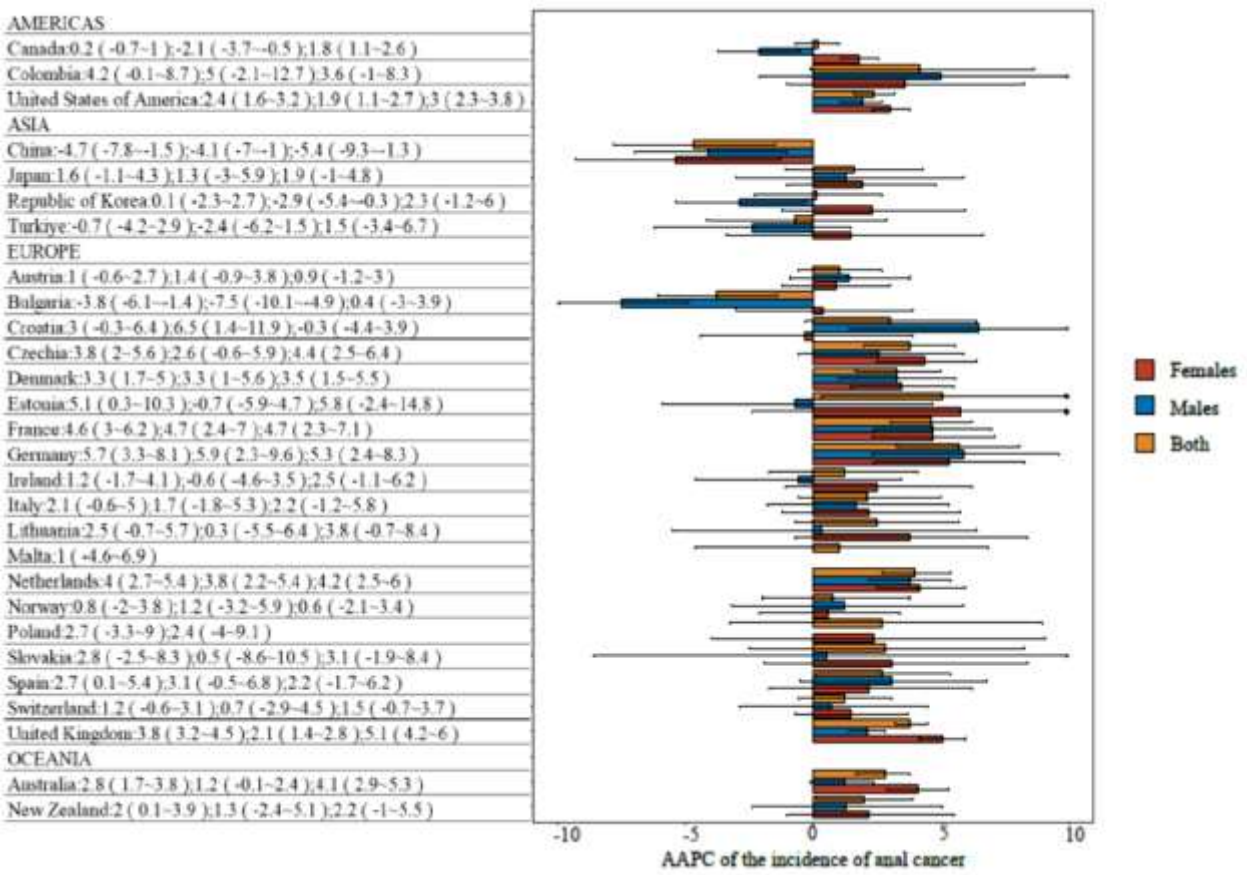

Conclusions: An increasing incidence of AC was observed in high-income countries, highlighting the need to promote the application of HPV vaccines, and to advance screening strategies.

Shift 02-035 / #97

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

COMPARISON OF THE PERFORMANCE, ACCEPTANCE, AND COMFORT OF TWO SAMPLING TECHNIQUES FOR HPV DNA DETECTION IN MALE GENITAL SITES

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Introduction: There is no global consensus regarding the sampling methods for HPV testing in male genital sites. We aimed to evaluate the performance, acceptance, and comfort of a modified sampling technique for HPV detection to facilitate population-based estimates of HPV prevalence in males.

Methods: We recruited 412 HIV-negative males aged 18-45 years in China. Two sampling techniques were randomised in a ratio of 1:1 to external genital, including penis/glans penis/coronary sulcus/scrotum (PGS), and perineum/perianal (PA) sites, which demonstrated as follows: 1) rubbing: a saline-moistened Dacron swab was used to brush after rubbing with a nail file; 2) brushing: directly brushing with a same swab. Each participant accepted two methods alternatively in the above sites. The samples with β-globin positive were recognized as valid for HPV PCR genotyping testing. The concentration of DNA extraction was assessed using NanoDrop 8000 in randomlly-selected 100 participants. Participants' acceptance and comfort of sampling were also collected using researcher-administered questionnaires.

Results: The positivity of brushing method for detecting 14 high-risk HPV (16/18/31/33/35/39/45/51/52/56/58/59/66/68)was non-inferiority to rubbing method in PGS (21.9% vs. 21.2%; P=0.005, 0.025 as the one-side P value of significance). Similar results were found in PA (15.3% vs. 14.9%, P=0.003). There were no statistically significant differences for positivie rates of other types between two methods, but unvalid rate of brushing method was statistically higher than rubbing in PA (8.2% vs 1.5%, P=0.001). The concentration of DNA in brushing samples were equivalent to rubbing in both sites (C_{PGS}: 16.33±17.37 ng/μl vs13.90±16.78 ng/μl,P_{PGS}=0.539; C_{PA}: 12.32±9.26 ng/μl vs 10.92±6.33 ng/μl, P_{PA}=0.110). The percentages of participants with good acceptance and comfort exceeded over 82% in both methods, irrespective of anatomical sites.

Conclusions: Our study suggests that both sampling techniques have similar good performance, acceptance and comfort for HPV genotyping testing, although only brushing with swab in PA sites shows a relatively high invalid rate.

Shift 02-036 / #368

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

CORRELATION OF HPV AND EBV CO-INFECTION WITH CYTOLOGICAL FINDINGS IN CERVICAL SAMPLES AMONG WOMEN ATTENDING KENYATTA NATIONAL HOSPITAL, NAIROBI, KENYA

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Introduction: Human Papilloma Virus (HPV) is associated with about 99.7% of cervical cancer which causes significant morbidity and mortality. Its incidence is high in countries like Kenya. Some studies show that interaction of two or more viruses increases the risk of tumorigeneses. HPV and Epstein Barr Virus (EBV) are correlated with 38% of all virus linked cancers

Methods: We used molecular testing to ascertain the presence of HPV and EBV co-infection in cervical samples of women from Kenyatta National Hospital for the period January to June 2018. We collected two samples from each participant; Liquid Based Cytology - Papanicolaou and molecular tests for Hybrid Capture 2(HC-2) and Polymerase Chain Reaction (PCR) were performed for HPV and EBV respectively.

Results: Of the 114 samples collected, 99 (86.8%) had no cervical lesions, 11 (9.6%) had microorganisms present, 32 (28.1%) were positive for high-risk HPV (HrHPV), 17 (14.9%) were also positive for EBV. The co-existence of HPV/EBV was in 6.1% of the cases. On microscopy, the lowest pre-cancerous lesion was Atypical Squamous Cells of Undetermined Significance (ASC-US) with 50% HrHPV but without EBV; Low Grade Squamous Intraepithelial Lesion (LGSIL) had 100% HrHPV with 50% EBV present while atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion (ASC-H) had similar findings as LGSIL. Table 1: Characteristics of Study Participants & Test

Results

Findings	Result	N (114)	n (%)
HIV Status	Positive	17	14.9%
	Negative	95	83.3%
	Unknown	2	1.8%
Cervical Lessions	NILM	99	86.8%
	LSIL	2	1.8%
	ASC-US	3	2.6%
	ASC-H	2	1.8%
	No sample/Insuffient sample	8	7.0%
Non neoplastic lesions	Negative	75	65.8%
	Inflammatory	27	23.7%
	Atrophic	6	5.3%
	Atrophic/Inflammatory	3	2.6%
	Insuffient	3	2.6%
Organisms	Negative	103	90.4%
	Candida	4	3.5%
	Bacterial Vaginosis	7	6.1%
HPV	Positive	32	28.1%
	Negative	82	71.9%
EBV	Positive	12	10.5%
	Negative	97	85.1%
	HPV & EBV Co-infection	7	6.1%

Conclusions: HPV/EBV dual infection exists most commonly in women with cervical lesions. This is consistent with the fact that HrHPV is present in almost all cervical cancer lesions and is more frequent as the lesion grade progresses, and so does the EBV virus.

Shift 02-037 / #550

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

PREVALENCE OF ORAL HUMAN PAPILLOMAVIRUS INFECTION AMONG HEALTHY POPULATION IN TAIWAN

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Introduction: Taiwan is one of the countries with the highest incidence (22.14 cases per 100,000 population in 2019) of head-and-neck cancer. Persistent oral Human papillomavirus (HPV) infection is recognized as a key contributing factor for head and neck cancer especially oropharyngeal cancer (OPC). However, the prevalence of oral HPV infection in Taiwan has never been evaluated. This study evaluated the overall prevalence of oral HPV infection among a healthy population, stratified by gender and age. We aimed to understand prevalence of HPV oral infection in both genders in Taiwan.

Methods: A non-interventional, cross-sectional study was conducted in 6 medical centers across Taiwan. Adult ages between 20 and 60 years old visiting the medicals clinic and without suspect head and neck precancerous lesions were included. Oral HPV prevalence was determined by detecting HPV DNA in oral rinse and gargle samples at a single timepoint by PCR at a central lab. Subject demographic, risk factors and sexual behavior were collected by questionnaire.

Results: 2,337 subjects (Male 1,103/Female 1,234) were enrolled. 18 male (1.6%) and 16 female (1.3%) subjects had any detectable HPV in oral gargle. Oral HPV DNA was detected in 1.0%, 1.3%, 1.6%, and 2.0 % of 20-30, 31-40, 41-50, and 51-60 year age group, respectively. Out of the positive samples, HPV type 18 (18%) and 52 (18%) were the most prevalent genotypes, followed by type 51 (9%) and type 16 (9%). 12% of DNA-positive subjects were infected by 2 types of HPV. HPV oral infection was associated with ever performed oral sex and higher number of oral sexual partners.

Conclusions: 1.3% - 1.6% of Taiwanese men and women has oral HPV infection with HPV 18 and 52 as leading oncogenic HPV genotypes. Findings highlight the increasing oral infection rate by age, and the need to expand HPV prevention in both genders.

Shift 02-038 / #555

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

COMPARISON OF CINTEC PLUS CYTOLOGY TEST AND QIASURE METHYLATION TEST IN TRIAGE OF HR-HPV POSITIVE, TWICE LBC NEGATIVE WOMEN.

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Introduction: Optimal triage of high-risk HPV-positive (HR-HPV(+)) women in molecular screening for cervical cancer is still to be determined. P16/Ki-67 dual staining and hypermethylation of the FAM19A4/hsa-mir124-2 gene promoters are promising triage methods in these women. We aimed to compare the performance of both methods in HR-HPV(+) twice LBC(-) women in an interim analysis of a pilot HPV study in Poland.

Methods: The HIPPO (HPV Testing In Polish POpulation-based cervical cancer screening program) is an ongoing randomised health services study nested in the Organised Cervical Cancer Screening Program. It assumes inclusion of 33,000 women aged 30-59 randomised in 1:1 ratio to either HR-HPV test or cytology. CINtec PLUS Cytology and QIASURE methylation tests are performed in primary HR-HPV(+) women with two negative LBCs at least 6 months apart. Either test positivity is an indication for colposcopy with biopsy. Positivity rates were calculated along with positive predictive values (PPVs) of colposcopy for detection of CIN2+ and a proxy of sensitivity for both triage tests.

Results: Among 13,925 women included in the HPV arm until August 15th, 2022, 139 (12.5%) had additional tests performed after HR-HPV(+) twice LBC(-) results: 23 methylation (16.5%) and 6 CINtec (4.3%) tests resulted positive (RR=3.8, 95%CI 1.6-9.1, p-value=.002). Among 27 women with colposcopy performed (19.4%), 4 cases of CIN2 were detected (14.8%): 3 among methylation(+) women (13.6%) and 1 in CINtec(+) patient (16.7%) (p-value=.625). Pointwise approximation of sensitivity of QIASURE compared to CINtec was 75% vs 25% but the difference was statistically insignificant (p-value=.317) (Tables 1-
2).

Table 1. Performance of additional tests in HR-HPV(+) twice LBC(-) women involved in the HIPPO study.

Performance of the test	QIASURE methylation test	CINtec PLUS Cytology	overall
women tested, N	139	139	139
positive results, N (% of women tested)	23 (16.5)	6 (4.3)	28 (20.1)
colposcopy performed, N (% of women tested)	22 (15.8)	6 (4.3)	27 (19.4)
CIN2+ detected, N (% of colposcopies performed / % of women tested)	3 (13.6 /2.2)	1 (16.7 / 0.7)	4 (14.8 / 2.9)

Table 2. Results of additional tests according to obtained histological examination results in HR-HPV(+) twice LBC(-) women involved in HIPPO study.

histology result	QIAsure methylation test (+)	CINtec PLUS Cytology (+)
no signs of dysplasia	12 (54.5)	3 (50.0)
CIN1	7 (31.8)	2 (33.3)
CIN2	3 (13.6)	1 (16.7)

Conclusions: Positivity rate is significantly higher for QIASURE compared to CINtec with low and comparable PPV for CIN2+ detection in HR-HPV(+) twice LBC(-) women. The difference in sensitivity for CIN2+ of QIASURE test compared with CINtec requires further verification on a larger group of patients which will be possible after the completion of the study.

Shift 02-039 / #601

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

PARTICIPATION IN THE NATIONAL CERVICAL SCREENING PROGRAM IN NSW WOMEN BY PLACE OF BIRTH: A DATA LINKAGE ANALYSIS USING THE 45 AND UP STUDY

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Introduction: The projected elimination of cervical cancer in Australia within the next decade is dependent on cervical screening. To ensure equity of elimination across the population, high participation in the National Cervical Screening Program (NCSP) must occur in all subgroups. We assess historical NCSP participation rates in immigrant women as a benchmark prior to the introduction of the 5-yearly HPV screening program, to identify where efforts should be focused to ensure equitable coverage across all immigrant subgroups.

Methods: Participation in the NCSP (≥1 cytology test) over a 3-year (2010-2012) and 5-year (2008-2012) period was assessed using individual-level linked data from women in NSW aged ≥45 years enrolled in the 45 and Up Study who were eligible for cervical screening. We considered country of birth, language spoken at home and years lived in Australia, adjusting for socio-demographic and health characteristics.

Results: Of 267,357 baseline 45 and Up Study participants, 67,350 women were eligible for screening between 2008-2012. Overall, 3-yearly participation was 77.0% (Table). Compared to Australian-born women, participation was significantly lower for women born in New Zealand (adjusted odds ratio [aOR] 0.77, 95% confidence interval [CI] 0.69-0.87), Oceania (0.67, 0.51-0.89), Middle East/North Africa (0.76, 0.60-0.97), South-East Asia (0.72, 0.60-0.87), Chinese Asia (0.82, 0.69-0.97), Japan/South Korea (0.68, 0.50-0.94) and Southern/Central Asia (0.54,0.43-0.67), but higher for women born in Malta (2.85, 1.77-4.58) and South America (1.33, 1.01-1.75). Participation increased with years lived in Australia but remained lower than for the Australian-born for most overseas-born women 20+ years post-immigration. Similar odds ratios were seen for 5-yearly

participation.

Table: Associations between 3-yearly (2010-2012) and 5-yearly (2008-2012) participation in the cervical cancer screening program† by place of birth and language spoken at home

	3-year participation			5-year participation		
	n/N (%)	Unadjusted OR (95% CI)	Adjusted OR* (95% CI)	n/N (%)	Unadjusted OR (95% CI)	Adjusted OR* (95% CI)
Total	49,086/63,772 (77.0)			52,693/62,882 (83.8)		
Place of birth						
Australia	37,758/48,525 (77.8)	Reference	Reference	40,408/47,805 (84.5)	Reference	Reference
New Zealand	1,030/1,441 (71.5)	*0.71 (0.64-0.80)*	*0.77 (0.69-0.87)*	1,148/1,426 (80.5)	*0.76 (0.66-0.86)*	*0.82 (0.72-0.95)*
Oceania[1]	182/269 (67.7)	*0.60 (0.46-0.77)*	*0.67 (0.51-0.89)*	198/266 (74.4)	*0.53 (0.40-0.70)*	*0.62 (0.46-0.83)*
United Kingdom & Ireland	4,281/5,522 (77.5)	0.98 (0.92-1.05)	1.01 (0.95-1.09)	4,604/5,465 84.3)	0.98 (0.91-1.06)	1.03 (0.95-1.11)
Germany	435/600 (72.5)	*0.75 (0.63-0.90)*	0.92 (0.76-1.11)	465/592 (78.6)	*0.67 (0.55-0.82)*	0.85 (0.69-1.05)
Netherlands	341/445 (76.6)	0.93 (0.75-1.17)	1.04 (0.83-1.31)	359/433 (82.9)	0.89 (0.69-1.14)	1.01 (0.78-1.32)
North-West Europe[2]	341/455 (75.0)	0.85 (0.69-1.06)	0.96 (0.77-1.20)	374/450 (83.1)	0.90 (0.70-1.15)	1.03 (0.79-1.34)
Italy	228/298 (76.5)	0.93 (0.73-1.22)	1.08 (0.83-1.43)	251/296 (84.8)	1.02 (0.74-1.40)	1.26 (0.91-1.76)
Malta	156/177 (88.1)	*2.12 (1.34-3.34)*	*2.85 (1.77-4.58)*	156/172 (90.7)	*1.78 (1.07-2.99)*	*2.58 (1.50-4.44)*
Southern Europe[3]	62/84 (73.8)	0.80 (0.49-1.31)	1.07 (0.65-1.78)	68/84 (81.0)	0.78 (0.45-1.34)	1.09 (0.62-1.92)
Greece	115/159 (72.3)	0.75 (0.53-1.06)	1.10 (0.76-1.59)	125/158 (79.1)	0.69 (0.47-1.02)	1.05 (0.70-1.57)
South-Eastern Europe[4]	245/345 (71.0)	*0.70 (0.55-0.88)*	1.02 (0.79-1.31)	270/341 (79.2)	*0.70 (0.54-0.91)*	1.10 (0.83-1.47)
Poland	91/127 (71.7)	0.72 (0.49-1.06)	0.94 (0.63-1.41)	100/128 (78.1)	*0.65 (0.43-0.99)*	0.93 (0.60-1.46)
Eastern Europe[5]	132/196 (67.4)	*0.59 (0.44-0.79)*	0.75 (0.55-1.03)	153/196 (78.1)	*0.65 (0.46-0.91)*	0.88 (0.63-1.26)
Lebanon	127/176 (72.2)	0.74 (0.53-1.03)	1.23 (0.86-1.76)	131/172 (76.2)	*0.58 (0.41-0.83)*	1.03 (0.70-1.51)
Middle East & North Africa[6]	240/368 (65.2)	*0.53 (0.43-0.66)*	*0.76 (0.60-0.97)*	260/365 (71.2)	*0.45 (0.36-0.57)*	*0.69 (0.53-0.89)*
Vietnam	198/273 (72.5)	*0.75 (0.58-0.98)*	1.13 (0.85-1.51)	213/271 (78.6)	*0.67 (0.50-0.90)*	1.12 (0.81-1.54)
Philippines	399/555 (71.9)	*0.73 (0.61-0.88)*	0.97 (0.79-1.19)	440/554 (79.4)	*0.71 (0.57-0.87)*	1.00 (0.79-1.26)
South-East Asia[7]	441/645 (68.4)	*0.62 (0.52-0.73)*	*0.72 (0.60-0.87)*	489/638 (76.7)	*0.60 (0.50-0.72)*	*0.74 (0.60-0.91)*
Chinese Asia[8]	682/945 (72.2)	*0.74 (0.64-0.85)*	*0.82 (0.69-0.97)*	743/940 (79.0)	*0.69 (0.59-0.81)*	*0.81 (0.67-0.98)*
Japan & South Korea	143/205 (69.8)	*0.66 (0.49-0.89)*	*0.68 (0.50-0.94)*	167/207 (80.7)	*0.76 (0.54-1.08)*	0.83 (0.58-1.19)
Southern & Central Asia[9]	256/396 (64.7)	*0.52 (0.42-0.64)*	*0.54 (0.43-0.67)*	275/386 (71.2)	*0.45 (0.36-0.57)*	*0.49 (0.38-0.62)*
Northern America	458/587 (78.0)	1.01 (0.83-1.23)	0.95 (0.78-1.16)	494/582 (84.9)	1.03 (0.82-1.29)	0.95 (0.75-1.21)
South America	261/341 (76.5)	0.93 (0.72-1.20)	*1.33 (1.01-1.75)*	287/333 (86.0)	1.14 (0.84-1.56)	1.80 (1.28-2.52)
Central America & Caribbean	26/34 (76.5)	0.93 (0.42-2.05)	0.93 (0.41-2.11)	31/34 (91.2)	1.89 (0.58-6.19)	2.11 (0.63-7.06)
Sub-Saharan Africa	458/604 (75.8)	0.89 (0.74-1.08)	0.84 (0.69-1.02)	484/588 (82.3)	0.85 (0.69-1.05)	*0.80 (0.64-1.00)*
p value		**<0.001**	**<0.001**		**<0.001**	**<0.001**
Language other than English spoken at home						
English speaker	44,490/57,340 (77.6)	Reference	Reference	47,667/56,502 (84.4)	Reference	Reference
Non-English speaker	4,596/6,432 (71.5)	*0.72 (0.68-0.77)*	*0.85 (0.78-0.93)*	5,026/6,380 (78.8)	*0.69 (0.65-0.73)*	*0.82 (0.75-0.91)*
p value		**<0.001**	**<0.001**		**<0.001**	**<0.001**

† The cervical cancer screening program consisted of 2-yearly conventional cytology with a reminder for screening sent at 27 months - the minimum analysis period chosen was three to allow some tolerance in attendance period.

OR: odds ratio; CI: confidence interval; * Adjusted for age on 31/12/2012, remoteness of residence at baseline, area-level socio-economic status at baseline, household income at baseline, high level of education at baseline, private health insurance status at baseline, parity at baseline, marital status at baseline, menopausal hormone therapy at baseline, smoking status at baseline, languages other than English spoken at home/place of birth (baseline is on the Baseline 45 and Up questionnaire);

1. Oceania excluding Australia & New Zealand; 2. North-West Europe excluding UK, Ireland, Germany & Netherlands; 3 Southern Europe excluding Italy and Malta; 4. South-Eastern Europe excluding Greece; 5. Eastern Europe excluding Poland; 6. Middle East & North Africa excluding Lebanon; 7. South-East Asia excluding Vietnam & Philippines; 8. Chinese Asia include China, Hong Kong, Macau, Mongolia and Taiwan; 9. Southern & Central Asia includes India, Pakistan

Conclusions: Women born in New Zealand, Oceania, Asia and the Middle East have lower participation in the NCSP than Australian-born women, which persists after immigration. The transition of the NCSP to primary HPV screening, and the recent option for universal self-collection, will offer new screening opportunities for these groups of women.

Shift 02-040 / #759

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

UNDERSTANDING THE INFLUENCE OF CERVICAL CANCER BELIEFS ON CERVICAL CANCER SCREENING AMONG HISPANIC WOMEN IN THE UNITED STATES

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Introduction: Hispanic women have a higher incidence of cervical cancer when compared to non-Hispanic whites, thus highlighting the importance of assessing barriers to cervical cancer screening. Various factors influence an individual's decision to obtain cervical cancer screening, including fear, knowledge, social influence, and familial history of a cancer diagnosis. To better understand the incidence of cervical cancer screening among Hispanic women, cervical cancer beliefs were assessed.

Methods: This study utilized a descriptive, correlational research design to understand the relationship between cervical cancer beliefs and cervical cancer screening. To achieve adequate power, a sample of 131 participants completed an online survey regarding cervical cancer screening. To assess cervical cancer beliefs, the Creencias Papanicolaou Cancer–28 (CPC-28) instrument was utilized.

Results: Pending: Data collection is still in process with over 80% of data collected. Remaining data collection and data analysis will be complete by December per study funding requirements.

Conclusions: Pending: Data collection is still in process with over 80% of data collected. The manuscript with findings will be complete by December per study funding requirements.

Shift 02-041 / #762

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

A COMPREHENSIVE UNIFIED HYBRID TRAINING MODEL ON CERVICAL CANCER HPV SCREENING AND THERMAL ABLATION TREATMENT FOR HEALTH PROVIDERS OF DIVERSE BACKGROUNDS

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Introduction: The Scale Up Cervical Cancer Elimination with Secondary Prevention Strategy – SUCCESS – Project supports the Guatemalan Ministry of Health (MOH) in its transition to HPV screening and treatment with thermal ablation. Implementation of the project is being done in 30 sites by a combination of nurses, auxiliary nurses and physicians who have varying degrees of training needs. Because of the COVID pandemic, opportunities allowed for the project and government to push their boundaries beyond typical educational approaches, and showcased the adaptive and flexible nature of facility staff to innovate and effectively navigate in the virtual space as in-person trainings were restricted Nov 2021 – Mar 2022 OBJETIVO DE LA CAPACITACIÓN.

Methods: A hybrid training program, based on the MOH updated technical guidelines for cervical cancer prevention and treatment, was developed including 3 components. The first is a virtual course on essential cervical cancer prevention content developed on the MOH e-learning platform including six weekly modules over. The second component uses a hybrid methodology, to allow practice on MOH updated information system, community interventions, and clinical skills for HPV screening and thermal ablation treatment of precancerous lesions. The third component is carried out at each participant's work place and includes necessary mentorship and certification of providers´ ability to carry out quality screening and treatment services.

Results: 126 providers (41 nurses, 46 auxiliary nurses and 39 physicians) were identified for training in the 30 sites, and they completed components -1 and 2; they await to participate in component-3.

Conclusions: Hybrid training is an effective means for reaching providers who are geographically dispersed and developing providers´ abilities in secondary cervical cancer prevention. Barriers include; providers' limited time to complete the online course and limited infrastructure for computer and online course. We recommend that these courses be part of a professional education system with credits, to ensure completion.

Shift 02-042 / #797

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

WHAT DOES EXTENDED GENOTYPING LOOK LIKE IN PRACTICE: REAL-WORLD EVIDENCE USING THE BD ONCLARITY ASSAY

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Introduction: The BD Onclarity HPV Assay received additional approval from FDA in 2021 to report extended genotypes, focusing on the 9-valent vaccine types. A study protocol was submitted to central Institutional Review Board (IRB) to collect de-identified extended genotyping information from routine clinical use and link it to cytology and histology outcomes. The study was determined to be exempt from IRB oversight per 45 CFR 46.104(d)(4).

Methods: Data from patients undergoing routine screening or referred for abnormal cytology or HPV results were collected, de-identified and then linked through the Laboratory Information System (LIS) to cytology and histology results. The data was then analyzed to investigate the contribution to disease of specific genotypes, stratified by age, cytology, and histology outcomes.

Results: To date, over 30,000 HPV tests representing over 3,000 HPV positive outcomes and over 100 cases of CIN2/3 disease have accrued. The results confirm findings from the BD Onclarity national registration trial and underline the important of HPV 31, second only to HPV 16, representing approximately 20% and 30% all disease cases, respectively. Age-stratification analysis of all HPV+ patients revealed that HPV 56_59_66 channel positivity was approximately 2-fold higher in women < 30 versus women > 50 years of age and that HPV 16 and other 9-valent infections increased with age, peaking in women 30-39.

Conclusions: The BD Onclarity extended genotyping results output allows clinicians to directly observe which high-risk types are contributing to disease and provide comprehensive risk assessment. HPV 31 was confirmed to be a major contributor to CIN2/3 disease and poses a sufficiently high risk to be referred directly to colposcopy. 9-valent vaccine types tend to peak in incidence in middle-aged women. The clinical utility of extended genotyping when combined with the ASCCP management principles of equal management of equal risk will be discussed.

Shift 02-043 / #812

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

EVALUATION OF HR-HPV TESTING OF SELF-COLLECTED VAGINAL SWABS COMBINED WITH VIA IN SCREENING FOR CERVICAL CANCER IN KENYAN AND UGANDAN WOMEN LIVING WITH HIV

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Introduction: High risk (HR)-HPV testing is available for cervical cancer screening in wealthier countries. However, HR-HPV testing has not been adequately studied in Africa. This study evaluated HR-HPV, VIA, and HR-HPV/VIA combinations for CIN2/3+ in Kenyan and Ugandan women.

Methods: Women living or not living with HIV (WLWH or WNLWH) aged 21 to 60 years provided self-collected vaginal swabs for HR-HPV testing (Roche Cobas Assay) and underwent VIA. Cervical biopsy was performed on all WLWH and on WNLWH with abnormal VIA. Sensitivity and specificity for biopsy-proven CIN2/3+ were estimated for both tests. CIN2/3+ detection among WLWH with combinations of HR-HPV and VIA results were also considered. CIN 2/3+ between WLWH and WNLWH were compared using chi-square tests.

Results: Of 240 women (121 WLWH, mean age 38.2 years; 119 WNLWH mean age 33.2 years), VIA was abnormal in 14.0% of WLWH and 3.4% of WNLWH (p=0.003); HR-HPV was detected in 42.1% of WLWH and 32.7% of WNLWH (p=0.149). VIA, HR-HPV, and biopsy results were available for 113 WLWH (Table 1). CIN2/3+ occurred in 10.6% of WLWH. Sensitivity/specificity of HR-HPV and VIA for biopsy-proven CIN2/3+ were 83.3%/63.4% and 50%/91.1% respectively. If HR-HPV-positive women (N=47) were subsequently assessed with VIA, this combined testing strategy would result in 83.3%/89.3% sensitivity/specificity, respectively, for detection of CIN2/3+ on biopsy.

Conclusions: CIN2/3+ occurred in 10.6% of WLWH. Future screening strategies could utilize HR-HPV testing as a triage for VIA, a test that lacks sensitivity but has good specificity for CIN2/3+ detection in WLWH. Table 1. CIN2/3+ detection in 113 WLWH with combinations of HR-HPV and VIA results

BIOPSY CIN2/3+	HR-HPV negative, VIA normal (N=61)	HR-HPV positive, VIA normal (N=37)	HR-HPV negative, VIA abnormal (N=5)	HR-HPV positive, VIA abnormal (N=10)
Negative	60 (98.4%)	32 (86.5%)	4 (80.0%)	5 (50.0%)
Positive	1 (1.6%)	5 (13.5%)	1 (20.0%)	5 (50.0%)

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IMPROVING CERVICAL SCREENING PROGRAMS AS A WAY TO ELIMINATE CERVICAL CANCER IN RUSSIA: EXPERIENCE, OPPORTUNITIES AND THREATS

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Introduction: At 72nd session of WHO Regional Committee for Europe 53 Members voted for a Roadmap to eliminate cervical cancer as a public health problem. This might come true if 90-70-90 ambitious goal is achieved by 2030. 100 000 women of 30-49 years should be screened in Kaliningrad Region from 2021 to demonstrate advantages of HPV testing in detection and treatment of HPV lesions and in protection of HPV negative women. Samples were collected simultaneously for HPV and cytology and triaged.

Methods: HC2 technique was chosen for HPV screening, triage was done by conventional cytology. ASC-US+ results were considered as abnormal. High risk (hrHPV)+ and PAP+ women were considered at risk and referred for colposcopy and biopsy for further histological examination. Unique pre-cancer electronic register was designed and used to ensure quality of screening and data storage.

Results: 32 201 women have been already tested. Women were invited for a screening by 37 Centers of Female's Health. 90,5% of the women had an adequate hrHPV test while 3 056 (9,5%) appeared to be hrHPV-positive. HrHPV-negative women were excluded from the screening for the next 10 years. A survey confirmed these women's satisfaction with regards to clinical outcomes and their protection against cervical cancer. HrHPV+ women were triaged by cytology. 2 140 HrHPV+ and PAP+ women were referred for colposcopy. All patients with histologically confirmed CIN 2+ were duly treated. 33 women with confirmed invasive cancer were referred to oncologists. Pre-cancer register used demonstrated high efficiency both in processing of patients data and in dividing different patient's streams especially during COVID-19 pandemic.

Conclusions: HrHPV-screening powered by novel pre-cancer register has proven to demonstrate considerable advantages in detection and treatment of women with cervical pre-cancer and cancer during an organized screening program in Kaliningrad Region and ensured long term protection of HrHPV-negative women.

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LONG-TERM FOLLOW-UP OF THE FINNISH RANDOMIZED HPV SCREENING TRIAL

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Introduction: Randomized controlled trials (RCTs) from high-resource countries have shown that a primary human papillomavirus (HPV) screening is more efficient in preventing invasive cervical cancers than a cytological screening. However, long-term effects of HPV screening on cervical cancer incidence and mortality are still missing. We conducted a long-term follow-up of the Finnish randomized HPV screening trial to assess these measures.

Methods: Since 2003, 118 000 individuals were randomized (1:1) to HPV and cytology screening in Southern Finland. Median follow-up time was 15 years. During 3.5 million person-years of follow-up, we observed a total of 129 cervical cancers in the cytology arm and 139 cancers in the HPV arm. To compare the study arms, we calculated the cervical cancer incidence and incidence-based mortality rate ratios using Poisson regression. We also assessed these by native language and education level. Analyses were performed following intention-to-treat -principle.

Results: The incidence rate ratio for cervical cancer was 1.08 (95 % CI 0.85–1.37) in the HPV arm compared to cytology arm. The mortality rate ratio for cervical cancer was 1.00 (95% CI 0.61–1.64) in the HPV arm compared to cytology arm. For non-native language the incidence rate ratio was 2.37 (95% CI 1.7–3.24) and mortality rate ratio 7.89 (95% CI 4.52–13.46) when compared to native language.

Conclusions: In our setting with highly effective cytological screening, HPV screening provided no added effectiveness to cervical cancer screening. We should focus on ensuring that the already established screening programmes reach all subpopulations equally.

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HOME-BASED ANAL PRECANCER SELF-SCREENING VS CLINIC SCREENING: INCREASED ENGAGEMENT IN HOME-BASED SCREENING WITH HIGH SPECIMEN ADEQUACY, THE PREVENT ANAL CANCER (PAC) SELF-SWAB STUDY (NCT03489707)

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Introduction: Depending on their age and HIV status, sexual minority men and transgender women (SMM/TW) may soon be asked to screen for anal cancer, a highly stigmatized condition. Since screening acceptability is central to screening programs, we evaluated screening engagement among individuals randomized to either home self-sampling or clinic-based sampling.

Methods: Community-recruited SMM/TW were randomized to receive a mailed self-sampling kit at home or to attend a clinic for swabbing by a clinician. Screening engagement was defined as returning a home-collected swab or attending a clinic swabbing. Specimen adequacy for HPV genotyping was assessed with SPH_{10}-$LiPA_{25}$. Intention-to-treat analyses were stratified by race-ethnicity and HIV status. Factors associated with screening engagement were assessed by multivariable logistic regression. Individuals randomized from January 2020 through July 2022 were included (n=215).

Results: Participant characteristics did not differ by study arm. Median age was 46 years, 28% were people living with HIV (PLH), and 65% were white non-Hispanic, 20% Black non-Hispanic, and 13% Hispanic. Screening engagement was higher for home-based sampling (90%) compared to clinic-based sampling (73%, p=0.001). Among PLH, 89% and 52% of home- and clinic-based individuals engaged in screening, respectively (p=0.002). Among Black individuals, 100% (25/25) in the home-based arm screened compared to 61% (11/18) in the clinic-based arm (p<0.001). Overall results did not change if randomization occurred pre-COVID-19 or during the pandemic. Specimen adequacy was >90% in both arms. Home-based participants had 3 times higher odds of screening engagement than clinic-based participants (adjusted OR (aOR) 3.38, 95% CI 1.48-7.69). Compared to individuals with ≤12 years of school, those with 16 years of school had 5 times higher odds of screening (aOR 5.58, 95% CI 1.45-21.51).

Conclusions: Self-collected anal swabs had high adequacy for HPV genotyping. PLH and Black non-Hispanic SMM/TW may be more likely to screen if given the opportunity to self-collect a swab at home.

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THE ROLE OF NON-MEDICAL PROVIDERS IN INCREASING ACCESS TO CERVICAL SCREENING: A SCOPING REVIEW

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Introduction: Cervical screening via self-sampling enables non-medical providers to be more widely involved in delivering or promoting cervical screening, across a wide range of settings. We undertook a scoping review of published literature to collate the role of non-medical providers in increasing cervical screening participation.

Methods: We searched three databases (MEDLINE, EMBASE and CINAHL) to identify scientific research articles referring to the role of non-medical providers in cervical screening published between 2016 and 2022 and extracted data using a standardised extraction tool.

Results: Our review identified 23 studies from a breadth of geographical and country-level income settings including Australia (n=1), Africa (n=4), Asia (n=2), Europe (n=2), North (n=10) and South (4) America. The included studies reported on a range of non-medical providers including community and lay health workers, community health educators, nurses and midwives involved in promoting or (via self-sampling) delivering cervical screening. Most studies focused on women aged 30+ years, who were not pregnant, from ethnic minority populations, living in rural and remote communities, or under-screened. Studies that used non-medical providers to deliver screening via self-sampling mostly offered it through home visits or community engagements. Other studies involved no change to how screening was delivered but involved non-medical providers in patient navigation activities, or delivering education or promotional activities relating to cervical screening. Studies that were randomised controlled trials (RCTs) (n=8) generally found a significant increase in screening uptake (odds ratio range: 1.11 – 42.73) for those receiving a non-medical provider delivered-intervention. In non-RCTs (n=15) where participants were offered screening including an option of self-collection, uptake ranged from 17% to 100%, although often from a low base (<10%) of screening participation.

Conclusions: Non-medical providers could play a wider and an important role in cervical screening, particularly in the context of self-sampling, and have the potential to increase access and equity in cervical screening.

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OPTIMISING REFERRAL TO COLPOSCOPY IN A NATIONAL HPV SCREENING PROGRAM

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Introduction: Following a review of national registry data, Australian cervical screening guidelines were updated to recommend that women aged <50 years with non-16/18 HPV detected and negative, ASC-US or LSIL cytology at both initial screening and a 12-month follow-up testing, return for another repeat HPV test in 12 months, rather than referring to colposcopy at 12 months.

Methods: A well-established model (Policy1-Cervix) was used to compare original and updated guidelines in terms of i) 20-year risk of cancer; ii) incremental number of colposcopies required to prevent a cervical cancer case, for original compared to updated guidelines (INNC). Findings were compared with previously established local benchmarks for: i) acceptable 20-year cancer risk for 12-month referral (1.4%; based on the earlier cytology program), and ii) an unfavourably high INNC (>341-401 per case prevented). Outcomes were examined in women aged 26, 36, or 46 at their 12-month repeat test in 2021 (representing women offered vaccination at age 12-13; offered vaccination at age 22-23; and not age-eligible for vaccination, respectively).

Results: The 20-year risk of cervical cancer marginally increased in women aged 46 (original guidelines 0.50% vs updated guidelines 0.58%) but remained well below the benchmark. The risk was even lower in younger cohorts who had been offered HPV vaccination (increase from 0.19% to 0.22% in women aged 36; 0.11% in both cases for women aged 26), and in all cases remained below the benchmark. Compared to the updated guidelines, the original guidelines required 605-7,170 additional colposcopies per cancer case prevented, much higher than the benchmark.

Conclusions: The updated guidelines for women with non-16/18 HPV and normal/low-grade cytology at 12-month repeat testing, represent a more favourable balance between benefits and harms. Countries introducing primary HPV screening should monitor and adapt triaging and referral processes in the light of initial experience and emerging evidence.

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MINIMAL ANXIETY AMONG SEXUAL MINORITY MEN PERFORMING ANAL SELF-EXAMS OR ANAL COMPANION EXAMS REGARDLESS OF POTENTIAL ABNORMALITIES: THE PREVENT ANAL CANCER PALPATION STUDY

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Introduction: Sexual minority men (SMM) have increased risk for anal cancer. The Prevent Anal Cancer Palpation Study evaluates if SMM and trans persons can accurately perform anal self-exams or companion exams (ASE/ACE) and the extent to which individuals experience anxiety if they detect an abnormality. This qualitative analysis aimed to describe participants' responses to performing an ASE/ACE.

Methods: Participants were recruited from Chicago and Houston. After persons were taught how to do an ASE/ACE at their initial study visit, a health care provider (HCP) performed a digital anal rectal examination (DARE), and then participants performed the ASE/ACE. An individual's result on the ASE/ACE and the HCP's DARE results were compared for concordance. All participants from January 2020 to October 2021 (n=349) with discordant or true positive results, and 5% of participants with true negative results, completed a 15-20 minute qualitative interview. A total of 126 recordings were transcribed and analyzed thematically.

Results: Participants were categorized based on concordance as true negative (2.4%), true positive (38.9%), false negative (33.3%), and false positive (n=25.4%). There were no differences in self-reported anxiety between participants by concordance category or HIV status. Across categories, participants described minimal anxiety even when a potential abnormality was detected. Participants described barriers to performing a DARE based on physical dexterity, self-reported sexual position, and racial/ethnic group affiliation.

Conclusions: Concerns that individuals would experience high anxiety when detecting an abnormality did not materialize. Encouraging SMM to perform an ASE/ACE as long as they contact a HCP when an abnormality is detected should have minimal effect on mental health. Future research should explore how to educate SMM with dexterity limitations and to what extent messaging needs to be tailored based on sexual position or racial/ethnic group affiliation.

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REACH, EFFECTIVENESS, ACCEPTABILITY AND IMPLEMENTATION OF AN HPV-BASED SCREENING STRATEGY FOR WOMEN LIVING WITH HIV IN ABIDJAN, CÔTE D'IVOIRE.

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Introduction: Cervical cancer is the fourth cause of cancer mortality worldwide with a higher incidence among women living with HIV (WLWHIV) even if preventable through effective screening. International recommendations support shifting to HPV-based screening, but its effectiveness in resources-constrained settings is underexplored. The AIMA-CC project aimed to assess the effectiveness and the implementation process of HPV-based screening in routine care delivered to WLWHIV in Abidjan, Côte d'Ivoire.

Methods: The screening strategy encompassed an HPV self-sampling at primary care, and same-day visual inspection (VIA) and treatment on-site. In an hybrid type I effectiveness-implementation study WLWHIV were recruited and followed for 12 months to assess screening effectiveness. Implementation process was deciphered through in-depth interviews with women and health providers. A mixed-method analysis using the RE-AIM framework was performed.

Results: From March 2019 to August 2021, 1,498 women were screened. Reach. The average of 4.3 (SD=2.43) women screened daily dropped in March 2020 due to the COVID pandemic. Effectiveness. Screening completeness was 87%. Out of 347 women treated, 96% completed the 12-month follow-up. Women were satisfied with the self-sampling procedure (92%) and further management (96%). 70% of women reported a high self-efficacy regarding self-sampling. Acceptability. Waiting time and the related anxiety hindered women's interest. Health providers considered the strategy efficient to prevent cancer, but inadequate for their internal organization and workload. Implementation. Same-day treatment was performed in 80% of cases. This did not affect the completeness, but reduced the satisfaction post-VIA (p=0.001). Involvement of health providers relied on a single champion. Power dynamic and tensions between gynaecologists and on-site medical doctors arose.

Conclusions: HPV-based screening for WLWHIV in primary care in Abidjan is feasible with a high screening completeness. The significant human resources it requires could hinder sustainability at primary care level. This study highlights key components to address to scale-up this screening strategy in similar settings.

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SCREENING FOR HPV-RELATED DISEASES AMONG MEN WHO HAVE SEX WITH MEN AND FEMALE SEX WORKERS IN CAMEROON (CASE OF ALCONDOMS CAMEROON)

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Introduction: HPV infections are almost always transmitted through sexual contact, with or without penetration. But for the remaining 10%, the complications are far from negligible as they are responsible for cancers. Condoms are not enough to protect against HPV infections. It is a very good way to avoid sexually transmitted infections, but it is less effective against HPV.

Methods: Sex workers and MSM have very common skin warts that appear on all genders on more than 150 strains ,40 affect the genitals, when these warts develop in the anal or genital area. It is estimated that about 80% of female sex workers and male sex workers will be infected with these viruses in their lifetime. Some of these human papillomaviruses (HPV16, HPV 18) are accompanied by the development of malignant tumours such as cervical cancer in women and anal cancer, penile cancer in men. However, a person can be a carrier of the virus without developing lesions. The challenge of screening is therefore to identify high-risk HPVs that can develop into cancer.

Results: In fiscal year 22 (FY22) between October 2021 and September 2022 Alcondoms Cameroon conducted screening and sensitisation activities for HPV and related diseases through the PROXIMITY project which is a screening, sensitisation and management of anal margin diseases among men who have sex with men and female sex workers. Alcondoms Cameroon screened 180 MSM and 80 condylomata registered and treated and 30 positive HIV tests. Among female sex workers we screened 100 TS.

Conclusions: Men have a particular susceptibility to HPV infection, as their natural immunity is likely to be less effective and screening for these cancers is clearly uneven, as there is no screening for anal, penile or ORL cancers, but there is for cervical cancers.
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CERVICAL CANCER SCREENING BASED ON FIRST-VOID URINE SELF-SAMPLING TO REACH UN(DER)-SCREENED WOMEN: STUDY PROTOCOL OF THE SCREENURSELF TRIAL

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Introduction: ScreenUrSelf aims to verify whether the offer of urine or vaginal self-sampling is more effective than an invitation letter to contact a physician for a Pap smear or no intervention, to generate participation in cervical screening without negatively impacting compliance to follow-up. Is home-collected urine sampling more preferred by un(der)-screened women than vaginal self-sampling? Can as such more women be reached that currently do not participate in organized screening?

Methods: To define which intervention is most effective to reach un(der)-screened women, a RCT will be embedded in the organized cervical screening program in Flanders (Belgium). Enrolling 48,000 women (30-64y) who are eligible for screening but did not respond to at least two invitation letters (≥six years not screened). Women will be randomized in six arms each comprising 8,000 women: two control (no intervention; recall invitation letter) and four intervention arms. Interventions consist of receipt of a first-void urine or vaginal self-sampling kit (opt-out scenario's) or receipt of a letter to order a first-void urine or vaginal self-sampling kit (opt-in scenario's).

Results: The primary outcome is the response rate: proportion of women that participate in each study arm within twelve months after initiation of the intervention (1/4/2023-31/3/2024). Response is defined as having a preventive cervical screen, by the self-sample or a Pap smear. Secondary study outcomes include percentage of screen positive women with follow-up, percentage of women with a positive screen test, PPV of a positive screen test, CIN2+ detection rate, preference and attitudes of women, age- and socioeconomic status-related differences in response rates, and cost-effectiveness outcomes.

Conclusions: Offering a cost-effective approach that reaches un(der)-screened women and assures compliance to follow-up should impact significantly on the burden of cervical cancer. If embedded in an organized screening program, this could positively impact both the patient's health as well as reduce costs for the healthcare system.

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ADHERENCE TO CERVICAL CANCER SCREENING AMONG EAST AFRICAN IMMIGRANTS IN WASHINGTON STATE

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Introduction: In the United States, East African immigrants (EAIs) have persistently low cervical cancer screening rates. To inform future interventions for EAIs, we investigated adherence to, and correlates of, cervical cancer screening (CCS) among EAIs in Washington State.

Methods: University of Washington Medicine (UWM) electronic medical records were examined to identify EAI females aged 21-65 years with ≥1 primary care clinic visit between 2017-2018. EAIs were identified based on self-reported language, country of birth, and/or ethnicity. CCS adherence was defined as documented Pap screening within ≤3.5 or co-testing ≤5.5 years. Potential correlates included age, requiring a language interpreter, comorbidity, social vulnerability, provider gender, duration of care at UWM, primary care visit frequency, and (if age-eligible) screening for breast and colorectal cancers. Univariate Poisson regression with robust standard errors was used to estimate prevalence ratios (PRs) and identify correlates of adherence.

Results: We identified 1,557 patients, including 569(40%) Ethiopian, 376(26%) Somalian, 274(19%) other Black/African/East African, and 103(7%) Eritrean. English was the preferred language for 34%, and 58% required a language interpreter. The majority (62%) were adherent, 11% were overdue, and 27% had no documented CCS. Factors associated with higher CCS adherence included not requiring a language interpreter (PR:1.15, 95%CI: 1.07-1.24), older age (PRs:1.52, 95%CI: 1.32-1.75 and 1.54, 95%CI: 1.33-1.78, respectively, for patients ages 31-40 and 41-50 vs 21-30 years), longer duration of care (PRs:1.32,95%CI: 1.18-1.48 and 1.43, 95%CI: 1.3-1.58, respectively, for 5-10 and >10 vs <5 years), higher visit frequency (PRs:1.23, 95%CI:1.1-1.37 and 1.45, 95%CI:1.31-1.59, respectively, for 3-5 and ≥6 vs 1-2 visits), and breast cancer screening adherence (PR:1.71, 95%CI: 1.45-2.02).

Conclusions: More than one-third of EAIs were overdue or had no documented CCS. Interventions focused on increasing healthcare access and utilization, and leveraging health encounters to address barriers faced by younger patients or those who use language interpreters could potentially increase CCS among EAIs.

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THE IMPORTANCE OF HPV MRNA GENOTYPE COMBINATIONS AMONG HIV POSITIVE AND NEGATIVE SOUTH AFRICAN WOMEN TO PREVENT CERVICAL CANCER - A CASE SERIES

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Introduction: Women living in countries with limited access to cervical cancer (CC) screening and HPV-vaccination may benefit from a “screen and treat” approach in prevention of CC. We assessed how test performances of two mRNA HPV-tests in a high prevalence HIV-population may affect CC prevention given treatment of all test positive women.

Methods: This case-series comprised 710 not pregnant, underscreened women, aged 25-65 years, with no known diseases in cervix uteri, recruited at three hospitals in South Africa. At the same visit, cervical sampling for cytology and HPV-testing were followed by visual inspection assessment, colposcopy, and biopsies. Both a 4-type and a 7-type HPV mRNA E6/E7 test (PreTect SEE_SA (16-18/45-35), PreTect HPV-Proofer'7 (16-18-31-33-45-52-58), PreTect AS, Norway) was performed on all samples, enabling evaluation of up to 8 genotype combinations. The preventive potential of the "screen and treat" strategy was estimated from published HPV-types isolated in CC tissue from patients at the same hospitals.

Results: The positivity rate more than doubled from a 3-type (16,18,45), (15.2%; 95% CI: 12.6-17.8) to the 8-type mRNA (31.5%; 95% CI: 28.8-34.9) combination. The prevalence of CIN3+ among HIV-positive (26.4%) was doubled that of HIV-negative women (12.9%) ($p<0.01$). With the 4-type combination (16,18,35,45), treating 20% of the entire population (30% of the HIV-positive, 10.7% of the HIV-negative population), will capture 41.1% of the prevailing CIN3-cases, which have the potential to prevent 77.6% (95% CI: 71.2-84.0) of the CC burden. Similarly, a 6-type combination (16,18,31,33,35,45) targets 25% of the population, captures 62% of CIN3 in the population, has the potential to prevent 85% of the CC disease (95% CI: 79.6-90.6).

Conclusions: A “screen and treat” strategy with mRNA HPV-tests in underscreened women may target the most progressive types for progression from CIN3 to invasive CC and reduce overtreatment in areas with limited resources for CC prevention.

Shift 02-055 / #989

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

USING BEST-WORST SCALING TO EXAMINE CANADIANS' PREFERENCES FOR HPV TEST-BASED PRIMARY CERVICAL CANCER SCREENING

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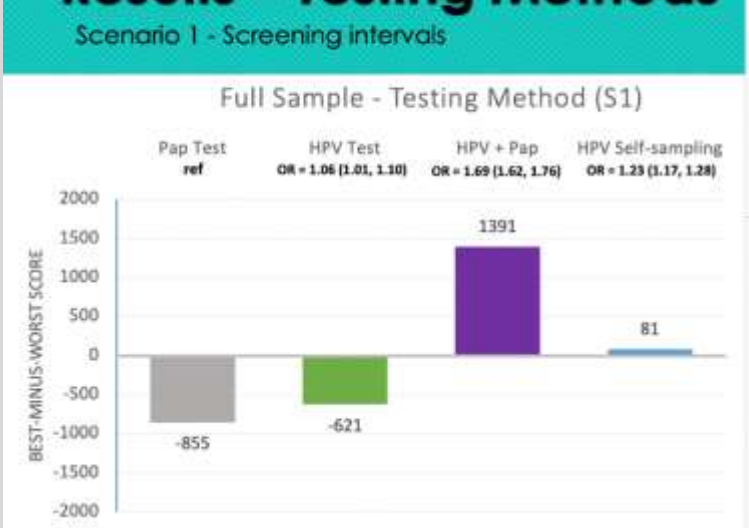
Introduction: In countries where HPV-based primary screening has been implemented, backlash has been frequent because of recommended increased screening intervals and later ages of initial screening. As most Canadian provinces are now planning to implement HPV-based screening, it is critical to examine Canadian women’s (and all people with a cervix) preferences for cervical cancer screening.

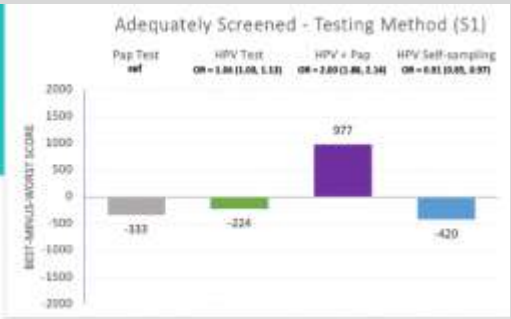
Methods: Participants, half of whom were underscreened (> 3 years since last Pap test) for cervical cancer, and half adequately screened (< 3 years since last Pap test) completed an online survey in October-November of 2021. Best-Worst Scaling methodology was used to conjointly assess preferences for cervical cancer screening methods (i.e., Pap, HPV, HPV and Pap co-testing, and self-sampling), and either length of screening intervals (Scenario 1; i.e., 3, 5, and 10 years), or ages of initial screening (Scenario 2; 21, 25, and 30 years). Data were analyzed for the whole sample, as well as the underscreened and adequately screened groups separately and preferences were estimated using conditional logistic regression and Best-minus-Worst scores.

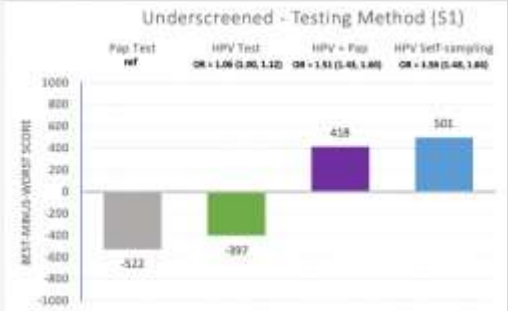
Results: A sample of N=1027 was analyzed. Compared to Pap, the adequately screened group preferred co-testing as a testing method. For the underscreened group, self-sampling and/or co-testing were both more preferred compared to the Pap test. Both the adequately and underscreened groups preferred testing at 3 year intervals over 5 year intervals and screening initiation at 21 or 25 years over 30 years.

Results – Testing Methods

Scenario 1 - Screening intervals

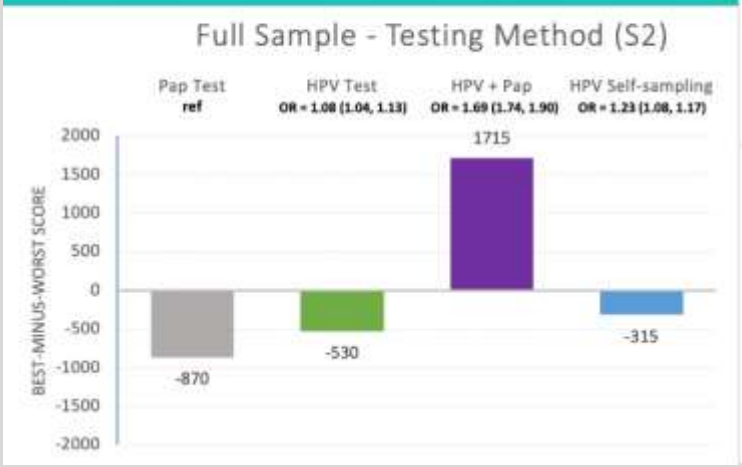


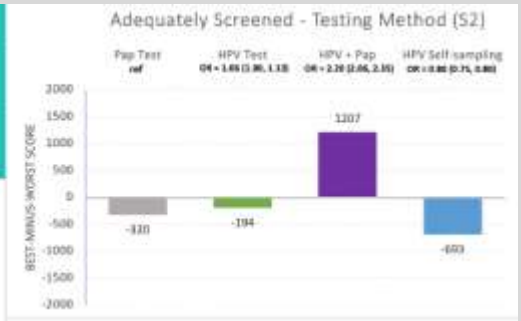


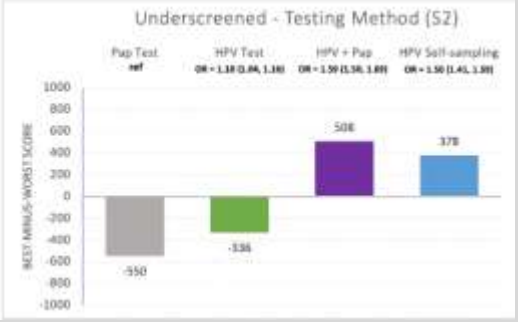


Results – Testing Methods

Scenario 2 - Age of screening initiation







Scenario 1: Screening Intervals

	Whole sample (n = 1027)		Adequately screened (n = 503)		Underscreened (n = 524)	
Attributes	**BWs**	**OR (95% CI)**	**BWs**	**OR (95% CI)**	**BWs**	**OR (95% CI)**
Pap Test	−895	ref	−353	ref	−523	ref
HPV Test	−621	1.06 (1.01; 1.10)	−224	1.06 (1.03; 1.13)	−397	1.06 (1.00; 1.12)
Pap and HPV test	1395	1.69 (1.62; 1.76)	977	2.00 (1.86; 2.14)	418	1.51 (1.43; 1.60)
HPV Self-Sampling	81	1.23 (1.17; 1.28)	−420	0.51 (0.45; 0.57)	501	1.56 (1.48; 1.65)
Levels for attribute: Pap test						
Every 3 years	306	1.75 (1.66; 1.84)	369	2.71 (2.51; 2.92)	−64	1.22 (1.14; 1.30)
Every 5 years	−108	ref	−44	ref	−64	ref
Every 10 years	−1062	0.49 (0.46; 0.51)	−658	0.31 (0.29; 0.33)	−394	0.68 (0.64; 0.73)
Levels for attribute: HPV test						
Every 3 years	341	1.65 (1.57; 1.73)	331	2.26 (2.13; 2.64)	10	1.28 (1.19; 1.38)
Every 5 years	−115	ref	−55	ref	−60	ref
Every 10 years	−847	0.54 (0.52; 0.57)	−500	0.39 (0.36; 0.42)	−347	0.69 (0.64; 0.73)
Levels for attribute: Pap and HPV test						
Every 3 years	1289	2.14 (2.03; 2.25)	938	3.61 (3.36; 3.94)	341	1.42 (1.33; 1.52)
Every 5 years	756	ref	443	ref	313	ref
Every 10 years	−650	0.56 (0.34; 0.38)	−414	0.22 (0.20; 0.24)	−236	0.52 (0.49; 0.56)
Levels for attribute: HPV self-sampling						
Every 3 years	585	1.68 (1.60; 1.77)	216	2.14 (1.99; 2.31)	369	1.42 (1.33; 1.52)
Every 5 years	243	ref	−44	ref	287	ref
Every 10 years	747	0.48 (0.46; 0.50)	392	0.27 (0.25; 0.30)	355	0.37 (0.33; 0.41)

Scenario 2: Ages of Initial Screening

	Whole sample (n = 1027)		Adequately screened (n = 503)		Underscreened (n = 524)	
Attributes	**BWs**	**OR (95% CI)**	**BWs**	**OR (95% CI)**	**BWs**	**OR (95% CI)**
Pap Test	−870	ref	−320	ref	−550	ref
HPV Test	−550	1.08 (1.04; 1.13)	−194	1.08 (1.00; 1.13)	−356	1.10 (1.06; 1.16)
Pap and HPV test	1715	1.82 (1.74; 1.90)	1207	2.20 (2.06; 2.35)	508	1.58 (1.50; 1.68)
HPV Self-Sampling	−315	1.12 (1.08; 1.17)	−691	0.80 (0.75; 0.85)	378	1.50 (1.41; 1.59)
Levels for attribute: Pap test						
21 years old	298	1.73 (1.63; 1.82)	305	2.33 (2.16; 2.50)	−9	1.36 (1.27; 1.46)
25 years old	−211	ref	−91	ref	−120	ref
30 years old	−952	0.54 (0.51; 0.56)	−531	0.41 (0.38; 0.44)	−421	0.66 (0.62; 0.7)
Levels for attribute: HPV test						
21 years old	421	1.72 (1.64; 1.81)	354	2.31 (2.14; 2.48)	67	1.36 (1.27; 1.46)
25 years old	−131	1.07 (1.01; 1.12)	−69	1.00 (0.90; 1.11)	−62	1.10 (1.03; 1.17)
30 years old	−820	ref	−479	ref	−341	ref
Levels for attribute: Pap and HPV test						
21 years old	1372	2.09 (1.99; 2.20)	961	3.17 (2.95; 3.43)	411	1.52 (1.42; 1.63)
25 years old	277	1.20 (1.14; 1.26)	497	1.19 (1.10; 1.28)	280	1.31 (1.13; 1.20)
30 years old	−434	ref	−251	ref	−183	ref
Levels for attribute: HPV self-sampling						
21 years old	387	1.58 (1.50; 1.66)	94	1.98 (1.84; 2.13)	293	1.34 (1.25; 1.43)
25 years old	37	1.15 (1.10; 1.21)	−158	1.17 (1.09; 1.26)	195	1.13 (1.06; 1.21)
30 years old	−739	ref	−629	ref	−110	ref

Conclusions: The results of our study suggest that increases to screening intervals and ages of screening initiation might be viewed unfavorably, and effective and targeted communication prior to implementation will be necessary. Co-testing is a highly acceptable option for most people, while HPV

test self-sampling is highly preferred for underscreened groups. Public health authorities should be careful to monitor population preferences during implementation.

Shift 02-056 / #1002

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

SMS INVITATION IN THE HPV-BASED CERVICAL CANCER SCREENING PROGRAMME IN CATALONIA (CERCA-SMS STUDY)

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Introduction: Catalonia, Spain, is shifting from opportunistic cytology-based cervical cancer screening (CCS) to an HPV-based organized program. In July 2021, a pilot started to establish the healthcare and information systems to introduce vaginal self-sampling via delivery through pharmacies. Women opportunistically seeking for CCS were contacted by phone to explain the new HPV screening and self-sampling program. As part of the pilot, the present study examined participation after an SMS (Short Message Service) invitation from the Health Department with a weblink for more information versus a phone call from the Cancer Screening Office (Interventional trial NCT05362669).

Methods: Up to 150 women per age group (30-40, 41-54, 55-65 years) were randomized into the intervention (SMS) or control (phone call) group to demonstrate non-inferiority of the SMS participation of 70% and that the absolute difference between the two arms (intervention vs control) was not inferior to -15%. Participation was defined as the proportion of invited women who collected the self-sampling device and returned the sample. Significance levels were set at 0.025 using one-sided Wald test.

Results: Among 450 women aged 30-65 years, participation was 82% and 80% in the intervention and control arms respectively, both non-inferior to 70% ($p<0.001$). Participation in the intervention arm was non-inferior to that in the control arm ($p<0.001$). Non-inferiority was also confirmed among women aged 30-40y (80% vs 75%, $p=0.003$) and 55-65y (89% vs 85%, $p<0.001$), but not for women aged 41-54y (77% vs 80%, $p=0.047$).

Conclusions: Participation was very high among women offered self-sampling when they seek for opportunistic CCS. Results show that receiving official SMS invitations to collect a self-sampling device at their pharmacy were sufficient for this group of women and not inferior to more individualized phone calls with verbal explanations.

Shift 02-057 / #1054

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

SELF-COLLECTION FOR CERVIX SCREENING IN NEVER AND UNDER-SCREENED IN THE BRITISH COLUMBIA, ORGANIZED CERVIX SCREENING POPULATION-BASED PROGRAM: PRELIMINARY PROGRAM FINDINGS

Gina Ogilvie[1], Laurie Smith[2], Edwin Khoo[2], Laura Gentile[3], Amy Booth[4], C.Sarai Racey[5], Brenda Smith[3], Stuart Peacock[2], Marette Lee[1], Gavin Stuart[1], Eduardo Franco[6], Lily Proctor[3], Dirk Van Niekerk[7]
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Introduction: HPV-based self-collection (HPV-SC) for cervix screening has the potential to improve screening coverage, particularly for the under-screened. British Columbia (BC), is poised to transform its longstanding population-based cervix screening program using cytology to an HPV-SC-based program. As part of the transformation, BC implemented a program offering HPV-SC to never and under-screened to assess feasibility and impact on screening coverage.

Methods: Individuals never-screened and >10yrs overdue for screening (Cohort1) and those 5 to <10yrs overdue (Cohort2) in select communities in BC were invited to participate. In each cohort, individuals were randomly allocated 2:1 to: 1) Invitation by mail to request a HPV-SC kit (Opt-in) or 2) Invited and sent a HPV-SC kit (Opt-out). Rates of uptake; kits requested and returned were compared between cohorts; and risk ratios between Opt-in and Opt-out within cohorts are presented.

Results: Between Dec2021 to June2022, 13,340 potentially eligible participants were identified: Cohort1, n = 8659; Cohort2, n=4681. In Cohort 1, 6,108 allocated to Opt-in, 765 (13%) requested a kit; 505(66%) returned kits for absolute return rate of 8% (505/6108). In Cohort 1, of 2,551 allocated to Opt-out, 562 (22%) returned kits. Opt-out participants were significantly more likely to return kits [RR: 2.66 (95%CI: 2.38, 2.98)]. In Cohort2, 3248 allocated to Opt-in, 711 (22%) requested a kit; 465 (65%) returned kits, for absolute return rate 14% (465/3248). In Cohort 2, of 1433 allocated to Opt-out, 390 (27%) returned kits. Opt-out participants were significantly more likely to return kits [RR: 1.90 (95%CI: 1.69, 2.14)].

Conclusions: This is the first North American HPV-SC implementation project fully embedded in an organized, population-based program. Our findings illustrate that mailed HPV-SC has the potential to increase screening coverage in the never/under-screened. Across cohorts, the Opt-out approach has a higher return rate than Opt-in. Additional data on HPV results and follow-up attendance will be presented.

Shift 02-058 / #1083

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

THE CONSTRUCTION AND PRELIMINARY VALIDATION OF CERVICAL PRECANCEROUS LESIONS SCREENING METHYLATION MARKERS BY RANDOM FOREST MODEL BASED ON A MULTIPLE-GENE PANEL

Yakun Wang[1], Tingting Chen[2], Changning Zhang[3], Jian Yin[4], Yu Dai[1], Yuan Yang[5], Xinyue Li[3], Tingyuan Li[6], Zhini Wang[7], Ziyue Huang[7], Hui Wang[7], Jinghong Yang[8], Jingchang Du[9], Wen Chen[1]
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Introduction: To establish a cervical precancerous lesions prediction model based on a multiple-gene panel.

Methods: Based on methylated genes identified by previous studies, 47 continuous high-association hypermethylated MHL loci regions of 25 genes that could identify women with ≥ CIN2 were screened. And we conducted three machine learning models, including random forest model based on 5-fold cross-validation, support vector machine model based on 5-fold cross-validation and Naive Bayes Model. 80 cytological samples were used for CpG site screening, among which 52 HR-HPV+ samples were used to establish human gene methylation model and internal validation of the model. And 101 HR-HPV positive cervical cytology samples were used to model validation of the human methylation index system.

Results: Using the area under the AUC as the evaluation criterion, the AUCs were: 0.92, 0.91 and 0.87. There was no significant difference in AUC among the three models, but there was a significant difference in specificity. Among the modeling samples, the specificity of random forest model and Naive Bayes model was 92.00(73.97-99.02) and 88.00(68.78-97.45), respectively, which was better than that of support vector machine model. The validation sample results showed that the specificity of random forest model was 92.31(74.87-99.05), showing stable performance.

Conclusions: Our results indicate that the random forest model of gene methylation is a promising and potential method for triaging HPV+ women. It can find methylated gene fragments that have a great impact on cervical cancer progression, and it is expected to explore more potential biomarkers of cervical cancer progression based on this result.

Shift 02-059 / #1094

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

ADHERENCE TO CERVICAL CANCER SCREENING IN MOROCCO

Aicha Yacouti[1], Abdeljalil El Got[1], A Aquil[1], Mm Ennaji[2], Rachida Baddou[2], A. Benider[3], Mustapha Mouallif[1]
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Introduction: In Morocco, cervical cancer is the second most common cancer affecting women after breast cancer. Encouraging more women to practice cervical cancer screening remains a major public health concern. There is a lack of data on awareness and of data concerning the determinants of the acceptability of Pap smear test in Morocco. To fill this gap, our study aims to assess the level of awareness of cervical cancer and Human papillomavirus (HPV) infection among Moroccan women and to understand the determinants of the acceptability of Pap smear test.

Methods: We conducted a cross-sectional study included 857 women in the following three Moroccan regions; Casablanca-settat, Marrakech-Safi and Tanger-Tetouan-Al Hoceima, by using a structured interviewer-administered questionnaire between November 2019 and February 2020

Results: Out of the total sample, almost 84% of participants were aware of cervical cancer, 87.2% of participants were unaware of HPV and almost 52% of participants were aware of Pap smear test. The rate of women who had ever had a Pap smear test in our population was only 19.36%. Moreover, our study revealed that more than 78% of participants were willing to undergo Pap smear test regularly in the future. The study revealed parity, age, educational level, risk perception and the belief that early screening improves the chances of successful treatment, as determinants of acceptability of Pap smear test.

Conclusions: Our results have shown that there is an urgent need to implement a strategy to sensitize women on the prevention of cervical cancer. Furthermore, the results of this study should be taken into account in the development of strategic and action plans for the prevention of cervical cancer.

Shift 02-060 / #1135

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

WOMEN AND ANAL DYSPLASIA ASSESSMENT (WANDA): A PILOT STUDY OF ANAL CANCER SCREENING IN WOMEN WITH A HISTORY OF HPV-RELATED LOWER GENITAL TRACT CANCERS

Mary Poynten[1], Fengyi Jin[1], Rhonda Farrell[2,3], Trevor Tejada-Berges[2], Carmella Law[1,4], Richard Hillman[1], Jennifer Roberts[5], Andrew Grulich[1]
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Introduction: Almost all anal cancer is caused by high-risk human papillomavirus (HRHPV). Women with prior lower genital tract cancers (LGT) are at disproportionate risk, with between 10-50 fold higher risk compared with women in the general population. There is no consensus on how to screen for anal HPV and cancer precursor lesions, high grade squamous intraepithelial lesions (HSIL). This pilot study aims to examine the uptake and results of an anal cancer screening program in women with prior LGT cancer.

Methods: Women diagnosed with cervical, vaginal or vulvar cancer, aged 18 years or older were enrolled at two clinical sites in Sydney, Australia. Participants underwent a digital anorectal examination (DARE), a lower vaginal/vulvar swab, a cervical/upper vaginal swab and an anal swab for HRHPV and p16/Ki67 testing, and completed a questionnaire on the acceptability of anal cancer screening. Participants with positive results were referred for a high resolution anoscopy (HRA).

Results: By October 2022, 48 participants were enrolled, with 7 providing demographic information only. Median age was 48 years (IQR 41-61). The majority of women had a history of cervical cancer (85.3%), with 7.3% vulvar and 7.3% vaginal cancer. Six (14.6%) had anal HRHPV detected (3 HPV16). Eight (19.5%) had positive p16/Ki67 staining, with invalid results for 23 (56.1%). Histology results were available for 4 of 9 women referred for HRA (2 normal, 2 HSIL). Thirty-four of the 41 participants completed questionnaires. The majority of participants reported that being screened was reassuring (33, 97.1%) and was positive for their health (33, 97.1%).

Conclusions: Anal HRHPV and p16/Ki67 detection was uncommon in this pilot study. The fact that half of the p16/Ki67 tests were unsatisfactory compromises the use of this test in screening. Anal cancer screening was viewed as a beneficial process by almost all participants.

Shift 02-061 / #1143

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

CAN HPV GENOTYPING AND CYTOLOGY TRIAGE FACILITATE HPV SCREENING OF PRIMARILY VACCINATED YOUNG WOMEN 23-29 YEARS OLD?

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Introduction: Primary HPV-screening of young women have been advised against on the premise that high HPV prevalence would lead to unnecessary referrals. The advent of the childhood HPV vaccinated women in the screening program, combined with molecular approaches to HPV-screening could change this dynamic in favor of HPV-screening. Here we present HPV prevalence and genotype frequencies in women age 23-29 attending the organized screening program in Denmark. The data is used to model referral outcomes using HPV-screening with HPV genotype and cytology triage.

Methods: 1000 SurePath cervical samples from women age 23-29 attending the cervical cancer screening program in the Capital Region of Denmark were collected, tested by the BD Onclarity HPV assay and combined with routine cytology outcomes. Referral rates were modelled upon the Danish algorithm for primary HPV screening for women age 30-59.

Results: Overall HPV positivity was 25%(N=252). Genotypes ranked by frequency was HPV18(0.8%), HPV16(2%), HPV31(5%), HPV45(6%), HPV33/58(15%), 51(16%), HPV52(25%), HPV 35/39/68(32%), and 56/59/66(35%). Overall, 3.5 % were HPV positive≥HSIL (N=16) or ASCUS/LSIL and either HPV16,18,31,33,52(N=19); 1.5% were HPV positive w. ASCUS/LSIL and either HPV35,39,45,51,56,66,68(N=15), and 20%(N=201) had normal triage cytology independent of genotype. One sample was invalid. Applying the algorithm, direct referral rate to colposcopy would be 3.5% compared to 1.9% with the current cytology algorithm. Overall, 4.3% of all tested would be referred to a re-test in 6 months.

Conclusions: HPV16 and 18 is close to be eradicated amongst these women, and the majority of HPV positive screening findings are one or more of HPV 35,39,56,59,66,68, generally considered so low in oncogenic potential that they do not merit immediate follow-up. Compared to current cytology screening, we conclude that difference in referral rate is limited when utilizing a HPV screening with genotyping and cytology triage and thus could make primary HPV screening feasible for women age 23-29 year.

Shift 02-062 / #1164

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

A VIRTUAL TRAINING PROGRAM FOR THE IMPLEMENTATION OF A NEW CERVICAL CANCER SCREENING PROTOCOL USING SELF-SAMPLING.

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Introduction: In the South Metropolitan Area of Barcelona (Spain), a pilot study is underway to implement of a new cervical cancer screening (CCS) using self-sampling. This pilot will be the basis for the implementation of the population-based CCS program in Catalonia. Aim: To develop an online training program for professionals involved in the new cervical cancer screening protocol with self-sampling.

Methods: The Catalan Institute of Oncology and its e-learning platform (www.e-oncologia.org) have developed this training program to support the implementation of the CCS program and the scale up to all Catalonia. The training consists of 2 online courses of 6 hours, one aimed to pharmacists (self-sampling devices are delivered through pharmacies) and another to all healthcare professionals involved in the cervical cancer screening program. The training courses are structured in 5 modules: HPV and CCS; The CCS early detection program; clinical protocol for CCS with self-sampling and FAQS). Each module includes a wide range of learning materials, from videos to structured theoretical material in question-answer format. Throughout each module, students monitor their learning with follow-up questions and at the end of the course they will have a final evaluation to obtain the course certificate.

Results: The first edition of the course was launched in May 2022. A total of 138 students completed the training. More than 83% of the participants who completed the course were satisfied with the relevance, usefulness, and duration. All participants rated it as good or better and 93% of them would recommend. These online training courses will be updated, and new editions will be held throughout 2023 and 2024 to support the implementation of CCS program in the whole Catalan territory.

Conclusions: This program proves the high acceptability of virtual training to facilitate the implementation of large population CCS programs. Acknowledgments: ICGON, COFB, PDO, ASSIRs

Shift 02-063 / #1198

Poster Viewing
POSTER VIEWING
04-16-2023 1:00 AM - 11:00 PM

PREVALENCE OF HIGH-RISK HUMAN PAPILLOMAVIRUS INFECTION AMONG WOMEN WITH SICKLE CELL DISEASE IN ACCRA, GHANA

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Introduction: Worldwide, about 20–25 million people are affected by Sickle Cell Disease (SCD) with approximately 60% of those affected, living in sub-Saharan Africa. SCD is associated with increased morbidity and mortality. The prevalence of hrHPV and cervical lesions have not been studied in women with SCD. We determined the prevalence of hrHPV and cervical lesions in a cohort of women with SCD and recommend strategies for reducing cervical cancer in such high-risk patients.

Methods: Through the mPharma Ten thousand (10,000) Women Initiative (TWI), women with SCD at the Ghana Institute of Clinical Genetics were screened by trained nurses using concurrent hrHPV DNA and mobile colposcopy (Enhanced Visual Assessment (EVA) system (MobileODT, Tel Aviv, Israel).

Results: 168 women were screened, mean age 43.0 (95%CI: 41.0 to 45.0) years. Mean hrHPV prevalence was 31. % (95%CI: 24.0% to 37.9%). 3.6% of patients (95%CI: 1.3% to 7.6%) had cervical lesions at colposcopy. When hrHPV prevalence was correlated with genotype of SCD, the prevalence if hrHPV was; SS – 29.4% (95%CI: 19.7% to 39.1%), SC – 32.5% (95%CI: 22.0% to 42.9%), SF – 20.0% (95%CI: 0.5% to 71.6%). Two clients with hrHPV had cervical lesions on EVA. One had a Loop Electrosurgical Excision Procedure (LEEP). Histopathology however showed no dysplasia. The other is scheduled for follow up.

Conclusions: Multidisciplinary healthcare of SCD patients reduces morbidity and mortality. The hrHPV prevalence rate of 30.8% is higher than the reported 21.5% (WHO) in West Africa (general population). There are variations in the hrHPV prevalence for SCD patients based on genotype (SS [29.4%] SC [32.5%] and SF [20%]) that require further study. Women with SCD may have higher risk of hrHPV infection requiring their prioritization for screening to prevent cervical cancer. There is urgent need for further study among SCD patients in relation to risk of hrHPV infection and cervical cancer.

Shift 02-064 / #1203

Poster Viewing
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ASCERTAINING BARRIERS TO ANAL CANCER PREVENTION IN PEOPLE LIVING WITH HIV, A PILOT STUDY

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Introduction: The ANCHOR study showed that treating high-grade anal lesions prevents anal cancer in people living with HIV. There is a 19-fold increase in anal cancer risk among PLWH which increases to 37-fold for HIV+ MSMs. Anal cancer screening modalities are underutilized but few studies have explored the factors contributing to non-adherence. No study has been focused in Louisiana despite the state ranking 4th nationally in new cases of HIV. The goal of this project is to identify barriers to anal cancer screening and develop effective advocacy and education.

Methods: A retrospective chart review was completed on 100 patients needing HRA at University Medical Center in New Orleans. Demographic data such as distance from the clinic, insurance, disease status at time of referral, and Health Professional Shortage Areas were assessed. Data was entered into RedCap and then analyzed in SPSS using Chi-Square tests to determine significance in the “no show” rates.

Results: The study population was 50% Caucasian, 47% African American; 71% had Medicaid/Medicare insurance; 73% lived within 10-20 miles of the clinic and 90% identified as Cisgender. Overall, 35% of the patients did not attend their appointment. Only 47% people who lived greater than 90 miles from UMC showed compared to 69% of the others (p=0.07). No other measured parameters were found to be statistically associated with missed clinic appointments.

Conclusions: Patients at the highest risk for anal cancer have high rates of non-adherence to recommended preventative screening modalities. This retrospective chart review only delineated distance from the clinic as a potential parameter. Other factors may be revealed by reviewing additional cases. We plan to survey both patients and providers to better understand the barriers to care. It is felt that navigation services and improved education will reduce the no-show rate and plans are to institute these measures.

Shift 02-065 / #1233

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
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COMPARING HR-HPV SCREENFIRE HPV RISK STRATIFICATION TEST WITH SEEGENE ANYPLEX II HPV28 DETECTION

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Introduction: Recently, HPV DNA tests have been introduced in cervical cancer prevention programs worldwide. However, newer, faster, near point-of-care tests still require further clinical evaluation. This study compared the concordance and agreement between the new ScreenFire HPV Risk Stratification (RS) Test (Atila BioSystems) and Anyplex II HPV28 Detection (Seegene) test.

Methods: Sixty de-identified clinician-collected cervicovaginal secretion samples, known to be HPV positive by Anyplex (+ threshold), were tested in the MARCO project (Management of Risk of Cervical Cancer) research laboratory located in Brasilia, Brazil, using ScreenFire. Samples were preserved in different media (SurePath, PreservCyt, Cell Preserv or GynoPrep), and the protocol for cell suspension was utilized. Cohen's kappa test for agreement and McNemar test for asymmetry were calculated in R.

Results: Test comparisons are shown in Table 1 for positive, negative, and divergent results for the 13 HR HPV types. Concordance and agreement at the HPV risk group level were highest for HPV16 and HPV31/33/35/52/58 (93.3% for both, κ=0.79 & κ=.85, respectively) and lower for the HPV18/45 and HPV39/51/56/59/68 groups (90.0% for both, κ=0.58 & κ=0.72, respectively). Anyplex had higher positivity for HPV18/45
(p=0.04).

Table 1. Result comparisons of ScreenFire HPV RS Test and Anyplex II HPV28 Detection (Reference) HPV tests for risk-grouped HR-HPV (13 types) from 60 HPV-positive samples.

HPV risk-group (ScreenFire/Anyplex)	+/+	-/+	+/-	-/-	Concordance (%)	Kappa (95 % CI)	McNemar test (P-value)
HPV16	10	0	4	46	93.33	0.79 (0.60 – 0.99)	0.13
HPV18/45	5	6	0	49	90.00	0.58 (0.25-0.90)	0.04
HPV31/33/35/52/58	19	2	2	37	93.33	0.85 (0.71-0.99)	0.99
HPV39/51/56/59/68	11	5	1	43	90.00	0.72 (0.51-0.93)	0.22

Conclusions: In this convenience sample of Anyplex HPV positive specimens some discordances were observed, but the evaluated HPV tests showed a good overall concordance. These preliminary results showed adequate ScreenFire performance even when different preservation media were used. If these results are confirmed in larger routine screening settings, considering how simple it is to run and its low cost, this new ScreenFire HPV test could be a promising option for rapid clinical management.

Shift 02-066 / #1282

Poster Viewing
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CLINICAL TRAINING DURING PANDEMIC: APPROACHES FOR EFFECTIVE HPV SCREENING LINKED TO TREATMENT

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Introduction: Countries with declining cervical cancer burden relied on organized screening and treatment access. Successful programs rest on competent providers to deliver high quality care. Project SUCCESS Philippines faced a daunting task implementing HPV DNA based cervical cancer screening when Covid 19 struck. Traditional clinical training approaches upended by pandemic responses energized the project team to innovate and move implementation of a self –collected HPV test and thermal ablation forward. This presentation details the effective approaches building clinical competencies using hybrid training.

Methods: Clinical skill training (CST) was redesigned in 2-part series starting with essential “need-to-know” knowledge delivered on a zoom platform complemented by a variety of apps including Mentimeter ®, Squidoo®, YouTube®. This followed an in-person practica under full covid 19 precautions to focus on skills acquisition and competency using simulated practice on anatomic models, flash card exercises progressing to supervised practice with women for screening in the clinic. Expected key competency outcomes included counseling, HPV screening and ablation, triaging with visual inspection, and infection prevention. Performance measured using tools for pre-and-post-tests, image exams, and clinical skills checklists.

Results: Over 7 months (Nov 2021-June 2022) trained 140 clinicians in 14 facilities. All trained providers met competency standards at 85% knowledge score and passed qualification criteria to perform HPV screening, VAT and ablation. They screened 5,784 women, 94% self-collected, reported 8.8% positive rate for general population and 28.6% in HIV+ women. Treatment rate is high at 97 % for women HPV positive and VAT eligible.

Conclusions: Challenges included supply access delays and provider availability due to Covid priorities. Hybrid approach provided better learning at a minimum time with lesser risk of exposures. Advantages and benefits of the hybrid approach appeals to program managers for post-covid use.

Shift 02-067 / #1289

Poster Viewing
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CERVICAL CANCER ELIMINATION IN THE PHILIPPINES: SCREEN AND TREAT WITH HPV TEST AND THERMAL ABLATION

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Introduction: Cervical Cancer in Philippines is second leading cancer in women, with 7,277 cases annually, majority diagnosed late resulting to unnecessary preventable deaths. Opportunistic screening with cytology or Visual Inspection with Acetic Acid has been the mainstay. WHO's call to eliminate cervical cancer provided the impetus for the DOH to partner with SUCCESS, a UNITAID funded project, implemented by a consortium of global agencies, to generate evidence on the feasibility, appropriateness, acceptability, cost of HPV test screening and thermal ablation treatment. This presentation will detail the health systems approach to mainstreaming these new technologies.

Methods: Aiming to screen with HPV test 40,000 women by June 2023 ages 30-49 from general population and 25-49 WLHIV and treat those eligible with thermal ablation or LEEP, 30 selected health facilities submitted to an initial assessment followed by enabling environment investment. Health Department (DOH) led collaboration is moving resources mobilization, procurement of essential equipment and supplies, policies update, health workers training, demand generation and information strengthening. Implementation research conducted aiming to generate evidence for scalability.

Results: From Nov 2021 to June 2022, cervical cancer prevention program and services needs were identified; a National Technical Working Group, Research Advisor Group and laboratories network were established; norms, guidelines, training and informational materials and mobilization tools updated. 140 health workers trained. 5,784 women screened with HPV test, 94% by self-sampling, 8.8% positive rate in general and 28.6% in WLHIV. Treatment was completed for 97 % of eligible HPV positive women

Conclusions: DOH with Project SUCCESS - introduced nationally HPV testing and thermal ablation in Philippines and developed tools for the scalability. The continuing political commitment, partnership of stakeholders is key for sustainability, pushing the fight to eliminate cervical cancer in the Philippines.

Shift 02-068 / #1373

Poster Viewing
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HIGH-RISK HUMAN PAPILLOMAVIRUS (HPV) CLEARANCE FOLLOWING THERMAL ABLATION AMONG WOMEN FROM THE GENERAL POPULATION, INCLUDING WOMEN LIVING WITH HIV IN MALAWI

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Introduction: In 2019, the World Health Organization (WHO) endorsed the use of thermal ablation to treat cervical precancer in low-and middle-income countries (LMICs). Data on the efficacy of thermal ablation from LMICs are limited, especially among women living with HIV (WLWH). We sought to determine the rates of high-risk HPV persistence at 12 months following ablation in Malawi.

Methods: We obtained de-identified data from Ministry of Health registers at eight health centers in Lilongwe, from HPV-positive women aged 25 – 49 years who underwent ablation and attended a 12-month post-treatment visit where HPV testing was repeated. High-risk (hr) HPV testing was performed using the GeneXpert assay, including overall and type-specific results for HPV16, HPV18/45, and other hrHPV. Age, HIV status, as well as overall and type-specific hrHPV infection status at baseline and follow-up, were analyzed.

Results: Of 191 women, 35.1% self-reported to be living with HIV. The median age was 33 years (range 25-49), which did not differ by HIV status (p=0.94). At baseline, 33 (17%) had HPV16 and 47 (25%) had HPV 18/45, and 19.4% had infection with more than one GeneXpert channel, which did not differ by HIV status. The mean time to follow-up HPV testing following ablation was 13.1 months (SD 2.3). Clearance of hrHPV infection at 12-months post-ablation was 61.8% (n=118) overall, and was similar among WLWH (55.2%, n=37) and HIV-negative women (65.3%, n=81) (p=0.151). Among those persistently HPV-positive at follow-up, 20.7% and 14.0% of HIV-positive and HIV-negative women had multiple types of HPV (p=0.45). Analyses of type-specific HPV clearance are ongoing.

Conclusions: Following thermal ablation, similar rates of HPV clearance by 12 months were observed among women living with and without HIV. Data on whether certain HPV types (e.g., HPV 16 & 18) are less likely to be cleared following ablation will inform future screening programs.

Shift 02-069 / #1391

Poster Viewing
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RESILIENCE AND SUSTAINABILITY OF CERVICAL CANCER SCREENING IN THE PERUVIAN AMAZON: THE PROYECTO PRECANCER EXPERIENCE

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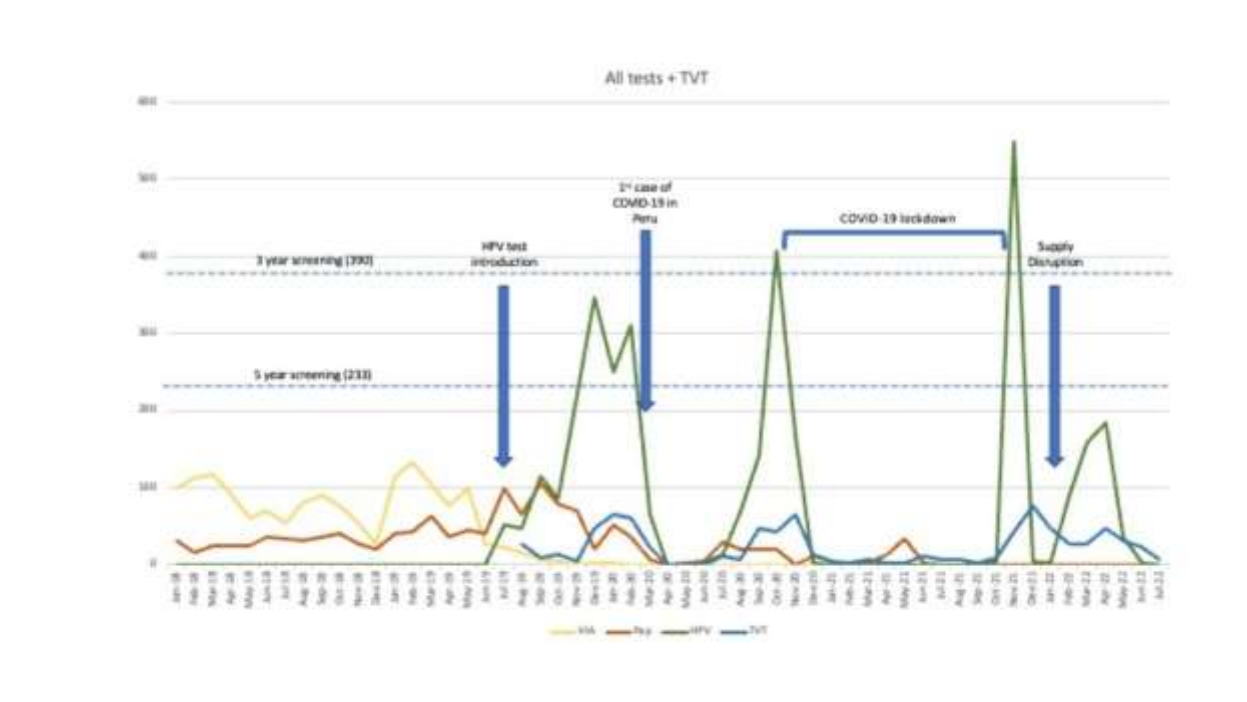
Introduction: From January 1, 2018 – April 30, 2022, we monitored cervical cancer screening and management in a public health system in Iquitos, Peru serving 20,000 screen-eligible women to evaluate the resilience and sustainability of an HPV-based screening model in the context of the COVID-19 pandemic and supply chain disruptions.

Methods: HPV testing by GeneXpert was implemented in July 2019 with visual assessment for treatment (VAT) and thermal ablation of eligible, screen-positive women. Coverage targets were estimated as monthly number of unique screening tests in women 30-49 years based on needing to screen 70% of 20,000 over a 3-year (VIA) or 5-year (HPV) period (n=389/month and 233/month, respectively).

Results: During the initial, pre-pandemic introduction of the HPV screening program (07/2019-04/2022), 3322 primary HPV screening tests were performed. Prior to the pandemic (07/2019-03/2020) the system screened on average 165.8 women/month. HPV screening rates following the first COVID lockdown were 159.6/month (07/2020-11/2020), and 164.7/month (11/2021-04/2022) following the second COVID lockdown (50%, 48%, and 49% average monthly coverage, respectively). The highest four-month HPV screening rates were observed immediately before the pandemic, reaching 281.8/month (11/2019-02/2022) or 85% screening coverage. While 2 notable pandemic-related disruptions in HPV screening occurred, the system was resilient in ultimately reaching screening targets following each disruption. Treatment with thermal ablation followed similar resiliency

trends.



Conclusions: In a single public health system, HPV-based screening surpassed WHO elimination targets within 6 months of implementation. The system also fully rebounded after two consecutive system pandemic lockdowns and reached 5 year screening goals until an ultimate supply chain disruption. If supply chains can be stabilized, HPV-based screening appears resilient and sustainable as a cervical cancer prevention strategy in the Peruvian Amazon.

Shift 02-070 / #1395

Poster Viewing
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"BARRIERS IN COMMUNITY PAP SMEAR LAB IMPLEMENTATION – EXPERIENCE AT FOUR REMOTE RURAL SUBCENTERS AT COMMUNITY HEALTH CENTER, KACHOLA, BHILWARA DISTRICT OF RAJASTHAN, INDIA"

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Introduction: Cervical cancer is second commonest cancer in rural Indian females. Our prospective study aimed to establish a community PAP smear lab as part of (demonstrable) healthcare reforms in rural India.

Methods: 1. The study involved 4 sub-centers at community health center (CHC), Kachola (Bhilwara) India. Community healthcare experts and oncologists formed the team. The travel time is 5-6 hours to reach the selected site. 2. A target population of 1970 women between 30-65 years was enlisted. Government doctors and female community health workers (CHW) were trained for PAP smear collection, staining, blood pressure and blood sugar measurement. 3. Community leaders were sensitized regarding the purpose of PAP smear labs and their cooperation for maximum participation. 4. Dates for screening camps were based on consensus amongst the community, health center personnel, considering local festivals to ensure maximum participation. 5. Qualified pathologists reported PAP smears- i. Reports were sent to participants while maintaining confidentiality. ii. Women with abnormal PAP Smears were linked to gynecologists of nearest government hospitals.

Results: 1. 7 camps were held between February 2019 and January 2022. Total 197/1970 (10%) women participated. Most enlisted women remained absent due to loss of daily wages. 2. Majority (90%) were 30-45 years aged from low socio-economic class. 3. Hemoglobin was less than 10 gm/dl in 90% participants. 4. Only 60/197 (30.4%) women agreed for PAP smear. None had pathologic abnormalities. 5. Poor genital tract hygiene and infections were observed in 79/197 (40%) females. 6. Barriers in screening observed were lack of motivation, trust and embarrassment to expose genitals (even to healthcare professionals).

Conclusions: 1. Education and motivation of the community is a major challenge. 2. Adequate incentives, incorporation of screening activities in CHWs' primary job responsibilities may lead to improved community participation. 3. Successful national cancer screening programs needs decentralization with focus on rural health centers.

Shift 02-071 / #1436

Poster Viewing
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ESTIMATING THE EFFECTS OF AGE AT STARTING SCREENING AND SCREENING INTERVAL FROM ENGLISH CERVICAL CANCER RATES

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Introduction: In 2004 the age at first screening invitation was raised from 20 to 25 in England. Little effect on cervical cancer prevention was expected because cervical cancer is rare below age 25. This was apparently confirmed, as there was no subsequent increase in incidence at age 20-24 for the birth cohort first screened at age 25. Cervical screening from age 25 or later is now recommended in most countries.

Methods: English cervical cancer rates in 2003-2007 and 2014-2016 were compared for women aged 25-29.

Results: The annual cervical cancer incidence rate per million at age 25-29 in England has almost doubled, from 113 in 2003-2007 (women first screened at 20) to 206 in 2014-2016 (women first screened at 25).

Conclusions: Cytology screening has little effect on cancer prevention within 5 years but a large effect beyond 5 years, and this is also likely to be true for HPV screening. These English cervical cancer rates in birth cohorts invited for screening from age 20 (born 1978) and from age 25 (born 1988) reflect the effects of a 5 or 10 year screening interval from a negative HPV test at age 15, because most women are HPV negative at age 15 but HPV infection is common at age 15-24. There is no evidence that the natural history of progression from HPV infection to cervical cancer or the effects of screening are different in young women, and cervical screening coverage is high (~80%) in England. These data therefore provide the best available evidence on the effects on cancer prevention of extending the screening interval from 5 to 10 years as well as the age at which screening should begin in unvaccinated women.

Shift 02-072 / #1456

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'PLEASE MAKE THIS AVAILABLE IN ALL COMMUNITIES': WOMEN'S PERCEPTION ON HUMAN PAPILLOMAVIRUS SELF-SAMPLE COLLECTION FOR CERVICAL CANCER SCREENING IN KENYA

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Introduction: Cervical cancer is the second most common cancer in Kenya, with over 5200 cases in 2020. Despite evidence of increasing knowledge on cervical cancer screening in Kenya, screening uptake has remained sub-optimal. The World Health Organization has proposed human papillomavirus (HPV) testing as one of the three key interventions to advance towards cervical cancer elimination. Kenya conducted an HPV testing pilot project in 2019–2020. We present women's perceptions on cervical cancer screening and HPV testing from the evaluation of the HPV pilot.

Methods: We conducted nine focused group discussions (FGD) among women screened during the HPV pilot. Each FGD had 5–7 women, was moderated jointly by the evaluation team and a local community health worker, and lasted approximately 60 minutes. Two transcribers independently undertook transcription, and the transcripts compared in sentence structure and key messages. We deductively analyzed the data through organization, interpretation, pattern identification, tying patterns to pilot objectives and drawing informed and verifiable conclusions.

Results: We identified four main themes on factors driving cervical cancer screening non-uptake: 1) The intrusive nature of cervical cancer screening procedures reduces uptake of cervical cancer screening; 2) Screening visit set-up and organization of the service also influence women's perception of the screening procedure and affects follow-up visits; 3) Misconceptions on cervical cancer, the screening process and cancer in general also contribute to low screening uptake; 4) The main factor driving acceptability of HPV-based screening is the possibility of self-sample collection; 5) A key challenge with HPV testing was interpretation and implication of a positive result, especially when the triaging test was negative.

Conclusions: Self-sample collection for HPV testing can drive screening uptake in Kenya and possibly other low and middle-income countries. However, public health authorities need to strengthen communication and pre-screening counselling for women undergoing screening through HPV testing.

Shift 02-073 / #1459

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

5-YEAR FOLLOW-UP OF CERVICAL CANCER PREVENTION IN EL SALVADOR (CAPE): COMPARING OUTCOMES BETWEEN CYTOLOGY TESTING AND A NOVEL PRIMARY HPV SCREEN-AND-TREAT APPROACH

Karla Alfaro[1], Leticia Lopez[2], Montserrat Soler[3], Elizabeth Torres[1], Kathleen Schmeler[4], Melissa Varon[5], Gabe Conzuelo[6], Julia Gage[7], Rachel Masch[8], Miriam Cremer[3], Juan Felix[9], Mauricio Maza[10]
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Introduction: Starting in 2012, the Cervical Cancer Prevention Project in El Salvador (CAPE) compared cytology and colposcopy (control) with a novel screen-and-treat approach utilizing HPV testing (careHPV, Qiagen, Gaithersburg, MD) followed by cryotherapy (intervention). Findings from CAPE resulted in the national adoption of screen-and-treat, but it is essential to demonstrate the long-term effects of this approach to ensure its sustainability. Here, we present results of a 5-year evaluation of CAPE.

Methods: From June 2018 to April 2022, community health promoters utilized listings that were created during CAPE to identify and recruit participants. Inclusion criteria were women aged 35 to 55, who had participated in CAPE, and who had their last HPV test between 5-6 years ago or cytology test at least 2 years ago (as outlined in El Salvador's guidelines). Exclusion criteria were pregnancy, and history of hysterectomy, cervical precancer or cancer. All participants were tested with careHPV at municipal health units. HPV positive (HPV+) women were referred to colposcopy and biopsy to determine further management.

Results: A total of 6,222 women were enrolled. Of these, 2,445 had been in the control group and 4,077 in the intervention one during CAPE. HPV positivity was higher in the control than the intervention group (269/2445 [11%] vs. 388/4,077 9.51%], p=.05), as was the proportion of cervical intraepithelial neoplasia grade 2 (CIN2+) among the HPV+ cases (41/269 [15.24%] vs. 28/388 [7.21%], p=.001). There was no significant difference in the proportion of invasive cancer cases (control: 1/269 [.003%] vs. intervention: 4/388 [.01%], p=.34).

Conclusions: After 5 years, fewer HPV+ and CIN2+ cases were found among women that participated in a HPV screen-and-treat strategy than those in a control group with cytology and colposcopy. These findings support the use of primary HPV screening in El Salvador and other countries that face challenges implementing cytology-based screening.

Shift 02-075 / #1508

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

IMPLEMENTATION OF COMMUNITY GENOMIC HEALTH PROMOTION PROGRAM IN FEDERALLY QUALIFIED HEALTH CENTER TO INTRODUCE DNA METHYLATION ALGORITHMS IN CERVICAL CANCER SCREENING PROGRAMS

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Introduction: The Community Genomic Health Promotion program (CGHP) introduces precision medicine tools for cervical cancer prevention among users, providers, and administrators of primary health care systems. CGHP combines elements from the PRECEDE-PROCEED model (PPM), Community Based participatory Research (CBPR) and the NIH I-Corps hypothesis-driven research method of customer discovery to disseminate the use of DNA methylation algorithms in community-based cervical cancer prevention programs.

Methods: Interviews and focus groups were conducted in Salud Integral para la Montaña (SIM) health care centers following the Logic Model shown on Figure
1.

Figure 1. Community Genomic Health Promotion Program Logic Model

SIM is the largest Federally Qualified Health Center in Puerto Rico, serving 60,000 residents of medically underserved rural communities. Seven interview sessions were conducted with key informants (n=37) to identify existing genomic health promotion strengths and needs at SIM health centers in Corozal, Naranjito, Bayamón, Barranquitas, Toa Alta, Comerio and Orocovis (Figure 2).to identify existing strengths and needs An Interview Guide was created to standardize the information gathering interviews.

Information standardization is one of the tools that guide the CGHP program implementation based on community needs. The meetings were recorded, transcribed, and analyzed by the CGHP internal evaluator. A CGHP Formative Evaluation Report was prepared and shared with SIM administrators.

Figure 2. Salud Integral en la Montaña (SIM) network of Federally Qualified Health Centers that provide primary and preventive services for the residents of Barranquitas, Comerío, Corozal, Naranjito, Orocovis, Bayamón and Toa Alta.

Results: The most important preliminary findings of the multilevel strengths and needs assessment are summarized in Figure 3.

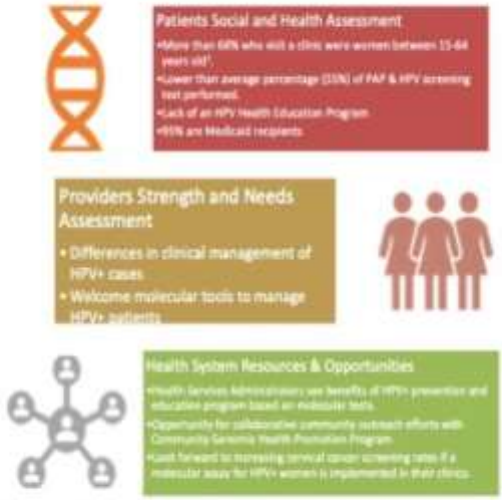

Figure 3. The most important preliminary findings of the multilevel strengths and needs assessment we performed during the Formative Evaluation Phase of the CGHP.

Conclusions: Genomic health promotion efforts can be used to introduce molecular screening in biofluids. Acceptance is linked to the communication strategies used to convey messaging to different age groups. Moving forward we may consider using generational myths, knowledge, and age appropriate technological/literacy tools. We may also consider inviting to CGHP activities a diverse representation of health care providers, in addition to Family Physicians and General Practitioners, who may engage with women who do not undergo cervical cancer screening according to established guidelines.

Shift 02-076 / #1522

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

UTILIZATION TRENDS FOR HPV TESTING AND OTHER CERVICAL CANCER SCREENING-ASSOCIATED SERVICES IN MEDICARE FEE-FOR-SERVICE BENEFICIARIES OVER AGE 65

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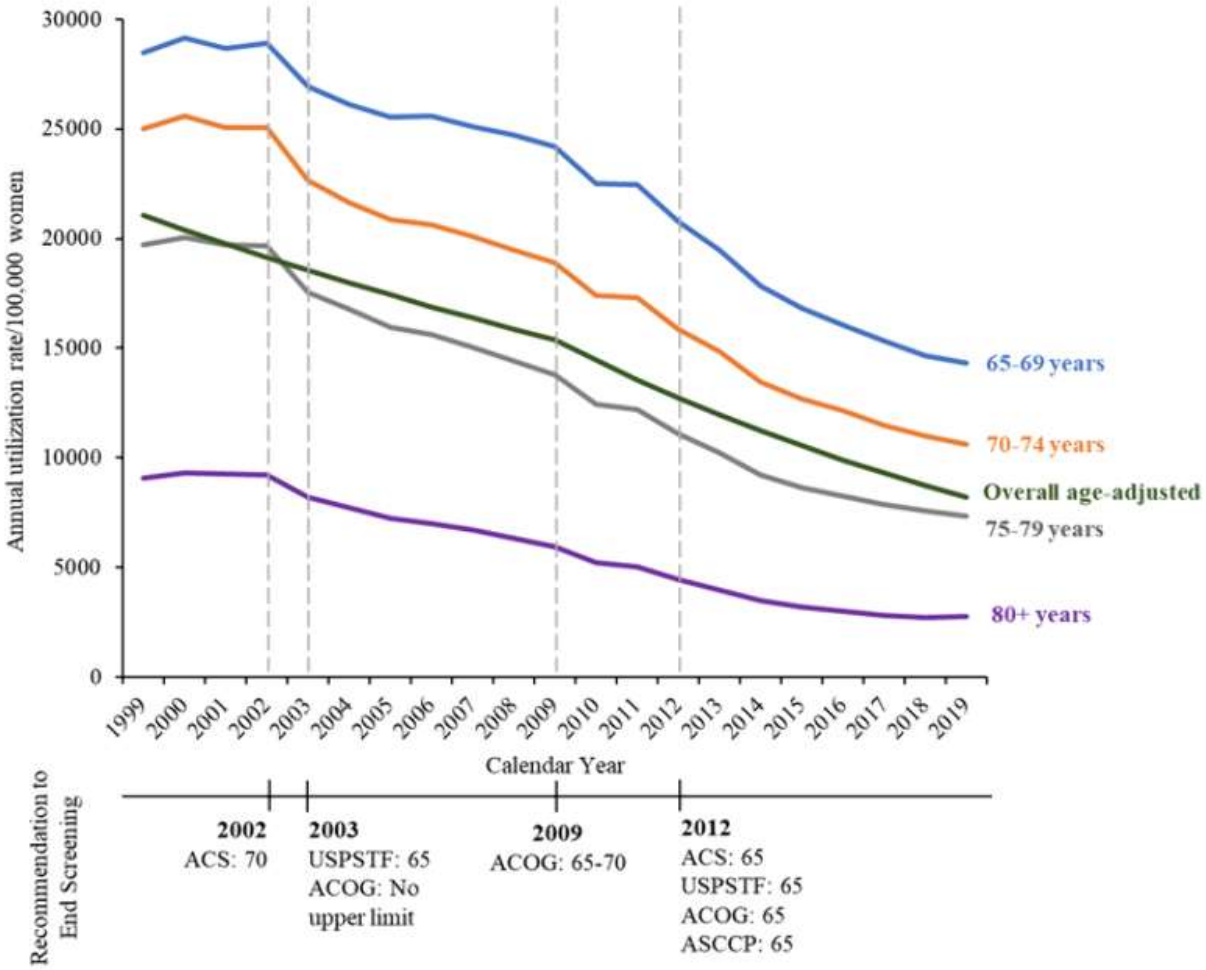
Introduction: The US Preventive Services Task Force has recommended against cervical cancer screening in average-risk women aged ≥65 years with adequate prior screening since 1996. Little is known about the utilization of cervical cancer screening-associated services in this age group. The objective of this study was to examine annual utilization trends over time in cervical cancer screening-associated services, specifically cytology and human papillomavirus (HPV) tests, colposcopy, and cervical procedures (loop electrosurgical excision procedure, cone biopsy, and ablation) in Medicare fee-for-service (FFS) beneficiaries.

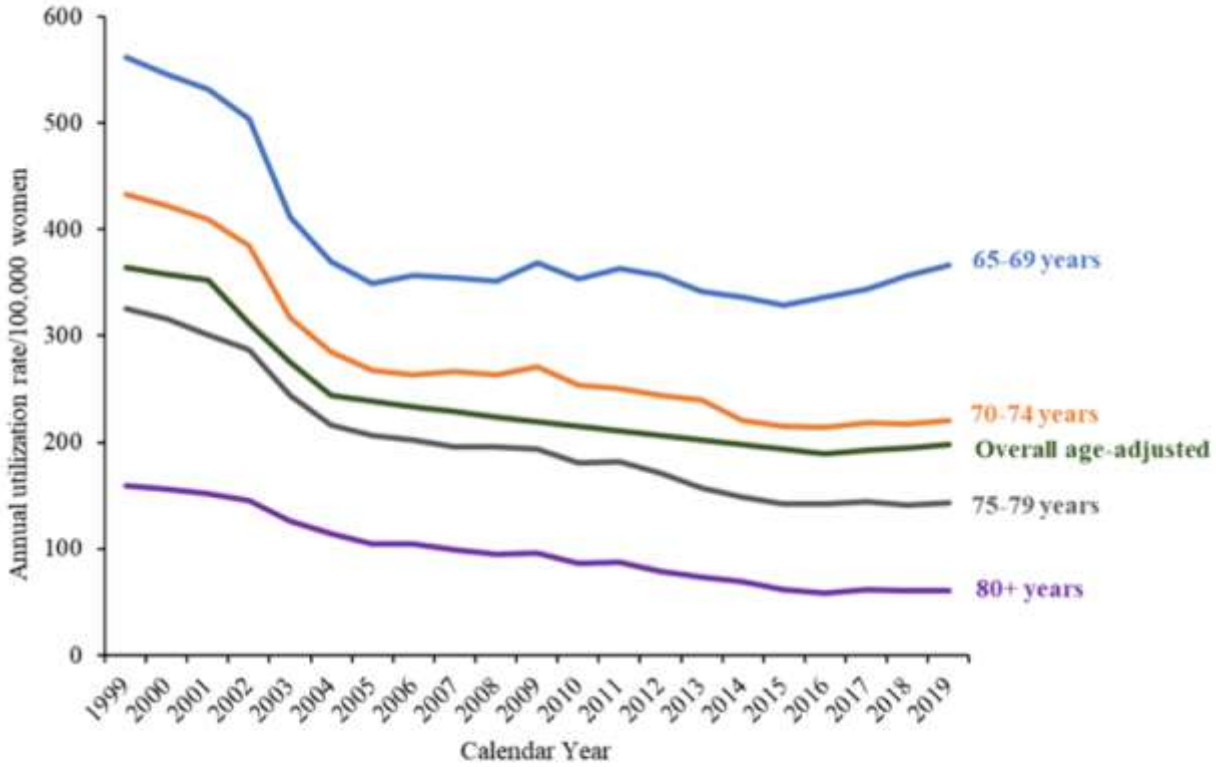
Methods: We used medical claims data for 100% of the Medicare FFS beneficiaries from 1999 through 2019, from women aged ≥65 years with continuous FFS enrollment each year (15–16 million women per year). We analyzed four age groups: 65-69 years, 70-74 years, 75-79 years, and ≥80 years. Annual utilization rates per 100,000 women were calculated for each calendar year, overall and by age group. We used Joinpoint software to characterize piecewise log-linear time calendar trends in the overall age-adjusted rates and calculated annual percent change and average annual percent change.

Results: From 1999 to 2019, the percentage of women who received at least 1 cytology or HPV test decreased from 18.9% (2.9 million women) in 1999 to 8.5% (1.3 million women) in 2019, a reduction of 55.3%; utilization rates of colposcopy and cervical procedures decreased 43.2% and 64.4%, respectively. Trend analyses showed a 4.6% average annual reduction in use of cytology or HPV testing during 1999–2019 ($P < 0.001$). Utilization rate of colposcopy and cervical procedures decreased prior to 2015 ($P < 0.001$) then plateaued during 2015–
2019.



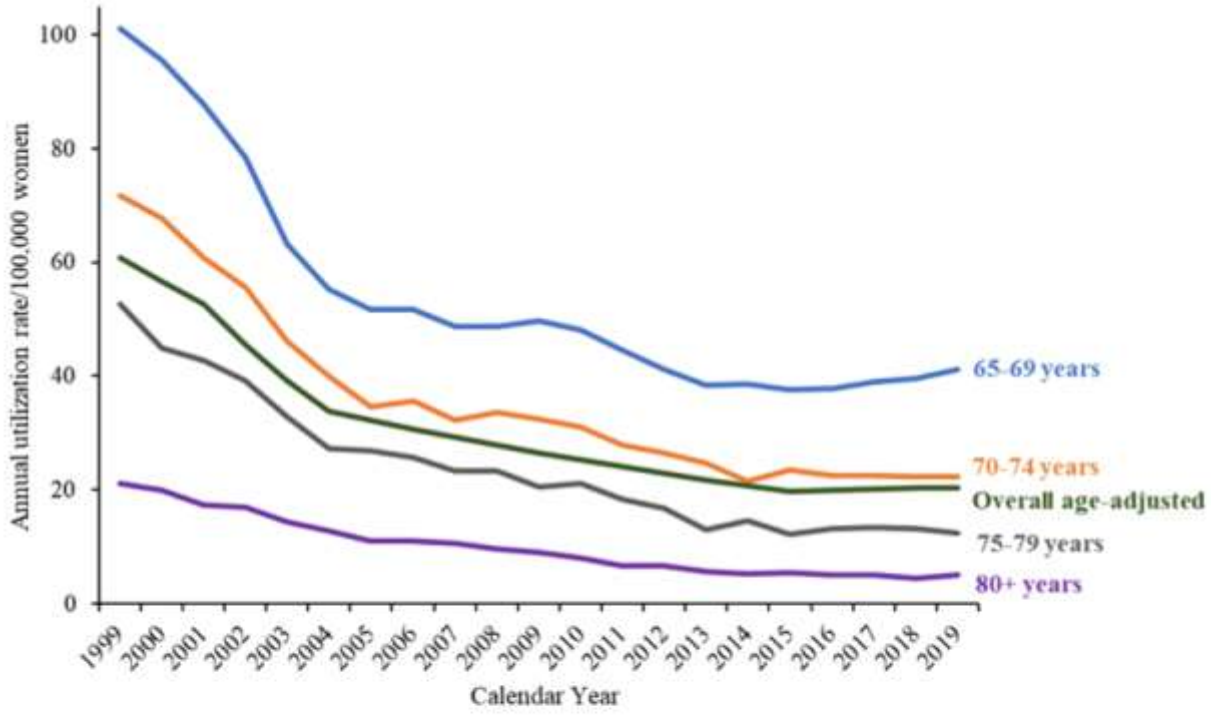
Trends with Joinpoint analyses for overall age-adjusted rate

Trend 1		Trend 2		Trend 3		Trend 4	
Year	APC	Year	APC	Year	APC	Year	APC
1999-2009	-3.1[c]	2009-2019	-6.1[c]	-	-	-	-
1999-2019 AAPC = -4.6[c]							



Trends with Joinpoint analyses for overall age-adjusted rate

Trend 1		Trend 2		Trend 3		Trend 4	
Year	APC	Year	APC	Year	APC	Year	APC
1999-2001	-1.6	2001-2004	-11.6[d]	2004-2016	-2.1[c]	2016-2019	1.5
1999-2019 AAPC = -3.0[c]							



Trends with Joinpoint analyses for overall age-adjusted rate

Trend 1		Trend 2		Trend 3		Trend 4	
Year	APC	Year	APC	Year	APC	Year	APC
1999-2001	-7.0	2001-2004	-13.7[d]	2004-2015	-4.8[c]	2015-2019	0.8
1999-2019 AAPC = -5.3[c]							

Conclusions: While annual utilization of cervical cancer screening-associated services in the Medicare fee-for-service population over age 65 has decreased over the last 2 decades, over 1.3 million women and over 130,000 women aged ≥80 years received these services in 2019.

Shift 02-077 / #1663

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

THE IMPACT OF HPV INFECTION SCREENING IN ALBANIA TO PREVENT THE CERVICAL CANCER

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Introduction: The National Cervical Cancer Screening Program (NCCSP) in Albania is pridominately based on HPV testing. The screening program will improve identification of women who are at higher risk for cervical cancer, detect in time the pre-cancer lesions, and treat them accordingly.

Methods: The initial program targets women 40-50 years old, whom used self-sampling HPV test. Capacity building for the NCCSP implementation took place from February to June 2019 with 538 health professionals from 400 primary health care (PHC). 96% of surveyed women received their results in 25 days.

Results:

High Risk HPV prevalence by age group

Age Group	HPV+	HPV+ (%)	HPV-	Total
35-39	19	7.6%	223	251
40-49	580	6.2%	8744	9314
50-55	21	4.8%	415	437
Total	620	6.2%	9382	10002

High Risk HPV Prevalence, by Urban and Rural Areas

	HPV+	HPV+ (%)	HPV-	TOTAL
Rural	265	4.7%	5423	5688

High Risk HPV Prevalence, by Urban and Rural Areas				
	HPV+	**HPV+ (%)**	**HPV-**	**TOTAL**
Urban	355	8.2%	3959	4314
Total	620	6.2%	9382	10002

In 2019 were distributed 13900 test kits in PHC and more than 10002 samples came back. The prevalence of HPV infection is 6.2%. The majority of women found self-sampling procedure very simple (60%) and not at all painful (72%). 87% of women with positive HR-HPV infection stated worries. Almost 80% of the women have received appropriate information during primary testing visit. 6.87% of women participating in the program were older or younger than the targeted category (prevalence of HPV 7.6%). At the time of the survey, around 90% of HPV-positive women followed up. From colposcopy, 27% of HPV-positive women resulted compatible with pre-cancer or cancer, while 73% reported negative results.

Conclusions: The benefit of organized HPV screening has resulted in a further decline of incidence rates. It's necessary to expand the screening program in 35-39 age group, since the age of the first sexual intercourse has been lowered.

Shift 02-078 / #1686

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

CAPACITY ASSESSMENT OF HEALTH SYSTEMS TO DEVELOP A TAILORED IMPLEMENTATION STRATEGY FOR CERVICAL CANCER SCREENING AMONG VULNERABLE WOMEN IN EUROPE

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Introduction: Quality of screening programme services requires improvement in several European countries. Vulnerable women remain hard-to-reach or have low adherence to screening, thus contributing to health inequalities. The EU-funded project CBIG-SCREEN aims to reduce this gap by implementing cervical cancer screening (CCS) strategies co-constructed by and tailored for vulnerable women in Estonia, Portugal, and Romania. Our objective was to assess the capacity of the CCS programme in each country, and ultimately contribute to the co-construction of implementation strategies to improve participation to CCS and further management.

Methods: A capacity assessment was conducted in the three countries (October 2021-July 2022) in three steps. Firstly, a desk review was carried out to assess the countries policies and guidelines related to CCS and especially for vulnerable women. Secondly, we conducted facility visits to screening and colposcopy centres to collect information in a structured way. A readiness score was ascribed to each facility in 8 dimensions – infrastructure, equipment and supplies, services, staffing, data management, procurement, infection control, and follow-up. Finally, key-informants were interviewed to understand key institutions’ organizational climate. Interviews were transcribed and coded using the CFIR codebook for implementation readiness. A strengths, weaknesses, opportunities, and threats (SWOT) matrix was developed for the local health system in each country using mixed-method analysis. The SWOT matrix was shared with local stakeholders for them to identify and prioritize areas for improvement.

Results: While strengths and weaknesses differ between the three countries, they share similar issues related to invitation and follow-up of screen-positive women. Due to different health system organization and health services readiness, areas of priorities were linked to the diffusion of information, health information system, health providers’ training to vulnerability and assuring upstream care for screen positive.

Conclusions: Capacity assessment provides valuable information to guide context-specific and prioritized strategies for system strengthening to improve CCS among vulnerable women.

Shift 02-079 / #1722

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

CERVICAL CANCER SCREENING: PREVALENCE OF HR HPV TYPES (NOT HPV16 AND/OR HPV18) IN THE REGION OF LISBON AN TEJO VALLEY

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Introduction: The implementation of organized screening programs allows the early diagnostic of cervical cancer. Screening abnormalities require follow-up, diagnosis, and treatment in order to prevent cancer or treat cancer at an early stage. Despite the high coverage of HPV vaccines in Portugal, an organized screening based on the HPV test was implemented at the national level for cervical cancer. We intend to verify the prevalence of HPV HR types (other than HPV16 and/or 18) by cytological result in the first organized screening program in the region of Lisbon and Tejo Valley.

Methods: HPV detection was carried out using Seegene's Anyplex II HPV HR according to the manufacturer's instructions. Reflex cytology was performed using the ThinPrep method and reported in accordance with the Bethesda System.

Results: A total of 20443 women (age range 29-66 years) were screened between December 2018 and December 2022. Clinical algorithms refer all HPV16 and/or HPV18 positive women for colposcopy (468 – 2.29%) and all samples with other HR HPV types (1749 – 8.56%) were forwarded to cytological evaluation; all the women with cell abnormalities were referred for colposcopy. The most prevalent HPV genotypes were HPV68 (18%), HPV31 (15%) and HPV52 (13%). HPV68 (13.15%), HPV66 (6.86%) and HPV52 (8.52%) were the most prevalent in women with negative cytology (n=1107, 63.29%); HPV68 (3.09%), HPV31 (2.34%), HPV35 and HPV31 (1.86%) were the most prevalent in ASCUS (n=280, 16.01%); HPV31 (1.89%), HPV52 (1.66%) and HPV51 (1.83%) were the most prevalent in LSIL (n=200, 11.04%); HPV31 (0.51%), HPV51 (0.40%) and HPV52 (0.34%) were the most prevalent in HSIL (38-2.17%); the only carcinoma identified in this group had HPV33.

Conclusions: HPV68 is the most prevalent HPV in our study, which can be related to the introduction of the vaccine in the National Vaccination Plan. The high prevalence of HPV68 has not confirmed in higher grade lesions.

Shift 02-080 / #1762

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

HUMAN PAPILLOMAVIRUS INFECTION AMONG TRANSGENDER WOMEN AND SEX WORKERS IN BANGLADESH

Mustafizur Rahman[1], Sezanur Rahman[1], Md Abir Hossain[1], Muntasir Alam[1], Mst. Noorjahan Begum[1], Golam Sarwar[2], Md. Masud Reza[2], Muhammad Manwar Morshed Hemel[2], Quamrun Nahar[3], Shams El Arifeen[3], Sharful Islam Khan[2]
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Introduction: Transgender women (TGW), Male Sex Workers (MSW) and Female Sex Workers (FSW) are disproportionately affected by Human papillomavirus (HPV), but the risk among these populations remains understudied, especially in low and middle-income countries.

Methods: Between September 14 to November 30, 2022, anorectal-swabs (AS) from 484 TGW, 220 MSW and cervical-swab from 126 FSW were collected from Dhaka and Jessore districts of Bangladesh. Testing for HPV DNA was conducted on the specimens by using a commercial real-time PCR kit (Hibribio Ltd, Hong Kong) for the detection of 17 high-risk (HR) and six low-risk (LR) HPV genotypes (GTs).

Results: The median age of TGW and MSW was 27 years, and FSW, 30 years. Any HPV was detected in 74% of TGW, 72% of MSW and 39% of FSW. HR-HPV infection was detected in 65% of the TG, followed by 62% MSW and 31% FSW. At least one HR-HPV was detected in 59% of the participants. Among HR-HPV, GT-16 was the most predominant (32%) followed by GT-58 (18%), GT-52 (17%), GT-18 (14%), GT-33 (5%), and GT-31 (4%) which are present in the current vaccines. In contrast, one-third of the HR-HPV genotypes identified in this population are not covered by the current HPV vaccines, such as GT-39 (17%), GT-59 (12%), GT-53 (11%), GT-82 (9%), GT-56 (5%), GT-51 (3%), GT-35 (2%), GT-68 (2%), and GT-73 (1%). The HPV detection rate was significantly higher in anal specimens than in cervical swabs. The anal specimens were also significantly less likely than cervical swabs to be naïve to GT-16; the scenario is just the opposite for GT-18.

Conclusions: This study reports, for the first time in Bangladesh, high rates of HPV infections and their genotypes in TGW, MSW and FSW. These results warrant routine vaccination among these populations who are still naïve to any HPV vaccines.

Shift 02-081 / #1782

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03D. SCREENING FOR HPV-RELATED DISEASE: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

INTEGRATING CERVICAL CANCER SCREENING AND MANAGEMENT CLINICAL DECISION SUPPORT INTO CLINICIAN WORKFLOWS: A PILOT PROJECT

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Introduction: Clinical Decision Support (CDS) based on computable guidelines could improve cervical cancer screening and management (CCSM) outcomes by increasing guideline adherence. However, differences between electronic health record (EHR) user interfaces, integration techniques, and workflows make integrating CDS burdensome. The Centers for Disease Control and Prevention (CDC) is supporting three clinical pilots focused on integrating CCSM CDS into separate clinical workflows, understanding how workflow interruptions can be minimized and how clinician interactions with CDS can be improved.

Methods: Current health technology standards define interoperable and widely supported methods of invoking CDS from within an EHR system. However, the effect CDS has on the clinician's user experience varies between health organizations. Three clinical pilots will be conducted using differing EHR systems, clinical workflows, and integration strategies. Working closely with clinicians will allow for insight into where CDS fits into their workflows, and what gaps may exist in translating CDS recommendations to an EHR interface.

Results: Clinician feedback will be used to iteratively refine how CCSM CDS tooling interacts with EHR user interfaces. This iterative improvement will allow for the development of a common, streamlined integration strategy for clinician-facing CDS with support for patient engagement.

Conclusions: Health technology standards define consistent methods of integrating CDS into a health system, but how CDS interacts with existing workflows and clinical user interfaces varies between organizations. Piloting will demonstrate that integration can be streamlined to improve clinician efficiency and scalability of future CDS tools.

Shift 02-086 / #194

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

CURRENT STATUS OF KNOWLEDGE, ATTITUDE, AND HUMAN PAPILLOMAVIRUS (HPV) VACCINE UPTAKE AMONG FEMALE ADULTS IN MAINLAND CHINA

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Introduction: Human papillomavirus (HPV) vaccination represents part of the best strategy to reduce and eliminate HPV-related diseases, especially cervical cancer. However, since launching in 2016, the coverage of HPV vaccines in mainland China has not been assessed. This study investigated the knowledge, attitude, and HPV vaccine uptake among female adults in mainland China.

Methods: We conducted a cross-sectional online survey in a random sample of female adults aged 18 to 52 years between 5 March to 7 April 2022 in seven geographical regions of China. The survey was composed of sociodemographic information, knowledge of the disease and its prevention, attitudes, and HPV vaccination practice. Women's knowledge of cervical cancer prevention was assessed and scored. Multivariate logistic regression was conducted to explore determinants associated with HPV vaccination practice and vaccination willingness.

Results: A total of 4,220 female adults (36.5±7.8y) were included in the final analysis. The median knowledge score was 15.24 out of 23. More than 75% of female adults remained unvaccinated, although 94.8% of them expressed a positive attitude towards HPV vaccination. Age, ethnicity, education level, marital status, occupation, vaccination history, and knowledge of HPV could influence vaccination practice. In addition, those younger female adults, the Han race, those who had health insurance, had a history of vaccination, and had known HPV before are more willing to vaccinate.

Conclusions: Overall, the overall vaccination coverage was low though Chinese female adults have strong intentions to vaccinate. Meanwhile, the knowledge level of cervical cancer and its prevention was found to be moderate. Multiple factors influence the vaccination practice and willingness to vaccinate. Our findings may provide guidance on future health education and training to help accelerate the promotion of the HPV vaccine in mainland China.

Shift 02-087 / #357

Poster Viewing
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KNOWLEDGE, ATTITUDES AND PRACTICES TOWARDS HUMAN PAPILLOMAVIRUS VACCINATION AMONG MEDICAL DOCTORS AT A TERTIARY HOSPITAL: A CROSS-SECTIONAL STUDY

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Introduction: Human papillomavirus (HPV) infection is a common sexually transmitted disease, with persistent infection with high-risk strains leading to malignant conditions such as cervical cancer. The HPV vaccine is a well-known primary preventive measure for HPV infections. In 2019, Zambia rolled out the free national HPV vaccination program targeting 14-year-old girls. However, the annual coverage is variable, with rates as low as 33% for 2021. Previous studies have shown that medical doctors' vaccine recommendation is one of the key strategies in improving HPV vaccine uptake

Methods: We conducted a cross-sectional study between September and December 2020. We used the analysis of variance to assess the mean differences in the overall scores for knowledge, attitude and practices towards the HPV vaccine. In addition, structural equation modelling (SEM) was used to test the traditional education theory as medical doctors' HPV vaccine knowledge, attitude, and practices cover several facets, and SEM can model latent variables.

Results: We enrolled 121 medical doctors, of whom 67 (44.6%) were male. The majority, 76 (62.8%), were registrars and 79 (65.3%) had more than ten years of clinical experience. The overall mean knowledge, attitude, and practice score of the HPV vaccine mean (SD) were 70.2 (15.1), 72.1 (18.5) and 77.1 (28.9), respectively. More than half of the medical doctors would advise anyone eligible to take the HPV vaccine 66 (54.6%). There was a positive correlation between attitude and practice towards the HPV vaccine (β= 0.03, p=0.017). Conversely, there was no evidence of a correlation between overall HPV knowledge and attitude (β = 0.01, p = 0.670) and rank of the medical doctors (β = -7.87, p = 0.355).

Conclusions: Knowledge was high with good attitudes and practices among medical doctors, which are vital in vaccine recommendation and subsequent uptake.

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SYSTEMATIC REVIEW OF DATA SYSTEMS RELATED TO CERVICAL CANCER AND HPV VACCINATION IN SELECTED MIDDLE-INCOME COUNTRIES

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Introduction: Cervical cancer is the fourth most common cancer in women. About 90% of the cervical cancer cases are linked with Human papillomavirus (HPV). Multiple public health agencies, including the WHO, have made the call to action for the elimination of cervical cancer. To assess the progress towards the elimination goal, population-level studies that evaluate the disease burden, and the impact and effectiveness of HPV vaccination and cervical cancer screening are needed. To conduct these studies, robust data are required for continuous evaluation and tracking against established targets. The goal of our study is to examine whether there exist reliable data systems in middle-income countries (MICs) that can support HPV-related research.

Methods: Following the PRISMA checklist, we conducted a systematic literature review to summarize data systems that contain information on cervical abnormalities and cervical cancer, HPV vaccination coverage, and cervical cancer screening in nine MICs: South Africa, Mexico, Turkey, Kenya, Russia, Philippines, Vietnam, Brazil, and Indonesia. We developed relevant keywords and searched PubMed for studies published in the past ten years. Two reviewers independently screened the retrieved articles in two rounds of screening. In each round, disagreements were discussed to reach a consensus or resolved by a third reviewer.

Results: Fifty-three studies were included in the final information extraction. The numbers of studies by country are: Brazil (26), South Africa (10), Mexico (5), Turkey (5), Kenya (3), Russia (3), Vietnam (1), Philippines (0), and Indonesia (0). South Africa, Brazil, and Mexico had data systems related to cervical abnormalities and cervical cancer and cervical cancer screening. Turkey, Kenya, and Russia had data systems related to cervical abnormalities and cervical cancer. Vietnam had data systems related to HPV vaccination coverage. Philippines and Indonesia had no relevant studies.

Conclusions: There is a lack of data systems in MICs that can support HPV-related research.

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SYSTEMATIC LITERATURE REVIEW ON HUMAN PAPILLOMAVIRUS VACCINATION RECOMMENDATIONS IN NATIONAL IMMUNIZATION PROGRAMS IN SELECT AREAS IN THE ASIA-PACIFIC REGION

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Introduction: Literature on current human papillomavirus (HPV) vaccination programs in the Asia-Pacific (AP) region is limited. This review aims to provide data on the current status of HPV vaccination programs in select AP areas (Hong Kong, Indonesia, Japan, South Korea, Malaysia, the Philippines, Singapore, Taiwan, Thailand, and Vietnam).

Methods: A systematic literature review was conducted from January 1, 2000, to February 25, 2022, using Medline and Embase. Grey literature searches were also performed of national government/ministry of health websites for the 10 areas. Information on the current HPV vaccination program in each area, including descriptions, recommendations, funding, and coverage (e.g., female only, catch up cohort, gender-neutral vaccination), were extracted.

Results: Eight of the 10 AP areas of interest include HPV in the national immunization programs (NIPs) for school-aged girls (Hong Kong, Japan, Malaysia, the Philippines, Singapore, South Korea, Taiwan, and Thailand). Singapore also has a National Adult Immunization Schedule that includes HPV vaccination for women aged 18 to 26 years. Indonesia has a demonstration program that was started in 2016. HPV vaccinations are currently not part of the NIP in Vietnam. Males are not included in HPV vaccination programs in any of the 10 areas. As of 2022, 1 vaccine option is included in the NIP for 6 areas: nonavalent HPV vaccine (9vHPV) in Hong Kong and Taiwan; quadrivalent vaccine (4vHPV) in Japan, the Philippines, and Thailand; and bivalent vaccine (2vHPV) in Singapore and Malaysia. The NIP in South Korea includes 2vHPV and 4vHPV.

Conclusions: While HPV NIPs are present in females in the AP region, opportunities remain to strengthen NIPs in broader populations (e.g., males, catch-up cohorts) to expand public health impact and provide gender equity in HPV vaccination.

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PUBLIC HEALTH PRACTICE CHANGE FOR ADDRESSING HPV VACCINE HESITANCY IN BRITISH COLUMBIA, CANADA: HPV VACCINE UPTAKE PROJECT

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Introduction: HPV vaccine (HPVV) coverage rates in British Columbia's school-based immunization program have remained below 70% since its introduction in 2008. This project aimed to leverage Public Health Nurses (PHNs), who typically administer HPVV in the school-based program (to 11-12 year-olds), to increase HPVV uptake through the implementation of tailored messaging with HPV vaccine-hesitant parents.

Methods: In collaboration with PHNs, a practice change was implemented in the 2019/2020 school year, to increase HPVV uptake. PHNs called two groups of parents, those who had not returned a consent (NC) form and those who declined HPVV on the consent form, and used motivational interviewing (MI) to identify and address parental vaccine concerns using tailored messaging. The number of parents called, telephone consents completed, parental vaccine concerns, conversation length, and audit of subsequent HPVV receipt were collected.

Results: A total of 137 parents received a phone call attempt, of which NC accounted for 58% (79/137) of calls, and 38% (49/137) were due to declining HPVV. PHNs completed conversations with 88 parents. Of those who initially declined, 10% (4/39) provided telephone consent and their child subsequently received the HPVV, and an additional 17% (6/35) who did not consent by phone went on to receive HPVV. Among NC, 49% (21/43) provided HPVV consent by phone. Concerns about vaccine safety were cited by 27% (24/88) of parents.

Conclusions: The addition of a telephone call to vaccine-hesitant parents using tailored messaging showed moderate increases in HPVV consent and uptake. Vaccine hesitancy was expressed through initially declining consent, but also, through disengagement from the consent process. HPV vaccine-hesitant parents are a challenging population to move towards vaccine acceptance. To reach the 90% coverage target, multiple approaches will be needed to further increase vaccine uptake in the school-based HPV immunization program.

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PARENTS' VIEWS ABOUT HPV VACCINE AND HESITANCY TOWARDS VACCINATION DURING THE COVID-19 PANDEMIC IN PUERTO RICO

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Introduction: In 2018, Puerto Rico (PR) implemented the human papillomavirus (HPV) vaccine as a school-entry requirement for adolescents. Studies have shown that an optimal HPV vaccination for teenagers might be affected by parental vaccine hesitancy, lack of knowledge, and inconsistent provider recommendations. We estimate the association between HPV vaccination knowledge and agreement with this vaccine as a school-entry requirement, respectively, and general vaccine hesitancy during the COVID-19 pandemic.

Methods: A sample of 114 parents (21 years old or more) completed an online survey in Spanish about their opinion of HPV and COVID-19 vaccination using social media from November 2021-January 2022. We used eight adapted questions from the Parents Attitudes about Childhood Vaccines (PACV) Scale to identify vaccine-hesitant parents. Descriptive analyses were performed. To determine the magnitude of association with HPV vaccination knowledge and agreement with the HPV vaccine school-entry requirement, adjusted odds ratios ($OR_{adjusted}$) were estimated with 95% confidence intervals.

Results: The parents interviewed had a mean age of 42 years old (±11.12) and 88.6% were females. A third (36%) of the respondents were hesitant about vaccination. Logistic regression multivariate model showed that those who reported limited knowledge about HPV vaccine had 53% higher odds of being hesitant toward vaccination than those with sufficient knowledge ($OR_{adjusted}$: 1.53, CI 95%: 0.65-3.59); however, this relative excess was not significant ($p>0.05$). Parents who disagreed with the HPV vaccine school-entry policy were significantly more likely to be hesitant against vaccination, when adjusting for age and sex ($OR_{adjusted}$: 11.99, IC 95%: 4.49-31.99).

Conclusions: Understanding vaccine-hesitant parents' views is essential to provide adequate education strategies. Overcoming vaccination distrust and the importance of school-entry policies in public health requires trusted messengers with updated, accurate and reliable information to ensure that parents are fully informed about the importance and safety of the HPV vaccine and reduce the burden of HPV-related cancers in Puerto Rico.

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ATTITUDES TOWARDS HPV VACCINATION AMONG URBAN GAY, BISEXUAL AND OTHER MEN WHO HAVE SEX WITH MEN IN CANADA

Anna Yeung[1], Veronika Moravan[2], Catharine Chambers[3], Ramandip Grewal[4], Marc Brisson[5], Troy Grennan[6], Alexandra De Pokomandy[7], Joseph Cox[8], Gilles Lambert[9], David Moore[10], François Coutlée[11], Shelley Deeks[12], Chantal Sauvageau[5], Gina Ogilvie[13], Darrell Tan[1], Nathan Lachowsky[14], Daniel Grace[3], Rosane Nisenbaum[1], Jody Jollimore[15], Trevor Hart[16], Ann Burchell[17]
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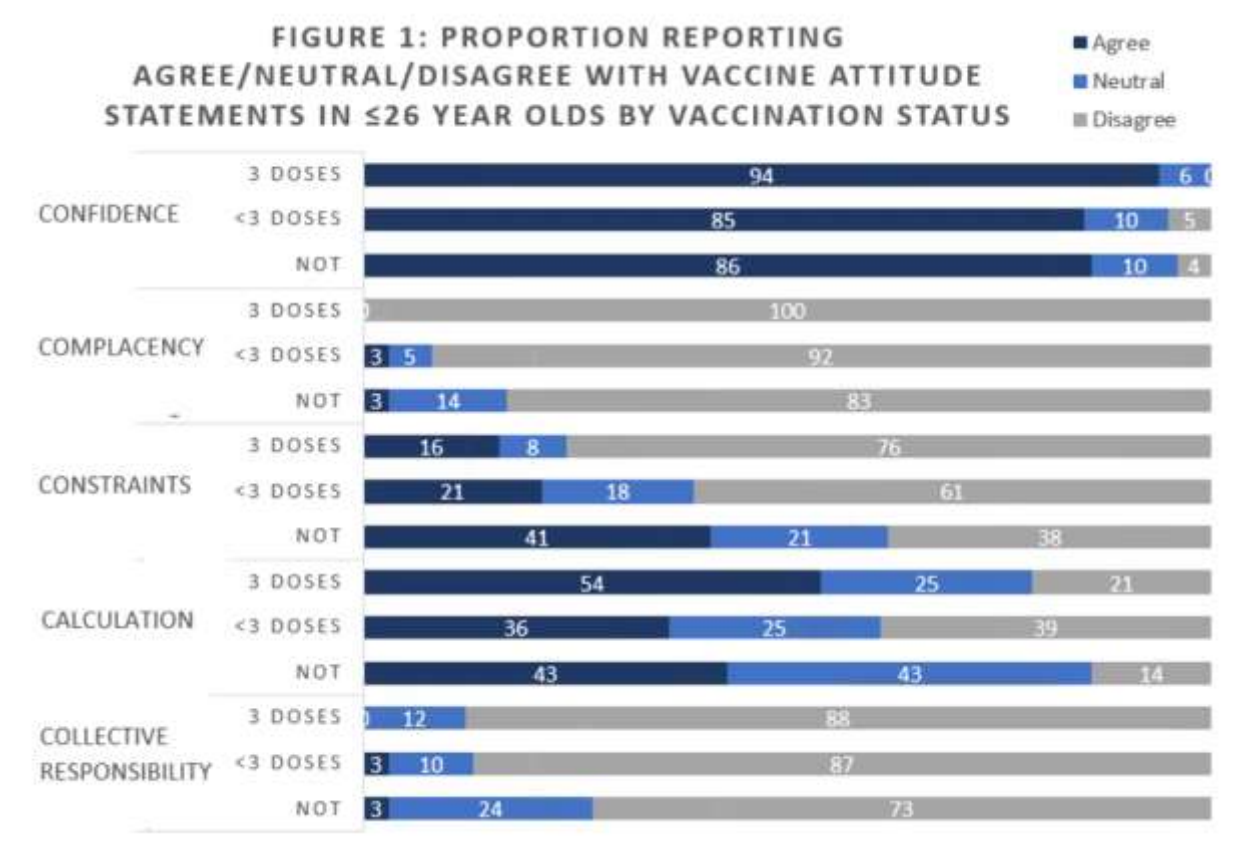
Introduction: INTRODUCTION: HPV vaccine for gay, bisexual and other men who have sex with men (GBM) aged ≤26 years is publicly funded in the Canadian provinces of Ontario, Quebec, and British Columbia. We examined HPV vaccine attitudes among GBM aged 16+ years living in Toronto, Montreal and Vancouver.

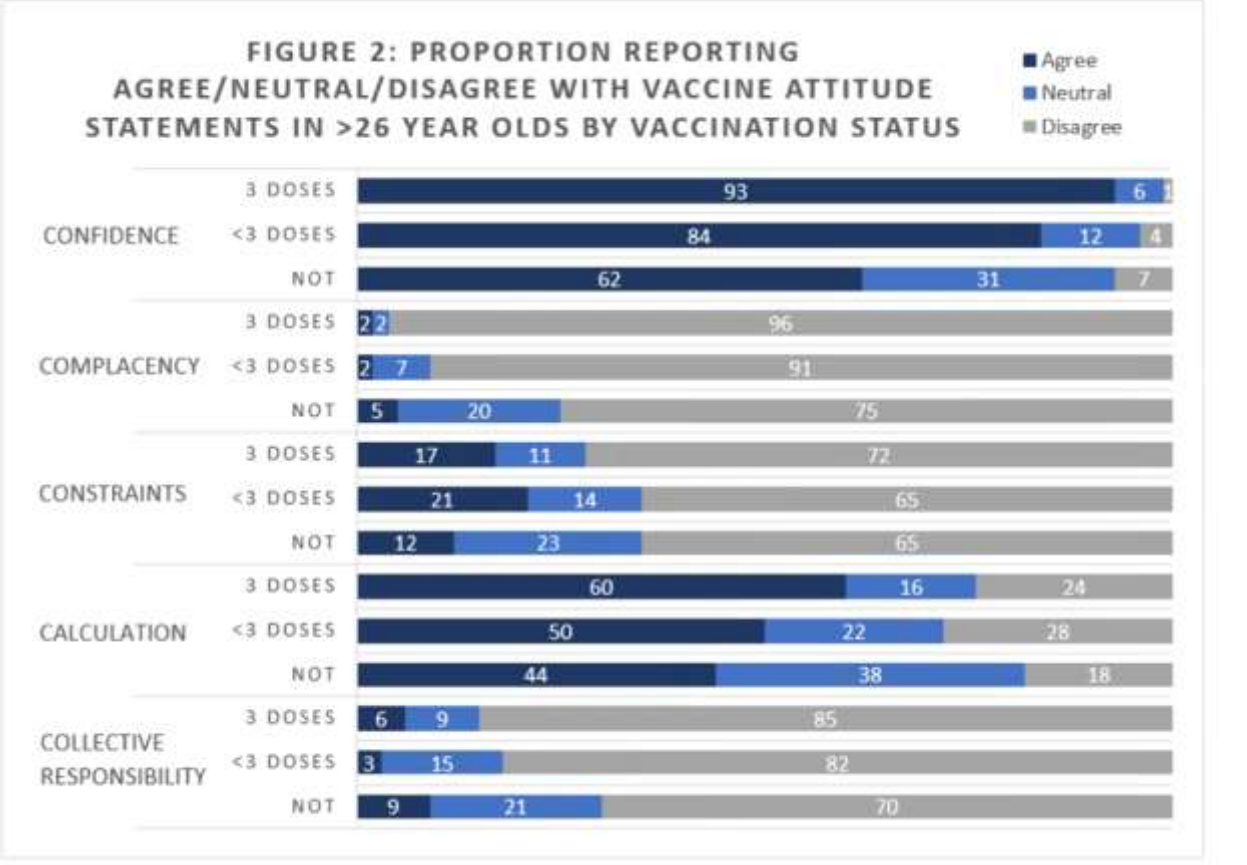
Methods: METHODS: Engage is a community-recruited cohort study; GBM enrolled between 2017 and 2019 and were followed every 6-12-months. At the 3-year visit, we asked vaccinated and unvaccinated participants about their agreement with statements adapted from the 5C scale (confidence, constraints, complacency, calculation, collective responsibility; Betsch et al 2018, PLoS One) We compared proportions agreeing (strongly agree/agree), neutral (neither agree nor disagree), and disagreeing (disagree/strongly disagree) by self-reported HPV vaccination status (3 doses/<3 doses/not vaccinated) and by age (≤26/>26) at the time of questionnaire using the Kruskal-Wallis test.

Results: RESULTS: A total of 1419 participants aged 19-83 years responded to statements about vaccine attitudes (854 Montreal; 232 Toronto; 333 Vancouver). Of these, 8.5% (120/1419) were aged ≤26 years; 20.4% received 3 doses (n=290/1419); and 15.4% received <3 doses (n=218/1419). Agreement that 'HPV vaccine is safe' was relatively high overall but significantly lower among unvaccinated older participants compared to unvaccinated younger participants (p=0.01, Figures 1 and 2). A higher proportion of unvaccinated younger participants agreed that it was 'inconvenient to attend vaccination appointments', compared to unvaccinated older participants (p=0.0002). Unvaccinated participants were more neutral in their responses (range 10%-43%) than 3-dose or <3-dose vaccinated participants (range 0%-25%).

Table 1: Vaccine Attitude Statements, adapted from 5C Scale (Betsch et al)

Antecedent	Corresponding statement asked of Engage participants
Confidence	I am completely confident that the HPV vaccine is safe
Complacency	HPV vaccination is unnecessary because only girls and women need to get the HPV vaccine
Constraints	For me, it is/was inconvenient to get to a clinic or doctor 3 times to get completely vaccinated for HPV
Calculation	When I think/thought about getting vaccinated for HPV, I weigh(ed) benefits and risks to make the best decision possible
Collective responsibility	If everyone is already vaccinated for HPV, I wouldn't have to get vaccinated too





Conclusions: CONCLUSIONS: As expected, most participants viewed HPV vaccination as safe. Unvaccinated participants were more neutral on the 5C scale as opposed to outright disagreement. We recommend that vaccination campaigns promote greater awareness of the safety of the HPV vaccine, and that programs improve accessibility and convenience.

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SUPPORT FOR VOLUNTARY HPV SCHOOL-BASED VACCINATION IN GERMANY – RESULTS OF A COUNTRY-WIDE SURVEY IN 2022

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Introduction: HPV vaccination rates in Germany are low among 15-year-old girls (47%) and boys (5%). Given the link between high HPV vaccination coverage and school-based HPV vaccination in other countries, the latter often has been discussed as a strategy able to increase significantly vaccination coverage in Germany. However, little is currently known about how the German population would support such a program. Therefore, the objective was to find out how the German population is willing to support a voluntary school-based HPV vaccination program.

Methods: We mandated a market research company to conduct a representative multi-topic telephone survey in 2022. German citizens aged 14 and over with at least one fixed network connection or at least one cell phone were interviewed. We used descriptive statistics for the data analysis.

Results: A total of 1,013 German citizens were surveyed: 49% of respondents were men and 51% women, 83% were living in former Western Germany and 17% in former Eastern Germany. Around 71% of respondents would support voluntary HPV vaccination programs in schools. The willingness to support such program is particularly high among adolescents aged 14 to 17 years (97%), school pupils (96%), adults aged 40 to 49 years. There was a significant difference in motivation to support the program between men (75%) and women (67%), a non-significant difference between Eastern (81%) and Western Germany (78%). The highest willingness in federal states was in Schleswig Holstein (95%), the lowest in Bavaria and in Baden-Württemberg (73%).

Conclusions: This survey shows a high public support for HPV school-based vaccination. Despite the difference between men and women as well as between federal states, which may challenge the program in Germany, the momentum of general high support should be used for the implementation of school-based HPV vaccination in the country.

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PERI-TREATMENT USE OF PROPHYLACTIC HPV VACCINES IN PATIENTS WITH HPV-ASSOCIATED DISEASE: REVIEW OF THE MECHANSIM OF ACTION

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Introduction: Individuals with HPV-related disease remain at risk for subsequent HPV-related infection and disease after undergoing treatment for specific HPV-related lesions. Prophylactic HPV vaccines have shown benefits in preventing subsequent HPV-related disease when administered before or soon after treatment. However, the terminology used to describe vaccine effects in these populations is ambiguous, sometimes implying adjuvant or direct therapeutic effects, which would be considered off-label. In such cases, the terminology can become misconstrued and cause confusion about when vaccination can be effective and how it works.

Methods: We reviewed the published evidence for using prophylactic HPV vaccines in patients with HPV-associated disease before, during or after treatment, in the context of potential mechanisms by which individuals with HPV-associated disease may or may not benefit from vaccination.

Results: Based on the current understanding of the HPV life cycle and vaccine mechanism of action, prophylactic HPV vaccination is not expected to clear active persistent HPV infection or unresected HPV-associated dysplastic tissue remaining after surgery. However, vaccination may reasonably be expected to prevent new HPV infections caused by a different HPV type as well as re-infection with the same HPV type, whether from a new exposure to an infected partner or through autoinoculation from an adjacent productively infected site.

Conclusions: Given the reviewed virus biology and vaccine mechanism of action, vaccination should be termed prophylactic HPV vaccination regardless of past or present HPV disease. Precise terminology relating to use of prophylactic vaccines in this population is critical to avoid the incorrect expectation that prophylactic vaccines have direct therapeutic potential.

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HPV VACCINATION CAN INTEGRATE OTHER ADOLESCENT HEALTH SERVICES IN TANZANIA

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Introduction: Integration of adolescent health services alongside human papillomavirus (HPV) vaccination delivery in low-resource settings has been recommended, but seldom implemented as part of routine HPV immunization. This well-studied example from Tanzania provides insights into what is feasible. The Ministry of Health (MOH), supported by Gavi and Jhpiego, the Johns Hopkins University affiliate, implemented the "HPV Plus" program over 2019-21. This provided health education, and screening of nutrition and vision, alongside HPV vaccination; most during school outreach, and also at facility and community levels.

Methods: Jhpiego, the International Vaccine Access (IVAC) at the Johns Hopkins University, and the Muhimbili University of Health and Allied Sciences collaborating with government authorities, conducted a mixed-methods evaluation. This included in-depth qualitative interviews into feasibility and acceptability in mid-2021, supplemented by analysis of service delivery and coverage data between 2021 and 2022.

Results: Interviews demonstrated high overall feasibility and acceptability. Specific issues of staffing, time management, resourcing and communications were identified as needed to improve scalability and sustainability within the broader HPV vaccination program. Service delivery data showed at least 90% of vaccinated 14 year old girls received the additional screening package, and education successfully delivered to a broader range of girls and boys. Many nutrition or vision problems were referred but stronger integration of schools with health services was needed. Administrative immunization coverage showed HPV Plus implementing regions as top performers in the country, demonstrating that the integrated package did not adversely impact coverage. Costs of the additional services, at less than USD1 per girl plus outreach costs, were judged as feasible within the continuing national HPV vaccination program.

Conclusions: Integration of a tailored package of adolescent health interventions can be feasibly delivered alongside routine HPV vaccination in Tanzania. Government support, and attention to specific aspects of management, staffing, resourcing and communications are essential to scale-up.

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HPV VACCINES UPTAKE IN KENYA: ACTIVE OUTPATIENT (OPD) SCREENING AND REFERRAL OF GIRLS CAN CLOSE MISSED OPPORTUNITIES GAPS FOR HPV VACCINATION

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Introduction: The Human Papilloma Virus (HPV) vaccine is the primary prevention of virus-attributable cervical cancer. Although school based approach has yielded higher coverage, the primary service delivery approach for HPV is facility based in line with national routine immunization. In 2019, Kenya rolled out the two-dose HPV vaccine to 10-year-old girls, with the doses delivered six months apart. Despite progress made in the first year, coverage rates dropped in 2020 due to the COVID-19 pandemic that necessitated school closures. This program leveraged facility outpatient (OPD) attendance as an opportunity for closing missed opportunities for HPV vaccination.

Methods: This work evaluated facility-based screening and referral system for HPV vaccine, utilizing DHIS2 data and a difference-in-difference regression analysis. It compared 28 public health facilities with 14 implementing active screening for 7 monthsPatients within the target cohort, were actively screened for HPV vaccine eligibility at the OPD and offered an opportunity for vaccination. Analysis was conducted using Stata-15.

Results: At baseline and endline, 721 and 1,198 girls received HPV-1 while 959 received HPV-2 in control facilities. For HPV-1, there was no statistical difference in uptake in control sites (MD 9.0, P-value 0.288 CI [8.52 – 28.39]). In the intervention facilities, HPV-1 doses administered increased significantly from 1,810 to 4,434, with a statistically significant result (MD 63.0; P-value 0.019, 95%CI [10.4 – 114.6]) and 2.85 times more girls received HPV-2 (IRR 2.85, P-Value <0.005 95%CI 2.430-3.354). Coverage in intervention facilities increased by 49%(IRR 1.474 P-value <0.005 95%CI [1.324 – 1.641].

Conclusions: A standardized offer to screen and vaccinate children accompanying caregivers or those attending health facilities for other services is feasible to scale up with minimal additional human resources. The active screening was acceptable to HCWs and caregivers and is a promising strategy to expand vaccines coverage while closing missed opportunity gaps for HPV vaccination.

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IMPACT OF A PAPILLOMAVIRUS VACCINATION PROMOTION PROGRAM IN MIDDLE SCHOOL TO RAISE VACCINAL COVERAGE IN REUNION ISLAND

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Introduction: In Reunion Island, cervical cancer is the third most common cause of cancer in women. Primary prevention is based on HPV vaccination, yet coverage rate is low (12.2%). The objective of the study was to evaluate the impact of a health promotion program on the proportion of middle school girls who have completed HPV vaccination schedule.

Methods: In this prospective, controlled intervention study of superiority, 12 classes were randomly selected in an intervention school where the promotion program took place, and in a control school where no specific intervention was planned. The program combined: students information during school classes, parents information by letter and phone calls, general practitioners information by letter and video conference call, free school-based vaccination (in a "health bus" parked in the schoolyard) with nonavalent HPV vaccine.

Results: In the intervention group, completion was achieved for 26 girls, which was significantly higher than in control group (3 girls, p<10-3). Initiated vaccination was also higher in intervention group (31 girls vs. 6 girls in control group, p<10-3). Same results were obtained for boys as for full or partial scheme (7 boys vs. 0, p=0.01; 16 boys vs. 1, p<10-3, respectively).

Conclusions: Implementing a health promotion program and offering free school-based vaccination raised vaccination coverage. These results are promising and may be a stepping stone to expand this program to the whole Reunion Island and hopefully someday decrease the burden of cervical cancer.

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Poster Viewing
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UNDERSTANDING BARRIERS AND MOTIVATIONS TO PAPILLOMAVIRUS VACCINATION IN A MIDDLE SCHOOL IN REUNION ISLAND

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Introduction: In Reunion Island, papillomavirus (HPV) vaccination coverage is low. A study encouraging vaccination in middle school, showed low rate of participation. The main objective of the study was to understand barriers and motivations to HPV vaccination in populations yet sensitized to its benefits.

Methods: The study was conducted among the population around the intervention school where the health promotion program was conducted during school year 2020-2021. Semi- structured face-to-face interviews, were conducted among children, children's parents, school staff, general practitioners, association members. A qualitative study was adopted using a grounded theory approach to obtain an indepth understanding of issues pertaining to HPV vaccination.

Results: A total of 19 school staff members, 20 parents of middle school children, 39 children, 5 general practitioners and 3 association members were interviewed in May 2021. Anti- vaccination attitudes could be explained by: fear of serious adverse effects due to lack of information and knowledge, mistrust of scientists and pharmaceutical industry, importance of the relay by social networks. School, general practitioners, story-telling testimonials and chasing fame on television, played a central role to invert the balance and motivate children's vaccination.

Conclusions: Specificities of our population was fear for teenage pregnancy, which rate is high in Reunion Island. We should lift this taboo related to sexuality and encourage dialogue between children and their close social network. This better understanding of barriers and motivations will lead to solutions to expand this HPV vaccination promotion program across all Reunion Island.

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COMMUNICATION TOOLS TO ADDRESS HPV VACCINATION WITH ADOLESCENTS

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Introduction: During school year 2020-2021, we conducted a study in two middle schools in Southern Reunion Island, where we compared HPV vaccination rate at the end of the year, following a health promotion program. In parallel we evaluated three communication strategies: one-shot students information during classes (passive communication), information all along school year with personalized discussion during coloring artwork (opportunistic communication), and information created by children themselves to raise awareness among their peers (participative communication). The objectives of the study were to evaluate the impact of these three groups receiving different communication tools on theoretical HPV vaccine acceptance, and effective HPV vaccination among adolescents.

Methods: The strength of the association between the communication mode and the vaccination intention or effective vaccination rate was measured by calculating the Relative Risks between the groups.

Results: As compared with the passive group, rate of students with intention to vaccinate against HPV was significantly higher in the participative group (RR 2.6 [1.9–3.5], $p< 0.001$) and in the opportunistic group (RR 1.6 [1.2–2.0], $p < 0.001$). Similarly, comparatively to passive group, effective vaccination significantly outperformed in the participative group (RR 30.3 [8.9–103.0], $p< 0.001$) and in the opportunistic group (RR 12.9 [4.1–40.9], $p < 0.001$).

Conclusions: Opportunistic and participatory communication, including empowerment for child and adolescent health promotion could be a solution to increase adolescents health literacy, and hopefully increase their vaccine uptake.

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UNDERSTANDING THE BARRIERS TO HPV VACCINE UPTAKE: AN EXPLORATION OF THE CANADIAN LANDSCAPE ON HPV IMMUNIZATION PROGRAMMING OPPORTUNITIES

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Introduction: The Canadian Partnership Against Cancer has provided funding to the Urban Public Health Network to assess the landscape of HPV immunization coverage, barriers, and opportunities at a sub-jurisdictional level, in order to achieve the target of 90% HPV immunization to support the work of the Action Plan to Eliminate Cervical Cancer in Canada by 2040. This work has involved engaging local public health organizations across Canada to uncover high-resolution quality improvement targets of investment for underimmunized populations.

Methods: This project uses a mixed-methods design to understand barriers and facilitators to increasing HPV immunization uptake at a sub-provincial level. Stakeholders were engaged from across Canada and analysts were placed in four local public health units, to extract sub-provincial level HPV programming insights. HPV immunization data was collected at a sub-provincial level, and in some cases, down to a postal code or school level. Coverage rates were then linked to socio-demographic indicators where possible to identify pockets of under-immunization. To further determine barriers and facilitators, surveys, focus groups, and interviews took place with caregivers and providers.

Results: Preliminary results indicate the availability of HPV immunization data is highly variable across Canada, as is HPV immunization programming. Barriers to immunization have been identified at both individual (e.g. lack of healthcare provider recommendation, misinformation) and systems-level (e.g. absence of a national immunization registry) in participating regions to varying degrees.

Conclusions: Understanding how barriers and facilitators impact HPV immunization uptake at a local level is critical to implementing innovative policies and programming. Findings will be reported by region and/or subgroup, as well as aggregated nationally to inform recommendations made to CPAC on ways to address inequities in access and uptake.

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SCHOOL-BASED HPV VACCINATION IMPLEMENTATION STRATEGIES AMONG MEDICALLY UNDERSERVED ADOLESCENTS IN THE UNITED STATES: ADDRESSING MISSED OPPORTUNITIES BEYOND SCHOOL-ENTRY VACCINE MANDATES FOR HPV ELIMINATION

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Introduction: Successful school-based HPV immunization programs have improved vaccination rates globally and are standard in many countries. However, HPV vaccination strategies in school settings in the United States (US) have mainly focused on school entry mandates, enacted in only five states/jurisdictions. We aimed to better understand other potential opportunities to improve adolescent HPV vaccination using school-based implementation strategies in the US by interviewing individuals serving communities at high-risk of HPV-associated cancers.

Methods: We conducted a secondary analysis on qualitative interviews and focus groups with clinic (providers, clinic leaders, staff) and community (racial/ethnic minority parents, advocates, payers, policy-level) members in safety-net healthcare settings in Los Angeles and New Jersey between December 2020-January 2022. We conducted thematic analysis on any text related to school-based HPV vaccination strategies to compare common and divergent perspectives across groups and regions.

Results: Participants (n=65) identified school-based settings as fertile opportunities to engage underserved adolescents/parents to improve HPV vaccine education, access, and uptake. Challenges of school partnerships due to politicization of vaccines and reproductive health education censorship had shifted the focus away from mandates towards other implementation strategies. Parents expressed trusting school-based clinic staff for vaccine-related information and other clinic and community members expressed the desire to directly engage adolescents and parents in schools to provide HPV vaccine education and address hesitancy and misinformation. Other opportunities to improve HPV vaccination access in school settings included policies such as limiting religious exemptions and COVID-19-related strategies such as the use of mobile vans for co-administration in schools.

Conclusions: Participants identified schools and school-based clinics as important venues for addressing missed opportunities for HPV vaccination in medically underserved communities. Parents and community members are open to engaging with each other in school settings to improve adolescent HPV vaccination, and implementation strategies that facilitate mutual interest should be explored.

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COMPARATIVE LONG-TERM IMMUNOGENICITY OF TWO VERSUS THREE EXTENDED DOSES OF QUADRIVALENT HPV VACCINE

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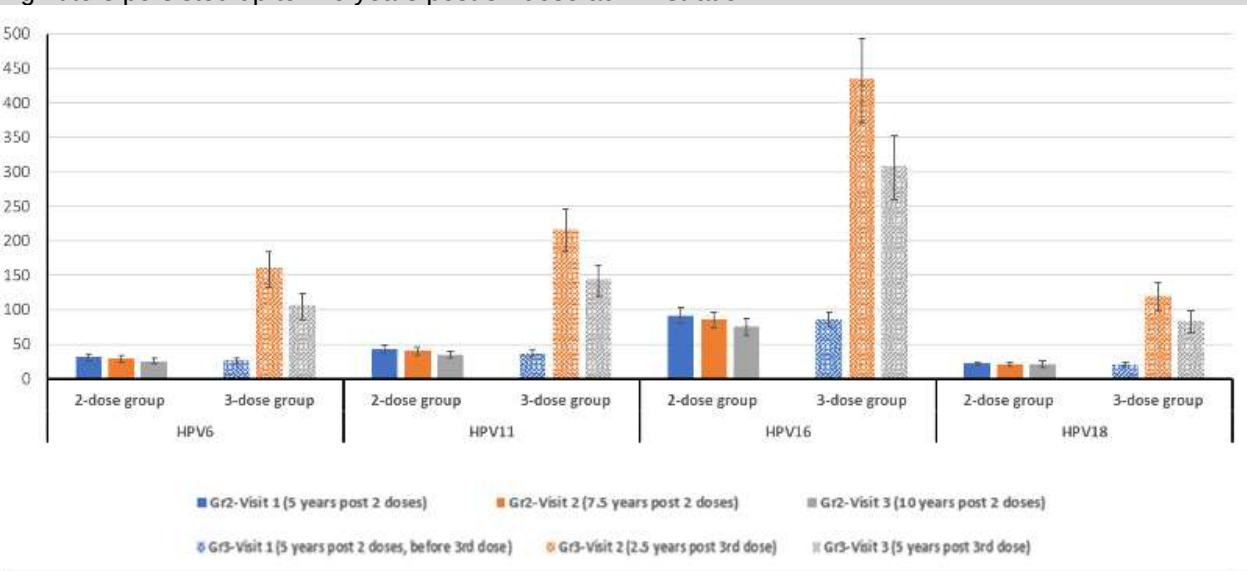
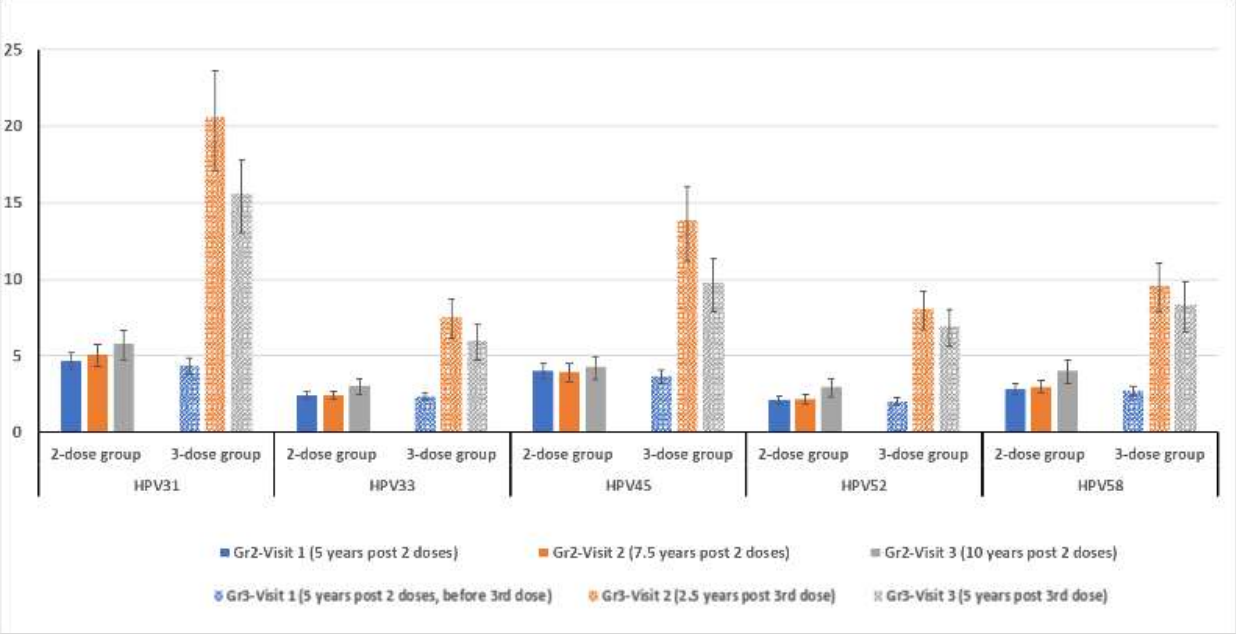
Introduction: The objective of this analysis was to assess the persistence of antibodies and their geometric mean titers (GMTs) after vaccination of 9 to 11 year-old girls either with two (0, 6 months) or three doses (0, 6 and 60 months) of quadrivalent human papillomavirus (HPV) vaccine (4vHPV) up to 10 years post-first dose.

Methods: Of the 3356 girls recruited and randomly assigned (1:1) to receive or not receive a 3rd dose of vaccine in the Impact des calendriers d'immunisation contre les VPH (ICI-VPH) study, 496 were included in the immunogenicity sub-study. Seropositivity and GMTs to 9 HPV types included in the nine valent (9vHPV) vaccine were assessed 5, 7.5 and 10 years post first dose using M9ELISA.

Results: Five years post two doses, seropositivity and anti-HPV types GMTs were similar among girls randomly assigned to receive (n=248) or not receive (n=248) a third dose of vaccine. In the subsequent 5 years, all participants (100%) remained seropositive with anti-HPV6, 11 and 16 antibodies detected through all timepoints. The anti-HPV18 positivity varied between 94% (2-dose group) to 99.3% (3-dose group). Anti-HPV positivity to the five additional HPV types included in the 9vHPV valent vaccine was also observed in both groups with HPV31 being the highest (94.3% 5 years post third-dose administration). GMTs to the four HPV types included in the 4vHPV were significantly higher in the 3-dose group, and

high titers persisted up to five years post 3rd dose administration.





Conclusions: These results are congruent with previously reported high clinical efficacy of HPV vaccines, even with low antibody levels. A booster dose of 4vHPV vaccine is highly immunogenic when administered several years post primary two-dose vaccination. The clinical significance of these findings will require correlation with HPV infection data from the ICI-VPH study.

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EXPLORING THE BARRIERS TO HUMAN PAPILLOMAVIRUS VACCINE UPTAKE IN LOW RESOURCE SETTINGS: UTILIZING THE "ONE HEALTH" CONCEPT FOR MULTIDISCIPLINARY SOLUTION

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Introduction: Cervical cancer is the second most common female malignancy which is both preventable and curable with appropriate/timely intervention(s). Introduction of Human Papillomavirus (HPV) vaccine is a major milestone in the fight against cervical and other HPV related malignancies. Determinants of HPV vaccine uptake are numerous and multifaceted especially in low resource settings. Nigeria, particularly northern part of the country has history of anti-vaccine activities. There is need for multidisciplinary approach using the "one health" concept with inputs from all relevant professionals for optimum results.

Methods: An organized cervical cancer screening/intervention exercise for general population of women (≥30years) was conducted between January and February 2021 in Gombe Nigeria. A semi-structured questionnaire to explore the experiences and determinants for uptake of HPV vaccine was administered.

Results: A total of 1033 women participated in the study out of which only 14 (1.4%) had ever received HPV vaccination but majority (96.0%) indicated their readiness to accept it for their daughters/wards. Majority of those that ever received the HPV vaccine are civil servants (64.3%), Christians (71.4%) and educated up to tertiary level (71.4%). Some of the reasons for not taking the vaccine among the participants include lack of awareness (77.0%), cost (7.5%) and fear of side effects (1.8%).

Conclusions: Among the respondents, majority are civil servants, Christians and educated up to tertiary level. These are minority groups in the larger society which is predominantly made of Muslim house wives and less educated women with low socio-economic status. This study further highlights the importance of awareness especially from religious/educational institutions, improved socio-economic status and a well-organized multidisciplinary system for better uptake of HPV vaccine and reduced prevalence of cervical cancer. The multiplicity and multifaceted determinants of HPV vaccine uptake especially in low resource settings requires multidisciplinary inputs from various professionals (medical and non-medical) borrowing from the "one health" concept.

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HIGH VACCINE EFFECTIVENESS AGAINST GENITAL HPV INFECTIONS FOLLOWING TWO DOSES WITH THE BIVALENT HPV VACCINE IN GIRLS: 7 YEARS FOLLOW-UP IN A PROSPECTIVE COHORT STUDY.

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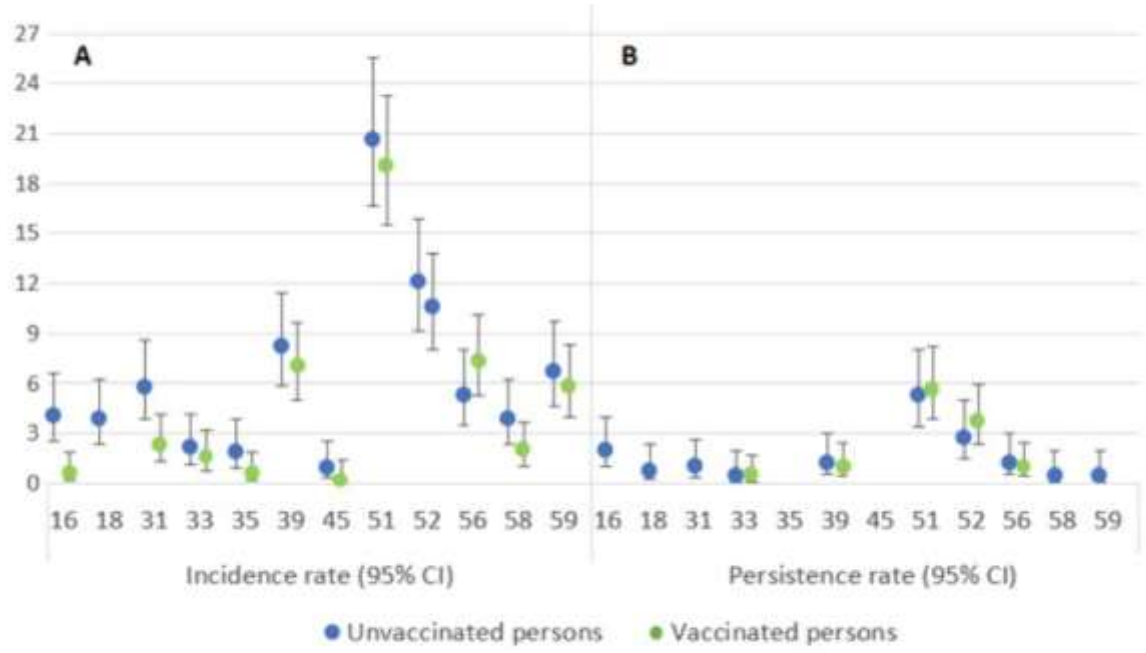
Introduction: High vaccine effectiveness against both persistent and incident HPV infections after a three dose (3D) schedule was observed after HPV-vaccination since 2010 with bivalent HPV vaccine (2vHPV) in the National Immunisation Programme in the Netherlands. In 2014 a reduced dosing schedule was implemented with two-dose (2D) of 2vHPV. The current study estimates vaccine effectiveness (VE) against HPV infections among girls eligible for routine 2D immunization. We analyzed data up to seven years post-vaccination.

Methods: Data were used from the longitudinal cohort study HAVANA2 (HPV Amongst Vaccinated and Nonvaccinated Adolescents after 2-doses). Every year, vaccinated and unvaccinated participants complete an online questionnaire and provide a vaginal self-sample for determination of HPV by the SPF10-LiPA25 assay, which is able to detect 25 HPV types including the 12 high-risk (hrHPV) types. Type-specific incidence and persistence rates were calculated. Adjusted VE estimates and 95% confidence intervals (95% CI) against incident and 12-month persistent vaccine targeted types HPV16/18 and cross-protective types HPV31/45 were estimated as 1-hazard ratio as calculated by a Cox proportional hazards model with shared frailty between HPV types.

Results: A total of 2002 girls were included in the VE analyses of whom 1100 (55.0%) were vaccinated according to a 2D schedule. The highest incidence and persistence rate was observed for HPV51 (vaccinated vs unvaccinated HPV51 19.0 vs 20.6 and 5.6 vs 5.3 per 1000 person-years, respectively) (Figure 1a and 1b). Adjusted pooled VE against incident HPV16/18 infections was 92.4% (95%CI 75.2%-97.7%). Additionally, we observed cross-protection against incident HPV31/45 infections (59.0%, 95%CI 20.0%-79.0%). Pooled VE against 12-month persistent HPV16/18/31/45 infections was

100%.

Figure 1a and 1b: Incidence- and persistence rate per 1000 person years of type-specific HPV infections among vaccinated and unvaccinated persons



Note: type-specific incidence- and persistence rate are not shown when no infections were determined.

Conclusions: Two doses of 2vHPV vaccination is - like three doses 2vHPV vaccination - highly effective in the prevention of incident and persistent HPV16/18 infections and additionally provides cross-protection to incident and persistent HPV31/45 infections up to seven years post-vaccination.

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DEVELOPMENT AND IMPLEMENTATION OF A BRIEF CLINIC- AND COMMUNITY-TRAINING FOR HPV VACCINE PROVIDER RECOMMENDATION

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Introduction: Provider recommendation is a strong predictor of HPV vaccination in the United States. While healthcare provider trainings are available, there was an unmet need to have brief and asynchronous trainings available for healthcare teams in clinic and community settings during the COVID-19 pandemic for Tarrant County, TX – an area with historically low HPV vaccination rates. We developed and implemented a brief, asynchronous training on HPV vaccine recommendations in clinical and community settings.

Methods: With input from clinical and HPV vaccine experts, a 20-minute training on HPV vaccine bundled recommendations, motivational interviewing, and brief responses to patient concerns was developed. The program was named HPV CHAT (Communicating about HPV to Adults and Teens). This quality improvement initiative recruited 7 clinics in a safety-net health system and 2 clinics in a practice-based research network.

Results: HPV CHAT was launched in April-May 2022 in 5 family medicine, 2 pediatric, and 2 school-based clinics. During April–July, 189 people completed the HPV CHAT training (66% of those eligible) and 171 had complete pre-post evaluation data. Knowledge about the HPV vaccine guidelines significantly improved (e.g., age at first dose 67% vs. 83%, $p<0.01$; 27-45-year-old recommendation 52% vs. 86%, $p<0.01$). We observed a significant increase in trainees' confidence to talk with patients about HPV vaccination (80% vs. 94%, $p<0.05$). Trainees' intentions to elicit patient concerns and recommend the HPV vaccine increased by more than 10% ($p<0.05$). At post-test, more than 90% of trainees reported their plan to routinely recommend the HPV vaccine.

Conclusions: This project demonstrated the feasibility and short-term outcomes of a brief HPV vaccine training for an under-vaccinated county in Texas. Next steps include an assessment of implementation outcomes based on qualitative evaluation and continued implementation of the training in additional clinics.

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THE COMMUNITY ADVISORY BOARD'S ROLE IN SUPPORTING HPV VACCINE SCHOOL-ENTRY POLICY IMPLEMENTATION IN PUERTO RICO

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Introduction: The study entitled 'Implementation of school-entry policies for vaccination of the Human Papillomavirus (HPV) vaccine' (HPV-PIVac) started in 2018 aiming to evaluate the impact of the implementation of the HPV vaccine as a requirement for school entry in Puerto Rico (PR). As part of this study's efforts, we organized a Community Advisory Board (CAB) whose members have worked for decades in HPV prevention. The purpose of the CAB is to contribute to interpreting HPV-PIVac study findings and provide recommendations to different sectors (government, academia, and community-based organizations) for improving policy implementation, future research, and community engagement.

Methods: The process of identifying the CAB members started in December 2019, with 20 representatives identified from public and private schools, community coalitions, medical associations, health surveillance systems, community programs, and the PR Department of Health. The CAB has been active since 2020, totaling 17 members and 20 meetings.

Results: During this period, the CAB has led a series of efforts, including revising an interview guide to assess key informants' views, barriers, and facilitators towards the implementation of the HPV school-entry policy in PR. Findings from the key informant's interviews led to the development of a survey that targeted teaching and non-teaching staff to understand their HPV knowledge and perception towards the vaccine requirement. These scientific collaborations led to the creation of a virtual educational webinar on school-required vaccines, including the HPV vaccine. The webinar was offered to 954 staff members from private and public schools, with accreditation of contact hours for the participants.

Conclusions: Over the last two years, the CAB has helped provide insight to HPV-PIVac investigators and has contributed to the development and implementation of scientific and educational strategies based on the results obtained from the HPV-PIVac study.

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LAUNCHING A PILOT MIDDLE SCHOOL-BASED EDUCATIONAL AND HPV VACCINATION PROGRAM TO INCREASE VACCINE UPTAKE IN THE RIO GRANDE VALLEY OF TEXAS

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Introduction: Human papillomavirus (HPV) vaccine uptake among US adolescents is far below the 80% Healthy People 2020 goal (51.1% completion rate). School-based vaccination helps support vaccination health literacy and decisional involvement, reduces fear and anxiety, and increases access to needed health services among medically underserved children and adolescents who may have limited encounters with healthcare providers. This study assesses the effectiveness of a pilot program that combines community-based education and onsite middle school-based HPV vaccinations in a rural, medically underserved Texas area.

Methods: The study included 2,276 students (1179 males and 1097 females) enrolled at 3 Rio Grande City Consolidated Independent School District (RGCCISD) middle schools (08/2016 – 02/2020). The intervention included a community-based, physician-led HPV education campaign starting in 08/2016, and a school-based vaccination program (Phase 1: 08/2017; Phase 2: 08/2018). Pre- and post-intervention HPV vaccination rates were tracked against 2016 National Immunization Survey – Teen rates (initiation 49.3%; completion 32.9%). Summary statistics were stratified by gender

Results: The overall HPV initiation and up-to-date (UTD) rates were 68.5% and 42.1%. The median age at HPV vaccine initiation and HPV UTD (range) were 11.2 years (9-15) and 12 years (9-15). The median interval between HPV vaccine doses (range) was 287 days (36-1576).

Conclusions: Our results support that middle schools serve as a feasible, effective setting for delivering and increasing HPV uptake among adolescents, which offer substantial long-term health benefits. Providing access to HPV vaccines encourages on-time vaccination and completion.

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UPTAKE OF HPV VACCINE IN NIGERIA: ENGAGING RELIGIOUS LEADERS AND CLINICAL EDUCATORS FOR ACTION

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Introduction: The introduction of human papillomavirus (HPV) vaccine has globally provided the potential for elimination of cervical cancer and other HPV associated malignancies. Uptake of the HPV vaccine has remained grossly sub-optimal particularly in low resource settings. Vaccine hesitancy in addition to ignorance, poverty and weak immunization programme constitute a major threat to HPV vaccine uptake in Nigeria. We set out to determine the perception and possible role of religious leaders and clinical educators on the uptake of HPV vaccine in Nigeria.

Methods: We conducted a qualitative study using key informant interview with two people drawn randomly from each from Islamic and Christian religious leaders while four people were drawn randomly from clinical educators. We used a guide to ask questions on their perception and possible role on the uptake of HPV vaccine in Nigeria.

Results: Religious leaders believe that their direct link and trusted relationship with majority of Nigerians make them well positioned in positively influencing HPV uptake. They opined the of pulpits/ sermons in convincing their followers for better acceptability of the vaccine. All the clinical educators interviewed agree that a stepwise and holistic implementation and sagacious inclusion of HPV vaccine information and awareness for students in all health-related disciplines is paramount in improving uptake. They opined that the training of trainers and raising the level of awareness and competence of all relevant healthcare workforce will improve acceptability and readiness to train others for seamless implementation of HPV vaccine programme.

Conclusions: Engaging religious leaders and clinical educators through sensitization, advocacy and well-organized/simplified training on the importance and cost-effectiveness of HPV vaccine in reducing the burden of particularly cervical cancer might be the best approach to achieving maximum results.

Shift 02-110 / #1010

Poster Viewing
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04-20-2023 7:00 AM - 4:00 PM

PREFERENCES AND ATTITUDES OF HEALTHCARE PROVIDERS TOWARDS INITIATION OF HUMAN PAPILLOMAVIRUS VACCINATION AT AGE 9 OR 10 IN THE UNITED STATES: INSIGHT FROM QUALITATIVE INTERVIEWS

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Introduction: Human papillomavirus (HPV) is responsible for nearly all cervical cancers and a substantial proportion of other anogenital and head and neck cancers. The Centers for Disease Control and Prevention (CDC) recommends routine vaccination to protect against HPV at ages 11-12 but notes vaccination can start as early as 9 years. This qualitative study examined physician attitudes regarding earlier initiation of HPV vaccination at 9-10 years of age.

Methods: Semi-structured qualitative interviews were conducted with US-based pediatricians. Physicians were recruited from an online panel and were eligible if they practiced for at least 2 years and routinely administer HPV vaccination.

Results: Physicians (n=20) had a mean age of 56 years; 30% were women. Less than half (44%) practiced in suburban locations; mean time in practice was 25 years. More than half typically recommended HPV vaccine initiation at 11 years, with the rest recommending at 9 or 10 years. Most who vaccinate at the CDC's recommended age introduce the idea of HPV vaccination at earlier visits. Child's gender did not influence the age at which HPV vaccination was recommended. Physicans who recommended earlier initiation attributed this to patients' early puberty or being able to separate vaccination from sexual activity. Physicians also perceived that earlier initiation may increase opportunities to complete vaccination at an earlier age and would mean fewer injections administered at 11-12 year-old visits. However, a shorter break between vaccinations, low attendance of 9-10-year-old well child visits, lack of a good reason to initiate earlier, and potential for increased parent resistance were raised as concerns regarding early initiation.

Conclusions: This sample of physicians had mixed perceptions and attitudes regarding earlier initation of routine HPV vaccination, noting both positives and concerns. Further data are needed to understand how early initiation of HPV vaccination could be facilitated to increase vaccine coverage and maximize the vaccine's benefit.

Shift 02-111 / #1017

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

CLINIC-LEVEL PRACTICES ASSOCIATED WITH HPV VACCINE INITIATION AND UP-TO-DATE RATES AMONG 11- TO-12-YEAR-OLDS

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Introduction: Human papillomavirus (HPV) vaccination rates remain low among the targeted age group of 11- to 12-year-olds in the United States. To increase understanding of clinic-level practices on HPV vaccination, we evaluated the association between clinic-level HPV vaccine initiation (≥ 1 dose) and up-to-date (second dose) rates among 11- to 12-year-olds and five inner setting constructs of Consolidated Framework for Implementation Research (relative priority, incentives, available resources, procedures, and scheduling).

Methods: Among 30 Florida clinics, we obtained HPV vaccine records for 11- to 12-year-olds from electronic health records and the state immunization registry. At each clinic (30/30), a staff member knowledgeable about the clinic's vaccination practices completed a survey. After confirming HPV vaccination rates met the linear model assumptions and there was no collinearity, we used R statistical software to evaluate the relationships between HPV vaccination and clinic-level practices. We created a numeric score with each affirmative answer scored as one to evaluate the clinics' use of AFIX (Assessment, Feedback, Incentives, and eXchange of information)-related practices.

Results: Across the 30 clinics, mean HPV vaccination initiation was 43.4% (range = 2.3% to 76.8%) and up-to-date was 24.6% (range = 0% to 66.7%). For initiation, eight of the ten characteristics were significant univariately and the multivariable model explained 87.3% of the variability (Table 1). For up-to-date, five of the ten characteristics were significant univariately (Table 2). In the multivariable model for up-to-date rates, 75.4% of the variability was explained and dismissing families who refuse vaccines was significantly associated.

Conclusions: When considered alone, several clinic practices were associated with HPV vaccination. The collective influence of practices is likely more important than any one practice. However, when considering other practices, dismissing patients who refuse vaccines may be influential for clinic up-to-date rates. Dismissal strategies remain controversial because they do not increase population-level vaccination
rates.

Table 1. HPV vaccine Initiation Rates and Clinic Practices

		Univariate Analyses*		Multivariable Analysis**	
Binary Clinic Practices	Number of clinics responding affirmatively	Mean Difference in Rate (95% CI)	p-value	Model-Estimated Mean Difference in Rate (95% CI)	p-value
Participated in any activity aimed at increasing HPV vaccination rates	19	0.30 (0.08, 0.52)	<0.01	0.01 (-0.27, 0.29)	0.93
"Go to" person for vaccines has an MD	12	0.24 (0.04, 0.44)	0.02	0.04 (-0.25, 0.33)	0.77
Reviews vaccine charts prior to all visits	27	0.34 (0.03, 0.65)	0.03	0.26 (-0.65, 0.13)	0.16
Standing orders for HPV vaccine at all visits	23	0.46 (0.22, 0.69)	<0.01	0.27 (-0.05, 0.59)	0.09
Uses all types of patient encounters to assess and provide vaccinations	27	0.28 (-0.03, 0.60)	0.08	--	--
Offers vaccine visits on evening and weekends	16	0.38 (0.24, 0.52)	<0.01	0.15 (-0.06, 0.36)	0.13
Always schedules HPV vaccine second dose visits at first vaccine visit	23	0.02 (-0.22, 0.26)	0.85	--	--
Clinic's responsibility to schedule second dose	23	0.35 (0.13, 0.56)	<0.01	0.002 (-0.28, 0.28)	0.99
Dismisses patients who refuse vaccines	15	0.33 (0.17, 0.49)	<0.01	0.08 (0.13 ,0.29)	0.44
	Median (IQR)	Linear slope (95% CI)	p-value	Linear slope (95% CI)	p-value
AFIX-related Score (0 to 7)	4 (1 to 7)	0.04 (0.003, 0.08)	0.04	0.02 (-0.02, 0.06)	0.31

* For binary clinic practices, t-tests comparing rates of initiation between those who respond affirmatively for the given construct and those who do not. For numeric AFIX-related score, univariate linear regression was used.
** Those practices observed to be statistically significant ($p < 0.05$) for univariate tests were included in a single linear model of initiation and collinearity assumptions were met.

Table 2. HPV Vaccine Up-to-Date Rates and Clinic Practices

		Univariate Analyses*		Multivariable Analysis**	
Binary Clinic Practice	Number of clinics responding affirmatively	Mean Difference in Rate (95% CI)	p-value	Model-Estimated Mean Difference in Rate (95% CI)	p-value
Participated in any activity aimed at increasing HPV vaccination rates	19	0.19 (0.01, 0.38)	0.04	0.01 (-0.15, 0.18)	0.87
"Go to" person for vaccines has an MD	12	0.12 (-0.05, 0.29)	0.17	--	--
Reviews vaccine charts prior to all visits	27	0.23 (-0.02, 0.48)	0.07	--	--
Standing orders for HPV vaccine at all visits	23	0.29 (0.08, 0.51)	<0.01	0.01 (-0.19, 0.20)	0.95
Uses all types of patient encounters to assess and provide vaccinations	27	0.19 (-0.07, 0.44)	0.15	--	--
Offers vaccine visits on evening and weekends	16	0.25 (0.13, 0.38)	<0.01	0.12 (-0.02, 0.26)	0.10
Always schedules HPV vaccine second dose visits at first vaccine visit	23	0.03 (-0.22, 0.15)	0.71	--	--
Clinic's responsibility to schedule second dose	23	0.26 (0.09, 0.44)	<0.01	0.14 (-0.03, 0.31)	0.11
Dismisses patients who refuse vaccines	15	0.28 (0.18, 0.39)	<0.01	0.23 (0.10, 0.37)	<0.01
	Median (IQR)	Linear slope (95% CI)	p-value	Linear slope (95% CI)	p-value
AFIX-related Score (0 to 7)	4 (1 to 7)	0.02 (-0.01, 0.05)	0.20	--	--

* For binary clinic practices, t-tests comparing rates of initiation between those who respond affirmatively for the given practices and those who do not. For numeric AFIX-related score, univariate linear regression was used.
** Practices observed to be statistically significant ($p < 0.05$) for univariate tests were included in a single linear model of initiation and collinearity assumptions were met.

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CANCER FATALISM IS ASSOCIATED WITH HPV VACCINE UPTAKE AMONG HISPANIC EMERGING ADULTS IN THE US

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Introduction: Cultural beliefs and norms are potential barriers to health-seeking behaviors and health outcomes among Hispanics. The current study examined the relationship between cancer fatalism and human papillomavirus (HPV) vaccine uptake among Hispanic female emerging adults in the US.

Methods: A total of 647 female Hispanic emerging adults aged between 18 and 26 years participated in a cross-sectional study conducted between August and December 2020 at a large university in the southeastern US. An anonymous online survey was completed by the participants using Qualtrics. Self-reported HPV vaccine uptake (receipt of at least one dose) was recorded. Cancer fatalism was measured using an eight-item Likert-type scale. Multiple logistic regression analysis was conducted to assess the association between cancer fatalism and HPV vaccine uptake.

Results: Overall, 56% of participants received at least one dose of the HPV vaccine. The average score for cancer fatalism among vaccinated and unvaccinated participants was 10.10 (SD = 5.15) and 10.95 (SD = 5.23), respectively. Unvaccinated participants had a significantly higher score in cancer fatalism compared to vaccinated participants ($p = 0.04$). After adjusting for sociodemographic factors, the odds of getting the HPV vaccine were 0.97 times lower for a 1-unit increase in cancer fatalism among female Hispanic emerging adults (95% CI: 0.92–0.99).

Conclusions: Some Hispanic emerging adults may believe cancer is beyond human control and that God determines fate, which may affect vaccination rates. Culturally appropriate health interventions may help to increase vaccine uptake among Hispanic emerging adults. This study provides evidence that reducing fatalistic beliefs may be an important mechanism to target with culturally appropriate health interventions.

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EXPLORATORY ANALYSIS OF BACTERIAL STI AND TYPE-SPECIFIC ANAL HPV PERSISTENCE AMONGST VACCINATED AND UNVACCINATED GAY, BISEXUAL, AND OTHER MEN WHO HAVE SEX WITH MEN

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Introduction: Co-infections with bacterial STIs may hinder HPV clearance. We hypothesized that bacterial STI co-infection would lead to greater HPV persistence amongst unvaccinated men, but not vaccinated men. We examined this association in young gay, bisexual, and other men who have sex with men (GBM).

Methods: The Engage cohort study enrolled GBM in Vancouver, Toronto, and Montreal, Canada, starting in 02/2017. Men aged 16-30 self-collected anal and oral samples for HPV, chlamydia, and gonorrhea, and provided blood for syphilis testing at baseline and 12 months. We restricted analysis to men with detectable anal infection with quadrivalent-vaccine types (HPV-6/11/16/18) at baseline; we calculated persistence per 100 person-years (PY). We used Poisson regression to generate prevalence ratios (PRs) with 95% confidence intervals (CI) comparing those with and without active bacterial STIs at follow-up and tested the interaction with ≥1 dose quadrivalent HPV vaccination at baseline.

Results: There were 60 participants with detectable anal HPV-6/11/16/18 at baseline who had a valid specimen result at follow up (mean 12.5 months, SD=1.5); 36.6% (22/60) were vaccinated at baseline and 38.3% (23/60) had an active bacterial STI at follow up. Type-specific persistence was 20.8 per 100PY (CI: 12.3-35.1) for those with an STI at follow-up versus 16.9 per 100PY (CI: 11.5-25) for those without an STI, for a PR of 1.23 (CI: 0.64-2.36). Compared with unvaccinated men with no bacterial STI at follow-up, PRs were 1.19 (CI: 0.58-2.42) for unvaccinated men with an STI, 0.85 (CI: 0.43-1.65) for vaccinated men without an STI, and 0.80 (CI: 0.33-1.94) for vaccinated men with an STI.

Conclusions: Persistent anal HPV-6/11/16/18 appears more likely for men co-infected with bacterial STIs among unvaccinated men but not among vaccinated men, although confidence intervals were overlapping. Ongoing monitoring of real-life impacts of vaccination is needed in high-risk populations including GBM.

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Poster Viewing
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KNOWLEDGE OF AND PREFERENCES FOR HUMAN PAPILLOMA VIRUS VACCINATION AMONG KENYAN ADOLESCENT GIRLS AND YOUNG WOMEN

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Introduction: Cervical cancer is a leading cause of morbidity and mortality among women in sub-Saharan Africa, yet vaccination against human papilloma virus (HPV)—a driver of cervical cancer—remains low. Adolescent girls and young women (AGYW) have close peer networks and often influence one another's healthcare seeking behaviors, which may have unexplored potential to support HPV vaccination uptake.

Methods: We conducted a cross-sectional survey among AGYW participating in a pilot study testing a novel peer referral model to HIV pre-exposure prophylaxis (PrEP) supported with HIV self-testing in Kenya (NCT04982250). Eligible AGYW were 16-24 years old who had either been using PrEP >3 months and were willing to refer peers to PrEP, or were referred to PrEP by a peer. We analyzed survey data on participants' knowledge of HPV vaccination and their preferences for vaccination delivery and reported descriptive statistics.

Results: From March to July 2022, 46 AGYW completed the survey (median age: 22 years, IQR 20-23). Many participants reported behaviors associated with HIV risk (65% casual sex partners only; 26% multiple sex partners) and had heard of cervical cancer (74%) and the HPV vaccine (61%). The majority of participants reported a preference for HPV vaccination access at public (56%) or private clinics (38%). Additionally, almost half (47%) reported that they would be comfortable accessing the vaccine at private pharmacies. Among the 65% (22/34) of participants who answered this question and reported a willingness to pay for HPV vaccination at their local pharmacy, the median amount was 350 KES (IQR 200-500 KES), ~$3.5 USD.

Conclusions: To support HPV vaccination uptake among AGYW in sub-Saharan African settings, knowledge gaps must be addressed and vaccination delivery at diverse locations, including pharmacies, should be considered. Future research should explore how peer education and referral might help maximize HPV vaccination knowledge and uptake among AGYW at risk of acquisition.

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Poster Viewing
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DEVELOPMENT AND USABILITY TESTING OF AN HPV MOBILE APPLICATION

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Introduction: HPVcancerFree, a mobile app created as part of a multilevel study to increase uptake of HPV vaccination, targets parents of unvaccinated adolescents and teens. The theory-based app aims to increase awareness and knowledge of HPV while reducing perceived barriers to vaccine initiation.

Methods: After initially launching the app as part of a randomized controlled trial, usage data (visitor logs, page views, bounce rates, visit duration, and exit rates) were collected and analyzed in conjunction with data from a parent usability survey. Modifications, including the addition of infographics, an informational video, and push notifications, were then made to increase interactivity and provide cues to action. The modified app was tested for usability among parents by conducting cognitive interviews using think-aloud methodology and administering standardized surveys. The interviews were transcribed, coded, and analyzed along with the surveys to inform final adaptations of the app.

Results: Preliminary usage results showed that 72% of users did not return after initial use and 45% of users exited after viewing the home screen (n=355). Survey responses indicated that low follow-up usage was partially attributable to low interactivity and 40% of respondents noted “forgetting about the app” as a reason for not using the app. Results from the modified app usability testing showed improvements in both interactivity and utility. Inclusion of infographics and a video was noted for holding parent attention and the added notification system was considered practical and useful by parents. Additionally, the modified app scored highly in functionality, practicality, and visual appeal when analyzing survey results.

Conclusions: In both the interviews and surveys, the modified app was shown to be a useful source of information and reminders for parents with unvaccinated children. Results from this usability study can inform future development of cancer prevention and health promotion apps targeting the general public.

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PREVALENCE OF ANAL HUMAN PAPILLOMAVIRUS (HPV) AMONG AUSTRALIAN ADOLESCENT GAY AND BISEXUAL MEN (GBM) FOLLOWING THE INTRODUCTION OF GENDER-NEUTRAL VACCINATION

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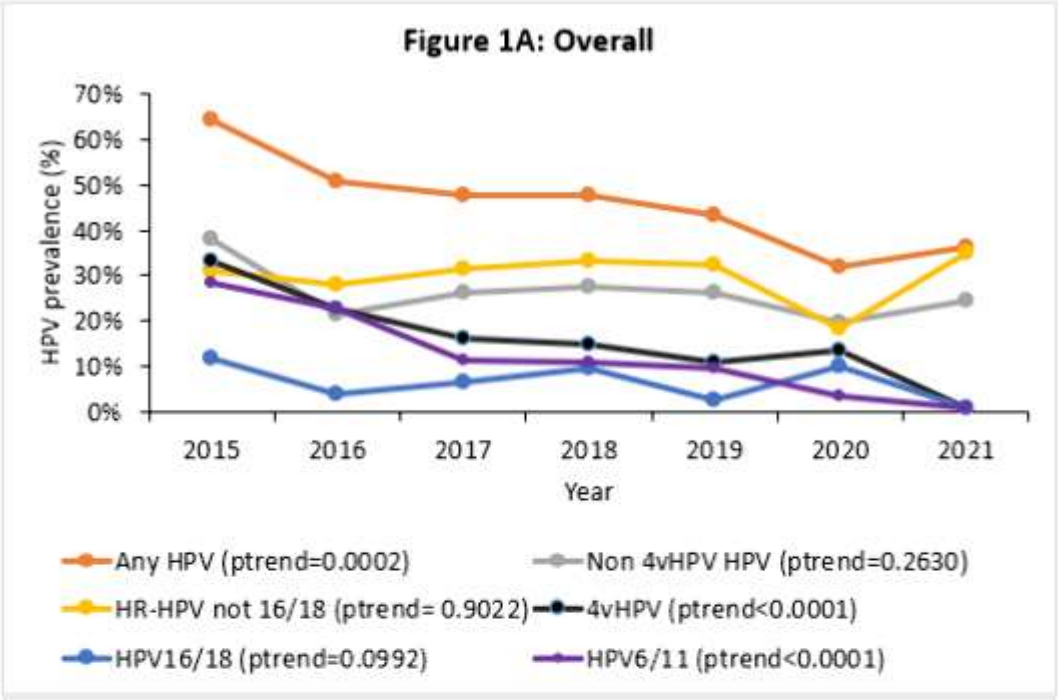
Introduction: GBM are at increased risk of HPV-associated anal pre-cancer and cancer. Australia introduced a school-based female-only HPV vaccination program in 2007 and a gender-neutral program in 2013. As of 2019, Australian GBM (<20 years) have emerged from cohorts offered vaccination at 12-13 years. We examined anal HPV prevalence among young GBM attending a sexual health clinic between 2015 and 2021.

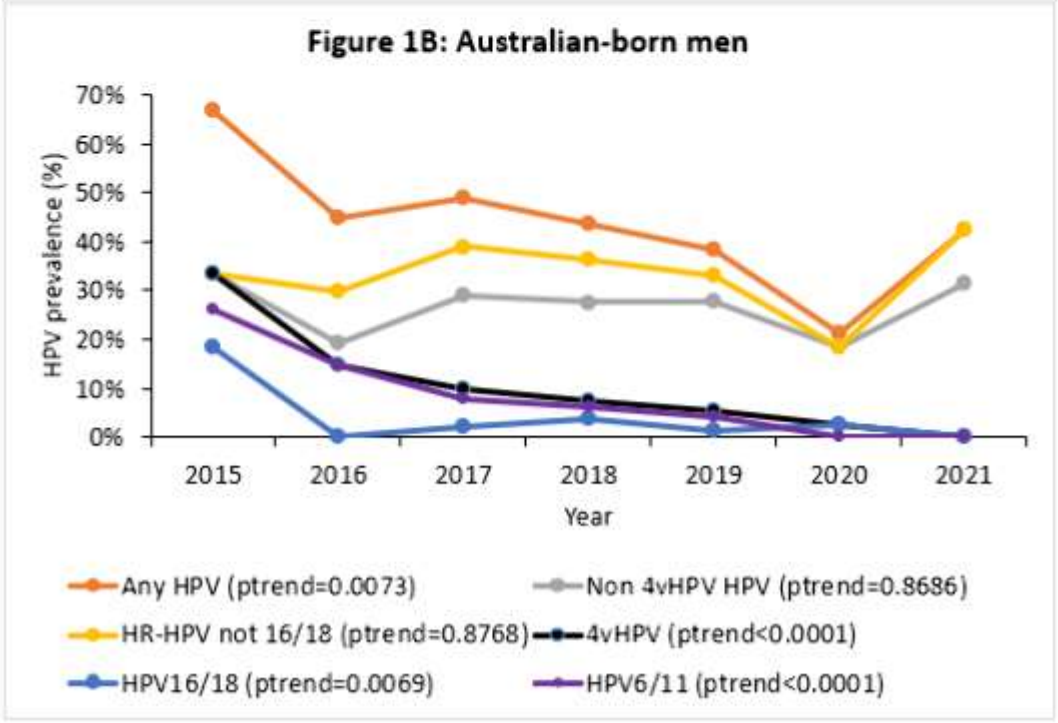
Methods: This was a preliminary analysis of stored rectal swab specimens collected from GBM aged 14–19 years who attended Melbourne Sexual Health Centre (Melbourne, Victoria) between 2015 and 2021 for STI testing. De-identified data on age, year of visit, country of birth, self-reported HPV vaccination status and sexual practices were extracted from clinical records. Specimens were tested for HPV using the Anyplex II HPV28 assay. Final analyses will include the 2022 time point.

Results: Overall, 750 men were included, with 85.3% aged 18-19 years and 56.3% Australian-born. Overall, 25.7% (n=154) self-reported receiving any vaccine doses; this increased from 14.8% (n=8/54) in 2015 to 41.2% (n=33/80) in 2021. The median number of sexual partners in the previous 12 months was 4 (IQR 1–7), with no difference by year (p-trend=0.115). Prevalence of quadrivalent vaccine-targeted HPV types 6/11 fell from 28.6% (15.7–44.8) in 2015 to 1.1% (0.0–5.8%) in 2021 (p-trend<0.001). The prevalence of HPV16/18 did not change over time (p-trend=0.10) (Figure 1A). In analyses restricted to Australian-born GBM (a surrogate marker of school program eligibility), HPV6/11 prevalence fell from 25.9% (11.1–46.3%) to 0.0% (0.0–5.6%) (p-trend<0.001). Prevalence of HPV16/18 also fell from 18.5% (6.5–38.1%) to 0.0% (0.0–5.6%) (p-trend=0.001) (Figure 1B). The prevalence of non-quadrivalent

vaccine-targeted types did not change (Figure

Figure 1. Prevalence of anal HPV among adolescent gay and bisexual men aged <20 years at Melbourne Sexual Health Centre, 2015–2021





1).

Conclusions: Gender-neutral vaccination is resulting in the near elimination of quadrivalent vaccine-targeted HPV types among adolescent GBM, with vaccine completion in Australia of about 77% in males by age 15 years.

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Poster Viewing
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UNDERLYING BELIEFS AND KNOWLAGE QUESTIONNAIRE ABOUT HPV VACCINATION DECREASING THE VACCINATION RATE IN CROSS-SECTIONAL SURVEY ON A SAMPLE OF WOMEN LIVING IN TBILISI (GEORGIA)

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Introduction: Cervical cancer is one of the most common causes of oncologic morbidity and mortality worldwide and in Georgia. 327 new cases are diagnosed annually in Georgia (estimation for 2020). Even though HPV vaccination is included in the national vaccination program (schedule), for girls 9-13 years old, and in January 2022 the Government approved a “catch up” program for girls 13-18, vaccination rates in Georgia are low, so we decided to introduce the questionnaire to country’s biggest OB/GYN clinic to assess knowledge and attitude to HPV-vaccination.

Methods: A cross-sectional survey was conducted on a sample of 320 unvaccinated women at the “Gagua Clinic” University Hospital in Tbilisi , aged 18–27. Age was determined due to possibility of being vaccinated, as HPV vaccine was introduced to the population in 2007. (Informed consent was taken from all the participants). Questionnaire included 15 questions (figure

1):

1) Do you know about aggressive nature of cervical cancer?
   - YES
   - NO
   - Somewhat
   - Do not have an answer
2) Do you know it can be prevented?
   - YES
   - NO
   - Somewhat
   - Do not have an answer
3) Have you ever heard about HPV vaccination?
   - yes
   - NO
   - somewhat
4) Are you favorable with the HPV vaccination?
   - yes
   - no
   - Not sure

   [if not, please give us your reason: _____]
5) Should HPV vaccination be in vaccine's national calendar?
   - yes
   - NO
   - do not have an answer

6) Do you know where and how you could be vaccinated?
   - yes
   - NO
   - somewhat
7) how safe do you consider HPV vaccine?
   - absolutely safe
   - somewhat safe
   - I find it dangerous for my health
   - I have no knowledge about HPV vaccinations safety
8) would you get vaccinated?
   - Yes
   - NO
   - Do not know exactly

   [if not, please give us your reason _____]
9) does the social stigma affect your decision?
   - yes
   - no
   - somewhat

10) have you ever been informed about HPV vaccination from your Gynecologist?
    - yes
    - NO
    - Do not recall
11) Do you have a daughter in an age group of HPV vaccination?
    - yes
    - NO
    - I do not know what is the suitable age group pf HPV vaccination

(if yes, please fill out the next 2 questions, if not leave them as a gap)

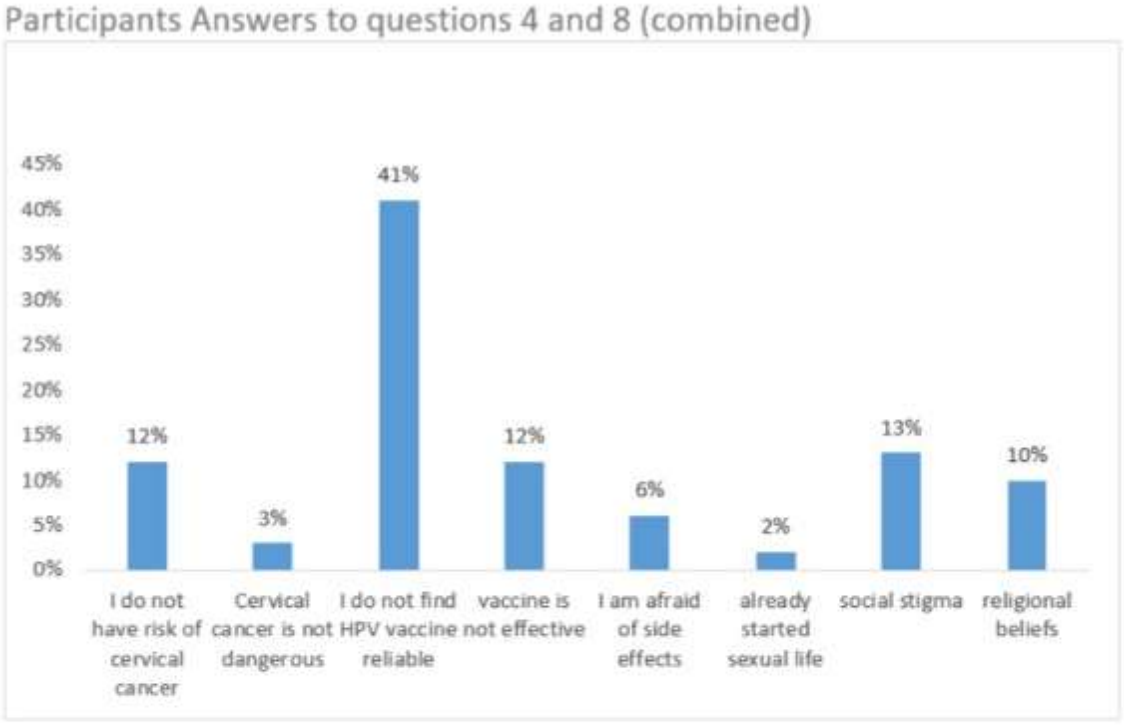
12) Has your daughter's pediatrician ever told you about free HPV vaccination?
    - yes
    - NO
    - do not recall
13) are you planning to vaccinate your daughter?
    - yes
    - NO
    - already vaccinated
    - Have not decided yet

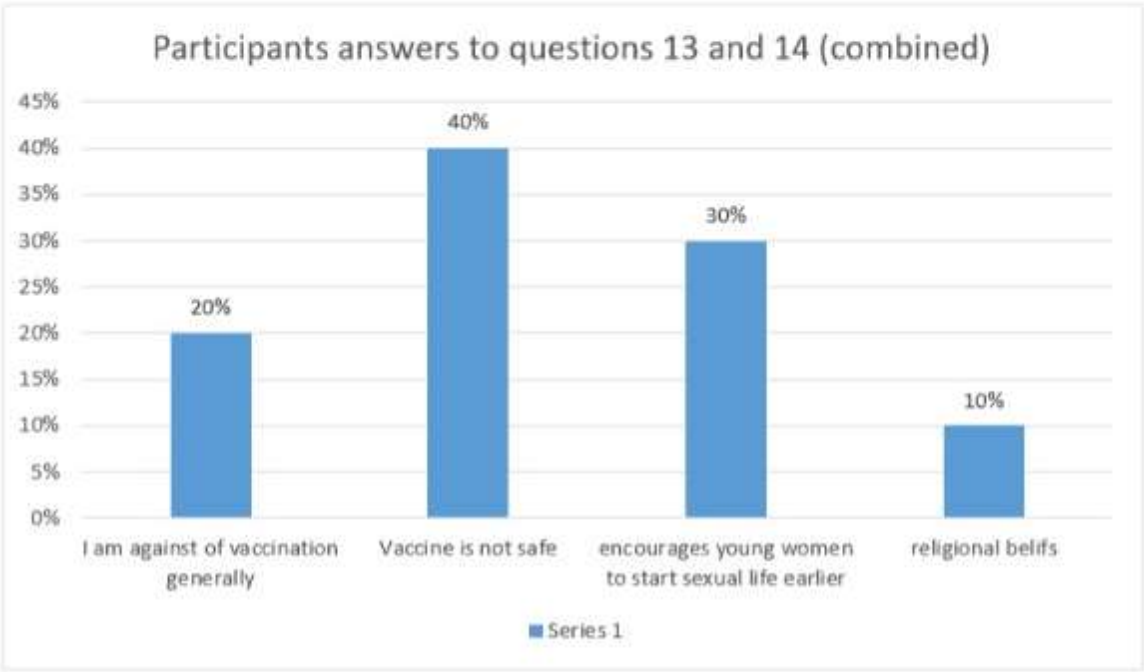
      [if not, please give us your reason _____]
14) would you recommend HPV vaccination to your family member?
    - yes
    - NO
    - Maybe
    - [if not, please give us your reason _____]
15) would you like to attend an educational meeting about HPV vaccination?
    - Yes
    - NO
    - maybe

Results: By evaluating answers, the main reason for refusal of vaccination is the lack of information, general resistance to immunization, concerns about safety and side effects, social stigma and belief that HPV vaccination encourages promiscuity. Results of the questionnaire is given in the figure

2: FIGURE 3 provides participants verbal answers to several

questions:





Conclusions: Although different socioeconomic aspects have impact on decision making, the main reason should still be lack of information from professionals and government. Due to the limitations on sample size, the topic requires further assessments and significant research to understand the vast socioeconomic, cultural and informative barriers preventing uptake among adolescents.

Shift 02-118 / #1300

Poster Viewing
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REDUCING COMMUNITY PREVALENCE OF HPV BY OFFERING A SINGLE DOSE OF HPV VACCINE TO BOYS AND YOUNG MEN IN TANZANIA – THE ADD-VACC TRIAL

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Introduction: The World Health Organization has set a target of cervical cancer elimination by 2030. Prophylactic human papillomavirus vaccination will be a key tool in achieving this target. However, many countries face challenges with HPV vaccine introduction and reaching high coverage with two doses. There is increasing evidence for the efficacy and immunogenicity of single dose prophylactic human papillomavirus vaccination in females. Offering one-off single dose HPV vaccination to boys may reduce community HPV prevalence and assist in protecting unvaccinated girls. This question is being addressed in the Add-Vacc trial in Tanzania (ClinicalTrials.gov Identifier:NCT04953130).

Methods: The study is an unblinded cluster-randomised trial with two arms: (i) the national HPV vaccination programme (girls aged 14 years; control arm) and (ii) the national programme plus male HPV vaccination given to a multi-year cohort of boys (aged 14-18 years; intervention arm). The study will be conducted in 26 communities/clusters (13 per arm) in Tanzania. A cross-sectional survey in all clusters prior to vaccination is measuring current HPV vaccine genotype prevalence in males and females aged 18-21 years. Fourteen-year-old girls in all clusters will be offered vaccination with 2 doses of the 4-valent HPV vaccine (Gardasil®) through the national HPV vaccination programme. Boys aged 14-18 years in intervention clusters will receive one dose of Gardasil®. Genital HPV prevalence in males and females aged 18-21 years will be compared between intervention and control clusters three years later. Blood sampling for immune responses and safety data collection will be performed in a subset of 200 male participants in selected intervention clusters.

Results: The study commenced activities in 2022. Data on baseline HPV coverage in females will be presented.

Conclusions: This is the first study to investigate whether adding one-off male single dose HPV vaccination to a female-only HPV vaccination programme can reduce community HPV prevalence with vaccine-specific genotypes.

Shift 02-119 / #1304

Poster Viewing
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HPV33 AND HPV35 ARE MOST COMMON GENOTYPE DETECTED AMONG VACCINATED ADOLESCENTS IN RURAL ZIMBABWE

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Introduction: Cervical cancer is preventable through human papillomavirus (HPV) vaccination. The progress towards reducing the burden of cervical cancer remains slow in low- and middle-income countries (LMIC), such as Zimbabwe. Our group previously identified unique HPV genotypes not included in any available vaccinations (e.g. HPV35), which raised concerns geographically unique HPV genotypes may contribute to the persistent burden of HPV even after introduction of the HPV vaccine. Given the recent introduction (2018-2019) of nationwide bivalent HPV vaccination in Zimbabwe, there is no available data on the prevalence of HPV infections among HPV vaccinated girls in rural Zimbabwe.

Methods: HPV-vaccinated girls living in the Hurungwe district (13+) were recruited by CHW home visits. HPV genotyping was performed on the Atila AmpFire HPV assay (Atlia Biosystems, Mountain View, CA, USA), which uses isothermal amplification with real time fluorescence detection for 15 genotypes of HPV (16,18,31,33,35,39,45,51,52,53,56,58,59,66 and 68), at the University of Zimbabwe Clinical Trials Research Centre laboratory.

Results: A total of 436 urine samples were collected from eligible girls. In total, 18% (n=80/436) samples were positive for one or more HR-HPV genotype. HPV33 and HPV35 were the most frequent genotype, identified in 7% (n=32 and 29, respectively) of samples. HPV16 was present in one sample and 3 harbored HPV18. Multiple genotypes were detected in 26 samples. Among young women living with HIV (YWLWH), 12% (n=4/33) were positive for HR-HPV; HPV33 and HPV58 were the most frequent genotypes (n=2 each).

Conclusions: HPV33 and HPV35 were the most frequent genotypes detected among HPV vaccinated girls in rural Zimbabwe, while HPV33 and HPV58 were the most frequent among YWLWH. Our study highlights differing genotypes that remain prevalent among young women of African ancestry even following HPV prophylactic vaccination. Additional follow-up study is required to determine whether these infections become clinically relevant and/or contribute to anogenital dysplasia/cancer.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
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INTEGRATED INFORMATICS PLATFORM FOR HPV TESTING AND VACCINATION

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Introduction: In the era of cervical cancer elimination, providing a robust and open-source solution for managing HPV vaccination and HPV testing is essential. We developed an integrated informatics platform covering the whole workflow for HPV vaccination and HPV testing, which is generic and easily customized for other countries and use cases.

Methods: The platform has two main software components for managing vaccination and self-testing sampling. The vaccination part enables the registration, consenting study participation and answering a health declaration questionnaire. Patient registration allows e-legitimation. The vaccinator assesses the patient's health declaration and registers the vaccination data and information about the HPV-testing method (self-sampling kit or on-site sampling). The self-sampling part enables users to order, register their HPV self-sampling kits using QR codes and mobile phones, and access their HPV-test results. This component systematically exports results and metadata associated with HPV self-sampling kits to a healthcare national Swedish register used by physicians to look for patients´ clinical history.

Results: The platform was tested as a pilot in 2021 at a clinic in Stockholm. The platform is now being transferred nationwide in Sweden, aiming at vaccinating and HPV-testing all women born between 1994-1999. The self-sampling web-service solution has been running since 2020. Women from high-risk groups for cervical cancer were reached to take part in a self-sampling study. More than 5600 self-sampling kit orders have been placed in 2022.

Conclusions: Implementing integrated and well-validated software management solutions eases the quality assurance in HPV testing and vaccination, which are essential for the ongoing HPV elimination programs.

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USABILITY AND FEASIBILITY OF AVP-IT: AN ONLINE TOOL TO FACILITATE THE IMPLEMENTATION OF EVIDENCE-BASED STRATEGIES TO INCREASE HPV VACCINATION RATES IN PEDIATRIC CLINICS

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Introduction: HPV vaccination is safe and effective yet rates remain far below the Healthy People 2030 goal of 80% completion for adolescents (13-15 yrs.). The Adolescent Vaccination Program (AVP) is an evidence-based, multi-component intervention demonstrated to increase HPV vaccination rates in pediatric clinics through the implementation of six evidence-based AVP strategies (immunization champions, assessment and feedback, continuing education, provider prompts, parent reminders, and parent education). The purpose of this study was to test the usability and feasibility of an online decision support program, the AVP Implementation Tool (AVP-IT), designed to enable pediatric clinics to independently implement the AVP.

Methods: Healthcare professionals (n=5) reviewed the AVP-IT for ten days and completed a usability survey assessing its features and how its content, function, and interface design could be improved. Feasibility was assessed in two community-based clinics in the Greater Houston area. Clinic champions (n=2) completed baseline and 2-month follow up surveys and an exit interview with AVP-IT project staff.

Results: In usability testing, most participants (70%) rated the AVP-IT as acceptable, easy, helpful, credible, impactful and appealing. They rated the AVP-IT as providing an easier, more effective, more thorough, and speedier way to implement the AVP evidence-based strategies than without AVP-IT guidance. In clinic feasibility testing, critical individual and organizational facilitators for successful AVP-IT implementation were identified that included a need for strong prescriptive leadership, ongoing technical support for each strategy, prioritization over competing demands in busy clinics, and allowance for staff turnover. Emergent tools and protocols (e.g. training videos) were developed to address these facilitators.

Conclusions: The AVP-IT provides accessible, utilitarian, and scalable decision support to implement evidence-based strategies to increase HPV vaccination rates in pediatric clinic settings. Results suggest its acceptability for healthcare professionals, the need to attend to critical implementation facilitators, and that further efficacy testing is indicated.

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EXPLORING OPPORTUNITIES TO INCREASE THE ROLE OF ORAL HEALTH PROVIDERS IN DISCUSSING AND RECOMMENDING THE HPV VACCINE TO PARENTS OF ADOLESCENTS

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Introduction: Human Papilloma Virus (HPV) vaccine rates continue to be suboptimal and with the growing incidence of HPV related oropharyngeal cancer, assessing the acceptability of discussion and recommendations by oral health providers is paramount. The purpose of this study is to assess parental attitudes regarding oral health providers discussing and recommending the HPV vaccine.

Methods: Parents of adolescents aged 11-12 years (n=1,047) were recruited to participate in a survey distributed via Qualtrics. Four parent subgroups were identified based on child's HPV vaccination status (vaccinated, intend to vaccinate, unsure of intention, and do not intend to vaccinate). The survey included questions related to HPV vaccination, where their child goes for health and dental care, discussing the vaccine with oral health providers, and attitudes toward oral health provider recommendation of the HPV vaccine. Frequencies were obtained and one-way ANOVA was conducted to determine differences between groups.

Results: The mean age of participants was 40.28±6.3 years, the majority were female (52.1%), White (76.0%), and had been vaccinated for HPV (56.0%). Most parents reported taking their child to see a dentist (86.5%); most went every six months (53.9%). In all vaccination groups, the majority reported a dental provider has never talked about the HPV vaccine with them. Among those that said a dental provider did discuss the vaccine, vaccination groups varied in how useful this information was in their HPV vaccine decisions ($F(3)=6.98$, $p<.001$, $\eta 2=.063$), with those that have or intend to vaccinate reporting it as more useful. Participants that either intend to vaccinate or are unsure of intention reported their child's dentist's recommendation as being less important than their family doctor, pediatrician, and pharmacist.

Conclusions: Opportunities to increase parents' awareness of the HPV vaccine's role in cancer prevention are needed. Oral health providers need to be more proactive in discussing the availability of the HPV vaccine.

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ASSESSING PARENTS' OPINIONS FOR VACCINATING THEIR CHILDREN FOR HPV IN ALTERNATIVE HEALTHCARE SETTINGS

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Introduction: HPV is associated with multiple cancers, and although a vaccine has been available since 2006, rates remain below the Healthy People 2030 target. Increasing access to the vaccine in healthcare settings besides doctor offices, such as dental offices and pharmacies is one strategy to increase rates. This study assessed parents' opinions on vaccinating their children against HPV in various healthcare settings.

Methods: Parents of adolescents (n=1,047) completed an online survey on HPV-related topics, including healthcare setting. Twenty-seven items measured parents' likelihood for vaccinating their child for HPV at eight healthcare settings.

Results: Most respondents were female (52.1%), White (76.0%), with mean age 40.28(±6.30). Childhood HPV vaccinations primarily occurred at pediatrician or family-practice offices during vaccination visits (69.2%) or annual exams (23.4%). When asked why they chose to get their child vaccinated at a particular location, most cited comfort in that healthcare setting (46.9%). Repeated measures ANOVA revealed likelihood of vaccination significantly differed by healthcare setting ($F(6)=163.25$, $p<.001$). Table 1 shows mean likelihood of vaccination by healthcare setting among parents either unsure of or intending to vaccinate. These parents indicated the pediatrician's office was most convenient and the dentist's office the least convenient setting. Table 1. Mean (SD) likelihood of vaccinating child for HPV by setting

Setting	Intend t
Pediatrician's office*	4.64(0.8
Family-practice office*	4.40(1.1
Dentist's office	2.28(1.4
Health department*	3.23(1.5
Pharmacy*	3.43(1.4
School health clinic*	3.22(1.6
Urgent care clinic*	3.35(1.5
Mobile vaccine/medical clinic*	3.28(1.5

1=not at all likely, 5=extremely likely *p<.01

Conclusions: Findings indicate intention to vaccinate in various settings other than traditional provider offices exists. This does not appear to be the same in the unsure group. Public health efforts to improve vaccination rates for both groups may be effective by engaging the settings to be more proactive.

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Poster Viewing
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PPREVALENCE OF PAPILLOMAVIRUS INFECTION ACCORDING TO VACCINATIONSTATUS IN MEN WHO HAVE SEX WITH MEN IN BRAZIL

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Introduction: Some countries have implemented publicly-funded human papillomavirus (HPV) vaccination for gays, as they are disproportionately affected by the virus. In Brazil, the Unified Health System offers the vaccine to girls and boys (9 to 14 years), people leaving with HIV and immunosuppressed people. Therefore, we aimed to analyze the prevalence of genital HPV among vaccinated and unvaccinated men who have sex with men.

Methods: Cross-sectional study using Respondent-Driven Sampling in 9 Brazilian state capitals between 2019-2022. HPV vaccine status was self-reported. Participants aged ≥18 years answered a questionnaire with sociodemographic and behavioral questions, and provided genital self-collected biological samples. All samples were processed in a central laboratory using Anyplex-II HPV-28 detection kit (Seegene®). Analyzes were based on weighting, which is inversely proportional to the size of the network.

Results: From the 1,226 men included, 11.20% reported been vaccinated against HPV. The mean age was 29.17 + 3.6 years and the majority was single (65.99%). Among the participants, 16.97% leave with HIV, but only 23,66% of those were vaccinated. There was no significant difference between age, relationship status, number of sexual partners, and use of condom and genital HPV prevalence (56.6% in vaccinated and 45.7% in unvaccinated) according to vaccination status (p = 0.14). Overall, the most prevalent HPV types were 6 (6,87%), 42 (6,49%), 43 (6,43%), 53 (5,60%) and 16 (5,51%). The prevalence of the four HPV types form quadrivalent vaccine (6, 11, 16 ,18) was not different between vaccinated and unvaccinated men. The difference was also not significative among HIV+ men.

Conclusions: Men who have sex with men presented a high prevalence of HPV and a low vaccination coverage. The lack of significant differences between vaccination status, could be due to the time of vaccination (age and HPV status) or due to the small number of vaccinated men.

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Poster Viewing
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DRIED BLOOD MICROSAMPLERS FOR HPV ANTIBODY DETECTION

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Introduction: The antibody response to human papillomavirus (HPV) vaccines is increasingly used as a primary endpoint in trials of biosimilar vaccines and reduced/alternate dosing schedules or novel delivery methods. Venipuncture, currently used to obtain serum or plasma requires trained personnel, risks needle-stick injuries and presents barriers to participants fearing needle sticks. Microsampling, relying on fingersticks, would remove these barriers and be more amenable for use in low-resource settings and self-collection. We evaluated detection of HPV antibodies in standard venipuncture samples compared with volumetric absorptive microsampling (VAMS) samples processed with differing elution methods and storage conditions.

Methods: Samples were sourced from 5-7 donors, 18-25 year old, who self-reported receiving HPV vaccination. Venipuncture blood was processed for serum and EDTA-plasma. Aliquoted samples were shipped on dry-ice. Fingerstick samples were collected using 8x 20ul Mitra® clamshell devices (Trajan Scientific) and shipped overnight at ambient temperature within a few days of collection. Two microsampler tips /donor were eluted with three different buffers at 4C and room-temperature. Remaining tips were stored at temperatures ranging from 80°C -45°C for times varying from 1 week -3 months. Total IgG quantification and M9ELISA were performed.

Results: For microsamples eluted within one week of receipt, no significant differences were observed in total IgG, stability of eluted antibodies following 3 freeze-thaw cycles and 9v antibody titers (n=3). The optimal elution was 400 ul of M9ELISA assay diluent for 2h at room temperature with agitation. Antibody titers measured in serum/plasma and one 20ul microsampler tip compared well, with less than 1.5 difference in titer across types (n=2). Stability analysis of microsamplers stored at various temperatures and over time prior to antibody elution is currently ongoing.

Conclusions: Once validated, use of whole blood microsampling could provide a reliable and safe alternative to venipuncture for studies of HPV antibody response.

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THE HPV VACCINE SCHOOL-ENTRY REQUIREMENT IN PUERTO RICO - THREE YEARS AFTER AND STILL HAVING SIMILAR IMPLEMENTATION BARRIERS

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Introduction: In Puerto Rico (PR), the Human papillomavirus vaccine has been required for school since 2018. After more than three years, several events such as the COVID-19 pandemic, could have affected the implementation efforts and outcomes of this policy. Through key informants' interviews (KI), we identified barriers and facilitators of the HPV vaccine school-entry requirement during the COVID-19 pandemic and explored recommendations by different KI groups.

Methods: We conducted 26 KI interviews with stakeholders from the PR's Department of Health (DOH) (n=6), school system (n=9), and health provider organizations (n=11) during August 2021 to March 2022. We used the Consolidated Framework for Implementation Research (CFIR) to develop the interview guide, and adapted questions to explore the COVID-19 pandemic effect. Interviews were transcribed verbatim, coded, and analyzed to identify barriers.

Results: The main barriers for the DOH and providers were parental vaccine hesitancy and delayed on the routine immunization schedule. In the schools, common barriers included the lack of educational materials and the parents' fear of getting COVID-19 in vaccine centers. For all KIs, the facilitators were the variety of engagement strategies employed by the health providers and nurses to convince the parents. Most KI from schools mentioned that parents were less hesitant about the HPV vaccine than in previous years. All groups recommended improving the education materials and promotion on social media about the HPV vaccine and its benefits.

Conclusions: Although less than in previous years, parental hesitancy, continuous to be a barrier for the implementation of the HPV vaccine school-entry requirement. A potential effect of the COVID-19 pandemic was the delay on immunization for children and adolescents. Re-evaluating the educational strategies and increasing access to the HPV vaccine could be a priority to reach a significant up-to-date percentage.

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ASSOCIATION OF CHILD'S AGE, PARENTAL HPV VACCINE HESITANCY, AND HPV VACCINE INITIATION

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Introduction: HPV vaccination is now approved for ages 9-45, but the vaccine is only effective prior to exposure to the virus, so it is targeted to younger children and adolescents. CDC's Advisory Committee on Immunization Practices recommends vaccine initiation at ages 11-12, but in recent years, the American Academy of Pediatrics has shifted their recommendation earlier, targeting ages 9-12 for initiation. This analysis examined the association of age with parental HPV vaccine hesitancy and uptake.

Methods: An online Qualtrics survey was administered to parents of children aged 9-17 years in Arkansas, Mississippi, Missouri, Tennessee, and Southern Illinois in July 2021. Responses from 926 parents were summarized and analyzed using chi-square tests and multivariate logistic regression.

Results: 18.6% of parents with a child aged 9-12 and 23.2% of parents with 13–17-year-olds were categorized as HPV vaccine hesitant. The majority of parent reported that they believed the ideal age for HPV vaccination was between ages 12-15. 18.6% of children ages 9-12 had received at least one dose of HPV vaccine, while 52.3% of 13–17-year-olds had received at least one dose. Overall, 13–17-year-olds were 6 times as likely to be vaccinated as 9-12 year olds (OR: 6.01, 95% CI: 3.98-9.08).

Conclusions: Despite recommendations to initiate HPV vaccine at earlier ages (9-12), most parents still believed that 12-15 years was the ideal age to vaccinate their children. Overall, rates of vaccination are low in the states across this 5-state region for adolescents aged 9-17 (42.3%), but the uptake is less than half for 9–12-year-olds compared to 13–17-year-olds. Given that only 2 doses are needed for ages <15 and completion rates have been found to be higher when the series is initiated earlier, efforts are needed to educate both parents and providers on the benefit of earlier age of HPV vaccine initiation.

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KNOWLEDGE OF HUMAN PAPPILOMAVIRUS AND VACCINATION AMONG MEN WHO HAVE SEX WITH MEN

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Introduction: Previous studies have demonstrated higher prevalence of HPV infection among men who have sex with men (MSM) than the general population. The knowledge of HPV and awareness of the associated risk can lead to protective behaviors and vaccine acceptance. The present study aimed to assess knowledge of HPV and vaccination among MSM.

Methods: Multicenter cross-sectional study using respondent-driven sampling between 2019-2021 including MSM aged 18 years or older from nine Brazilian cites. All completed a validated HPV knowledge questionnaire (on a 16-item scale) and an interview with sociodemographic characteristics, that was applied by trained primary health care professionals.

Results: From the 1,226 MSM included, 44.73% were from social class C, had higher education 65.95% and 53.95% were pardo/black. Most were single (66.1%) with a mean age of 29.1 + 9.1 years. The majority (86.15%) reported knowing HPV but only 66.1% know about HPV vaccine. 20,06% believe that HPV always have symptoms and 39.30% that can be cured using antibiotics or that there is no need for treatment (19.95%). Higher Scores were associated to higher rates of vaccination ($p<0.001$) but not with HIV status. Lower and higher age ranges are associates to lower scores ($p<0.01$).

Conclusions: Despite the included participants had a high level of education when compared to the Brazilian population, many participants still unaware about the vaccine against the virus and have misconceptions about the HPV virus epidemiology, transmission and treatment. Public health efforts to educate and increase awareness about HPV and vaccine in this population should be strengthened and expanded.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

PROVIDERS PERCEPTIONS AND CLINIC READINESS TO IMPLEMENT HPV VACCINATION IN HIV COMMUNITY CLINICS

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Introduction: People living with HIV (PLWH) are more likely to be diagnosed with HPV-associated cancers than the general population. The HPV vaccine is an effective approach to reduce the risk of HPV-related disease. However, HPV vaccine programs tailored and implemented for PLWH is lagging for this high-risk group. We assessed providers and clinic staff perceptions and readiness to HPV vaccination at three HIV community clinics in Georgia, USA.

Methods: We conducted three semi-structured interviews with HIV providers and clinic staff and administered the HPV IQ Pre-Implementation Questionnaire and the 4Pillars™ Immunization Toolkit Practice Improvement Readiness Questionnaire. Herein, we report the descriptive findings of the providers and staff responses from the two questionnaires.

Results: Eighteen respondents completed the questionnaires. Five respondents reported their role as nurses (27.8%); two respondents were vaccine providers (11.1%), two respondents were office members (11.2%), and the remaining reported their role as “other” (pharmacist, social worker, etc.; 50%). For improvement of HPV vaccination, 44% (8) of respondents strongly agreed that it is an important goal for their clinic, whereas 39% (7) strongly disagreed. Respondents mostly strongly agreed (7, 38.9%) they felt confident their clinic could improve HPV vaccination. Regarding clinic readiness, 73.3% (11) of respondents reported providers routinely recommended general vaccines at their respective clinic and 60% (9) of respondents reported their clinic administered routine vaccines.

Conclusions: Although respondents mostly believed improving HPV vaccination is an important goal for their clinic, many respondents also disagreed to this goal. The lack of consensus may be due to competing current clinic needs that may take precedence over HPV vaccination (i.e., COVID-19 and monkeypox vaccination). Yet, providers and clinic staff reported to offering and encouraging routine vaccination which may facilitate including HPV vaccination to routine HIV care. These findings provide insight in possible barriers and facilitators of implementing an HPV program in HIV community clinics.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
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MULTISECTOR, MULTILEVEL STAKEHOLDER'S PERSPECTIVES OF THE ADOLESCENT GIRLS' HPV VACCINATION PROGRAMME IN COLOMBIA: AN EXPLORATORY QUALITATIVE SERVICE EVALUATION

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Introduction: The HPV vaccination program in Colombia was disrupted by a massive psychogenic event in 2014 and vaccination dropped from 88% in 2012 to 36.2% in 2021. We conducted an exploratory evaluation process to inform an implementation research project design to identify strategies to increase HPV vaccination in Colombia.

Methods: This is a qualitative study to document stakeholders' perspectives about the challenges of implementing the HPV vaccination program. Between October and November 2021, we conducted four semi-structured interviews with central level informants from Ministry and Secretaries of health, and health facility immunizations program, thirty-three structured surveys, and four focus groups (FG) with educators, vaccination staff, and parents. Instruments and interview guides were informed by the Consolidated Framework for Implementation Research (CFIR). Transcripts were coded for two researchers using content analysis using pre-defined CFIR constructs.

Results: Barriers more frequently identified were limited staff, issues with state immunization registries, parents, and girls' vaccine-related misconception, competing priorities, levels of funding, training needs, delivery modalities for rural settings, insufficient organizational planning, and articulation. For vaccination staff, the informed consent and assent document facilitated the process of vaccination. Adding the HPV vaccine to the expanded program of immunization for children already in place in the country, was perceived by vaccinators as a facilitator. Regarding coverage in urban and rural areas, the vaccinating team highlighted inter-institutional coordination with primary health care teams.

Conclusions: These findings informed a protocol for a multisectoral alliance to develop and testing implementation interventions to increase HPV vaccination rates in Colombia.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
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BARRIERS AND FACILITATORS FOR HUMAN PAPILLOMA VIRUS (HPV) VACCINE INTRODUCTION AND SCALE-UP IN LOW- AND MIDDLE-INCOME COUNTRIES: NATIONAL STAKEHOLDERS' PERSPECTIVES

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Introduction: Cervical cancer, caused by human papillomavirus (HPV) infection, is a leading cause of mortality among women in low resource settings. The HPV vaccine prevents against high-risk strains of HPV that cause cervical cancer, however the integration of HPV vaccines into national immunization programs within many LMICs has been suboptimal. This study explored challenges and facilitators to HPV vaccine introduction and scale-up in LMICs through key informant interviews with national stakeholders.

Methods: A stakeholder analysis coupled with semi-structured in-depth interviews were conducted with national stakeholders. Countries in Africa and Asia were identified by conducting a mapping exercise to obtain information such as geographical region, HPV vaccine introduction status, dosing schedule, target age cohort, delivery strategy, and coverage. Interview data were analyzed through qualitative descriptive methods.

Results: A total of 18 stakeholders were interviewed, including 10 national immunization stakeholders and 8 non-governmental organization stakeholders. Interview findings were divided into different themes focused on introduction challenges; HPV vaccine delivery, stakeholders' mobilization and coordination, training of healthcare workers, communication and impact of COVID-19 on HPV vaccination programs.

Conclusions: Local data availability is crucial for countries to be able plan well for HPV vaccination programs i.e., enumerating eligible girls and to conduct efficient microplanning for HPV vaccine delivery. Stakeholders strongly voiced the need for refresher training of healthcare workers due to staff turnover and to update them with new information. Trainings need to cover the disease etiology, clear instructions on eligibility criteria, different types and choice of the vaccine and address misconceptions. There is a need for stakeholders' mobilization and a clear framework on stakeholders coordination, identifying needs at the local level and taking a bottom-up approach to improve coverage. COVID-19 pandemic has widely impacted HPV vaccination programs in Africa and requires robust approach to restore coverage and to catch up the missed adolescents.

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Poster Viewing
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ATTITUDES AND KNOWLEDGE ABOUT HPV VACCINATION OF SCHOOL CHILDREN AND THEIR PARENTS FOLLOWING USE OF A TARGETED INFORMATION

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Introduction: This study aimed to investigate children's' and parents' attitudes and knowledge about HPV (human papillomavirus) following introduction of gender-neutral HPV vaccination in the national immunization program (NIP) in Sweden. An evaluation of a tailored information package for parents and children launched by the Public Health Agency (PHAS) alongside the introduction of gender-neutral HPV vaccination was also performed.

Methods: In total, 276 parents and 206 children from 22 School Health Services responded to a web-based survey, spring 2021 to January 2022.

Results: Overall, parents (78%) perceived HPV vaccination to be of importance for their child's health. About half of the participating children and two thirds of the parents had used the tailored information package for the HPV vaccination. The fact sheet was mostly used by parents (55%) and children (20%) and also perceived as easy to understand (99% and 68% respectively). For both children and parents, the school nurse (70% respectively) was the primary source for information. The teacher (59%) was also a common source of information of HPV vaccination for the children.

Conclusions: The school nurse is essential for informing about HPV vaccination for both children and parents. There is a need to strengthen the knowledge regarding HPV vaccination among teachers as they also are a key source of information for the majority of the children. Additional interventions are needed to support parents in making informed decisions for HPV vaccinations.

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EXAMINING THE ASSOCIATION BETWEEN PATIENT-CENTERED COMMUNICATION AND HPV VACCINE ACCEPTABILITY AMONG ADULTS: A SYSTEMATIC REVIEW

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Introduction: Despite the HPV vaccine's long-standing availability, vaccine coverage remains suboptimal among a large proportion of adolescents and vaccine-eligible adults. Parents and young adults often express hesitancy surrounding HPV-related discussions during clinical encounters. The coronavirus disease (COVID-19) pandemic has shifted the way clinicians interact with patients, and has reinforced patient-centeredness in clinical practice. Experts now unanimously agree on the need to adopt patient-centered practices to address vaccine hesitancy. Drawing on this understanding, our study systematically examines the relationship between patient-centered communication and HPV acceptability among adults.

Methods: We conducted the review following the PRISMA specifications, and systematically searched five databases: Medline Complete (EBSCO), CINAHL (EBSCO), Embase (OVID), Global Health, and Health Source- Consumer Edition (EBSCO). We retrieved both qualitative and quantitative peer-reviewed articles published between January 2006 and June 2021. The cut-off year 2006 marks the launch of the first FDA approved HPV vaccine. A study was determined eligible if it: a) was published in English between 2006 and 2021, b) examined constructs related to patient-centered communication, c) targeted adult clients, and/or providers d) determined the relationship between patient-centered communication and HPV vaccine acceptability. We identified 1730 potentially eligible articles, and included 12 articles for full-text screening.

Results: Patient-centered communication measures in our review included Motivational Interviewing, and communication techniques involving patient-centered constructs such as reflective listening, spending enough time, providing assurance/ empathy, providing adequate information, giving a chance to ask questions. Providers adopting patient-centered communication report high comfort/ self-efficacy discussing the HPV vaccine, favorable attitudes to vaccinate, and vaccine delivery. Among patients, patient-centered communication positively impacts vaccine-eligible adults' intention to vaccinate, improves parental attitudes towards child's vaccination, and renders high vaccine uptake among teens.

Conclusions: Given the success of patient-centered communication in improving HPV vaccine acceptability, widespread implementation of evidence-based, patient-centered strategies will help in reducing HPV-related illnesses, globally.

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ASSOCIATION BETWEEN PATIENT-CENTERED COMMUNICATION, HPV KNOWLEDGE, AND PERCEIVED EFFECTIVENESS OF THE HPV VACCINE AMONG U.S. ADULTS: A HEALTH INFORMATION NATIONAL TRENDS SURVEY (HINTS) STUDY

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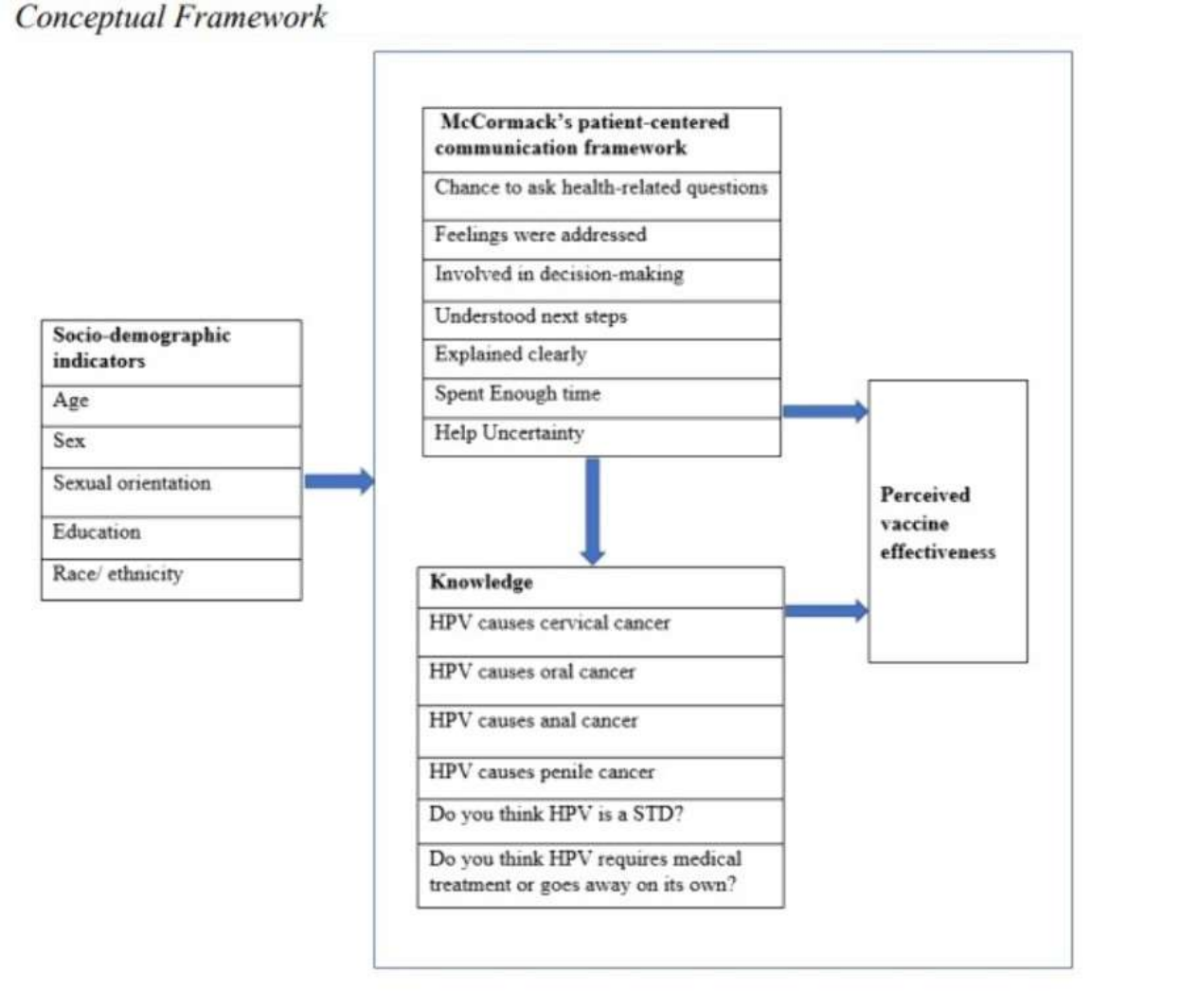
Introduction: Patient-centered communication is a significant, direct contributor to HPV knowledge. In turn, higher knowledge about HPV encourages people to seek prophylactic measures and improves acceptability towards the HPV vaccine. Drawing on evidence-based paths established from previous studies, our study examines the direct and indirect relationship between patient-centered communication, HPV knowledge and perceived HPV vaccine effectiveness. We have also explored the socio-demographic factors impacting patient-centered communication, HPV knowledge and perceived HPV vaccine effectiveness. Perceived HPV vaccine effectiveness has been previously cited as a strong indicator of HPV vaccine acceptability. Therefore, factors influencing perceived HPV effectivness ultimately contribute to improving HPV vaccine acceptability.

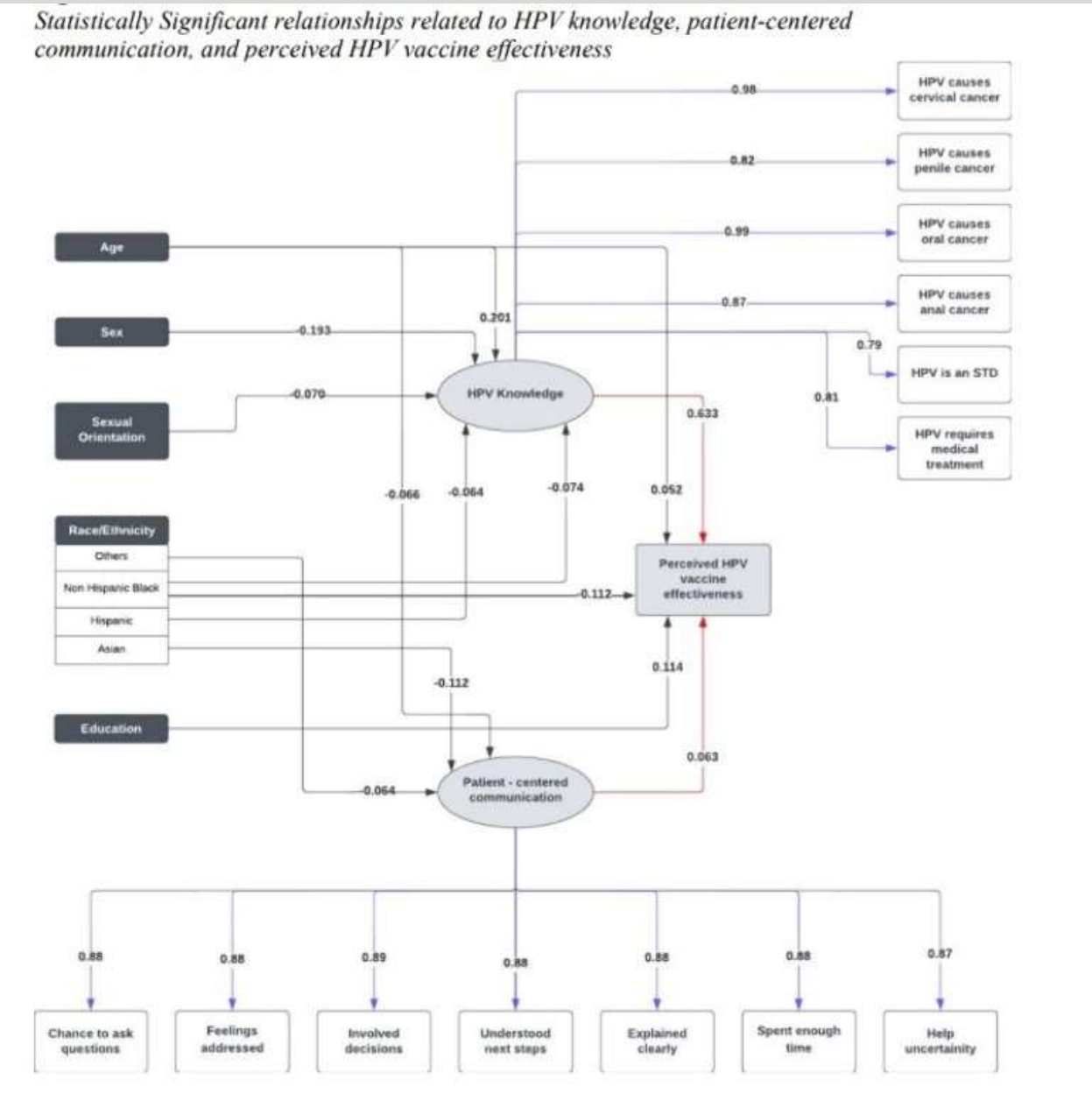
Methods: We analysed data from the Health Information National Trends Survey (HINTS) 5, Cycle 1. We used Mplus for modelling and Stata for descriptive analysis. We employed Structural equation modeling (SEM) to test our hypothesized conceptual model (Figure 1). Given the categorical nature of our response variables, we implemented the weighted least squares (WLSMV) method to estimate the parameters. Figure

1:



Results: Our sample N=2,522 comprises U.S adults aged 18-79 (mean age 47.98 years), Non-Hispanic White (67.65%), females (53.31%), and heterosexual (95.12%). Model fit results signify a good fit: RMSEA= 0.039, CFI=0.99 TLI= 0.99, and SRMR =0.070. Figure 2 illustrates the socio-demographic indicators related to patient-centered communication, HPV knowledge and perceived HPV vaccine effectiveness. Additionally, we observed statistical significance ($p<0.05$) in the path linking HPV Knowledge → HPV vaccine effectiveness ($\beta=0.633$), and patient-centered communication → HPV vaccine effectiveness ($\beta=0.063$). We observed lack of statistical significance ($p>0.05$) in the path linking patient-centered communication to HPV knowledge ($\beta=0.011$), and the indirect, knowledge-mediated path linking patient-centered communication and HPV vaccine effectiveness ($\beta=0.007$). Figure

2:



Conclusions: Parsing the direct and indirect channels leading up to vaccine acceptability will help future researchers startegise and plan interventions to improve HPV vaccine acceptability.

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Poster Viewing
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PROTECTION AGAINST HPV16/18 PERSISTENT INFECTIONS FOR UP TO 13 YEARS AFTER VACCINATION OF 9-11-YEAR-OLD GIRLS WITH 2-DOSE OR 3-DOSE EXTENDED-SCHEDULE OF QUADRIVALENT VACCINE

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Introduction: In the Province of Québec, Canada, the school-based HPV vaccination program initiated in 2008 included two doses of the quadrivalent vaccine (4vHPV) in grade 4. The ICI-VPH study, initiated in 2013, evaluated whether a 2-dose schedule (0-6 months) is non-inferior to a 3-dose extended schedule (0-6-60 months) for the prevention of persistent HPV16/18 infections.

Methods: From 2013 to 2017, we randomly assigned (1:1) 13–16-year-old girls who had been vaccinated five years earlier with two doses of 4vHPV in grade 4 (9-11-y-o), to receive a 3rd dose of 4vHPV or no intervention. Participants self-collected vaginal samples every six months. We routinely tested specimens on a yearly basis and banked the others. We used a generic test to detect HPV DNA, followed by Linear Array or Anyplex™ (Seegene) to genotype positive samples. Banked specimens preceding and following positive samples were later tested. Participants provided sexual and behavior data through online questionnaires every year.

Results: A total of 3356 13-16-year-old girls were randomly assigned to the 2-dose (n=1675) or 3-dose extended group (n=1681). Over a median follow-up of 5.5 years (median of 10.9 years after first dose; max: 13.3 years), 82.8% of randomized participants reported ever having had sex and 39.7% had at least one positive HPV sample. HPV6/11 was detected in one participant in the 2-dose group and 6 participants in the 3-dose group. HPV16/18 infections were detected in 11 participants in the 2-dose group compared to 17 in the 3-dose group. Among these, only one participant in the 3-dose group had a persistent HPV16 infection, which cleared before the end of follow-up.

Conclusions: Two doses of 4vHPV given 6 months apart provide excellent protection against persistent HPV16/18 infections for up to 13 years, suggesting a delayed 3rd dose may not provide additional benefit.

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DIFFERENCES IN SOCIODEMOGRAPHIC PREDICTORS OF UP-TO-DATE HPV VACCINATION STATUS AMONG ADOLESCENTS INITIATING AT AGES 9-10 VS. AT AGE 11 OR LATER, 2016-2021

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Introduction: Recent guidelines from the American Cancer Society stress HPV vaccination series initiation at earliest opportunity, i.e. age 9 years. Literature suggests initiating HPV vaccination at ages 9-10 years may be associated with higher rates of up-to-date (UTD) status later in adolescence. In this study, we examine differences in sociodemographic predictors of nationally representative UTD HPV vaccination rates among adolescents who initiated the series younger (ages 9-10 years) vs. older (≥ 11 years).

Methods: Six years of pooled data (2016-2021) from National Immunization Survey-Teen were used to estimate UTD HPV vaccination prevalence among younger vs. older initiating 13-17-year-olds. Adjusted logistic regression models estimated prevalence ratios (aPRs), differences (aDs), and difference in differences (aDDs) in prevalence of being UTD to assess differences in sociodemographic predictors of UTD status among younger vs. older initiators.

Results: Significant interactions were observed by sex ($p= 0.003$), insurance status ($p< 0.001$), and current age ($p < 0.001$) for the association between initiation status and being UTD for the series. Among older initiators, prevalence of UTD status was 5% lower in male adolescents in comparison to female adolescents ($p < 0.001$), 14% lower in uninsured adolescents in comparison to privately insured adolescents ($p < 0.001$), and 12% ($p<0.001$), 16% ($P<0.001$), 18% ($p<0.001$), and 17% ($p <0.001$) lower in 13-year-olds in comparison to 14-, 15-, 16-, and 17-year-olds, respectively. Significant differences by sex, insurance status, and current age were not observed among younger initiators.

Conclusions: Results indicate sociodemographic disparities observed among older initiators are not observed among younger initiators. Additional research is needed to determine if younger initiation may indeed be associated with improved vaccine access, as this finding may have significant implications for initiatives addressing disparities in HPV vaccination uptake, potentially leading to stronger emphasis of the importance of initiating the series at ages 9-10.

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Poster Viewing
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CREATION AND PROMOTION OF AN EVIDENCE BASE FOR HPV VACCINATION STARTING AT AGE 9

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Introduction: Starting the HPV vaccination series at age 9 is recommended by the American Cancer Society, American Academy of Pediatrics, and the National HPV Vaccination Roundtable (HPVRT), which includes leading thought experts from clinical, public health, and academic research institutions. Guidance from the Centers for Disease Control and Advisory Committee on Immunization Practices recommends routine HPV vaccination at age 11 or 12 years but notes that HPV vaccination can be given starting at age 9 years old. There are many benefits to initiating the HPV vaccine series at age 9. While many clinicians and health systems have demonstrated the feasibility and effectiveness of routinely recommending HPV vaccination starting at age 9, only a few studies have been published.

Methods: The HPVRT, in collaboration with St. Jude, sponsored a special journal issue supplement to solicit evidence on the impact of starting vaccination at age 9. This was accompanied by an open call for papers.

Results: We have received 13 solicited articles and 6 articles from the open call. The articles are a combination of research studies and commentaries. Video abstracts by the authors are being added to the HPVRT website and YouTube channel.

Conclusions: The HPVRT created a number of resources to support health systems and health plans as part of the 'Start at Age 9 Campaign', including an Evidence Summary, Resource Sheet, Toolkit, and Poster. Creation of an evidence base, collated in a special journal issue and accompanied by video abstracts from authors as well as other promotional strategies such as webinars and social media posts, will facilitate efforts to improve on-time HPV vaccination.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
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ECONOMIC BURDEN OF CERVICAL CANCER IN MAINLAND CHINA: A SYSTEMATIC LITERATURE REVIEW

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Introduction: As cervical cancer is the fifth common female malignant tumor in China, it is important to assess disease burdens to inform early prevention like HPV vaccine. We aimed to estimate the economic burden of cervical cancer and cervical intraepithelial neoplasia (CIN) in China.

Methods: We conducted a systematic literature review of English and Chinese publications between 2001-2020. All costs and epidemiological data for cervical cancer and CIN patients in China were structurally extracted. The national total direct and indirect costs were estimated through incidence-based approach. Costs were discounted to 2020 Chinese Yuan (CNY) by local health care consumer price indices.

Results: A total of 155 studies were included, with 116 reporting costs from healthcare records/claims/surveys, and 39 from economic analysis. Estimated annual cost per cervical cancer was CNY 58,189 for incident patients and CNY 13,025 for prevalent patients in China. The per-capita annual cost increased from CNY 6,452 for CIN 2 to CNY 13,602 for CIN 3. Total economic burden of cervical cancer nationwide was estimated at CNY 9.69 billion, with 72% from direct medical cost. Cervical pre-cancer (CIN 2 and 3) imposed an additional burden of CNY 2.03 billion, with 48%-50% from direct medical cost. Using HPV attribution fraction, total costs preventable by nonavalent vaccine was CNY 8.72 billion and CNY 1.42 billion for people with cervical cancer and pre-cancer, respectively; by other HPV types 16/18 targeted vaccines (i.e., bivalent and quadrivalent vaccines), the preventable costs for cervical cancer and pre-cancer were CNY 6.88 billion and CNY 0.94 billion, respectively.

Conclusions: Cervical pre-/cancer is associated with significant economic burden in China. Scaling up HPV vaccination can reduce economic losses.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
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ECONOMIC BURDEN OF HPV-RELATED NON-CERVICAL DISEASE IN MAINLAND CHINA: A SYSTEMATIC LITERATURE REVIEW

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Introduction: Human papillomavirus (HPV) can cause a variety of non-cervical cancers, and non-cancer diseases including anogenital warts (AGW) and recurrent respiratory papillomatosis (RRP). However, little is known about the economic burden of those diseases. This study aimed to quantify the economic burden of non-cervical HPV-related diseases in China.

Methods: We conducted a systematic literature review on English/Chinese publications between 2001-2020. Structured methods were used to select studies reporting related epidemiological data and various costs in Chinese population. All costs were adjusted to 2020 Chinese Yuan (CNY) using local health care price indices.

Results: We included 62 studies with data pertaining to costs for head and neck cancer (n=57), AGW (n=7), vaginal cancer (n=1), vulvar cancer (n=1), anal cancer (n=1), penile cancer (n=1), and RRP (n=1). Cost per case varied by cancers and by phase: from the highest of CNY 79,567 for head and neck cancer to the lowest of CNY 62,670 for penile cancer in the first year after diagnosis, and from CNY 27,965 for anal cancer to CNY 14,659 for penile cancer in follow-up years. The per-capita annual cost for AGW and RRP was CNY 11,819 and CNY 41,329, respectively. Total national economic burden of non-cervical cancer diseases was CNY 6.31 billion, of which 22%, 87% and 90% could be prevented by bivalent, quadrivalent, and nonavalent vaccine, respectively, estimated based on HPV attribution fraction.

Conclusions: Non-cervical cancer HPV-related diseases imposed a significant economic burden in men and women in China and vaccination can largely reduce the costs.

Shift 02-140 / #657

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-20-2023 7:00 AM - 4:00 PM

MODELLING THE LONG-TERM EFFECTIVENESS AND RESOURCE IMPACT OF HPV-BASED CERVICAL SCREENING STRATEGIES FOR BRITISH COLUMBIA, CANADA

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Introduction: Human papillomavirus (HPV)-based cervical screening can improve pre-cancer detection, but has yet to be widely implemented due to uncertainty in how best to integrate HPV testing into existing programs. The purpose of this study was to compare impact of alternative HPV-screening approaches on population-level effectiveness, resource use, and cost-effectiveness for the province of British Columbia (BC), Canada.

Methods: We identified four alternative screening strategies of interest, based on primary screening test, frequency, and age ranges (Table), with a reference strategy reflecting current policy in BC. We conducted our analysis using OncoSim-Cervical, a microsimulation model developed by the Canadian Partnership Against Cancer, that simulates the natural history of cervical cancer for the Canadian population, including HPV transmission, infection, and subsequent disease progression. Model parameters for HPV vaccination, screening participation, follow-up compliance, and cost were updated to reflect local rates in BC. We simulated outcomes for the BC population, from 2022 to 2050, including cervical cancer incidence and mortality, number of screening and follow-up tests, number of pre-cancer treatment procedures, and
cost.

Table: Alternative screening strategies implemented in OncoSim-Cervical microsimulation model

Screening strategy	Primary test	Secondary test	Frequency (years)	Starting age (years)	Ending age (years)
BC Base case	Cytology	-	3	25	69
HPV q5 years	HPV	Cytology	5	25	69
Netherlands	HPV	Cytology	5, 10	30, 40	60
USPSTF	Cytology, HPV	Cytology	3, 5	21, 30	65
Australia	HPV 16/18 genotyping	Cytology	5	25	69

USPSTF: United States Preventive Services Task Force

Results: indicate that adoption of HPV-based screening would increase demand for colposcopy and pre-cancer treatment by up to 77% and 35% respectively by 2025, but would decrease over the long term. At current participation rates, HPV screening would lead to a moderate reduction in cervical cancer incidence and mortality.

Conclusions: A transition to HPV-based screening in BC would reduce cervical cancer incidence and mortality. However, the transition to HPV screening will increase costs in the short term, and considerably increase demand for colposcopy and pre-cancer treatment services. The way in which screening programs transition to HPV-based screening will affect service demand and cost. Our future work will explore alternative approaches to implementing HPV screening in BC, to support a fair and equitable transition.

Shift 02-141 / #840

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-20-2023 7:00 AM - 4:00 PM

GENDER-NEUTRAL 9-VALENT HUMAN PAPILLOMAVIRUS VACCINATION IN TAIWAN: A COST-EFFECTIVENESS ANALYSIS

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Introduction: Human papillomavirus (HPV) can cause cancers and HPV diseases in both genders. Many countries have transitioned from female-only vaccination (FOV) to gender-neutral vaccination (GNV), directly protecting men against HPV infection and diseases and possibly further reducing HPV-related diseases in women. Starting September 2022, the Taiwanese government has been providing the 9-valent HPV vaccine (9vHPV) free of charge to 13-year old girls as part of the National Immunization Program (NIP). This study assesses the health impact and cost-effectiveness of 9vHPV GNV vs. 9vHPV FOV strategies in Taiwan.

Methods: Using Taiwanese data, a validated dynamic transmission model was adapted to assess the expansion of the current FOV strategy (9vHPV FOV) to include boys (9vHPV GNV). HPV-associated health outcomes included cervical lesions (CIN-1/2/3), cervical, vaginal, vulvar, head and neck (H&N), anal, and penile cancers as well as genital warts (GWs) and recurrent respiratory papillomatosis (RRP). Costs, quality-adjusted life-years (QALY), and incremental cost-effectiveness ratio (ICER) were estimated. The model assumed lifelong duration of vaccine protection, herd immunity, a discount rate of 3% for costs and QALYs.

Results: Compared to 9vHPV FOV strategy, 9vHPV GNV strategy would prevent more cases of HPV-related diseases and cancers (1,182 cervical cancer, 9,229 CIN-1/2/3, 17 vaginal, 44 vulvar, 6,928 H&N, 292 anal and 107 penile cancer, 86,941 GWs, and 435 RRP) and death (675 cervical cancer, 7 vaginal, 20 vulvar, 4,462 H&N, 156 anal and 61 penile cancer, and 21 RRP) over 100 years. The ICER of 9vHPV GNV strategy vs. 9vHPV FOV strategy was NTD 874,006/QALY.

Conclusions: A 9vHPV GNV strategy for girls and boys would have additional public health and economic impact and would be considered cost-effective as compared to the current 9vHPV FOV strategy, relative to per capita GDP, which is estimated at NTD 924,796 for Taiwan.

Shift 02-142 / #980

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-20-2023 7:00 AM - 4:00 PM

ADAPTING A MICROSIMULATION MODEL OF CERVICAL CARCINOGENESIS TO REFLECT BLACK WOMEN IN THE U.S.

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Introduction: To explore factors that contribute to cervical cancer incidence and mortality disparities by race, we adapted a microsimulation model of HPV natural history in all women in the U.S. to reflect Black women only

Methods: We integrated race-stratified demographic, epidemiological and screening data for U.S. Black women into a general population model of HPV and cervical cancer. Demographic data on all-cause mortality and hysterectomy rates came from national death data and the Behavioral Risk Factor Surveillance Survey. Epidemiologic data included age- and genotype-specific HPV prevalence from the 2002-2006 National Health and Nutrition Examination Survey and HPV type distribution within cervical precancer and cancer from the literature. Cervical cancer incidence, mortality, and survival by race and age came from the Surveillance, Epidemiology, and End Results Program. Cervical cancer screening patterns were estimated from the METRICS sites of the PROSPR consortium. We calibrated HPV incidence in the model to fit empirical data on HPV prevalence and type distribution in Black women.

Results: Compared to all women, the empirical data showed that cancer incidence and mortality were higher among Black women, and HPV type distribution in precancer was different. The calibrated model for Black women achieved good fit to HPV prevalence and type distribution. When race-specific cervical cancer screening patterns were incorporated, the model reproduced observed disparities in incidence and mortality.

Conclusions: There are substantial differences in demographics, screening patterns, and cervical cancer between Black women and all women in the U.S. Important drivers of cervical cancer incidence include all-cause mortality and hysterectomy rates that impact the number of women at risk. Ongoing work will describe the relative contributions of demographics, screening, and epidemiology to observed disparities in incidence and mortality.

Shift 02-143 / #1217

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-20-2023 7:00 AM - 4:00 PM

MICRO-COSTING CERVICAL SCREENING IN A BASIC HEALTH UNIT IN THE FEDERAL DISTRICT, BRAZIL

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Introduction: In Brazil, the Unified Health System (SUS) is in charge of running the cervical cancer screening program. Conventional cytology is recommended every two years for women between 25 and 64 years old. Recently, switching to newer more effective strategies have started. We estimated the current cost of cervical screening in a basic health care unit in the Federal District of Brazil, in preparation for future cost-effectiveness analysis of different screening and triage strategies.

Methods: Micro-costing methods based on an ingredients-based approach were used. Direct and indirect medical costs were extracted from the national platforms for records of consultations (SISCAN – Cancer Information System) and the Health Price Database (BPS), as well as on-site interviews with professionals responsible for tracking in the unit. The reference year for all estimated values was 2019. We collected data on number of Pap smears; equipment; supplies; human resources and user costs (i.e., the cost of transportation to the facility).

Results: The estimated cost of the procedure for the basic health unit was R$ 78.63 (US$ 19.60). The average cost of transportation for women was R$ 8.1 (US$ 2.02). The reimbursement amount from the central level to the health facilities for this procedure was R$ 6,97 (US$ 1.73) in 2019 and from 2020 onwards it increased to R$ 14,37 (US$ 3.58) but remained substantially less than the actual cost to the health unit. The cost of moving the woman to the basic health unit was R$ 2.70 (US$ 0.67).

Conclusions: Reimbursement values for Pap testing are substantially less than the actual cost to the basic health unit. The discrepancy may impact financing and diminish quality of care and access to screening. Findings may contribute to stakeholder planning and financing decisions.

Shift 02-144 / #1312

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-20-2023 7:00 AM - 4:00 PM

ELECTRONIC HEALTH RECORDS TO PERSONALIZE RISK PREDICTION OF CERVICAL CANCER SCREENING

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Introduction: INTRODUCTION Efficient and effective cervical cancer screening programs are of great importance for the elimination of cervical cancer as a public health concern. Moving away from one-size-fits-all screening towards an approach based on individual risks can drastically improve the program's performance. Risk-based models created from electronic health records (EHR) could be an answer to a more personalized approach.

Methods: Our data source was nationwide population-based electronic healthcare administrative data from 2005 to 2020. We used a 5-year lookback period (2005–2010) preceding the observation period (2011-2020) to develop risk prediction models with two main outcomes: CIN3 and cervical cancer. Cox proportional hazard model to estimate the determinants of risk for both outcomes was used. The model was validated by splitting the data into training and validation samples.

Results: Overall, we identified 1443 and 4839 women with cervical cancer and CIN3+ respectively during the 10-year follow-up period. The absolute 10-year risk of cervical cancer and CIN3+ was 0.41% and 1.4% respectively. The risk of cervical cancer was strongly associated with a number of abortions aHR 1.23 (95%CI 1.09-1.38), having low-grade aHR 3.26 (95%CI 2.61-4.08), and high-grade aHR 2.17 (95%CI 1.50-3.15) dysplasia in 5 preceding years. Those who have been covered by regular cervical cancer screening had lower risks for cervical cancer aHR 0.67 (95%CI 0.53-0.85). Predictors for CIN3+ were similar with the addition of contraceptive use aHR 1.22 (95%CI 1.06 - 1.40). The model had better predictions for CIN3 than cancer with C-statistic in the validation sample 0.62 and 0.68 respectively.

Conclusions: Our study aimed to derive risk models from EHRs and explore how well classifiers can identify future cervical cancer cases. We believe that public health agencies have a strategic opportunity to use health data-rich EHR to assist in planning personalized screening programmes. The model can be recalibrated for different epidemiological and prevention settings.

Shift 02-145 / #1323

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-20-2023 7:00 AM - 4:00 PM

COST-EFFECTIVENESS OF THE SCREEN AND TREAT STRATEGIES USING HPV TEST LINKED TO THERMAL ABLATION FOR CERVICAL CANCER PREVENTION IN CHINA: A MODELLING STUDY

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Introduction: Self-sampling HPV test, thermal ablation are effective tools to increase screening coverage and treatment appliance for accelerating cervical cancer elimination. We assessed cost-effectiveness of their combined strategies to inform accessible, affordable and acceptable cervical cancer prevention strategies.

Methods: We developed a hybrid model to evaluate costs, health outcomes and incremental cost-effectiveness ratios (ICER) of six screen (triage)-and-treat strategies combining HPV testing (self-sampling or physician-sampling), triage modalities (HPV genotyping, colposcopy or none) and thermal ablation, from a societal perspective. A designated initial cohort of 100000 females born in 2015 were considered. Strategies with an ICER less than Chinese gross domestic product (GDP) per capita ($10 350) were considered highly cost-effective.

Results: Compared with current strategies in China (phy-HPV with genotype and cytology triage), all screen (triage)-and-treat strategies were cost-effective and self-HPV without triage was optimal with the most incremental quality-adjusted life-years (QALYs) gained (220 to 43 440) in rural and urban China. Each strategy with self-collected samples was cost-saving compared with current strategies ($-818 430 to $-3540) whereas more costs were incurred using physician-collected samples compared with current phy-HPV with genotype ($20 840 to $182 840). In utilizing screen-and-treat strategies, proportion of costs on cancer treatment would be reduced by 4.38-12.80% accompanied with more investments towards screening and precancerous treatment. Notably, more than 81.59% of HPV-positive women would be overtreated, that could be reduced by triage with HPV 7 types (2.00 to 2.47%) or HPV 16/18 (10.34 to 14.38%) with a few cancer cases

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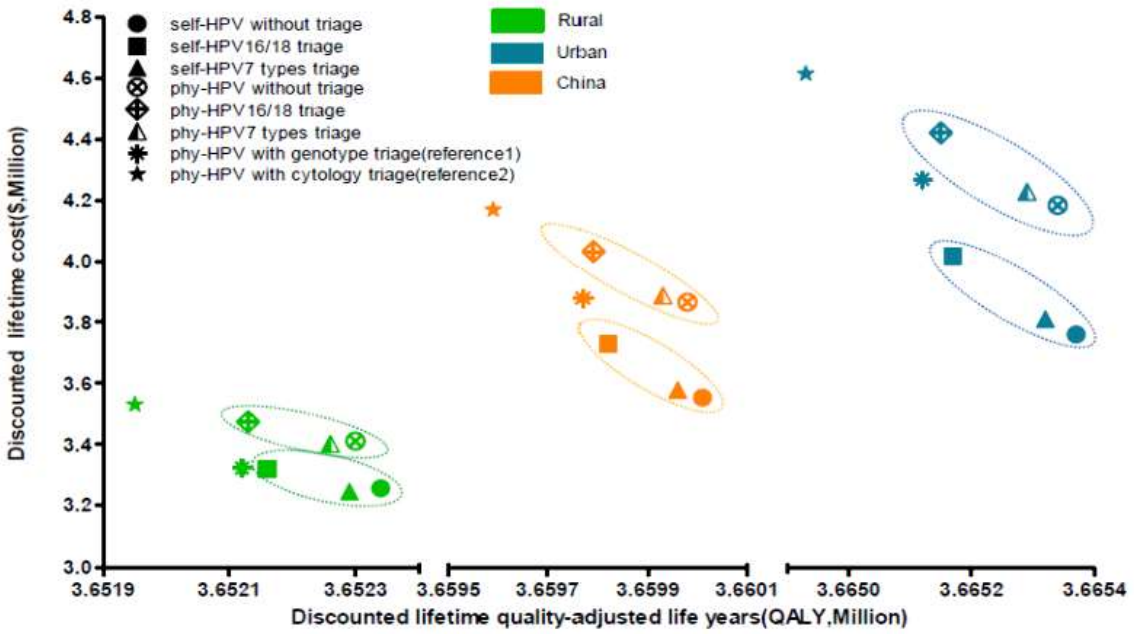

Scenarios	Rural		Urban		China	
	ICER ($/QALY) scenario 7 as reference	ICER ($/QALY) scenario 8 as reference	ICER ($/QALY) scenario 7 as reference	ICER ($/QALY) scenario 8 as reference	ICER ($/QALY) scenario 7 as reference	ICER ($/QALY) scenario 8 as reference
1(self-HPV without triage)	-206·71	-657·95	-1857·18	-1856·90	-1238·98	-1401·73
2(self-HPV16/18 triage)	-95·17	-1032·86	-4791·69	-2489·91	-3214·10	-1941·82
3(self-HPV7 types triage)	-378·67	-813·47	-2208·16	-2036·12	-1527·90	-1572·68
4(phy-HPV without triage)	898·28	-125·90	95·89	-807·09	393·47	-549·50
5(phy-HPV16/18 triage)	15504·52	-213·50	6964·90	-770·75	8900·17	-564·35
6(phy-HPV7 types triage)	1001·47	-233·93	246·20	-869·74	523·46	-629·73
7(phy-HPV with genotype triage)	/	-1240·11	/	-1856·53	/	-1618·34
8(phy-HPV with cytology triage)	-1240·11	/	-1856·53	/	-1618·34	/

Figure 1: Cost-effectiveness analysis for all screen (triage) and treatment strategies versus the currently used strategies

HPV=human papillomavirus. QALY= quality-adjusted life-years. phy=physician. ICER= incremental cost-effectiveness ratio

Conclusions: Screen-and-treat strategy using self-sampling HPV test linked to thermal ablation could be the most cost-effective for cervical cancer prevention in China. Additional triage with quality-assured performance could reduce overtreatment and remains highly cost effective compared with current strategies.

Shift 02-146 / #1742

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-20-2023 7:00 AM - 4:00 PM

HEALTH AND ECONOMIC IMPACTS OF HPV VACCINATION AGAINST HPV-RELATED NON-CERVICAL CANCERS IN CHINA: A MODELLING STUDY

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Introduction: HPV vaccination is an effective and cost-effective cervical cancer prevention measure, its protection against HPV infection could also reduce other HPV-related cancer burdens. Quantifying these additional benefits and exploring their impacts on the cost-effectiveness evaluation in China may motivate the initiation of a national HPV vaccination program.

Methods: A previously described transmission-natural history model was combined with a mathematical equation to estimate the health and economic impact of HPV vaccination, taking non-cervical cancers into account. Non-cervical cancers include cancers of the penis, vulva/vagina, anus, oral cavity, oropharynx, and larynx. For vaccination scenarios, we considered the different modes of delivery (routine vaccination targeting 12-year-old girls, with or without catch-up vaccination through to 18 years) and 4 types of vaccines. We calculated the cumulative cancer cases and deaths averted of different cancer types, discounted costs, and QALYs averted during the 100-year horizon. We also evaluated the impact of considering non-cervical cancers on the cost-effectiveness and return on investment calculation.

Results: The routine vaccination is predicted to avert 337,870-474,851 non-cervical cancer cases, and 28,008-39,341 related deaths during the 100-year time horizon, among which anal cancers account for the largest proportion (about 30% for cases and 25% for deaths). The reduction of the non-cervical cancer burden would produce additional cost-saving of $2.53 billion to $3.41 billion, and QALYs of 24,322 to 32,812. Taking non-cervical cancer into account would make the vaccination more cost-saving, and the net benefits gained from every dollar invested on vaccination would increase by $0.52-$0.96. These additional benefits would be further expanded when adding a multi-age cohort vaccination through to 18 years.

Conclusions: Besides preventing cervical cancer, HPV vaccination could also produce substantial health and economic benefits in reducing the non-cervical cancer burden. Our results contribute towards a better understanding and recognition of the benefits of HPV immunization.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03F. ECONOMICS AND MATHEMATICAL MODELLING
04-20-2023 7:00 AM - 4:00 PM

THE IMPACT OF ALTERNATE HPV VACCINATION AND CERVICAL SCREENING STRATEGIES IN JAPAN: A COST EFFECTIVENESS ANALYSIS

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Introduction: The Japanese 2020 cervical screening guidelines recommend conventional cervical cytology screening. The nonavalent human papillomavirus (HPV) vaccine has also recently been approved for use in Japan. Therefore, we aimed to evaluate the cost-effectiveness of the cervical cancer screening guideline strategies with universal vaccination of girls (9-14 years) using the nonavalent HPV vaccine.

Methods: A cost effectiveness analysis was performed using an age-specific Markov microsimulation model for Japan to evaluate costs, quality adjusted life-years (QALYs) gained, incremental cost-effectiveness ratios (ICER), number of colposcopies, biopsies, and precancer treatments for cervical cancer of 29 screening and vaccination strategies outlined in the 2020 guidelines (e.g. conventional cytology, liquid-based cytology (LBC), and HPV DNA testing). Analysis included self-collection for women under or never-screened. A health systems perspective for a cohort of 100,000 girls (12-14 years-old) over a lifetime vaccinated with the nonavalent HPV vaccine was used (current very-low vaccination coverage = 0.08%, maximum coverage = 70%). Discount rate = 0.03. A univariate and probabilistic sensitivity analysis was performed to assess the robustness of findings. Costs are reported in US dollars (2022).

Results: Compared with conventional cytology, strategies would incur an additional cost of US$839,280–738,182,669 and result in 62,755–247,347 quality-adjusted-life-years gained. HPV DNA testing distinguishing HPV16/18 with reflex LBC (3-yearly) would be most cost-effective with an ICER of US$1,279 per QALY gained. The probability of it being cost effective was 70%. Strategies that include self-collection were more cost-effective than primary-screening strategies alone at a willingness-to-pay (WTP) of 1-times per-capita GDP. Increasing vaccination coverage to 70% did not affect ranking of the most cost-effective screening

strategy.

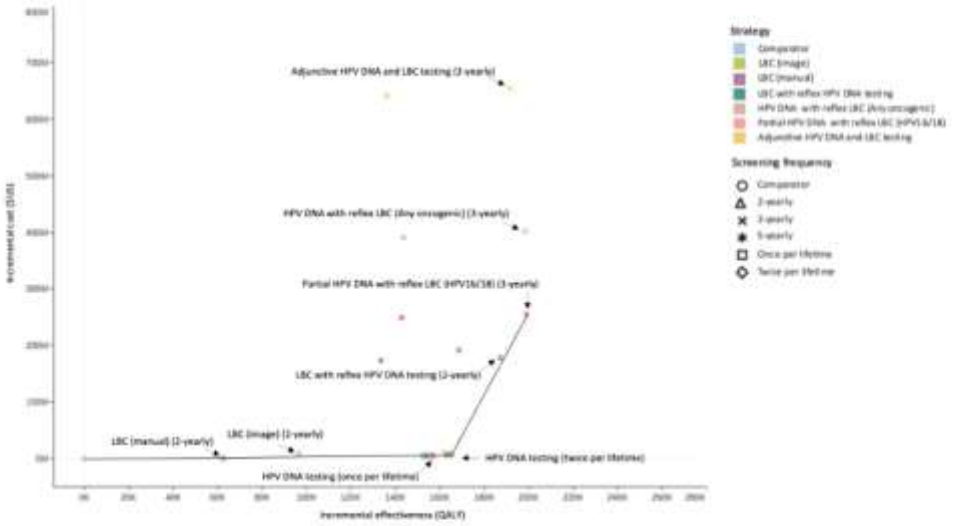

Figure 1: Cost effectiveness frontier for intervention strategies included in the Japanese cervical screening guidelines. Incremental QALYs and incremental costs of intervention strategies compared with current screening and vaccination coverage. Names of the strategies located on the cost- effectiveness frontier and their incremental cost-effectiveness ratios compared with the lower-cost non-dominated strategy are shown. LBC: Liquid based cytology. HPV: Human papillomavirus.

Conclusions: HPV DNA testing with reflex LBC for HPV16/18 (3-yearly) is the most cost-effective strategy for cervical cancer prevention in Japan. Including self-collection for under or never-screened women would make it more cost-effective. These findings provide important evidence to reduce cervical cancer in Japan.

Shift 02-148 / #510

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

HUMAN PAPILLOMAVIRUS GENOTYPES AMONG SOUTH INDIAN WOMEN ATTENDING COMMUNITY BASED CERVICAL CANCER SCREENING: A CROSS-SECTIONAL STUDY

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Introduction: Understanding the distribution of Human papillomavirus (HPV) genotypes circulating in a region is crucial for the planning and implementation of national vaccination and screening program. However, there is limited data available in India about the circulating HPV strains. This study examined the HPV genotypes of women who tested for positive for HPV DNA during a community-based cervical cancer screening program in rural Mysore, India.

Methods: Between 2021 to 2022, a two-year program for opportunistic cervical cancer screening using HPV DNA Hybrid Capture 2 Assay (Qiagen, Gaithersburg, Maryland) and Visual Inspection of Acetic Acid (VIA) or Liquid Based Cytology (LBC) was conducted using mobile clinics in rural Mysore communities. Genotyping was done using AmpFire Multiplex HPV Assay (Atila BioSystems, Mountain View, CA) which detected the presence of 15 high-risk HPV genotypes.

Results: HPV DNA screening done in 1,240 women. The average age was 35.6 years (SD: 11.1), 80% were married, and 40% had primary/no education. Of the 143 (11.5%) HPV-DNA positive women, 89 had genotyping results and the most prevalent strain was HPV16 (28.7%), HPV58 (17.5%), HPV33 (14.0%), HPV31 (13.3%), HPV59 (12.6%), HPV51 (11.9%), and less prevalent strains were HPV18 (11.2%), HPV35 (9.1%), HPV52 (8.4%), HPV68 (7.7%), HPV39 (4.2%), HPV53 (4.2%), HPV45 (2.8%), and HPV66 (2.8%); 82 had at least one of vaccine preventable high-risk types (HPV16, 18, 31, 33, 45, 52, and 58). Of these, 60 women had two or more HPV high-risk types.

Conclusions: Our study found women to have all nine vaccine-preventable HPV subtypes. HPV16 and HPV58 genotypes were found to be significantly higher compared with the other HPV genotypes. As the bivalent and quadrivalent vaccines offer limited cross-protection against HPV58, India should consider a multivalent vaccine that contains more than just HPV16 and 18 for prevention of cervical cancer.

Shift 02-149 / #580

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

THE ROLE OF STORYTELLING AND ENVIRONMMENTAL CUES IN HPV PUBLIC HEALTH CAMPAIGNS TO ELIMINATE CERVICAL CANCER IN VULNERABLE POPULATIONS

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Introduction: Latinas in Los Angeles County (LAC) face substantial disparities in HPV infections, vaccinations, screening, and deaths from cervical cancer due to socioeconomic status, language, culture, low-education, and lack of access. Latinas' cervical cancer rates in LAC are double Non-Hispanic Whites' (NHW) (14.3% versus 7.5%) with mortality among Latinas also significantly higher (3.4 versus 2.5 deaths per/100,000 among NHW)[1]. Innovative educational campaigns using storytelling and environmental cues can transform public health education and accelerate elimination of HPV associated cancers.

Methods: We developed two educational campaigns to increase cervical cancer screening among Latinas. Tamale Lesson is an 11-minute film that educates on the HPV virus and encourages cervical cancer screening in a multigenerational family while women cook tamales for a quinceañero. Es Tiempo (It's Time) uses an environmental cue (blooming of the Jacaranda tree) in a multi-media campaign to remind women to get HPV vaccinations and cervical cancer screening.

Results: Mexican-American, European-American, and African-American women (n=704) from high-risk communities participated in a controlled experiment to evaluate Tamale Lesson. Within six months Tamale Lesson eliminated cervical cancer screening disparities found at baseline; with 38% of Mexican-Americans, 22% of European-Americans, and 34% of African-Americans getting cervical cancer screening. For It's Time, women in two clinics were exposed to an intervention (n=1428) or control (n=745). The intervention consisted of HPV-related outdoor banners, billboards, posters, and clinic materials. The control received standard clinic reminders. Findings showed a 13% difference (X^2, $p<.001$) with overall 46% of women in the intervention group vs 33% in the control group, became compliant with screening guidelines. Based on clinic records, among 445 women who received educational materials at home, 65% of those in the intervention versus 34% in the control got screened.

Es Tiempo

Exploit the blooming of a local Jacaranda tree's annual bloom as a reminder and environmental cue to come in for screening (if have not been screened) and/or get daughters and sons vaccinated against HPV.

Tamale Lesson HPV film to increase cervical cancer screening

Conclusions: Culturally and language-specific HPV campaigns increase cervical cancer screening especially in high-risk communities, such as LAC's Latinas.

Shift 02-150 / #650

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

A PUBLIC HEALTH APPROACH TO CERVICAL CANCER PREVENTION IN EAST AFRICA THROUGH COMMUNITY-BASED HPV VACCINATION, SELF-ADMINISTERED SCREENING AND MOBILE TREATMENT

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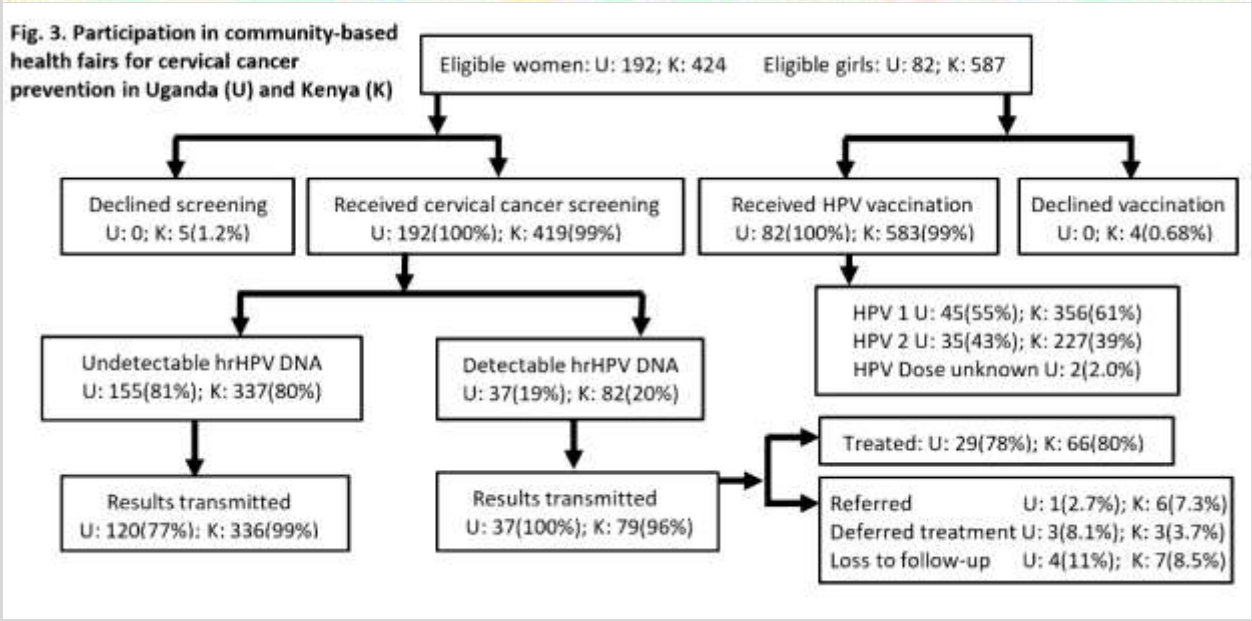
Introduction: In resource-limited settings, HPV-based vaccination and screening for cervical cancer control are currently often facility-based, and with a few exceptions, underutilized. In Uganda, we earlier developed a community-based campaign approach featuring self-collected HPV screening at health fairs followed by mobile in-community treatment. To expand this “public health approach” for cervical cancer prevention, we assessed the feasibility of adding HPV vaccination to the campaigns, and we evaluated the acceptability in another setting — Kenya.

Methods: We evaluated campaigns in rural Uganda and Kenya (Fig. 1), in which Community Health Workers mobilized residents to attend local health fairs that provided (i) HPV screening using self-collected cervicovaginal specimens for women 30 to 64 years old; and (ii) HPV vaccination for girls 10 to 14 years. Women who tested positive for HPV received therapy by a mobile treatment team. After fair completion, we visited a probability sample of households to learn the % of service-eligible residents who were aware of the fair and the % who elected to attend the

fairs.

Fig 1. Sites in East Africa (denoted by ●) in which community-based campaigns for cervical cancer prevention were implemented.

Results: We evaluated 10 fairs performed from Dec. 2021 to June 2022 (Fig. 2), at which 616 screening-eligible-women and 669 vaccine-eligible girls attended; 99.2% of the women received screening, and 99.4% of girls got vaccinated (Fig. 3). HPV prevalence was 20%. Of the HPV-infected women, 80% received treatment, and 11% had treatment appropriately referred/deferred. Post-fair surveys found that 62% of service-eligible residents in the target communities in Uganda and 85% in Kenya were aware of the fairs, and, of those aware, 42% in Uganda and 55% in Kenya attended the fairs.



Conclusions: In rural settings in East Africa, community-based campaigns featuring HPV vaccination, self-collected HPV testing, and mobile treatment were feasible and readily accepted by residents. This public health approach represents a promising model to achieve global health equity for cervical cancer prevention.

Shift 02-151 / #826

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

ARTIFICIAL INTELLIGENCE TO SUPPORT DECISIONS IN VISUAL INSPECTION WITH ACETIC ACID FOR CERVICAL CANCER SCREENING IN RURAL BANGLADESH, INDIA AND UGANDA: PRE-IMPLEMENTATION STUDY.

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Introduction: Coverage and uptake of cervical cancer screening is low in poor resource settings where the burden for cervical cancer is highest. Visual Inspection with Acetic acid (VIA) the available screening method, is limited by subjectivity and lack of skilled human resource. A decision support system (DSS) based on artificial intelligence (AI) could be the innovation to address this. The Manipal Academy of Higher Education (MAHE) developed an accurate AI algorithm under laboratory conditions. Before implementation this AI-DSS must be validated and studied under field conditions. We therefore conducted a pre-implementation study to determine the diagnostic performance of VIA by experts, healthcare workers (HCWs) and the AI algorithm.

Methods: Altogether 9 Experts, 22 healthcare workers (HCWs) and the AI algorithm assessed a set of 100 cervical images taken after application of acetic acid. Their diagnostic performance was analyzed by determining sensitivity, specificity, and area under the curve (AUC). Agreement between teams was measured using Kappa values.

Results: Sensitivity, specificity and AUC for experts were 81.6%, 93.5% and 0.932 (95% CI = 0.866 – 0.999) respectively, AI device was 80.0%, 83.3% and 0.862 (95% CI = 0.774 – 0.950) respectively and HCWs was 80.7%, 84.3% and 0.801. (95% CI = 0.703 – 0.898) respectively. Kappa value for experts, HCWs and AI was 0.683, 0.454 and 0.631 respectively.

Conclusions: Diagnostic performance of the experts was good qualifying them for consultations from the field. The HCWs performed well to provide quality screening. Diagnostic accuracy of the AI was lower than the expert's. Agreement between the teams was comparable. A pre-implementation study of AI is necessary to assess quality and diagnostic accuracy of the involved experts, HCWs and AI at baseline when comparing simultaneous implementation in different countries. Results will be used for further training of staff in the field and for improving the AI algorithm.

Shift 02-152 / #985

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

THE MOTHER-DAUGHTER PROJECT: A COMMUNITY-BASED APPROACH TO CERVICAL CANCER PREVENTION IN WESTERN KENYA

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Introduction: Rural women have the highest incidence of cervical cancer in Kenya. A community-based pilot study known as the Mother-Daughter Project (MDP) was initiated in 2019. Aims of MDP are to 1) screen rural Kenyan women for cervical cancer and determine if a triage strategy using HPV testing followed by VIA can be developed, and 2) vaccinate their daughters against HPV.

Methods: A community entry strategy was utilized to introduce the MDP and invite participants. At community meetings, women are educated about cervical cancer, then provided self-collected vaginal swabs for oncogenic HPV testing (Roche Cobas Assay). All women then travel to the local clinic for VIA. In all three 2-year cycles of the MDP (MDP-1/2/3), women with abnormal VIA undergo cervical biopsy. In MDP-3, 20% of women with normal VIA will undergo biopsy, and biopsy of suspected anogenital warts will be performed. Daughters (ages 9 through 14) of women in MDP-2/3 are offered HPV vaccination (Gardasil, quadrivalent). Additionally, benefits of the MDP and obstacles to participation will be evaluated.

Results: Five hundred women were enrolled in MDP-1/MDP-2 (mean age 36.7 years); 82.8% HIV-uninfected and 17.2% HIV-infected; 497 women preformed vaginal swabs; HR-HPV test results were available for 422 women; positive in 112 women (29.1%). VIA was performed in 485 women, abnormal in 19 (3.9%); biopsies were positive (CIN2/3+) in 7/19 women (36.8%). The distribution of HR-HPV and VIA results by HIV status will be determined. A total of 2091 girls received their first HPV vaccine dose at community meetings.

Conclusions: The MDP has built trust in the community. Kenyan women are willing to attend meetings, learn about cervical cancer, provide swabs for HPV testing, travel to the clinic for VIA, and have their daughters vaccinated against HPV. As a result of this pilot study, this community-based strategy to prevent cervical cancer will be continued.

Shift 02-153 / #1136

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

VALUE OF A CATCH-UP HPV TEST IN WOMEN AGED 65 AND ABOVE: A POPULATION-BASED NON-RANDOMIZED INTERVENTION STUDY

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Introduction: In several countries, high-risk human papillomavirus (HPV) test has replaced cytology as the primary cervical cancer screening test due to superior sensitivity, but in most countries women over 65 years have never had a HPV test. We evaluated the effectiveness of a catch-up high-risk human papillomavirus (HPV) cervical cancer screening test among 65-69-year-old women with no previous record of HPV-based screening.

Methods: This population-based non-randomized intervention study included Danish women aged 65-69 with no record of cervical cancer screening in the previous ≥ 5.5 years and no HPV-exit test at age 60-64. Eligible women residing in the Central Denmark Region were invited for a catch-up HPV test either by attending clinician-based sampling or requesting a vaginal self-sampling kit (intervention group). Women residing in the remaining four Danish regions received standard care which was the opportunity to have a cervical cytology collected for whatever reason (reference group). Main outcome measures were screening uptake and detection of cervical intraepithelial neoplasia (CIN) grade two or worse (CIN2+) per 1,000 women eligible for the screening offer with 95% confidence intervals (CIs).

Results: The study population consisted of 11,192 and 33,387 eligible women in the intervention and reference groups, respectively. In the intervention group, 6,965 women (62.2%) were screened, while 743 (2.2%) women had a record of a cervical cytology in the reference group. The CIN2+ detection was significantly higher in the intervention group (3.9, 95% CI: 2.9 to 5.3, n=44/11,192) as compared to the reference group (0.3, 95% CI: 0.2 to 0.6, n=11/33,387).

Conclusions: The intervention was associated with high screening uptake and resulted in 13-fold higher CIN2+ detection. Decisions on whether women aged 65 and above should be offered a catch-up HPV test may depend on the available resources and attitudes to cervical cancer risk in each country.

Shift 02-154 / #1156

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

IDENTIFYING NATIONAL (US) CERVICAL CANCER PRIORITIES

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Introduction: In response to President Biden's relaunch of the Cancer Moonshot and the 2022 President's Cancer Panel Report, the American Cancer Society launched the National Roundtable on Cervical Cancer (NRTCC) in October 2022. Through multivariate data analysis, we identified stakeholder and community priorities for cervical cancer elimination.

Methods: Qualitative data were collected using interviews with approximately 50 stakeholders representing diverse providers, consumers and advocates, infrastructure organizations, advocacy and service organizations, and policymakers. Four consumer focus groups, three community conversation groups, and conversations with community specialists with lived experiences provided additional perspectives. Emerging themes were further explored with a stakeholder survey. Using grounded theory, the analysis established common themes. This formative assessment was used to create the strategic plan of the NRTCC.

Results: Preliminary themes include improving provider and patient messaging, addressing cervical healthcare disparities related to access, diagnosis, and standard of care, improving patient navigation, and reducing time for follow-up after an abnormal test. Stakeholders identified needs for improved alignment and medical management, increased use of self-sampling, approaches to reach victims of sexual trauma and those with disabilities, integration of a whole woman screening approach, data disaggregation, and reducing costs and logistical barriers.

Conclusions: Establishing the foundation of the NRTCC with formative stakeholder research is necessary to understand the needs of communities where unscreened and under-screened people are still dying of cervical cancer. The resulting strategic plan will guide the NRTCC to work toward fairness and justice by systematically assessing disparities and redressing [those] disparities through targeted actions. Additional strategies will be added as new data are made available.

Shift 02-155 / #1163

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

BARRIERS AND FACILITATORS TO UPTAKE OF CERVICAL CANCER SERVICES AMONG WOMEN IN ZAMBIA: A QUALITATIVE STUDY

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Introduction: Zambia has one of the world's highest cervical cancer (CC) incidence rates, which remains the leading cause of cancer related death among women. Screening uptake remains low with access to the national CC prevention programme hampered by various social-cultural, logistical, and financial barriers. We aimed to explore the barriers and facilitators to CC service uptake in Zambia.

Methods: We conducted 16 focus group discussions (FGDs) with CC screened and unscreened women and two FGDs and 18 in-depth interviews with healthcare workers providing antiretroviral treatment and/or CC services in three districts. Discussions explored knowledge and awareness of CC, community perceptions, health seeking attitudes and behaviours, and screening and treatment experiences. Transcripts were coded and analysed using thematic analysis.

Results: While CC awareness was high, there was misinformation regarding causation and screening procedures. Fear of screening procedures and outcomes, delays in coming to the health facility due to use of traditional interventions, delayed or lost histology results, long wait times at the health facility, and poor referral, linkage, and follow-up systems were barriers to uptake of CC services. Facilitators included encouragement from peers, positive interactions with healthcare workers, experiencing signs and symptoms of CC, and perceived freedom associated with knowing one's CC status.

Conclusions: To improve screening and management of CC, community sensitization should include information on signs and symptoms of CC and address the current fears, traditional beliefs and practices, and misinformation. Additionally, a community based "know your status" campaign led by CC screened women and healthcare workers could be used to spread information, lessen stigma, and drive demand for CC screening. Lastly, health system strengthening is needed to provide efficient government laboratory diagnostic services, and capacity to track women across the continuum of CC care ensuring low-cost linkage to screening and treatment

services.

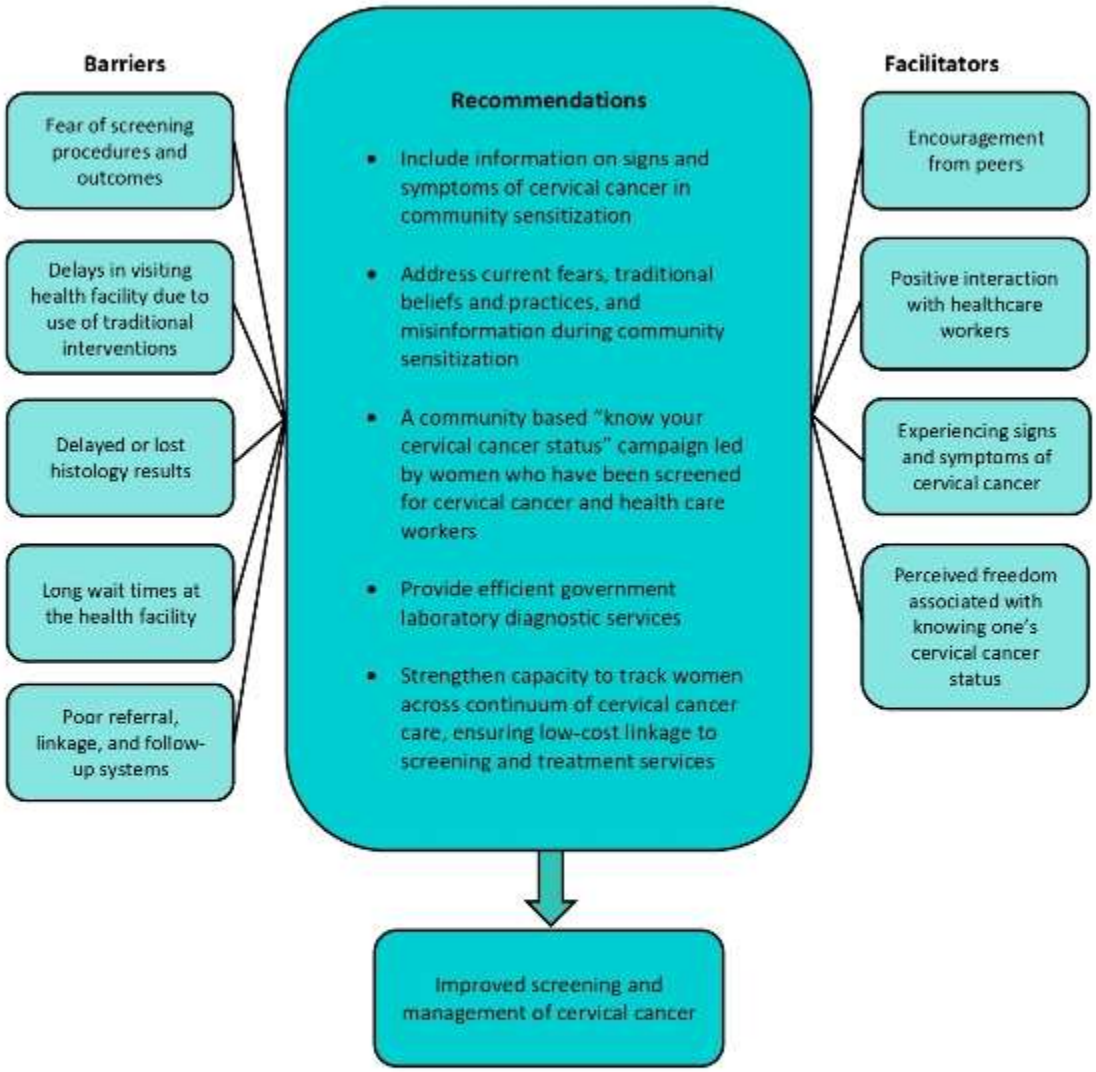

Figure: Barriers and facilitators to uptake of cervical cancer services

Shift 02-156 / #1210

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

STRENGTHENING PRIMARY HEALTH FACILITIES FOR THE MANAGEMENT OF ELIGIBLE HR-HPV POSITIVE WOMEN IN LIMA, PERU.

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Introduction: In Peru, 12 women are diagnosed daily with cervical cancer; of these, 6 will die due to a lack of proper follow up. Peru guidelines are aligned with the World Health Organization's vision of elimination of cervical cancer through early detection and treatment (EDT) of women positive to high risk-human papilloma virus (HR-HPV+); however, women requiring specialized care are still not receiving it, leading to deaths from cervical cancer. The commitment to preventing deaths from cervical cancer, combined with challenges in the health care system, led to the decision to restructure our EDT system, by implementing the management of women positive for HR-HPV in primary health units in Lima.

Methods: In coordination with primary health facilities, a new strategy was implemented throughout Lima for the EDT of HR-HPV+, including specialized management at this level, as well as pre- and post-treatment counseling. Funding has allowed for the acquisition of equipment and instruments for ablative treatment and cervical biopsies at the primary level, as well as the incorporation of new health professionals.

Results: To initiate management of HR-HPV+, women who had no evidence of receiving treatment were identified and contacted for follow up at a primary level facility; eligible women received ablative treatment. The most common reasons for not being eligible were poor cervical exposure and bleeding.

Conclusions: An effective EDT strategy implemented at the primary level, including management of eligible women with HR-HPV+ with ablative therapy, is feasible. Monitoring and evaluation data being collected will allow us to evaluate the success of this new screen-and-treat strategy in Lima.

Shift 02-157 / #1238

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

THE PATHWAY TOWARDS CERVICAL CANCER ELIMINATION IN PACIFIC ISLAND NATIONS: A MODELLED EVALUATION OF THE EFFECTIVENESS OF HPV SCREENING IN THE FEDERATED STATES OF MICRONESIA

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Introduction: The PACe (Pacific Against Cervical Cancer) project, supported by US Centre of Disease Control and Prevention, is working collaboratively with partners in Yap - one of four states of the Federated States of Micronesia (FSM) to implement primary HPV-based screening. We evaluated the effectiveness, cost-effectiveness, and timeline for cervical cancer elimination for a future FSM cervical HPV screening program.

Methods: An extensively validated model platform ('Policy1-Cervix') was fitted to HPV prevalence and a range of cervical cancer incidence rates reported for FSM. We compared the current VIA screening with HPV screening in two scenarios: 1) cervical screening and treatment scale-up with current girls-only HPV vaccination coverage of 50%-60%; 2) cervical screening and treatments scale-up with increased girls-only HPV vaccination coverage to WHO elimination targets (90%). In consultation with field collaborators, the WHO recommended 'HPV-screen, VIA-triage-and-treat' and 'HPV-screen-and-treat' modalities were considered. Costs of screening, diagnosis and treatment were estimated from project data. HPV vaccine cost per dose was assumed at three times the Gavi-supported price.

Results: At either scenario 1 or scenario 2, HPV screening modalities were more effective, compared to VIA screening. HPV screening strategies could reduce the cancer incidence rates by ~64% (scenario 1) and by 88% (scenario 2) over 2023-2100; In both scenarios, HPV screening strategies were cost-effective (the incremental cost-effectiveness ratio (ICER)<US$1,500/life-years saved (LYS), willingness-to-pay-threshold:US$3,477). Introducing HPV screening would mean FSM reached the elimination-threshold by 2073 if the current burden of disease was at the lower-end of the feasible range in scenario 1 and by 2057-2061 (range varies depending on the burden of disease) in scenario 2.

Conclusions: Scaling up HPV screening and cancer treatment in the context of either current or higher HPV vaccination coverage rates in FSM would be effective, cost-effective and could reach elimination by 2057-2073. Elimination would not be reached with current VIA screening and treatment.

Shift 02-158 / #1264

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

FINDINGS OF A SURVEY TO INFORM THE DEVELOPMENT OF THE REGIONAL CERVICAL CANCER ELIMINATION STRATEGY IN THE EASTERN MEDITERRANEAN REGION

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Introduction: In the Eastern Mediterranean Region (EMR), despite many Member States (MS) reporting a low incidence of cervical cancer, the burden is increasing. We conducted a consultation survey to gather information on MS willingness and readiness to adopt WHO's Global Strategy to Accelerate the Elimination of Cervical Cancer.

Methods: The emailed survey was completed online in REDCap or by emailed copy between 22/3 - 22/6/2022. Contacted individuals had authority/expertise in cancer control, women's health, or immunisation as nominated by Health Ministries in each MS. Twenty of the 22 MSs nominated contacts. We collected data about elimination overall (Country Overview), HPV Immunisation, Cervical Screening and Cancer Treatment/Palliative Care.

Results: All 20 MS responded (100%). Most (80%) thought the elimination incidence target of 4 per 100,000 was appropriate for them and 70% believed it appropriate for the region. Nearly all (95%) would support a relative reduction target. Most strongly agreed that elimination should be a priority for cancer control locally. Common barriers to scale up included lack of resources or capacity and elimination not being prioritised. Three had national HPV vaccination programs, eight were considering future implementation, and nine had decided against. Main barriers identified were vaccine hesitancy (stigma and safety), cost, vaccine supply, and lack of demand. Five MSs had national screening programs (three cytology, one VIA, one co-testing), seven subnational and eight none. Cancer treatment modalities were not widely available in the public sector. Commonest barriers to treatment were women not knowing where to seek care, lack of clear referral pathways, practical barriers (geographic, cost) and lack of primary care expertise.

Conclusions: The findings directly informed the development of the regional elimination strategy. Across the EMR, there are major scale up challenges to be overcome including lack of infrastructure, universal health coverage and population awareness, vaccine hesitancy, and stigma.

Shift 02-159 / #1424

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

ELIMINATION ACTION: GUIDING THE IMPLEMENTATION OF HPV SCREENING AND FOLLOW UP

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Introduction: Implementing HPV primary screening and supporting appropriate follow-up care is critical to advancing the Action Plan for the Elimination of Cervical Cancer in Canada, 2020-2030 (Action Plan), and eliminating cervical cancer in Canada by 2040. However, evidence has shown that such a significant change in cervical cancer screening may prove to be difficult for providers and patients alike.

Methods: The Canadian Partnership Against Cancer created an Annotated HPV Screening and Follow-up Pathway (the Pathway) to support change management across Canadian jurisdictions as they implement HPV primary screening. A comprehensive review of evidence was conducted to identify specific changes required across the health system to implement HPV primary screening and appropriate follow up. Extensive partner engagement, including representatives in primary care, cytology, colposcopy, and cancer screening participants, took place to identify barriers and facilitators for each change.

Results: The Pathway presents evidence-based recommendations and considerations HPV primary screening implementation and appropriate follow-up care. Over 40 recommendations are outlined with a specific focus on change management, highlighting barriers and facilitators to support the screening and follow-up continuum (e.g., participant recruitment, HPV primary screening and self-sampling, initial and follow-up triage, and colposcopy) and enable Canadian jurisdictions to plan and deliver HPV primary screening in a way that meets the needs of those impacted by this change. The pathway also includes key insights from leading practices and resources in HPV primary screening internationally and in Canada, and specific recommendations on how to support community engagement and ensure implementation plans embed equity and cultural safety.

Conclusions: HPV primary screening is important to move Canada toward the goals of the Action Plan. However, implementation requires engagement and collaboration with key stakeholders, highlighting potential barriers and facilitators to implementation and ensuring more relevant considerations on how to manage the changes associated with HPV primary screening implementation.

Shift 02-160 / #1705

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

MAXIMIZING CANCER PREVENTION IN SAFETY-NET SETTINGS OF CARE – INTRODUCING THE FEDERAL CERVICAL CANCER COLLABORATIVE

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Introduction: Rapid evolution of cervical cancer screening technologies and changing guidelines prompted the Health Resources and Services Administration Office of Women's Health and federal partners to develop the Federal Cervical Cancer Collaborative (FCCC). This partnership aims to realize the vision of the Cancer Moonshot[SM] in safety-net settings to reduce disparities in cervical cancer and bridge the U.S. government's priorities of cancer research and health care delivery.

Methods: From September 2020-February 2021, the FCCC reviewed literature and federal grantee research for a landscape analysis on facilitators and barriers to cervical cancer screening in safety-net settings. From January-February 2022, the FCCC conducted an online multiple-choice and open-ended survey of 72.3% of National Cancer Institute-Designated Cancer Centers (n=47) to identify opportunities to strengthen collaborations with safety-net settings. From February-June 2022, the FCCC convened five roundtables, with stakeholders across the U.S. territories and freely associated states, national organizations, academia and federal agencies to inform provider technical assistance.

Results: The landscape analysis defined the extent to which select HHS-supported projects have improved the uptake of cervical cancer screening. In response to the survey, Cancer Centers reported patient-level barriers as the most challenging, compared with clinician-level, organizational-level, and systems-level barriers. The most common barriers to following-up to abnormal cancer screening included: transportation/travel time (98%), health literacy (96%), and caregiving responsibilities (95%). The roundtable series led to the development of a provider toolkit and federal opportunities report to strengthen cervical cancer prevention, screening, and management in safety-net settings of care.

Conclusions: The findings can inform public health interventions to strengthen partnership between Cancer Centers and safety-net settings through dissemination of the provider toolkit and federal opportunities report. Findings directly inform long-term FCCC commitments to support equitable cervical cancer prevention, screening, and management in safety-net settings.

Shift 02-162 / #1729

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

EXAMINING THE ASSOCIATION BETWEEN PREFERENCE AND TRUST IN DIFFERENT INFORMATION SOURCES WITH HUMAN PAPILLOMAVIRUS KNOWLEDGE AND BEHAVIORS

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Introduction: Cervical cancer rates have decreased due to prevention techniques and screening practices, but significant disparities are still present. It is important to understand the role of trust and preference in information sources. This study assesses how trust and preference in information sources impacts knowledge and behaviors in addition to demographic differences to identify health disparities.

Methods: This cross-sectional study utilizes data from the Health Information National Trends Survey 5 Cycle 2 and 4. Weighted Chi-square tests and multivariate logistic regression are used to examine the association between knowledge and behaviors in addition to demographic differences.

Results: Women who reported low trust in information from a doctor (aOR: 0.499; 95% CI: 0.252–0.989) and whose first source preference was from written materials (aOR: 0.312; 95% CI: 0.122–0.793) had lower odds of having heard of HPV. Women who reported low trust in information from charity organizations (aOR: 0.647; 95% CI: 0.461–0.909) had lower odds of believing that HPV caused cervical cancer, but women whose first choice was the internet (aOR: 1.544; 95% CI: 1.026–2.324) had higher odds. There was a significant difference among women who reported differing levels of trust in information from religious organizations/leaders with time since last pap test (p-value: 0.0012). Women in minority populations, older ages, and lower education had significantly lower levels of HPV knowledge.

Conclusions: Findings from this study add information on preferred and trusted information sources and their impacts on HPV knowledge and behaviors, which can help improve future interventions.

Shift 02-163 / #1736

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

IMPLEMENTING AMPFIRE HPV TEST AND ITS QUALITY ASSURANCE PROGRAM IN THE FRAME OF A CERVICAL CANCER ELIMINATION STRATEGY: THE BELIZE LABORATORY EXPERIENCE

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Introduction: Transitioning from cytology screening to HPV testing is recommended to improve effectiveness of screening and contribute to achieve cervical cancer elimination. The Belize Ministry of Health, supported by the Pan American Health Organization (PAHO) and UNFPA started a program to support the introduction of HPV testing as primary screening, including Quality Assurance (QA) component. Objective: To share experience in the introduction of HPV testing and its QA in Belize, focusing on the laboratory aspects.

Methods: In 2022, the Ministry of Health and Wellness from Belize decided to embark on primary HPV screening using the AmpFire HPV Screening 16/18/HR kit (Atila BioSystems). PAHO supported the Laboratory of Belize through a strategy that included the organization of a Training Workshop as part of a Comprehensive Program for the Prevention and Control of Cervical Cancer in Belize, which involved: - Preparation of laboratory manuals: HPV detection techniques and key concepts around QA of HPV testing - On-site visit of external experts: talks, sample processing, analysis of results and discussion - Participation in a HPV DNA screening proficiency study (International HPV Reference Center [HPV- RC], Sweden), for External Quality Assessment.

Results: The laboratory manuals provided an updated background to review the technical foundations and main concepts of QA to begin designing a local quality program. The expert visit gave training in the test and validated the laboratory competence; so far, more than 250 screening samples have been analyzed. Performance evaluation panel has already been processed (the HPV-RC report will be available next March).

Conclusions: Although these are the first steps, the Belizean experience is valuable and can encourage other countries to implement HPV testing and its QA, ideally when starting each HPV program. All efforts to strengthen HPV laboratories are crucial to ensure the effective implementation of HPV-based cervical screening.

Shift 02-164 / #1740

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

BREAKING NEWS: DRASTIC CHANGES IN HPV VACCINATION POLICY IN JAPAN

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Introduction: Cervical cancer incidence and mortality rates among Japanese women younger than 50 years old are increasing because of the low uptake of cervical cancer screening among young women, even though Japan is a developed country. Contrary to our promotion, the Japanese government suspended proactive recommendation of HPV vaccines in July 2013, following repeated media reports of adverse events after the vaccination. Major symptoms, such as chronic pain and motor impairment, were evaluated as “functional somatic symptoms”, and the recent investigation revealed that young girls and boys with such symptoms existed with or without HPV vaccination in Japan.

Methods: Due to the evidence of effectiveness and safety of HPV vaccines, the governmental recommendation for HPV vaccines was restarted in April 2022 after the 9-years’ suspension. I'll report on recent movements in Japan on behalf of the Japan Society of Obstetrics and Gynecology.

Results: During the 9-years’ suspension, the prevalence of HPV vaccines drastically decreased from 80% to near zero. It is reported that the target 13-year-old girl vaccination rate is still about 30% at present. At the end of 2022, the Ministry of Health, Labor and Welfare announced they would make the following bold changes to the HPV vaccine program. In the national vaccination program in Japan from April 2023, the 9-valent HPV vaccine will be implemented. Free vaccination will be provided for women aged 12 to 26 years old, and the number of target women for the free-catchup vaccination is estimated to be above 4,000,000. The details of the actual operation will be explained at the IPVC2023.

Conclusions: It will take some time for Japanese people to regain trust in HPV vaccines. It is crucial that as many women as possible benefit from HPV vaccines, and the success from the alliance of HPV-related societies will have a great impact on Japan to realize cervical cancer elimination.

Shift 02-165 / #1766

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

PRECLINICAL PERFORMANCE OF A NOVEL DRUG DELIVERY DEVICE FOR RELIABLE INTRADERMAL VACCINATION

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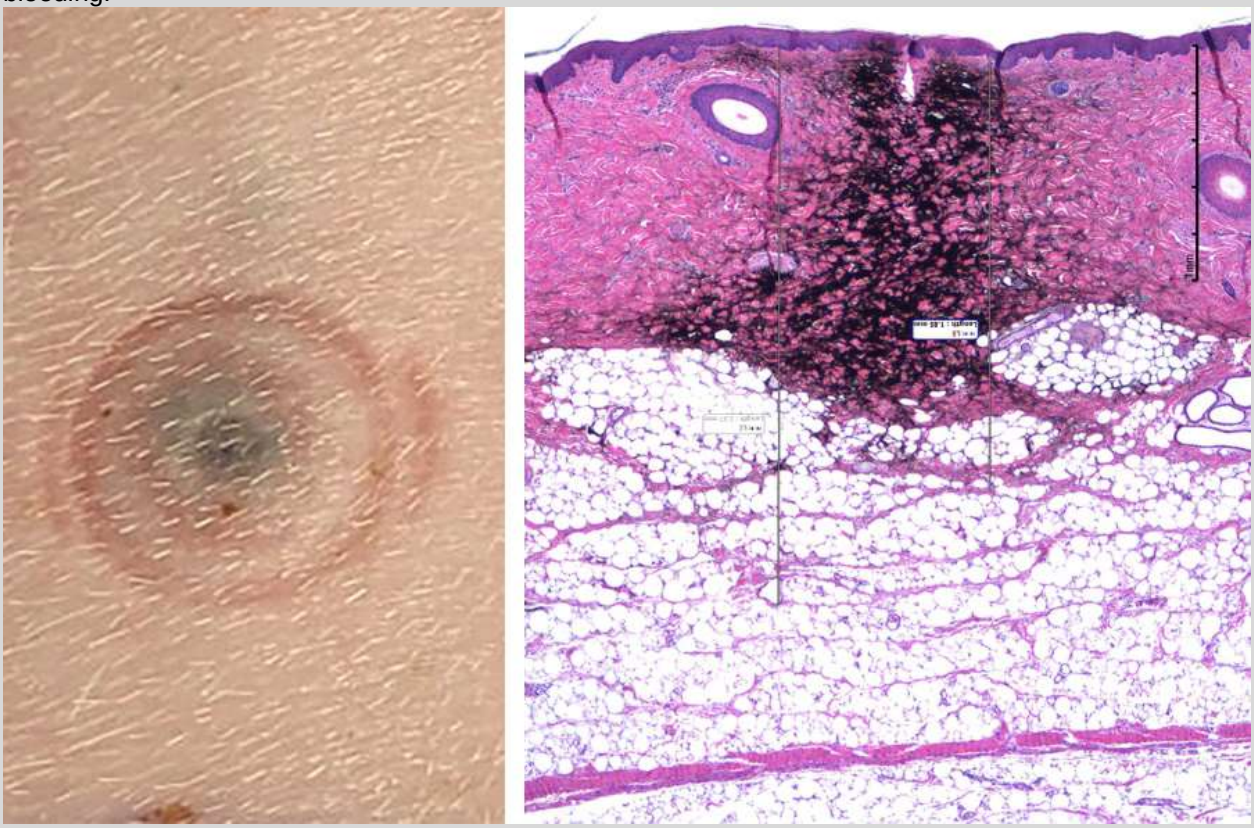
Introduction: Intradermal vaccination with a lower dose - into the rich network of antigen-presenting cells of the skin - has been shown to elicit a non-inferior immune response compared to intramuscular vaccination with a full dose. As a result, intradermal vaccination could offer a promising solution to increase vaccine availability in the fight against cervical cancer. The aim of the current study was to assess the performance of VAX-ID, a novel intradermal drug delivery device, in a preclinical setting.

Methods: Two piglets (12kg) received 19 injections using VAX-ID preconfigured with a 32G needle with a predefined penetration depth of 0.85mm. An injection dye mixture of NaCl 0.9% and Chinese ink 1:0.15 ratio was injected in triplicate in the neck, back, and abdomen. Visual inspection was performed to evaluate bleb (wheel) formation, leakage, and adverse effects. Tissue samples (n=19) were collected and stained with hematoxylin and eosin (H&E) for histological analysis. The slides were evaluated for liquid deposit and distribution in the skin and injection depth.

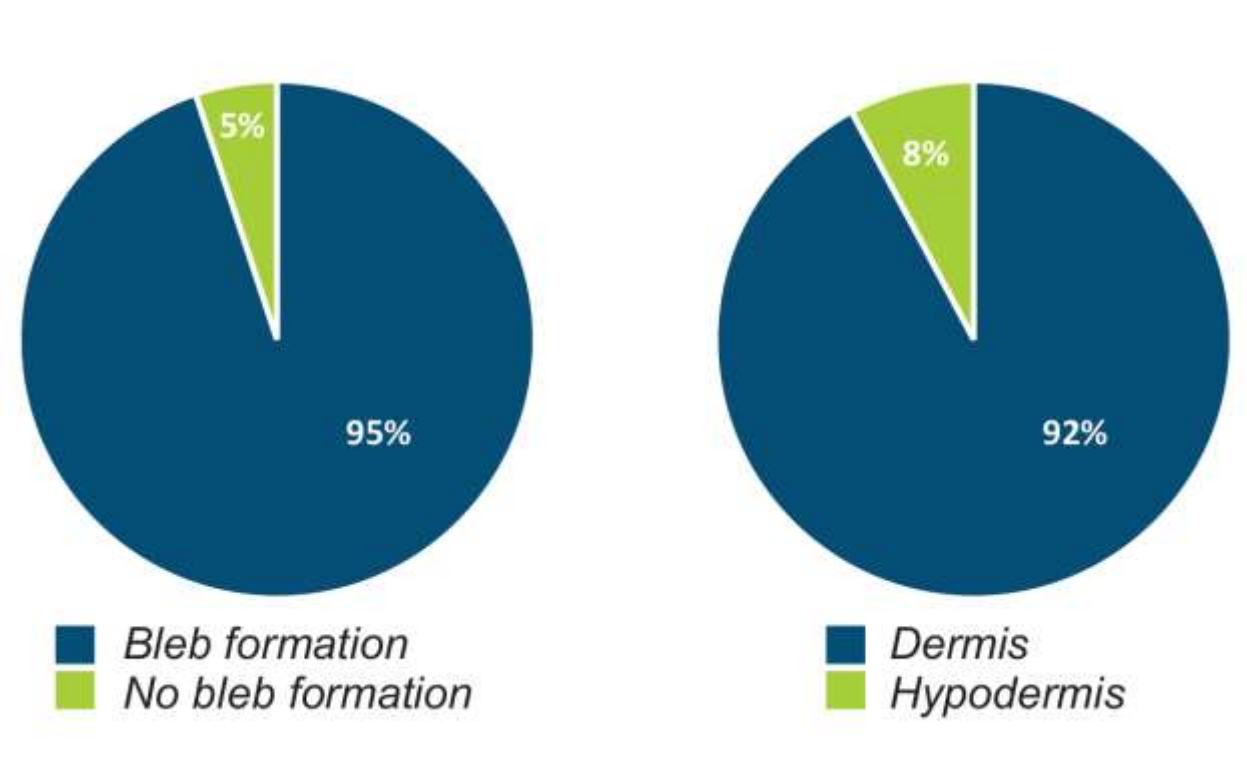
Results: Visual inspection showed bleb formation in 95% of the samples with an average bleb diameter of 0.61cm. VAX-ID injection demonstrated deposition of the dye reaching both the papillary and reticular

dermis in 92% of the samples. At the injection site transient erythema was observed. Micro bleeding was seen in only two samples and none of the samples showed macro bleeding.



Bleb formation (left) and dye deposit

(right)



Conclusions: VAX-ID preconfigured with a 32G needle was able to successfully inject the dye in the dermal layer of the skin in 12kg piglets, as confirmed by the histological evaluation. The injections induced bleb formation, a visual check of a successful intradermal injection. No serious adverse events were observed. Studies in humans will allow confirming these findings as well as assess effectiveness of prophylactic and therapeutic vaccines.

Shift 02-166 / #1063

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03H. VACCINE SAFETY
04-20-2023 7:00 AM - 4:00 PM

4- AND 9-VALENT HPV VACCINE REAL-WORLD SAFETY: FINDINGS FROM 3 STUDIES IN OVER 500,000 MALES AND FEMALES

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Introduction: A data-driven assessment of possible adverse events is a critical factor in encouraging vaccine acceptance. We conducted three observational post-marketing safety studies of the 4-valent (4v) and 9-valent (9v) HPV vaccines as commitments to regulatory agencies to describe the safety of the vaccines when administered in routine healthcare use.

Methods: For 4vHPV vaccine, one study included 189,629 females (346,972 doses administered 2006-2008), and a second study included 114,035 males (202,737 doses administered 2009-2016). For 9vHPV vaccine, males and females were included in a third study (215,965 individuals, 330,774 doses administered 2015-2017). The three studies were conducted in large-linked US insurance healthcare databases supplemented by medical records review as needed. Protocols and safety findings were reviewed by independent safety review committees. General safety was assessed by comparing rates of medically attended events occurring during post-vaccination risk and self-comparison intervals. Analyses also included new-onset autoimmune conditions, inadvertent pregnancy exposures, day of vaccination events, and death.

Results: There was no new safety signal from any of the three studies. All identified events were already included in the vaccine label. The increased conditions following vaccination most frequently recorded included skin infections/injection site reactions and allergic events on day of vaccination. No unanticipated safety signals were identified in over 500,000 males and females immunized during 11 years of vaccine safety surveillance.

Conclusions: The findings from the three large observational studies including more than 500,000 males and females who received close to 900,000 vaccine doses were consistent with HPV vaccines' safety profile seen during the25-year clinical development programs and 17 years of post-marketing safety surveillance.

Shift 02-167 / #1398

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01B. ANIMAL MODELS AND PAPILLOMAVIRUSES
04-20-2023 7:00 AM - 4:00 PM

COMPARATIVE ANALYSIS OF THE IMPACT OF INTERFERON REGULATORY FACTORS ON INTERFERON AND INTERFERON STIMULATED GENE EXPRESSION IN HUMAN AND CANINE KERATINOCYTES

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Introduction: Dogs are used to model many human diseases, and they can spontaneously develop similar viral skin disorders as their human counterparts. Research dogs with mutations causing severe combined immunodeficiency, for example, are highly susceptible to canine papillomavirus 2 (CPV2) infection, which induces cutaneous papillomas that progress to cancer. Humans with similar mutations are also highly susceptible to cutaneous papillomavirus (PV) infections. Our group has previously shown the E6 and E7 genes from CPV2 can abrogate the interferon (IFN) response in keratinocytes. Yet, while keratinocytes are key barrier cells able to mount a robust IFN antiviral response, regulation of IFNs within keratinocytes has only been minimally investigated. One of the critical factors driving IFN regulation are interferon regulator factors (IRFs). IRFs are crucial in upregulating type I or type III IFNs, which then subsequently upregulate hundreds of antiviral effector proteins called interferon stimulated genes (ISGs).

Methods: We sought to comparatively analyze how IRF1, 3 and 7 regulate type I and III IFNs and ISGs using canine and human keratinocyte cultures.

Results: We demonstrated that compared to canine keratinocytes, human keratinocytes express higher basal type I IFN-b and ISGs, induce significantly higher levels of type III IFNs upon stimulation, and overall express higher IFN and ISG copies. While both IRF3 and IRF7 are critical for type I and III induction following activation of cytosolic dsDNA and dsRNA, neither can account for differences in the induced type I versus III IFN expression between dog and human, suggesting non-IRF1, 3, or 7 mechanisms underlying this regulation.

Conclusions: These studies provide support for use of the dog as a model to discern mechanisms underlying high basal type I and ISGs in human keratinocytes, how high basal ISGs can modulate the antiviral response, and uncover non-IRF mediated mechanisms regulating the type I versus type III response in keratinocytes.

Shift 02-168 / #987

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01B. ANIMAL MODELS AND PAPILLOMAVIRUSES
04-20-2023 7:00 AM - 4:00 PM

IDENTIFICATION AND CHARACTERIZATION OF NATURAL MMUPV1 INFECTION IN AN ANIMAL FACILITY

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Introduction: Mouse papillomavirus 1 (MmuPV1) is the first known papillomavirus capable of productive infection of laboratory mice. While originally discovered as the cause of cutaneous warts on immunodeficient mice in a vivarium, MmuPV1 can also establish persistent infections in both cutaneous and mucosal tissues of immunocompetent mice, that can progress to cancer, thus enhancing its utility as a powerful tool in studying of papillomavirus-induced pathogenesis. With increasing use comes concerns about the accidental spread of MmuPV1 infection within mouse colonies, particularly given its ability as a nonenveloped virus to persist in the environment for a long time retaining infectious potential.

Methods: Using histological and molecular biology techniques we identified and characterized a widespread outbreak of natural MmuPV1 infections in an animal facility.

Results: The outbreak was initially identified as skin lesions on the muzzles and tails of Nu/Nu nude mice which were histologically consistent with papillomavirus-induced papillomas. No active MmuPV1 experiments were ongoing at the time of the outbreak. However, the facility was previously used to study an experimental strain of MmuPV1. RNA in situ hybridization (RNA-ISH) for detection of MmuPV1 E6/E7, and L1 viral transcripts and immunohistochemical staining to detect MmuPV1 L1 capsid protein confirmed active MmuPV1 gene expression and virus replication in collected papillomas. PCR amplification and whole-genome sequencing of the DNA extracted from the papillomas identified the MmuPV1 genome sequence as the MmuPV1 laboratory strain used in the facility for previous studies. PCR-based swab surveys confirmed the presence of MmuPV1 DNA in other housed mouse colonies including immunocompetent mice, as well as in environmental samples collected throughout the facility.

Conclusions: Our data indicate prolonged persistence and infectivity of MmuPV1 in an animal research environment. Given this occurrence, there is a need to establish animal care, surveillance, and environmental control standards to prevent future MmuPV1 outbreaks in animal facilities supporting MmuPV1 studies.

Shift 02-169 / #1775

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01B. ANIMAL MODELS AND PAPILLOMAVIRUSES
04-20-2023 7:00 AM - 4:00 PM

TWO NOVEL HPV16 E6/E7-DEPENDENT ORTHOTOPIC TUMOR MODELS IN MHC-HUMANIZED MICE FOR DEVELOPMENT OF THERAPEUTIC HPV16 VACCINATION AND T-CELL TARGETING STRATEGIES

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Introduction: Therapeutic vaccines against HPV16-associated malignancies that have shown promise in in-vivo experiments often failed to translate into the clinic. One reason might be the used murine tumor models, which were either located at a heterotopic site or were immunologically murine.

Methods: We established a novel HPV16 E6/E7-dependent cancer cell line from the A2.DR1 MHC-humanized mouse strain. A2.DR1 lung cells were immortalized with the HPV16 oncoproteins E6 and E7. Functionality of the HPV oncogenes was assessed by Western blot for $p16^{INK4}$, and oncogene-dependence by a senescence assay. Additionally, the cells were transfected with the oncoprotein $HRAS^{G12V}$ for tumorigenicity and firefly luciferase for intracorporeal tracking of tumor growth. MHC-presentation of HPV peptides was assessed by immunopeptidomics. Tumor cells were implanted either vaginally or stereotactically into the base of the tongue. Tumor growth was monitored by luminescence measurements and by MRI. Tumors were characterized histologically. Concurrently to tumor model establishment, ways of eliciting HPV16-specific T-cell responses in the genital mucosa were investigated.

Results: After successfully validating the expression of all introduced proteins, and showing HPV-oncogene-dependence of the new cell line by senescence induction upon E6/E7 knockdown, the new cell line was termed E6/7-lucA2. Immunopeptidomics analysis revealed the surface presentation of the well-known HLA-A2-restricted epitope E7/11-19. E6/7-luc-A2 cells were also killed by T-cells specific for this epitope. Tumors grew successfully in the female genital tract or in the base of the tongue. Histologic analysis showed immune cell infiltration. We identified promising strategies to enhance vaccination-induced HPV-specific T-cells at the mucosal target site, which will now be used to tackle established orthotopic tumors.

Conclusions: The new orthotopic tumor models reflect the correct tumor microenvironment of HPV-driven cancers and are suited to assess HPV16-specific therapeutic vaccinations and other immunotherapies, by allowing to study ways of efficient T-cell targeting to the mucosal tumor site.

Shift 02-170 / #785

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01D. REGULATION OF GENE EXPRESSION, POST-TRANSCRIPTIONAL MODIFICATION
04-20-2023 7:00 AM - 4:00 PM

MULTIPLEXED DETECTION OF HPV TRANSCRIPTS IN FFPE TISSUE USING UNAMPLIFIED ISOTACHOPHORESIS EXTRACTS ON NANOSTRING PLATFORM

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Introduction: We evaluated isotachophoresis RNA extraction (Purigen FFPE-to-RNA kit #33010) with NanoString (NS) detection to study HPV transcripts in formalin-fixed paraffin-embedded (FFPE) tissue.

Methods: Total RNA was extracted followed with DNase treatment from 24 FFPE samples (12 cervical precancers, 8 anogenital, and 4 oropharyngeal cancers), quantified with a Qubit Fluorometer and evaluated with Tape Station [RNA integrity number (RIN values) and % of fragments > 200 nt (DV200)]. NS designed CodeSets for splice-site specific E6*I and E1^E4 (E4) transcripts for 20 HPV types and human Ubiquitin C (UBC) internal control. Detection followed the manufacturer's protocol (50 ng RNA/sample) and included 3 cell lines [CaSki, SiHa and HeLa] and water as controls. NS results were evaluated for the pattern of E6*I and E4 transcripts (E6*I only, E4 only, E6*I >E4, E4 >E6*I, E6*I ~E4) as well as HPV types contributing transcripts.

Results: All samples yielded RNA, [mean 1460 ng; range 60 - 4460], but quality was poor (mean RIN 1.6; mean DV 200 18.6%). UBC transcript varied widely (1-2856 NS Counts). Transcript patterns in cell lines gave expected results based on known HPV integration status (E6*I only in SiHa and HeLa, and both E6*I and E4 in CaSki). Six samples were unsatisfactory for evaluation (UBC and HPV negative). An additional 6 were UBC positive but HPV negative. The remaining 12 were UBC and HPV positive (4 anogenital, 1 oropharyngeal, and 7 cervical). Viral transcripts from multiple types were found in 8 samples. The transcript pattern in most samples (17/18, 94%) was E4>E6*I' and E4 only.

Conclusions: While combining isotachophoresis extraction with NS detection identified HPV transcripts within FFPE tissues, RNA quality is poor and further work is needed. The transcripts identified an inverse relationship between E6*I and E1^E4 expression consistent with transcript initiation from p97 and p670 promoters and differentiation-dependent expression.

Shift 02-171 / #577

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01G. VIRUS – HOST INTERACTIONS
04-20-2023 7:00 AM - 4:00 PM

TLR POLYMORPHISMS AND HPV INFECTION IN PATIENTS WITH OVARIAN CANCER

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Introduction: Epithelial ovarian cancer (EOC) is one of the most common cancers threatening women's lives around the world. The presence of human papillomavirus (HPV) DNA in blood, as well as in cancerous ovarian and fallopian tissues was found. Toll-like receptors (TLRs) play a vital role in pathogen recognition and are important regulators of tumor biology. It was hypothesized that the presence of TLR4 and TLR9 genotypes may be associated with HPV-related EOC cases.

Methods: Four SNPs, two each in TLR4 (rs4986790 and rs4986791) and TLR9 (rs187084 and rs5743836), were analyzed in patients with EOC using polymerase chain reaction–restriction fragment length polymorphism (PCR-RFLP). Viral loads were estimated by a digital droplet PCR (ddPCR) method.

Results: No association was observed between the HPV16 and HPV18 DNAemia and studied TLR polymorphisms (P>0.05). However, HPV16 viremia was slightly lower among individuals who had a wildtype genotype for the TLR4 rs4986791 compared with those who were heterozygous or homozygous recessive for this polymorphism (P = 0.055). We found an increased frequency of heterozygous genotype and minor allele of the TLR4 rs4986790 SNP in women with EOC compared with healthy controls (P<0.0001).

Conclusions: This preliminary study revealed no association of TLR4 and TLR9 polymorphisms with HPV infection in OC patients. However, the findings suggest that the TLR4 Asp299Gly polymorphism could be a genetic risk factor for the development of EOC. This work was supported by the National Science Centre of Poland, grant No. 2019/33/B/NZ7/02872.

Shift 02-172 / #625

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01G. VIRUS – HOST INTERACTIONS
04-20-2023 7:00 AM - 4:00 PM

CHARACTERIZATION OF ONCOGENIC HUMAN PAPILLOMAVIRUS VIRAL LOAD AMONG WOMEN AT RISK OF CERVICAL INTRA-EPITHELIAL NEOPLASIA.

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Introduction: The persistence of carcinogenic Human papillomaviruses (HPV) is thought to be necessary for development of cervical intraepithelial neoplasia (CIN) and cervical cancer. We assessed whether higher viral loads of such viruses predict risk of CIN recurrence post-treatment in a cohort of 200 South African women living with HIV, aged 18-65 years who were prospectively followed up in the HATCH cohort.

Methods: Participants all presented with abnormal pap smears, had surgical excision of CIN2+ and were followed up for 2 years with cytological screening to confirm treatment outcomes. We measured the viral load for 13 types of carcinogenic HPV (relative light units normalised to 1 pg/mL positive controls [RLU/PC]) using Hybrid Capture 2 testing of cervicovaginal lavages obtained at enrolment, 6- and 12-months post-treatment.

Results: Over 90% of study participants were infected with high-risk HPV. Higher oncogenic HPV viral load was associated with increased risk of CIN recurrence ($p < 0.001$). There was a decrease in oncogenic HPV viral load overtime for participants who cleared CIN ($p < 0.001$).

Conclusions: These data reinforce the need to include high-risk HPV genotyping during cervical cancer screening and the potential role of HPV viral load quantification as prognostic tool in identifying women at highest risk of CIN3+.

Shift 02-173 / #1200

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01G. VIRUS – HOST INTERACTIONS
04-20-2023 7:00 AM - 4:00 PM

A LONGITUDINAL STUDY OF HIGH-RISK-HPV GENOMES REVEALS INTRA-HOST TEMPORAL CHANGES TO VIRAL SINGLE NUCLEOTIDE VARIANTS

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Introduction: Recent sequencing data suggests that HPV genomes can change within hosts during infections. We investigate the frequency of HPV single nucleotide variant changes over time within women with persistent infections of high-risk HPV types (HPV16/18/31/33/35/39/45/51/52/56/58/59/68) using serial samples from 367 women enrolled in the 7-year follow-up of the Guanacaste Costa Rica Natural History Study.

Methods: We HPV whole-genome sequenced a total of 1,316 high-risk HPV-positive specimens from women with persistent infections, including 2-9 serial samples (over 2-8 years) per woman. We assessed viral genetic changes and serial sample changes in variant allele fractions (VAF) across the genomes of all high-risk types per woman.

Results: There were both increases and decreases in the VAFs, or fraction of viral sequence reads within a woman with an observed variant, over time across the genomes of a total of 66.8% of the high-risk HPV persistent infections. For example, one woman with three consecutive serial samples positive for HPV33 had a non-synonymous variant in the E7 oncogene (N62T) showing a 17.4% rate increase in its VAF (46.2% to 80.9%) during her 2-year infection. Another woman positive for HPV18 with four consecutive serial samples had a variant in the upstream regulatory region that showed a 16.5% rate decrease in its VAF (70.2% to 19.4%) during her 3-year infection. Interestingly, neither woman progressed to CIN2+. Additionally, women that were HPV-positive with an intervening HPV-negative PCR test (type-specific skip-infections) showed evidence of viral latency/re-appearance: both HPV-positive samples before/after the HPV-negative test were exactly the same viral isolate (genome); and, in the instances that the PCR-negative sample was available for HPV sequencing, we detected a low-level of the same exact HPV isolate in that sample with our deep sequencing.

Conclusions: Using a large longitudinal study, we demonstrate that high-risk HPV variant genomes can change proportions over time within a woman during infection.

Shift 02-174 / #1519

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01G. VIRUS – HOST INTERACTIONS
04-20-2023 7:00 AM - 4:00 PM

HUMAN PAPILLOMAVIRUS 16 GENOMES REVEAL A MORE EXPANSIVE POPULATION STRUCTURE AND LINEAGE C ASSOCIATION WITH CERVICAL DYSPLASIA IN SUB-SAHARAN AFRICAN WOMEN

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Introduction: INTRODUCTION: Cervical cancer (CC) is a main cause of mortality among women. Infection with high-risk (HR) HPVs drives development of precursor cervical lesions that often progress to CC. Previous cross-sectional analysis of HIV-infected and uninfected Kenyan women shows frequent detection of HPV16 with lesions. HPV16 is classified into four main evolutionary-derived variant lineages A, B, C, and D, and specific variants have been associated with increased CC risk. To better understand HPV16 variation and whether HIV differentially interacts with HPV16 lineages and how this impacts CC etiology, we performed a whole-genome sequence analysis to compare HPV16 genetic relatedness and diversity between HIV-infected and uninfected Kenyan women.

Methods: METHODOLOGY: Archived HPV16 isolates from HIV-infected (N=40), and uninfected (N=21) women were collected in western Kenya. Genotyping and whole-genome sequencing were performed with Roche Linear Array and Oxford Nanopore, respectively. Variants were called with Pepper-Margin-DeepVariant. MEGA was used in phylogenetic analysis.

Results: RESULTS: A total of 344 variants were detected in these sixty-three individuals. Using tSNE, we observed two major groupings from (N=40) fully assembled genomes. Interestingly, 47.5% of samples were solely related to C sublineage, and the remaining cluster contained all other sublineages. A greater probability of detecting lineage C in HIV women (OR=3.0; p=0.040). Furthermore, lineage C was found to be associated with SNP 7387 (OR=75; p=0.000) and cervical lesions (OR= 4.4; p=0.017), while HIV was associated with SNP 7387 (OR=3.0; p=0.0001).

Conclusions: CONCLUSION: The C lineage is more expansive and the major lineage in our population, from western Kenya differs from the USA and Europe where A is predominant. The C lineage associates with known SNP confirmed to be associated with cervical lesions and cancer.

Shift 02-175 / #591

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01I. GENOMICS OF HPV-ASSOCIATED DISEASE
04-20-2023 7:00 AM - 4:00 PM

A PREVALENCE OF HUMAN PAPILLOMAVIRUS, CYTOMEGALOVIRUS AND EPSTEIN-BARR INFECTIONS IN OVARIAN CANCER PATIENTS

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Introduction: Human papillomavirus (HPV) is commonly detected in gynecological cancers, including cervical, vulvar and vaginal cancers. The role of HPV and human cytomegalovirus (HCMV) in the development of epithelial ovarian cancer (EOC) is unknown. EOCs originate from the ovarian surface epithelium and from serous tubal intraepithelial carcinomas from the fallopian tube (FT) epithelium. High-grade serous ovarian carcinoma (HGSOC) is the most aggressive and common EOC subtype. We sought to analyze the prevalence of HPV16/18, HCMV and EBV in EOC tissue and fallopian tube specimens.

Methods: Whole blood, EOC and fallopian tube tissue samples were analyzed by both qualitative and quantitative PCR, including the droplet digital PCR (ddPCR). The specific primers and probe sets for HPV16 E6 and HPV18 E7 oncogenes were used. ddPCR was used for the detection of the HCMV UL55 gene. Patients with benign tumors as a control group were included in the study.

Results: The presence of viral DNA was higher in EOC than in benign tumor cases. The detection of HPV16 and HPV18 DNA was observed in 32% and in 36% of cancerous ovarian tissues and FT samples, respectively. Co-infection HPV16/18 was detected in 10% of pathological samples. HCMV infection was found in 37% of cancerous ovarian tissues, while EBV DNA was not detected.

Conclusions: The results revealed that the presence of HPV16/18 and HCMV occur in one-third of EOC samples. This work was supported by the National Science Centre of Poland, grant No. 2019/33/B/NZ7/02872.

Shift 02-176 / #1495

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01I. GENOMICS OF HPV-ASSOCIATED DISEASE
04-20-2023 7:00 AM - 4:00 PM

THE PAPILLOMAVIRUS EPISTEME – PAVE 2.0

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Introduction: The Papillomavirus Episteme (PaVE) is a database of curated and annotated papillomavirus genome sequences, analysis tools and information (https://pave.niaid.nih.gov). PaVE was initiated by NIAID in 2008 and has been an invaluable resource. Over time, the software infrastructure became severely outdated and so PaVE was redeveloped.

Methods: PaVE 2.0 has a redesigned interface, updated infrastructure, and improved tools. The underlying libraries and hosting platform have been upgraded and rebuilt. Open-source GoCD pipelines for CI/CD (continuous integration and deployment) of applications and data (now in S3 cloud storage) have been developed. PaVE 2.0 is hosted on an on-demand virtual server using NIAID's Monarch tech stack and Amazon Web Services. The framework is now Python Flask with a JavaScript/JINJA template front end, and the database switched from MySQL to Neo4j. A Swagger API performs database queries, and executes jobs for BLAST, MAFFT, and the L1 typing tool. All tools such as BLAST, L1 typing tool, Locus Viewer, phylogenetic tree generation and viewer, multiple sequence alignment (MSA), and protein structure viewer have been enhanced. A Celery stack supports longer running tasks and MSA uses MAFFT instead of CLUSTAL. The structure viewer switched from Jmol to Mol*, the new embeddable PDB viewer.

Results: PaVE2.0 is a major infrastructure update. PaVE currently contains 665 papillomavirus genomes 7361 genes/regions, 5397 protein sequences, and 77 protein structures. Users can explore, download, and analyze sequences and visualize transcripts on linear and circular genomes. Genomes are now available in GFF3 format. Evolutionary relationships can be analyzed using MSA and phylogenetic trees and virions explored in the 3D Viewer. Protein structures can be analyzed and compared using the protein structure viewer. The image library contains 170 gross clinical and histopathological images.

Conclusions: PaVE 2.0 has a redesigned interface, updated infrastructure, and improved analytical tools that allows NIAID to continue to provide this essential resource.

Shift 02-177 / #1021

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01J. PAPILLOMAVIRUS VACCINES (I.E NEW DEVELOPMENTS)
04-20-2023 7:00 AM - 4:00 PM

HUMAN PAPILLOMAVIRUS (HPV) SINGLE TYPE-SPECIFIC MONOCLONAL ANTIBODIES DERIVED FROM B CELLS ISOLATED FROM HPV VACCINE RECIPIENTS

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Introduction: There is a strong demand for standardization of human papillomavirus (HPV) serology across laboratories, especially those participating in vaccine efficacy testing. We aim to generate and characterize monoclonal antibodies with single specificity to HPV types 16, 18, 6, 11, 31, 33, 45, 52 and 58, from B cells/plasmablasts from nonavalent (9vHPV) HPV vaccine recipients, which could potentially be used as serology standards.

Methods: Whole blood was collected from recipients who received 9vHPV vaccine (Gardasil-9). PBMCs were separated and HPV specific B cells isolated and singly sorted using flow cytometry. Variable regions from heavy and light chains were cloned and expressed as full-length IgG and the resulting monoclonal Abs (mAbs) were screened for specificity towards L1 antigen of HPV types 6, 11, 16, 18, 31, 33, 45, 52 or 58 using GST fusion protein based Luminex assay. Neutralizing activity of mAbs 16, 18, 31 and 45 is being determined using pseudo virion-based neutralization assay.

Results: Ten mAbs were found to bind HPV L1 antigens tested. 3 mAbs bound to multiple HPV types and hence were removed from further analysis. Out of the remaining 7 antibodies, one antibody each showed binding capacity to L1 antigens of HPV types 6, 11, 16, 18, 31, 45 and 52 with median florescence intensity (MFI) of 11676, 6317, 10870, 7404, 4292, 3241 and 3511 respectively. Neutralizing activity of HPV 16, 18, 31 and 45 specific mAbs to the corresponding HPV types was confirmed with the titres yet to be determined.

Conclusions: The antibodies cloned and expressed from singly sorted B cells produced monoclonal antibodies that bound to L1 antigens of HPV types 6, 11, 16, 18, 31, 45 and 52 and could be potential candidates to be used as standards for serological experiments. We are currently screening for antibodies with specificity towards HPV 31 at 58.

Shift 02-178 / #1066

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01J. PAPILLOMAVIRUS VACCINES (I.E NEW DEVELOPMENTS)
04-20-2023 7:00 AM - 4:00 PM

LIPOPLEXES FOR THE SILENCING OF THE HPV16 E6 ONCOPROTEIN

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Introduction: HR-HPV 16 and 18 are associated with the development of CC, due to the E6 and E7 oncoproteins. The treatments used in CC are highly invasive, cytotoxic and with low bioviability. In recent years, the therapy based on nucleic acids has had a great impact as an alternative therapy for cancer, and the use of siRNAs (small interfering RNA) has been a promising alternative due to its function to induces gene silencing by targeting complementary mRNA for degradation. However, due to its easy degradation in in vivo systems, delivery systems (liposomes) have been developed, these systems allow easy binding and protection of siRNAs (lipoplexes), improving delivery to the tumor site.

Methods: Lipoplexes were prepared using DOTA, DOPE and Cholesterol, by the lipid layer rehydration method. The Quant-iT™ RiboGreen® RNA assay was used to quantify the amount of uncomplexed siRNA. An MTT (Roche®) assay was performed to evaluate the viability in SiHa cell treated with lipoplexes.

Results: Lipoplexes had a size between 95.93 ± 5.89 (mean + standard deviation) and 94.66 ± 6.87 nm, respectively and presented a Z potential from a range of 45.9 ± 4.33 to 50.03 ± 3.33 mV. The percentage of coupling of the siRNA to the liposomes was greater than 70%. The liposomes were able to protect the siRNA from degradation by RNases. In the in vitro model, approximately 45% decreases of cell growth were observed after 24 hours of treatment with Lipoplexes.

Conclusions: Lipoplexes had excellent physical-chemical characteristics and shown to significantly decrease cell proliferation in SiHa, which are important characteristic to be proposed as good, targeted delivery system.

Shift 02-183 / #1221

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01K. BETA AND GAMMA CUTANEOUS HPV INFECTION, BIOLOGY, AND NATURAL HISTORY
04-20-2023 7:00 AM - 4:00 PM

BETAPAPILLOMAVIRUSES IN SQUAMOUS VULVAR INTRAEPITHELIAL LESIONS

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Introduction: Precursors of vulvar squamous cell carcinoma (SCC) are grouped as human a-papillomavirus (HPV)-associated (known as high-grade squamous intraepithelial lesion, HSIL or vulvar intraepithelial neoplasia, VIN) and HPV-independent (differentiated VIN, dVIN). However, a third category of atypical verruciform lesions (AVL) with features that do not neatly fit into either category has recently been described. β HPV is a known risk factor for SCC in the skin but has rarely been identified in the vulva. We hypothesized that β HPV may be associated with AVL.

Methods: We subjected 26 vulvar precursor lesions adjacent to SCC to HPV genotyping (Luminex-based assays), p16 and p53 immunohistochemistry, targeted gene expression analysis (nCounter, Nanostring), and consensus morphology review.

Results: Based on consensus review, 14 lesions (53.8%) were $p16^+$ and categorized as HSIL (n=14); 12 (46.2%) were $p16^-$ and designated as dVIN (n=3) or AVL (n=9). Overall, 11 patients (42.3%) had detectable β HPV DNA, 3 (11.5%) as single genus infections and eight (30.8%) as mixed β and α . Most patients with AVL lesions (7/9, 78%) had detectable β HPV DNA without integrated α HPV, when co-infected. In AVL lesions lacking a integrated HPV, differental gene expression analysis revealed higher immune cell infiltration (T, NK, B cells).

Conclusions: We identified β HPV infections in 11 precursor lesions (42.3%), most in $p16^-$ AVL and as co-infections with high-risk α HPV in HSIL. Lesions harboring β HPV show increased infiltration of T cells, NK cells, and B cells compared to those with α HPV. This is, to our knowledge, the first report of the association between $p16^-$ lesions with atypical verruciform morphology and β HPV in vulvar SCC precursors.

Shift 02-184 / #1214

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01L. MICROBIOME
04-20-2023 7:00 AM - 4:00 PM

MICROBES ASSOCIATE WITH INFLAMMATION IN THE CERVIX OF HISPANICS LIVING IN PUERTO RICO

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Introduction: The incidence of cervical cancer in Hispanic women living in Puerto Rico is higher than those of women in the US. It is the fourth most frequent cancer in women and its etiologic agent, Human Papilloma Virus (HPV), is the most common sexually transmitted disease. However, research focused on understanding the role of microbial communities in the progression of pre-cancerous lesions to cancer in Latino women is scarce. Therefore, we aimed to investigate the relationship between the cervicovaginal microbiome and inflammation while considering cervical neoplasia and HPV infection in women living in Puerto Rico.

Methods: We collected cervical swabs and lavages from 91 participants coming to colposcopy clinics in San Juan, Puerto Rico (IRB #1050114). Genomic DNA was extracted from swabs, and 16S rDNA V4 region genes were amplified and sequenced by Illumina MiSeq. Inflammatory (IL-1β, TNFa, IFNg, IL-6), anti-inflammatory (IL-4, IL-10, TGFβ1), and trafficking (IL-8, MIP1a, MCP1, IP10) cytokines were measured from cervical lavages, using Luminex MAGPIX technology. Cytokines were related to microbes via an inflammation scoring index based on the quartile and tercile distribution of the cytokine's concentration.

Results: We found significant differences in the diversity and composition of the microbiota according to HPV risk, cervical disease, and cytokine abundance. The most dominant community state types (CST) were III and IV featuring high diversity and anaerobic bacteria. Increasing IL1-β, IL-10, and IFN-γ were associated with decreased Lactobacillus communities. Bacteria associated with dysbioses, such as Gardnerella, Prevotella, and Atopobium, increased with pro-inflammatory cytokines.

Conclusions: Our study highlights that the cervical microbiota of Caribbean women is diverse and volatile, with a decrease in Lactobacillus promoting inflammatory processes likely associated with disease progression. The joint host-microbe interaction analyses via cytokine signaling and microbiota in the pre-cancerous lesion are confirmed to have great translational potential.

Shift 02-185 / #1509

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01L. MICROBIOME
04-20-2023 7:00 AM - 4:00 PM

CHARACTERIZATION OF CERVICAL MICROBIOTA COMPOSITION AND ASSOCIATION WITH IMMUNE GENES EXPRESSION

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Introduction: HPV infection is the main cause of cervical cancer, the fourth most prevalent in women worldwide. PRRs expressed by epithelial cells, can induce proinflammatory cytokines production through NF-κB and type I Interferon pathways. Differential expression of PRRs and cytokines have been described in cervical cells and may play an important role in HPV infection. It has been shown that microbiota and PRRs expression impact in gut homeostasis, however their effect in vaginal mucosa is poorly understood. Vaginal microbiome can be classified into community state types (CST): I, II, III, IV and V, dominated by Lactobacillus crispatus, L. gasseri, L. iners, anaerobic bacteria and L. jensenii, respectively. Healthy vaginal environment shows low bacterial variety (CST I, II and V), while high diversity and anaerobic dominance is known as bacterial vaginosis. In the present study we characterize cervical bacteriome of HPV infected (n=11) and non-infected (n=11) women followed at Instituto de Ginecologia (UFRJ), Brazil and correlate these findings with immune genes expression.

Methods: Genomic DNA and mRNA from cervical samples were isolated. Bacteriome was determined by amplification and high-throughput sequencing of 16S rRNA. Expression of 15 genes involved in PRRs pathways were evaluated by qRT-PCR.

Results: Four distinct CSTs were identified: CST I (n=3), CST III (n=11), CST IV (n=6) and CST V (n=1). Here we classified women in three groups, Lactobacillus no-iners (grouping CST I and V), L. iners (CST III) and Anaerobic (CST IV). Samples with L. no-iners dominated mucosa expressed higher levels of TLR3 and IFNαR2 than L. iners dominated. Previous studies showed that increased TLR3 expression during HPV infection have been associated with HPV16 clearance and correlated with IFNα2 levels.

Conclusions: Our results corroborate with the association of TLR3 expression and a healthy mucosal environment (HPV- and L. no-iners). However, the interplay between these microbiome and host components needs further investigation.

Shift 02-186 / #1350

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01M. OTHER BASIC RESEARCH
04-20-2023 7:00 AM - 4:00 PM

ALTERED LC3B SUGGESTS DYSREGULATED AUTOPHAGY IN RECURRENT RESPIRATORY PAPILLOMATOSIS, A POSSIBLE REASON FOR FAILURE TO SECRETE IL-36GAMMA.

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Introduction: A hallmark of recurrent respiratory papillomatosis (RRP)[BMS1] is uncontrolled papillary growth of HPV-infected keratinocytes of the upper airway epithelium without evidence of inflammation. Autophagy is dysregulated in many cancers and contributes to non-classical protein secretion of leaderless proteins. Compared to normal larynx, cultured papilloma tissues overexpress but fail to secrete the proinflammatory cytokine Interleukin-36γ. A causal link between altered autophagosome dynamics and suppressed IL-36γ release in RRP remains unknown. IL-36γ is induced and released from healthy keratinocytes when exposed to TLR3 agonist poly(I:C) and TLR5 agonist flagellin. We used that system to study the role of autophagy in IL-36γ secretion.

Methods: LC3b in papilloma biopsies and cultured human foreskin keratinocytes (HFKs) was measured by western blot. Autophagosome abundance was measured by a fluorescent autophagy assay. Secreted IL-36γ was assessed by ELISA.

Results: Overexpression of IL-36γ was confirmed in papillomas, compared to near undetectable levels observed in normal adjacent epithelium. LC3b-II/β-actin ratios showed an approximate 50% reduction in papillomas compared to normal adjacent tissues (p=0.012) suggesting perturbed autophagic flux. Treatment of HFKs with poly(I:C), but not flagellin, promoted LC3b-I conversion to LC3b-II between 8 and 24-hours of stimulation compared to untreated controls (p=0.043). Additionally, poly(I:C)-treated HFKs showed a 2-fold increase in fluorescently labeled autophagosome abundance at 8 hours (p=0.032) and a 4-fold increase at 24 hours[BMS1] , with no change by flagellin treatment. Finally, inhibiting autophagosome turnover and breakdown by bafilomycin A1 led to an approximate 70% increase in IL36γ secretion during poly(I:C) stimulation (p=0.044) while bafilomycin A1 had no effect on flagellin-mediated release.

Conclusions: Respiratory papillomas clearly display altered LC3b patterns that are consistent with dysregulated autophagic flux. IL-36γ-inducing molecules; poly(I:C) and flagellin have divergent effects on autophagy in HFKs. Modulating autophagy affects IL-36γ secretion, providing evidence that its release may be linked to the autophagosome.

Shift 02-187 / #1504

Poster Viewing
POSTER VIEWING - SHIFT 02: BASIC SCIENCE-01M. OTHER BASIC RESEARCH
04-20-2023 7:00 AM - 4:00 PM

CHARACTERIZATION OF HPV16 GENETIC VARIANTS IN WOMEN FROM SOUTHEAST BRAZIL

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Introduction: Persistent infection by high-risk HPV types in the cervix is the main risk factor for intraepithelial lesions and cervical cancer development. Among them, HPV16 is the most prevalent and the distribution of its intratype variant lineages and sublineages are heterogeneous worldwide. HPV16 variants can be found in different cytology and some lineages and mutations are associated with a higher risk for intraepithelial neoplasias and cervical cancer. Therefore, assessing the distribution of HPV16 variants is essential to understand cervical cancer risk and guide prevention and screening approaches. The aim of this study is to characterize the HPV16 intratype variants present in cervical samples from women from Minas Gerais, Southeast Brazil.

Methods: Cervical samples were collected from patients recruited during routine medical screening at the Family Health Strategy Program of Juiz de Fora, Minas Gerais, Brazil, between 2010 and 2012. DNA from HPV16 positives samples were extracted and subjected to amplification of regions E6 and LCR. PCR products were purified and sequenced by Sanger. Sequences were aligned to HPV16 reference and classified following the SNPs described by Cornet I et al. (2012).

Results: Twenty-one samples positives for HPV16 were analyzed so far. The most prevalent HPV16 variant found was the A1/2 (90,5%), and the remaining two samples were classified as D1 and D2 each. Non-A HPV16 lineages have a higher risk for intraepithelial neoplasias and cervical cancer. Two viruses carried both T350G and G145T mutations, while only one of these mutations was found in six and one viruses, respectively. These mutations are associated with HPV carcinogenesis.

Conclusions: A low prevalence of intratype variants with high risk to cervical cancer development was observed. However, mutations associated with carcinogenesis were found in 43% of the samples. These study is in progress and contribute to evaluate the risk of cervical cancer in Southeast Brazil.

Shift 02-188 / #483

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-20-2023 7:00 AM - 4:00 PM

INTRODUCING HPV SELF-SAMPLING TO CERVICAL CANCER SCREENING IN ESTONIA: FROM FEASIBILITY STUDY TO IMPLEMENTATION

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Introduction: Cervical cancer incidence and mortality rates in Estonia are one of the highest in Europe. Participation in organised cervical cancer screening is low. In 2020 and 2021, the effect of HPV self-sampling on screening participation was checked in two randomised studies.

Methods: First, a randomised feasibility study was conducted in 2020 among long-term non-attenders in cervical cancer screening. From them, 12,000 women were randomly allocated to three equal-sized study groups. Women in the opt-out group received a self-sampling device and a questionnaire by ordinary mail, women in two opt-in groups with different sampling devices a web-link to order the self-sampler and questionnaire. Secondly, a randomised pilot study was carried out in 2021. A random sample of 26,000 having not participated in the organised screening after the first invitation was randomly allocated to one opt-in and one opt-out group of equal size. They were offered either routine testing at the clinic or HPV self-sampling in the reminder. The 32,000 women who received an ordinary reminder formed the control group.

Results: Overall participation in the feasibility study in 2020 was 16% with a significant difference between the opt-out (26%) and two opt-in (11%) groups. There was no difference in the participation rate between two opt-in groups with different self-sampling devices. The user experience and willingness to use self-sampling in the future were similar in all three groups, 88% stated that they preferred self-sampling in the future. The results of the randomised pilot study conducted in 2021 within organised screening showed a 10% overall increase in participation (6% in the opt-in and 14% in the opt-out group).

Conclusions: Studies showed feasibility and high acceptance of HPV self-sampling. In 2022, the possibility to order a self-sampler or to give a test at the clinic will be offered in the screening reminder to everyone.

Shift 02-189 / #795

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-20-2023 7:00 AM - 4:00 PM

DEMOCRATIZATION OF HPV SELF-SAMPLING: A NEW HIGH-THROUGHPUT WORKFLOW ON THE BD COR™ SYSTEM

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Introduction: The BD COR™ System is a unique high-throughput fully integrated pre-analytic and analytic system for molecular diagnostic testing and has obtained CE Marking for cervical cancer screening using self-collected Copan FLOQSwabs™ using a manual intervention step. Self-collected specimens are non-inferior to physician collected samples and have a proven ability to reach women who do not attend screening. The global COVID-19 pandemic has led to deferred testing and vaccination, significantly increasing the number of underserved women. Self-collection offers a means to close this gap and reduce the burden of cervical disease, but to date, has lacked a high-throughput solution for large-scale implementation.

Methods: Standard validation methods were used to establish a new workflow on the BD COR System with a custom assay definition file (ADF) for dry-collected swab specimens.

Results: Samples are self-collected using Copan FLOQSwabs, broken at the score mark and the swab head placed directly into an empty barcoded BD HPV sample tube, sealed with a reclosing silicone septum cap. The dry samples are stable at ambient temperature and can be mailed to the laboratory. The samples are placed in racks and loaded directly onto the BD COR™ System. The system identifies and uncaps each tube individually, fills it with HPV diluent and replaces the cap. Specimens then cycle through the automated extraction and real-time PCR detection modules and extended HPV genotyping results are automatically uploaded to the laboratory information system (LIS). A single BD COR™ System can process up to 1,050 tests in a 24-hour period (~273,000 tests per year) .

Conclusions: The new BD COR System workflow requires no user intervention and represents the first true “load and go” workflow for self-collected vaginal specimens. This streamlined workflow can help enable national self-collection deployment, reduce program costs while increasing both disease detection and the number of women screened.

Shift 02-190 / #815

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-20-2023 7:00 AM - 4:00 PM

PRIMARY CARE PROVIDER AND STAFF VIEWS ON IMPLEMENTING HPV SELF-SAMPLING IN CLINIC TO ADDRESS CERVICAL CANCER SCREENING DISPARITIES AMONG SOMALI WOMEN IN THE UNITED STATES

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Introduction: Somali women living in the U.S. experience persistently low cervical cancer screening rates due to a complex mix of barriers. An HPV self-sampling option in primary care clinics could increase screening by positioning providers to address barriers related to modesty and enabling opportunistic screening in more clinical encounters. We conducted interviews with primary care providers and staff to inform intervention materials and implementation strategies for an effectiveness-implementation study of primary care-based HPV self-sampling for Somali women.

Methods: We recruited 30 primary care providers and staff from two clinics in Minneapolis, Minnesota that serve large Somali patient populations. Guided by the Consolidated Framework for Implementation Research, semi-structured interviews explored views on offering HPV self-sampling to Somali patients, and anticipated needs or barriers to implementing this approach into the clinic setting and clinical encounter.

Results: Providers and staff anticipate positive patient reactions to the option of HPV self-sampling, although some voiced concern about patients perceiving HPV self-sampling as a less effective option and worry about the lack of a physical exam. HPV self-sampling was mostly viewed favorably as a modality to help increase screening and was seen as straightforward to integrate into existing clinic workflows. Providers largely lacked awareness of the evidence supporting HPV primary testing and the accuracy of HPV self-sampling for cervical cancer screening and thought clinic-wide staff and patient education would be needed.

Conclusions: HPV self-sampling in clinic was viewed favorably, particularly as a means to reach underscreened populations, and considered easy to implement into current workflows. Clinic-wide education on the current evidence on HPV primary testing and HPV self-sampling will be essential to support implementation.

Shift 02-191 / #1284

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-20-2023 7:00 AM - 4:00 PM

COMPARISON OF ALLPLEX™ HPV HR DETECTION AND COBAS® 4800 HPV TEST IN PAIRED PHYSICIAN (THINPREP ® LIQUID-BASED CYTOLOGY) AND SELF-COLLECTED (EVALYN BRUSH) VAGINOCERVICAL SPECIMENS

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Introduction: Human Papillomavirus (HPV)-based screening is replacing cytology-based one and this also facilitates the introduction of self-collected samples for cervical cancer screening. Here, we compared the HPV testing results obtained with the new Allplex™ HPV HR assay (Seegene) with two validated tests, Anyplex™ II HPV HR (Seegene) and COBAS® 4800 HPV (Roche), in a set of paired physician and self-collected vagino-cervical specimens.

Methods: A total of 286 paired specimens (143 self-collected vaginal specimens using the Evalyn brush and 143 Thinprep® liquid-based cytology specimens) were analyzed with COBAS® 4800 HPV, Anyplex™ II HPV HR and Allplex™ HPV HR Detection. Allplex™ HPV HR Detection is a real time PCR-assay (1h and 43 min) which amplifies specific targets for HPV detection and individual genotyping of 14 HR-HPV types. Additionally, it provides an individual Ct value for each target.

Results: The overall percent agreement (OPA), the positive percent agreement (PPA) and the negative percent agreement (NPA) of Allplex™ HPV HR with COBAS® 4800 HPV, using Thinprep® specimens, was 96.5%, 88.9% and 100%, respectively (Table 1). For the detection of HPV16, HPV18 or other HR-HPV OPA was 98.6%, 100% and 95.1%, respectively (Table 2). For self-collected samples, OPA, PPA and NPA were 95.8%, 100% and 95.8%, respectively (Table 3 and Table 4). The analysis of the comparison between Allplex™ and Anyplex™ HPV HR Detection is ongoing and will be presented at IPVC23
conference

Table 1. Comparison between Allplex™ HR HPV (Seegene) and Cobas® HPV test (Roche) in physician-collected Thinprep® cytology specimens

Thinprep® HR-HPV types		Cobas® HPV			PPA	NPA
		Positive	Negative	Total		
Allplex™ HR HPV	Positive	40	0	40	88,9%	100%
	Negative	5	98	103		
	Total	45	98	143		

OPA: overall percent agreement; PPA: the positive percent agreement; NPA: negative percent agreement.

Table 2. Overall percent agreement (OPA) and Kappa analysis in physician-collected Thinprep® cytology specimens

	LBC Thinprep® (Allplex™ HPV HR vs Cobas® HPV)			
	OPA	95% CI	Kappa	95% CI
Total HR-HPV	96.5% (138/143)	92.03% to 98.86%	0,92	0.85 to 0.988
HPV16	98.6% (141/143)	95.04% to 99.83%	0,87	0.69 to 1
HPV18	100% (143/143)	97.5% to 100%	1	1.000 to 1
Other HR HPV	95.1% (136/143)	90.2% to 98.01%	0,88	0.79 to 0.97

OPA: overall percent agreement; PPA: the positive percent agreement; NPA: negative percent agreement.

Table 3. Comparison between Allplex™ HPV HR (Seegene) and Cobas® HPV test (Roche) in self-collected dry samples using Evalyng brush device and diluted in Thinprep®.

Self-collected samples HR-HPV types		Cobas® HPV			PPA	NPA
		Positive	Negative	Total		
Allplex™ HR HPV	Positive	39	0	39	86,7%	100%
	Negative	6	98	104		
	Total	45	98	143		

OPA: overall percent agreement; PPA: the positive percent agreement; NPA: negative percent agreement.

Table 4. Overall percent agreement (OPA) and Kappa analysis in physician-collected self-collected samples

	Self-collected samples (Allplex™ HPV HR vs Cobas® HPV)			
	OPA	95% CI	Kappa	95% CI
Total HR-HPV	95.8% (137/143)	91.1% to 98.4%	0,89	0.82 to 0.98
HPV16	97.9% (140/143)	94% to 99.6%	0,81	0.61 to 1
HPV18	100% (143/143)	97.5% to 100%	1	1 to 1
Other HPV	95.1% (136/143)	90.2% to 98.01%	0,88	0.79 to 0.97

OPA: overall percent agreement; PPA: the positive percent agreement; NPA: negative percent agreement.

Conclusions: Allplex™ HPV HR assay showed a good analytical performance for detecting and genotyping the HR-HPV types when is compared with COBAS® 4800 HPV assay. However, further studies using the international HPV guidelines defined by Meijer and VALGENT consortium are needed to confirm the clinical validation of the Allplex™ HPV HR Detection and to evaluate the clinical impact of the Ct value obtained for each individual target.

Shift 02-192 / #1305

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02A. SELF-SAMPLING AND THE OTHER NEW TECHNOLOGIES FOR CERVICAL SCREENING
04-20-2023 7:00 AM - 4:00 PM

COPAN UNIVERSE PERMITS AUTOMATED PREPARATION OF VAGINAL SELF-COLLECTED SWABS FOR HPV MOLECULAR TESTING

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Introduction: UniVerse™ (Copan) is a fully automated pre-analytical system dedicated to preparation of specimens for molecular testing; tube vortexing, uncapping, recapping, managing of sample traceability and liquid transfer to secondary containers are the instrument's core activities. Recently UniVerse™ has been equipped with a liquid dispenser to automatically rehydrate vaginal self-collected swabs to permit downstream Human Papilloma Virus (HPV) molecular testing. This study demonstrates the equivalence of UniVerse™ with manual elution of HPV from dry swabs and, highlights the utility of UniVerse™ for automated pre-analytical process to support high volume population-level HPV screening programs.

Methods: PROCEEDx™ FLOQ® swabs (Microbix Biosystem) containing HPV 16 were used to simulate self-collected vaginal swab specimens for this experimental challenge. 20 PROCEEDx™ FLOQ® swabs were hydrated by UniVerse in 5ml of MSwab medium (Copan) and in parallel, 20 swabs were manually eluted and vortexed for 30 seconds in equivalent volume. Aliquots of specimen eluted in MSwab medium were analyzed using a molecular assay for the qualitative detection of HPV 16. Results were compared using the two one-sided test (TOST) to verify their equivalence (±2 Ct). Both methods allowed detection of HPV 16 with no significant difference in Ct values.

Results:

Method	N	Mean HPV 16 Ct	Standard deviation	Reproducibility of use of PROCEEDx™ FLOQ® HPV 16 Swab Positive Sample (CV%)
UniVerse	20	34.73	1.27	3.67%
Manual	20	34.56	0.95	2.75%
ΔCt	0.17 (95% C.I. -0.54÷0.89)			

Conclusions: This study provides the proof of concept data for accurate detection of HPV with self-sampled vaginal swabs collected dry and subsequently eluted on the UniVerse and, demonstrates the equivalence between UniVerse and manual workflow. This ongoing study will integrate findings from a broader panel of contrived specimens representing self-collected swabs with vaginal matrix and HPV to investigate the potential use of dry transported swabs for HPV screening programs.

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Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-20-2023 7:00 AM - 4:00 PM

PREVALENCE OF HIGH-RISK HUMAN PAPILLOMAVIRUS INFECTIONS DETECTED IN HISPANIC WOMEN LIVING IN PR WITH CIN 2/3 LESIONS BY VACCINATION STATUS AND VACCINE SEROTOYPE COVERAGE

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Introduction: Cervical cancer disparities in Puerto Rico (PR) are represented in an incidence rate of 2.4% mean annual percent change from 2001-2017. Persistent infection with High-Risk Human Papillomavirus (HPV-HR) is the main cause of cervical cancer. There is limited data about HPV genotypes in association with CIN2/3 cases in PR. We aim to describe a sample of CIN2/3 in biopsy samples in patients by age, number of sexual partners, pregnancy status, HPV vaccine and HR-HPV serotypes.

Methods: We performed secondary frequency analysis on data from protocol “Meta-Omic approaches to Study Microbiome Dynamics for Cervical Cancer Prevention (#10510114)”. Sixty patients with CIN2/3 were identified and genomic DNA extracted using QIAGEN’s power soil kit. HPV DNA was genotyped using SPF10/LiPA25 (DDL Diagnostic Laboratory, Rijswijk, the Netherlands) characterizing 25 HPV types, including 14 high-risk types.

Results: Demographics are presented in Table 1. Overall HPV HR frequency is 97%. HPV16 is the most common genotype (33%), both with single (15%) and co-infection with other HR genotypes (11%) followed by HPV 52 and 51 (14%) and (13%) identified similarly in single or multiple infections. Only 11.7% of patients with CIN2/3 were vaccinated. Unvaccinated patients with CIN2/3, had greater prevalence of HPV 16 and of HPV 16 with OHR Type. 26% of patients had HPV types uncovered by the

vaccine.

Table 1. Description of study demographic characteristics such as age and HPV Vaccination Status, Pregnancy, Number of Sexual Partners and Body Mass Index.

Sociodemograhic Charasteristic	
Age	**Frequency**
21-30	28 (47%)
31-40	20 (33%)
41-50	9 (15%)
51-60	3 (5%)
Pregnancy	**Frequency**
No	43 (72%)
Yes	17 (28%)
Sexual Partners	**Frequency**
0-2	11 (18%)
3-4	20 (33.3%)
5-9	18 (30%)
≥10	3 (5%)
Doesn't know	2 (3.3%)
Abstained	6 (10%)
BMI	**Frequency**
Underweight	2 (3.3%)
Normal Weight	17 (28.3%)
Overweight	19 (32%)
Class I Obesity	14 (23%)
Class II Obesity	6 (10%)
Class III Obesity	2 (3.3%)
HPV Vaccination Status	**Frequency**
Vaccinated	7 (11.7%)
Unvaccinated	42 (70%)
Does not know	11 (18.3%)

Conclusions: ASCCP guidelines recommend colposcopy if HPV 16/18 are identified regardless of NILM result. If HPV is OHR, management is co-testing in one year. In our sample of CIN2/3, 52% of patients had HPV OHR. Delaying immediate colposcopy in a population affected by increasing incidence of

cervical cancer requires further study. Detection of HPV 51 among the most common types, not covered with vaccination, suggests different HPV epidemiology than other countries. Although a small sample size, prevalence of OHR types affecting this population merits further study.

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Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-20-2023 7:00 AM - 4:00 PM

DIVERSITY OF CERVICOVAGINAL HUMAN PAPILLOMAVIRUS GENOTYPES AMONG A CONTEMPORARY SERIES OF CERVICAL CANCER CASES AND HPV-16/18/45 VARIANTS IN SOME SELECTED INDIVIDUALS IN GHANA

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Introduction: The disease associated burden of some HPV genotypes and genotype-specific variants in cervical cancer (CxCa) cases can be population dependent. AIM: To determine the diversity of cervicovaginal HPV genotypes and HPV-16/18/45 variants in a contemporary clinical cohort of Ghanaian women referred for disease assessment.

Methods: A cross-sectional study among patients attending two teaching hospitals in Ghana with suspicion of CxCa and confirmed CxCa/precancer cases. Cervical swabs were collected during routine medical examination with age/pathology. HPV-testing was performed using Optiplex(L1 testing)-genotyping. Furthermore E6/E7-PCR, sequencing and BLAST analysis was carried out on a convenience sample (HPV-16+/HPV-18+/HPV-45+).

Results: 207 samples from consented individuals were collected and HPV tested, including 155/207 CxCas (139xSCC/13xADC/3xCxCa-unconfirmed morphology). 135/155(87.1%) of CxCas were HPV+; 91/135(67.4%) and 44/135(32.6%) harboured one HPV type(1HPV) and more than one HPV type(>1HPV) respectively. HPV-16(55/135,40.7%); HPV-18(36/135,26.7%) and HPV-45(21/135,15.6%) were the three dominant types among CxCas(1HPV/>1HPV). Additionally, the overall cohort, irrespective of histology documented, included 172/207 HPV+ samples: HPV-16(41.86%,72/172), HPV-18(23.25%,40/172) and HPV-45(16.28%,28/172). A convenience sample of 36 HPV 16+ samples, 26 HPV-18 samples and 10 HPV-45+ samples were sequenced to gain insight into prevalent sublineages in this cohort. Of which 32/36(88.89%) were HPV-16-lineage-B/C including 21/36 sublineage-C1 harbouring E6-SNPs-T109C/G132T/A403G together with E7-SNP-647G(N29S). Additionally, 24/26(92.31%) were HPV-18-lineage-B/C including 22/26 lineage-B (10/22 were with E7-SNP-C665T). For HPV-45, 9/10(90.0%) were of sublineage-A1.

Conclusions: Our study confirms the dominance of HPV-16/18/45 with high occurrence of single HPV-16 infection among CxCas in Ghana using L1-based-genotyping. This study demonstrated the feasibility of sampling of cervicovaginal swabs alongside routine medical follow up of women with suspected high grade lesions in an LMIC setting. Additionally, our study provides the first data in Ghana on naturally occurring E6/E7 SNPs of HPV-16/18/45; we hope these data will serve as a baseline for future

assessment and modelling of the impact of prophylactic/therapeutic vaccines and putative antivirals against HPV-16/18/45.

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Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-20-2023 7:00 AM - 4:00 PM

THE EFFECT OF HIGH-RISK HPV E6/E7 MRNA ON THE EFFICACY OF TOPICAL PHOTODYNAMIC THERAPY WITH 5-AMINOLEVULINIC ACID FOR CERVICAL HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESION

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Introduction: E6 and E7 high-risk human papillomavirus (HR-HPV) oncoproteins are closely associated with the initiation and progression of cervical cancer (CC) and pre-cancerous lesions. Cervical high-grade squamous intraepithelial lesions (HSIL), as pre-cancerous lesions, have a 5% chance of progressing to invasive cancer. Topical 5-aminolevulinic acid photodynamic therapy (ALA-PDT) is a novel non-invasive targeted therapy for intraepithelial lesions. Herein, we analyzed the effect of HR-HPV E6/E7 mRNA on ALA-PDT for cervical HSIL.

Methods: A retrospective analysis of 256 HR-HPV-positive patients diagnosed with cervical HSIL and receiving ALA-PDT was carried out. ALA-PDT was performed with 20% ALA thermosensitive gel, and irradiation at wavelength of 635 nm and density of 80–100 J/cm2 for 20–30 min. The therapeutic instruments of LED and semiconductor laser were applied for cervical lesions and lesions in endocervical canal, respectively. All patients were tested for HPV E6/E7 mRNA before and after PDT, and then followed up at 3, 6, and 12 months after treatment, and every six months thereafter.

Results: At the 6-month follow up, the complete remission (CR) rate of patients' lesions was 85.5% (219/256), whereas the total HPV clearance rate was 70.7% (181/256). It was evident that positive E6/E7 mRNA before treatment had a significant effect on HPV clearance rate (66.2% VS 77.8%, P = 0.048) and CR rate (79.6% VS 94.9%, P = 0.001). The E6/E7 mRNA associated with HPV16/18 and HPV16/18 combined with other HR-HPV (HPV16/18 and other HR-HPV) affected HPV clearance (P = 0.001) and lesions CR (P = 0.037), respectively.

Conclusions: This study has shown that ALA-PDT is an effective, safe, and alternative treatment for cervical HSIL, especially for the patients of childbearing age. However, its efficacy is relatively poor in patients with persistently positive E6/E7 mRNA before and after treatment, who are relatively insensitive to ALA-PDT.

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Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-20-2023 7:00 AM - 4:00 PM

DEVELOPMENT OF ON-CHIP P16 INK4A/KI-67 DOUBLE IMMUNOSTAINING CERVICAL CYTOLOGY SYSTEM USING MICROFLUIDIC DEVICE TECHNOLOGY

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Introduction: p16/Ki-67 double-stained cytology is considered high clinical significance and is expected to be a triage method for high-risk HPV-positive women. p16/Ki-67 double staining can reduce the number of unnecessary tests. However, p16/Ki-67 double-staining cytology requires advanced diagnostic skills to be acquired by specialized cytotechnicians. In this study, we aim to develop an automated on-chip immunostaining method using a microfluidic device.

Methods: This study used a microfluidic device called electroactive microwell array (EMA), patterned thin-film electrodes at the bottom of each microwell for single-cell capture by dielectrophoresis (DEP). Immunostaining was performed on diagnosed cytology samples stored on a liquid basis and examined by double staining for p16/Ki-67 with the EMA device. We measured the number of p16/Ki-67 double-stained cells captured by the EMA device. The proportion of double-stained positive cells from cervical intraepithelial neoplasia (CIN) lesions was then examined.

Results: We examined three samples from cervical carcinoma in situ (CIS), ten samples from CIN3, and five samples from CIN2. A total of 5,000 positive cells were counted using an automated cell counting program (BZ-X800, KEYENCE). The percentage of double-positive cells was 7.2% for CIN2, 17.5% for CIN3, and 32.1% for CIS. All experiments were repeated three times. The positive staining for p16/Ki-67 in the population significantly increased with the severity of the cervical lesions.

Conclusions: The p16/Ki67 double immunostaining using the EMA device is as sensitive as the conventional method in confirming the histopathological diagnosis without losing valuable cervical samples and allows quantified parallel analysis at the individual cell level.

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Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-20-2023 7:00 AM - 4:00 PM

EFFICACY OF PROPHYLACTIC HPV16, 18-VACCINE ON THE PREVALENCE OF HPV INFECTIONS AND SQUAMOUS INTRAEPITHELIAL LESIONS (SILS) IN JAPAN (JHERS 2020.)

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Introduction: Many Japanese girls received a prophylactic HPV 16- or 18- type vaccine between 2009 and 2013. To elucidate vaccination effectiveness, the prevalence of HPVs and SILs was compared between vaccinated and unvaccinated subjects.

Methods: From April 2020–Aug 2022, cervical HPV genotyping and Pap tests were performed in subjects aged 16–39 years who had visited 10 out-patient clinics in seven districts and agreed to participate in the study. HPV-vaccination status was obtained from the patients' records. The prevalence of HPVs and SILs in the present study (vaccinated group; JHERS-2020) was compared with that in the same age groups in a previous study (unvaccinated group; JHERS-2011). Statistical analyses (Fisher's exact test) were performed using JMP-14.

Results: Of 987 subjects aged 16–39 years, 704 presented for cervical cancer screening, and 283 for colposcopy examination/other gynecological problems (excluding cancer). The vaccinated and unvaccinated groups contained 210 and 735 women, respectively. In total, 401 subjects were positive for high-risk HPV types, including 30 with HPV16 and 20 with HPV18. Among the vaccinated subjects, a Pap test revealed that one was infected with HPV16 and NILM; no subject had HPV18. The prevalence of HPV types 16 and 18 was significantly lower in vaccinated than in non-vaccinated subjects ($P<0.001$). LSIL and HSIL were identified in 28 and 12 subjects, respectively; there were no HSIL cases among the vaccinated subjects. Comparison of subjects aged 20–29 years between the vaccinated and unvaccinated groups revealed that the former had a significantly lower incidence of HPV16 ($P < 0.0001$) and HPV18 ($P < 0.0263$) infections, and LSIL development ($P < 0.0263$), but there was no difference in HSIL development.

Conclusions: HPV type 16 and 18 vaccination apparently inhibited HPV infections and significantly reduced LSIL development, which has convinced many Japanese girls to be vaccinated.

Shift 02-199 / #1442

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-20-2023 7:00 AM - 4:00 PM

DNA METHYLATION AT SPECIFIC CPG SITES OF EPB41L3, HTERT, AND FAM19A4 GENES IS USEFUL FOR THE DETECTION OF CERVICAL HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS (HSIL)

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Introduction: Host DNA methylation markers are a promising option for the detection of HSIL in HPV+ women. However, limited information is available on the performance of methylation at specific CpG-sites. We assessed DNA methylation at specific CpG-sites of the EPB41L3, hTERT, and FAM19A4 genes as triage tools for predicting HSIL in self-collected and clinician-collected paired samples in Papua New Guinea (PNG).

Methods: Women participating in an HPV 'self-collect test and treat' cervical screening trial in PNG were included in the study. In total, 44 paired high-risk HPV (hrHPV+) samples, based on LBC/p16-Ki67 (4 cancers, 19 HSIL, 4 LSIL, 17 normal) were analyzed. DNA methylation at specific CpG-sites of EPB41L3 (1-6 CpG-sites), hTERT (1-10 CpG-sites), and FAM19A4 (1-5 CpG-sites) was assessed through pyrosequencing. Area under the curve (AUC) was used to assess the performance of DNA methylation for detection of HSIL or cancer (HSIL+).

Results: In clinician-collected samples, methylation of EPB41L3 (1-6 CpG-sites) was significantly higher in HSIL vs normal/LSIL samples ($p<0.01$), and cancer vs normal/LSIL ($p<0.05$). Methylation at sites 4 and 5 of EPB41L3 were the strongest predictors of HSIL (AUC >0.83), with site 4 showing the strongest predictive value for cancer (0.925). The strongest predictor of HSIL in self-collected samples was methylation of FAM19A4 site 5 (0.67), and the strongest predictors of cancer were CpG sites 1 and 3 (0.77). The combination of EPB41L3 sites 2/4 showed the best performance for HSIL+ [sensitivity of 95.5% (95% CI 77.2-99.9) and a specificity of 60% (95% CI 36.1-88.9)] in clinician-collected samples and FAM19A4 CpG site 5 was the best marker [sensitivity of 73.9% (95% CI 51.6-89.8) and specificity of 57.1% (95% CI 34.0-78.2)] in self-collected samples.

Conclusions: Analysis of DNA methylation at specific CpG-sites of the EPB41L3 and FAM19A4 genes could be useful as a triage test for hrHPV+ screening in clinician and self-collected samples.

Shift 02-200 / #1677

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-20-2023 7:00 AM - 4:00 PM

EFFICACY OF HIGH-RISK PAPILLOMAVIRUS GENOTYPING COMPARED TO THE PAP-TEST FOR CERVICAL CANCER SCREENING

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Introduction: Cervical cancer is a public health problem worldwide, especially in emerging countries like Brazil. This neoplasm is the 4th cause of death in Brazilian women, where the screening program is based on the conventional Pap-Test. Global guidelines indicate high-risk oncogenic papillomavirus (HR_HPV) genotyping is the best tool to screening and evaluate the disease. The identification of DNA HR_HPV in women without any clinical manifestation can prevent the development of the disease early. The aim of this study was to compare the efficacy of the molecular genotyping test for HR_HPV between the liquid-based cytology (LBC) in cervical samples analyzed at the Research Center – INSDIE Laboratory - São Paulo - BRAZIL.

Methods: Analysis of 1986 cervical samples results were evaluated. The samples were collected by cervical brushing and preserved in liquid medium (Kolplast™) and analyzed at the Inside research center. Molecular samples were tested using the qPCR method (Anyplex ™ HPV 28 – Seegene™) to identify 19 HR_HPV and 9 LR_HPV. Cytological samples were automatically processed in the KPL 2000 equipment and subjected to Papanicolaou staining. The analysis was performed by optical microscopy and the results classified by the Bethesda 2014 System.

Results: From the 1986 results analyzed and compared, 398 (20.04%) genotyped samples were positive for HPV, 312 (16.21%) samples positive for HR_HPV. HPV 16 (15.14%), HPV 68 (6.41%), HPV 54 (6.15%) and HPV 53 (5.99%) were the most prevalent types. Cytological analysis showed 6.1% of cytological changes, 85 (4.3%) samples classified as LSIL, 25 (1.3%) samples classified as ASC-US, 8 (0.4%) samples classified as ASC -H and 4 (0.2%) samples classified as HSIL.

Conclusions: The study showed the superior efficacy of HR_HPV genotyping over Pap-Test for cervical cancer screening and prevention.

Shift 02-201 / #1689

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
04-20-2023 7:00 AM - 4:00 PM

HPV INFECTION IN MALE AND FEMALE PARTNERS

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Introduction: HPV still remains quite a conundrum with regard its potential ability to cause precancerous and malignant transformation in every individual case. Global estimates of HPV-related morbidity rate and well-known balance of probability don't enable care-givers with reliable leverage in early recognition of HPV-related lesions with high malignant potential when screening testing either has low sensitivity/specificity or is unable to cover everybody of targeted population with proper regularity. Chronic hypertrophic laryngitis (CHL) affects mostly male population as well as leukoplakia. Both are considered as precancerous lesions, but the link with HPV-infection isn't so irrefutable as for cervical squamous intraepithelial lesion. Our study scrutinized association of CHL in males with cervical lesions in their female partners.

Methods: The study had accrued 117 men with newly recognized CHL and then involved their female partners. Both were checked for local HPV infection (oropharengeal for both, genital in women). Female also underwent colposcopy liquid-base cytology (LBC), biopsy of required.

Results: It turned out that 53.8% males with CHL were HPV+, 99.15% were smokers either current or in the past. Their female partners were users of COC in 9.40%, smokers in 58.12%, but only 1.70% showed findings consistent with CHL, 19.66% were oropharengeal HPV+ though. 47.86% women neglected regular gynaecologic visits, 50.43% were newly recognized genital HPV+ (the same strain like in a man or a combination), 36.75% - LSIL, 8.55% - HSIL, 1.70% - cervix AIS, 0.85% - vulvar intraepithelial lesion. All women with cervical lesions were tested positive for bacterial vaginosis (BV).

Conclusions: Female partners of oropharengeal HPV-positive men with CHL are prone for persistent cervix HPV infection but mostly free from clinical evidence of overt oropharengeal HPV-related lesion even despite smoking. BV is associated with risk of persistent hrHPV infection and progression to HSIL.

Shift 02-202 / #1764

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
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DIAGNOSTIC PERFORMANCE OF HPV E6/E7 MRNA VERSUS ONCOGENIC HPV DNA AS A SECONDARY TRIAGE TEST IN VIA BASED PRIMARY CERVICAL CANCER SCREENING PROGRAM.

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Introduction: High sensitivity but low specificity of primary cervical cancer screening tests results in excess referrals as well as increased cost of unnecessary investigations and treatment on the health system. Thus for a program to be cost effective, its important to identify and treat only those lesions that will develop into invasive cervical cancer. The study was designed to identify a highly specific test to triage excess false positives from primary cervical screening programs with Visual Inspection with 5% Acetic acid [VIA].

Methods: Women in the age group of 25-65 years were screened with the primary screening test VIA between 2013 to 2018. VIA test positive women were further offered secondary screening tests viz Hybrid Capture-II (HC-II) and HPV E6/E7 mRNA test. The reference standard for final disease status was Histopathology.

Results: The sensitivity and specificity of HPV DNA testing was 77.94 (95% CI: 66.24-87.10), 91.57 (95% CI: 89.68-93.22) and that of HPV E6/E7 mRNA test was 60.29 (95% CI: 47.70-71.97), 93.05 (95% CI: 91.22-94.59) respectively. The False positive rate of HPV DNA was 8.98 (95% CI: 7.23 - 11.00) and that of HPV E6/E7 mRNA was 6.95 (95% CI:7.23 -11.00).

Conclusions: The E6/E7 mRNA test is more specific but less sensitive with a very low false positivity rate than HPV DNA test. Detection of HPV oncogene activity through the detection of E6/E7 mRNA may therefore be a better indicator of HPV infection associated with increased risk of progression to neoplasia than mere detection of HPV DNA. Detection of mRNA will help treat only those lesions with oncogenic activity and therefore reduce the number of women that would be subjected to unnecessary and expensive diagnostic follow-up.

Shift 02-203 / #1776

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02B. HPV DIAGNOSTICS & BIOMARKERS FOR EARLY DETECTION AND MANAGEMENT OF CERVICAL CANCERS AND RELATED PRECURSORS
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A PRECISION DNA METHYLATION TEST IDENTIFIES CANDIDATE BIOMARKERS FOR TRIAGE AND CLINICAL MANAGEMENT OF HPV AND SARS-COV-2 CO-INFECTED PATIENTS IN CERVICAL CANCER PREVENTION CLINICS

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Introduction: Two competing hypotheses surmise how SARS-CoV-2 may impact premalignant progression of cervical epithelium from Low Squamous Intraepithelial Lesions (LSIL) to Cervical Intraepitelial Neoplasia (CIN) grades 1-3: 1) SARS-CoV-2 could directly infect cervical epithelium resulting in adverse effects and disease progression; 2) COVID-19 indirectly impacts cervical dysplasia due to an exhausted immune system. Consequently, immune pressure on cervical tissue under SARS-CoV-2-infection is reduced enabling rapid progression of cervical dysplasia. We have previously shown that the CervicalMethDx test can provide a CIN grade 2-3 risk score, by assessing promoter DNA methylation by quantitative Real Time Methylation Specific PCR (qMSP) in a panel of three human genes (ZNF516, FKBP6 and INTS1).

Methods: We hypothesized that there would be a correlation between biomarkers of premalignant lesions and the presence of SARS-CoV-2 nucleic acids in cervical epithelium cells from Human Papilloma Virus positive (HPV+) women. We tested the correlation between the CervicalMethDx test and the TaqPath COVID-19 Combo Kit (ThermoFisher) on discarded HPV+ cervical epithelium liquid cytology samples (n=696) collected from clinical laboratories in Puerto Rico, from June 4 to August 31, 2020. The TaqPath COVID-19 Combo kit is designed to coamplify sections of three SARS-CoV-2 viral genes: Nucleocapsid (N), Open Reading Frame 1ab (ORF1ab), and Spike (S).

Results: We found N gene amplification in 5% of the samples (CT range: 32.4 - 35.8). We found a significant inverse pairwise correlation between ZNF516 methylation and N amplification (-0.45; p=0.016) and a marginally significant correlation between FKBP6 methylation and N amplification (-0.36; p=0.061).

Conclusions: Our data suggests a link between promoter DNA methylation of genes associated with CIN grade 2-3 risk and SARS-CoV-2 viral nucleic acids in cervical epithelium cells. DNA methylation biomarkers, combined with clinical, cellular, and genetic factors, could be useful for triage and clinical management of HPV and SARS-CoV-2 co-infected patients in cervical cancer prevention clinics.

Shift 02-208 / #662

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02C. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED ANOGENITAL CANCERS OTHER THAN CERVIX: PENILE, VAGINAL, VULVAR AND UROLOGICAL CANCER AND RELATED PRECURSORS
04-20-2023 7:00 AM - 4:00 PM

HPV-ASSOCIATED CANCERS – LOOKING BEYOND THE CERVIX: EXPERIENCES FROM A ZIMBABWEAN COHORT OF PEOPLE LIVING WITH HIV

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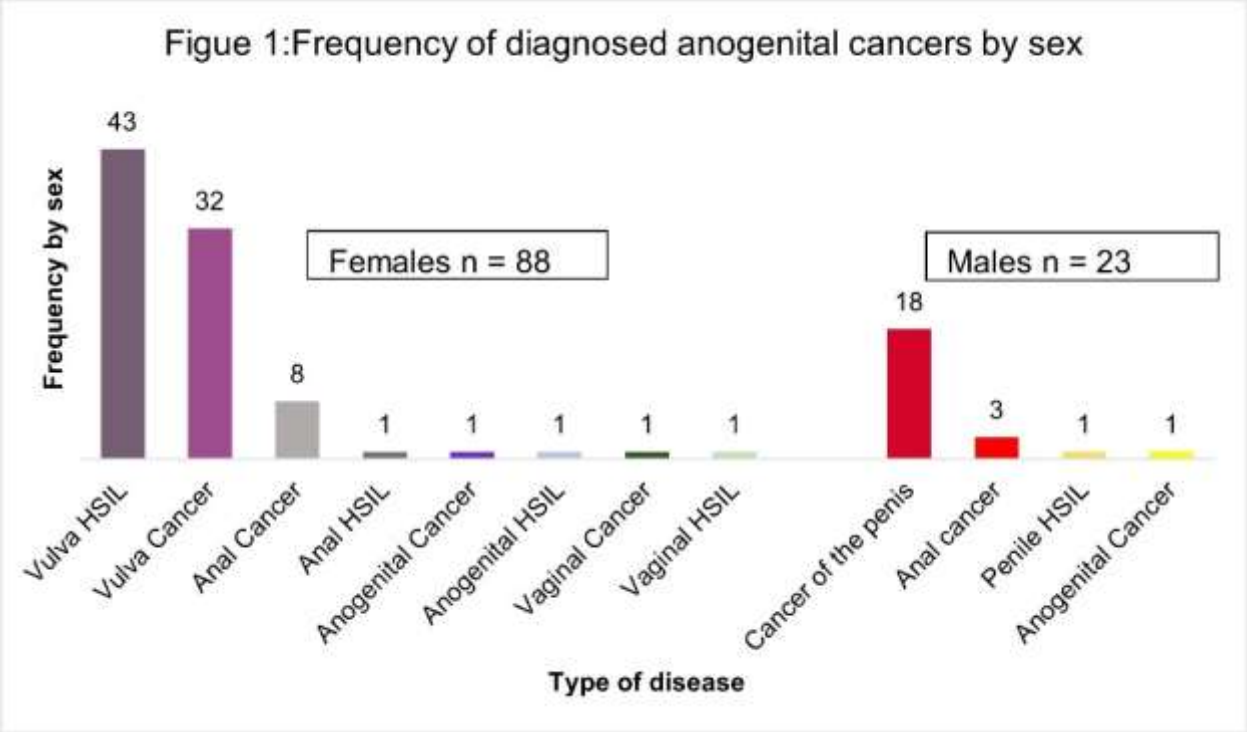
Introduction: The dual epidemics of HIV and human papillomavirus (HPV) in Sub-Saharan Africa have resulted in a high prevalence of HPV-associated disease. Women living with HIV (WLHIV) and HPV are at increased risk of cervical cancer (CC), and the spotlight on HPV-associated disease has focused on cervical disease. There is limited data in people living with HIV (PLHIV) presenting with HPV-associated disease at other anogenital sites. We present data from an African cohort of PLHIV with HPV-associated anogenital pre-cancer and cancer (AGD) with a background cohort prevalence of high-risk HPV of 53% in women attending CC screening.

Methods: A retrospective review of the case notes of 111 patients with a histological diagnosis of non-cervical anogenital high grade squamous intraepithelial neoplasia (HSIL) and squamous cell cancer (SCC) was conducted between January 2018 and July 2022. Routinely collected demographic data and HIV disease parameters were abstracted from the patient electronic medical records. Key summary statistics are presented.

Results: Of the 111 patients included in the analysis, 88 were female and 23 male. Mean age at diagnosis of AGD was 46 and 50 years for females and males respectively. Median CD4 count was 442 and 67% of patients had an undetectable HIV viral load (≤ 50copies/ml). Of the 88 females, 75 (85.2%) had vulvar disease, 43 with HSIL and 32 with SCC. 9 (10.2%) had anal disease, 1 with HSIL and 8 with SCC. 2 (2.3%) had vaginal disease, 1 with HSIL and 1 SCC. 2 women had multisite AGD. In the male cohort, 18 (78.3%) had penile SCC, 1 penile HSIL. 3 (16.7%) had anal cancer and 1 had multisite

AGD.



Conclusions: These data highlight the emerging challenge of HPV-associated AGD in PLHIV, despite adequate HIV disease control. Cervical disease remains the greatest concern, but other AGD cannot be ignored, and men must not be forgotten.

Shift 02-210 / #1283

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02C. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED ANOGENITAL CANCERS OTHER THAN CERVIX: PENILE, VAGINAL, VULVAR AND UROLOGICAL CANCER AND RELATED PRECURSORS
04-20-2023 7:00 AM - 4:00 PM

PREFERENTIAL TISSUE SITES OF DIFFERENT CANCER -RISK GROUPS OF HUMAN PAPILLOMAVIRUSES

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Introduction: One factor for determining oncogenic potential of human papillomavirus might be tissue tropism of each HPV type. It has been known that cervical cancer and its precursor lesions develop in the squamo-columar junction of the cervices, and most such lesions are induced with high-risk (HR) HPV types. This suggests that HR types preferentially infect to the cervix, whereas preferential infection site for low-risk (LR) types is not well defined. There is uncertainty of the way to determine HPV tropism, when we use cytology samples, since it is difficulty to avoid contamination of cell samples between the cervix and the vagina.

Methods: We carefully collect cell samples by independently scraping the cervix and vagina, and determined HPV types. We could define preferential location of each HPV type if it were positive only in either site of the cervix or the vagina.

Results: This method revealed that all LR types were identified only in vaginal samples, whereas 87% of HR types were in cervical ones. This suggests that LR types preferentially infect to the vagina, whereas HR types to the cervix.

Conclusions: These findings suggest that preferential tissue tropism of certain HPV type is likely to be one factor for malignant progression.

Shift 02-211 / #1749

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02C. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED ANOGENITAL CANCERS OTHER THAN CERVIX: PENILE, VAGINAL, VULVAR AND UROLOGICAL CANCER AND RELATED PRECURSORS
04-20-2023 7:00 AM - 4:00 PM

TREATMENT OF VULVAR HIGH -GRADE SQUAMOUS INTRAEPITHELIAL NEOPLASIA WITH IMIQUIMOD: HUMAN PAPILLOMAVIRUS DETERMINATION AND RECURRENCE.

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Introduction: Vulvar high-grade squamous intraepithelial lesion (vulvar HSIL) is a premalignant condition. Imiquimod is a topical drug with low morbidity. We aimed to assess the long-term response to imiquimod and to analyze the role of HR-HPV (high-risk human papillomavirus) pre/ post- treatment in the recurrence of vulvar HSIL.

Methods: Retrospective study between 2011 and 2022. Setting: gynecology department. University Hospital. Population: 20 women with vulvar HSIL treated with imiquimod. The inclusion criteria were vulvar HSIL, vulvar HR-HPV determination by pre- and post-treatment biopsy, at least one follow-up and 4 weeks of treatment. Main outcome measures: Histological diagnosis of vulvar HSIL with pre/ post-imiquimod HPV determination. Response to treatment (complete, (CR) partial (PR), no response (NR), recurrence.

Results: After imiquimod, 10 (50%), 6 (30%) and 4 cases (20%) had CR, PR or NR, respectively. Before treatment, 19 (95%) cases were HR-HPV+ (16, HPV16). After treatment, 10 cases (50%) were HR-HPV+ (8 HPV16): 2 cases (20%) with a CR, 5 (83.3%) PR and 3 (75%) with NR. 8/10 HR-HPV- cases (80%) post-treatment showed a CR. HPV16 was present in 84.2% pre-and in 80% cases post-treatment. The 2 HIV and 3 immunosuppressed patients showed a PR, and were HR-HPV+ pre- and post-treatment (100%). Response to imiquimod was associated with post-treatment HR-HPV+ (P = 0.03). Recurrence was observed in 7 patients (35%) (10% with a CR; 66.6%, PR, and 50% with a NR). 57% of the recurrences were HIV or immunosuppressed. 85% of the recurrences were HR-HPV+ post-treatment (all HPV16). compared to 30.7% of the non-recurrences (P = 0.05)(50% HPV 16).

Conclusions: Imiquimod is an effective treatment for vulvar HSIL. Cases with a CR show less HR-HPV+ post-treatment than PR or NR cases. Recurrences are more frequent in PR or NR than in CR. In recurrent cases, 85% were HR-HPV+ post-treatment, while it was 30.7% in non-recurrent cases..

Shift 02-212 / #939

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02D. BEHAVIOURAL SCIENCE ASPECTS OF NEW TECHNOLOGIES IN CERVICAL SCREENING INCLUDING DISSEMINATION/COMMUNICATION RESEARCH
04-20-2023 7:00 AM - 4:00 PM

TOWARDS SELF-SAMPLING AND RAPID HPV TESTING FOR CERVICAL CANCER SCREENING: A MIXED-METHODS ANALYSIS OF INDIANA CLINICIANS' WILLINGNESS TO ADOPT

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Introduction: Cervical cancer screening rates in the United States have declined with notable disparities across race/ethnicity and insurance status. The inclusion of primary HPV testing without cytology in 2018 clinical guidelines now enables screening innovations, such as patient-collected samples and rapid HPV testing, which may address existing barriers to screening and increase coverage of marginalized populations.

Methods: An online cross-sectional survey of clinicians who perform cervical cancer screening in Indiana (n=224), followed by in-depth interviews with a subset of respondents (n=20), were conducted in 2021. This mixed-methods study examined clinician awareness, perceived benefit, and willingness to adopt primary HPV testing, patient self-sampling, and rapid HPV testing (both at the point-of-care and as a patient self-test) for cervical cancer screening.

Results: Only 3% of clinicians reported using primary HPV testing for screening-eligible patients, 54% responded correctly to a knowledge question on the effectiveness of primary HPV testing, and only 50% were willing to adopt it as the preferred cervical cancer screening method for asymptomatic average-risk women ages 30-65. Regarding self-sampling, 72% of clinicians believed it would improve cervical cancer screening coverage, but only 50% were willing to adopt it. Most clinicians (82%) were willing to adopt point-of-care HPV testing as their primary screening method; however far less (48%) were willing to adopt rapid HPV testing as a patient self-test. Interviews revealed knowledge gaps regarding primary HPV testing effectiveness, and concerns about patient-collected samples including accuracy and missing out on other preventive care.

Conclusions: Despite guidelines and evidence on the effectiveness of primary HPV testing, almost no Indiana clinicians have adopted this screening method, and only half expressed willingness to adopt it. Although most clinicians believe self-sampling and rapid HPV testing would improve cervical cancer screening coverage, this study revealed key concerns and knowledge gaps that must be addressed to facilitate adoption.

Shift 02-213 / #1472

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02D. BEHAVIOURAL SCIENCE ASPECTS OF NEW TECHNOLOGIES IN CERVICAL SCREENING INCLUDING DISSEMINATION/COMMUNICATION RESEARCH
04-20-2023 7:00 AM - 4:00 PM

CROSS-CULTURAL ADAPTATION OF SCALES MEASURING STIGMA RELATED TO HPV, HIV, AND CERVICAL CANCER STIGMA FOR USE IN A KENYAN CONTEXT

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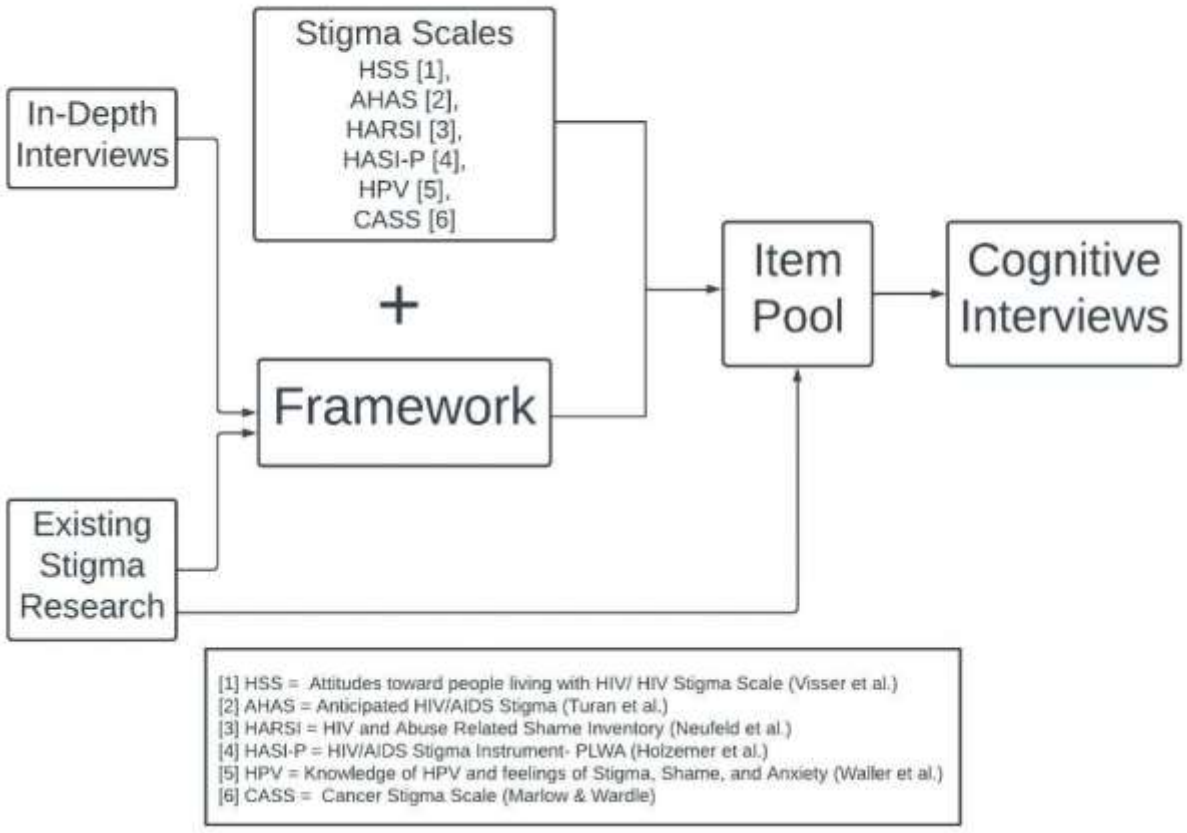
Introduction: Human Papillomavirus (HPV) vaccination and testing greatly reduce cervical cancer rates in high-income communities; yet, cervical cancer remains the most common cause of cancer and cancer-related deaths in many low-resource countries, including Kenya. Understanding behaviors and beliefs around HPV and cervical cancer, including stigma, will help ensure uptake of these effective interventions. A culturally adapted tool to measure stigma will be allow measurement of the levels and impact of HPV and cervical cancer-related stigma.

Methods: We used a stigma framework developed from previous in-depth interviews on HPV and cervical cancer knowledge, attitudes, and behaviors conducted in Kisumu, Kenya to develop an item pool. We adapted items from existing validated scales for HIV, HPV and cervical cancer-related stigma and added additional items based on the qualitative data (Figure 1). Items covered the three dimensions of stigmatizing attitudes, enacted, and internalized stigma across the health domains of Cervical Cancer and HPV. Items were developed in English, translated into Dholuo and then back-translated. Selected items from validated HIV scales were translated into Dholuo for psychometric testing in this setting. Cognitive interviews assessed cultural fit, understanding, and acceptability (Table 1).

Figure 1: The Inputs and Ouputs to the Framework of Creating the Context-Specific Stigma Item Pool for HPV, HIV, and Cervical Cancer



[1] HSS = Attitudes toward people living with HIV/ HIV Stigma Scale (Visser et al.)
[2] AHAS = Anticipated HIV/AIDS Stigma (Turan et al.)
[3] HARSI = HIV and Abuse Related Shame Inventory (Neufeld et al.)
[4] HASI-P = HIV/AIDS Stigma Instrument- PLWA (Holzemer et al.)
[5] HPV = Knowledge of HPV and feelings of Stigma, Shame, and Anxiety (Waller et al.)
[6] CASS = Cancer Stigma Scale (Marlow & Wardle)

Table 1: Questions Asked of Cognitive Interviewiers for each Stigma Question

Question Number	Question	Responses			
1	Did you understand this question?	Yes	No	Don't Know	Declined to answer
2	Did you have any diffiuclty using the response options?	Yes	No	Don't Know	Declined to answer
3	Please, tell us in your own words what the question is asking.	Explain			
4	Were there any words or ideas you did not know/understand?	Yes	No	Don't Know	Declined to answer
5	Do you think the questions should be simplified?	Yes	No	Don't Know	Declined to answer
6	Would this question make women feel uncomfortable?	Yes	No	Don't Know	Declined to answer
6b	Please explain, regardless of Y/N response	Explain			
7	Would women feel like they could answer this question truthfully?	Yes	No	Don't Know	Declined to answer
7b	If yes, please explain	Explain			
8	Do you think this question should be eliminated?	Yes	No	Don't Know	Declined to answer
8b	If yes, why should it be eliminated?	Explain			
8c	If no, why not?	Explain			

Results: A total of 134 items were developed, with 48 about HIV, 52 about HPV, and 34 about cervical cancer (Table 2). Cognitive interviews were carried out among 101 participants, with 37 conducted in English and 62 in Dholuo. Participants assessed an average of 13.18 questions. A total of 22 questions were eliminated, 9 due to fear or judgement, 3 for discomfort, 3 pain, 1 for difficulty understanding, and 6

for perceived unacceptability.

Table 2: Questions Asked About HPV, HIV, and Cervical Cancer Across the Stigma Dimensions

	Stigma Dimensions			
Health Domain	Attitudes	Anticipated Internalized	Anticipated	Total Questions
HPV	16	17	19	**52**
Cervical Cancer	11	12	11	**34**
HIV for HIV-Negative Women	20	16	12	**48**
HIV for WLWH*	**	16 "	12	**28**

Example Adaptation	**Reference Scale Used**	**Stigma Dimension**	**Original Question from Existing Scale**	**Question Adaptation**
	HARSIH6	Anticipated Internalized	I am ashamed that I'm HIV positive.	I would be ashamed to have HPV.

WLWH* = Women Living with HIV
** = To reduce potential additional stigma for women living with HIV, we did not ask stigmatizing attitudes questions for WLWH
16 " = Internalized, not Anticipated Internalized

Conclusions: To our knowledge, this is the first set of culturally adapted items to measure HPV and cervical cancer related stigma in East Africa. After assessment of psychometric properties, this tool holds potential to guide the development and evaluation of stigma-responsive cervical cancer prevention.

Shift 02-214 / #1404

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02E. DIAGNOSIS AND MANAGEMENT OF ANAL CANCER AND RELATED PRECURSORS: SCREENING, DIAGNOSIS AND MANAGEMENT
04-20-2023 7:00 AM - 4:00 PM

DOES CADM1, MAL, AND MIR124-2 HOST DNA METHYLATION FROM ANAL SWABS PREDICT LESION GRADE AND PERSISTENCE?

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Introduction: Anal cancer is preceded by HSIL. There is limited information on DNA methylation in anal swabs from well-characterized single lesion-based HSIL. Aims: To analyze the association between CADM1, MAL, and miR124-2 DNA methylation detected using anal swabs and causing HPV infections and other risk factors.

Methods: Samples were obtained as part of the Study of the Prevention of Anal Cancer (SPANC), a 3-year longitudinal study of gay and bisexual men (GBM), aged ≥35 years. Participants with histologically confirmed HSIL (HSIL-AIN2 and HSIL-AIN3) at the baseline underwent LCM and HPV genotyping, in baseline and follow-up biopsies. DNA methylation analysis also was performed on residual ThinPrep. ThinPrep samples at baseline were subjected to methylation-specific-qPCRs. A specific algorithm of persistence was used to establish lesion-based HSIL persistence by the location and causal HPV type of the lesion at baseline and follow-up. The mean percentage of DNA methylation of each marker was assessed with histological grade, causing HPV type, HIV status, the persistence of HSIL, and age.

Results: At baseline, 131 men who had histological HSIL and attended at least one follow-up visit underwent DNA methylation analysis. In total 190 LCM-HSIL lesions were identified (143 AIN3 and 47 AIN2). CADM1, MAL, and miR124-2 methylation were higher in AIN3 lesions than in AIN2 ($p<0.001$, $p=0.012$, and $p=0.013$ respectively). Only MAL methylation was significantly associated with HIV positivity ($p=0.044$). CADM1 had higher levels of methylation in participants with HPV16+ HSIL than those with HPV16- HSIL ($p<0.001$), in men 50+ years compared to younger men ($p= 0.016$), and in persistent AIN3 than in non-persistent AIN3 ($p=0.019$).

Conclusions: Methylation analysis of CADM1, MAL, and miR124-2 in anal swabs can be used for the prediction of AIN3 lesions. High levels of CADM1 methylation predict persistent AIN3. This information is an important step toward the identification of HSIL patients in need of urgent treatment.

Shift 02-215 / #1724

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02E. DIAGNOSIS AND MANAGEMENT OF ANAL CANCER AND RELATED PRECURSORS: SCREENING, DIAGNOSIS AND MANAGEMENT
04-20-2023 7:00 AM - 4:00 PM

THE ACCURACY OF THE ANAL SELF-EXAM TO DETECT AN ABNORMALITY AT THE ANAL CANAL OR PERIANUS: THE PREVENT ANAL CANCER PALPATION STUDY

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Introduction: Anal squamous cell carcinoma (ASCC) tumors average >30 mm in diameter and presumably could be detected by self-palpation. We set out to determine if sexual and gender minority (SGM) individuals can detect anal canal or perianal abnormalities after performing an anal self-exam (ASE).

Methods: Through December 30, 2022, 622 individuals were trained to perform an ASE with pelvic mannequins to detect any abnormality (yes/no), which was defined as any atypical condition, e.g., hemorrhoids, suspicious lumps, or condyloma. The clinician then performed a digital anal rectal examination (DARE) on the participant (without immediately disclosing results), after which individuals performed the ASE. Clinicians and participants were asked to report abnormalities, regardless of size. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for ASE compared to DARE were estimated.

Results: Median age was 40 years, 37.5% were HIV-positive and 45.2%, 25.0%, and 23.1% identified as white, Black, or Hispanic, respectively. Clinicians recorded 83 anal abnormalities (median size=3 mm in diameter, range=1-8 mm) and 174 perianal abnormalities (median size=3 mm in diameter, range=1-20 mm). Overall agreement between clinician and participant was 73.0%. Overall ASE sensitivity was 59.2% (95%CI 52.7% – 65.6%). Sensitivity increased with anal canal lesion size: 58.9% (95%CI 47.6% – 70.2%) for lesions 1-4 mm in diameter and 90.0% (95%CI 71.4% – 100%) for lesions ≥5 mm. Overall ASE specificity was 79.9% (95%CI 76.2% – 83.7%). PPV was 60.0% (95%CI 53.5% – 66.5%) and NPV was 79.4% (95%CI 75.6% – 83.1%). Almost all individuals (97.4%) said they planned to do an ASE in the future.

Conclusions: SGM individuals are generally successful with detecting abnormalities of ≥5 mm in diameter after being taught the ASE. Since sparse screening infrastructure and anal cancer stigma may cause delays in clinical screening for some people, self-detection of abnormalities may facilitate earlier evaluation of cancer symptoms.

Shift 02-216 / #798

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02F. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER
04-20-2023 7:00 AM - 4:00 PM

HPV DRIVEN OROPHARYNGEAL CANCER BURDEN IN PARIS REGION FROM 1981 TO 2021

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Introduction: France has the 2nd highest oropharyngeal cancer (OPC) incidence in Europe with approximately 5000 new cases diagnosed in 2018. Despite this, the impact of high-risk HPV (HR-HPV) on OPC epidemiology over time remains poorly investigated. The primary objective of this study is to estimate the fraction of OPC attributable to HPV from 1981 to 2021 based on the large sample collection of 2 French referral hospitals.

Methods: All OPCs diagnosed in 1981, 1986, 1991 1996, 2001, 2006, 2011, 2016 and 2021 were identified and corresponding medical records abstracted. P16 IHC was assessed in all available samples and HPV genotyping was performed in those overexpressing p16 in >70% of tumor cells. Samples positive for both p16 and HR-HPV DNA were considered as HPV-driven.

Results: 735 OPC samples were retrieved from the tumor biobanks. The rate of p16-positive tumors rose from 7% (6/90) in samples collected before 2001 to 54% (93/171) in those diagnosed in 2021. Similarly, 3.3% (3/90) of OPCs were HPV-driven before 2001 versus 50% in 2021. The Data are summarized in Table 1. HPV16 was the most frequent genotype (91,5%), followed by HPV33 (4,9%) and HPV35 (4,9%). Most patients were male. We noted an increase in the proportion of patients above 70 years and in non smokers over time.

	From 1981-1996 (n=90)	2001 (n=99)	2006 (n=109)
p16-positive	6 (7%)	23 (23%)	13 12%)
HPV-driven	3 (3,3%)	9 (9%)	9 (7%)

Conclusions: Rates of HPV-driven OPC has substantially increased in Paris region over the last 4 decades.

Shift 02-217 / #921

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02F. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER
04-20-2023 7:00 AM - 4:00 PM

HPV SIGNATURE IN ORAL CANCER AMONG INDIAN POPULATION

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Introduction: Human Papilloma Virus may play a major contributing role in a subset of non-tobacco associated oral cancer patients. The current study aimed to investigate HPV association among Indian Oral Squamous cell carcinoma(OSCC)

Methods: A total of 1000 cases were included in the study. Among them 800 cases were of Oral squamous cell carcinoma and 200 control cases consisted A 800 cases were of Oral squamous cell carcinoma and 200 control cases were enrolled along with recording of clinical history and detailed examination. The biopsy samples of all the participants were done. The immunohistochemistry for p16 (E6H4 clone, CINtec histology, Roche diagnostics) was done. The cases with 2+/3+ positive nuclear staining with more than 75% cells immunopositive were taken as p16 immunopositive as per the AJCC criteria. All p16 immunopositive cases were subjected to HPV DNA PCR

Results: The OSCC cases were compared with control cases in terms of staining and histomorphology. However, the grading of immunopositivity was seen among OSCC cases. Out of 800 OSCC cases 139 (17.37%) showed p16 immunopositivity by AJCC criteria. Out of these, 104 (104/139, 74.8%) cases were positive by HPV DNA PCR for HPV-16/18. The patient's characteristics associated with a higher proportion of p16 and HPV DNA positivity were urban residence, vegetarian diet, illiteracy, graduate or higher education. No correlation was noted with gender, tobacco smoking or chewing habits, religion, occupation or site of tumor. The p16 immunopositivity was higher in the younger age group with no tobacco habits.

Conclusions: A significant proportion of OSCC cases in India are associated with HPV infection. Out of total OSCC cases, younger patients with no tobacco habits showed higher percentage of p16 immunopositivity that indicated towards a distinct subset of patients in whom HPV may be major contributing factor.

Shift 02-218 / #935

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02F. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER
04-20-2023 7:00 AM - 4:00 PM

THE DETECTION OF HYPOXIC MARKERS IN NON-HPV AND HPV-ASSOCIATED HEAD AND NECK TUMORS

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Introduction: In the microenvironment of growing solid tumors, the oxygen level often decreases, and a hypoxic state is induced. This can lead to a worse response to treatment, and consequently, to a worse patient prognosis. One of the hypoxia-responding genes is aspartate-β-hydroxylase (ASPH) whose activity promotes the growth, invasiveness, and metastasis of many solid tumors. Tumors in head and neck location (HNC) are very heterogeneous. A part of HNC is etiologically associated with human papillomavirus (HPV) infection. We have focused on the ASPH expression in tumors with different HPV status in relation to hypoxia.

Methods: Selected hypoxic markers (hypoxia inducible factor 1 subunit alpha – HIF1A, HIF2, vascular endothelial growth factor A - VEGFA, glucose transporter 1 - GLUT1, prolyl 4-hydroxylase subunit alpha 1- P4HA1, carbonic anhydrase 9 - CA9, matrix metallopeptidase 9 - MMP9, MMP13) and ASPH were detected by quantitative PCR and/or multiplex fluorescent immunohistochemistry in HNC samples. The results were correlated with the viral etiology of the tumors and the clinical and pathological characteristics.

Results: In the preliminary study, we have analyzed 40 HNC. In the group of HPV-negative samples compared to HPV-positive samples, we found a higher level of VEGFA on both the mRNA and protein level. Statistically significantly elevated protein expressions of ASPH, HIF1A, GLUT1, and MMP13 were detected in the HPV-positive tumor group. Except for MMP9 and MMP13, elevated expression of markers and ASPH was detected in the tumor parenchyma.

Conclusions: The expression of ASPH and hypoxic markers is significantly different in HNC tumors associated and non-associated with HPV. Preliminary results indicate that HPV-positive tumors express higher levels of hypoxic markers. These differences might partially explain the effect of HPV infection on the prognosis of HNC and the response to treatment.

Shift 02-219 / #1099

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02F. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER
04-20-2023 7:00 AM - 4:00 PM

AN OCCULT 2MM HPV-DRIVEN OROPHARYNGEAL CANCER DISCOVERED THROUGH A SALIVA TEST

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Introduction: The last decade has seen a continued escalation in rates of human papillomavirus related oropharyngeal malignancy (HPV-OPC). In contrast, HPV associated cervical cancer incidence rates have declined, due in part to effective cervical cancer screening programs. This then raise the question as to whether similar HPV screening method could be used for early detection of HPV-OPC. Persistent oral hrHPV is a prerequisite for the development of HPV-OPC and can be accurately detected in saliva.

Methods: We recruited 665 cancer-free individuals in Australia. We quantified HPV16 DNA using in-house developed PCR method. Individuals with (n = 9) or without (n = 12) oral HPV16 infections at baseline were followed for a median duration of 2 years. Individuals with persistent oral HPV16 infection (≥ 30 mo) were invited for clinical examination of their oral cavity and oropharynx by an otolaryngologist.

Results: Oral HPV16 DNA was detected in 12 out of 650 cancer-free individuals (1.8%; 95% confidence interval [CI]: 1.0-3.2). Of the 3 individuals with persistent oral HPV16 infection, the first individual showed no clinical evidence of pathology. The second individual was diagnosed with a 2 mm invasive squamous cell carcinoma (T1N0M0) positive for both p16INK4a expression and HPV16 DNA. The third individual was found to have a mildly dysplastic lesion in the tonsillar region that was negative for p16INK4a expression and HPV16 DNA and she continues to have HPV16 DNA in her saliva.

Conclusions: We report the first ever case of occult OPC detected as a direct result of a theoretical screening test—in this case HPV-16 DNA analysis in saliva samples. Our clinical and pathological findings increase our understanding of both the natural history of the disease and the potential for wider screening to identify early stage OPC, facilitating less morbid treatments. Larger multicenter studies are warranted to extend and confirm the results of the current investigation.

Shift 02-220 / #1113

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02F. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER
04-20-2023 7:00 AM - 4:00 PM

HPV16 E5 SPECIFIC TRANSCRIPT AS PROGNOSTIC BIOMARKER IN HPV-ASSOCIATED OPSCC

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Introduction: An assay to reveal HPV16 E5 specific transcript was already developed. Preliminary data showed that this transcript can be detected in cervix scrapes. Since no study explored presence of this E5 specific transcript on OPSCC, HOPE5, a multicentre Project, was developed to investigate this point together with EGFR and HLA. Here, we present early data from part of a retrospective cohort of HPV-associated OPC and of oral rinse samples of healthy subjects from ENT outpatients of five different LILT Provincial Committees. HOPE5 is started on January 2022 and is actively enrolling patients.

Methods: A retrospective cohort of HPV16 OPSCC with a follow-up report of at least two years was identified in IRE Biobank. FFPE sections were utilised for RNA extraction with commercial kits. Primers for E6-E7-E5 and those for E5 specific transcript were utilised in RT-real time PCR. Oral rinse (liquid biopsy) from healthy individual were analysed with same technologies. Matching samples of cohort patients were analysed by IHC for EGFR and HLA.

Results: Up to know, 24 samples of OPSCC patient were analysed. DNA and mRNA were successful extracted from all FFPE. Polycistronic transcripts for E6-E7 major HPV16 oncogenes as well as those containing sequences of E5 gene were detected. The specific transcript coding for production of E5 protein was detect only in about 10% of samples. Liquid oral biopsy collection just started on beginning of September and 2 out of 48 samples were HPV16 positive. EGFR immunostaining was showed in 50% of HPV+ samples as reported in literature.

Conclusions: Four % of liquid biopsy samples from healthy individuals were positive for HPV16 confirming dat from large population study. Presence of E5 specific transcript in FFPE samples was detected exclusively in patients that experienced disease relapse, suggesting that the E5 specific mRNA could represent a prognostic marker for OPSSC.

Shift 02-221 / #1124

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02F. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER
04-20-2023 7:00 AM - 4:00 PM

BIOTOTOP STUDY: CTHPVDNA AND CLINICAL OUTCOME OF OPSCC

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Introduction: Despite recent advances in diagnosis and therapy, a quarter of HPV$^+$ oropharyngeal squamous cell carcinoma (OPSCC) patients will experience some relapse. So far, conventional tissue biopsy or imaging showed a limited predictive value for disease monitoring. On the contrary, circulating tumor HPV DNA (ctHPVDNA) in liquid biopsies (LB) showed promising results. The study was performed to detect ctHPVDNA by digital PCR (dPCR) in a real-world clinical environment and to ascertain its correlation with radiomics imaging.

Methods: Biototop study involves collection of tissue, blood and saliva samples at first diagnosis and during follow up from patients affected by OPSCC undergoing surgery and/or chemo/radiotherapy. Since the study is actively enrolling patients (150 at the end of enrolment), present results become from a small number of patients and it is expected to present data from a larger number at IPVS Conference. Serial blood drawings were collected and analysed with standard protocols by three different platforms, QuantStudio 3D Digital, QuantStudio Absolute Q Digital PCR and QX200 Droplet Digital PCR System, respectively.

Results: A perfect concordance between ctHPVDNA and p16 status was revealed. At starting point, a wide range of ctHPVDNA was detected in OPSCC with no correlation to tumor size or lymph-node status. Serial LBs tracked disease evolution, anticipating response evaluation by imaging in some cases. After surgery or during treatments ctHPVDNA levels varied, suggesting presence of residual tumor or documenting poor/good responses to therapy, respectively. Remarkably, a strong reduction in ctHPVDNA levels was detected at the first evaluation in almost all patients undergoing surgery or chemo/radiotherapy. Correlation with radiomics analysis will be presented.

Conclusions: Overall, our data confirm that ctHPVDNA analysis is clinically meaningful, suggesting a potential role as prognostic marker and in personalized treatment decisions for OPSCC patients.

Shift 02-222 / #1268

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02F. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER
04-20-2023 7:00 AM - 4:00 PM

ARTIFICIAL INTELLIGENCE FOR IMAGE-BASED HPV STATUS PREDICTION IN HEAD AND NECK CANCER: A SYSTEMATIC REVIEW AND META-ANALYSIS

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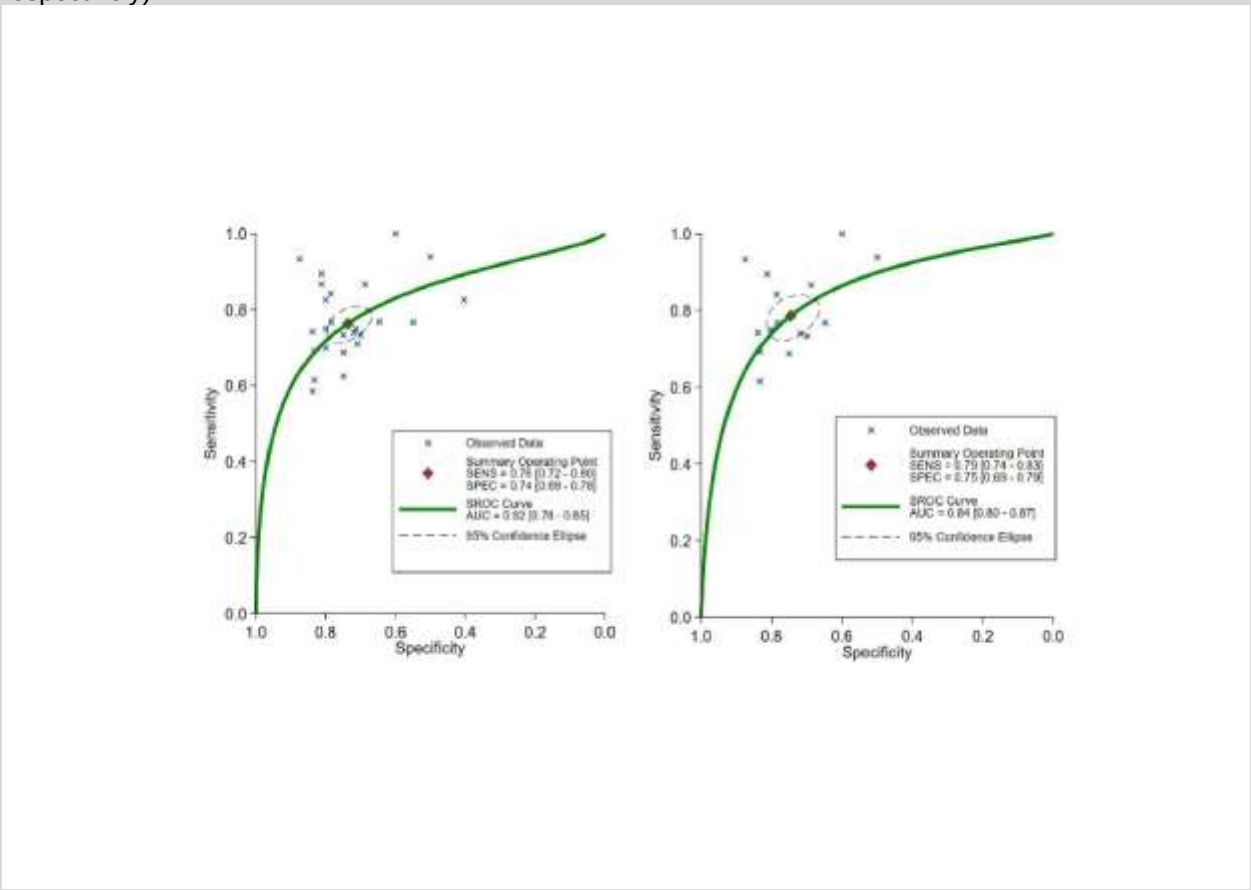
Introduction: Early detection of the human papillomavirus (HPV) status is crucial to stratify head and neck cancer (HNC) patients, personalize treatment options, and predict prognosis. This systematic review and meta-analysis aims to evaluate the clinical performance of artificial intelligenceon HPV status prediction in HNC.

Methods: This systematic review and meta-analysis was performed in accordance with the PRISMA guideline. A systematic literature search was conducted in databases including Ovid-MEDLINE, Embase, and Web of Science Core Collection for studies published in English from inception up to 30th October, 2022. Pertinent studies with synonymous keywords “AI”, “HPV”, and “HNC” were included. A mixed effect model was used for meta-analysis synthesis and we mainly reported the pooled sensitivity, specificity, area under the curve (AUC), and their 95% confidence intervals (CI) for all studies and studies only reporting the highest performance.

Results: Totally, 21 original studies were included in the systematic review, 15 of which were eligible to generate 26 contingency tables for meta-analysis. The pooled sensitivity and specificity for all studies were 0.76 (95% CI: 0.73-0.80) and 0.74 (95% CI: 0.69-0.78) respectively, with an AUC of 0.82 (95% CI: 0.78-0.85). When only including one contingency table reporting the highest performance in each study, the pooled sensitivity and specificity were 0.79 (95% CI: 0.74-0.83) and 0.75 (95% CI: 0.69-0.80) with an AUC of 0.84 (95% CI: 0.80-0.87). Only low and moderate heterogeneities were observed (I^2 of sensitivity and specificity were 37.21% and 57.92%

respectively).



Conclusions: This study shows an acceptable performance of AI algorithms to predict HPV status in HNC. This fast and low-cost method might be useful to be further applied in cancer screening or clinical practice. However, both the sensitivity and specificity of AI are relatively low compared to the routine test p16 immunohistochemistry. The exploitation and optimization on AI algorithms warrant further research.

Shift 02-223 / #1586

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02F. DIAGNOSIS AND MANAGEMENT OF HPV-RELATED OROPHARYNGEAL, HEAD AND NECK CANCER
04-20-2023 7:00 AM - 4:00 PM

INTEGRATION AND VIRAL ONCOGENE EXPRESSION OF HUMAN PAPILLOMAVIRUS TYPE 16 IN HEAD AND NECK CANCER AND GASTRIC CANCER

Qiang Xu[1], Haoru Dong[1], Zhiyu Wang[1], Pei Zhang[1], Zhi-Ming (Thomas) Zheng[2], Xu Qian[1]
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Introduction: Persistent high-risk human papillomavirus (HR-HPV) infections cause cervical cancer and a fraction of head and neck cancer.

Methods: To investigate whether HR-HPV infection might be also involved in the development of gastric cancer (GC), we developed a platform utilizing a rolling circle amplification (RCA)-based nested L1 PCR with Sanger sequencing to genotype the HPV DNA in cancer tissues of 361 GC and 89 oropharyngeal squamous cell carcinomas (OPSCC).

Results: HPV transcriptional activity was determined by E6E7 mRNA expression and a 3' rapid amplification of cDNA ends was performed to identify HPV integration and expression of virus-host fusion transcripts. Nine of 361 GC, two of 89 OPSCC, and one of 22 normal adjacent tissues were HPV L1 DNA positive. Five of the 9 HPV-positive GC were genotyped as HPV16 by sequencing and one of 2 GC with RCA/nested HPV16 E6E7 DNA detection exhibited HPV16 E6E7 mRNA. Two OPSCC displayed HPV16 L1 DNA and E6E7 mRNA, of which one OPSCC tissue showed virus-host RNA fusion transcripts from an intron region of KIAA0825 gene involving DNA repair.

Conclusions: Together, our data reveal a low frequency of HPV16 infections in GC and OPSCC in China but suggest a possible etiology role of HPV infections in gastric carcinogenesis.

Shift 02-225 / #1557

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02G. DIAGNOSIS AND MANAGEMENT OF CUTANEOUS WARTS AND OTHER SKIN LESIONS
04-20-2023 7:00 AM - 4:00 PM

NAIL BOWEN DISEASE AND SQUAMOUS CELL CARCINOMA AS HIGH-RISK HPV-ASSOCIATED RESERVOIR SITES FOR SEXUALLY TRANSMITTED INFECTIONS.

Akira Shimizu[1], Reimon Yamaguchi[1], Kazushi Anzawa[1], Yuko Kuriyama[2], Kuniaki Ohara[3]
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Introduction: Squamous cell carcinoma (SCC) in the genital area is recognized to be caused by human papillomavirus (HPV) infection. However, the association between high-risk HPV infection and nail SCC/SCC in situ is less well recognized. In this study, we collected body surface SCC/SCC in situ cases and examined HPV infection to determine the significance of nail apparatus for high-risk HPV infection.

Methods: DNA was extracted from 137 formalin-fixed paraffin-embedded samples taken from SCC/SCC in situ. PCR with HPV consensus primers and subsequent direct DNA sequencing were performed. For nail Bowen's disease, a SCC in situ, the area of infection around the nail was examined in detail. In addition, PCR was performed on a swab obtained from the nail surface keratin to detect mucosal high-risk HPV. Furthermore, previous cases of HPV-associated nail SCC/SCC in situ were reviewed in the literature to determine their clinical features.

Results: Mucosal high-risk HPV was detected in 5 out 5 cases (100%) in the genital area, 4 out of 9 cases (44%) in the nail apparatus. On the other hand, only 2 out of 123 cases (2%) were HPV-positive on other body surfaces. The nail apparatus is an important site of mucosal high-risk HPV infection, as is the genital area. HPV-positive cells were distributed even in the epithelial cells of the proximal nail fold. Mucosal high-risk HPV was detected from the swab material. By reviewing previous cases of nail SCC/SCC in situ, the mean age was 52 years, which was younger than usual for SCC/SCC in situ. The sex ratio showed a male predominance. The left 3 and right 1-3 fingernails are favorite sites.

Conclusions: The nail apparatus is a characteristic region for high-risk HPV infection. We propose that nail SCC/SCC in situ is a high-risk HPV-associated reservoir site for sexually transmitted infection.

Shift 02-226 / #1035

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02H. PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-20-2023 7:00 AM - 4:00 PM

THE RIFT PROJECT: ASSESSING THE REDUCTION OF VIRAL INFECTIVITY IN HPV16/18-POSITIVE WOMEN AFTER ONE, TWO, AND THREE DOSES OF GARDASIL-9

Victoria López-Codony[1], Álvaro De Andrés-Pablo[1], Maria Eulalia Fernandez[2], Marta López-Querol[1], Sara Tous[1,3], Juan Carlos Torrejón[2], Yolanda Pérez[2], Angelica Ferrando-Díez[4], Laia Bruni[1,3], Patricia Guijarro[1], Laia Alemany Vilches[1,3], Xavier Bosch[1,3,5], Miquel Angel Pavon Ribas[1,3]
[1]Catalan Institute of Oncology, Bellvitge Biomedical Research Institute (IDIBELL), Cancer Epidemiology Research Programme, L'Hospitalet de Llobregat, Barcelona, Spain, [2]Bellvitge University Hospital (HUB), Department Of Gynecology, L'Hospitalet de Llobregat, Barcelona, Spain, [3]Carlos III Institute of Health, Biomedical Research Networking Center For Epidemiology And Public Health (ciberesp), Madrid, Spain, [4]Catalan Institute of Oncology, Germans Trias i Pujol University Hospital (HGTiP), Medical Oncology Department, Badalona, Barcelona, Spain, [5]Open University of Catalonia (UOC), Faculty Of Health Sciences, Barcelona, Spain

Introduction: Human Papillomavirus (HPV) vaccination has proven effective in preventing new infections, but it does not treat existing HPV infections or associated diseases. Hence, there is still an important reservoir of HPV in adults, as vaccination programs are mainly focused on young women. The purpose of our study is to evaluate if a 3-dose regimen of Gardasil-9 could reduce the infective capacity of body fluids from HPV-positive women. We aim to assess if vaccine-induced antibodies could neutralize virions present in the mucosa of HPV-positive women, thus preventing the release of infectious particles and HPV transmission to sexual partners.

Methods: A non-randomized, open-label trial, has been designed to recruit two different cohorts (RIFT-HPV1/RIFT-HPV2) of non-vaccinated adult women, positive for HPV16 and/or HPV18. Given that E1^E4 mRNA is a surrogate biomarker of active viral infection, an adaptation of the E1^E4-HaCaT model will be performed to assess the infectivity levels of cervical, anal, and oral fluids, obtained from patients after each dose of the standard schedule (0,2,6 months). HPV positivity (Anyplex HPV28), virion production (HPV-L1 ELISA), seroconversion and the presence of antibodies in the exudates (HPV-L1Ab ELISA

and/or cLIA) will be evaluated to attribute infectivity reduction to vaccination.

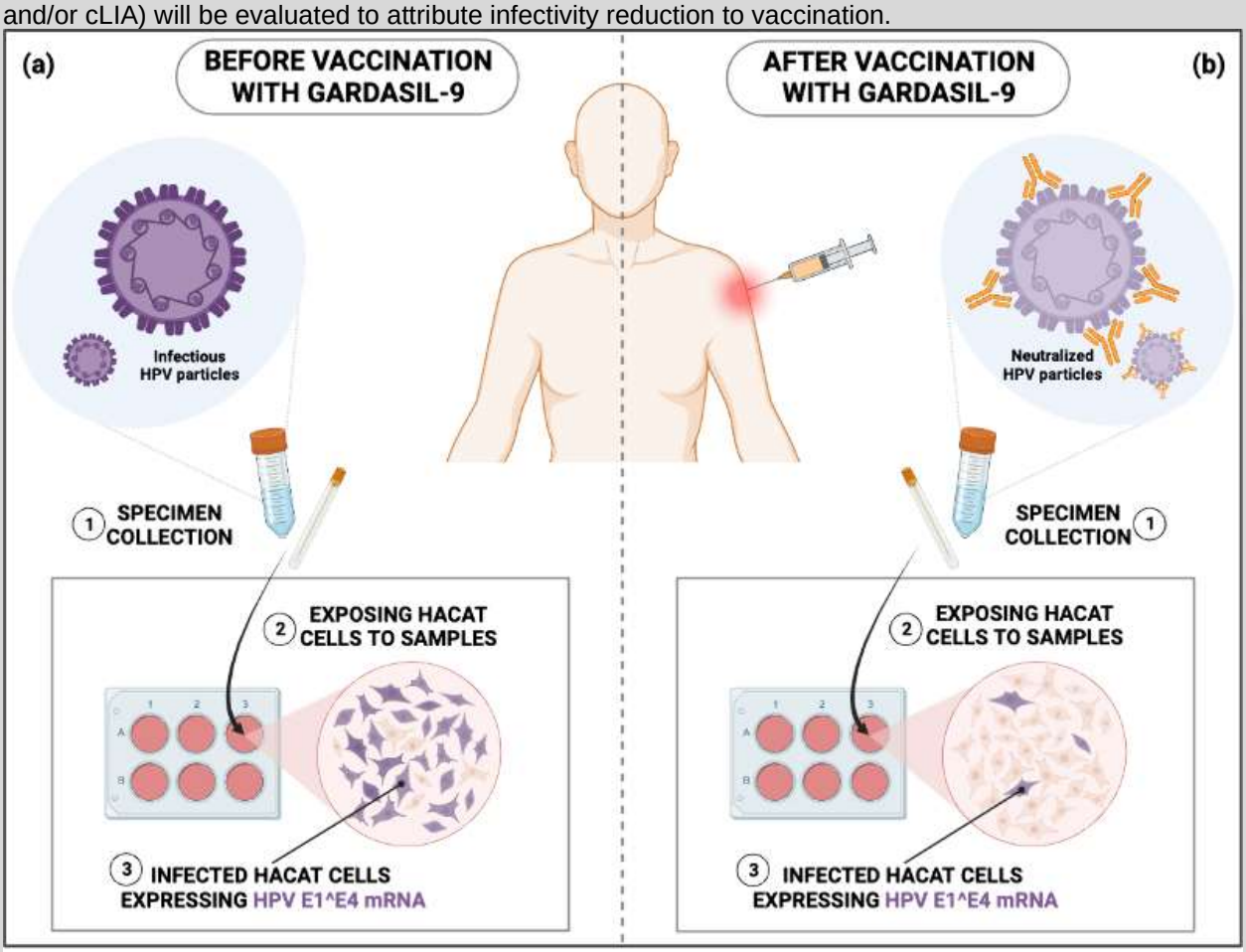


Figure 1. Infectivity assay performed on HaCaT cells before and after vaccination with Gardasil-9
In vitro functional assay based on the expression of HPV E1^E4 mRNA in HaCaT cells after incubation with HPV-containing body fluids. a) Before vaccination with Gardasil-9, higher levels of E1^E4 mRNA are expected. b) After vaccination with Gardasil-9, E1^E4 mRNA levels should be lowered by the generated neutralizing antibodies and consequent reduction of the body fluids' infective capacity.

Adapted from "Delivery Strategies of Genome-Editing Machinery", by BioRender.com (2022). Retrieved from https://app.biorender.com/biorender-templates

Results: The RIFT project has been approved by the Spanish Agency of Medicines and Medical Devices (AEMPS) and the Clinical Research Ethics Committee (CEIC). The first cohort, RIFT-HPV1, will include patients without lesions or with cervical intraepithelial neoplasia (CIN)1/2 lesions. The second cohort, RIFT-HPV2, will include patients with condyloma acuminata and/or multiple anogenital lesions. Patient recruitment started in September 2022 and the analysis of preliminary data is currently ongoing.

Conclusions: Even though prophylactic HPV vaccines would not eliminate a pre-existing infection, our results will determine if Gardasil-9 could be considered as a new complementary strategy to prevent HPV-associated diseases by reducing viral spread. Trial registration: https://clinicaltrials.gov/ct2/show/NCT05334706

Shift 02-227 / #1235

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02H. PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-20-2023 7:00 AM - 4:00 PM

RATIONALE AND DESIGN OF A STUDY TO EVALUATE REDUCED DOSING OF THE NONAVALENT HPV VACCINE IN WOMEN LIVING WITH HIV

Elisabeth Mcclymont[1], Isabelle Boucoiran[2], Chelsea Elwood[3], Shariq Haider[4], Catherine Hankins[5], Marina Klein[6], Mona Loutfy[7], Valerie Martel-Laferrière[8], Valerie Nicholson[9], Gina Ogilvie[10], Vanessa Poliquin[11], Manish Sadarangani[12], Joel Singer[10], Marie-Louise Vachon[13], Sharon Walmsley[7], Mark Yudin[14], Deborah Money[3]
[1]University of British Columbia, Pediatrics And Obstetrics & Gynecology, Vancouver, Canada, [2]University of Montreal, Obstetrics & Gynecology, Montreal, Canada, [3]University of British Columbia, Obstetrics & Gynecology, Vancouver, Canada, [4]McMaster University, Medicine, Hamilton, Canada, [5]McGill University, School Of Population And Global Health, Montreal, Canada, [6]McGill University, Medicine, Montreal, Canada, [7]University of Toronto, Medicine, Toronto, Canada, [8]University of Montreal, Medical Microbiology & Infectious Diseases, Montreal, Canada, [9]BC Centre for Excellence in HIV/AIDS, N/a, Vancouver, Canada, [10]University of British Columbia, School Of Population And Public Health, Vancouver, Canada, [11]University of Manitoba, Obstetrics & Gynecology, Winnipeg, Canada, [12]University of British Columbia, Pediatrics, Vancouver, Canada, [13]Laval University, Medical Microbiology & Infectious Diseases, Quebec City, Canada, [14]University of Toronto, Obstetrics & Gynecology, Toronto, Canada

Introduction: The World Health Organization now recommends one-dose HPV vaccine schedules in girls and women aged 9-20, with two doses recommended for those aged ≥21. A positive step towards improving HPV vaccination rates globally, this reduces costs and increases feasibility of HPV vaccination programs. However, the 18 million women living with HIV (WLWH) globally, at highest risk for cervical cancer, still require three doses given the complete lack of reduced dosing data for WLWH. Requiring additional doses for WLWH undermines the feasibility of vaccination for individual women and for vaccine programs in HIV-endemic countries. We have initiated The NOVA-HIV Study, a randomized clinical trial of nonavalent HPV (9vHPV) vaccination in WLWH, to address this knowledge gap.

Methods: The NOVA-HIV Study will enrol 450 WLWH aged 18-45 who have not previously received an HPV vaccine from 10 clinical sites across Canada. Participants will be randomized 1:1 to receive 3 doses of 9vHPV vaccine following the routine vaccine schedule of 0/2/6 months or an extended schedule of 0/6/12 months.

Results: The primary objective will assess non-inferiority of peak anti-HPV16/18 geometric mean titers (GMTs) to 2 doses of 9vHPV vaccine compared to peak anti-HPV16/18 GMTs to 3 doses. Secondary endpoints include comparison of peak GMTs to 3 doses in the routine versus extended vaccination schedule, antibody persistence at 24 months of follow-up, and acceptability of HPV self-sampling among WLWH. Exploratory objectives include describing peak GMTs to one-dose of vaccine in both study arms, 9vHPV vaccine safety among WLWH, and early 9vHPV vaccine efficacy assessed via persistent 9vHPV infection.

Conclusions: The NOVA-HIV Study will provide critically needed data to inform reduced dosing of HPV vaccines in WLWH, thereby advancing global progress towards elimination of cervical cancer and global health equity.

Shift 02-228 / #1811

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02H. PROPHYLACTIC VACCINES – CLINICAL ASPECTS
04-20-2023 7:00 AM - 4:00 PM

SEROLOGY ASSESSMENTS FOR ALL 9 HPV TYPES IN THE 9-VALENT HPV VACCINE BY TOTAL IGG MULTIPLEX AND PSEUDOVIRION NEUTRALIZATION ASSAYS AT 24-MONTHS AFTER A SINGLE-DOSE

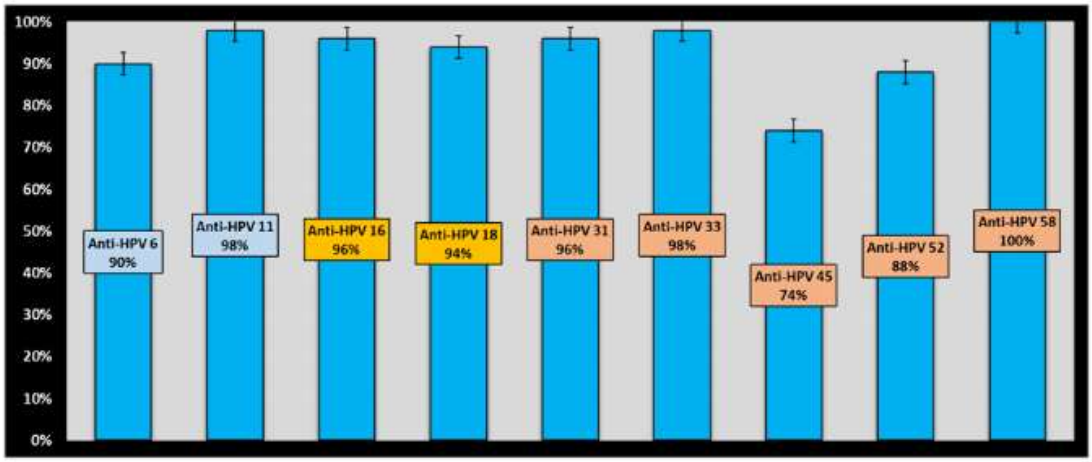
Vikrant Sahasrabuddhe[1], Troy Kemp[2], Anna-Barbara Moscicki[3], Yi Zeng[4], Heide Woo[5], Chiu-Hsieh Hsu[6], Eva Szabo[7], Eileen Diamond[8], Julie Bauman[6], H-H Sherry Chow[6], Ligia Pinto[9]
[1]National Cancer Institute, Division Of Cancer Prevention, Rockville, United States of America, [2]Frederick National Laboratory for Cancer Research, Vaccine, Immunity And Cancer Directorate, Hpv Serology Laboratory, Frederick, United States of America, [3]University of California, Los Angeles, Pediatrics, Los Angeles, United States of America, [4]Amgen, Inc, Hemotology/oncology, Thousand Oaks, United States of America, [5]University of Los Angeles California, Pediatrics, Los Angeles, United States of America, [6]University of Arizona Cancer Center, Translational Research, Tucson, United States of America, [7]National Cancer Institute, Lung And Upper Aerodigestive Cancer Research Group, Bethesda, United States of America, [8]National Cancer Institute, Breast And Gynecologic Cancer Research Group, Bethseda, United States of America, [9]Frederick National Laboratory for Cancer Research, Vaccine Immunity And Cancer Directorate, Frederick, United States of America

Introduction: A single dose of the nonavalent HPV (9vHPV) vaccine has been shown to induce protective efficacy similar to 2-dose schedules in children, yet evidence on durability of serologic responses to HPV types beyond HPV16 and HPV18 is limited. We sought to fill this gap through an analysis within a deferred booster dosing study of healthy young vaccine recipients in the US.

Methods: In a single-arm, non-randomized clinical trial (NCT02568566), 201 healthy 9-11-year-old girls and boys received a 9vHPV vaccine dose at baseline and a deferred booster dose at 24-months. In a subset analysis using 50 samples from the 24-month visit (pre-booster blood draw), we evaluated HPV seropositivity rates for all 9 HPV types covered by the 9vHPV vaccine using two serology assays: (i) HPV multiplex binding assay ('9v-multiplex', based on total IgG measurement), and (ii) pseudovirion neutralization HPV assay based on the secreted alkaline phosphatase (SEAP) reporter gene ('SEAP-NA').

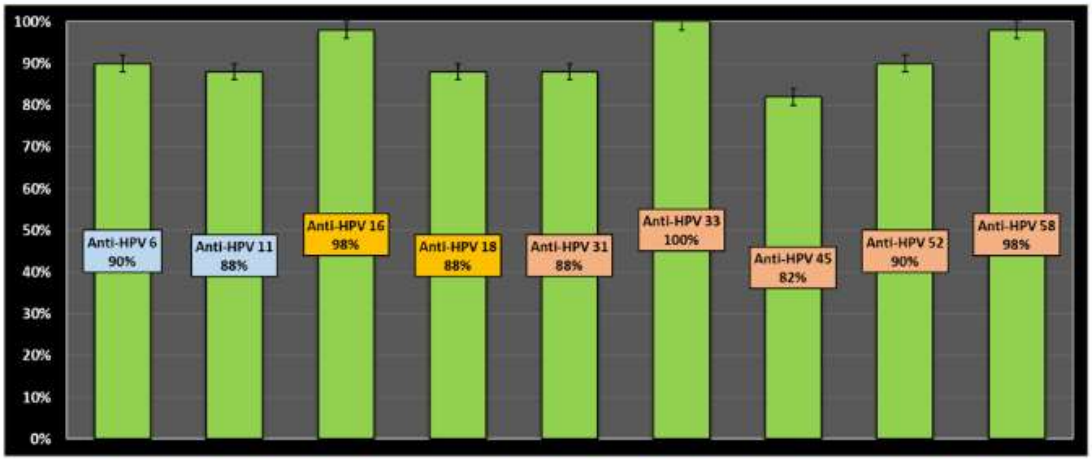
Results: HPV seropositivity by both assays at 24-months was seen in a high proportion (88%-100%) of participants for all types, with the exception of HPV45 where a fewer proportion (74% by 9v-multiplex and 82% by SEAP-NA) demonstrated seropositivity (Fig 1). There was high correlation between the 9v-multiplex and SEAP-NA assay results for all 9 HPV types, with the Spearman's rank correlation coefficient (ρ) ranging between 0.86 to 0.95 (all p-values<0.001) (Fig 2).

Seropositivity rates (%) at 24 months after 1 dose (n=50 participants; subset analysis) for anti-HPV 6/11/16/18/31/33/45/52/58 by HPV total IgG multiplex binding assay



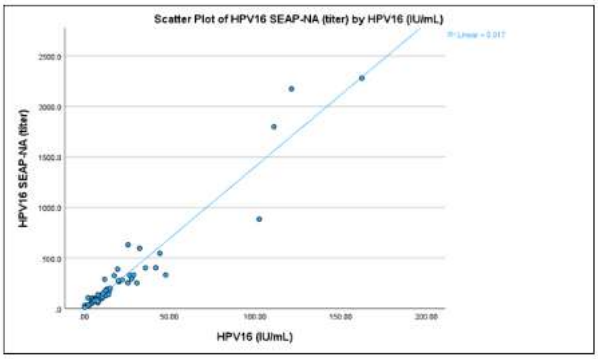
Seropositivity thresholds (all AU/mL) for HPV6: 5.6; HPV11: 1.0; HPV16: 2.8; HPV18: 1.5; HPV31: 1.5; HPV33: 1.5; HPV45: 0.6; HPV52: 5.6; HPV58: 5.8.

Seropositivity rates (%) at 24 months after 1 dose (n=50 participants; subset analysis) for anti-HPV 6/11/16/18/31/33/45/52/58 by HPV SEAP-neutralization assay

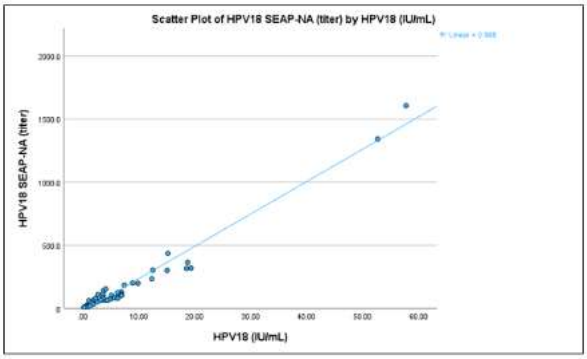


Seropositivity thresholds (arbitrary titer values): HPV6: 14; HPV11: 16; HPV16: 10; HPV18: 8; HPV31: 19; HPV33: 10; HPV45: 9; HPV52: 10; HPV58: 5.

Correlation scatterplots: levels at 24 months after 1 dose (n=50 participants; subset analysis) between SEAP-neutralization assay and HPV total IgG multiplex binding assay (IU/ml): HPV16 and HPV18

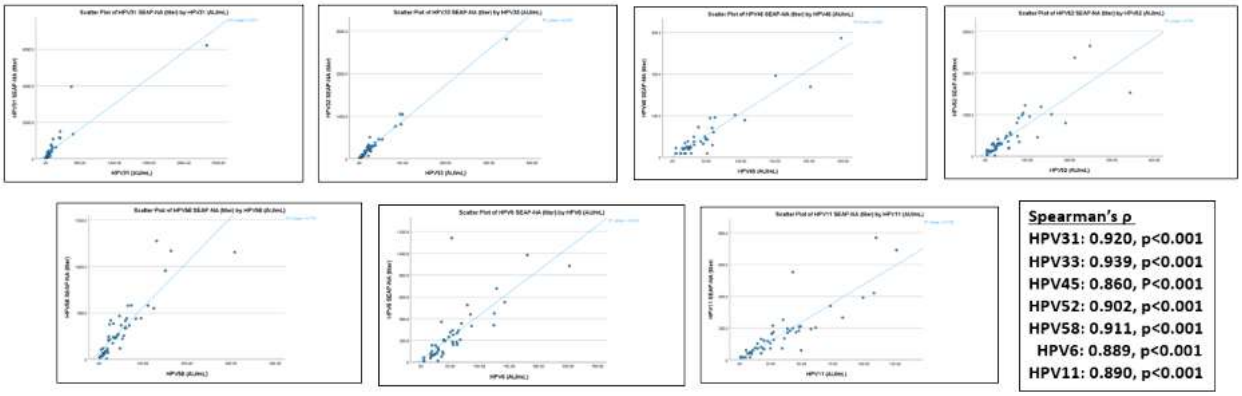


Spearman's ρ = 0.945, p<0.001



Spearman's ρ = 0.936, p<0.001

Correlation scatterplots: levels at 24 months after 1 dose (n=50 participants; subset analysis) between SEAP-neutralization assay and HPV total IgG multiplex binding assay (AU/ml): HPV31, HPV33, HPV45, HPV52, HPV58, HPV6, HPV11



Spearman's ρ
HPV31: 0.920, p<0.001
HPV33: 0.939, p<0.001
HPV45: 0.860, P<0.001
HPV52: 0.902, p<0.001
HPV58: 0.911, p<0.001
HPV6: 0.889, p<0.001
HPV11: 0.890, p<0.001

Conclusions: Durable serologic responses evidenced by high seropositivity rates at 24-months for most types in the 9vHPV vaccine by both the total IgG multiplex and neutralization assays adds further evidence about the potential for protection from single-dose or deferred booster dose schedules. Reasons for lower serologic responses to HPV45 and longer-term (i.e., beyond 24-months) durability merit further study.

Shift 02-229 / #697

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02I. THERAPEUTIC VACCINES – CLINICAL ASPECTS
04-20-2023 7:00 AM - 4:00 PM

COMBINED SYSTEMIC AND INTRALESIONAL 9-VALENT HUMAN PAPILLOMAVIRUS VACCINE FOR RECURRENT SQUAMOUS CELL CARCINOMA IN SITU OF THE PENIS.

W. Austin Wyant[1], Sonali Nanda[2], Evangelos Badiavas[1], Tim Ioannides[1,3], Anna Nichols[1,4]
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Introduction: Squamous cell carcinoma in situ (SCCIS) is an intraepithelial neoplasm typically treated surgically. In patients with recurrent lesions or lesions in sensitive areas, surgery may not be optimal. We report a case of recurrent SCCIS of the penis successfully treated with combined systemic and intralesional 9-valent human papillomavirus (HPV) vaccine.

Methods: A 48-year-old male with a past medical history of non-Hodgkin lymphoma in 1997, type 2 diabetes mellitus, undetectable HIV on HAART, anogenital HSV infection, and a 13-year history of recurrent SCCIS of the penis treated with over 10 surgeries presented with a painful, ulcerated plaque on his penis. Biopsy revealed SCCIS. He declined additional surgery. He received three injections of the systemic 9-valent HPV vaccine (Gardasil-9; Merck & Co Inc) on 03/03/2016, 04/21/2016, and 09/29/2016. Although the patient experienced clinical improvement after the second dose, the SCCIS ultimately recurred and was confirmed with repeat biopsy on 03/23/2018. At this time, the patient received a systemic 9-valent HPV vaccine booster. He also started applying imiquimod 5% cream (1/5 of a packet) and 5-fluorouracil 2% solution (1 drop) 1-2 times a week, but these were discontinued due to side effects and minimal response. Alternative therapies were discussed, and the patient chose to be treated intralesionally with four doses of the 0.5mL 9-valent HPV vaccine on the following dates: 09/27/2019, 12/05/2019, 01/16/2020, and 03/10/2021.

Results: The patient experienced clinical resolution of the SCCIS. The patient did not experience any side effects and has not had a recurrence as of 07/27/2022.

Conclusions: Combined systemic and intralesional 9-valent HPV vaccine may be a useful alternative treatment for patients with penile SCCIS who are poor surgical candidates.

Shift 02-230 / #1405

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02I. THERAPEUTIC VACCINES – CLINICAL ASPECTS
04-20-2023 7:00 AM - 4:00 PM

SAFETY AND IMMUNOGENICITY OF PROXIMAL VERSUS DISTAL SITE INTRAMUSCULAR HPV16 L2E7E6 FUSION PROTEIN VACCINATION AS ADJUVANT THERAPY FOR PATIENTS WITH HISTORY OF HPV16-ASSOCIATED CERVICAL CANCER

Stephanie Gaillard[1], Jade Alvarez[2], Hao Wang[1], Hua-Ling Tsai[1], Amy Deery[1], Amanda Nickles Fader[3], Warner Huh[4], Rebecca Arend[5], Margaret Liang[4], Michael Straughn[5], Tzyy Choou Wu[2], Charles Leath[4], Richard Roden[2]
[1]Johns Hopkins University, Oncology, Baltimore, United States of America, [2]Johns Hopkins University, Department Of Pathology, Baltimore, United States of America, [3]Johns Hopkins University, Gynecology/obstetrics, Baltimore, United States of America, [4]University of Alabama at Birmingham, Obstetrics And Gynecology, Birmingham, United States of America, [5]University of Alabama at Birmingham, Division Of Gynecologic Oncology, Birmingham, United States of America

Introduction: In patients who had previously been treated for HPV16-related cervical cancer in the past year and have no evidence of disease recurrence, the safety and tolerability of a single dose level (100µg) of HPV16 L2E7E6 fusion protein (TA-CIN) vaccine administered three times at monthly intervals to their arm or thigh was assessed in a pilot study. Since vaccination proximal to the tumor site is more effective in animal models, an important element of this study is to explore whether one of the two immunization sites induces greater HPV-specific immune responses.

Methods: Serum antibodies are assessed by ELISA and peripheral T cell-mediated immune responses by ELISPOT and VIRAFEST. Time to disease recurrence is examined by standard-of-care imaging and HPV DNA load in plasma. Safety is assessed by frequency and grade of toxicity (CTCAEv5.0).

Results: Fifteen patients were enrolled, median age 44 (range 35-82). Nine (60%) were White, 4 (27%) Black, 2 (13%) other race. Eight (53%) had squamous cell carcinoma, and 6 (40%) adenocarcinoma. One patient experienced a non-vaccine related adverse event (adhesion-related bowel obstruction) after 1 dose and withdrew. The remaining 14 patients received 3 doses (randomized; n=7 arm, n=7 thigh). Treatment-related adverse events were all grade 1, including 8 skin/injection site reactions, and 1 episode each of arthralgia, myalgia, and fatigue. Peak TA-CIN-specific serum antibody titers occurred at month 3, when patients vaccinated in the thigh trended higher (11,298 range 106-18,707) than those administered TA-CIN in the arm (1,161, range 0-3,793, p=0.12). Further immune studies will be presented.

Conclusions: Adjuvant TA-CIN immunotherapy is safe, feasible and results in immune responses in cervical cancer patients who have completed primary definitive therapy and have no evidence of disease. Vaccination in the thigh will be used in our future studies exploring prevention of recurrence.

Shift 02-231 / #810

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02J. DIAGNOSIS AND MANAGEMENT OF HPV DISEASE IN PEOPLE LIVING WITH HIV AND OTHER FORMS OF IMMUNOCOMPROMISE
04-20-2023 7:00 AM - 4:00 PM

HIGH PERSISTENCE OF HR-HPV AMONG KENYAN WOMEN WITH HIV AT 12 MONTHS AFTER LEEP FOR CIN2/3

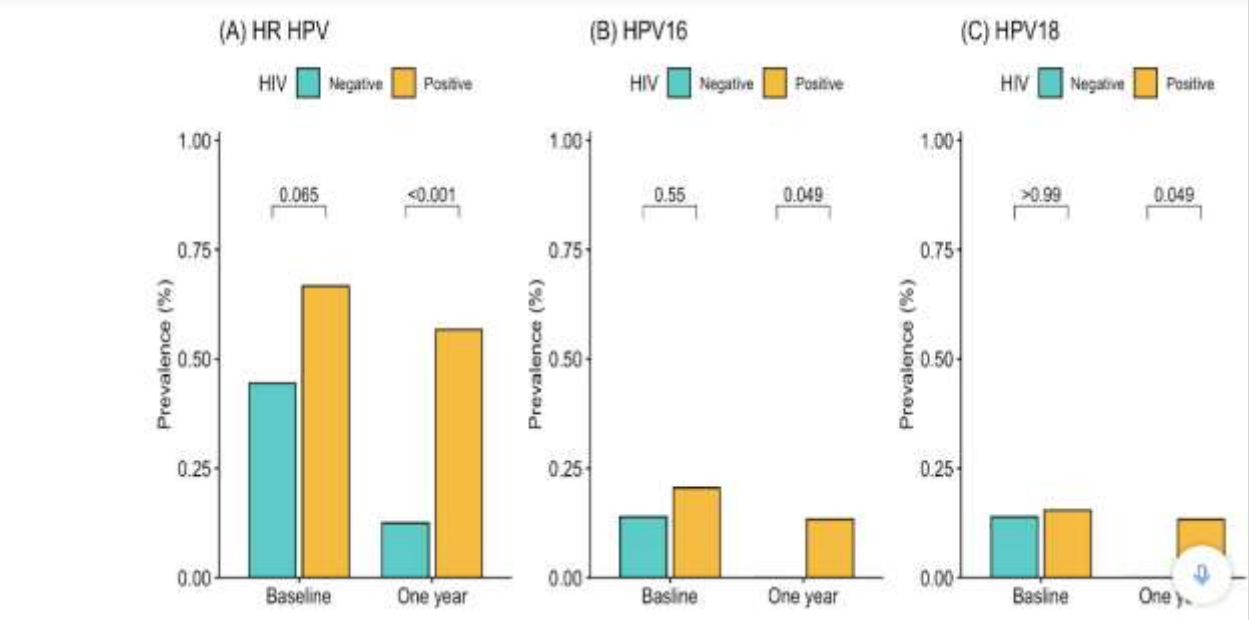
Omenge Orang'O[1], Tao Liu[2], Aaron Ermel[3], Peter Itsura[4], Phillip Tonui[4], Kapten Muthoka[5], Patrick Loehrer[3], Darron Brown[3], Susan Cu-Uvin[6]
[1]Aga Khan University, Obstetrics And Gynaecology, Nairobi, Kenya, [2]Brown University School of Public Health, Biostatistics, Center For Statistical Science, Providence, United States of America, [3]Indiana University School of Medicine, Medicine, Indianapolis, United States of America, [4]Moi University, Reproductive Health, Eldoret, Kenya, [5]Moi University, Cervical Cancer Screening Program, Ampath,, Eldoret, Kenya, [6]Brown University, Obstetrics And Gynecology, Providence, United States of America

Introduction: Almost all cervical cancers are caused by persistent high-risk human papillomaviruses (HR-HPV) infection. Persistent HR-HPV infection is more common among women with HIV (WHIV) compared to HIV-negative women (HNW). The study aims to compare the prevalence before Loop Electrosurgical Excision Procedure (LEEP) and persistence of HR-HPV at 12 months after LEEP for CIN2/3
among WHIV and HNW

Methods: A prospective observational study was conducted of baseline HR-HPV and at 12 months after LEEP for CIN2/3 diagnosed by biopsy. Data on demographics, CD4, HIV viral load, and antiretroviral therapy were collected. IARC HR-HPV include: HPV16,18,31,33,35,39,45,51,52,56,58,59 and 68. HPV typing was performed using Roche Linear Assay. Prevalence is defined as presence of HR-HPV and type at baseline. Persistence is defined as presence of the same HR-HPV and type after LEEP in the same woman. Differences between WHIV and HNW were compared using Fisher's exact test. Changes from baseline to 12 months post-LEEP were compared using McNemar's test.

Results: 75 women with diagnosed CIN2/3 underwent LEEP, including 39 (52%) WHIV and 36 (47%) HNW. HNW were younger, had higher education, and used less condoms. At baseline, HR-HPV prevalence was higher in the WHIV group (67% vs 44%) but the difference was marginally insignificant (p=0.065). The most common HR-HPV was HPV16 for both groups (21% WHIV vs 14% HNW, p=0.55). At
12 months (n=50) after LEEP, persistent HR-HPV was higher among WHIV compared to HNW at 46% and
12%, respectively (p=0.007). HPV18 was the most common persistent type (13% WHIV vs 0% HNW, p=0.092). Among WHIV, neither CD4 nor HIV viral load was predictive of HPV prevalence or

persistence.



Conclusions: There is a high prevalence of HR-HPV infection among women with CIN2/3 regardless of HIV status. Despite LEEP, persistent HR-HPV infection is more common in WHIV. LEEP does not completely eradicate HPV infection, especially in WHIV.

Shift 02-232 / #813

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02J. DIAGNOSIS AND MANAGEMENT OF HPV DISEASE IN PEOPLE LIVING WITH HIV AND OTHER FORMS OF IMMUNOCOMPROMISE
04-20-2023 7:00 AM - 4:00 PM

AN INTEGRATED HUMAN PAPILLOMAVIRUS TESTING BASED COMPREHENSIVE CERVICAL CANCER PREVENTION AMONG WOMEN LIVING WITH HIV IN A RESOURCE LIMITED SETTING

Dorcas Obiri-Yeboah[1], Patrick Akakpo[2], Sebastian Ken-Amoah[3], Nancy Enyan[4], Elizabeth Agyare[5], Emmanuel Salia[1], Leonard Derkyi-Kwarteng[2], George Adjei[6]
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Introduction: Women living with HIV (WLHIV) have proven higher burden of persistent human papillomavirus (HPV) infection, and associated conditions. Recent recommendation towards the global elimination targets require reducing HPV infection, increase testing and management of associated conditions. This study sought to pilot a comprehensive and integrated programme based on HPV testing for WLHIV.

Methods: The study was conducted at the antiretroviral therapy (ART) clinic of Cape Coast Teaching Hospital, Ghana. Eligible WLHIV 25-65 years old were recruited using simple random sampling. Questionnaires were administered. Detection of 15 high-risk HPV genotypes from self-collected cervico-vaginal samples was done using the AmpFire HPV detection system (Atila BioSystem, Mointain View, CA) in a “screen-triage-treat” approach. Triaging, treatment and follow up were based on the World Health Organisation 2021 guidelines. Activities were scheduled within the routine clinic visit as much as possible. Educational leaflets were distributed to WLHIV in English or the local dialect of Fante. Data were exported to STATA 16.0 for cleaning and analysed using descriptive and logistic regression methods.

Results: Total of 330 participants with mean age 47.2 years (SD ±10.7), were included. Hr-HPV prevalence was 42.7% (n=141, 95%C.I: 37.4-48.1), commonest types were HPV59 (50.4%), HPV18 (30.5%), and HPV35 (26.2%). Multiple hr-HPV rate was 60.3% (n=85) and 57.4% (n=81) had 2-5 genotypes and 37.6% (n=53) had HPV16/18. High HIV viral load (AOR=5.58, 95%CI: 2.89-10.78, p<0.001) was associated with being co-infected with HPV. Educational level (AOR=7.55, 95%CI: 1.34-42.43, p=0.022) was associated with cervical cancer knowledge.

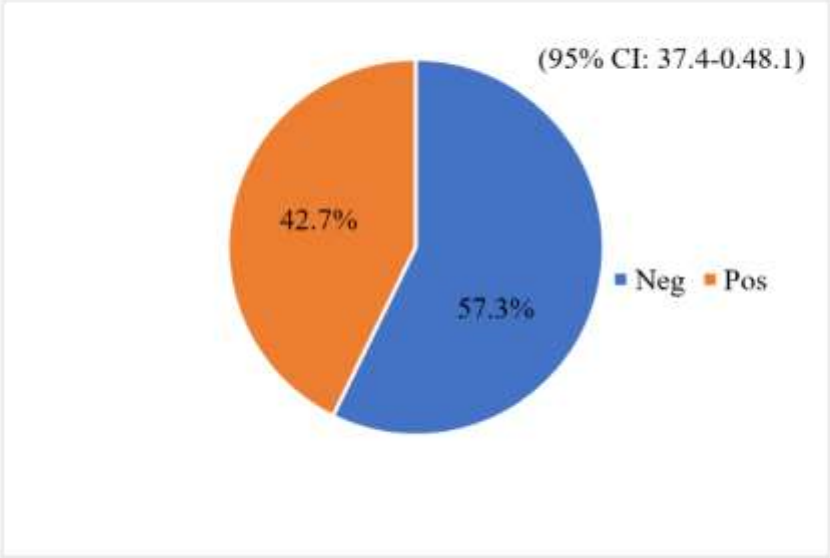

Figure 1: The distribution of hr-HPV prevalence among study participants (N=330)

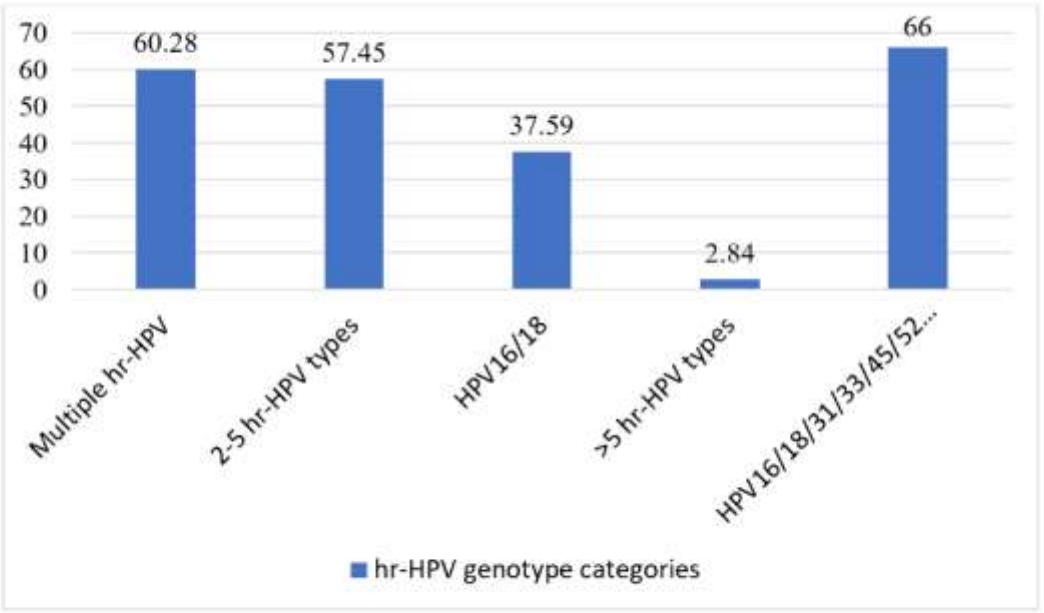

Figure 2: Types of hr-HPV genotype categories of coinfected participants (N= 141)

Conclusions: The hr-HPV prevalence remains high in women with HIV in this study with high rates of multiple infections and infection with genotypes 16/18. Comprehensive HIV care for these women should be integrated with their service provision. HPV-based screen-triage-treat approach with partial genotyping may reduce precancerous lesion treatment waiting time and should be further investigated in the local context of LMICs.

Shift 02-233 / #932

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02J. DIAGNOSIS AND MANAGEMENT OF HPV DISEASE IN PEOPLE LIVING WITH HIV AND OTHER FORMS OF IMMUNOCOMPROMISE
04-20-2023 7:00 AM - 4:00 PM

INCIDENCE AND PERSISTENCE OF CERVICAL AND ANAL HIGH-RISK HPV IN KIDNEY TRANSPLANT RECIPIENTS: RESULTS FROM A DANISH CLINICAL STUDY

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Introduction: Certain cancers related to infection with high-risk human papillomaviruses (hrHPV), such as cervical and anal cancer, are more common in kidney transplant recipients (KTRs). KTRs receive lifelong immunosuppressive therapy, which may decrease their ability to clear a hrHPV infection, but currently limited knowledge exists on the natural history of hrHPV infection in KTRs. In this prospective clinical study, we compared the incidence and persistence of cervical and anal hrHPV infection in KTRs to immunocompetent controls.

Methods: During 2016–2017, we recruited 125 female KTRs and 125 female immunocompetent controls. Liquid-based cervical and anal cytology samples (BD SurePath) were tested for HPV DNA (BD Onclarity HPV test) at baseline and at follow-up approximately 1–2 years later. All participants answered a questionnaire on lifestyle and sexual behavior at baseline and at follow-up. Incident infection was defined as testing positive at follow-up for an HPV type not identified at baseline. Persistent infection was defined as testing positive for the same HPV type at baseline and follow-up.

Results: KTRs had a higher incidence of cervical hrHPV infection than controls (OR = 3.74, 95% CI: 1.18–11.87) after adjustment for age, time since baseline, and vaginal sex since baseline, while no difference was observed for incident anal hrHPV infection (OR = 0.74, 95% CI: 0.30–1.82). Furthermore, among hrHPV positive at baseline 87.5% of KTRs and 10.0% of controls had a persistent cervical hrHPV infection, while 89.7% of KTRs and 64.7% of controls had a persistent anal hrHPV infection.

Conclusions: Female KTRs had a higher incidence of cervical hrHPV than controls, and were more likely to have persistent infection with both cervical and anal hrHPV compared to controls. Our findings support that KTRs are at an increased risk of HPV infection and HPV-related diseases, and that prevention efforts in this population are required.

Shift 02-235 / #1461

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02J. DIAGNOSIS AND MANAGEMENT OF HPV DISEASE IN PEOPLE LIVING WITH HIV AND OTHER FORMS OF IMMUNOCOMPROMISE
04-20-2023 7:00 AM - 4:00 PM

US-LATIN AMERICAN-CARIBBEAN HIV/HPV-CANCER PREVENTION CLINICAL TRIALS NETWORK (ULACNET): DEVELOPMENT, MANAGEMENT, AND PROGRESS OF AN INTERNATIONAL CANCER RESEARCH INITIATIVE

Vikrant Sahasrabuddhe, Margaret House, Emma Brofsky, Silvina Frech, Brandy Heckman-Stoddard, Nci Ulacnet Management Team
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Introduction: Evidence informing strategies and approaches for preventing HPV-related cancers is lacking/limited for persons living with HIV who are at high-risk for the development of these cancers. Optimization of intervention strategies (e.g., dosing, delivery, triage/management) and validation of novel innovations in this sub-population remains underexplored in this population and demands rigorous evaluations in clinical trials.

Methods: With a goal to expand evidence on outstanding prevention-focused research questions, the National Cancer Institute (NCI) launched 'ULACNet', a new U54-Cooperative Agreement-funded clinical trials network in 2019, where US-based lead academic institutions work collaboratively with Latin American and Caribbean (LAC) institutional counterparts and with the NCI to develop and conduct multicenter prevention clinical trials focused on filling key scientific gaps and evaluating novel interventions. We report on progress over the past three years and highlight successes and opportunities.

Results: With seven partnering countries (US, Puerto Rico, Brazil, Mexico, Peru, Dominican Republic, and Haiti), over twenty partner institutions, and >150 collaborating scientific investigators, clinical and public health practitioners, research staff, and patient advocates, ULACNet is collaboratively designing and conducting nine clinical trials in persons with HIV (two prophylactic HPV vaccine trials in adults and children/adolescents, three trials for clinical validation of molecular biomarkers and imaging technologies for cervical/anogenital screening and triage, and four trials of candidate therapeutic vaccines/topical therapeutic agents for HPV/precancer). Network interactions occur via a Coordinating Committee and Working Groups, and activities with special emphasis for community/participant involvement, accrual monitoring, data reporting, and quality assurance are supported by NCI centrally. Despite delays due to COVID, three open/active trials have cumulatively enrolled >510 participants (October 2022), and others are in various stages of development/approvals.

Conclusions: ULACNet is nurturing international partnerships that are expected to generate actionable evidence for improving clinical care and enhance human and institutional capacity of partnering LAC institutions to conduct high-quality HIV/HPV-cancer prevention clinical trials.

Shift 02-237 / #855

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-20-2023 7:00 AM - 4:00 PM

IMPROVING THE COLPOSCOPY PERFORMANCE OF JUNIOR COLPOSCOPIST VIA ARTIFICIAL INTELLIGENCE

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Introduction: Well-trained colposcopists are in huge shortage worldwide, especially in low resource areas. Here we aimed to evaluate The Colposcopic Artificial Intelligence Auxiliary Diagnostic System (CAIADS) to detect abnormalities based on digital colposcopy images, especially focus on its role in assisting junior colposcopist to correctly identify the lesion areas where biopsy should be performed.

Methods: This is a hospital-based retrospective study, which recruited 366 out of 1146 women who met inclusion and exclusion criteria between September 2021 to January 2022 in China. Anonymized colposcopy images were reviewed by CAIADS and a junior colposcopist separately, and the junior colposcopist reviewed the colposcopy images with CAIADS results (named CAIADS-Junior). The diagnostic accuracy and biopsy efficiency of CAIADS and CAIADS-Junior were assessed in detecting CIN2+ (cervical intraepithelial neoplasia grade 2 or worse), CIN3+, and cancer in comparison with the senior and a junior colposcipist

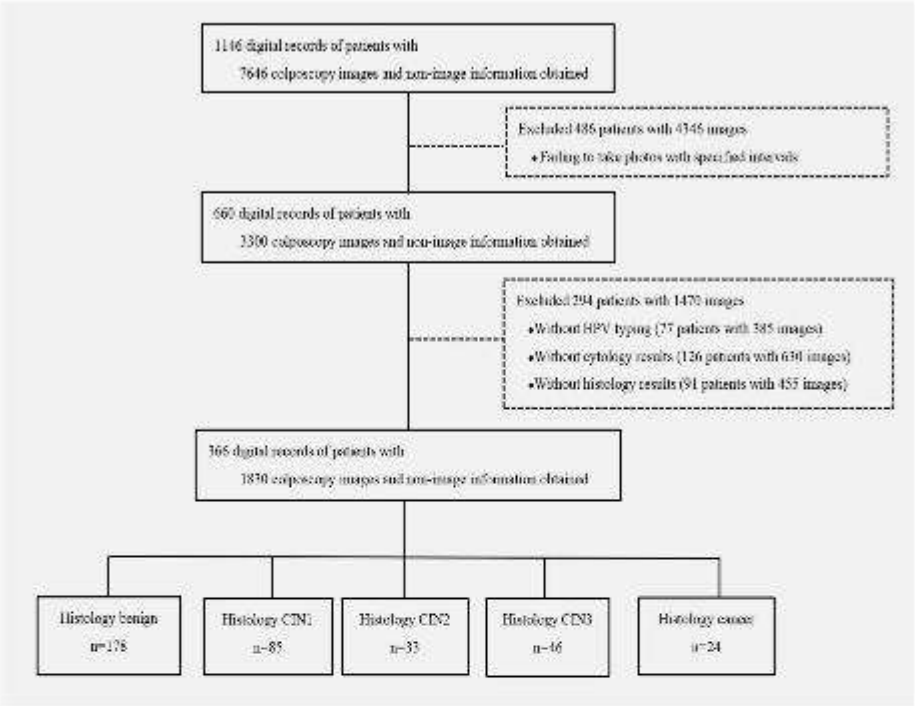

Figure 1 Study flowchart.
Note: Non-imaging information includes clinical characteristics (HPV, cytology, colposcopy impression, biopsy, etc.) and demographic characteristics (age, education, reproductive history, menopausal experience, etc.) from women's medical record.
Abbreviations: CIN, Cervical Intraepithelial Neoplasia; HPV, human papillomavirus; CIN1, CIN2, CIN3 represented CIN grade 1, CIN grade 2, CIN grade 3.

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Results: For CIN2+ and CIN3+ detection, CAIADS-Junior was significantly higher than junior colposcopist in sensitivity (for CIN2+: 95.1% vs 79.6%, p=0.002 and for CIN3+: 97.1% vs 85.7%, p=0.039), and were comparable to senior colposcopist (for CIN2+: 95.1% vs 91.3%, p=0.388 and for CIN3+: 97.1% vs 90.0%, p=0.125). In detecting cervical cancer, CAIADS achieved the highest sensitivity

at 100% and also assisted junior colposcopist to improve the sensitivity from 87.5% to 95.8% (p=0.625). When CIN grades became higher, the average biopsy numbers decreased for the subspecialists and CAIADS required minimum biopsies number to detect per case (2.2-2.6 cut-points). Meanwhile, the biopsy sensitivity of junior colposcopist was the lowest, but CAIADS assisted junior colposcopist to achieve a higher biopsy
sensitivity.

Table 1. Diagnostic Performance of subspecialists for different clinical end-points

Subspecialists	AUC 95% CI	Sensitivity (%) (n/N) 95% CI	Specificity (%) (n/N) 95% CI	PPV (%) (n/N) 95% CI	NPV (%) (n/N) 95% CI
CIN2+					
Senior colposcopist	0.690 0.640-0.737	91.3 (94/103) 84.2-95.3	46.8 (123/263) 40.8-52.8	40.2 (94/234) 34.1-46.6	93.2 (123/132) 87.6-96.4
CAIADS	0.720 0.671-0.766	80.6 (83/103) 71.9-87.1	63.5 (167/263) 63.0-71.4	46.4 (83/179) 39.2-53.7	89.3 (167/187) 84.1-93.0
Junior colposcopist	0.641 0.590-0.691	79.6(82/103) 70.8-86.3	48.7 (128/263) 42.7-54.7	37.8 (82/217) 31.6-44.4	85.9 (128/149) 79.4-90.6
CAIADS-Junior	0.717 0.668-0.763	95.1(98/103) 89.1-97.9	48.3 (127/263) 42.3-54.3	41.9 (98/234) 35.7-48.3	96.2 (127/132) 91.4-98.37
CIN3+					
Senior colposcopist	0.661 0.610-0.710	90.0 (63/70) 80.7-95.1	42.2 (125/296) 36.7-47.9	26.9 (63/234) 21.7-33.0	94.7 (125/132) 89.5-97.4
CAIADS	0.692 0.642-0.739	80.0(56/70) 69.2-87.7	58.4 (173/296) 52.8-63.9	31.3 (56/179) 25.0-38.4	92.5 (173/187) 87.8-95.5
Junior colposcopist	0.663 0.612-0.712	85.7(60/70) 75.7-92.1	47.0 (139/296) 41.4-52.7	27.6 (60/217) 22.1-34.0	93.3 (139/149) 88.1-96.3
CAIADS-Junior	0.705 0.656-0.752	97.1 (68/70) 90.2-99.2	43.9 (130/296) 38.4-49.6	29.1 (68/234) 23.2-35.2	98.5 (130/132) 94.6-99.6
Cancer					
Senior colposcopist	0.648 0.597-0.697	91.7 (22/24) 74.2-97.7	38.0 (130/342) 33.0-43.3	9.4 (22/234) 6.3-13.8	98.5 (130/132) 94.6-99.6
CAIADS	0.773 0.727-0.815	100.0 (24/24) 86.2-100.0	54.7 (187/342) 49.4-59.9	13.4 (24/179) 9.2-19.2	100.0(187/187) 97.99-100
Junior colposcopist	0.651 0.600-0.700	87.5 (21/24) 69.0-95.7	42.7 (146/342) 37.6-48.0	9.7 (21/217) 6.4-14.3	98.0 (146/149) 94.25-99.31
CAIADS-Junior	0.671 0.620-0.719	95.8 (23/24) 79.8-99.3	38.3 (131/342) 33.3-43.6	9.8 (23/234) 6.6-14.3	99.2 (131/132) 95.8-99.9

Abbreviations: CAIADS, Colposcopic Artificial Intelligence Auxiliary Diagnostic System; CAIADS-Junior, CAIADS-assisted junior colposcopist; NPV, negative predictive value; PPV, positive predictive value; CIN2, cervical intraepithelial neoplasia grade 2; 95% CI, 95% confidence intervals; CIN1+, CIN1 or worse; CIN2+, CIN2 or worse; CIN3+, CIN3 or worse; AUC, area under the curve, respectively.

Conclusions: CAIADS could assist junior colposcopist to improve the diagnostic accuracy and biopsy efficiency in cervical cancer screening, which might be a promising solution to improve cervical cancer screening quality in low resource settings. Still, we need population-based cohort evaluate the real-world effectiveness of CAIADS.

Shift 02-238 / #1240

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-20-2023 7:00 AM - 4:00 PM

HOW TO IMPROVE BRAZIL'S CERVICAL CANCER PREVENTION PROGRAM: THE MARCO PROJECT PROPOSAL

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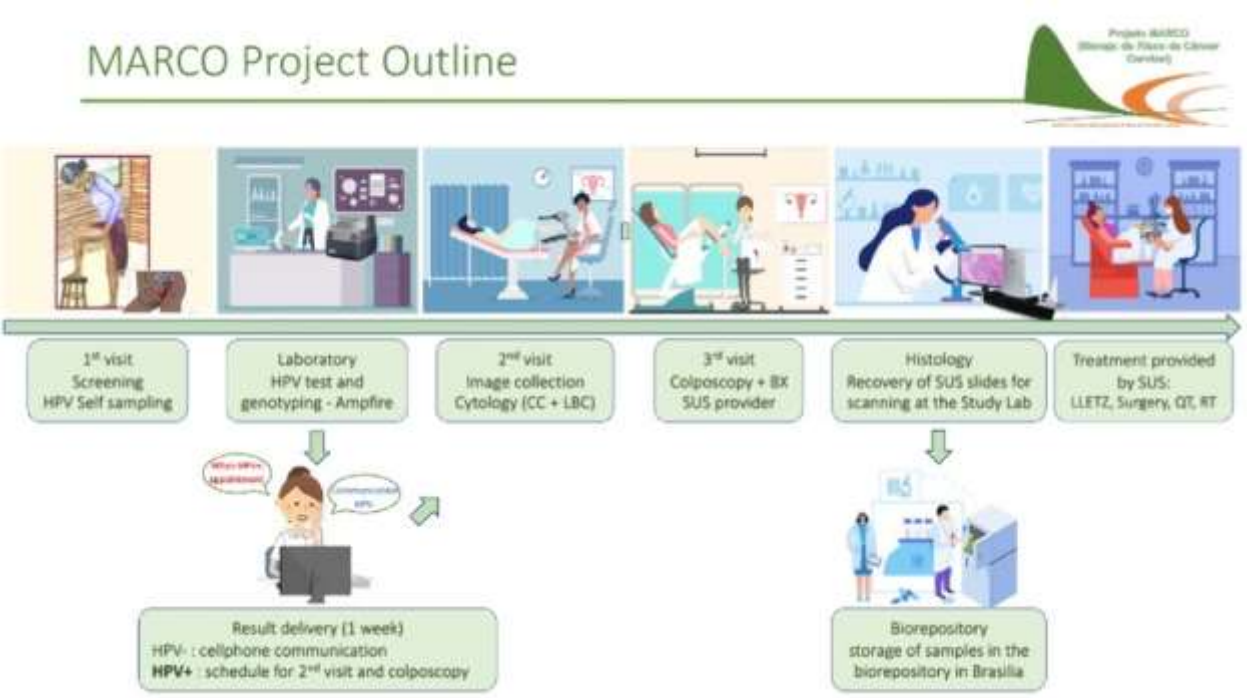
Introduction: For decades, the Brazilian Public Health System (SUS) has been screening women 25-64 years old with conventional cytology. HPV vaccination was introduced in 2014. However, mortality and incidence rates are still high, 4.6 deaths per 100,000 women in 2020 and 15.4 new cases per 100,000 women are expected for 2022 with substantial regional differences. Countries are switching to HPV primary screening since it has been shown to be cost-effective. However, scant data regarding how to triage and manage HPV positive women is still a major problem especially when considering the different scenarios found within Brazil?

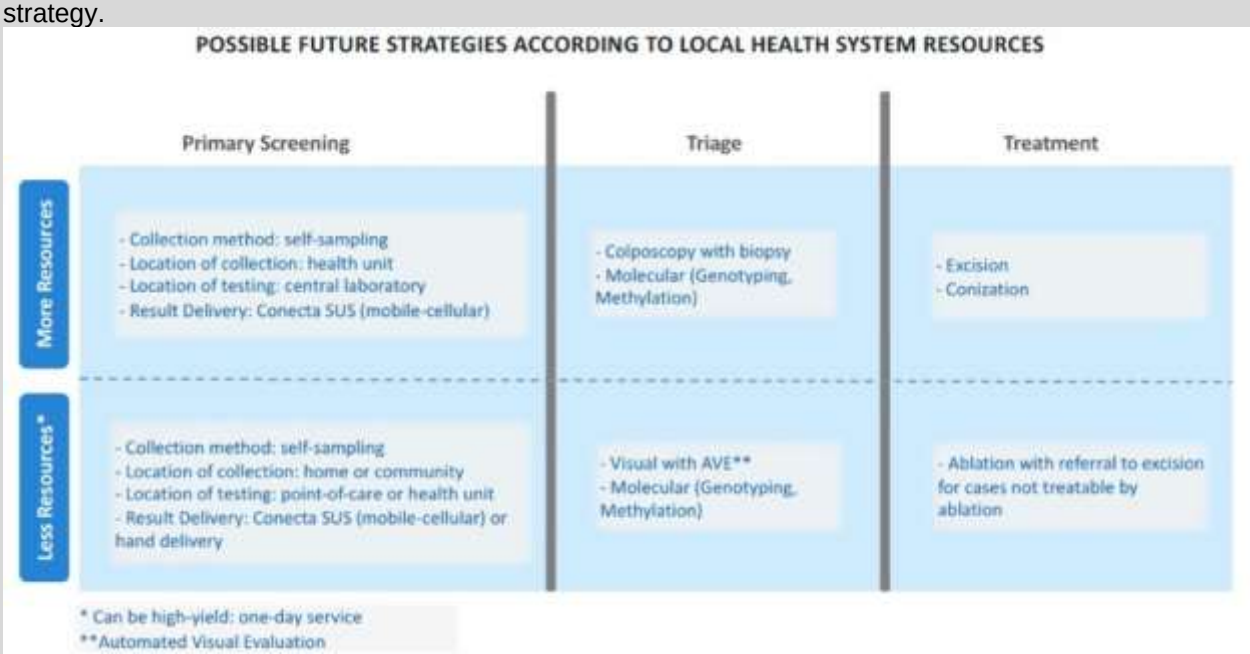
Methods: In Brasília and Manaus, dry self-collected cervical samples will be collected for HPV testing from up to 20,000 consenting women, 30 to 49 years of age in areas with limited infrastructure. Among women who test positive for high-risk HPV we will collect cervical samples and images after acetic acid application. We will perform cost-effectiveness evaluation of the following triage tests: HPV genotyping with automated visual evaluation of cervical images (AVE), colposcopic impression, conventional and liquid-based cytology. HPV positive women also will be referred for colposcopic evaluation with multiple biopsies of acetowhite areas. Treatment will be performed by SUS according to Brazilian

guidelines.



Results: In Brazil, despite the universal health care system, many socially vulnerable areas do not have immediate access to basic health, such as remote areas or informal settlements. Delayed results delivery in addition to long waiting lists for specialized care increase the loss to follow-up of those attending screening, thus further decreasing the potential impact of the current prevention program.

Conclusions: A comprehensive comparison of different triage tests after a positive self-collected HPV test result will provide critical evidence for newer up-to-date flexible guidelines that adapt to the local scenario looking forward towards a one-day point of care excellent risk stratification and treatment strategy.



Shift 02-239 / #1329

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-20-2023 7:00 AM - 4:00 PM

TREND IN INCIDENCE OF CERVICAL CANCER AMONG 35 YEAR OLD WOMEN AND BELOW IN A TERTIARY CENTER IN LOW INCOME COUNTRY; NIGERIA.

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Introduction: There are conflicting reports in the incidence and trend of cervical cancer (CC) among the young people. However, not much in known about this group in the in LMICs. Thus, the objective of this study is to evaluate the trend of cervical cancer among the young CC Patients, histological pattern and socio- demographic data among the young CC patients.

Methods: An 11 year(2009 -2019) retrospective review of histological diagnosed CC among 35 years and below pts at National Hospita Abuja, a tertiary institution in Nigeria .Data was extracted from the cancer registry and from the patients' folders. Data analysis was carried out using IBM SPSS version 25. Descriptive statistics was carried out and data was summarized using mean, and standard deviation, median and ranges for quantitative variables such as age. Categorical variables were summarized using frequencies and percentages. Line graph was used in showing trends of cases over the years .

Results: A total of of 1469 cases of cervical cancer was recorded under the study period of which 114 (7.7%) were 35 years and below. 92 out of the 114 were analysed. there was sustained increase in from 2009 to 2012 with slight decrease in 2013. However, the decrease was not sustained. the highest increase was recorded in 2015(15.2%) and the lowest was in 2017. Squamous cell carcinoma accounted for the commonest histological type(84.8%) while Adenocarcinoma accounted for 15.2%.The mean age of 31.85. Most of the patients were married (73.9%) , para 3 was the commonest parity (32.6%) followed by para 2 (26.1%). Unfortunately, Most of the patients presented late (stage 2- 44.6% & 3 - 43.5%)

Conclusions: There is a need for more research among young young age group with CC in low resource country and more awareness of CC among them to prevent the late presentation recorded in this study

Shift 02-241 / #1414

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-20-2023 7:00 AM - 4:00 PM

ASSOCIATIONS OF BACTERIAL VAGINOSIS AND SMOKING WITH HPV CLEARANCE AND PRECANCER IN STRIDES: STUDYING RISK AND IMPROVING DISPARITIES IN MISSISSIPPI.

Carolann Risley[1,2], Nicolas Wentzensen[2], Rajesh Talluri[3], Nita Maihle[4], Masoumeh Karimi[1], Sydney Reaves[1], Laree Hiser[1], Kim Geisinger[5], Ken Owens[6], Ashish Jannela[6], Rhonda Rives[7], Thomas Dobbs[8,9], Mary Stewart[1], Lei Zhang[1], Megan Clarke[2]
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Introduction: STRIDES (Studying Risk and Improving Disparities) is a statewide longitudinal cohort, including individuals undergoing cervical cancer screening in Mississippi, USA. STRIDES was designed to evaluate HPV natural history and biomarkers for cervical carcinogenesis in a racially diverse population with a high burden of cervical precancer and cancer. Here we evaluated the association between smoking and cytology-diagnosed bacterial vaginosis (BV) and carcinogenesis by race.

Methods: STRIDES includes 37,897 individuals screened with Pap cytology from 1/4/2018 to 8/18/2022. HPV testing was done with either cobas4800® or Onclarity™. From the full cohort we selected a sample of those with cervical intraepithelial neoplasia (CIN2+) at any visit; clearance = HPV positive at visit 1 and HPV negative at visit 2; and persistence = HPV positive at both visits. We performed logistic regression analyses adjusted for age, race, smoking, and BV, combining clearance and persistence as the reference category.

Results: A total of 231 with CIN2+, 394 with clearance, and 631 with persistence were included. A majority (70.9%) are Black, followed by White (22.8%), and mean age of 37 years. Compared to never smokers, current smokers were 1.48 (95% CI 1.037-2.097) times more likely to have CIN2+ vs clearance/persistence. When stratified by race, current smoking White individuals were 2.36 (95% CI 1.24-4.64) times more likely to have CIN2+ vs clearance/persistence; while no association was seen for Blacks (1.18, 95% CI 0.75-1.82). Those with BV were 0.48 (95% CI 0.32-0.69) times less likely to have CIN2+ compared to clearance/persistence. When stratified by race, no differences were seen.

Conclusions: In this diverse population with elevated risk for cervical cancer, smoking is associated with increased odds of CIN2+, in line with other studies and cohorts. Interestingly, BV was significantly associated with decreased odds of CIN2+. Further investigation of these associations using molecular BV classification is underway.

Shift 02-242 / #1429

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-20-2023 7:00 AM - 4:00 PM

PREVENTING CERVICAL CANCER IN OLDER VIETNAMESE WOMEN: A PILOT STUDY

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Introduction: Our aim is to establish the feasibility and response rate of a population-based screening programme for Vietnamese women aged over 50. Almost all cervical cancers in post-menopausal women are caused by HPV infection acquired before age 50 and about 80% of cervical cancer deaths occur after age 50. A single HPV test after menopause with treatment of HPV positive women either immediately or after retesting a year later to exclude transient infections is therefore a practicable means of achieving a large reduction in lifetime cancer risk.

Methods: Women aged 50-64 resident in 10 small districts in Ho Chi Minh City will be invited. Recruitment will continue until 300 have been screened. A sample of 100 current or former female sex workers will also be invited. Younger women are at substantial risk of acquiring a new HPV infection, so a single test cannot confer high lifelong protection, and radical cervical treatment can predispose to subsequent premature delivery. Participants will attend a district health centre to complete a questionnaire and provide a self-administered vaginal swab followed by a nurse-taken LBC sample. Cytology will be done only on HPV+ samples. HPV+ women with abnormal cytology will be referred for colposcopy and management according to hospital guidelines. Other HPV+ women will retested after a year. Those still HPV+ (with or without cervical abnormality) will be offered colposcopy and LEEP if deemed feasible.

Results: Initial findings will include recruitment, HPV prevalence, and attitudes and knowledge on HPV and screening. The main outcomes at follow-up will be the proportion of HPV+ women who attend for retesting, the HPV clearance rate within a year and the proportion of those still HPV positive in whom LEEP can be performed.

Conclusions: We hope to demonstrate that national HPV screening of older women is feasible and affordable.

Shift 02-243 / #1765

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-20-2023 7:00 AM - 4:00 PM

REFLEX CYTOLOGY VERSES MOLECULAR HPV DNA TEST TO TRIAGE WOMEN SCREENED WITH VISUAL INSPECTION BASED PRIMARY CERVICAL CANCER SCREENING PROGRAM IN INDIA.

Sharmila Pimple[1], Tanuja Teni[2], Gauravi Mishra[1], Saleem Pathuthara[3]
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Introduction: Visual Inspection with Acetic acid [VIA] for cervical cancer screening has shown wide variation in its performance due to the subjective nature of test interpretation. VIA positivity have variable clinical outcomes and most do not have clinically significant disease. Thus Low specificity and low positive predictive value have resulted in excess referrals as well as increased cost of unnecessary treatment with " See and Treat " strategies adopted in LMIC settings.

Methods: Primary Objective: To identify a highly specific test to triage excess false positives from primary cervical screening programs with Visual Inspection with 5% Acetic acid [VIA].Women in the age group of 25-65 years were screened with the primary screening test VIA between 2013 to 2018. VIA test positive women were further offered secondary screening tests viz Hybrid Capture-II (HC-II) and conventional cytology test. The reference standard for final disease status was Histopathology.

Results: The sensitivity and specificity with 95%CI of HPV DNA testing was 77.94 (66.24-87.10), 91.57 (89.68-93.22) and that of cytology test was 77.94 (66.24-87.10), 97.96 (96.83-98.77) respectively. The positive predictive value [PPV] of HPV DNA was 38.69 (33.16-44.52) and that of cytology was 73.61 (63.72-81.59).

Conclusions: Conventional cytology test is equally sensitive and more specific with higher PPV than HPV DNA test. Laboratory infrastructure for establishing Molecular HPV DNA testing in public health programs is still unaffordable in many LMIC settings. In countries like India where basic infrastructure for conventional cytology exists in secondary health care settings at the District and rural hospital settings, can therefore offer reflex cytology triage for VIA positive women to avoid unnecessary overtreatments with a high sensitive but a subjective VIA screening test for cervical cancers .

Shift 02-244 / #1834

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02K. SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN LOW-RESOURCE SETTINGS
04-20-2023 7:00 AM - 4:00 PM

CLINICAL OUTCOME AT ONE-YEAR-POST-TREATMENT OF HUMAN PAPILLOMA VIRUS AND PRECANCEROUS LESIONS OF THE CERVIX AMONG FEMALE SEX WORKERS IN CAMEROON

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Cameroon Baptist Convention Health Services, Women's Health Program, Yaounde, Cameroon

Introduction: In 2020, we screened 940 female sex workers (FSWs) in Cameroon ≥25yrs with visual inspection with acetic acid and Lugol's iodine (VIA-VILI) enhanced by Digital Cervicography (DC) plus AmpFire HPV genotyping for those ≥30yrs. A total of 42.3% FSWs were positive for HPV and/or VIA-VILI-DC. Those with positive VIA-VILI-DC were provided Large Loop Excision of the Transformation Zone (LLETZ) or Thermal Ablation (TA). Those positive for HPV without VIA-VILI-DC lesions were provided TA. We were interested to find out the 1-year posttreatment clearance of HPV and/or VIA-VILI-DC lesions among FSWs in Cameroon.

Methods: In 2021, we did a cross-sectional study of the cohort that was positive in 2020 whether treated/not treated

Results: We followed up 173(58.4%) of the anticipated 296 FSWs. Of the 173 FSWs, 152 had HPV genotyping in 2020 and only 55 (36.2%) had HPV clearance. Among the 55, 25 (45.5%) cleared spontaneously while 28 (50.9%) cleared after treatment. Among the 152 genotyping, 97 (63.8%) had persistent HPV infection including; 54 (55.7%) who were treated in 2020 and 43(44.3%) who were not treated. However, some had acquired additional HPV types to those they were originally identified with in 2020 while some had cleared some of the originally identified HPV types. Of particular interest, 1 FSWs who received no treatment had no change in her VIA-VILI-DC results but, her HPV changed from Types 35, 39, 52 to Types 45, 58, 66, 68. Another FSW had a post TA lesion that had progressed from a TA - eligible to a LLETZ-eligible lesion which came out CIN3. This particular FSW had increased of HPV types from 7 to all 15 types present in the AmpFire platform

Conclusions: FSWs have a high frequency of persistent/recurrent HPV and/or VIA-VILI-DC lesions at 1-year posttreatment

Shift 02-246 / #1388

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02L. NOVEL THERAPEUTIC APPROACHES TO TREATMENT OF HPV-RELATED DISEASE INCLUDING ANTIVIRALS
04-20-2023 7:00 AM - 4:00 PM

HPV DETECTION IN A CLINICAL TRIAL OF MEN WITH HIGH SQUAMOUS INTRAEPITHELIAL LESIONS (HSIL) TREATED WITH POMALIDOMIDE (CLINICAL TRIAL NCT 03113942)

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Introduction: Pomalidomide is an immunomodulatory agent with broad effects on immune activation and responsiveness including increased IL-2, enhanced CD4+/CD8+ T cell co-stimulation, and natural killer activity. The Study of Pomalidomide in Anal Cancer Precursors (SPACE), is evaluating whether treatment with this drug clears HPV-associated lesions in men with persistent HSIL, potentially preventing progression to anal cancer. Aim: To analyze the presence of HPV infections in the SPACE study.

Methods: The SPACE study is a single-center, open-label phase II trial. Participants received 2mg Pomalidomide once a day for 6 months. Anal cytology and anal swabs for HPV genotyping were collected at screening, in Cycle 1 to Cycle 6 of treatment (weeks 4, 8, 16, and 24), and 6 and 18 months of follow-up. HPV detection was evaluated using the Roche Linear Array HPV Genotyping kit and Anyplex II HPV HR detection assay, and composite results are presented combining the results of both assays.

Results: There were 27 participants at screening for HPV detection. Of these participants, 25 (92.6%) had follow-up samples (making a total of 150 samples). Composite results are shown in Table 1. At screening, HPV was detected in 96.3% of the samples, with hrHPV types in 85.2%, and multiple HPV infections in 81.5% of the samples. During treatment and follow-up, HPV was detected in 95.9% of the samples, with hrHPV types in 95.1% of the samples and multiple infections in 91.8%. There were no significant differences when comparing the proportion of participants with HPV infection before treatment and at >6 months of follow-up (p=0.3487). For individual participants, 100% had one concordant HPV type and 92% had two concordant types in at least three consecutive

visits.

Table 1. HPV detection before and after treatment with Pomalidomide in the SPANC study

	Base Line (n=27)	Treatment and follow up visits (n=123) *
Quality control negative	0 (0%)	1 (0.8%)
Quality control positive	27 (100%)	122 (99.2%)
HPV not detected	1 (3.7%)	5 (4.1%)
HPV detected	26 (96.3%)	117 (95.9%)
hrHPV	23 (85.2%)	116 (95.1%)
Single Infections	4 (14.8%)	5 (4.1%)
Multiple infections	22 (81.5%)	112 (91.8%)

*The denominator was 122 for the last five rows

Conclusions: In participants with persistent HSIL, there were no differences in the proportion of participants with HPV infection after treatment with Pomalidomide.

Shift 02-247 / #814

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02M. NOVEL DIAGNOSTIC TECHNOLOGIES FOR HPV-RELATED DISEASE
04-20-2023 7:00 AM - 4:00 PM

TOWARDS SAMPLE-TO-ANSWER HRHPV MRNA DETECTION FOR EARLY CERVICAL CANCER PREVENTION

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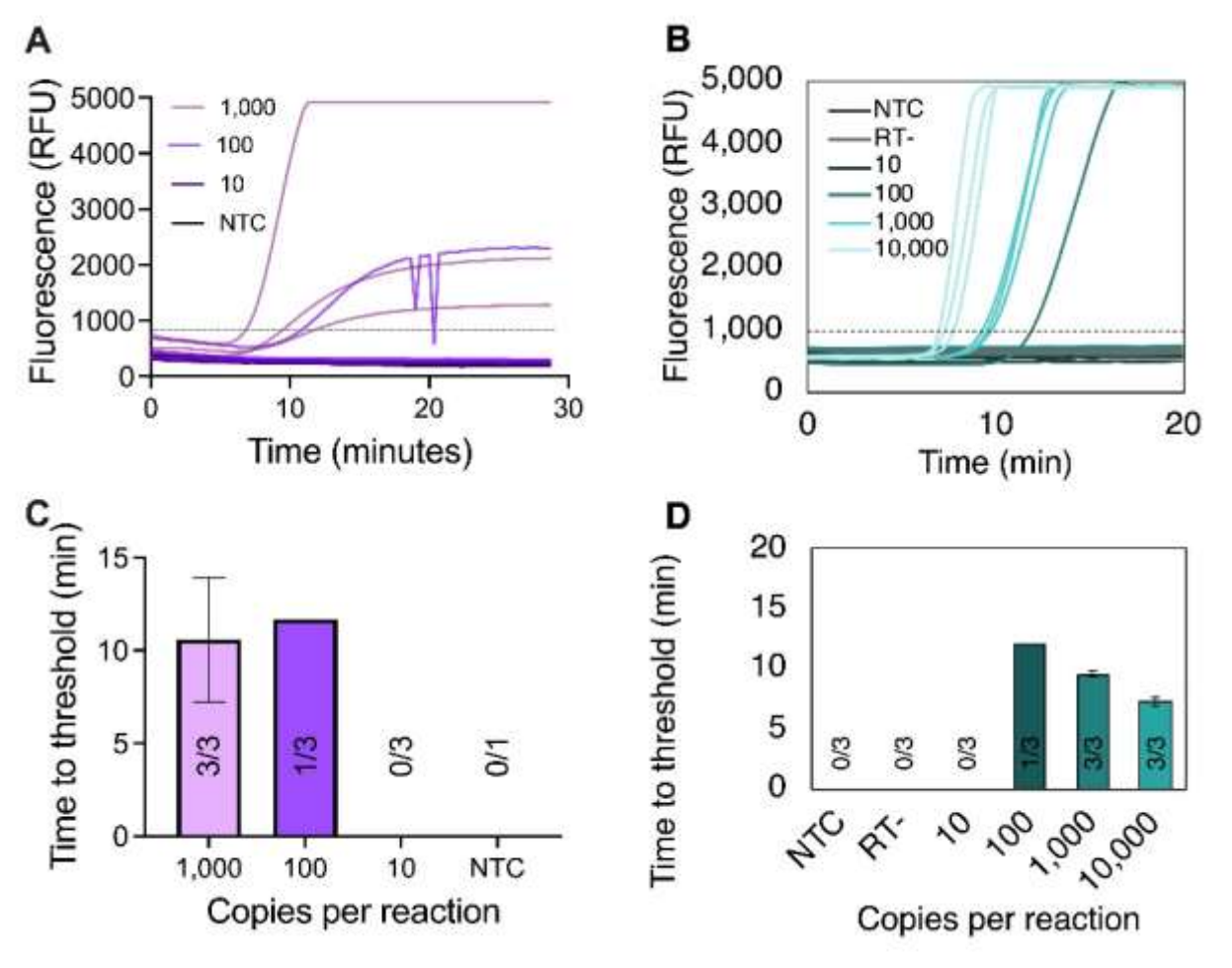
Introduction: Cervical cancer is preventable if detected early, but screening methods that identify pre-cancer are often not accessible to low- and middle-income countries (LMICs). The World Health Organization recommends high-risk HPV (hrHPV) screening for screen-and-treat programs, but since most HPV infections clear naturally, DNA testing can lead to overtreatment. mRNA is a more specific biomarker than DNA because when mRNA is detectable in a cervical sample, that infection is more likely to progress to pre-cancer. Current hrHPV mRNA testing methods, however, are insufficient for use in LMICs due to high costs, infrastructure limitations, and usability barriers.

Methods: Real-time reverse-transcription recombinase polymerase amplification (RT-RPA) reactions (TwistDx) were designed to detect HPV 16 and 18 mRNA in a tube and on a GF/DVA membrane (Cytiva). Next, cells lysed with achromopeptidase (ACP) (Sigma-Aldrich) were added to a paper assay. Each sample flowed down a nitrocellulose membrane (Unistart) to an area with cross-linked poly-thymine oligonucleotides (IDT) that captured the mRNA poly-A tails. Then, the mRNA was released by centrifugation and amplified using RT-qPCR. RPA amplification of HPV 18 DNA permitted optimization of the optical detection system.

Results: In-tube RT-RPA reactions amplified HPV 16 and 18 mRNA purified from cells at 100 copies per reaction (Figure 1). Purified HPV 16 mRNA and RNA from SiHa cells lysed with ACP were successfully recovered from the poly-T capture zone of the nitrocellulose and amplified using RT-qPCR (Figure 2). Finally, HPV 18 DNA amplified in GF/DVA and produced a quantifiable fluorescent signal.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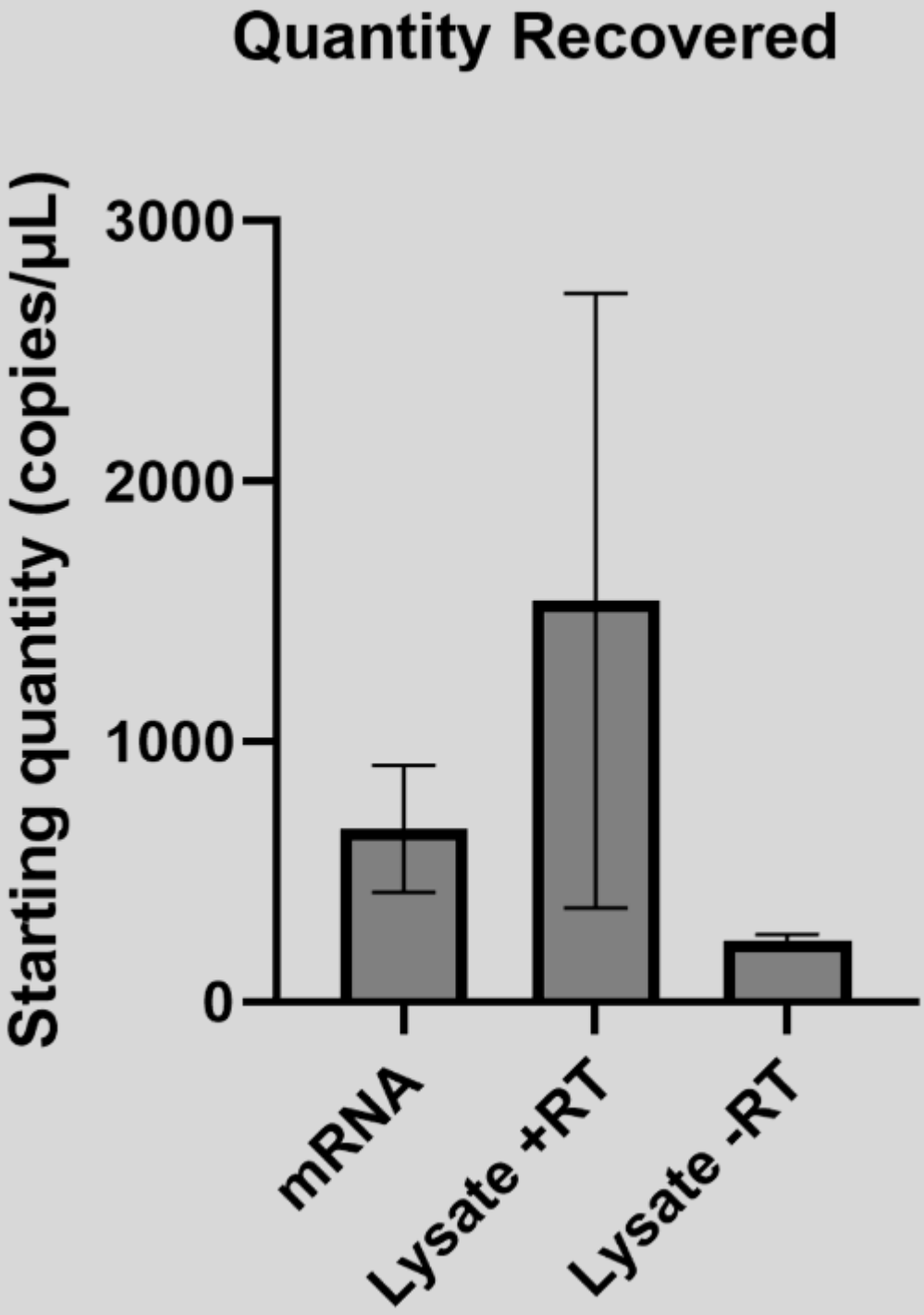
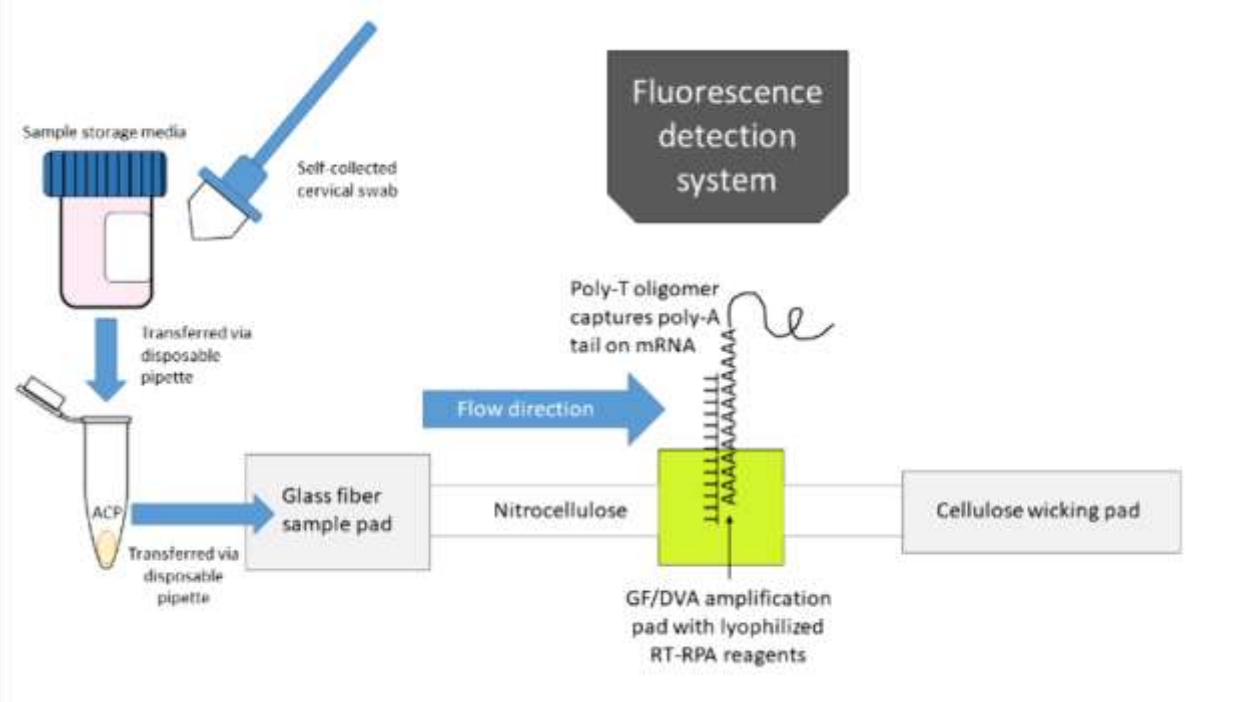


Conclusions: RT-RPA assays successfully amplified HPV 16 and 18 mRNA at near-clinically relevant limits of detection. Additionally, poly-T oligonucleotide capture is a promising method for equipment-free mRNA purification that can be integrated with on-paper amplification. Future work will include improving poly-T mRNA capture, designing a point-of-care optical reader and quantification algorithm, and

combining these components into a sample-to-answer device (Figure 3).



Shift 02-248 / #881

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02M. NOVEL DIAGNOSTIC TECHNOLOGIES FOR HPV-RELATED DISEASE
04-20-2023 7:00 AM - 4:00 PM

EVALUATION OF KAPA2G FAST TAQ IN HPV TYPESEQ, A NEXT GENERATION SEQUENCING PLATFORM FOR DETECTION OF 54 HUMAN PAPILLOMAVIRUS GENOTYPES

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Introduction: TypeSeq is a multiplexed next generation sequencing (NGS) based HPV typing assay that consists of 3 PCR steps. Step 1 PCR utilizes RNase H-dependent PCR (rhPCR) for improved specificity. The current protocol uses 60 mU of RNase H2, Vent Exo- polymerase, and the addition of several laboratory prepared reagents coupled with a 4 min annealing and extension (AE time). This study evaluated the use of Kapa2G, a Fast Taq polymerase that is contained in an optimized ready-to-use buffer mix for multiplex PCR.

Methods: Optimization of Kapa2G used 8 pools of synthetic DNA controls (SC) targeting 54 HPV types (each at 25 copies) and 4 pools of SC for 13 high risk (HR) types with 100, 50, 25 and 10 copies within each pool. Different AE times and amounts of RNase H2 were evaluated. Sequencing was done using MiSeq. Data was analyzed with a custom-built pipeline to evaluate the impact of changes in Step 1 PCR on its call-rate, read counts and bias (expressed per pool of HPV types). The standard Vent Exo- protocol was used as the comparator.

Results: With 4 min of AE, both Kapa2G and Vent Exo- protocols met the acceptance criteria (pass 102 out of 106 [>96%] HPV calls). With 2.5min of AE, Kapa2G resulted in 96.7% call-rate. Drop-out rate increased with AE faster than 2.5min. Performance of Kapa2G improved to 99.53% call-rate with 100mU RNaseH2 and 2.5 AE, compared to Vent Exo 98.1%. Comparison of read numbers and bias found no statistical difference between protocols. With Kapa2G, TypeSeq can be completed in 2 days and reduces the need for laboratory prepared reagents.

Conclusions: Kapa2G within TypeSeq reduces assay complexity and shortened assay time to 2 days from 3 days without affecting sensitivity. Additional validation of Kapa2G TypeSeq with surveillance specimens is in progress.

Shift 02-249 / #1266

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02M. NOVEL DIAGNOSTIC TECHNOLOGIES FOR HPV-RELATED DISEASE
04-20-2023 7:00 AM - 4:00 PM

AGREEMENT ON LESION LOCATION AT COLPOSCOPY

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Introduction: Colposcopy is a cornerstone in detecting and managing cervical precancer. Due to its subjective nature, colposcopy has high intra- and interobserver variation and low sensitivity. However, these estimates are based on grading of the colposcopic impression instead of agreement of the lesion location. In this study, we aimed to investigate the agreement of lesion location between colposcopists and if agreement increased with lesion severity.

Methods: Five colposcopists reviewed a series of images from 268 colposcopic examinations conducted with the DYSIS colposcopic system. Images were selected based on histologic diagnosis, i.e., normal (n=25), CIN1 (n=25), CIN2 (n=50), CIN3 (n=100), AIS (n=53), and invasive cancer (n=15). Each colposcopists annotated areas suspect of lesion. Hereafter, we compared the annotated area between colposcopists and estimated the average agreement for each case using the Dice coefficient (estimates range between 0-1 with 1 representing total agreement). Estimates of agreement were stratified by the histologic diagnoses.

Results: Overall, 209 out of 268 images were considered evaluable by at least three colposcopists. There was a trend towards higher agreement with increasing lesion severity; the agreement was lowest for cases with normal histology (0.12 (95% CI 0.06-0.7)), while the agreement was highest for CIN3 cases (0.48 (95% CI 0.29-0.66)). Of note, the agreement of AIS and invasive cancer was slightly lower than CIN3 corresponding to 0.41 (95% CI 0.17-0.63) and 0.44 (95% CI 0.27-0.624), respectively.

Conclusions: The preliminary results suggest low agreement of lesion location between colposcopists. However, there was a trend towards higher agreement among cases with CIN3 compared to those with normal histology.

Shift 02-251 / #958

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02N. RECURRENT RESPIRATORY PAPILLOMATOSIS
04-20-2023 7:00 AM - 4:00 PM

EVALUATION OF ANTIBODY RESPONSE TO HPV6,11,16 AND 18 IN CHILDREN WITH JUVENILE-ONSET RECURRENT RESPIRATORY PAPILLOMATOSIS

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Introduction: We conducted a multi-center observational study to assess the current seroepidemiology of juvenile onset recurrent respiratory papillomatosis (JORRP), a rare but serious condition involving wart-like lesions in the upper respiratory tract, caused by HPV 6 and 11.

Methods: Sera from 200 of 224 children with JORRP enrolled between January 2015 and August 2021 from multiple pediatric otolaryngology centers across the United States were tested for antibodies to HPV 6, 11, 16 and 18 using M4ELISA. Antibody titers were calculated using the parallel line method. Cut-off value for seropositivity was determined based on median+2SD of antibody titers after removal of outliers, generated from children's sera. Demographic and clinical information was abstracted from clinical records. Seropositivity to HPV 6, 11, and 16 (+/-18) was assumed to indicate prior exposure to quadrivalent HPV vaccine.

Results: Overall, 78 (39%) children with JORRP had evidence of quadrivalent HPV vaccine exposure. Among the remaining 122 children likely vaccine unexposed, 72 (59%) were seronegative to all types and 38 (31%) were seropositive to HPV 6 or 11. Geometric mean titers were 110 to 140-fold higher in vaccine-exposed compared to unexposed (HPV 6 – 88.3 vs. 0.35 AU/ml; HPV 11 - 41.9 vs. 0.29 AU/ml). Exposed and unexposed did not differ by race or sex, but children classified as vaccine-exposed were older than those unexposed (median age 12 years (range 1-19) vs 6.5 years (range 1-18). Among vaccine-unexposed, median number of lifetime surgeries was higher for those HPV 6/11 seropositive compared to those seronegative (9 vs 4, $p = 0.001$).

Conclusions: Many children (39%) with JORRP had serologic evidence suggesting HPV vaccination. Without vaccine-exposure, only about a third of children generated antibodies to HPV 6 or 11 and this seropositivity was associated with higher number of lifetime surgeries.

Shift 02-252 / #672

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02O. HPV NAAT SCREENING QUALITY CONTROL/ASSURANCE GUIDELINES
04-20-2023 7:00 AM - 4:00 PM

A HUMAN PAPILLOMAVIRUS (HPV) WHOLE GENOME PLASMID REPOSITORY: A RESOURCE FOR HPV DNA QUALITY CONTROL REAGENTS

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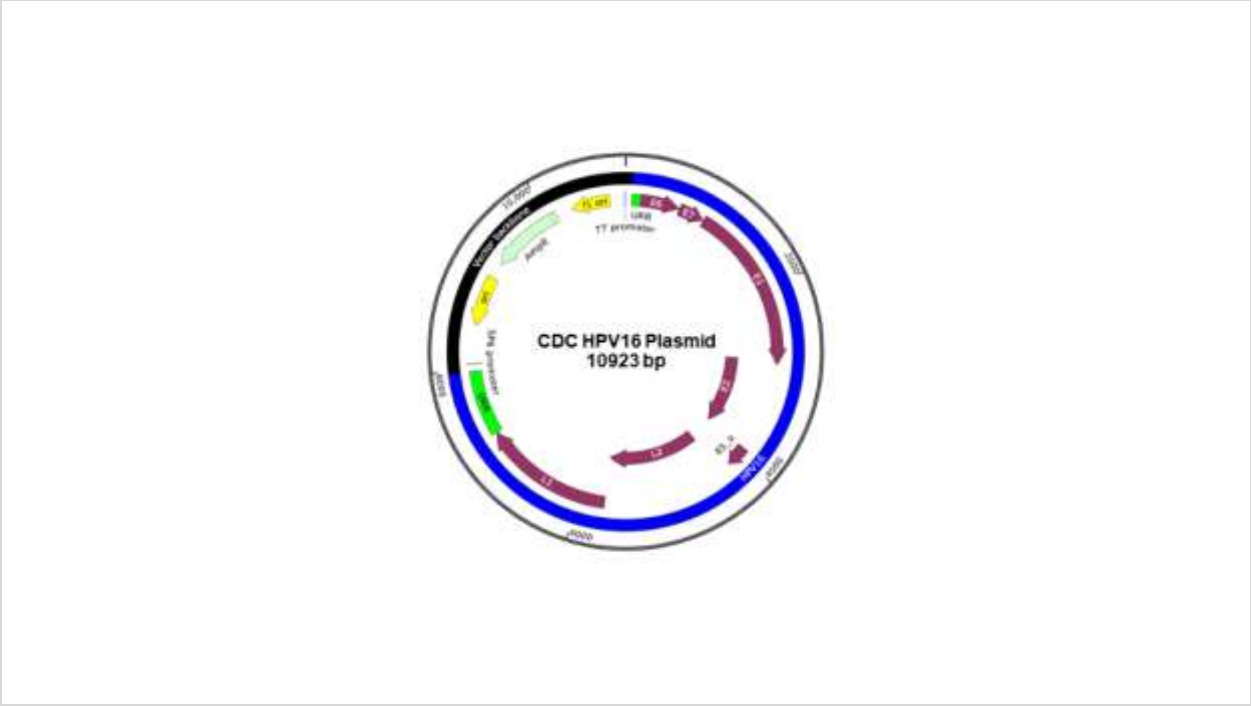
Introduction: Well characterized reference reagents are useful for assay validation, proficiency/competency assessment, daily run controls and to improve inter-laboratory comparisons. Synthetic human papillomavirus (HPV) DNA fragments and plasmid clones are available, but synthetic fragments are often truncated genomic segments and many HPV plasmids have interrupted coding regions or contain partial genomes, so they are not always useful for all available typing assays. We aim to develop a standardized plasmid repository of all known HPV types in a standard vector, each cloned to contain the whole genome with uninterrupted coding regions.

Methods: Whole genome HPV plasmids were constructed using same pGEMT Easy plasmid backbone for standardization. Overlapping DNA fragments for both HPV and the vector backbone were generated using PCR and then assembled into a plasmid using Gibson assembly technology.

Results: To date, HPV plasmid clones for 16 HPV types, (including all vaccine types and 14 types in clinical assays: HPV6, 11, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68a) have been constructed and were validated by sequencing and the Novaplex HPV typing assay. The whole genome of each HPV is present with no interruptions in coding regions (a map for the HPV16 plasmid is shown as an example). To date, only HPV31 has presented cloning challenges. This clone required propagation in a Stbl2 E.coli strain, suggesting that the genome of HPV31 is

unstable.



Conclusions: The Gibson assembly method is a feasible approach for developing whole genome HPV reference materials universally applicable to DNA-based HPV typing assays. The newly constructed HPV plasmids can serve as a quality control reagent resource for HPV DNA assays and are available for public health and research laboratories. The methods presented here can be applied to generate and improve DNA reference reagents for all known HPV types, as well as other pathogens.

Shift 02-253 / #353

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02P. OTHER CLINICAL RESEARCH
04-20-2023 7:00 AM - 4:00 PM

PREVALENCE OF HUMAN PAPILLOMA VIRUS IN URINE AMONG PREGNANT WOMEN ATTENDING KENYATTA NATIONAL HOSPITAL.

Ruth Nasozi[1], Wairimu Waweru[1], Derrick Abila[2], Lucy Muchiri[1]
[1]University of Nairobi, Human Pathology, Nairobi, Kenya, [2]Makerere University, Human Pathology, Kampala, Uganda

Introduction: The Human Papilloma Virus (HPV) is a highly prevalent, sexually transmitted infection, with a prevalence of approximately 70% among sexually active people globally. Close to 99.7% of invasive cervical cancers are caused by HPV. It is thought that during pregnancy, HPV acquisition increases due to hormonal influences and immunological depression as the pregnancy progresses. HPV infection is also found in the placenta and is believed to be associated with probable placental dysfunction leading to preterm births and spontaneous abortions.

Methods: One hundred pregnant women aged 18 years and above provided self-collected urine samples. Each urine sample was processed using liquid-based cytology, and DNA was extracted for HPV detection and genotyping using Real-Time Polymerase Chain Reaction.

Results: The prevalence of high-risk HPV in urine was 22% (22/100), with 13 (59.1%) having a single infection, 6 (27.3%) with two HPV types, and 3 (13.6%) having multiple infections (Table 1). Only one sample tested positive for Low-Grade Urothelial Neoplasia (LGUN). Other urogenital infections identified in smears included bacterial infection (21%), candida (9%), and trichomonas infection

(1%).

Trimester	Genotypes	Cytomorphology	Infection
First	35	Unsatisfactory	None
	56	Negative	None
	31, 58	Negative	None
Second	45	Negative	Bacterial infection
	31	Negative	Bacterial infection
	35	Negative	None
	56	Negative	None
	18, 39	Negative	Candida
	18,52	Negative	Bacterial infection
	45, 58	Negative	None
	56, 51	Unsatisfactory	None
	45, 35, 68	Negative	None
Third	18	Negative	Candida
	18	Negative	None
	31	Negative	None
	33	Negative	Bacterial infection
	56	Negative	Candida
	56	Negative	Trichomonas infection
	66	LGUN	None
	66, 51	Negative	Bacterial infection
	16, 66, 51	Negative	Bacterial infection
	18, 39, 58	Negative	None

Conclusions: The prevalence of high-risk HPV infection among this cohort of pregnant women is relatively high in urine samples. However, the prevalence of HPV-associated urothelial neoplasia was very low, with only one case reported. Larger studies with paired samples be conducted to validate urine as an alternative screening sample for genitourinary HPV-associated neoplasia, especially during pregnancy when a cervico-vaginal sample is undesirable.

Shift 02-254 / #701

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02P. OTHER CLINICAL RESEARCH
04-20-2023 7:00 AM - 4:00 PM

IMMUNOTHERAPY USING THE CELL WALL SKELETON OF MYCOBACTERIUM BOVIS BACILLUS CALMETTE-GUÉRIN (BCG-CWS) FOR CERVICAL CANCER

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Introduction: BCG has the potential to promote adaptive immunity. We describe the synergistic effect of BCG-CWS vaccination on cervical cancer patients undergoing conventional treatments including surgery, chemotherapy, and/or radiation.

Methods: In this observational study, we analyzed the cases of 103 patients (13 cases administered BCG-CWS vaccine and 90 controls without BCG-CWS) who underwent standard treatment for cervical cancer from 2005 to 2021. The BCG-CWS group underwent repeated intradermal injections of the BCG-CWS vaccine from 2011 to 2018 as well as the standard treatments including surgery. The vaccination was repeated weekly for 1 month prior to surgery, and then every 4 weeks thereafter. We evaluated the effectiveness of the BCG-CWS vaccination by determining the hazard ratios (HRs) of overall survival between the BCG-CWS vaccine group and the control group using the Cox model for multivariate analysis. HRs for the following clinical parameters were determined: BCG-CWS, surgery, chemotherapy, radiation, age, stage, HPV, and pathology. HPV types were identified using cytological sampling from the cervix or in formalin-fixed, paraffin-embedded cervical tissue.

Results: The prevalence of HPV was high, 100% (13/13 patients), in the BCG-CWS group and 65.6% (59/90 patients) in the control group ($p=0.351$, Fisher's test). This observational study demonstrated a clearly better prognosis for HPV-positive cervical cancer patients than for HPV-negative patients (HR: 0.031, $p<0.001$). Long-term follow-up revealed a significantly better prognosis (HR: 0.2108, $p=0.008$) for patients with cervical cancer in the BCG-CWS group compared to patients in the control group.

Conclusions: BCG-CWS therapy has the potential of being a clinically applicable immune adjuvant therapy for cervical cancer. The effects of the BCG-CWS on cervical cancer must be examined further in randomized control studies, and it remains necessary to clarify its underlying mechanisms to slow the progression of cervical cancer with this vaccination.

Shift 02-255 / #830

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02P. OTHER CLINICAL RESEARCH
04-20-2023 7:00 AM - 4:00 PM

GIANT CONDYLOMA ACUMINATA IN THIRD HOSPITAL : STUDY EPIDEMIOLOGIC AND LITERATURE REVIEW

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Introduction: Giant Condyloma Acuminata (GCA) is a rare anogenital wart with the incidence of only 0.1% in general worldwide. Its pathogenesis is not fully understood, but presumably it is, from HPV 6/11. Decreased immunity in GCA patient leads to HPV clearance failure, it is at high risk from developing malignancy. Anogenital HPV infection rate is very high among homosexual patients with HIV. This study aimsto find out the profile of Giant Condyloma Acuminata patients at Dr. Moewardi General Hospital. as a level 3 referral hospital and a primary teaching hospital, with an emphasis on epidemiology, risk factors and therapeutic management.

Methods: A descriptive analytic retrospective study was conducted in Dr. Moewardi Hospital, Surakarta from the 2019 to 2021. We included GCA patient with genital warts who had koilocyte cells. The samples were taken with total sampling technique.Immunohistochemical staining to identify high-risk HPV strains using HPV 16 and 18 E 6 Bioss® polyclonal antibodies carried out at the Laboratory of Anatomical Pathology, Faculty of Medicine, Sebelas Maret University, Surakarta-Indonesia The data was taken from medical records based on age, sex, occupation, smoking habit, HIV status, sexual behavior, HPV risk, and treatment.

Results: There were GCA cases which were dominated by men (76.9%), age 21-40 years (84.6%), private workers (76.9%), homosexuals (61.5%), HIV reactive (84.6%), smoking (61.5%), genital lesions (30.75%), anal lesions (30.75%), TCA 90% therapy (61.5%), and low risk HPV (92.3%).

Conclusions: Giant Condyloma Acuminata is more common in males aged <50 year old with homosexual orientation and smoking habit.

Shift 02-256 / #1468

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02P. OTHER CLINICAL RESEARCH
04-20-2023 7:00 AM - 4:00 PM

IDENTIFYING CERVICAL CELL POPULATIONS AND THEIR ROLES IN HOMEOSTASIS AND HPV-RELATED NEOPLASIA

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Introduction: The cervical transformation zone (TZ) is the most susceptible cervical area to deregulated human papillomavirus (HPV) gene expression and the development of neoplasia. The reserve cell is a stem-like cell, characteristic of the cervical TZ, and is currently believed to be one of the primary cell types vulnerable to high-risk HPV infection, although the origin and role of the reserve cell in HPV-related neoplasia are still controversial. Other TZ cell types, such as the columnar cells, have not been extensively studied in the context of HPV infection, even though they are the cellular origin of adenocarcinomas. The aims of this study are to elucidate new aspects of the cellular mechanisms of tissue homeostasis in the cervical TZ, and how it is dysregulated by HR-HPV.

Methods: This study relied on clinical tissue specimens collected from individuals of various age and medical history. Fluorescent immunohistochemical staining was performed on these specimens.

Results: First, we identified the cell types present at the transformation zone: secretory and ciliated columnar cells, reserve cells, and squamous cells. The ciliated columnar cells were characterised, staining for basal and stem cell markers, like the cervical and endometrial progenitor cells, implying an important role in epithelial homeostasis. Preliminary results, probing for viral mRNAs suggest the susceptibility of the columnar epithelium to HPV infection and replication, with a potential tropism for the ciliated columnar cell sub-type. Additionally, the viral E6/E7 mRNA patterns at the cervical TZ revealed the concentration of abortive infection patterns at the crypt entrances, making them the main site of deregulated viral gene expression.

Conclusions: Elucidating the cellular origin of HPV-related neoplasia in the cervical epithelium, namely the role of columnar cells will provide an improved cancer model. Understanding the origin of HPV-induced cervical cancers will influence risk assessment, diagnosis, and treatment of the disease.

Shift 02-257 / #1756

Poster Viewing
POSTER VIEWING - SHIFT 02: CLINICAL RESEARCH-02P. OTHER CLINICAL RESEARCH
04-20-2023 7:00 AM - 4:00 PM

THE ROLE OF ORAL CIMETIDINE AS AN IMMUNE RESPONSE MODIFIER AGENT IN CONDYLOMA ACUMINTA (STUDY IN FOXP3+ TREG CELLS EXPRESSION IN CONDYLOMA ACUMINATA LESIONS)

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Introduction: Condyloma Acuminata (CA) is an anogenital wart caused by Human Papillomavirus (HPV). Prevalence CA shows an increasing trend. Use of biological markers Foxp3+ Treg cells can be used as markers of immune response in CA. Cimetidine can act as immunodilator in the cell-mediated immune system. Thus, this study aims to determine the effect of oral cimetidine on Foxp3+ Treg cells in CA lesions.

Methods: A cross-sectional analytic observational study conducted at dr. Moewardi and Faculty of Medicine, Sebelas Maret University, Surakarta-Indonesia, June-August 2022. Subject were condyloma acuminata (CA) patients who met inclusion criteria. Treatment group was given oral cimetidine 3x400 mg for 4 weeks. Assessment of Foxp3+ Treg cells and was carried out by immunohistochemistry. Data interpretation is done descriptively

Results: Subjects consisted of 28 women and 12 men, majority were 18-30 years age group, majority were private sector workers, 50% were heterosexual, 52.5% were HIV reactive with low-risk HPV strains. The 32 subjects were classified into the treatment group with the other 8 being classified as the control group. Predilection CA lesions was genital (27.5%), anorectal (45%), perineal (7.5%), perianal (12.5%), and others (7.5%). Mean expression of Foxp3+ Treg cells in the control (3.34) and treatment (2.75) groups (p=0.018).

Conclusions: Oral administration of cimetidine has a significant effect on Foxp3+ Treg cells expression in CA lesions

Shift 02-258 / #686

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03I. IMPACTS OF COVID-19 PANDEMIC ON HPV VACCINATION IMPLEMENTATION
04-20-2023 7:00 AM - 4:00 PM

GETTING BACK ON TRACK – COVID 19 - PANDEMIC RESPONSE BY THE NATIONAL HPV VACCINATION ROUNDTABLE

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Introduction: The COVID-19 pandemic had immense implications on HPV vaccinations and completion rates. Due to the emergency declaration which prompted cancelled or delayed well child visits, loss of healthcare workers and prioritization of new protocols, HPV ordering was down by 2.5 million doses as of February 2022 compared to pre pandemic rates.

Methods: To aid our member organizations and partners to get back on track, we developed several initiatives to mitigate those pandemic impacts. These included a commentary article in the Journal of Adolescent Health, evidence summaries on the impact of Rural Disparities in HPV Vaccination Coverage and Vaccination at Age 9-12, collaborating with AMGA on an HPV Learning Collaborative for Quality Improvement, and developing resources on starting vaccination at age 9. A post assessment was conducted using the 2021 Annual Member Survey to determine impact.

Results: Fifty-three members (out of a total of 81 members) completed the survey for a response rate of 65.4%. A substantial proportion of respondents (21%) reported that COVID-19 had impacted their HPV work in some way and that they had to step back from their HPV focus over the prior year due to COVID-19. However, more than half (57%; 30 of 53) of respondents indicated that they have or would use resources to address HPV vaccination by encouraging the initial age for vaccination downward to age 9, communicating the importance of catching up on any vaccines missed, and increasing vaccine confidence (or decreasing vaccine hesitancy) through their outreach and education.

Conclusions: The National HPV Vaccination Roundtable's role as national convener assisted organizations in getting back on track amidst the COVID-19 pandemic. These results demonstrate the perceived value of the HPV Roundtable in raising awareness about HPV, facilitating the generation of ideas and sharing of information about HPV, and bringing together stakeholders.

Shift 02-259 / #694

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03I. IMPACTS OF COVID-19 PANDEMIC ON HPV VACCINATION IMPLEMENTATION
04-20-2023 7:00 AM - 4:00 PM

IMPACT OF COVID-19 DISRUPTIONS TO HPV VACCINATION ON HPV-RELATED CANCERS: A MODELLED EVALUATION

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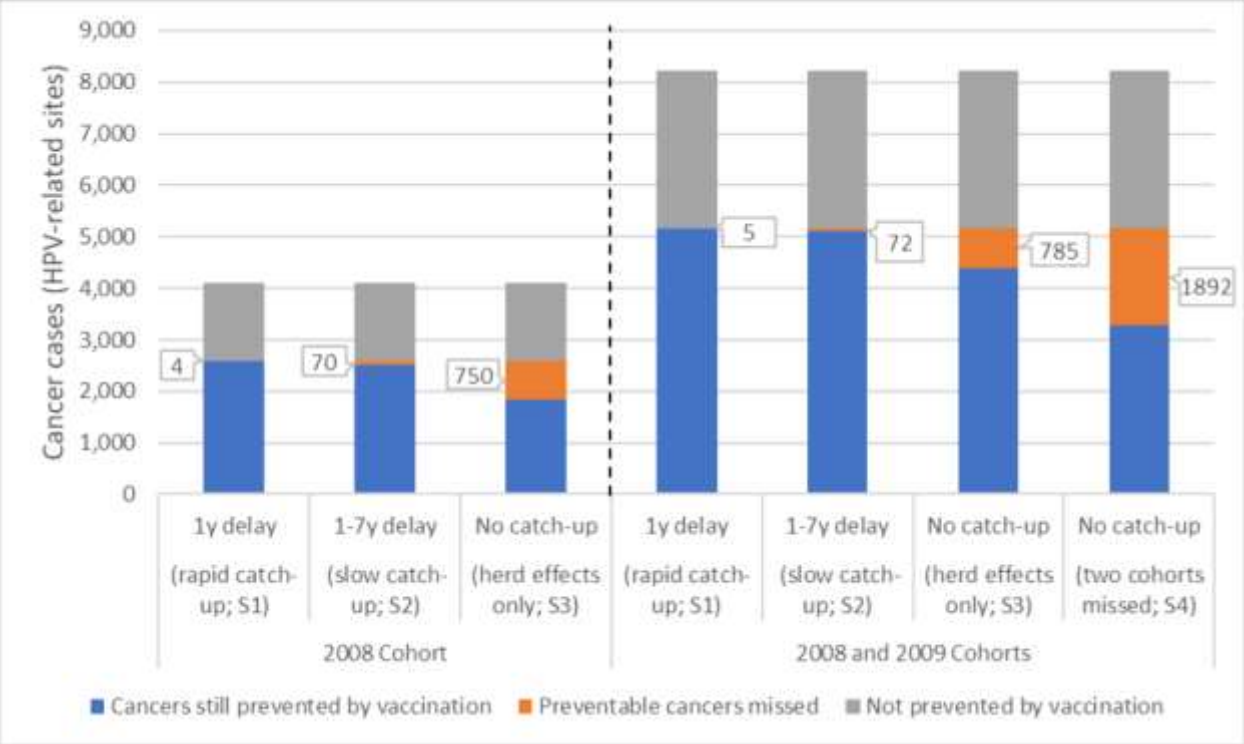
Introduction: The COVID-19 pandemic has disrupted essential health services including the delivery of school-based human papillomavirus (HPV) vaccination programs in many countries. In Australia, one-dose HPV vaccination coverage was maintained in 2020 despite school closures but a drop was observed in 2020 for the second dose.

Methods: We used a well-established model of HPV natural history, vaccination, cervical screening and HPV-related cancers (Policy1-Cervix) to estimate the long-term impact on HPV-related cancers (anus, cervix, oropharynx, penis, vagina, and vulva) from disruptions or delays to adolescent HPV vaccination. We used Australia as an example of a high-income setting with an established vaccination program. Four different scenarios were modelled. Compared to a no disruption scenario (uninterrupted nonavalent complete-course vaccine uptake at age 12 of 82.4% in females and 75.5% in males as in Australia), additional lifetime HPV-related cancer cases (both sexes) were calculated for three disruption scenarios affecting one birth cohort (cohort born 2008; 322,115 people): i) 1-year delay; ii) a 1 to 7-year delay (slower catch-up); iii) no catch-up (herd effects only). A fourth scenario assumed vaccination was disrupted for two birth cohorts (2008 and 2009) with no catch-up.

Results:



A 1-year delay in HPV vaccination affecting one cohort resulted in four (0.3%) more HPV-related cancers but the increase was greater for slower catch-up (5%; 70 cases), especially if there's no catch-up (49%; 750 cases). The additional cancers in the 'no catch-up' scenario were predominantly cervical (25%), oropharyngeal (males:23%) and anal (females:18%; males: 13%). For the two-missed-cohorts scenario 62% more HPV-related cancers would be diagnosed (n=1,892) although vaccination still prevented 40% of cancers (reduced from 63%).

Conclusions: Short-term delays in vaccinating young adolescents are likely to have minimal long-term effects on cancer. In extreme worst-case scenarios, failure to catch-up missed cohorts has significant impacts even with cervical screening and strong herd effects.

Shift 02-260 / #736

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03I. IMPACTS OF COVID-19 PANDEMIC ON HPV VACCINATION IMPLEMENTATION
04-20-2023 7:00 AM - 4:00 PM

LEVELS AND DETERMINANTS OF COVID-19 VACCINE HESITANCY AMONG SUB-SAHARAN AFRICAN ADOLESCENTS

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Introduction: With unprecedented speed, multiple vaccines against SARS-CoV-2 were developed one 74 year after the beginning of the coronavirus disease 2019 (COVID-19) pandemic.

Methods: This cross-country study was based on an ongoing survey that used a novel mobile platform and computer-assisted telephone interviewing to collect data from sub-Saharan African adolescents, adults, and healthcare providers. The Round 1 survey was conducted between July and November 2020, and the Round 2 survey was conducted between July and December 2021. For the Round 2 survey, all households with adolescents aged 10 to 19 years that participated in the Round 1 survey were contacted again. A small number of participants aged 19 years during Round 1 and aged 20 years at the time of Round 2 were also eligible for inclusion.

Results: Log-binomial models were used to calculate the adjusted prevalence ratios (aPRs) and 95% confidence intervals (CIs) for associations between potential determinants and COVID-19 vaccine hesitancy. The percentage of COVID-19 vaccine hesitancy was 15% in Kersa, 24% in Ibadan, 31% in Nouna, 33% in Ouagadougou, 37% in Addis Ababa, 48% in Kintampo, 64% in Lagos, 76% in Dar es Salaam, and 88% in Dodoma. Keeping themselves and their families safe was the most common motivation for vaccination. Perceived low necessity, concerns about vaccine safety, and concerns about vaccine effectiveness were the leading reasons for hesitancy. Healthcare workers, parents or family members, and school teachers had the greatest impacts on vaccine willingness. Perceived lack of safety (aPR: 3.61; 95% CI: 3.10, 4.22) and lack of effectiveness (aPR: 3.59; 95% CI: 3.09, 4.18) were associated with greater vaccine hesitancy.

Conclusions: The levels of COVID-19 vaccine hesitancy among adolescents are alarmingly high across the five sub-Saharan African countries, especially in Tanzania. COVID-19 vaccination campaigns among sub-Saharan African adolescents should address their concerns and misconceptions about vaccine safety and effectiveness.

Shift 02-261 / #948

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03I. IMPACTS OF COVID-19 PANDEMIC ON HPV VACCINATION IMPLEMENTATION
04-20-2023 7:00 AM - 4:00 PM

HUMAN PAPILLOMAVIRUS VACCINATIONS DURING COVID-19: HOW A MIDDLE SCHOOL-BASED EDUCATIONAL AND VACCINATION PROGRAM INCREASED VACCINE UPTAKE AT RECOMMENDED AGES IN THE RIO GRANDE VALLEY

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Introduction: Studies have shown that the human papillomavirus (HPV) vaccine is a safe, effective strategy for reducing HPV-associated diseases, and school-based vaccination programs increase HPV vaccine uptake among US adolescents. The ongoing global pandemic of coronavirus disease 2019 (COVID-19) has impacted health service delivery (drops in annual well visits, cancer screenings, and immunizations). The objective was to evaluate COVID-19 pandemic adaptions to a community-based education and school-based HPV vaccination program and increase HPV vaccination rates among medically underserved, economically disadvantaged, rural middle schoolers (Rio Grande Valley [RGV], Texas).

Methods: The intervention combined community-based HPV education (2016) with school-based vaccinations (2019). Pre- and post-intervention HPV vaccination rates were tracked against 2016 National Immunization Survey – Teen rates (initiation 49.3%; completion 32.9%). The study included 1,766 middle school students (884 females; 882 males) who received at least one HPV vaccine dose through our school-based vaccination program between 08/2016-06/2022. Summary statistics were stratified by age at initiation (≤ age 11 years vs. age 12 years and older) and gender. Adjustments were made to safely interact with the community (phone calls and virtual meetings through Zoom to educate the community, and continuing vaccination efforts through mobile clinics).

Results: The overall HPV up-to-date (UTD) rate was 59.7% (95% Confidence Interval: 57.4-62.0%). The median age at HPV UTD (range) was 12 years (9-19) and median interval between HPV vaccine doses (range) was 316 days (150-2,855). Extensive recovery efforts continued the program's progress and minimized the potential long-term consequences despite school and clinic closures and limited gatherings. Between 03/2020-03/2021, 24 school-based interventions provided 268 HPV vaccine doses.

Conclusions: Our COVID-19 adaptations allowed for a safe environment for middles schoolers to get vaccinated. Recommending HPV vaccine initiation at age 11–12 increases completion of the HPV vaccine series and providing access to HPV vaccines encourages on-time vaccination and completion.

Shift 02-262 / #685

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03J. IMPACTS OF COVID-19 PANDEMIC ON PUBLIC HEALTH ASPECTS OF HPV SCREENING
04-20-2023 7:00 AM - 4:00 PM

THE IMPACT OF THE FIRST YEAR OF THE COVID-19 PANDEMIC ON CERVICAL PRE-CANCER DIAGNOSES – UNITED STATES HUMAN PAPILLOMAVIRUS VACCINE IMPACT MONITORING PROJECT (HPV-IMPACT)

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Introduction: During the COVID-19 pandemic, utilization of preventive care, including cervical cancer screening, decreased. To better understand the pandemic's impact on detection of cervical precancers, we compared characteristics of women diagnosed with cervical intraepithelial neoplasia (CIN) grade 2 or higher or adenocarcinoma in situ (AIS) — collectively, CIN2+ — in 2019 (pre-pandemic) with those diagnosed in 2020 (first pandemic year).

Methods: We analyzed CIN2+ data among women aged 20–64 years in a 5-site, population-based cervical precancer surveillance system. Screening was estimated using administrative claims and laboratory data. Demographics, diagnoses, and HPV vaccination (among women aged <40 years) were obtained from medical charts, registries, and other sources. Based on residential census tracts, women were assigned percentile rankings of Social Vulnerability Index (SVI) overall and four SVI themes (socioeconomic status, household composition and disability, minority status and language, and housing type and transportation); top decile was defined as vulnerable. Differences by year were evaluated using chi-square tests.

Results: In 2019, 27.3% of catchment area women were screened and 2453 CIN2+ cases were reported. In 2020, 19.7% were screened and 2030 CIN2+ cases were reported (Table). Age (median 33 years), insurance (62% private), race and ethnicity (47% and 48% non-Hispanic White), and diagnosis (29.0% and 30.8% CIN3/AIS) were similar by year; a higher proportion of women in 2020 compared with 2019 had a history of ≥1 HPV vaccination dose (35.9% vs. 30.9%). Similar proportions of women were in the

highest SVI overall decile (10.5% vs. 11.4%) as well as all four themes each year.

Table: Number and characteristics of CIN2+ cases diagnosed among women 20-64 years old in 2019 and 2020, Human Papillomavirus Vaccine Impact Monitoring Project (HPV-IMPACT)[1]

	2019		2020		
	n	%	n	%	p value
CIN2+ Total	2453		2030		
Age (years)					
20–24	131	5.3	101	5.0	0.52
25–29	631	25.7	496	24.4	
30–34	700	28.5	561	27.6	
35–39	390	15.9	331	16.3	
40–44	230	9.4	194	9.6	
45–64	371	15.1	347	17.1	
Median (years)	33		33		
Insurance Status[2]					
Private	1506	61.7	1250	61.8	0.10
Public	483	19.8	361	17.8	
Uninsured	55	2.3	37	1.8	
Other	196	8.0	172	8.5	
Not Available	200	8.2	204	10.1	
Race and Ethnicity					
Non-Hispanic White	1178	48.0	953	47.0	0.95
Non-Hispanic Black	294	12.0	236	11.6	
Hispanic	430	17.5	362	17.8	
Asian	252	10.3	222	10.9	
Other	50	2.0	42	2.1	
Unknown	249	10.2	215	10.6	
Diagnosis					
CIN2	1194	48.7	973	47.9	0.10
CIN2/3	504	20.6	469	23.1	
CIN3/AIS	755	30.8	588	29.0	
Vaccination Status[3]					
Vaccinated	571	30.9	534	35.9	<0.01
Not Vaccinated	258	13.9	162	10.9	
Unknown	1022	55.2	792	53.2	
Social Vulnerability Index (Overall)[4]					
≥90th Percentile	277	11.4	211	10.5	0.35
<90th Percentile	2160	88.6	1801	89.5	
Socioeconomic Status[4]					
≥90th Percentile	205	8.4	154	7.7	0.36
<90th Percentile	2232	91.6	1858	92.4	
Household Composition[4]					
≥90th Percentile	106	4.4	96	4.8	0.50
<90th Percentile	2331	95.7	1916	95.2	
Minority Status & Language[4]					
≥90th Percentile	292	12.0	226	11.2	0.44
<90th Percentile	2145	88.0	1786	88.8	
Housing Type and Transportation[4]					
≥90th Percentile	422	17.32	325	16.2	0.30
<90th Percentile	2015	82.7	1687	83.9	

[1] The HPV-Impact Network includes 5 sites: Alameda County, California; New Haven County, Connecticut; Monroe County, New York; Portland, Oregon; Davidson County, Tennessee. Refer to http://www.cdc.gov/ncird/surveillance/hpvimpact/surveillance-areas-partners.html for a complete list of all partners.
[2] 19 cases were missing insurance information.
[3] Restricted to women <40 years old. 2 cases in this age group were missing vaccination information. The HPV vaccine has been recommended since 2006 for 11–12-year-old females with catch up through age 26 and has been available for persons through age 45 years since 2019.
[4] 34 cases were missing census tract information.

Conclusions: Fewer CIN2+ diagnoses occurred in surveillance areas in 2020 vs 2019, but no disparities were identified by race and ethnicity, insurance, or social vulnerability indices. Similar characteristics

among women diagnosed with CIN2+ in 2019 and 2020 suggest that providers should make broad efforts to reach women for screenings missed during the pandemic.

Shift 02-263 / #1182

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03J. IMPACTS OF COVID-19 PANDEMIC ON PUBLIC HEALTH ASPECTS OF HPV SCREENING
04-20-2023 7:00 AM - 4:00 PM

RESULTS DELIVERY DELAY AND COLPOSCOPY ATTENDANCE AFTER AN ABNORMAL CYTOLOGY RESULT IN THE CONTEXT OF THE SARS-COV-2 PANDEMIC

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[1]Federal University of Amazonas, Medicine, Manaus/AM, Brazil, [2]Federal University of Amazonas, Immunology, Manaus/AM, Brazil, [3]Oswaldo Cruz Foundation (Fiocruz), Center For Epidemiology And Health Surveillance, Brasília, Brazil, [4]Amazonas State Oncology Control Foundation - FCECON, Research Director, Manaus/Amazonas, Brazil, [5]Municipal Health Secretary, Ginecology, Manaus/Amazonas, Brazil, [6]University of Brasília (UnB), Department Of Public Health, Faculty Of Ceilândia, Brasília, Brazil, [7]National Cancer Institute, Division Of Cancer Epidemiology And Genetics, Rockville, United States of America

Introduction: Prevention of cervical cancer remains a public health challenge, especially in resource limited regions. In Brazil, women with abnormal cytology are referred for colposcopy examination with biopsy as needed. The SARs-CoV-2 pandemic caused a reduction in activities within the women's health network with a potential impact in women's adherence to the program. We identify the pandemic´s impact on colposcopy adherence by comparing the pre-pandemic (2019) and pandemic (2020, 2021 and 2022) attendance and waiting time to colposcopy within the public health services of Manaus, Brazil.

Methods: In this descriptive observational study data was collected from review of follow-up records and meetings with local health teams. The time deltas between cytology collection and colposcopy evaluation (Δt1) and between biopsy collection and result delivery (Δt2) were calculated. The study was approved by FCECON ethical review board.

Results: 1,266 women were included. Most were referred by an ASC-H or HSIL cytology reading and 36 to 45 years old. The mean time between cytology collection and colposcopic evaluation was 126 days in 2019, 120 in 2020, 120 in 2021 and 134 in 2022 (Figure 1). The mean time between biopsy collection and histopathology report was 300 days in 2019; 130 in 2020; 52 in 2021 and 45 in 2022. An important drop in attendance was observed, 43.2% in 2020, 29.0% in 2021 and 38.4% in 2022 when compared to pre-pandemic period (Figure 2).

Figure 1. Time deltas between cytology collection and colposcopy evaluation (Δt1) and between biopsy collection and result delivery (Δt2)

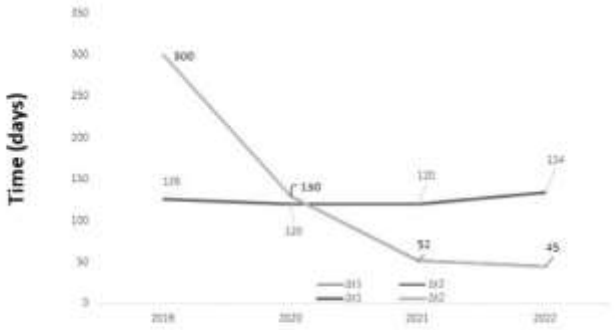
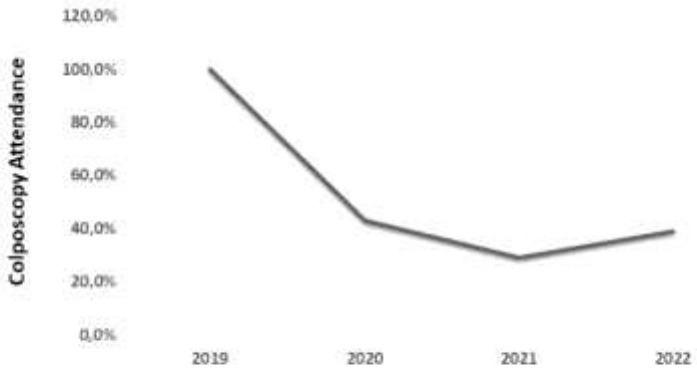


Figure 2 – Comparison of colposcopy attendance in relation to 2019. For the year 2022, the equivalent period of the year 2019 was considered (january to july)



Conclusions: There was a decline in adherence to colposcopy during the pandemic compared to the pre-pandemic period. Decreases in the waiting time for colposcopic evaluation after referral and for receiving the histopathology result were observed, probably explained by a decrease in the total number of women having their screening cytology collected.

Shift 02-264 / #1288

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03J. IMPACTS OF COVID-19 PANDEMIC ON PUBLIC HEALTH ASPECTS OF HPV SCREENING
04-20-2023 7:00 AM - 4:00 PM

CERVICAL CANCER SCREENING ACTIVITY IN THE CAPITAL REGION OF DENMARK DURING THE COVID-19 PANDEMIC

Birgitte Tønnes Pedersen, Helle Pedersen, Reza Serizawa, Si Brask Sonne, Emilie Korsgaard Andreasen, Jesper Bonde
Hvidovre Hospital, Dept. Pathology, Ahh-hvidovre Hospital, Copenhagen University Hospital, Hvidovre, Denmark., Hvidovre, Denmark

Introduction: We assessed the impact of the COVID-19 pandemic on cervical cancer screening activity in the Capital Region of Denmark. From March 2020 through January 2022, Denmark went through different levels of COVID-19 restrictions including periodic lockdowns, however an unaltered continuation of all cancer screening programs was stipulated. Yet, access to clinician collected cervical screening was at times limited.

Methods: Cervical screening activity was defined as screening by invitation, opportunistic screening, and screening participation by HPV self-sampling. Activity was monitored during and after the COVID-19 pandemic (2020-2022) and compared descriptively to a 3-year pre-pandemic reference (2017-2019).

Results: The activity of cervical cancer screening by invitation was affected most in March-May 2020 with a monthly change in screening activity of -49%, -51% and -19%, respectively. This was offset throughout the remainder of 2020 resulting in a yearly screening activity reduction of 8%. For 2021, <1% difference in activity of screening by invitation was observed. Opportunistic screening activity was impacted more with an annual reduction of 14% in 2020 and 25% in 2021. In 2022, the trend continues with a reduction in activity of 31%, even after lifting the last societal COVID-19 restrictions in January 2022. Participation in cervical screening by HPV self-sampling increased significantly from 17% (2017-2019) to 21% (2020-2021) and, in contrast to the pre-pandemic period, participation increased by age ($p<0.001$). Overall screening activity was reduced by 9% during 2020-2021.

Conclusions: The COVID-19 pandemic impacted the activity of cervical cancer screening by invitation most in 2020 and mainly during the initial lockdown periods, resulting in a reduction of 8% in 2020. In 2021, the impact was minimal. Opportunistic screening activity decreased during the pandemic and a continuous decreasing trend is observed. Pandemic screening participation by HPV self-sampling was higher than pre-pandemic screening participation. Denmark has not instated any special post-pandemic cervical cancer screening initiatives.

Shift 02-265 / #1650

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03J. IMPACTS OF COVID-19 PANDEMIC ON PUBLIC HEALTH ASPECTS OF HPV SCREENING
04-20-2023 7:00 AM - 4:00 PM

IMPACT OF COVID-19 ON CERVICAL CANCER PREVENTIVE CARE IN A LARGE U.S. HEALTH SYSTEM

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Introduction: We analyzed the impact of COVID-19 pandemic on screening for cervical cancer and management of abnormal screening results at baseline (2019) compared to 2020-2021.

Methods: Electronic medical record identified females between the ages of 21 and 64 without hysterectomy history who completed a visit with a primary or gynecology provider within the prior 36 months. Completed screening was defined as cytology and high-risk HPV testing within the prior 36-60 months per age-based guidelines. The record was also queried for all colposcopy and LEEP (loop electrosurgical excision procedure) appointments with outcomes of completion, cancellation or no show. Completed colposcopy and LEEP volumes were subjected to univariate and multivariate analysis. Comparisons were made across patient age, race and payer status.

Results: Cervical cancer screening declined significantly from 79% in 2019 (baseline) to 71% in 2020-2021 (post-COVID). The number of completed colposcopies declined 16% from baseline, with 18% fewer colposcopies under age 30 and 11% fewer colposcopies over age 30. Colposcopy volumes declined among all races, with White and Black females completed colposcopy at 12% and 16% lower volumes compared to baseline. When patients were grouped by age, race and payer, multivariate analysis revealed a 30% decline in colposcopy volumes from baseline among Black females over age 50. Further analysis by payer showed a 7% decline among commercially insured and a 43% decline among Medicaid and Medicare insured. There was a 23% decline in 2020-2021 LEEP volumes compared to 2019 (baseline). Changes in volumes were most notable in females under age 30 across all races, demonstrating a 47% decline between 2019 and 2020-2021.

Conclusions: Significant declines in screening and management of abnormal screening results in post-COVID period increase the risk of cervical cancer in this population. These findings will inform actions within our health system and our communities to address ongoing gaps in care.

Shift 02-266 / #1687

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03J. IMPACTS OF COVID-19 PANDEMIC ON PUBLIC HEALTH ASPECTS OF HPV SCREENING
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CHANGES IN HPV PREVALENCE, INCIDENCE, AND CLEARANCE AMONG MSM IN URUMQI, CHINA AFTER IMPLEMENTATION OF NONPHARMACEUTICAL INTERVENTIONS TO CONTROL COVID-19: AN INTERRUPTED TIME-SERIES ANALYSIS

Tian Tian[1], Leiwen Fu[1], Zhen Lu[1], Xinsheng Wu[1], Bingyi Wang[1], Xinyi Zhou[1], Yi-Fan Lin[1], Zewen Zhang[2], Lirong Liu[2], Miaomiao Xi[2], Zhen Chen[2], Jianghong Dai[2], Huachun Zou[1,3]
[1]Sun Yat-sen University, School Of Public Health (shenzhen), Shenzhen, China, [2]Xinjiang Medical University, School Of Public Health, Urumqi, China, [3]University of New South Wales, Kirby Institute, Sydney, Australia

Introduction: China implemented strict nonpharmaceutical interventions (NPIs) to respond to the outbreak of COVID-19. We aimed to assess the effects of COVID-19 NPIs on the HPV epidemic among men who have sex with men (MSM) in Urumqi, China.

Methods: In our observational cohort study, we enrolled and followed HIV-uninfected MSM aged ≥18 years in Urumqi, China, between September 1, 2016 and March 31, 2022. Anal swab samples were collected at each visit to test for HPV DNA. Our primary outcomes were the monthly prevalence, semiannual incidence (proportion of participants who had incident infections) and clearance (proportion of participants who had cleared infections) of HPV. We used interrupted time-series analysis to characterize the temporal trend in the monthly prevalence, semiannual incidence and clearance of HPV before (September 1, 2016 to July 16, 2020) and during the implementation of COVID-19 NPIs in Urumqi, China (July 17, 2020 to March 31, 2022). We used binomial segmented regression models to estimate the impact of COVID-19 NPIs on the primary outcomes.

Results: We recruited 1296 MSM who contributed 5374 HPV tests. COVID-19 NPIs were associated with a 37.9% decrease in the prevalence (prevalence ratio [PR], 0.621; 95% CI, 0.465 to 0.830), 52.2% decrease in the incidence (risk ratio [RR], 0.478; 0.377 to 0.606), and 40.4% increase in the clearance (RR, 1.404; 1.212 to 1.627) of any HPV during the implementation of COVID-19 NPIs in Urumqi, China (since July 17, 2020). There was no marked change in the prevalence of individual HPV genotypes. The impact of COVID-19 NPIs on the incidence and clearance of HPV varied by HPV genotype.

Conclusions: COVID-19 NPIs may lead to lower transmission and higher clearance of HPV among MSM. Efforts are needed to prepare for a potential rebound in HPV transmission as COVID-19 NPIs are reduced.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
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SOCIAL DETERMINANTS OF HUMAN PAPILLOMAVIRUS VACCINE UPTAKE IN THE UNITED STATES: A SYSTEMATIC REVIEW

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Introduction: Human papillomavirus (HPV) vaccine uptake remains low in the United States and disparities exist. Disparities have been identified in areas including income, race/ethnicity, and geographic location. However, little research exists that synthesizes empirical links between many other Social Determinants of Health (SDOH) and HPV vaccine uptake. This systematic literature review utilized the Healthy People SDOH Framework to assess studies analyzing empirical associations between determinants and HPV vaccination uptake among vaccine eligible populations in the U.S.

Methods: Databases searched include PsycInfo and PubMed. The search string was developed based on SDOH key areas in the Healthy People SDOH Framework including education, neighborhood and built environment, health and healthcare, community context, and economic stability. Researchers used MeSH terms for Social Determinant of Health variables when possible. Included studies had been published since the release of the HPV vaccine and were U.S.-based, reviewed, quantitative, primary data sources that measured at least one SDOH and a measure of HPV vaccine uptake. Exclusion criteria were qualitative, non-U.S. based studies and interventions. Studies that met all inclusion criteria were assessed for empirical links between determinant areas and pregnancy following the Matrix Method

Results: 113 studies met all inclusion criteria. Most represented areas include education, income, insurance, and healthcare utilization. No studies reported utilizing a SDOH framework. Most often, SDOH were included as demographics or control variables, not as main outcome variables.

Conclusions: Implications of this research indicate a need to expand the range of Social Determinants of Health that are analyzed with HPV vaccine uptake in the U.S. and to focus interventions on social determinant areas that have empirical links with HPV vaccination uptake.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
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ADVANCING EDUCATION ON HPV AND ITS RELATED DISEASES - IPVS EDUCATION COMMITTEE

Marc Steben
HPV global action, Chair Of Ipvs Education Committee, Montréal, Canada

Introduction: The IPVS Education Committee has been working hard on several educational initiatives with the goal of educating HPV experts and non-experts working in the field.

Methods: Our webinars in 2022 educated a wide range of professionals around the globe, with an average of 790 registrations and 303 attendees per webinar. The sessions were on basic science, clinical research, and public health. In total, over 290 questions were asked throughout the seminars, which received an average satisfaction score of 4.49/5. By the end of 2021, the committee launched the IPVS Education Center, a year-round platform for educational resources on HPV and its related diseases. The platform hosts the recordings of past webinars, materials of previous IPVCs (abstracts, e-posters, workshops, session recordings), and information on E-Oncologia and Project ECHO®. The E-Oncologia project in collaboration with the Catalan Institute of Oncology (ICO) saw an even higher impact than its first year. Through E-Oncologia, over 95 IPVS members registered to an online course on Cervical Cancer Prevention throughout 2021 and 2022. After completing the course, learners can apply to become tutors in their region and use the teaching materials to educate groups in their local institution or hospital. The first IPVS ECHO® meeting took place in May 2021. IPVS ECHO® is a telementoring initiative to support IPVS members in the clinical management of patients with HPV-related diseases. It consists of multidisciplinary meetings in which a brief didactic lecture is presented, followed by the presentation of 2 patient cases by IPVS members, who receive management and follow-up recommendations by the experts present at the meeting.

Results: The Education Committee is working on other innovative initiatives. Stay tuned!

Conclusions: Committee: Marc Steben, Nelly Mugo, Mauricio Maza, Margaret Heffernan, Samara Perez, Elisabeth McClymont, Ida Ismail-Pratt, Joel Palefsky, Xavier Bosch, Assumpta Company, Kimon Chatzistamatiou, Hélène De Pauw Staff: Coralie Deguerville, Pamela Funes

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
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SYSTEMATIC LITERATURE REVIEW ON THE EPIDEMIOLOGY OF HUMAN PAPILLOMAVIRUS RELATED DISEASES IN SELECT AREAS IN THE ASIA-PACIFIC REGION

Isaya Sukarom[1], Lily Wu[2], Queenie Wong[3], Omer Zaidi[4], Frieda Du[5], Alyssa Simon[6], Mark Bernauer[4]
[1]MSD Thailand, Center For Observational And Real-world Evidence, Bangkok, Thailand, [2]MSD Taiwan, Global Medical And Scientific Affairs, Taipei, Taiwan, [3]MSD Hong Kong, Global Medical And Scientific Affairs, Hong Kong, Hong Kong PRC, [4]OPEN Health, Evidence And Access, Bethesda, United States of America, [5]OPEN Health, Evidence & Access, Shanghai, China, [6]OPEN Health, Evidence & Access, Bethesda, United States of America

Introduction: Human papillomavirus (HPV) is among the most common sexually transmitted infections globally. The purpose of this review was to summarize the incidence and prevalence of HPV-related diseases in select Asia-Pacific (AP) regions.

Methods: A systematic literature review was conducted from January 1, 2000, to February 25, 2022, using Medline and Embase. Observational studies reporting the incidence or prevalence of HPV-related disease among adults (age ≥ 18 years) from select areas in the South-East Asia and Western Pacific regions (including Hong Kong) were included.

Results: A total of 3113 publications were identified, of which 299 were included. Incidence rates of HPV-related disease were reported in 14 publications from Hong Kong, Japan, the Philippines, Singapore, South Korea, Taiwan, and Thailand. The reported incidence per 100,000 person-years (PY) ranged from 0.2-13.7 for anal cancer (n=4 publications), 15.4-252.0 for cervical cancer (n=4 publications), and 0.2-55.5 for head and neck cancer (n=7 publications). Prevalence outcomes were reported in 238 publications from Bangladesh, Bhutan, Cambodia, Fiji, Hong Kong, Indonesia, Japan, Laos, Malaysia, Mongolia, Myanmar, Nepal, the Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Thailand, and Vietnam. HPV prevalence ranged from 0.0%-100.0% among patients with anal cancer (n=4 publications) and from 9.1%-100.0% among patients with cervical cancer (n=39 publications). Among patients with genital warts in the Philippines, South Korea, and Taiwan (n=5 publications), HPV prevalence ranged from 0.0%-100.0%. The prevalence of HPV among patients with precancerous lesions ranged from 11.8-100.0% (n=46 publications). HPV prevalence ranged from 0.0%-95.6% among patients with head and neck cancer (n=48 publications), 36.0%-79.6% among patients with penile cancer (n=4 publications), and 44.0%-82.0% among patients with vaginal/vulva cancer (n=3 publications).

Conclusions: The evidence from this SLR shows the high burden of HPV-related disease in the AP region. Methodological differences (e.g., population studied, detection methods, vaccination status) may contribute to the high data variability.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-20-2023 7:00 AM - 4:00 PM

AWARENESS AND KNOWLEDGE OF HPV AND ITS ROLE IN CERVICAL SCREENING AMONG WOMEN IN GREAT BRITAIN: AN ONLINE POPULATION-BASED SURVEY

Jo Waller, Frances Waite, Laura Marlow
King's College London, Comprehensive Cancer Centre, London, United Kingdom

Introduction: HPV primary testing and concomitant extensions to screening intervals are being implemented around the world. Where this has not been clearly communicated, there has been public backlash. We explored HPV awareness and knowledge about primary HPV screening in Great Britain where it has been in place for several years. Scotland and Wales recently extended screening intervals from 3 to 5 years for 25-49 year-olds; England is yet to make this change.

Methods: Women aged 18-70 (n=2,037) were recruited by YouGov from their online panel in August 2022. The weighted sample was population representative by age, region, education, and social grade. We measured HPV awareness, knowledge (excluding those unaware of HPV) using eight true/false items, and understanding of the role of HPV testing in cervical screening. We also assessed demographic characteristics and screening status.

Results: Overall, 76% of women were aware of HPV of whom 64% had heard about it in the context of cervical screening and 71% in the context of HPV vaccination. When asked to identify the statement describing how cervical screening works, only 12% correctly selected the statement reflecting HPV primary screening (13% in screening-eligible women). Mean knowledge score was 3.7 out of 8 (SD=2.2). Most participants aware of HPV knew that an HPV-positive result does not mean a woman will definitely develop cervical cancer (73%) but far fewer were aware of the slow timeline for HPV to become cancer (19%).

Conclusions: Even though HPV testing has been used in the screening programme in Britain since 2011, only 3 in 4 women are aware of the virus, and knowledge of HPV primary screening is very low, even among women of screening age. This points to continued need for awareness-raising campaigns to ensure informed choice about screening and mitigate public concern when screening intervals are extended.

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Poster Viewing
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RISING CERVICAL CANCER LATE-STAGE OCCURRENCE AND NO CHANGE IN MORTALITY IN PUERTO RICO: EVIDENCE TO SUGGEST THE RISING INCIDENCE IS REAL

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[1]University of Puerto Rico Comprehensive Cancer Center, Cancer Control And Population Sciences, San Juan, Puerto Rico, [2]University of Puerto Rico Comprehensive Cancer Center, Puerto Rico Cancer Center Registry, San Juan, Puerto Rico, [3]University of Puerto Rico, Medical Science Campus, Upr/mdacc Partnership, San Juan, Puerto Rico, [4]Medical University of South Carolina, Hollings Cancer Center, Charleston, United States of America

Introduction: Cervical cancer incidence is rising rapidly in Puerto Rico (PR). However, whether the increase is real or reflective of increased diagnostic scrutiny remains unclear. We describe trends in cervical cancer incidence according to stage at diagnosis and mortality trends in PR compared to the United States (US).

Methods: We analyzed 2001-2019 data from the PR Central Cancer Registry and the Surveillance, Epidemiology, and End Results Program (SEER). Cervical cancer cases were identified using the International Classification of Diseases for Oncology, 3rd Edition site codes C53.0 to C53.9 and histology codes 8010 to 8671 and 8940 to 8941. SEER*Stat, version 8.4.0 was used to calculate incidence and mortality rates. Joinpoint Regression Program software, version 4.9.1.0 (Division of Cancer Control & Population Sciences), was used to estimate average annual percent changes (AAPCs).

Results: From 2001-2019, the overall cervical cancer incidence increased 1.8%/year (95%CI, 0.6% to 3.0%) (from 9.2/100,000 to 11.7/100,000] in PR. In the US, AAPC during this time was -0.9 [95%CI, -1.3% to -0.6%. In PR, AAPC for localized stage cervical cancer was 1.0% [95%CI, -2.8% to 4.9%], while rapid increase occurred for regional (AAPC, 1.5% [95%CI, 0.1% to 2.8%]) and distant stage cancer (AAPC, 5.0% [95%CI, 1.9% to 8.2%]). In the US, AAPC for localized stage was -1.7% [95%CI, -2.1% to -1.3%], regional stage was -0.5% [95%CI, -1.6% to 0.6%], and distant stage was -0.1% [95% CI, -1.4% to 1.2%] during the same period. During 2001-2019, no change in mortality occurred for PR (AAPC, 0.0% [95%CI, -1.4% to 1.4%]); in the US, AAPC in mortality was -1.1% (95%CI, -1.6% to -0.7%).

Conclusions: Increased occurrence of late-stage disease in PR, with concurrent no change in mortality, suggests that the rising cervical cancer incidence is real. Future research must elucidate the factors that underlie the increase to address the magnifying disparities.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-20-2023 7:00 AM - 4:00 PM

PATIENT ACCEPTABILITY OF A CERVICAL HPV SCREEN AND TREAT PROGRAM IN HAITI

Rachel Masch[1], Michael Anello[2], Kathy Walmer[2], Thermozier Danache[3], David Walmer[2]
[1]Basic Health International, Ob/gyn, Pittsburgh, United States of America, [2]Family Health Ministries, Public Health, Chapel Hill, United States of America, [3]Family Health Ministries, Public Health, Leogane, Haiti

Introduction: Haiti has one of the highest incidence rates of cervical cancer in the world. HPV self-sampling has been shown to increase access to screening. In April, 2019 Basic Health International and Family Health Ministries implemented a screen and treat strategy using HPV self-testing followed by ablation for HPV+ women in one urban (Port au Prince, PAP) and one rural (Tom Gato, TG) clinic. A patient acceptability questionnaire was collected after the HPV collection at each site

Methods: Women aged 30–49-year-old from PAP and TG were enrolled from 4/09/19 to 7/01/22 and taught to self-collect HPV samples by trained health promoters. A patient acceptability questionnaire was collected and included queries on understanding instructions, comfort, accuracy of test, pain, embarrassment, home collection, and whether they would recommend this to a friend.

Results: More than 97% of women at PAP and 99% at TG strongly agreed/agreed to understanding the instructions, felt they collected the sample correctly, and were not embarrassed by the collection process (74% at PAP, 85.6% at TG). However, the two sites differed in whether they thought self-collection was painful (17.4% PAP, 32.2% TG); whether they would feel comfortable collecting the sample at home (63.5% PAP, 38.7% TG); if they thought the results would be accurate (46.1% PAP, 87% TG) and whether they would recommend it to a friend (73% PAP, 97.2% TG).

Conclusions: Women from urban and rural clinics in Haiti agreed that the instructions for HPV self-collection were easy to understand, felt they collected it properly and were not embarrassed. However, they differed in their perception of how painful it was, whether they would feel comfortable collecting at home, whether they thought the results would be accurate and if they would recommend it to a friend. Further research is needed to see if these differences persist in other areas of Haiti

Shift 02-274 / #884

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
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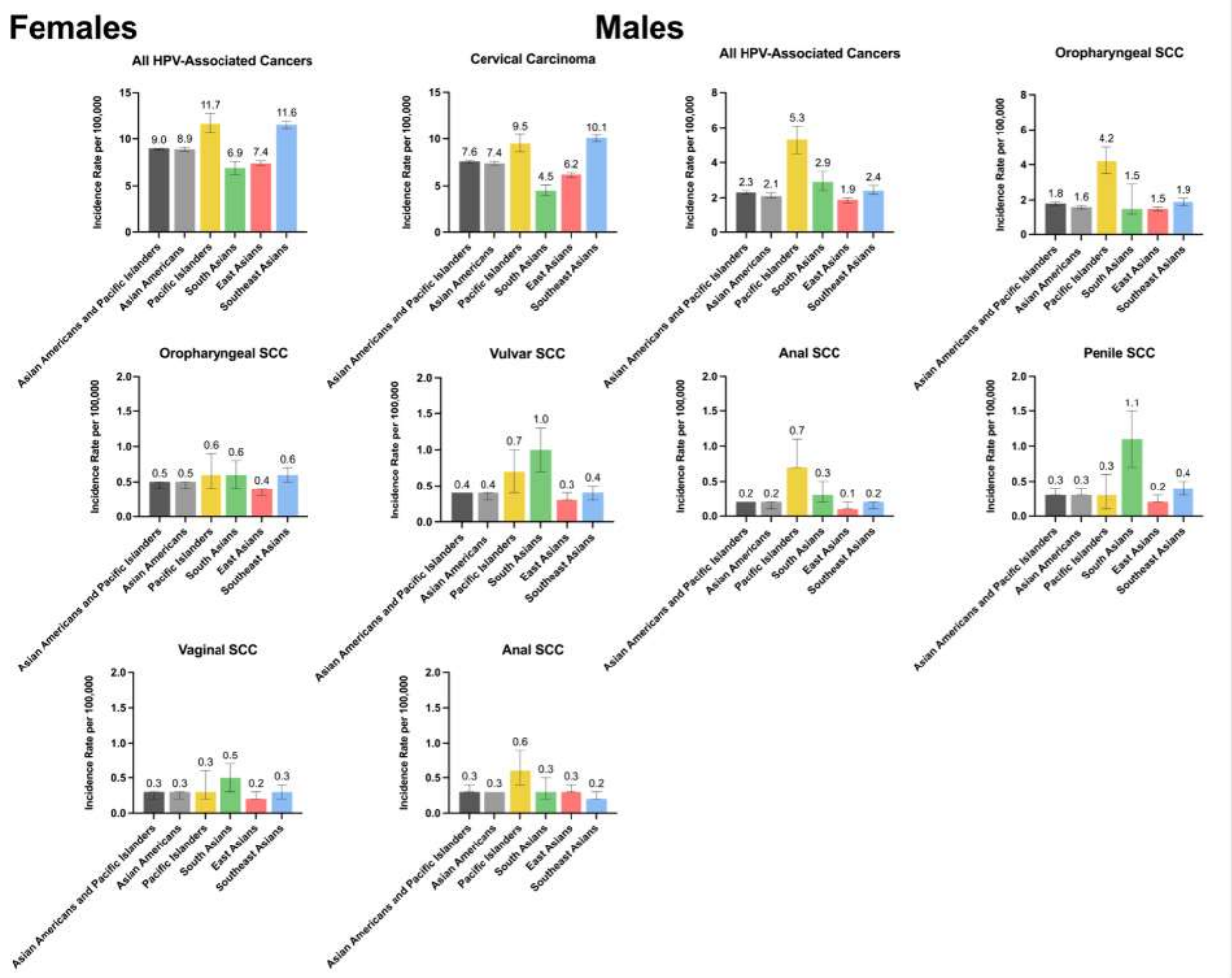
THE INCIDENCE OF HPV-ASSOCIATED CANCERS AMONG DISAGGREGATED ASIAN AMERICAN AND PACIFIC ISLANDER ETHNOGEOGRAPHIC REGIONS AND ETHNICITIES: A POPULATION-BASED STUDY IN THE UNITED STATES

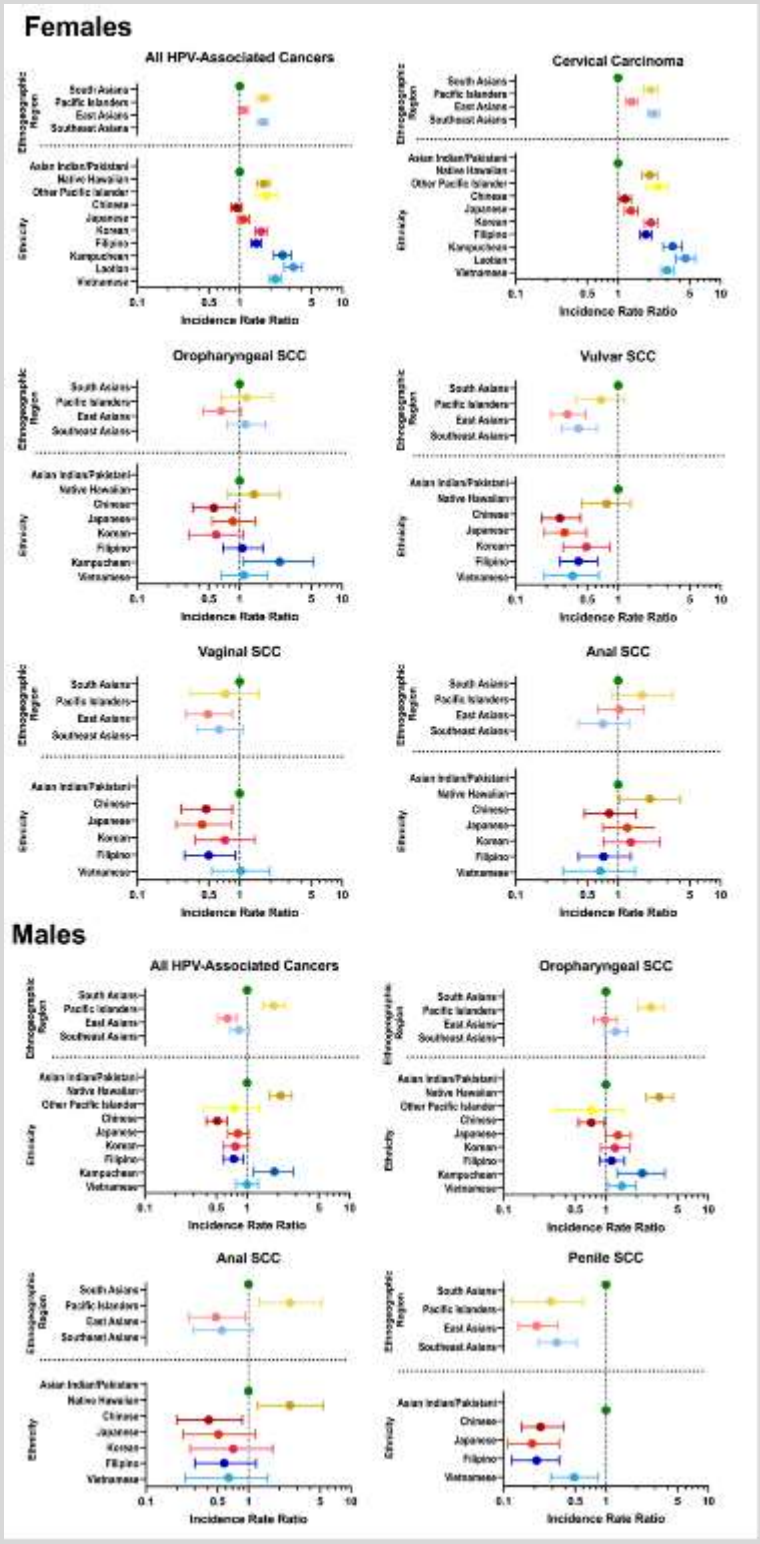
Jaimie Shing[1], Jereme Corbin[2], Aimee Kreimer[1], Loretto Carvajal[1], Kekoa Taparra[3], Meredith Shiels[1], Jacqueline Vo[1]
[1]US National Cancer Institute, Division Of Cancer Epidemiology And Genetics, Rockville, United States of America, [2]Davidson College, Political Science Department, Davidson, United States of America, [3]Stanford Medicine, Department Of Radiation Oncology, Palo Alto, United States of America

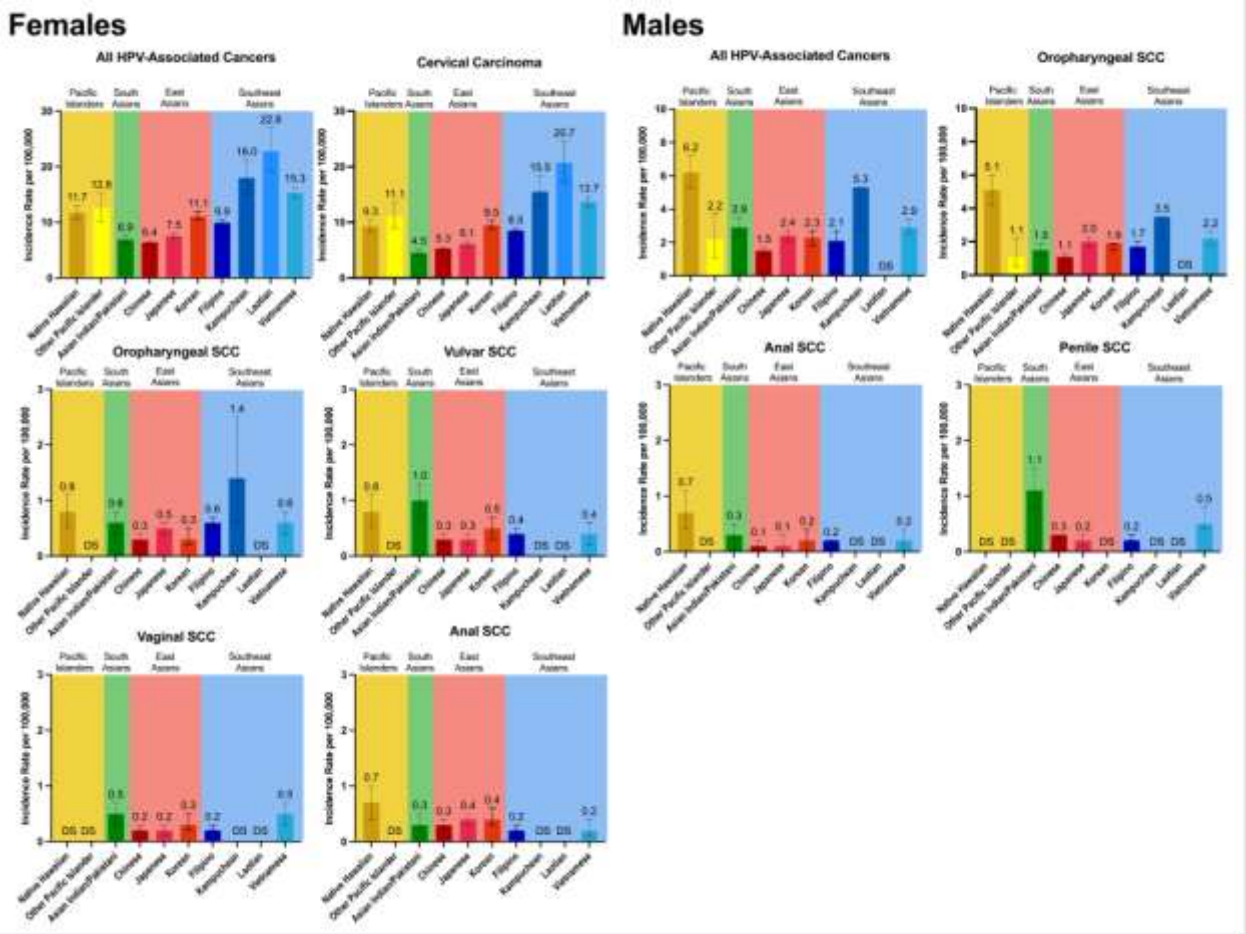
Introduction: Asian Americans (AAs) and Pacific Islanders (PIs) have low human papillomavirus (HPV) vaccination and cancer screening rates versus other races/ethnicities. AAs and PIs are often aggregated in research, masking disparities characterized by varying immigration patterns and cultural/religious beliefs. We examined HPV-associated cancer incidence among AA and PI individuals by ethnogeographic region and ethnicity.

Methods: Using the Surveillance, Epidemiology, and End Results specialized AA and PI database, we calculated 1990-2014 age-adjusted incidence per 100,000 and 95% confidence intervals (95%CIs) for cervical carcinoma, oropharyngeal squamous cell carcinoma (SCC), vulvar SCC, vaginal SCC, anal SCC, and penile SCC, by region (and ethnicity): South Asian (Asian Indian/Pakistani), East Asian (Chinese, Japanese, Korean), Southeast Asian (Filipino, Kampuchean, Laotian, Vietnamese), and PI (Native Hawaiian, other PI). Rate ratios (RRs) were calculated, compared to South Asians (Asian Indians/Pakistanis). Trends were estimated using Poisson regression.

Results: Among females, regional differences were observed for cervical carcinoma, vulvar SCC, and anal SCC (Fig1). Notably, the aggregated cervical carcinoma incidence was 7.6 (95%CI=7.4-7.7) but ranged from 4.5 (95%CI=4.0-5.1; South Asian) to 10.1 (95%CI=9.7-10.4; Southeast Asian); compared to South Asians, rates were significantly higher for all regions and ethnicities (RR range=1.2-4.6) (Fig2). Large differences occurred across ethnicities (Fig3); among Southeast Asians, cervical carcinoma rates ranged from 8.5 (95%CI=8.1-8.9; Filipino) to 20.7 (95%CI=17.2-24.6; Laotian). Among males, regional differences were observed for oropharyngeal SCC, anal SCC, and penile SCC. Specifically, the aggregated oropharyngeal SCC incidence was 1.8 (95%CI=1.7-1.9) but was substantially higher for PIs (4.2; 95%CI=3.5-5.0); rates were significantly higher for Vietnamese (RR=1.4), Kampuchean (RR=2.3), and Native Hawaiian (RR=3.3) males versus Asian Indian/Pakistani males. Cancer site-specific time trends also varied across
ethnicities.


Females
Males
All HPV-Associated Cancers
Incidence Rate per 100,000
9.0 8.9 11.7 6.9 7.4 11.6
Cervical Carcinoma
7.6 7.4 9.5 4.5 6.2 10.1
All HPV-Associated Cancers
2.3 2.1 5.3 2.9 1.9 2.4
Oropharyngeal SCC
1.8 1.6 4.2 1.5 1.5 1.9
Oropharyngeal SCC
0.5 0.5 0.6 0.6 0.4 0.6
Vulvar SCC
0.4 0.4 0.7 1.0 0.3 0.4
Anal SCC
0.2 0.2 0.7 0.3 0.1 0.2
Penile SCC
0.3 0.3 0.3 1.1 0.2 0.4
Vaginal SCC
0.3 0.3 0.3 0.5 0.2 0.3
Anal SCC
0.3 0.3 0.6 0.3 0.3 0.2
Asian Americans and Pacific Islanders
Asian Americans
Pacific Islanders
South Asians
East Asians
Southeast Asians


Females
All HPV-Associated Cancers
Cervical Carcinoma
Oropharyngeal SCC
Vulvar SCC
Vaginal SCC
Anal SCC
Males
All HPV-Associated Cancers
Oropharyngeal SCC
Anal SCC
Penile SCC
Incidence Rate Ratio



Conclusions: We observed heterogeneity in HPV-associated cancer incidence among AAs and PIs. Future studies among AAs and PIs should disaggregate by ethnogeographic region and/or ethnicity to better address disparities between subpopulations.

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Poster Viewing
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CERVICAL CANCER SCREENING AMONG ELDERLY WOMEN– LESSONS LEARNT FROM A RESOURCE-LIMITED SETTING IN UGANDA

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Introduction: In Uganda, frailty has constrained the utilization of cervical cancer screening services. The burden is exacerbated especially among the marginalized elderly. We report our lessons learnt from a community-based cervical cancer screening project among women aged ≥60 years in rural Uganda.

Methods: We nested a community-based cervical cancer screening project into a rural facility located in Luweero district. The strategy involves targeted mobile out reaches to frail elderly women. We have mentored a pool of elderly peer educators to capture emerging issues. The strategy also focuses on psychosocial support, social protection and advocacy for rights and justice. Visual inspection with acetic acid and Pap smears are performed to consecutive elderly women by trained medical personnel. Health education is given before screening. Primary care level cryotherapy for pre-cancerous cervical lesions is offered. Women requiring further management are referred to the district hospital.

Results: Lessons learnt: From our programmatic experience, majority of the elderly women in our care are weak, sickly and can hardly afford the costs of traveling to health facilities. They live in rural communities where poverty is rife, economic opportunities and medical support are limited. Interestingly, social and cultural values take precedence over treatment for cervical cancer in elderly women. Furthermore, the majority of the elderly are not prepared for old age and it takes a human understanding to work with the aged. However, working with elderly peers has increased responsiveness and demand creation for cervical cancer screening. Aging comes with frailty and vulnerability thus family support mechanisms are crucial for care of the elderly.

Conclusions: As cervical cancer prevention and control services are being scaled up in sub-Saharan Africa, Uganda inclusive, age specific approaches are needed to increase screening coverage and control. Cervical cancer services need to be tailored to the individual needs of the elderly women in resource limited settings.

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ORAL HPV PREVALENCE BY GENOTYPE AMONG MEN WITH HIV IN PUERTO RICO, BRAZIL, AND MEXICO

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Introduction: HPV-related oropharyngeal cancer (HPV-OPC) incidence is increasing among men with highest risk in men living with HIV (MWH). HPV vaccine efficacy against HPV-OPC has been inferred from effectiveness against anal and cervical cancer but has not been established through trials. A clinical trial in the US-Latin American-Caribbean HIV/HPV-Cancer Prevention Clinical Trials Network (ULACNet) was designed to evaluate 9vHPV vaccine efficacy for prevention of persistent (≥6 month) oral HPV infection among MWH. This study reports detection of prevalent oral HPV prior to vaccination.

Methods: A double-blind, placebo-controlled trial among MWH aged 20-50 years (n=500) is on-going in Brazil, Mexico, and Puerto Rico. MWH are randomized 1:1 to receive 9vHPV vaccine or placebo on Day 1, and Months 2 and 6, with randomization stratified by country and age group. Day 1 oral HPV prevalence among all MWH enrolled was evaluated using the SPF10 PCR-DEIA-LiPA25 system (DDL Diagnostic Laboratory, the Netherlands). HPV genotype distribution was examined for the overall trial cohort and by country and age group (20-30, 31-40, and 41-50 years). Comparisons by country and by age group were tested using Pearson's Chi-squared test.

Results: Trial enrollment began February 2021; as of October 6, 2022, 354 participants were enrolled (175 Brazil, 149 Mexico, and 30 Puerto Rico) with enrollment completion expected by February 2023. Oral HPV prevalence was 17.2%, 7.3%, 6.2%, and 1.0% for any HPV type, oncogenic HPV, 9vHPV types, and HPV 16 respectively. The most commonly detected oncogenic HPV types were HPV 33 (3.6%) and HPV 35 (1.6%). There were no significant differences in oral HPV type distribution between countries or age groups although MWH ages 41-50 consistently had higher prevalence of any HPV, oncogenic HPV, and HPV 16 compared to ages 20-30 and 31-40.

Conclusions: Among MWH, prevalence of oncogenic HPV, particularly HPV16, was low and similar across age groups and countries.

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CONSIDERATIONS FOR A CERVICAL CANCER SCREENING PROGRAM AMONG WOMEN IN LOW-RESOURCE SETTINGS IN LAGOS NIGERIA: A QUALITATIVE STUDY

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Introduction: In developing countries cervical cancer remains the second most common cancer in women. Women residing in low-resource settings such as those residing in slums have a higher risk of cervical cancer, and lower uptake of cervical cancer screening. Diverse barriers influence the uptake of cervical cancer screening among women in low-resource settings. This qualitative study was conducted prior to the introduction of a cervical cancer screening program in two slum areas in Lagos Nigeria and explored women's knowledge about cervical cancer, and their perceived barriers and recommendations for the program.

Methods: Four focus group discussions (FGD) were conducted among 35 women between the ages of 21 – 65 years residing in two urban slums in Lagos, Nigeria. Voice recordings were transcribed verbatim and thematic analysis was done.

Results: Majority of the women were not aware of cervical cancer and none knew the symptoms or risk factors of cervical cancer. Participants were of the opinion that a cervical cancer screening program would be well accepted in the community, however, expressed concerns about the cost of the screening test and the sex of the person performing the test. The recommendations proffered for a successful cervical cancer screening program include; reducing the cost of the test or providing the test free of charge, using female health care providers, using a private location within the community or nearby primary health center, having people that speak the local language as part of the team, and publicizing the program with the use of SMS, phone calls, town crier, and health talks.

Conclusions: Interventions to increase uptake of cervical cancer screening among women in low resource settings should improve knowledge of cervical cancer and address barriers to cervical cancer screening such as cost, distance, and as much as possible, sex of the healthcare provider should be considered.

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EVIDENCE FOR THE CONSTRUCT VALIDITY OF THE PATIENT ANAL CANCER KNOWLEDGE SCALE (PACKS) AMONG A SAMPLE OF BLACK AND HISPANIC SEXUAL AND GENDER MINORITIES

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Introduction: Anal cancer disproportionately impacts Black and Hispanic men who have sex with men and transgender women (MSM/TGW) who have high rates of HIV. Lack of anal cancer information is a major barrier to the utilization of primary and secondary prevention (i.e., vaccination and screening). A validated measure of anal cancer knowledge is needed to assess patient education needs. The purpose of this study was to evaluate the construct validity of the Patient Anal Cancer Knowledge Scale (PACKS).

Methods: Data were from Black and Hispanic MSM (aged 18–30 years) in the U.S. who were participants in larger cohort study (N_{total}=300). Only participants aware of anal cancer (63%) were administered the PACKS (n=188). We hypothesized as a 3-factor scale representing (1) risk and primary prevention (9-items), (2) symptoms (5-items), and (3) screening (3-items). Responses were recorded as Yes/No/Not Sure. Construct validity was assessed using Confirmatory Factor Analysis and bivariate statistics.

Results: The 3-factor model demonstrated adequate fit (RMSEA=0.02; CFI=0.99). All items loaded on their respective factors ($p<0.01$). The most discriminating items for each factor were as follows: Risk & Primary Prevention (Factor 1: there is a vaccine proven to prevent anal cancer), Symptoms (Factor 2: feeling lump or mass in the anus), and Screening (Factor 3: abnormal pap means that abnormal cells might turn into cancer). Scale scores indicated low/moderate anal cancer knowledge and acceptable reliability: Factor 1 (M=3.5; SD=2.3; Range:0-9; α=.71), Factor 2 (M=2.9; SD=1.9; Range:0-5; α=.85), and Factor 3 (M=2.0; SD=1.2; Range:0-3;α=.79). History of HPV vaccination (51.3%) was positively correlated with factors 1-3, respectively ($r=0.25, 0.16, 0.15$; $p<0.05$).

Conclusions: The PACKS demonstrated good construct validity related to knowledge of anal cancer risk/prevention, symptoms, and screening. Limited anal cancer awareness and knowledge among Black and Hispanic MSM is a potential barrier to the uptake and utilization of prevention recommendations.

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FROM HPV TO COVID-19 AND BEYOND: LEVERAGING THE POWER OF SEROLOGY AND STANDARDS

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Introduction: The SARS-CoV-2 pandemic created a crucial need for high quality serology assays to evaluate seroprevalence and antiviral immune responses. The initial flood of serology assays entering the market with inadequate performance emphasized the urgent need of standardization and independent evaluation.

Methods: To assist in the pandemic response, the HPV Serology Laboratory (HSL) at the Frederick National Laboratory for Cancer Research leveraged their HPV serology and standards expertise and partnerships and quickly pivoted to develop SARS-CoV-2 assays and standards. In April 2020, HSL engaged in a trans-governmental collaboration to independently evaluate the performance of commercial SARS-CoV-2 serology assays and help inform U.S. Food and Drug Administration (FDA) regulatory decisions. This was the nation's first independent SARS-CoV-2 serology assay performance evaluation program, which was established to assist the FDA on the evaluation of the quality of the emerging commercial SARS-CoV-2 antibody tests.

Results: HSL developed the SARS-CoV-2 ELISA assays based on their HPV ELISA platform, built the first assay evaluation panel and started the assay evaluations in April 2020. HSL conducted over 91 serology evaluations and about one-third (n= 27) achieved Emergency Use Authorization. Data for all evaluations are available at the FDA and CDC websites (https://open.fda.gov/apis/device/covid19serology/, and https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/serology-test-evaluation.html). In addition, the HSL produced the first U.S. SARS-CoV-2 Serology Standard using the same approach followed for the HPV standards, and made it available to the scientific community to enable comparison of results across different studies and vaccines. This work led to the establishment of the SARS-CoV-2 Serological Sciences Network (SeroNet) in October 2020. SeroNet is a multidisciplinary research network with the overall goal of expanding the nation's capacity for SARS-CoV-2 serologic testing and advancing the understanding of immune responses to SARS-CoV-2 infection and vaccination among diverse populations.

Conclusions: Our standardization infrastructure and framework can be used as a model for other infections and technologies.

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MULTILEVEL DETERMINANTS OF PAP TEST RECEIPT IN WOMEN LIVING WITH HIV: INDIVIDUAL, CLINICAL AND HEALTHCARE LEVEL PATTERNS OF CERVICAL CANCER PREVENTION MODALITIES

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Introduction: Women living with HIV(WLH) have interacting, synergistic interactions between HIV and HPV infection, elevating risk of developing HPV-associated cancers. We examined patterns of cervical cancer screening and prevention modalities that occur at the individual, clinical and healthcare level amongst diverse WLH.

Methods: Retrospective chart reviews, using New Jersey Ryan White Part D CAREWare 6 administrative reports between 2015 – 2019, identified WLH engaged in HIV care. Abstracted information included: patient demographics, cervical cancer screening, HIV care indicators, sexually transmitted infection screenings, insurance coverage, housing status and clinic engagement. Chi-square tests identified factors associated with ever receipt of Pap test during 2015-2019.

Results: Among the 925 WLH included, the majority were NH-Black, mean age of 45.6(SD=12.6) and mean years living with HIV was 16.9(SD=7). Overall, Pap test utilization was high (89%), which varied from 68% to 100% among the seven different clinics. Cervical cancer screening prevention modalities: HPV co-testing ($p<0.001$), receipt of HPV vaccine ($p=0.033$), and HIV care indicators, including viral suppression ($p<0.001$) and CD4 cell count ($p=0.002$) were associated with receipt of Pap test. In addition, being engaged in routine clinic visits ($p<0.001$) was also associated with Pap test receipt. Healthcare level determinants such as colocation of OB/GYN and HIV services had higher rates of Pap Test receipt (90% vs. 78%, $p=0.001$) compared to those who were co-located within the larger healthcare facility (90% vs 68%, $p<0.001$). Additionally, Pap test receipt was higher within the HIV clinic (90% vs 80%, $p=0.003$) compared to those with Pap tests outside of the HIV clinic (90% vs. 77%, $p<0.001$).

Conclusions: Multilevel factors influenced Pap test receipt, most WLH received a Pap test within a 5-year period however HPV vaccination was low. As a group with increased risk of cervical cancer development, routine HPV vaccination and identification of multilevel barriers to vaccine uptake should be further explored.

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EDUCATIONAL CAMPAIGN DEVELOPMENT FOR THE PROMOTION OF THE HPV VACCINE IN PUERTO RICO AND TEXAS

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Introduction: Human Papilloma Virus (HPV) is the most common sexually transmitted infection. Despite the availability of an effective vaccine, HPV vaccination uptake is suboptimal in the United States. Over the past decade, the Puerto Rico Community Cancer Control Outreach Program (PRCCCOP) has implemented strategic, evidence-based practices developing culturally specific educational programs and training for HPV vaccination uptake in Puerto Rico (PR). Recently, our long-term partner, UTHealth, has also initiated the dissemination of PRCCCOP programs in Texas (TX).

Methods: Qualitative data from focus groups and key informants, as well as epidemiological and Sociobehavioral indicators, served as key steps in planning two bilingual (Spanish/English) educational campaigns disseminated in PR and TX.

Results: Our educational campaigns focus on raising awareness of the importance of HPV vaccination for cancer prevention. Actuemos a Tiempo addresses parental concerns about the vaccination of children aged 9-17. Parents in PR are also reminded that HPV vaccination is required for school attendance. Si Te Falta Te Toca targets adults aged 18-26 who have not initiated or completed their HPV-vaccine series. Both campaigns feature culturally and audience-relevant educational materials (flyers, videos, postcards, and radio and television adverts) and workshops, all available on our websites. Health promoters have assisted campaign dissemination thru participation at community, school, and college health fairs. Collaborations with clinics (private and public) and community-based organizations have also allowed us to reach our target populations through educational material dissemination and radio and television appearances. A solid social media presence has allowed us to disseminate these campaigns extensively.

Conclusions: Conclusion: To efficiently deliver an HPV prevention and vaccination campaign, the messaging and delivery must address the needs and preferences of the target groups. We aim our ongoing efforts help raise awareness about the importance of vaccination to eliminate HPV-related cancers.

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HUMAN PAPILLOMAVIRUS VACCINE UPTAKE: ATTITUDES AND PRACTICES AMONG MOROCCAN PHYSICIANS

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Introduction: Cervical cancer is considred as a major public health problem worldwide. In Morocco, cervical cancer is a serious public health problem with an estimated number of 2165 new cases and 1199 deaths in 2020. The Human PapillomaVirus (HPV) vaccine has been available in Morocco since 2008 but it is not currently included in the national programme for prevention of cervical cancer. Few data are available on physicians' practices and attitudes toward HPV vaccine. Hence, this study aim to evaluate physicians' awareness and practice towards HPV vaccine and to highlight the main factors affecting physicians' recommendation of this vaccine in Morocco, as well as the level of physicians' willingness to recommend this vaccine.

Methods: We have carried out a structured interviewer-administered questionnaire with 500 physicians in different Moroccan regions between March 2019 and March 2020.

Results: This study showed an insufficient level of awareness of the most common types of HPV associated with genital warts (14.2%) and of the most common types of HPV associated with cervical cancer (36.6%). The rate of HPV vaccine recommendation did not exceed 16.6%. However, more than 63% of participants who were aware of HPV vaccine were willing to recommend it for their future eligible patients. Age (p-Value<0.01), sector of activity (p-Value<0.01), awareness of the two most common types of HPV associated with genital warts (p-Value=0.02), of the vaccine schedules (p-Value=0.03) and of the commercial name of this vaccine (p-Value <0.01), were significant factors influencing physicians' recommendation of HPV vaccine.

Conclusions: Indeed, raising physicians' awareness and including the HPV vaccine in national programme for the prevention of cervical cancer are urgently needed to improve both; physicians' awareness of HPV and HPV vaccine and, HPV vaccine coverage within moroccan population.

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COVERAGE OF THE PAP SMEAR IN DIFFERENT INFORMATION SYSTEMS: SITUATION OF THE FEDERAL DISTRICT, BRAZIL.

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Introduction: Cervical cancer (CC) was the third most common type of cancer among women in Brazil in 2021 according to the National Cancer Institute (INCA). The periodic performance of the Pap smear remains the most adopted strategy for screening in Brazil. The aim of this study was to analyze the coverage of the Pap smear in women aged 25 to 64 years in the Federal District (DF), Brazil from 2019 to 2021 from two health information systems.

Methods: Data from the SISAB (Health Information System for Primary Care) and SISCAN (Cancer Information System) information systems of Pap smear tests performed on women aged 25 to 64 years in the period from 2019 to 2021 in the Federal District, Brazil, were used. The SISAB uses the coverage indicator of the Pap smear for payment purposes to primary health care (PHC) teams. The SISCAN aims to register tests for screening and diagnostic investigation. The proportion of women between 25 and 64 years of age treated in PHC who underwent at least 1 pap smear in the 3-year interval was considered, in relation to the total number of women in the same estimated age group of the Federal District (Table 1).

Table 1. Total number of women in the Federal District per age group from 25 to 64 years registered in PHC. IBGE.

	2019	2020	2021
Women from 25 to 64 years registered in PHC	495.777	469.582	563.063
Total women in the Federal District	1.565.434	1.585.771	1.605.747

Source: SISAB, 2022. IBGE, 2022.

Results: In 2019, SISCAN registered the care of 57,175,000 women and the SISAB, 35,187,000 and in 2021 SISCAN registered the care of 38,516,000 women and the SISAB, 60,673,000 women. Coverage in the SISAB went from 7 to 11%, even considering the Covid-19 pandemic and coverage in SISCAN went from 12 to 7% (Table

2).

Table 2. Total Pap smear tests performed on women aged 25 to 64 years registered with SISCAN and SISAB in the years 2019 to 2021. Federal District. Brazil.

	SISCAN		SISAB	
	Total women aged 25 to 64 years	Coverage (%)	Total women aged 25 to 64 years	Coverage (%)
2019	57.175	12	35.187	7
2020	29.064	6	47.939	10
2021	38.516	7	60.673	11

Source: SISCAN, 2022. SISAB, 2022

Conclusions: Information systems are indispensable tools for the proper functioning of a health system and assist in decision making. Unified information-based health systems enable reliable monitoring and evaluation of this information, enabling both CC screening and PHC financing purposes.

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THE BURDEN OF HPV IN HEAD AND NECK CANCERS - THE BROADEN JAPAN STUDY

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Introduction: Human Papillomavirus (HPV) is a cause of a sub-set of head and neck cancers (HNC). Based on tissue samples collected from 1990 to 2012, Castellsagué et al. estimated that 22.4%, 4.4%, and 3.5% of oropharyngeal, oral cavity, and laryngeal cancers, respectively, were attributable to HPV. Recent studies have reported an increase in the proportion of oropharyngeal cancers (OPC) caused by HPV. This may be due to changes in sexual practices since the 1970s combined with the decrease of other risk factors particularly smoking. Evidence on the attributability to HPV for non-OPCs is very limited, as clinical guidelines do not recommend routine HPV testing for these sites. This study aims to estimate the fraction of HNC attributable to HPV per anatomic site, in two time periods (2008-2009 and 2018-2019) in five European and two Asian countries (France, Germany, Italy, Portugal, Spain, China and Japan).

Methods: A non-interventional, cross-sectional study of patients diagnosed with HNC is conducted in a sample of hospitals with established local biobanks in the seven participant countries.

Results: Approximately 9,000 patients diagnosed with HNC during the two defined study periods, with HNC tissue available, will be included in the study. Tissue samples will undergo three HPV tests (detection of HPV DNA, and HPV E6*I mRNA, and assessment of p16INK4a expression) at a central laboratory. Analyses to estimate the country-specific, regional and global proportion of HNC attributable to HPV will be stratified by single and grouped HNC anatomic sites (OPC vs non-OPC). Results in Japan are expected by end of 2022.

Conclusions: The results from this study will contribute to the understanding of the past (2008-2009) and current (2018-2019) involvement of HPV in HNC at OPC and non-OPC anatomic sites using a standardized methodology for HPV testing via a central laboratory.

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CAPACITY BUILDING FOR THE PREVENTION OF HPV-RELATED CANCERS AND PROMOTION OF THE HPV VACCINE IN PUERTO RICO AND TEXAS

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Introduction: Human Papilloma Virus (HPV) is the most common sexually transmitted infection worldwide. Despite the availability of an effective vaccine, HPV vaccination uptake is suboptimal in the United States. The Puerto Rico Community Cancer Control Outreach Program (PRCCCOP) along with our long-term partner, UTHealth, has developed an HPV vaccination training series tailored to healthcare professionals and public health workers for implementation in Puerto Rico (PR) and Texas (TX).

Methods: We conducted structured qualitative interviews with healthcare providers (physicians, nurses, and medical assistants) and public health workers (health educators, community health workers, health promoters (promotores), and undergraduate and graduate student volunteers) to determine knowledge about HPV, HPV vaccination, HPV vaccine communication strategies and recommendation practices including barriers and facilitators. We used the Coding and Analyzing Method to categorize interview data.

Results: Providers and public health workers indicated they are not receiving necessary training or continued education regarding HPV, the vaccine, and HPV-related cancers. Most participants lacked the skills needed to address parental/patient concerns and provide effective age-appropriate recommendations, such as a bundled approach for children aged 11-12, which then leads to missed or delayed vaccination. These findings led to the development of a bilingual (English/Spanish) training series (webinar, in-person, and self-guided) entitled 'Actuemos a Tiempo/Let's Act on Time: an HPV knowledge and communication training program for health professionals, addressing the aforementioned topics and tailoring them to the different types of health professionals.

Conclusions: Health professionals need fundamental learning techniques regarding effective approaches that will deter parents and age-eligible adults from avoiding HPV vaccination. Creating tailored trainings in various delivery forms (webinar, in-person, and self-guided) facilitates access to information and allows health professionals to obtain training specific to their needs.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
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HUMAN PAPILLOMAVIRUS (HPV)-ASSOCIATED AND HPV-ATTRIBUTABLE CANCERS IN UNITED STATES, 2015 -2019

Virginia Senkomago, S. Jane Henley, Mary O'Neil, Simple Singh, Mona Saraiya, Manxia Wu
CDC, Cancer Prevention And Control, Atlanta, United States of America

Introduction: U.S. Cancer Statistics (USCS) [www.cdc.gov/cancer/uscs/] include high quality cancer incidence data from CDC's National Program of Cancer Registries and NCI's Surveillance, Epidemiology, and End Results (SEER) Program. CDC routinely analyzes USCS data to examine the number of HPV-associated cancers and estimate the number of HPV-attributable cancers in the United States.

Methods: HPV-associated cancers are invasive cancers at anatomic sites with cell types in which HPV DNA frequently is found including the cervix, vagina, vulva, penis, anus, rectum, and oropharynx. HPV-attributable cancers are cancers probably caused by HPV, estimated based on a CDC population-based genotyping study that examined cancer tissue to estimate the percentage of HPV-associated cancers probably caused by HPV. Using SEER*Stat 8.4.0, CDC examined USCS data to assess counts and incidence rates of HPV-associated cancers and estimate the number of HPV-attributable cancers.

Results: Based on USCS data between 2015–2019, covering 99% of the U.S. population, about 47,199 new HPV-associated cancers were reported each year: 26,177 among women, and 21,022 among men. An estimated 37,300 cancers (79%) were attributable to HPV annually. Of these, we estimated that 34,400 (92%) cancers could have been prevented by the 9-valent HPV vaccine, including 30,100 caused by HPV types 16 and 18 and 4,300 caused by HPV types 31, 33, 45, 52, and 58. Women had higher overall incidence of HPV-associated cancers than men (14.0 versus 11.2 per 100,000 respectively), however men had higher rates of oropharyngeal cancers (9.0 versus 1.7 per 100,000).

Conclusions: These annual estimates of HPV-associated and HPV-attributable cancers provide useful data for prevention and control strategies including HPV vaccination and cervical cancer screening. The latest USCS data, including the numbers and rates of HPV-associated cancers, are available to the public through the USCS Data Visualizations tool [www.cdc.gov/cancer/dataviz]. Data on HPV-attributable cancers are published annually in USCS Data Briefs [www.cdc.gov/cancer/uscs/about/publications.htm].

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Poster Viewing
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PREPARING FOR SCALING UP: REALIST EVALUATION OF HPV SCREEN AND TREAT STRATEGY IN AMAZON BASIN OF PERU.

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Introduction: The Proyecto Precancer (PPC) is an implementation science project that worked with national and regional health partners to facilitate adoption of a new HPV-based screen-and-treat (SAT) strategy for cervical cancer early detection and treatment in the Amazonian city of Iquitos. Both screening and follow up increased significantly, approaching or surpassing monthly elimination goals. To support sustained adoption of this strategy in new regions, a realist evaluation (RE) is being conducted with PPC participants to learn what mechanisms worked and for whom they were most effective.

Methods: RE uses a phased implementation process: 1) formulation of initial program theories (IPT), 2) development of hypotheses summarizing what works, for whom, and why, 3) test of hypotheses with stakeholders, and 4) refinement of program theories. For the IPT formulation, our research team: 1) developed initial context-mechanism-outcome configurations via weekly discussions and review of research documents, and 2) conducted a focus group with 14 health professionals and authorities. Literature review to further inform the IPT is ongoing.

Results: Several IPT developed by the research team coincided with those that emerged inductively during the focus group: 1) use of mental models to visualize SAT system, 2) access to ongoing external expert advice and implementation support, 3) development of communities of practice, 4) task-shifting from the secondary/tertiary to the primary level of care, 5) importance of a data collection system that integrates data from entire SAT system, 6) acceptance by the population of the new strategy, and 7) effects of socio-political instability on organizational turnover.

Conclusions: IPT will be developed into hypotheses and tested, allowing the PPC to translate the process that led to sustained adoption of the HPV SAT strategy into an implementation strategy to facilitate context-adaptation and adoption of this strategy in new regions.

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Poster Viewing
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"IF YOU WANT TO GO FAR, GO ACCOMPANIED": CRITICAL ROLE OF ACADEMIC-GOVERNMENT PARTNERSHIPS FOR SYSTEMS-LEVEL CHANGE IN CERVICAL CANCER EARLY DETECTION AND TREATMENT

Victor A. Palacios[1], Carlos Santos Ortiz[2], Andrea Matos Orbegozo[3], Maria Del Carmen Caruhapoma O.[4], Graciela Meza-Sánchez[5], Henrry Diaz[6], Valerie Paz Soldán[7]
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Introduction: The Peruvian Ministry of Health (MOH) has prioritized using an HPV Screen-and-Treat (SAT) strategy for early detection and treatment (EDT) of cervical cancer. By shifting screening and treatment to the primary level, and referring patients who require specialists to hospitals, women receive more timely care, fewer individuals are lost to follow-up, and the burden on hospitals is diminished. However, systems changes can be challenging. To adopt this strategy, professional groups requested locally-generated evidence, creating implementation delays. The MOH partnership with the Proyecto Precancer (PPC) research team – conformed by various US universities and a Peruvian non-governmental organization – enabled evidence generation that facilitated systems-level changes for nationwide scale-up of this approach.

Methods: The PPC facilitated a participatory process to ideate, plan, and pilot a locally-developed HPV SAT approach in Iquitos, Peru. Routine meetings between PPC and the MOH, whose team was developing national guidelines for HPV SAT, led to requests for evidence that could not be financed or conducted by the MOH. One example included assessing acceptability of treatment at the primary level among HPV+ women and health professionals. Likewise, PPC needed to ensure alignment with MOH guidelines before piloting the HPV SAT program.

Results: Change is highly challenging for an underfunded MOH operating within a hierarchical and complex health system that does not easily incorporate new evidence. Frequent political turnover and conflicts of interest present further challenges. Funded external researchers at PPC had the capacity and resources to ask critical questions and test assumptions while welcoming failure as an opportunity to learn. Likewise, PPC also drew from this partnership to impact the long-term goal of adopting, sustaining, and scaling-up new strategies.

Conclusions: Collaboration between the MOH and PPC enabled generation of evidence that proved critical to the adoption of a new HPV SAT strategy currently scaled up throughout Peru.

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Poster Viewing
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DEVELOPMENT OF BIOMEDICAL VISUALIZATIONS TO ADDRESS COMMUNICATION BARRIERS BETWEEN BENCH AND BEDSIDE

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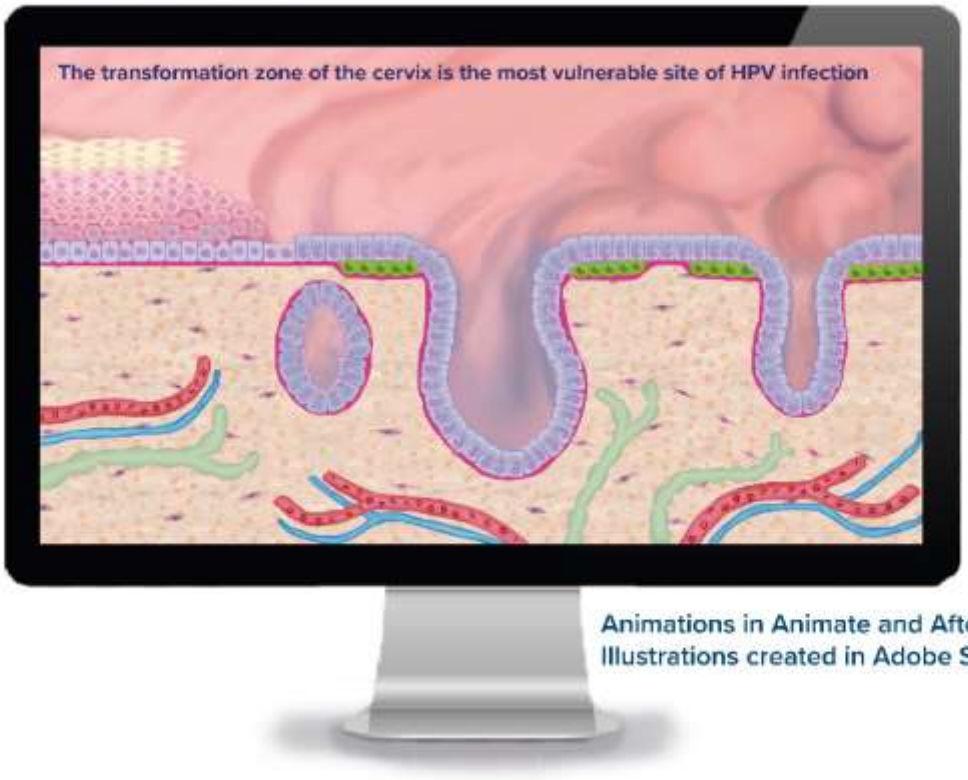
Introduction: The continuing worldwide burden of HPV-related cervical cancer is exacerbated by the persistent communication gap between researchers and healthcare providers, often slowing the “bench to bedside” idea. It is often challenging to entirely envisage in-vivo disease progression through the inference of scientific processes over time; one of the solutions to provide clarity is through scientific animations and illustrations. Our aim was to establish a cross-disciplinary education tool that conveys HPV disease infection and disease management strategies.

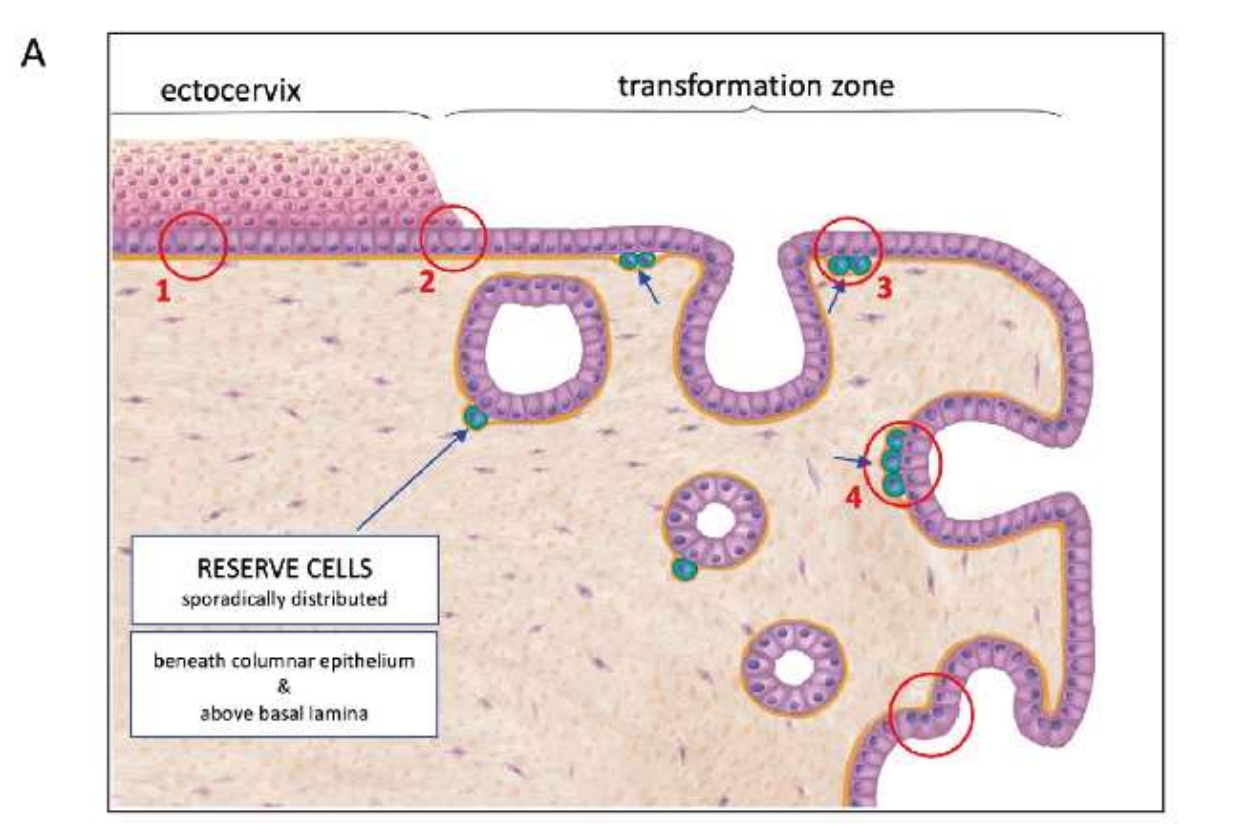
Methods: Current knowledge about HPV from collaboration with researchers was converted into animations and illustrations to help bridge the communication barrier. Four key areas were determined for visualizations: basic infection and disease progression, vaccination, diagnostic tools, and treatment. Adobe programs (Animate, After Effects, Photoshop, and Illustrator) were utilized to create versatile two-dimensional scientific animations and illustrations, which were based on clinical images. Visuals were presented to clinicians and researchers, for assessment of educational merit in a qualitative and quantitative manner, through interviews and questionnaires, respectively.

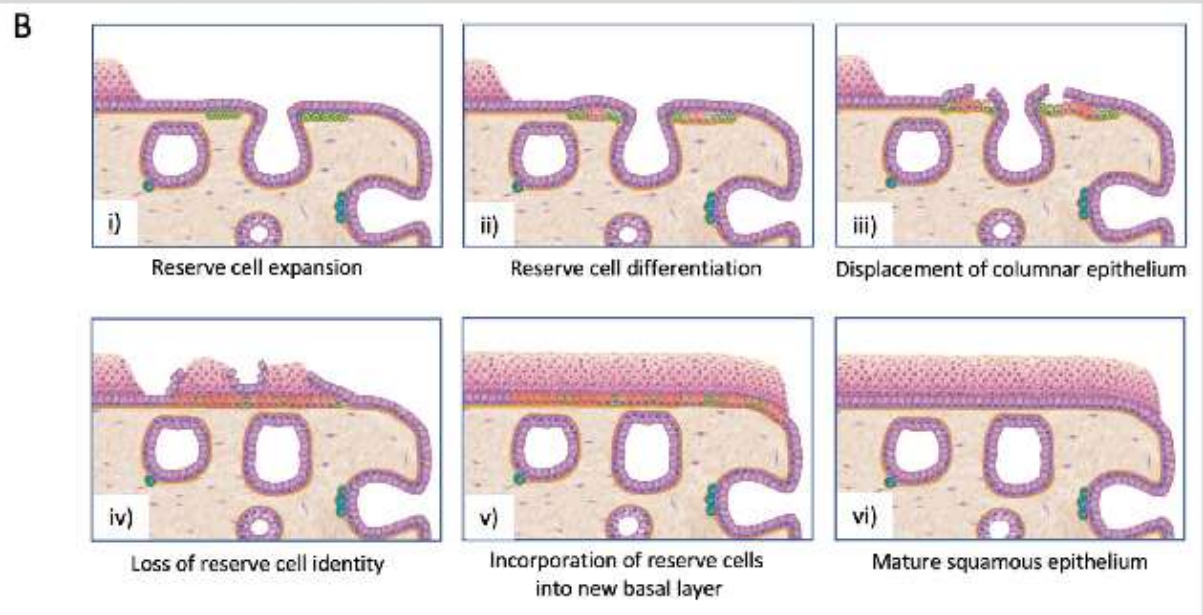
Results: A series of animations were created to show basic infection and disease progression, vaccination, diagnostic tools, and treatment. The visuals were created by reviewing the literature and interviewing researchers to qualitatively ensure scientific accuracy of the graphical contents. Subsequently, quantitative analyses were conducted on these visuals through questionnaires of target audiences consisting of clinicians and researchers. The testing methods were piloted at conferences and confirmed the hypothesis that visuals can help to mitigate barriers quickly and efficiently between the two fields.

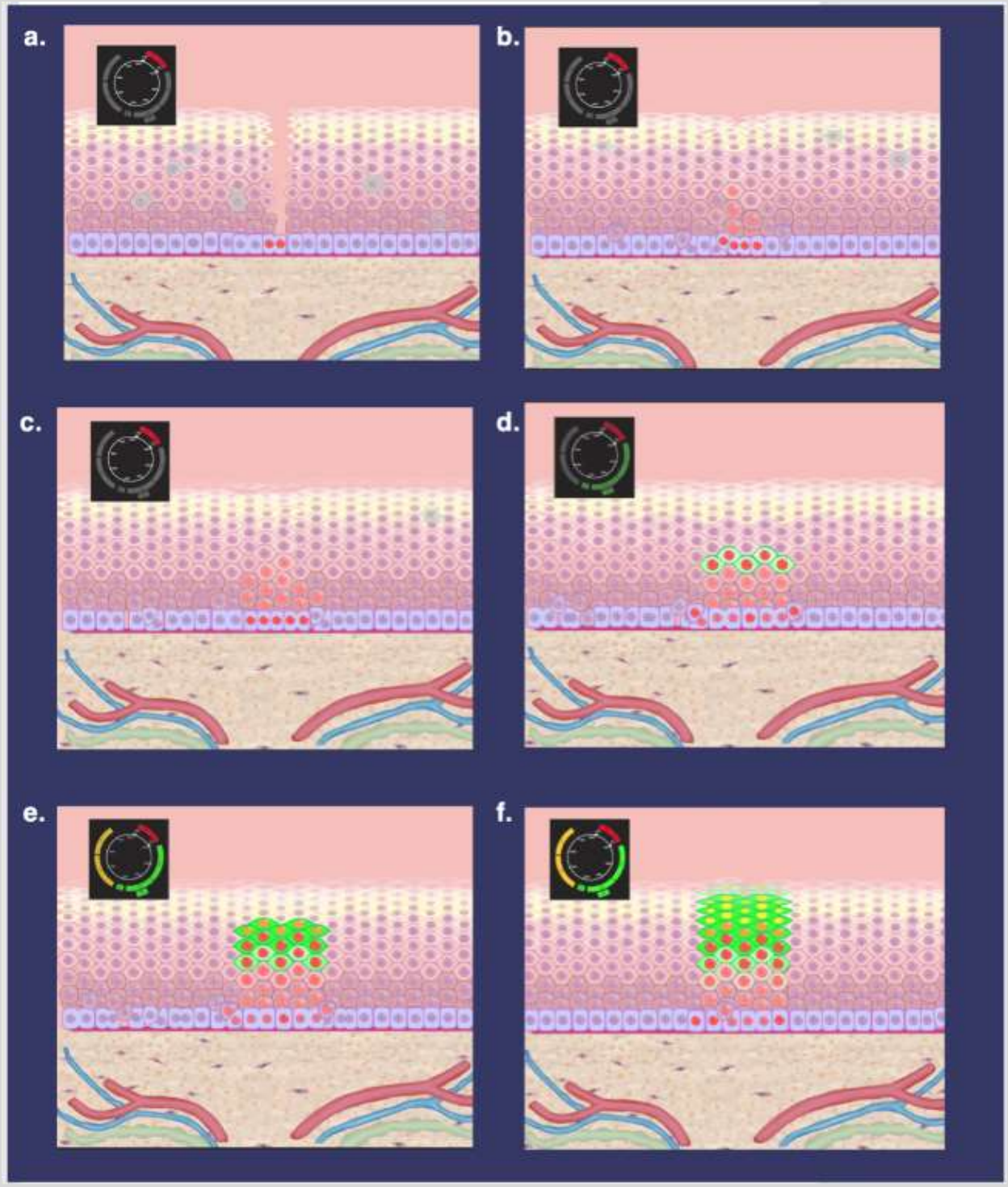
2D Animations



Animations in Animate and After Effects
Illustrations created in Adobe Suite


A
ectocervix
transformation zone
1
2
3
4
RESERVE CELLS
sporadically distributed
beneath columnar epithelium
&
above basal lamina


B
i)
Reserve cell expansion
ii)
Reserve cell differentiation
iii)
Displacement of columnar epithelium
iv)
Loss of reserve cell identity
v)
Incorporation of reserve cells into new basal layer
vi)
Mature squamous epithelium



Conclusions: Preliminary results suggest the importance of visuals aiding in cross-disciplinary knowledge transfer. Wide success thus far provides the model that visuals can contribute to translating complex information, aiding between bench to bedside. In turn, these will contribute widely to understanding these four key areas that work towards the same goal of addressing the worldwide burden of HPV-related cervical cancer.

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Poster Viewing
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IMPLEMENTATION OF SELF-SAMPLING-BASED HUMAN PAPILLOMAVIRUS SCREENING IN HIV-INFECTED WOMEN IN BAMAKO, MALI

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Introduction: In Mali, cervical cancer (CC) is the second most common cancer in women after breast cancer with 25.1% of all cancers (So et al., 2020), yet no prevention program exists. Secondary prevention through self-sampling (SS) for screening for Human Papillomavirus (HPV) has been suggested to address important barriers associated with other CC screening methods. The objective of this study was to evaluate the implementation of SS-based HPV screening in high-risk HIV-infected women in an HIV Care Center in Bamako, Mali.

Methods: The self-sampling kits were given to the participants after an explanation of the method and answering questions on preferences. Cepheid Xpert HPV test which detects the 14 most frequent HPV subtypes was used. Participants who were high-risk (hr)-HPV+ underwent visual inspection tests, and histology before being treated if cancerous lesions were present.

Results: A total of 92% of the 100 HIV-infected women enrolled, chose to do their self-sampling on-site, and the other 8% preferred to have it at home. Of the 8 women, only four brought back their samples from home, while 100% of the remaining provided their samples at the clinic. They all appreciated the concept of self-sampling as opposed to physician-collected samples. We found that 40.6% of the women were positive for high-risk HPV, HPV18/45 with 45% of cases, followed by the P3 (HPV31, 35, 33, 52, 58) group with 33%. There were many co-infection cases, and all positives agreed to undergo additional tests and treatment when needed.

Conclusions: Most women, 92% preferred to self-collect their samples at the clinic. This strategy of SS for HPV screening seems to be accepted by HIV-infected women in Mali and can be widely implemented to reduce the incidence of CC in low-resource settings.

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Poster Viewing
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ASSOCIATION BETWEEN HUMAN PAPILLOMAVIRUSES, METABOLIC SYNDROME, AND ALL-CAUSE DEATH; ANALYSIS OF THE U.S. NHANES 2003-2004 TO 2017-2018.

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Introduction: Human papillomavirus (HPV) is the most common sexually transmitted infection, attributed to 4.5% of all cancers worldwide (U.S. DHHS, 2022). Co-infection with the metabolic syndrome (MetS), a common cluster of cardiometabolic risk factors, has been shown to increase the persistence of HPV (Lee et al., Gyn Oncol, 2021). The purpose of this study was to estimate the association between HPV and MetS on mortality risk.

Methods: Data for the current study was drawn from eight consecutive cycles (2003-2004 to 2017-2018) of the U.S. NHANES (18-65y, n=13,763, 71% F), with mortality follow-up to Dec. 31st, 2019. Baseline HPV status was assessed by either vaginal swab or oral rinse, and used to classify participants as: no HPV (n=5,624), low (n=2,665), probable (n=1,495), and high-risk (n=3,979; 13% type 16, and 5% type 18) HPV using IARC criteria (WHO, 2007). MetS was assessed by the Harmonized criteria (Alberti et al., Circ, 2009).

Results: The average follow-up was 9.4 y with 370 all-cause deaths [no HPV (n=79); low (n=94); probable (n=55), and; high-risk (n=142)]. Compared to those with no HPV (referent), individuals with low-risk (HR=1.79, 95% CI: 1.21-2.42), probable (1.83, 1.29-2.59) and high-risk (1.74, 1.31-2.30) HPV had an elevated risk of mortality. After adjusting for covariates, no significant relationships remained in women, and effects were attenuated in men. Cross-classification into discrete MetS/HPV strata yielded a stepwise gradient of increasing risk in men; in women, only MetS was related to mortality.

Conclusions: In this study, low, probable, and high-risk HPV and MetS were differentially related to mortality risk in men and women. Further work is necessary to separate the temporal, age, vaccination, and sex effects of HPV diagnosis in these relationships using prospective studies with detailed histories of HPV infection and persistence.

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Poster Viewing
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BURDEN OF HEAD AND NECK TUMOR ATTRIBUTABLE TO HPV FROM 1990 TO 2019 AND PROJECTIONS UNTIL 2039 IN CHINA

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Introduction: There still remains unknown about trends in head and neck tumor burden attributed to human papilloma virus(HPV) in China.

Methods: Head and neck cancer burden of China were extracted from the Global Burden of Disease(GBD) study in 2019. Lacking direct data of HPV attributed to this cancer in China, we used the data from a cross-sectional study to estimate. The age-period-cohort(APC) analysis were conducted to display the trend from 1990 to 2019. A Bayesian APC model was used to predict the disease burden until 2039.

Results: Age-standardized head and neck cancer mortality (ASMR) and age-standardized disability-adjusted life years (ASDR) decreased in total population, male and female (Table 1.). In APC of total population, the annual percentage change(net drift) across the study period was -2.03(95%CI:-2.215,-1.845), which suggested a significantly decreased trend of head and neck cancer deaths that could be attributed to HPV(Figure 1.D.). The risk of death increased in the first several birth cohorts but declined in cohorts born after 1950(Figure 1.C.). In total population, the prediction model indicated that in age groups from 0-14 to 70-74, ASMR will decrease gradually from 2020-2039, but in age groups above 75, ASMR will increase, which was similar to the trend in male. In female, ASMR in all age groups will gradually decrease, exempt for

95+.

Table 1. The burden of head and neck cancer cases that can be attributed to HPV

		1990		2019		Percentage Change (CI)	
Total population							
Death	Numbers(n)	2906	(2656,3155)	4536	(4099,4974)	56.12	(36,76)*
	PAF(all ages, %)	6.00	(5.26,6.73)	5.88	(5.07,6.69)	-1.93	(-20.06,16.20)
	Mortality(all ages)	0.25	(0.22,0.27)	0.32	(0.29,0.35)	29.93	(13.14,46.71)*
	ASMR	0.33	(0.31,0.36)	0.23	(0.21,0.25)	-31.86	(-40.29,-23.44)*
	Age-standardized PAF(%)	5.98	(5.29,6.67)	5.86	(5.07,6.65)	-2.00	(-19.32,15.31)
DALYs	Numbers(n)	94189	(85386,102991)	126254	(113658,138849)	34.04	(16,52)*
	PAF(all ages, %)	6.02	(5.22,6.82)	5.92	(5.08,6.77)	-1.60	(-20.79,17.59)
	All-age rate	7.96	(7.21,8.70)	8.88	(7.99,9.76)	11.55	(-3.70,26.80)
	ASDR	9.59	(8.73,10.44)	6.19	(5.58,6.79)	-35.48	(-44.00,-26.96)*
	Age-standardized PAF(%)	6.01	(5.25,6.78)	5.91	(5.09,6.73)	-1.68	(-20.20,16.84)
Male							
Death	Numbers(n)	2002	(1784,2219)	3561	(3138,3984)	77.93	(49,107)*
	PAF(all ages, %)	6.04	(5.09,6.98)	5.90	(4.90,6.90)	-2.30	(-24.84,20.24)
	Mortality(all ages)	0.33	(0.29,0.36)	0.49	(0.43,0.55)	49.79	(25.66,73.92)*
	ASMR	0.48	(0.44,0.53)	0.38	(0.34,0.42)	-21.63	(-33.25,-10.01)*
	Age-standardized PAF(%)	6.03	(5.18,6.88)	5.86	(4.93,6.79)	-2.77	(-23.45,17.90)
DALYs	Numbers(n)	65574	(58088,73061)	100479	(92992,107966)	53.23	(32,74)*
	PAF(all ages, %)	6.07	(5.13,7.00)	6.70	(5.72,7.68)	10.36	(-13.09,33.81)
	All-age rate	10.75	(9.52,11,97)	13.86	(12.16,15.56)	28.99	(7.38,50.61)*
	ASDR	13.35	(11.91,14.79)	9.98	(8.79,11.17)	-25.23	(-37.25,-13.20)*
	Age-standardized PAF(%)	6.05	(5.12,6.99)	5.92	(4.91,6.93)	-2.22	(-24.68,20.24)
Female							
Death	Numbers(n)	904	(788,1021)	975	(856,1094)	7.84	(-11,27)
	PAF(all ages, %)	5.91	(4.83,6.99)	5.82	(4.80,6.83)	-1.52	(-11.00,23.34)
	Mortality(all ages)	0.16	(0.14,0.18)	0.14	(0.12,0.16)	-11.34	(-27.06,4.39)
	ASMR	0.21	(0.18,0.23)	0.10	(0.08,0.11)	-53.30	(-61.37,-45.23)*
	Age-standardized PAF(%)	5.89	(4.86,6.92)	5.81	(4.81,6.81)	-1.36	(-25.61,22.88)
DALYs	Numbers(n)	28614	(24706,32522)	25775	(22389,29161)	-9.92	(-27,7)
	PAF(all ages, %)	5.92	(4.79,7.04)	5.85	(4.76,6.95)	-1.05	(-27.39,25.28)
	All-age rate	4.99	(4.31,5.67)	3.70	(3.21,4.18)	-25.94	(-39.97,-11.91)*
	ASDR	5.88	(5.09,6.66)	2.55	(2.22,2.88)	-56.67	(-64.76,-48.58)*
	Age-standardized PAF(%)	5.91	(4.79,7.03)	5.85	(4.76,6.93)	-1.07	(-27.31,25.18)

Percentage change(PC) was calculated to describe whether the trend of the variables was statistically significant. Symbol '*'represents the trend with statistical significance.

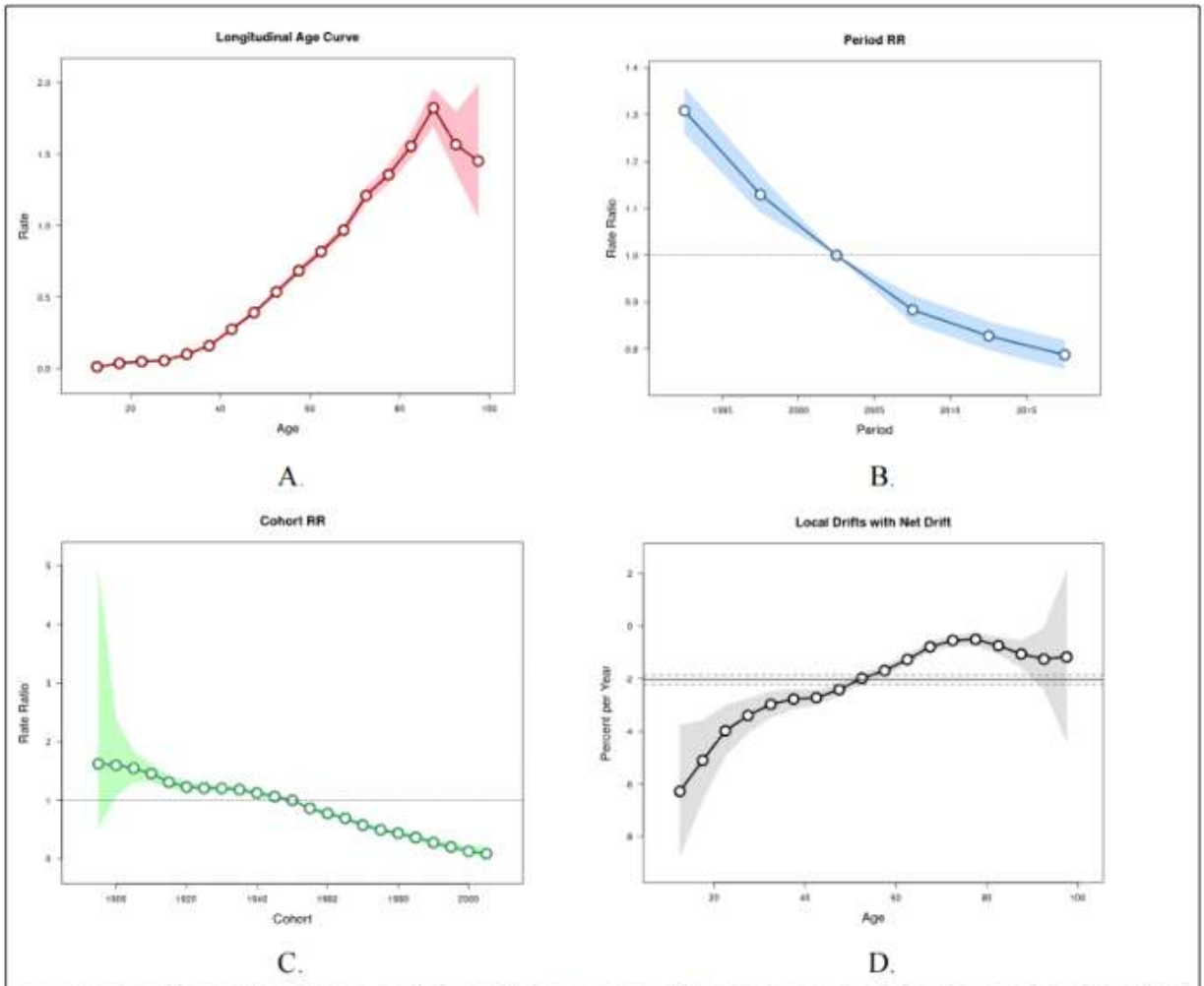

Figure 1. Effects of age, time period, and cohort on head and neck cancer deaths attributed to HPV from 1990 to 2019 in China. A. Fitted longitudinal age curves of mortality. In the same birth cohort, the mortality rate increased with increasing age, except for age ≥ 85years, which might be explained by competing risks of other diseases. B. Relative risks of each period compared with the reference period (2000–2004). The time-period RRs were ≥1 before 2003, and were ≤1 after 2003. C. Relative risks of each cohort compared with the reference cohort (1940-1944). The risk of death increased in the first several birth cohorts but declined in cohorts born after 1950. D. Local drifts with net drift values. The annual percentage change(net drift) across the study period was -2.03(95%CI:-2.215,-1.845). Besides, this trend varied according to age(local drift), but the percentages of all the age group were below 0, indicating a decreased trend.

T

Conclusions: The increased risk in the early birth cohort might be due to widespread exposure to HPV. Data from 1990 to 2019 show an overall decline in head and neck cancer deaths that could be attributed to HPV. In the future, deaths among women are expected to decline significantly in all age groups, which can be explained in part by the rollout of the HPV vaccine in China.

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Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-20-2023 7:00 AM - 4:00 PM

ASSOCIATION BETWEEN PATIENT-CENTERED COMMUNICATION AND HPV-RELATED KNOWLEDGE, ATTITUDES, BEHAVIORS AND PRACTICE (KABP) AMONG U.S ADULTS AND PROVIDERS: A SYSTEMATIC REVIEW

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Introduction: Human papillomavirus vaccination is inadequate in the United States. HPV continues to be a taboo topic and patients often express hesitancy discussing HPV-related topics with their providers. Since HPV discussions occur mainly during clinical encounters, provider's communication style is a major contributor in fostering positive attitudes and beliefs, and improving HPV literacy. Patient-centered communication has emerged as an effective way to navigate complex health topics, including HPV. Therefore, through this study, we aim to systematically review the impact of patient-centered communication on Human Papilloma Virus (HPV)-associated knowledge, attitudes, behaviors and practices among adults in the United States.

Methods: We followed the PRISMA guidelines and searched six databases: [Medline Complete (EBSCO), CINAHL (EBSCO), Health Source- Consumer Edition (EBSCO), Embase (OVID),Northern Light Life Sciences Conference Abstracts (OVID), and BIOSIS Citation Index (Web of Science)]. We reviewed quantitative empirical studies published between 2006 and 2020. Studies were eligible if they a.) comprised primary, quantitative data, b) were published in English between 2006 and 2020, c) examined constructs related to patient-centered communication, d) targeted adults clients and providers, e) determined the relationship between patient-centered communication and HPV-associated knowledge, attitudes, behaviors, and practices (KAPB), and f) were conducted in the United States. Two independent reviewers (AT AND MS) screened 1574 titles/ abstracts, and 79 full-text articles. Fourteen studies were included for final analysis.

Results: Among patients, communication techniques involving patient-centered constructs (reflective listening, spending enough time, clarifying concerns, respecting values and needs etc.) led to improved knowledge about HPV, intention to vaccinate or get their child (ren) vaccinated, and lower odds of vaccine delay/ refusal. Providers following patient-centered guidelines reported improved vaccine delivery rates, self-efficacy recommending the HPV vaccine and HPV-related subjective norms.

Conclusions: Given the success of patient-centered communication on HPV-associated KABP, practices must consider integrating patient-centered guidelines to improve HPV-related health outcomes.

Shift 02-295 / #1837

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-20-2023 7:00 AM - 4:00 PM

CLINICAL DECISION TOOLS TO IMPROVE CERVICAL CANCER SCREENING AND MANAGEMENT-PRELIMINARY PILOT FINDINGS AND SUSTAINABILITY

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Introduction: Objective: Cervical cancer is highly preventable when detected early and appropriately managed. Despite evidence that cervical cancer screening saves lives, we see increased inequities for screening followup and higher burden of precancers and cancer among women in low-resources settings. The complexity and frequent updates to cervical cancer screening and management (CCSM) guidelines make it challenging for clinicians to stay abreast of the latest recommendations. The Centers for Disease Control and Prevention is leading a multi-year initiative to develop clinical decision support (CDS) tools to increase awareness and adoption of the latest evidence-based CCSM guidelines.

Methods: Existing guidelines were translated into a standards-based, computable format and developed as open-source CDS tools. The tools will be used by clinicians at the point of care while being piloted at multiple clinical sites that provide care to underserved. The pilots will provide insight on integration feasibility across disparate IT platforms. The CDS tools will be evaluated to understand the impact on care decisions and the end user experience.

Results: Challenges to evaluation in pilot settings include: the lack of structured pathology results in the EHR and an inability to evaluate long-term follow-up because of the six-month timeframe. Pilot results and user feedback will be used to iterate and continually improve the CCSM CDS.

Conclusions: Limited availability and accessibility to health IT decision supports make it difficult for medically underserved populations to receive appropriate CCSM care. Standards-based CDS that is open-source provides a potential means to facilitate adoption of updated CCSM guidelines in diverse settings and ultimately decrease disparities in cervical cancer outcomes.

Shift 02-BOARD ONSITE01 / #611

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

ROLE OF HUMAN PAPILLOMAVIRUS (HPV) VACCINATION ON HPV INFECTION AND RECURRENCE OF HPV RELATED DISEASE AFTER LOCAL SURGICAL TREATMENT: SYSTEMATIC REVIEW AND META-ANALYSIS

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Introduction: The efficacy of human papillomavirus (HPV) vaccination on the risk of recurrent diseases related to HPV infection in individuals undergoing local surgical treatment constitutes a matter of debate.

Methods: In this study we screened data sources for studies reporting on the risk of HPV infection and recurrence of disease related to HPV infection after local surgical treatment of preinvasive genital disease in individuals who were vaccinated. Independent and in duplicate data extraction and quality assessment were performed. Grading of Recommendations Assessment, Development, and Evaluation (GRADE) was implemented for the primary outcome (recurrence of cervical intraepithelial neoplasia grade 2 or higher (CIN2+)). Pooled risk ratios and 95% confidence intervals were calculated with a random effects meta-analysis model.

Results: 18 studies reported data from a non-vaccinated group and were included in the meta-analyses. The risk of recurrence of CIN2+ was reduced in individuals who were vaccinated compared with those who were not vaccinated (11 studies, 19 909 participants; risk ratio 0.43, 95% confidence interval 0.30 to 0.60; I2=58%, τ2=0.14). The effect estimate was even stronger when the risk of recurrence of CIN2+ was assessed for disease related to HPV subtypes HPV16 or HPV18 (six studies, 1879 participants; risk ratio 0.26, 95% confidence interval 0.16 to 0.43; I2=0%, τ2=0). Confidence in the meta-analysis for CIN2+ overall and CIN2+ related to HPV16 or HPV18, assessed by GRADE, ranged from very low to moderate, probably because of publication bias and inconsistency in the studies included in the meta-analysis.

Conclusions: HPV vaccination might reduce the risk of recurrence of CIN, in particular when related to HPV16 or HPV18, in women treated with local excision. Large scale, high quality randomised controlled trials are required to establish the level of effectiveness and cost of HPV vaccination in women undergoing treatment for diseases related to HPV infection.

Shift 02-BOARD ONSITE02 / #977

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

FROM PRIORITY-SETTING TO POLICY-MAKING: DATA TOOLS TO GUIDE NATIONAL HPV VACCINE DECISION-MAKING

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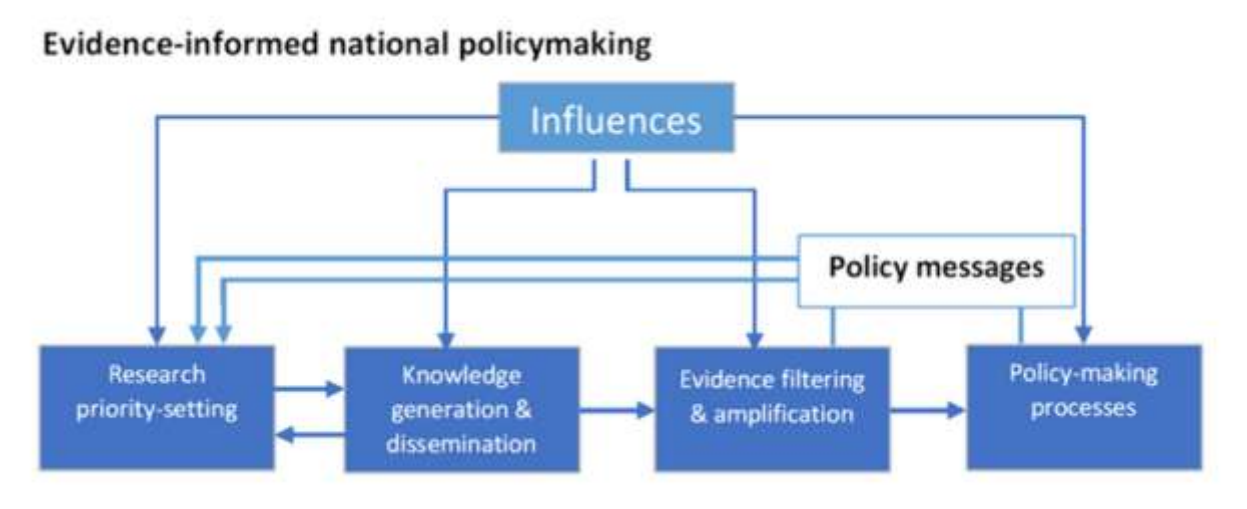
Introduction: Updated, reliable data is critical to drive informed policy-making. To date, 120 countries have introduced HPV vaccines and 21 countries are planning introduction. Government authorities and policy-makers need trusted and reputable data sources to guide HPV decision-making. To bridge the gap between research and policy/decision-making, VIEW-hub and VoICE are innovative tools created to aid knowledge generation and dissemination and evidence filtering and amplification.



Methods: We describe development of these resources: VIEW-hub is a platform for accessing continuously updated data about global vaccine coverage, use, and impact. A new HPV module includes: HPV vaccine introduction status, level of implementation and program characteristics (e.g., current product use, delivery platform for distribution, target population). Detailed country-level data on HPV vaccination is available for use in several formats. VoICE (Value of Immunization Compendium of Evidence) is an online, searchable database created to examine broader topics linked to immunization and vaccines. This resource collates and synthesizes the latest peer-reviewed evidence so advocates can highlight broad benefits of immunization, such as the role of HPV vaccines in economic equity analyses. HPV-specific literature can be retrieved by using HPV as a keyword and results can be filtered by region.

Results: These tools have provided critical information about HPV vaccines to inform global an national decision-making to combined audiences of over 50,000 users across over 100 countries.

Conclusions: Vaccine advocates rely on effectively communicating evidence to influence policy. Free, accessible resources to access the latest evidence are vital for mobilizing policymakers, allocating resources, and supporting an informed HPV vaccine plan of action.

Shift 02-BOARD ONSITE03 / #897

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03E. VACCINATION: IMPLEMENTATION, EVALUATION AND IMPACT
04-20-2023 7:00 AM - 4:00 PM

REACHING THE FIRST 90 OF THE 90/70/90 BY 2030 IN AFRICA- WHAT WILL IT TAKE? FINDINGS FROM A MULTI-COUNTRY CONSULTATION

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Introduction: Cervical cancer is leading cancer affecting women in Africa. To date, 23 countries in the region introduced routine vaccination against human papillomavirus (HPV) following the World Health Organization (WHO) call to vaccinate 90% eligible girls with the HPV vaccine towards cervical-cancer elimination. Less than 20% of eligible girls in the Region received vaccination in 2020, partly due to disruptions in immunization service delivery caused by the pandemic. We convened a meeting to facilitate peer-to-peer learning across countries in the region on challenges, key issues, possible solutions, partnerships, and how to accelerate progress in the introduction, access, program optimization, restoration, and sustainability of HPV vaccination.

Methods: In September 2022, the Coalition to Strengthen the HPV Immunization Community (CHIC) convened 50 program managers, and technical experts from 13 countries, in Addis Ababa, for a consultative workshop following a two-day symposium. Workshop speakers updated participants on the resource landscape for HPV programs, discussing vaccine pipeline, new partner consortiums, and donors available to support country programs. Participants were placed in groups in which countries at different stages of introduction were represented. Participants then worked together, sharing experiences; identifying key issues; deliberating potential strategies; and outlining next steps required to scale-up and optimize vaccination.

Results: We will present workshop outputs demonstrating regional convergence on areas identified for support. Themes will include: technical and political advocacy for HPV vaccination; evidence need for adaptation of single-dose schedules; evidence on effective and efficient service delivery models; catch-up campaigns; integration with adolescent health; mobilizing community support; and additional opportunities for peer-to-peer learning.

Conclusions: Using participatory methods to promote cross-country learning on HPV vaccination proves beneficial to program planners to learn from each other, regardless of their country's stage of introduction. Sub-regional, expert-lead, peer-learning workshops are recommended as a critical element to enable locally-tailored adoption of WHO recommendations, especially regarding options for a single-dose schedule.

Shift 02-BOARD ONSITE04 / #899

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03G. CERVICAL CANCER ELIMINATION
04-20-2023 7:00 AM - 4:00 PM

WE BUILT IT: WHY DIDN'T SOME OF THEM COME? REASONS FOR NON-ENGAGEMENT WITH COMMUNITY-BASED CERVICAL CANCER PREVENTION INTERVENTIONS

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Introduction: East Africa bears the brunt of the global cervical cancer burden. Facility-based delivery of prevention interventions, effective in resource-rich settings, has not achieved population coverage in the region. We developed an approach in Kenya and Uganda to deliver HPV screening and vaccination through health fairs in residents' communities and sought to determine reasons for non-engagement.

Methods: We held health fairs in rural Western Kenya and Uganda, offering education and free-of-charge self-collection of specimens for HPV for women and HPV vaccination for adolescent girls. Afterward, we conducted door-to-door probability sampling to ascertain the fraction of service-eligible residents who were aware of the fairs and the reasons for non-attendance. A purposive sample of non-attenders was offered in-depth interviews to explore reasons for non-

attendance.

Fig 1. Sites in East Africa (denoted by ●) in which community-based campaigns for cervical cancer prevention were implemented.

Results: After 10 fairs, we interviewed 578 screen-eligible women (Kenya 416, Uganda 162) and 147 (Kenya 101, Uganda 46) caregivers of vaccine-eligible girls. Overall, 78% of screen-eligible women had been aware of the fairs, and 54% (Kenya 51%, Uganda 63%) did not attend. The most cited reason for non-attendance was competing domestic, job, or social responsibilities (Table). Interviews enriched these reasons, with women reporting privacy concerns and fear that the procedure would be painful, cause infections or involve removing the uterus. Among caregivers of vaccine-eligible girls, 82% were aware of the fairs, and 37% did not take/send their girls to the fair (Kenya 33%, Uganda 52%). The most cited reasons were girls being in school (43%). Overall, 2% stated not believing in vaccines. Interviews revealed fears of vaccines making the girls sick, promiscuous, or sterile.

Table. Reasons for non-attendance of community-based health fairs for cervical cancer screening and HPV vaccination in Kenya and Uganda.

Reasons for Fair Non-Attendance	Kenya	Uganda	Overall
Among Screening-Eligible Women	**(n=181)**	**(n=66)**	**(n=247)**
Competing responsibilities	51%	29%	45%
Illness or post-partum	10%	22%	13%
Fear of the process	12%	9.2%	11%
Felt not needed - screened in the past	10%	11%	10%
Aware of fair too late or forgot	5.0%	5.0%	5.0%
Did not see benefit	1.2%	9.2%	3.0%
Other*	11%	15%	13%
Among caregivers of vaccine-eligible girls	**(n=30)**	**(n=14)**	**(n=44)**
Child away	53%	21%	43%
Parent away/busy/sick	13%	29%	18%
Thought girl too young	3.3%	21%	9.0%
No reason	3.3%	21%	9.0%
Other‡	27%	7.0%	21%

Most common "Other" reasons. *Screening. Discouraged from attending; venue too far; had insufficient information about the fair. ‡ HPV vaccination. Needle phobia; does not believe in vaccines

Meaningful quotes explaining some reasons for non-participation in community-based health fairs for HPV vaccination for adolescent girls and cervical cancer screening using self-collected specimens for HPV testing

Women eligible for cervical cancer screening	"I just heard them (women previously screened) talk amongst themselves saying that when you go there, they put something thing in you and torch you which can hurt you and give you infections in the womb including getting cancer of the cervix ..." (35-year-old) "I am scared about 2 things: One, I heard people say they put their entire hand into your private parts! That scared me because even in my deliveries that did not happen. Two, I fear having someone see my private parts when I am not in labor. I might let a woman because I want the service but a man? No!" (37-year-old) "I did not have money so had no use going to the fair. What would I do if I was screened and told I was sick but did not have money for the treatment? I would rather remain in the dark than know." (37-year-old)
Caregivers of adolescent girls eligible for HPV vaccination	"Others say that these people (HPV vaccine promoters) want to make our children promiscuous and prevent them from giving birth in the future." (51-year-old). "Some people say vaccinating a child will make the child sick." (51-year-old).

Conclusions: Competing responsibilities were the most prominent reason residents declined to engage in cervical cancer prevention-related health fairs held in their communities. Misperceptions about safety, efficacy, or intent of the services were uncommon. These reasons can inform messaging around and implementation of community-based campaigns to maximize participation.

Shift 02-BOARD ONSITE05 / #1763

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-20-2023 7:00 AM - 4:00 PM

INCREASING VISIBILITY ON ACCESS AND AVAILABILITY OF HPV VACCINES IN KENYA; LESSONS FROM CHANJO ELMIS

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Introduction: In Kenya, about 9 women die every year from Cervical Cancer. The HPV vaccine was introduced in the country in 2019 and was targeted toward 10-14-year-old girls Since the vaccine's introduction, its movement and consumption have been tracked on Chanjo ELMIS, a web-based logistical management platforms used in 1 national store, 9 regional stores, and 306 sub counties. This increased visibility has improved the planning and routine distribution of the vaccine

Methods: In collaboration with the National Vaccines and Immunisation Program (NVIP), CHAI worked on the system to allow the addition of the HPV vaccine and related dry commodities such as syringes and safety boxes. CHAI also deployed the cold chain module, an active inventory of all cold chain equipment (CCE) in the country, detailing the CCE's functionality, maintenance, and storage capacity. CHAI also worked with the government to include key indicators that can be tracked through transactions entered the system. These indicators were routinely reviewed at different levels of the supply chain in data review meetings. Chanjo ELMIS was integrated with the central data store DHIS. This provides further linkage between the supply chain and consumption

Results: Increased visibility of cold chain capacity and functionality as well as current vaccine balances has facilitated effective vaccine distribution. Collection cycles have reduced from an average of 3 per supply period in 6 out of the 9 regions to 1.2 in q4 of 2022. The number of health facilities that offer HPV immunization has been seen to increase from 874 in 2019 to 4031 in December 2022.

Conclusions: Chanjo ELMIS has enabled end – to end visibility of the supply chain and offers real time data for data-driven vaccine planning

Shift 02-BOARD ONSITE06 / #1348

Poster Viewing
POSTER VIEWING - SHIFT 02: PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE-03K. OTHER PUBLIC HEALTH, EPIDEMIOLOGY AND IMPLEMENTATION SCIENCE RESEARCH
04-20-2023 7:00 AM - 4:00 PM

KNOWLEDGE OF HUMAN PAPILLOMAVIRUS AND CERVICAL CANCER SCREENING RECOMMENDATIONS AMONG UNDERSCREENED WOMEN IN AN URBAN SAFETY NET HEALTH SYSTEM

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Introduction: In the United States (US), safety-net health systems provide essential healthcare services to low-income populations who may not otherwise have healthcare access. Cervical cancer screening is often challenging in these settings due to structural, cultural, and personal barriers, including knowledge gaps. This study describes knowledge of human papillomavirus (HPV) and cervical cancer screening recommendations among underscreened women in a safety-net setting.

Methods: We used data from 230 telephone surveys as part of the Prospective Evaluation of Self-Testing to Increase Screening (PRESTIS) trial—a randomized controlled trial designed to evaluate self-sample HPV testing to improve screening participation among underscreened women in an urban safety-net healthcare system. Demographics, HPV knowledge, and barriers to screening were assessed and compared across race/ethnicity and primary language using Fisher's exact tests.

Results: The median age of participants was 47 years. Most (69%) were Hispanic, 61% were Spanish-speakers, and 65% were not born in the US. Almost half (45%) had less than high school education and 89% reported an annual household income less than $40,000. Almost two-thirds (65%) reported that the safety-net system was their only source of healthcare, and this was significantly more prevalent among Hispanics (70%, p=0.04). The majority had heard of cervical cancer (79%) and HPV (78%) prior to the trial, and most (78%) thought a positive HPV test meant a high chance of having or developing cancer. Over one-third (36%) reported that not knowing how often they needed a Pap test was a barrier to cervical cancer screening, and this barrier was significantly more prevalent among Spanish- versus English-speakers (43% vs. 26%, p<0.01).

Conclusions: Our results suggest low knowledge about HPV and screening recommendations among underscreened safety-net system patients. Effective interventions are needed to address knowledge-related barriers to increase cervical cancer screening in urban, low-income women in the US.

Posters Virtual

VIRTUAL-001 / #501

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

GENOMIC CHARACTERIZATION OF BOVINE PAPILLOMAVIRUS TYPES 1 AND 2 PROVIDES INDICATIONS TO INFER THE DIRECTION OF CROSS-SPECIES TRANSMISSION BETWEEN CATTLE AND HORSES

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Introduction: Clinical management of the most common skin neoplasm in horses, termed the equine sarcoid, remains challenging because of the gap in knowledge regarding (cross-species) viral transmission and the mechanisms underlying host-specific clinical presentation of bovine papillomavirus (BPV)-infection. Earlier studies highlighted the potential functional significance of intratypic sequence variants, along with the existence of sarcoid-associated BPV variants. Therefore, we aimed to explore the genetic diversity of these genotypes in both hosts and investigated if associations exist between BPV variation and host species.

Methods: Recent work of our group introduced a new approach for genome-wide nanopore sequence analysis of BPV types 1 and 2 originating from clinical samples. Based hereupon, a barcoded nanopore sequencing library was prepared by amplification of eight overlapping amplicons in two multiplex PCR reactions. For phylogenetic analysis, separate alignments were made of all available complete genome sequences for BPV-1/-2. The resulting alignments were used to infer Bayesian phylogenetic trees.

Results: Generating a significant amount of full BPV genomes deriving from equine sarcoids and bovine papillomas revealed the presence of identical isolates in both host species, which is an epidemiologically relevant finding. The majority (55%) of detected non-synonymous single nucleotide variants (n= 40) was exclusively present in horse-derived samples. Accordingly, all the major deletions were sarcoid-sourced.

Conclusions: Our results suggest (1) co-evolution of BPV within the horse population, and (2) that viral transfer from cattle to horses is a recurrent and potential ongoing occurrence. While further research on the functional significance of the genomic variants is warranted, inferring the direction of viral transmission appears valuable to the development of preventive measurements against the spread of sarcoids in the horse population, demonstrating that next-generation sequencing in this context is not of mere academic interest.

VIRTUAL-002 / #1374

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

PGE2 SECRETED BY HPV6/11-INDUCED RESPIRATORY PAPILLOMAS BLOCKS NK DEGRANULATION IN RECURRENT RESPIRATORY PAPILLOMATOSIS.

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Introduction: Recurrent respiratory papillomatosis (RRP) is characterized by multiple innate and adaptive immune deficiencies. Previously, we showed the absence of select NK KIR activating receptor genes and altered KIR haplotypes in RRP patients. We also showed that papilloma cells fail to express classical MHC Class I, but strongly express the non-classical MHC Class I alleles, which would protect against NK targeting. We have now further explored the mechanisms that prevent NK cell degranulation within respiratory papillomas.

Methods: NK cells were isolated from blood of RRP patients and controls, and from papilloma tissue. Sub-populations were analyzed by flow cytometry. Degranulation was measured by CD107a expression after exposure of NK cells to K562 cells. PGE_2 levels were measured in papilloma cell-conditioned media (CM) by ELISA. PGE_2 synthesis was inhibited with the COX-2 inhibitor NS398. NK cells were incubated with inhibitors for the PGE_2 receptors EP2 and EP4.

Results: NK cells isolated from papillomas show reduced expression of the key activating receptor NKG2D and CD62L, and impaired degranulation compared to blood-derived NK cells from patients and controls ($p<0.001$). NK degranulation was reduced ($p<0.01$) when blood-derived NK cells were co-cultured with minced papilloma explants or with CM from cultured papilloma cells. PGE_2 was elevated in CM from cultured papilloma cells compared to CM from tonsil epithelia ($p<0.01$), and treating papilloma cells with NS398 blocked the ability to suppress NK degranulation. Finally, inhibiting the NK EP2 receptor prevented suppression of degranulation by papilloma CM. Addition of both EP2 and EP4 inhibitors completely reversed PGE_2 NK suppression

Conclusions: PGE_2 secreted by papilloma cells is the major inhibitor of NK cell degranulation. NK cell inhibition is principally mediated through the PGE_2 receptor EP2, and to a lesser extent through EP4 signaling. NK inhibition contributes to the immune evasion of HPV6/11-induced respiratory papillomas.

VIRTUAL-003 / #620

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

MULTI-OMICS CHARACTERIZATION OF SILENT AND PRODUCTIVE HPV INTEGRATION IN CERVICAL CANCER

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Introduction: Cervical cancer (CC), which is caused by high-risk human papillomavirus (HPV), remains a significant public health problem worldwide. HPV integration sites can be silent or actively transcribed leading to production of viral-host fusion transcripts.

Methods: Using large-scale, multi-omics (clinical, genomic, transcriptional, proteomic, phosphoproteomic, and single-cell) data, we studied the characterization of silent and productive HPV integration in cervical cancer.

Results: we demonstrate that only productive HPV integration sites were nonrandomly distributed across both viral and host genomes suggesting that productive integration sites are under selection and likely contribute to CC pathophysiology. Furthermore, we demonstrate that tumors with productive HPV integration are associated with higher E6/E7 proteins and enhanced tumor aggressiveness and immunoevasion. Importantly, productive HPV integration increases from carcinoma in situ to advanced disease.

Conclusions: This study improves our understanding of the functional consequences of HPV fusion transcripts on the biology and pathophysiology of HPV-driven CCs suggesting that productive HPV integration should be evaluated as an indicator of high-risk for progression to aggressive cancers.

VIRTUAL-004 / #617

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HPV16 E6/E7 PROTEINS ALTER CHLAMYDIA TRACHOMATIS DEVELOPMENT AND INFECTIOUS PROGENY GENERATION

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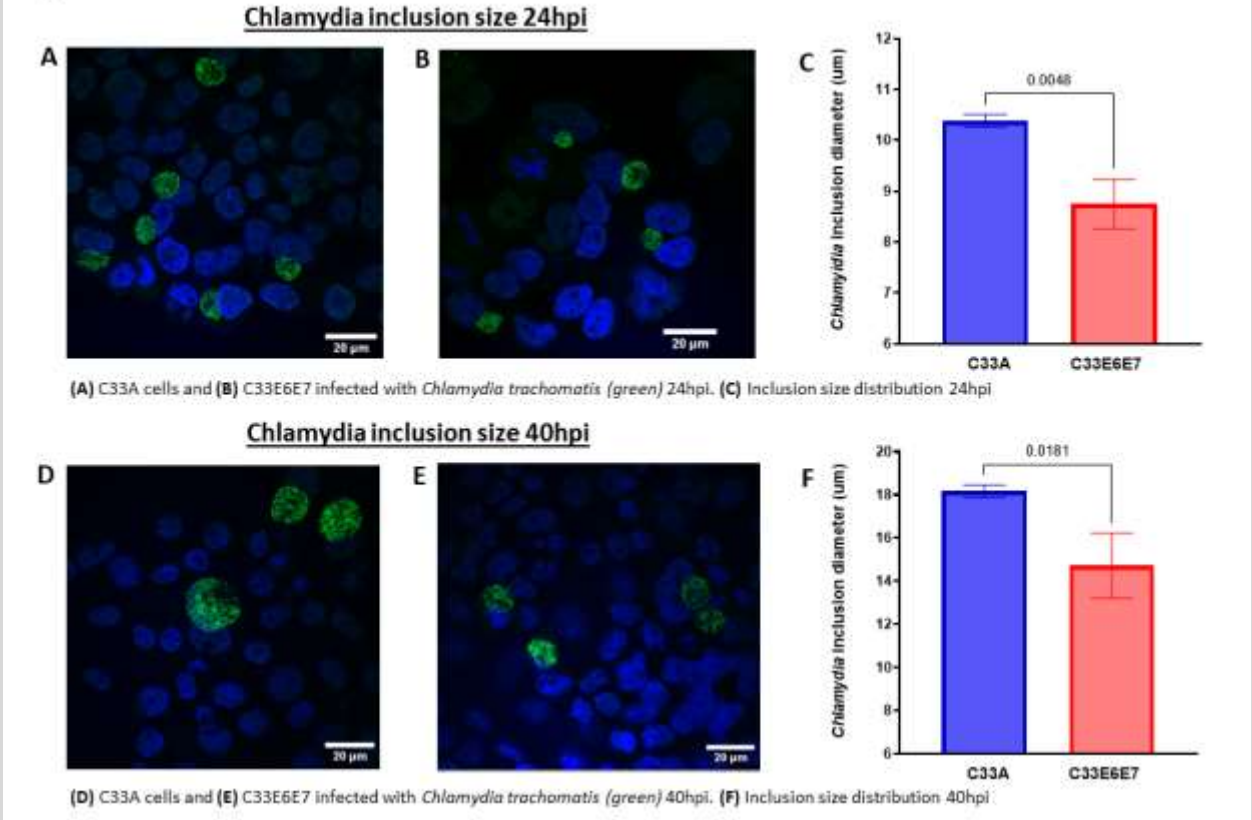
Introduction: HPV and Chlamydia trachomatis (Ct) are highly prevalent sexually transmitted pathogens worldwide. It is frequent in clinical practice to find HPV and Ct co-infections, which correlate to exacerbated development of cervical cancer. However, the pathogenesis underlying HPV and Ct co-infection remains unclear. The aim of the present study is to evaluate the interaction between E6/E7 HPV-16 proteins and Ct in an in-vitro model of human cervical epithelial cells in order to investigate the effects of HPV on Ct development and immune response.

Methods: Carcinoma endocervical C33-A cells expressing or not E6/E7 proteins from high-risk HPV 16 were infected with Ct LGV-L2 strain and evaluated at 24 and 40 hours post infection (hpi). Ct inclusions size, number and infectious progeny generation were assessed by immunofluorescence microscopy using Chlamydia-specific CT043 antibodies. In addition, flow cytometry was used to analyze the expression of immune co-inhibitory molecules in C33A and C33E6E7 cells infected or not with Ct.

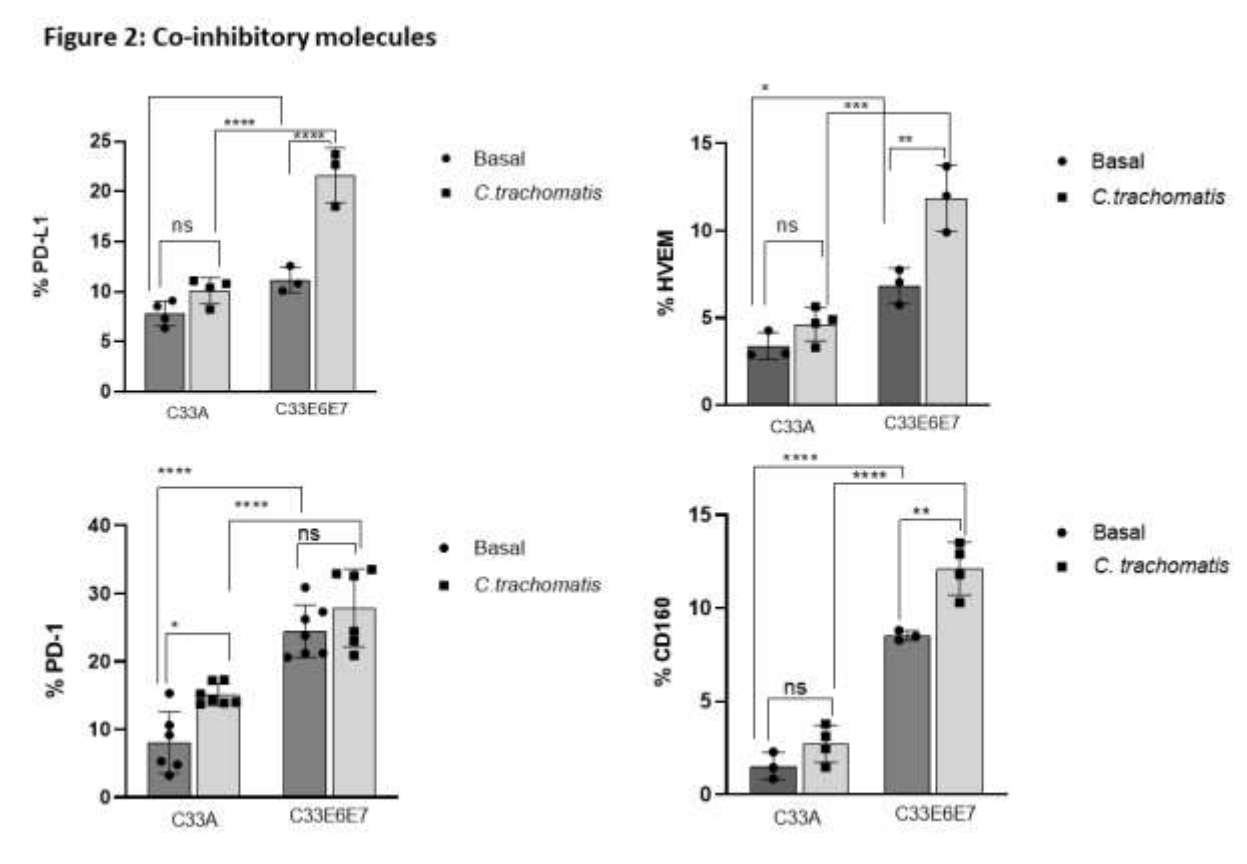
Results: E6/E7 HPV-16 proteins affects the intracellular development of Ct revealed by smaller inclusion size as compared to C33-A cells in the two time-points analyzed (Figure 1). Further, Ct from C33E6E7 cells showed a marked reduction in infectious progeny generation compared to those from C33-A cells. In addition, we found that C33E6E7 cells express higher levels of the co-inhibitory molecules PD-1, PD-L1, CD160 and HVEM and infection with Ct enhanced even more these inhibitory molecules expression (Figure
2).

Figure 1



(A) C33A cells and **(B)** C33E6E7 infected with *Chlamydia trachomatis (green)* 24hpi. **(C)** Inclusion size distribution 24hpi

(D) C33A cells and **(E)** C33E6E7 infected with *Chlamydia trachomatis (green)* 40hpi. **(F)** Inclusion size distribution 40hpi



Conclusions: Expression of E6/E7 HPV-16 proteins resulted in decreased inclusion size and infectious progeny generation, pointing out that HPV may impair Ct development and induce Ct entry into persistence. Moreover, an increased expression of co-inhibitory molecules could decline the induction of an accurate immune response and may be linked to disease exacerbation observed during HPV and Ct co-infections.

VIRTUAL-005 / #962

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A NEW ALGORITHM FOR CLASSIFICATION OF HUMAN PAPILLOMAVIRUS 16 AND 18 INTO LINEAGES AND SUBLINEAGES

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Introduction: . HPV genomes are classified into lineages and sublineages based on sequence differences and phylogenetic topologies. Genomes from different lineages in the current classification show average nucleotide differences of 1.0–10.0% while sublineages differ only by 0.5–1.0%. Since the number of sequenced HPV genomes is growing fast there are two important objectives: (1) develop a computational method for automatic classification and re-classification of all known HPV genomes, and (2) develop an efficient method for automatic assignment of incomplete HPV sequences from clinical samples to the type, the lineage and the sublineage.

Methods: . We present an algorithm of parsing a phylogenetic tree built for a set of HPV genomes of a given type into lineages and sub-lineages. The algorithm defines clusters and subclusters based on phylogenetic topology and determines the inter- and intra-cluster distances characterizing lineage and sublineage separations. A set of representative genomes for the sublineages is then selected and used to assign an incomplete HPV sequence to a sublineage and, therefore, to a lineage.

Results: . We analyzed 2,000 HPV16 and 150 HPV18 complete genomes with the algorithm. The algorithm-derived classification had significant concordance with the earlier established classifications for these two HPV types, however, new candidate sub-lineages of HPV-16 were identified. We also assessed the accuracy of assigning incomplete genomic sequences to lineages and sublineages. As expected, accuracy strongly depends on the extent of genome coverage. Errors increase if the sequence is shorter than 20% of the HPV genome.

Conclusions: . The new algorithm can be used for faster classification or re-classification of HPV variants as well as taxonomic classification of incomplete genomic sequences with greater sensitivity and specificity than established computational methods.

VIRTUAL-006 / #1734

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TRANSCRIPTOME-WIDE ANALYSIS OF LONG NONCODING RNAS REVEAL THEIR INTERACTION WITH HOST CODING TRANSCRIPTS AND HPV16 ENCODED ONCOPROTEIN E7 IN CERVICAL CANCERS

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Introduction: Long noncoding RNA genes (lncGs) play a pivotal role in cervical cancer (CaCx) pathogenesis by interacting with viral oncoproteins and regulating different coding genes. We aimed to unfurl such regulations and interactions considering a genomic correlative approach and functional assays.

Methods: Differentially expressed coding (DEcGs) and lncGs (DElncGs) were identified in HPV16-positive CaCx patients compared to HPV-negative normal individuals, through RNA-seq. Weighted Gene Co-expression Network Analysis (WGCNA) was employed on tumor samples to analyse the long intergenic noncoding (linc) genes (DElincGs), co-expressing with DEcGs. Significant changes in the correlative relationships of antisense and their respective coding genes among tumor and normal samples were estimated. The underlying basis of interaction between one such pair was investigated in depth employing various molecular assays.

Results: WGCNA revealed 5 functional modules consisting of DElincGs which co-express and correlate with DEcGs. Significant correlations were evident between 4 such modules and traits, like viral physical status, lymph node involvement and overall survival (OS) portraying a collaborative effect of all genes present within specific modules. CTD-2619J13.13, a lincRNA hub gene of a module, was found to be associated with OS of patients. Analysing antisense genes, a set of 24 pairs of significantly correlated DEcGs and DElncGs with altered correlation coefficients was recorded among patients over normal individuals. The correlated gene pair MAL and its novel antisense, was selected for further study, where MAL was associated with poor patient survival. We found through RIP-qPCR, the interactive roles of its antisense with HPV16-E7, EZH2 (PRC2 complex member) respectively in the HPV16 positive SiHa cell line, resulting in the silencing of the promoter region of MAL through enhancement of chromatin suppression mark H3K27me3, employing a knockdown approach for E7.

Conclusions: This study shows the importance of DElncGs in CaCx, and therefore these are of immense translational and therapeutic relevance.

VIRTUAL-007 / #811

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OBTAINING THE L1 PROTEIN OF THE TYPE 16 HUMAN PAPILLOMA VIRUS FROM CUBAN CLINIC SAMPLE, IN E. COLI SHUFFLE® T7

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Introduction: Cervical cancer is the third most common cause of cancer in women worldwide. Human Papillomavirus (HPV) is associated with 99.7% of cervical cancer cases, of which 70% is related to high-risk types HPV 16 and 18. The three current prophylactic vaccines against HPV (Cervarix®, Gardasil® and Gardasil® 9) have proved to be very effective, however, their high costs limit their implementation in developing countries. Cuba does not count in its national vaccination program, with preventive vaccines against HPV, due to its high costs. In the present work, the L1 protein of HPV 16 was purified, from the E. coli SHuffle® T7 strain.

Methods: The E. coli SHuffle®T7 strain transformed with the plasmid pETHPV16L1myc-His was used to produce the HPV-16 L1-His protein grown under autoinduction conditions. The L1-His protein was purified by Ni2+ ion chelate affinity chromatography (IMAC-Ni2+) after extraction of the inclusion bodies (IC) with 8 M urea and subsequent renaturation by inverse dilution. The molecular size of the renatured L1-His protein is assessed by native electrophoresis and size exclusion chromatography.

Results: HPV-16 L1-His protein accumulated in IC in E. coli SHuffle®T7, accounting for ~12% of the total proteins. It was purified by IMAC-Ni^{2+} under denaturing conditions, with ~90% purity and ~40% yield. Renaturation of the purified L1-His allowed obtaining ~9 mg of pentamers/L of culture, with a final process yield of ~62%.

Conclusions: In this work, the purification of pentamers of the HPV-16 L1-His protein, encoded by a cloned L1 gene from a cervical cancer sample from a Cuban patient, was described for the first time, from E. coli ICs. SHuffle®T7. The developed strategy could be an alternative for obtaining L1-His capsomeres, to develop a vaccine candidate against HPV-16

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CURRENT STATUS OF HPV VACCINE USE AND LONG-TERM EFFICACY IN ADULT WOMEN IN CHINA

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Introduction: Cervical cancer is a leading cause of mortality among women in China. In November 2020 , WHO issued “Global strategy to accelerate the elimination of cervical cancer”, China is making a push for HPV vaccination.

Methods: Currently, there are five HPV vaccines approved for use in China: bv-HPV (GSK, UK), qv-HPV and 9v-HPV (MSD, USA), E-coli bv-HPV (Wantai, China), Pichia pastoris bv-HPV (Zerun, China). The first four were approved for use in women aged 9-45 y, and Pichia pastoris bivalent was approved for use in women aged 9-30. Two doses of the bv-HPV are available to giris aged 9-14 years.

Results: At 7 months after HPV vaccination, all vaccinated subjects had the same immunogenic response to either HPV16 or HPV18, ranging from 96 to 100%, and antibody production in girls aged 9 – 14 years was 2–3 times higher than that in adult women. Efficacy of the four vaccines against CIN2 ranged from 87.3% to 100%, with prevention of HPV-associated infection reaching 96% – 97% at 12 months. Clinical trials showed bv-HPV and qv-HPV vaccine were also safe in women aged 18–45 years. We then examined 368 women aged 20 to 45 years after completing three doses of qv-HPV vaccination, were long-term follow-up for a median of 94 months and a maximum of 125 months to observe the protective effect of qv-HPV vaccine on HPV-associated precancerous lesions. CIN, VIN and VaIN associated with HPV16/18 were not found in any vaccinated women. Two HPV16-related cases (CIN/VaIN) were identified in the placebo group, and two additional HPV-related cases (non-vaccine HPV types) were identified.

Conclusions: Conclusion HPV vaccine is effective in preventing HPV vaccine-related infections and lesions in Chinese adult women, and has a long-term efficacy of qv-HPV up to 11 years.

VIRTUAL-009 / #505

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ACETONE CRUDE EXTRACTS OF TOONA CILLIATA, SERIPHIUM PLUMOSUM AND SCHKUHRIA PINNATA EXHIBIT ANTIOXIDANT AND CALCIUM-DEPENDENT APOPTOTIC ACTIVITIES AGAINST A HELA CERVICAL CANCER CELL

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Introduction: Cervical cancer is the fourth most common cancer in women, a majority of cases in less developed regions of the world. Traditional medicinal plants provide an important avenue for the development of novel anticancer agents.

Methods: These include secondary metabolite detection and quantification using standard chemical methods and quantitative antioxidant activity assay (DPPH assay), Ferric reducing power, calcium influx determination using a calcium colorimetric assay, EC50 values of the selected plants for their DPPH scavenging and ferric reducing power activities and evaluation of the presence of secondary metabolites.

Results: Finding revealed that anthraquinones, anthocyanins, phlobatannins and saponins were absent. S. pinnata tested positive for proteins and glycosides while T. cilliata for glycosides, and high amount of total phenolic and flavonoid content in S. plumosum and T. cilliata. S. plumosum extract had the best DPPH scavenging (EC50 = 1.573 mg/ml) and ferric reducing powers (EC50 = 3.374 mg/ml). All the plants at the lowest concentrations tested, inhibited the proliferation of HeLa cells by 50%. The apoptosis inducing ability of the extract in HeLa cells indicate higher calcium influx into cells with increase in extract treatment concentrations.

Conclusions: The leaf extracts from T. cilliata, S. plumosum and S. pinnata contain compounds of various polarities with free-radical, antioxidant and anti-cancerous activities and may play an important beneficial role in the treatment of cervical cancer. Further studies are needed to isolate bioactive chemical entities from these plants for further anti-cancer screens.

VIRTUAL-010 / #491

Poster Viewing
VIRTUAL POSTERS
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URINE VS CERVICAL MOLECULAR DIAGNOSTIC OF HPV AND CORRELATION WITH

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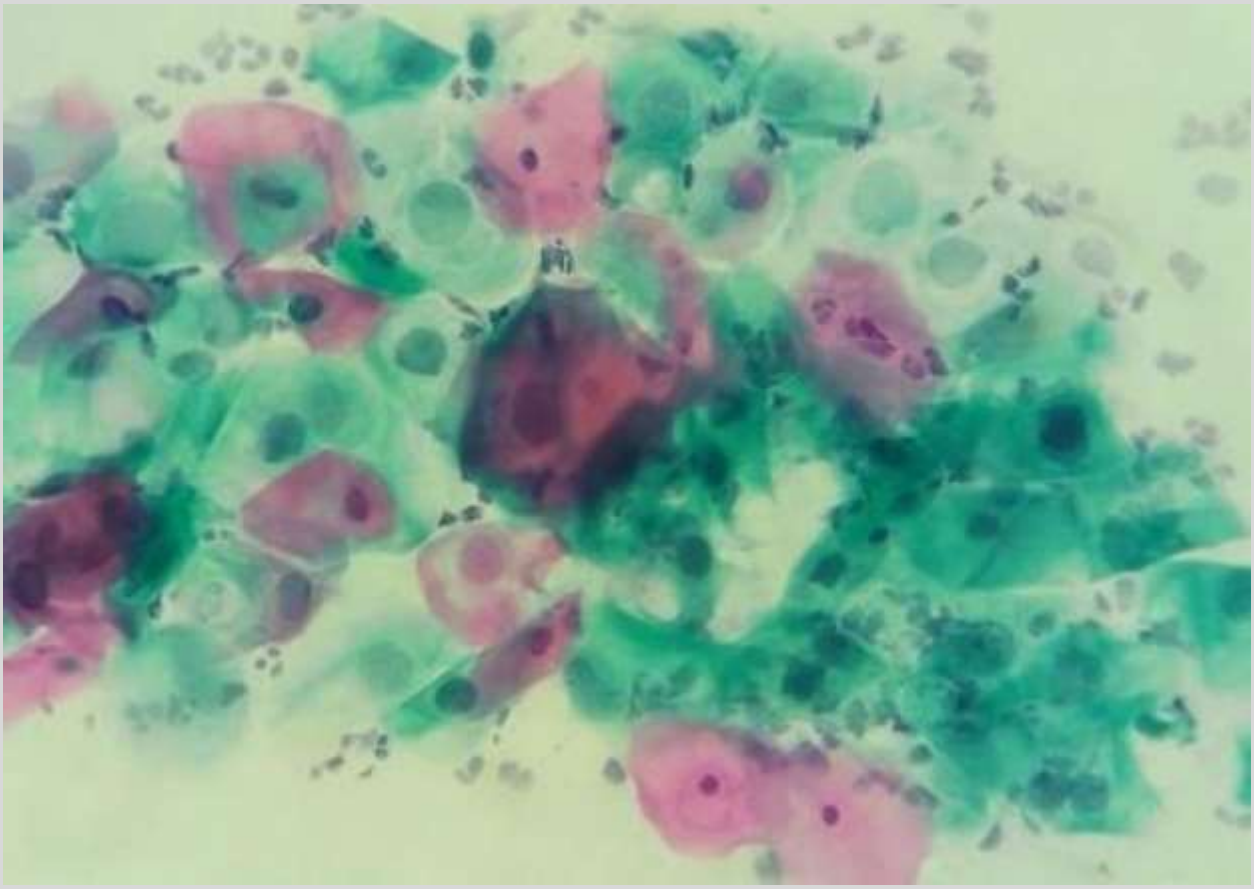
Introduction: Cervical cancer is the second leading cause of cancer deaths in low- and middle-income countries with almost 285,000 new cases every year. In Mexico, there are 4800 deaths per year related to cervical cancer with an overall incidence of 12.6 per 100,000 women. Self-sampling for HPV DNA detection opens opportunities to increase the participation in screening programs and may improve cervical cancer prevention. The present study aims to compare the results of HPV detection on liquid based cervical cytology and molecular testing versus molecular testing using urine samples.

Methods: This study is based on patients which went to the gynecologist with screening purposes. Liquid-based cervical cytology sampling was done using Citocell preservative solution. The cervical sample was used to perform a pap smear as well as PCR screening. Patients also provided a urine sample for HPV molecular testing. Two PCR kits were compared: a screening kit (Geneproof,CZ) detects 24 high risk HPV subtypes and the Seegene Anyplex™II HPV 28 Detection kit that genotypes and discriminates 19 high risk and 9 low risk genotypes.

Results: 40 samples were analyzed using colposcopy, pap smear staining and PCR (with cervical and with urine samples). Mean average age of screened women was 33 yrs old. Colposcopy and pap smear detected only 4 patients with lesions related to probable malignancy due to HPV as shown in Fig 1 Pap smear of PX 12, CIN1



Concordance of PCR results of cervical and urine samples was 100% related to positives and 90% on genotypes. HPV-58 was the most frequent genotype and only one HPV18 was detected.

Conclusions: PCR genotyping has higher sensitivity for HPV detection in patients without intraephitelial lesions compared to cytology. Urine self-sampling and PCR genotyping is a solid method to detect presence of HPV in low risk patients and has good potential for screning in Mexico.

VIRTUAL-011 / #1102

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NON-INVASIVE POINT-OF-CARE NANOBIOSENSING OF CERVICAL CANCER AS AN AUXILIARY TO PAP-SMEAR TEST

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Introduction: A potential cancer antigen (Ag), Protein-Phosphatase-1-gamma-2 (PP1γ2) with a restricted expression in testis and sperms has been identified as a biomarker specific to cervical cancer (CaCx) in the urine samples of the affected patients. Further, a point-of-care biosensor has been developed targeting PP1γ2 detection noninvasively from the urine sample of the patients.

Methods: For the identification of the PP1γ2 biomarker, urine samples and cervicovaginal fluid (CVF) was collected from a total of 200 patients undergoing treatment at King George Medical College, Lucknow, India. Antibodies against PP1γ2 was grown in rabbit and conventional western blot analysis was used to confirm the presence of PP1γ2 in the urine samples. The proposed portable POCT device is prepared using gold nanoparticles immobilized with anti-PP1γ2 antibodies and its interaction with PP1γ2 in the urine sample was observed as a change in localized surface plasmon resonance (LSPR) of the sensor.

Results:

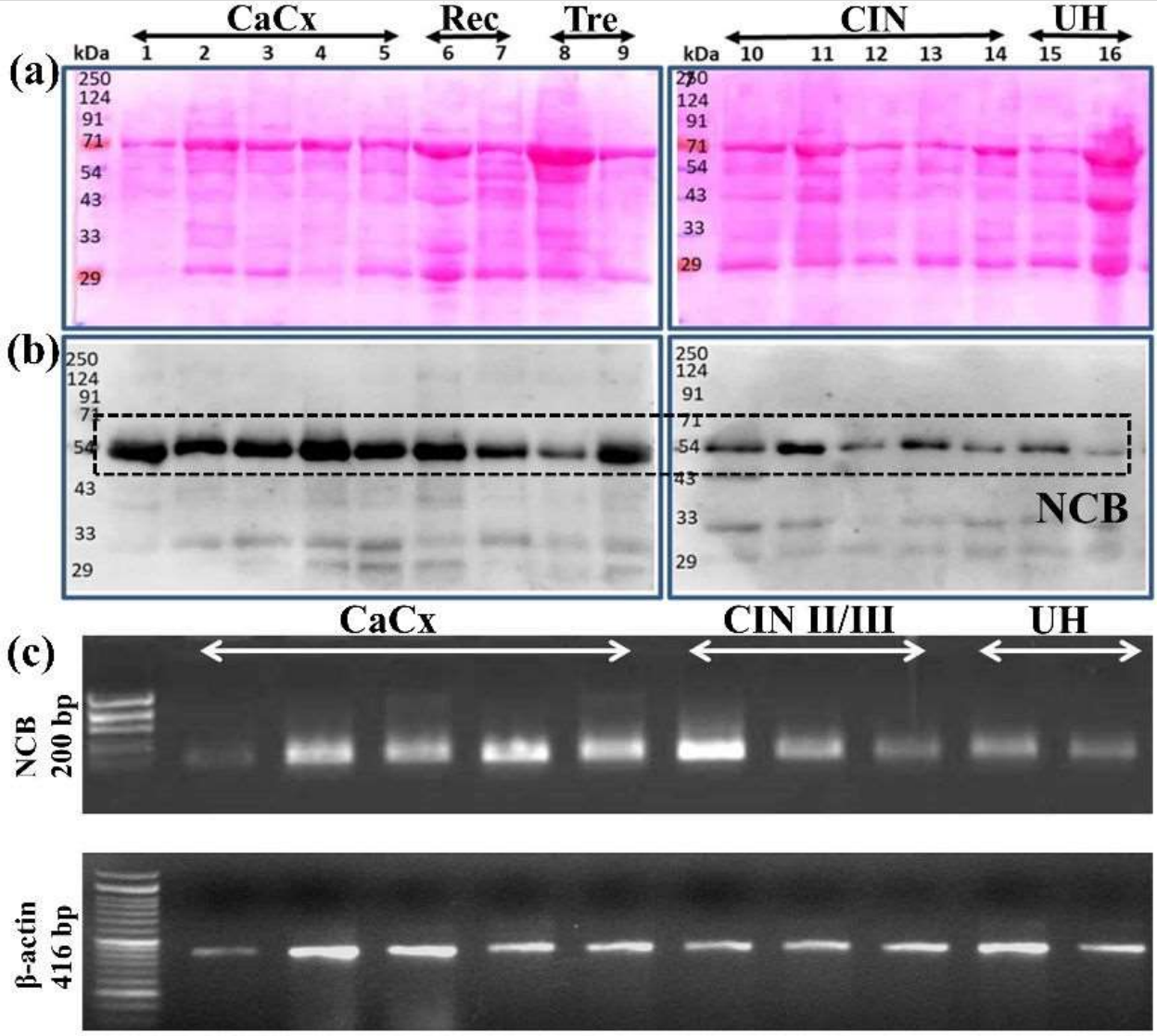

Fig1 confirms the presence of PP1γ2 named as Novel Cancer Biomarker (NCB) in urine samples of different stages of CaCx (lanes 1-5), reoccurring cases (6,7), undergoing treatment (8,9), cervical intraepithelial neoplasia (10-14), and unhealthy cervix (15,16).

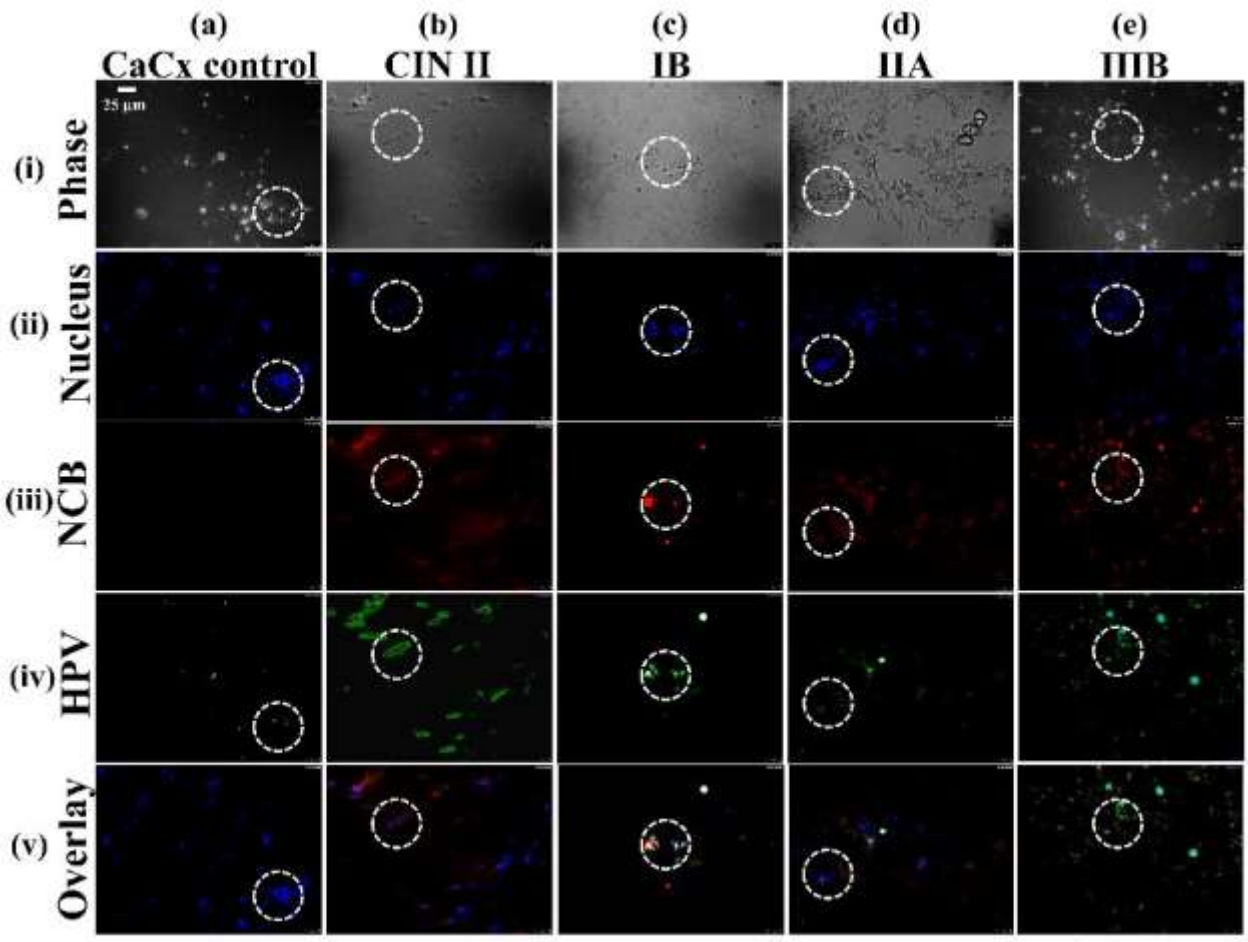

Fig2 shows the confocal photomicrograph showing co-expression of NCB and HPV in CVF collected from early and advanced stages of CaCx patients. Columns (a)–(e) show the response from the samples from the different stages of CaCx, i.e. control, CINII, IB, IIA, and IIIB.

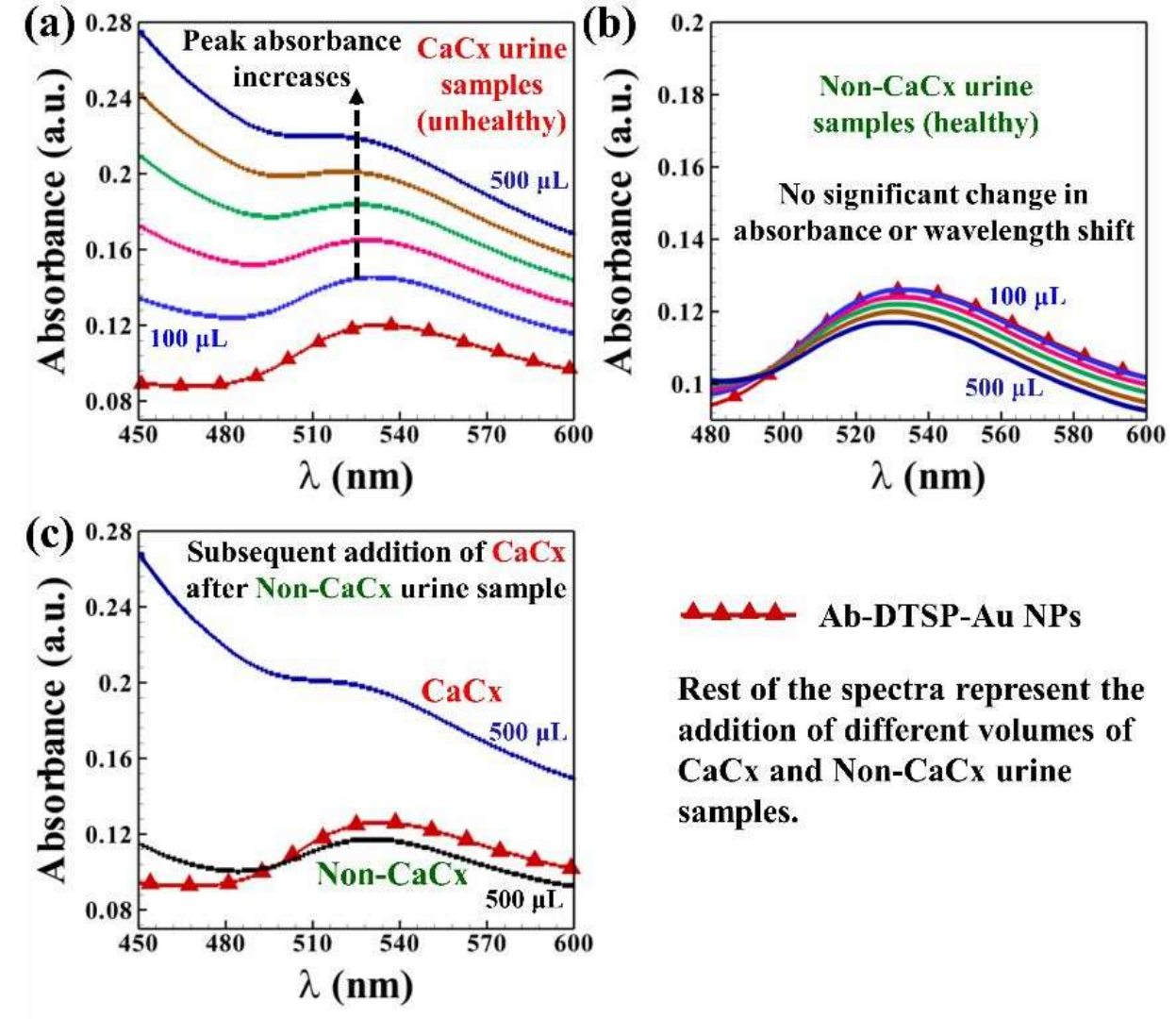

Fig3 shows the UV-Vis spectroscopic results of the proposed POCT device developed using anti-PP1γ2 immobilized gold nanoparticles. (a) shows LSPR enhancement of gold nanoparticles in the presence of PP1γ2 in the CaCx urine sample, no LSPR enhancement in the healthy sample (b), and no LSPR interference in the non-CaCx sample (c).

Conclusions: The research work showcases the development of a point-of-care device from establishing a sensing principle to the prototype development for hassle-free, economical, and robust screening of cervical cancer following a non-invasive pathway.

VIRTUAL-012 / #581

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METABOLOME ANALYSIS FOR CERVICAL NEOPLASIA TARGETING PRIMARY METABOLITES

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Introduction: Cervical cancer is a 4th most common cause of cancer incidence worldwide. The current screening methods for cervical cancer includes cytology or HPV test. Because cytology showed the low sensitivity whereas a HPV test has low specificity, a more accurate method is desired. In this study, we investigated changes in cervical local metabolism using vaginal discharge and searched for metabolic biomarkers in cervical cancer and its precursor lesions.

Methods: Vaginal discharge samples (Normal n=48, CIN1 n=19, CIN2 n=80, CIN3 n=82, and SCC n=69) were collected. Metabolome analysis was performed by liquid chromatographic mass spectrometry (LC-MS/MS, Shimadzu). The statistical or pathway analysis was performed by SPSS or MetaboAnalyst web-based analysis platform.

Results: In volcano analysis, metabolic significant differences between normal vs. CIN1 (Up: n=12), vs. CIN2 (Up: n=6, Down: n=13), vs. CIN3 (Up: n=9, Down: n=7), vs. SCC (Up: n=23, Down: n=11) were observed. ($p < 0.05$ and 2-fold change<) Malic acid was significantly increased in CIN1, CIN2, CIN3, and SCC compared to normal (Kruskal-Wallis $p < 0.05$). In ROC curve analysis, all AUCs showed> 0.81. Oxidative glutathione, Kynurenine, and Malic acid were significantly higher, especially in cancer, and in ROC curve analysis, they showed all AUC > 0.90. In the pathway analysis, the TCA cycle were significantly altered in the cases of normal vs CIN1-3 and cervical cancer with Impact> 0.20. The cysteine and methionine metabolic pathways were significantly altered only in SCC. (FDR $p < 0.01$, Impact >0.41)

Conclusions: Metabolome analysis revealed the unique metabolites for cervical cancer and its precursor lesions, possibly resulting in candidate biomarkers. In addition, significant metabolic pathways involving these metabolites were also observed.

VIRTUAL-013 / #842

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CHARACTERIZATION OF ANTIBODIES AGAINST THE E5 ONCOPROTEIN FROM HUMAN PAPILLOMAVIRUS TYPE 16 IN THE NATURAL HISTORY OF CERVICAL CANCER

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Introduction: Cervical cancer (CC) is associated with the presence of human papillomavirus (HPV) infections. Women with high-risk HPV persistent infections, especially HPV16, are at risk of developing precancerous lesions that could progress to CC. During HPV infection, a non-protective humoral immune response against early proteins (E1, E2, E4, E5, E6, and E7) is generated. This immune response against HPV has been suggested as a source of early detection biomarkers for CC. Serum antibodies against E6/E7 are associated with cervical intraepithelial neoplasia 3 (CIN-3) and CC, and CIN 1-2 with anti-E4 antibodies. No clear results have been reported on anti-E5 antibodies as a biomarker. Therefore, we aimed to characterize the antibody response against HPV16-E5 in the natural history of CC and its usefulness as a biomarker of the stage disease.

Methods: This study was conducted at the Cuautla General Hospital, Morelos, Mexico, with women (18 to 64 age), that accepted to participate. Samples were obtained from 335 women with uterine cervical lesions and 150 women with a negative Papanicolaou. HPV-genotyping was performed by PCR and pyrosequencing, and anti-E5 antibodies were detected by slot blot. Logistic regression with contrast analysis was done to analyze the interaction between anti-E5 antibodies, HPV-DNA, and disease stage.

Results: Anti-E5 antibodies prevalence in the study was 17.5%, with a downward trend associated with disease progression, being 32.1% for CIN1, 11.5% for CIN2-3, and 6.9% for CC. Contrast analysis showed interactions between anti-E5 and HPV-DNA, with the no lesion group (NL) (OR=1.17), CIN1 (OR=1.53), and CIN2-3 (OR=1.36). These results showed that the presence of anti-E5 antibodies is dependent on the presence of HPV-DNA in CIN1 and CIN2-3 lesions.

Conclusions: The generation of anti-E5 antibodies in early lesions (CIN) may be useful as surrogate biomarkers of E5 protein expression, which in turn could also reflect an active infection (presence of episomal HPV-DNA).

VIRTUAL-014 / #1096

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P16/KI67 LEVELS TO REVOLUTIONIZE CELLULAR DYSPLASIA DETECTION IN CERVICAL CANCER

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Introduction: Several immunohistochemical markers are studied to improve the diagnostic value of cytology coupled with or without HPV DNA testing in the diagnosis of cervical neoplasia. Immunocytochemical staining (ICS) to study co-expression of anti-proliferative p16 and proliferation Ki-67 markers is one of these techniques. Despite the improved diagnostic accuracy compared with conventional cytology, the high cost and dependency on the expertise of the operator has limited its practice. This article compares the diagnostic value of p16 and Ki-67 levels using an in-house Enzyme-Linked ImmunoSorbent Assay (ELISA) with existing techniques in predicting women at-risk of or with dysplasia.

Methods: Twenty cervico-vaginal samples (semi-cervical samples taken by clinicians mocking self-samples) from among those collected between January 2020 and July 2022 as part of the ‘early detection of cervical cancer in hard-to-reach populations of women through portable and point-of-care HPV testing’ (ELEVATE), a H2020 project, were tested. The samples were divided into 5 parts and underwent cervical cytology, HPV Cobas, flowcytometry, P16/Ki67 ICS, and ELISA investigations.

Results: Discrimination analysis showed Ki-67 levels to have the highest specificity for detecting dysplastic cells (Wilk’s Lambda: 0.746). It also showed a 100% sensitivity and positive predictive value, which was higher than other studied techniques (Table 1).

Conclusions: ELISA could be used in combination with HPV testing to improve the triage process during cervical cancer screening programs. The need for less experienced staff and less pricey infrastructure makes the technique promising specially for lower income countries. Further studies with larger sample size are needed to confirm our results.

VIRTUAL-015 / #1037

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

E6/E7 SEROLOGICAL PREVALENCE AMONG WOMEN FREE OF HPV-ASSOCIATED CANCERS IN EUROPE IN THE PRE-VACCIANTION ERA

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Introduction: Despite the promising scenario in the prevention of HPV-related cancers through HPV vaccines, the development of secondary prevention strategies to reduce HPV-related disease burden, as in cervical cancer, is also important. HPV early antigen (E) serology has demonstrated to be a promising biomarker for anal and oropharyngeal cancers. The aim of this study is to estimate the HPV type-specific E6/E7 seroprevalence among European women free of HPV-associated cancers, by age and country, and its determinants

Methods: Between 1992 and 2000, 343,009 women aged 20-70 years, participating in the European Prospective Investigation into Cancer and Nutrition (EPIC) study, were recruited from 10 European countries (France, Italy, Spain, United Kingdom, The Netherlands, Greece, Germany, Denmark, Norway, Sweden). Participants provided sera and risk-factor data at recruitment. We randomly selected an age-stratified sample of women who had not developed an HPV-related cancer at the end of follow-up. 3,370 women were included in the study (excluding Greece). HPV E6/E7 serum antibodies for HPV types 16/18 were tested by Glutathione S-transferase capture and fluorescent bead-based multiplex serology at DKFZ. Descriptive analyses of HPV E6/E7 seroprevalence were performed by age and country. Logistic regression models were conducted to evaluate determinants of HPV E6/E7 seropositivity.

Results: HPV16 and HPV18 E6 seropositivity was 1.2% and 0.8% respectively. Seropositivity reached 8.9% for HPV16 E7 and 1.5% for HPV18 E7. Determinants of combined HPV 16 and/or 18 E6 seropositivity (1.8%) included older ages, Northern countries, single marital status, high level of education, and longer duration of oral contraceptive use. Similar determinants were found for HPV16 E6 seropositivity. The main determinant of combined HPV 16 and/or 18 E7 seropositivity (10%) was older ages.

Conclusions: Having information on cancer-free population will be useful to guide if HPV blood-based serological markers might be used as potential secondary prevention method for HPV-associated cancers.

VIRTUAL-016 / #964

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

IMMUNOHISTOCHEMICAL STUDY OF THE ROLE OF HUMAN PAPILLOMAVIRUS, EPSTEIN–BARR VIRUS, AND P16INK4A EXPRESSION IN HEAD-AND-NECK SQUAMOUS CELL CARCINOMAS

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Introduction: Studies over the years have established that human papillomavirus (HPV) and Epstein–Barr virus (EBV) are major etiological agents in subsets of head-and-neck squamous cell carcinomas (HNSCCs). This study further explores the concurrence of HPV and EBV together with $P16^{INK4a}$ expression in HNSCCs, providing additional insights into their unique role in establishing a virus-induced carcinogenesis.

Methods: A retrospective cross-sectional study utilizing immunohistochemistry was employed to establish the presence of HPV, EBV, and $P16^{INK4a}$ expression in HNSCC archived tissue samples. A total of 121 HNSCC cases were considered suitable for further analysis using immunohistochemistry. From these suitable tissue blocks, tissue microarray (TMA) was prepared using Micarray by Micatu Inc., USA. Immunohistochemical staining was performed according to standard procedures. Antibodies for HPV, EBV, and $P16^{INK4a}$ were used.

Results: A total of 121 selected HNSCC cases were included in the study, with male preponderance (n = 86) and majority of the cases occurring in patients ≤ 54 (n = 62). The most common site of occurrence was the oral cavity (n = 29), followed by larynx (n = 27) and nasal cavity and paranasal sinuses (n = 24), respectively. The study recorded 18 (14.9%) HPV-positive tumors, 7 (5.8%) EBV-positive tumors, and 2 (1.7%) tumors coinfected with HPV and EBV. $P16^{INK4a}$ expression was recorded in 42.1% (n = 51) of the tumors. Although $P16^{INK4a}$ expression correlated weakly with both HPV (r = 0.116) and EBV (r = 0.205) positivity, it showed a statistically significant expression with EBV positivity (P = 0.024).

Conclusions: The observed pattern of HPV association with $P16^{INK4a}$ overexpression was consistent with earlier reported studies, and as such, the study reinforces the assertion that $P16^{INK4a}$ can be used as a surrogate marker for HPV-positive tumors. However, additional studies are required to validate its suitability in tumor sites other than oropharyngeal squamous cell carcinoma.

VIRTUAL-017 / #1001

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

HUMAN PAPILLOMAVIRUS-ASSOCIATED PLANTAR EPIDERMOID CYSTS: CASE REPORTS AND LITERATURE REVIEW

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Introduction: Human papillomavirus-associated plantar epidermoid cysts (HPV-PEC) are more common in Asians. HPV-PEC is mainly caused by infection with HPV type 60. In contrast, a systematic review of published case reports has not been conducted to date.

Methods: An online search, as well as an extensive review of PubMed, and the Japanese Central Journal of Medicine using the keywords “plantar epidermoid cyst”, “epidermoid cyst”, “plantar epidermal cyst”, ”epidermal inclusion cyst”, “HPV”, or “HPV type 60” was performed to identify research studies published before September 30, 2022. Refer- ences within the search results were also reviewed to identify additional studies available. In this study, we have examined the site of HPV-PEC, race, age, gender ratio, HPV genotypes, and histopathological characteristics. We further analyzed our experience with HPV-PEC cases in the same way.

Results: HPV-PEC is clinically more common in 20-29-year-old females, and is more common on the ball-of-foot of plantar area. Histopathologically, HPV-PEC is characterized by the presence of eosinophilic intracytoplasmic inclusion bodies and vacuole-like structures, an HPV-specific cytopathic effects, in the cyst wall and cyst contents of plantar epidermal cysts. Many cases of HPV-PEC are positive for HPV antigen, consistent with cell nuclei. PCR analysis showed HPV type 60 is often detected in HPV-PEC.

Conclusions: To our knowledge, HPV-PEC is a cutaneous disease found on the ball-of-foot of plantar area in Asians.

VIRTUAL-018 / #1679

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

TWO NOVEL PROPHYLACTIC 4- AND 9-VALENT HUMAN PAPILLOMAVIRUS L1 VIRUS-LIKE-PARTICLE VACCINES ELICIT COMPARABLE IMMUNOLOGIC RESPONSES WITH GARDASIL (TYPE 6/11/16/18) IN CHINESE WOMEN

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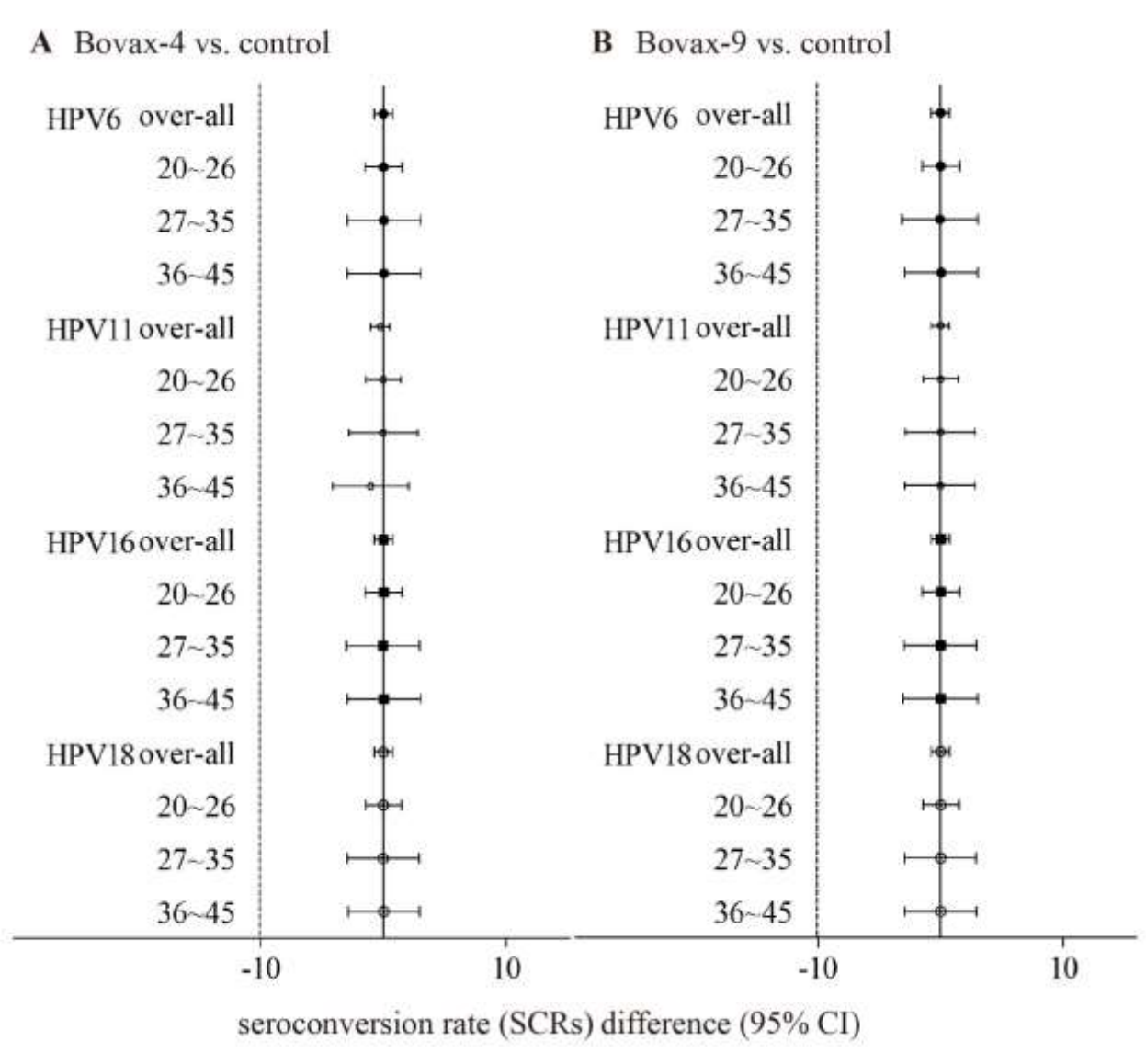
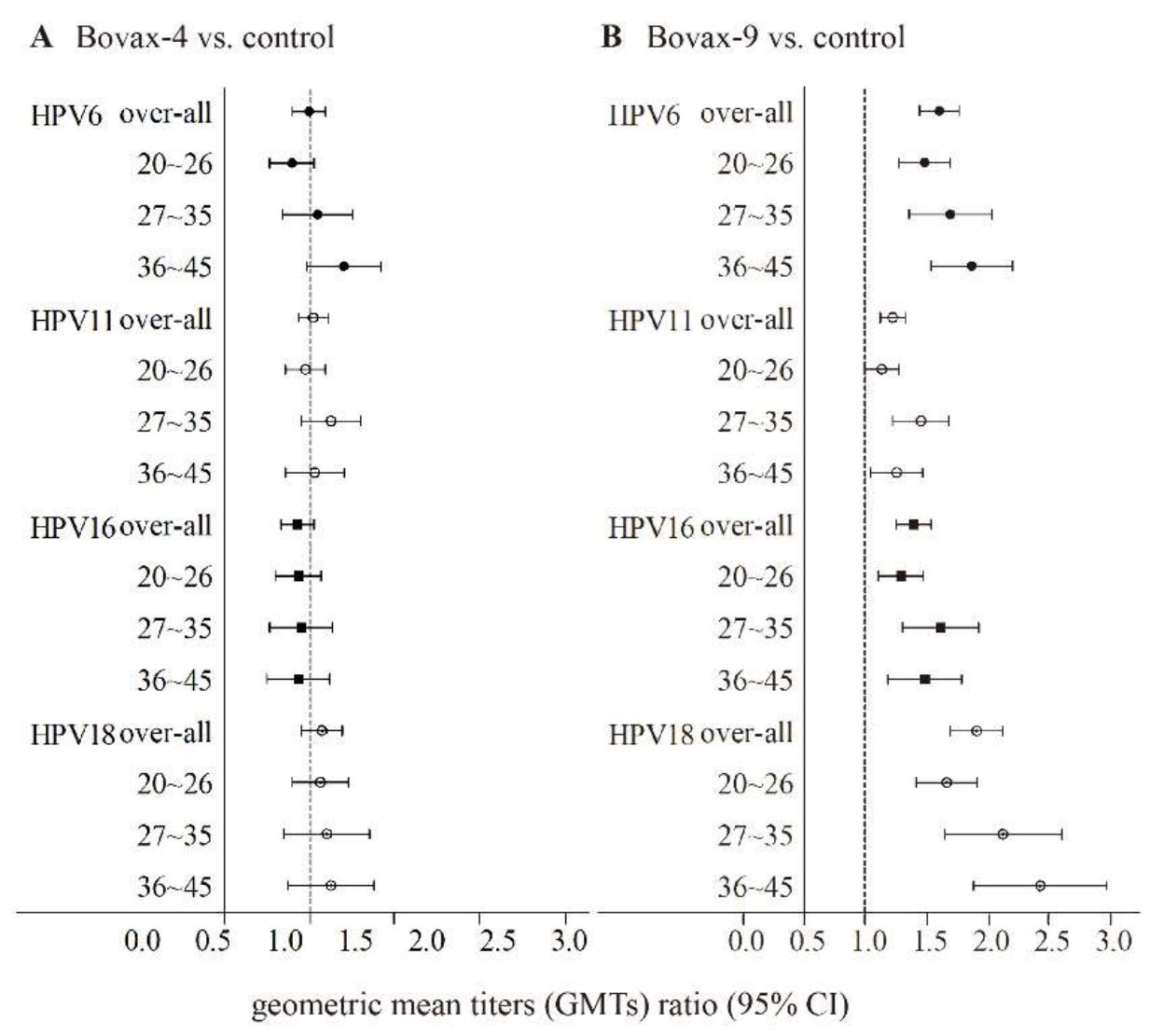
Introduction: Two newly developed 4- and 9-valent human papillomavirus (HPV) vaccines (Bovax-4, 6/11/16/18; Bovax-9, 6/11/16/18/31/33/45/52/58), with similar technical basis as Gardasil (Table 1), have yet demonstrated to be safe and highly immunogenic in phase Ⅰ placebo-controlled trials (NCT03085381, NCT03676101). Whereafter, a randomized blind phase Ⅲ study was designed to compare immunogenicity and tolerability of Bovax-4 and Bovax-9 with Gardasil (4-valent) (NCT04425291).

	Bovax-4	Bovax-9	Gardasil
Antigen (each 0.5-mL vaccine dose)	20, 40, 40 and 20 mcg of HPV-6, 11, 16 and 18 L1 VLPs	30, 40, 60, 40, 20, 20, 20, 20, and 20 mcg of HPV-6, 11, 16 18, 31, 33, 45, 52 and 58 L1 VLPs	20, 40, 40 and 20 mcg of HPV-6, 11, 16 and 18 L1 VLPs
Expression system	*O. polymorpha*	*O. polymorpha*	*S. cerevisiae*
Adjuvant (μg)	APA (225)	APA (500)	AAHS (225)
Manufacturer	Chongqing Bovax Biopharmaceutical Co., Ltd. (China)	Chongqing Bovax Biopharmaceutical Co., Ltd. (China)	Merck & Co., Inc (USA)

Methods: 560 Chinese adult females aged 20-45 years in each group, randomized in a 2:1:1 ratio to 20-26, 27-35, or 36-45 y subgroups, were enrolled to receive Bovax-4, Bovax-9 or Gardasil (control) at month 0, 2, and 6. HPV type-specific neutralizing antibodies were tested by a pseudovirion-based method before vaccination and 30 days after dose-3 and expressed as seroconversion rates (SCRs) and geometric mean titers (GMTs). Vaccine safety was also evaluated.

Results: A total of 1680 subjects were finally recruited. More than 99% of the enrollees seroconverted for all 4 HPV types across the vaccine groups. Besides, comparing between the test and control groups (Bovax-4 vs. control; Bovax-9 vs. control), the lower bounds of 95% confidence intervals (CIs) of SCRs for covered HPV types all exceed -5%, met the predefined noninferiority criteria (-10%) (Fig. 1); and the corresponding HPV type-specific GMT ratios also all reached the predetermined non-inferior standards (0.5) (Fig. 2). As for safety, participants received Bovax-9 had slightly higher injection-site adverse events (AEs) (46.43%) compared with Bovax-4 and control group (25.54% and 31.79%, respectively), most of which were mild to moderate (grade <3). Meanwhile, systemic and serious AEs were similar between groups ($p>0.05$). No deaths
reported.


A Bovax-4 vs. control
B Bovax-9 vs. control
HPV6 over-all
20~26
27~35
36~45
HPV11 over-all
20~26
27~35
36~45
HPV16 over-all
20~26
27~35
36~45
HPV18 over-all
20~26
27~35
36~45
-10
10
-10
10
seroconversion rate (SCRs) difference (95% CI)



Conclusions: This trial suggested compelling evidence that Bovax-4 and Bovax-9 had strong immunogenicity and good safety profiles when compared with Gardasil, indicating both groups of the investigational vaccines have the potential to be desirable HPV candidates.

VIRTUAL-019 / #602

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

CURRENT STATUS OF HPV VACCINE USED AND LONG-TERM EFFICACY IN ADULT WOMEN IN CHINA

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Introduction: Cervical cancer is a leading cause of mortality among women in China. issuedTo achieve the goal of WHO issued “Global strategy to accelerate the elimination of cervical cancer”,, China is making a big push for HPV vaccination.

Methods: Currently, there are five HPV vaccines approved for use in China: bv-HPV (GSK, UK), qv-HPV and 9v-HPV (MSD, USA), E-coli bv-HPV (Wantai, China), Pichia pastoris bv-HPV (Zerun, China). The first four were approved for use in women aged 9-45 years of age and Pichia pastoris bivalent was approved for use in women aged 9-30 years of age. Two doses of the three bv-HPV are available to adolescent females aged 9-14 years.

Results: At 7 months after HPV vaccination, all vaccinated subjects had the same immunogenic response to either HPV16 or HPV18, ranging from 96 % to 100%, and antibody production in girls aged 9~14 years was 2–3 times higher than that in adult women. Efficacy of the four vaccines against CIN2 ranged from 87.3% to 100%, with prevention of HPV-associated infection reaching 96% ~ 97% at 12 months. Clinical trials showed bv-HPV and qv-HPV vaccine were also safe in women aged 18–45 years. We then examined 368 women aged 20 to 45 years after completing three doses of qv-HPV vaccination, were long-term follow-up for a median of 94 months and a maximum of 125 months to observe the protective effect of qv-HPV vaccine on HPV-associated precancerous lesions. CIN, VIN and VaIN associated with HPV16/18 were not found in any vaccinated women. Two HPV16-related cases (CIN1/VaIN) were identified in the placebo group, and two additional HPV-related cases (non-vaccine HPV types) were identified.

Conclusions: HPV vaccine is effective in preventing HPV vaccine-related infections and lesions in Chinese adult women, and has a long-term efficacy of qv-HPV up to 11 years.

VIRTUAL-020 / #659

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

INTEGRATING POINT-OF-CARE HPV TESTING INTO HIV CARE FOR KENYAN WOMEN LIVING WITH HIV

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Introduction: Current cervical cancer screening methods for women living with HIV (WLHIV) in Kenya are underutilized, including visual inspection of the cervix with acetic acid (VIA) and/or of Lugol's iodine (VILI). Identifying WLHIV at highest risk for cervical cancer could motivate VIA/VILI screening and improve uptake. We integrated Xpert HPV testing for high-risk human papillomavirus (HR-HPV) within routine HIV care with the aim of increasing uptake of cervical cancer screening among WLHIV enrolled in HIV care at Kenya's national referral hospital.

Methods: WLHIV aged ≥18 years enrolled in HIV care at Kenyatta National Hospital (KNH) HIV clinics were eligible and approached for participation during their routine HIV clinic visits. We extracted medical records among consenting WLHIV to establish baseline VIA/VILI uptake. Cervical smears were collected among consenting WLHIV by study nurses and analyzed on Gene Xpert platform in the HIV care clinic molecular laboratory. Results were provided during that same HIV care visit and women with HR-HPV were referred for VIA/VILI in the HIV clinic.

Results: Overall, 691 WLHIV were enrolled. The median age was 42 years (IQR 37-48) and 72% of participants had secondary education or above. Among those not previously screened (n=518), most (95%) accepted Xpert HPV. Prevalence of HR-HPV was 35% (232/656); 10 % HR-HPV-16, 8% HR-HPV-18 and/ or 45 and 82% for other 11 HR-HPVs not individually genotyped by Xpert HPV. The median time to return Xpert HPV results was 60 minutes (IQR 60-80). All the results were available in the same HIV clinic visit. Overall, 96% of WLHIV with positive Xpert HPV results subsequently accepted and received VIA/VILLI assessment; of those, 26% had results predicting cervical abnormalities.

Conclusions: Integrating Xpert HPV into HIV care was feasible with high uptake and prevalence of HR-HPV. Xpert HPV could potentially enhance cervical cancer screening programs for WLHIV in high-burden settings.

VIRTUAL-021 / #1337

Poster Viewing
VIRTUAL POSTERS
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EFFECTIVENESS OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HPV+ AND HIV+ PATIENTS: A PILOT OBSERVATIONAL STUDY

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Introduction: Immunosuppressed, Human immunodeficiency virus (HIV) -positive, patients have an increased risk of incident, persistent, or recurrent human papillomavirus (HPV) infection. They also have lower clearance rates, higher viral load, and a marked predisposition for being colonized by several serotypes: all leading to more frequent and severe HPV-dependent lesions . A Coriolus versicolor-based vaginal gel has been shown to repair HPV-dependent low-grade cervical lesions and to increase high-risk HPV clearance in immunocompetent HPV-positive patients . The aim of this study is to provide evidence about the effectiveness of a multi-ingredient Coriolus versicolor-based vaginal gel on HPV-dependent cervical alterations and HPV clearance in HIV+ patients.

Methods: In this pilot, prospective, one-cohort, observational study, 15 HIV-positive patients with HPV endocervical colonization and anomalous cervicovaginal cytology were included to receive a Coriolus versicolor-based vaginal gel 1 cannula/day for 21 days during first month + 1 cannula/alternate days for 5 months. Analysis of HPV patients with normal cytology and colposcopy (improved alterations) and patients with HPV clearance (measured using hybrid capture test) is presented.

Results: The overall HPV clearance and cytological normalization rates were 73.33% and 80%, respectively. Endocervical colonization by HPV also partially cleared in 13.33% of the cases. At the end of the study, the normalization of the colposcopy was achieved in 55.56%.

Conclusions: Our results suggest that a 6-mounth treatment period with Coriolus versicolor-based vaginal gel could be an effective therapy in the management of endocervical HPV infection in HIV + patients. Its effects are similar to those obtained in immunocompetent HPV patients

VIRTUAL-022 / #1319

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

SCREENING, DIAGNOSIS AND TREATMENT OF CERVICAL PRECANCER IN A LOW RESOURCE SETTING; A REVIEW OF QUINTA HEALTH CERVICAL CANCER CAMPAIGN IN KWARA STATE, NIGERIA.

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Introduction: Cervical screening with acetic acid and lugol iodine, diagnosis of cervical precancerous lesions and treatment with Cryotherapy are among the most effective ways to reduce the high incidence and mortality resulting from cervical cancer among underserved women in low resource settings like Nigeria. Cytology based screening program and other screening methods are not readily available. In Nigeria, poor health literacy, socio-cultural barriers, poor amenities and infrastructure, inconsistent health policies and data collection, lack of resources, and poverty all provide challenges to screening, diagnosis and treatment. The aim of this study is to assess factors influencing effectiveness of VIA (visual inspection with acetic acid)/VILI (visual inspection with lugol iodine) and treatment (Cryotherapy) of cervical precancerous lesions in a low resource setting.

Methods: Between 12th and 23rd February 2020, 1574 women across 20 screening centres in kwara state were recruited into a cervical cancer screening campaign which was conducted by visual inspection after application of 5% acetic acid (VIA) and lugol iodine (VILI). A cross sectional study was carried out using the convenient sampling technique to recruit all consenting women. Result was analyzed using percentage.

Results: 1574 women age 25- 59 were screened using VIA/VILI method, 120 (7.62%) tested positive for cervical precancerous lesion while 115 (7.31%) were treated using Cryotherapy. All Positive women were scheduled for follow up and appropriate referral was made where necessary.

Conclusions: Cervical cancer prevention through screening, diagnosis and treatment of precancerous lesion is the most available and yet potent elimination strategy in low resource settings where HPV vaccines are not readily available. Despite the recent WHO recommendation to engage HPV DNA testing, VIA/VILI screening method with Cryotherapy treatment still remain quick, accurate and efficient against most screening/treatment barriers in low resource settings. This becomes very important for such settings as one type of screening/treatment is better than none.

VIRTUAL-023 / #801

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

HIGH-RISK HUMAN PAPILLOMAVIRUS INFECTION AMONG WOMEN IN URBAN AND RURAL POPULATION OF BANGLADESH

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Introduction: Cervical cancer screening is available in all districts and almost three fourth of the sub-districts in Bangladesh. The government of Bangladesh (GOB) adopted the visual inspection of cervix with acetic acid (VIA) method for cervical cancer screening for women of 30-60 years age. Studies on high-risk (HR) HPV genotype distribution and its regional variation are very few in Bangladesh. This study was performed to find out the prevalence of HR-HPV genotypes by polymerase chain reaction (PCR) among women in urban and rural populations of different regions of Bangladesh.

Methods: This cross-sectional study was carried out at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka (July 2021-June 2022). Cervical samples (N= 3856) were collected from women of 30-49 years age attending VIA screening from eight divisions of Bangladesh. HPV tests were performed by a fully automated real-time PCR amplification and detection analyzer at BSMMU. Ethical clearance was received from the Institutional Review Board (IRB) of BSMMU Ethics and Scientific Review committee.

Results: Among 3856 asymptomatic women, the overall prevalence of HR-HPV was 3.6% with 49 (1.3%) women with HPV 16, 12 (0.3%) HPV 18, and 65 (1.7%) with Other HR-HPV positive reports. A significant variation of HR-HPV prevalence among the divisions (P=.001) was found with highest infection (7.1 %) among women of rural Sylhet and lowest in rural Mymensingh (0.5%). No significant difference in HR-HPV prevalence was found between the urban and rural women except Mymensingh.

Conclusions: The low prevalence of HR-HPV (3.6%) among Bangladeshi women with regional variation should be considered by policymakers during the development of cervical cancer prevention policies. The developed VIA-based screening infrastructure should be utilized during the introduction of HPV tests for primary screening or co-testing. Large implementation research is necessary to provide better information to policymakers.

VIRTUAL-024 / #930

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

CERVICAL DYSPLASIA AND CANCER MISSED AMONG HIGH-RISK HUMAN PAPILLOMAVIRUS PRIMARY SCREEN-POSITIVE WOMEN WITH A SECONDARY VISUAL TRIAGE-NEGATIVE TEST IN BOTSWANA

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Introduction: To prevent cervical cancer, the World Health Organization (WHO) calls for high-performance screening with high-risk human papillomavirus (hrHPV) testing followed by a second triage test (indicated for HIV patients, optional for general populations). Data about the performance of secondary triage tests is limited in Low-and-Middle-Income-Countries (LMICs).

Methods: We employed primary hrHPV screening among self-collected swabs of women matched by HIV status who presented to a peri-urban clinic in southeast Botswana using Atila AmpFire HPV (AAF) (Atila Biosystems, USA) which detects individual hrHPV subtypes 16/18/31/33/35/39/45/51/52/53/56/58/59/66/68). All who screened positive for any hrHPV were visually assessed and a biopsy taken for histological evaluation.

Results: Among 1,500 consenting women, 47.1% (706/1500: HIV+: 52.3% (392/750); HIV-: 41.9% (314/750) screened positive for hrHPV. We completed visual assessment for treatment (VAT) and histological evaluation on 92.8%. Of the 190/655 (29.0%) who screened positive by VAT, histological evaluation revealed 59 (31.1%) had CIN2+ [10 (5.3%) CIN 2; 49 (25.8%) CIN3+). The CIN3+ category included the diagnosis of two adenocarcinoma-in-situ, one adenocarcinoma, and one squamous cell carcinoma. However, among the 71.0% (465/655) of women who screened negative by VAT and routinely would have screened again in three or five years depending on HIV status, the histological evaluation revealed 54 (11.6%) had CIN2+. Thirty-two (6.9%) had CIN3+, including one adenocarcinoma-in-situ, and one adenocarcinoma). Nearly 70% (22/32) of CIN2 and 40% (32/81) of CIN3+ cases, including two-fifths (2/5) of glandular abnormalities, detected in the study would have been missed under routine screening conditions. A higher proportion of CIN2+ cases were missed among HIV-negative women, compared with HIV-positive ones (p-value=0.02).

Table 1: Results by screening type, histological finding, and HIV-status (percentage)

	HIV-positive		HIV-negative		Overall		p-value*
	%	(a/n)	%	(a/n)	%	(a/n)	
% who tested positive for HPV	52.3%	(392/750)	41.9%	(314/750)	47.1%	(706/1500)	
% HPV+ histologically evaluated	92.6%	(363/392)	93.0%	(292/314)	92.8%	(655/706)	
Among histologically evaluated...							
% positive by VAT	33.3%	(121/363)	23.6%	(69/292)	29.0%	(190/655)	0.007
% negative by VAT	66.7%	(242/363)	76.4%	(223/292)	71.0%	(465/655)	
% VAT-positive with CIN2+	34.7%	(42/121)	24.6%	(17/69)	31.1%	(59/190)	
% VAT-negative with CIN2+	11.2%	(27/242)	12.1%	(27/223)	11.6%	(54/465)	0.75
% VAT-positive with CIN3+	28.9%	(35/121)	21.7%	(14/69)	25.8%	(49/190)	
% VAT-negative with CIN3+	6.6%	(16/242)	7.2%	(16/223)	6.9%	(32/465)	0.81

CIN: cervical intra-epithelial neoplasia; HIV: human immunodeficiency virus; VAT: visual assessment for treatment
*Chi-square test

Table 2: Proportion of cases missed, by HIV-status

	HIV-positive		HIV-negative		Overall		p-value*
CIN2+ cases missed by VAT result	39.1%	(27/69)	61.4%	(27/44)	47.8%	(54/113)	0.02
CIN3+ cases missed by VAT result	31.4%	(16/51)	53.3%	(16/30)	39.5%	(32/81)	0.07

CIN: cervical intra-epithelial neoplasia; HIV: human immunodeficiency virus; VAT: Visual assessment for treatment
*Chi-square test

Conclusions: Although hrHPV DNA testing offers a highly sensitive primary screening solution, currently recommended secondary visual triage testing may miss severe disease in those who screen negative. Better approaches to secondary triage testing for LMICs remain urgently needed.

VIRTUAL-025 / #1261

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

HR-HPV GENOTYPE AS A METHOD OF CERVICAL CANCER SCREENING IN TERTIARY HOSPITAL

Asma Akter Sonia, Ashrafun Nessa
Bangabandhu Sheikh Mujib Medical University, Gynecological Oncology, Dhaka, Bangladesh

Introduction: Cervical cancer is the 4th most common gynecological malignancy globally. In Bangladesh, cervical cancer is a burning issue due to high prevalence of risk factors. Human Papilloma Virus (HPV) is one of the common sexually transmitted infection that may be persistent and may lead to cervical cancer. Identification of high-risk (hr) HPV type is essential to investigate epidemiology and clinical characteristics of particular type. To find out HPV genotype (16, 18, & others) distribution among asymptomatic women. Comparison of the effectiveness of hr-HPV genotype with VIA for cervical cancer screening.

Methods: This cross-sectional study was carried out in the Department of Gynecological Oncology, Bangabandhu Sheikh Mujib Medical University, Dhaka. A total of 300 asymptomatic women (30-60 years) fulfilling inclusion criteria were included in this study. Data were collected using the structured questionnaire designed for interview, clinical examination, hr-HPV genotyping, Visual Inspection of Cervix with Acetic Acid (VIA), and Colposcopy of the women. Hr-HPV genotyping was performed by Polymerase chain reaction.

Results: It was observed that HPV 16 (4.7%) was the most prevalent type, followed by other hr- HPV (3.7%) types, HPV 18 (.7%) and combination of HPV 16 and other hr- HPV (0.3%) types. Most of the HPV genotype-positive patients belonged to 35-39 years of age (25%) and mean age was 42.0±7.4. There was significant association between HPV genotype with early age of marriage and age of first delivery. This study showed that HPV genotype had higher sensitivity (87.1%) and specificity (99.6%) than VIA.

Conclusions: Conclusion: HPV genotype has much better sensitivity and specificity then VIA to identify preinvasive and invasive cervical diseases. HPV genotype can be used as effective method for cervical cancer screening including identification of women at risk of cervical cancer.

VIRTUAL-026 / #693

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

PHOTODYNAMIC THERAPY FOR HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESION OF THE CERVIX(HSIL/CIN2) IN WOMEN WITH FERTILITY REQUIREMENTS.

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Introduction: Photodynamic therapy (PDT) is a novel and minimally-invasive strategy for the treatment of cervical intraepithelial neoplasia (CIN). PDT has the function of targeting and aggregating pathological tissues, and has little damage to normal tissues.

Methods: Between Jan 2021 and June 2022, 39 patients aged 21-37 years with CIN 2. (primary CIN2 37 cases; CIN2 and VAIN2 2 cases) were treated by Photodynamic Therapy. Infection with high-risk genotypes of HPV (16, 18, 31, 33, 35, 39,45, 51,52,56,58,59,68) was detected. 39 patients received PDT with 5-Aminolevulinic Acid (ALA) photosensitizers. A 20% ALA was applied to the lesions and sealed with plastic film for 3 h. Patients were irradiated with a red light at a wavelength of 635±15 nm. The light dose is 80mw/cm2. The duration of a PDT session varied from 25 min. All patients completed 6 treatment cycles. The interval of treatment was 7-14 days. The main adverse effects of ALA-PDT were abdominal distension , pain, and increased vaginal discharge. Cervical cytology, HPV testing, colposcopy, and histopathology were performed 3, 6 months after PDT.

Results: 82.1% patients(32/39）HPV was detected and high-risk HPV (16 +) was detected in 19 patients（48.7%）. No severe adverse events were observed . HPV was negative 6 months after PDT treatment in 30 patients. The pathological regression rate is 89.7%（35/39）
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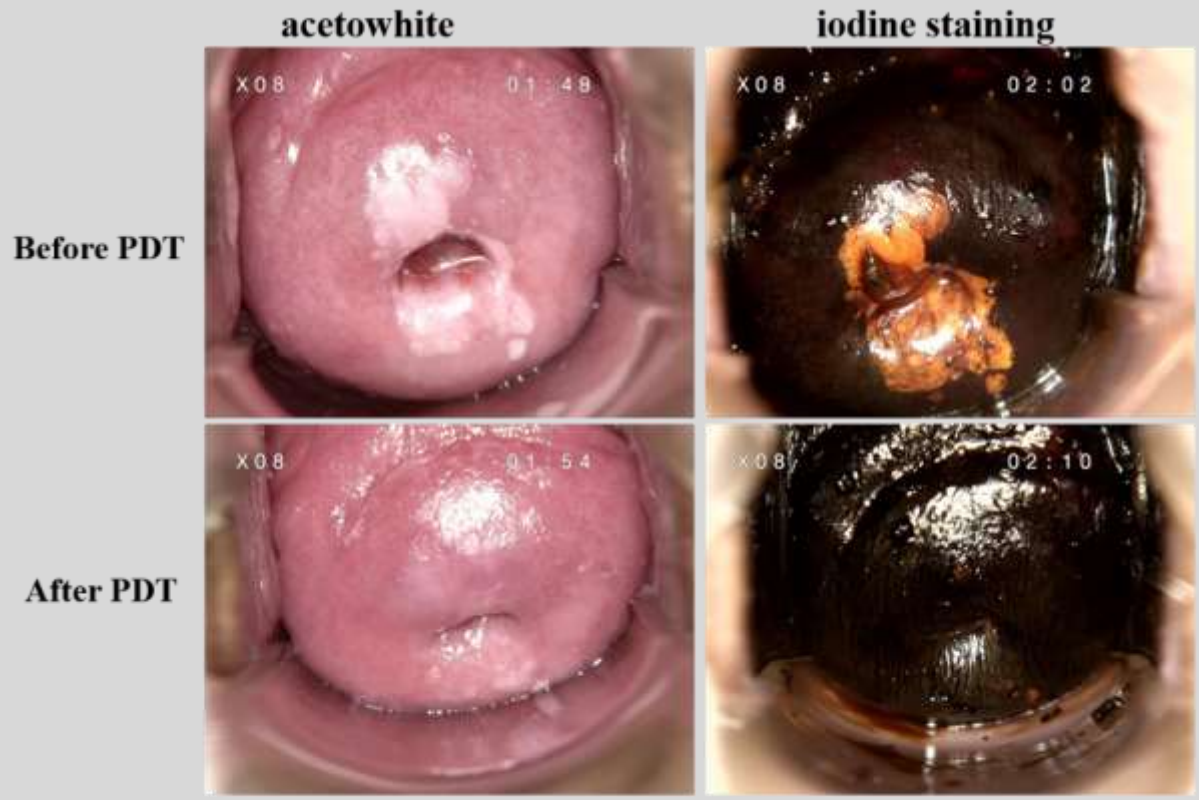

Fig. 1. Colposcopy images （HSIL/CIN2） ,the left depicts the aceto-white dysplastic lesion areas ,the right column depicts atypical epithelium after use of iodine solution .(Bafore and after PDT)

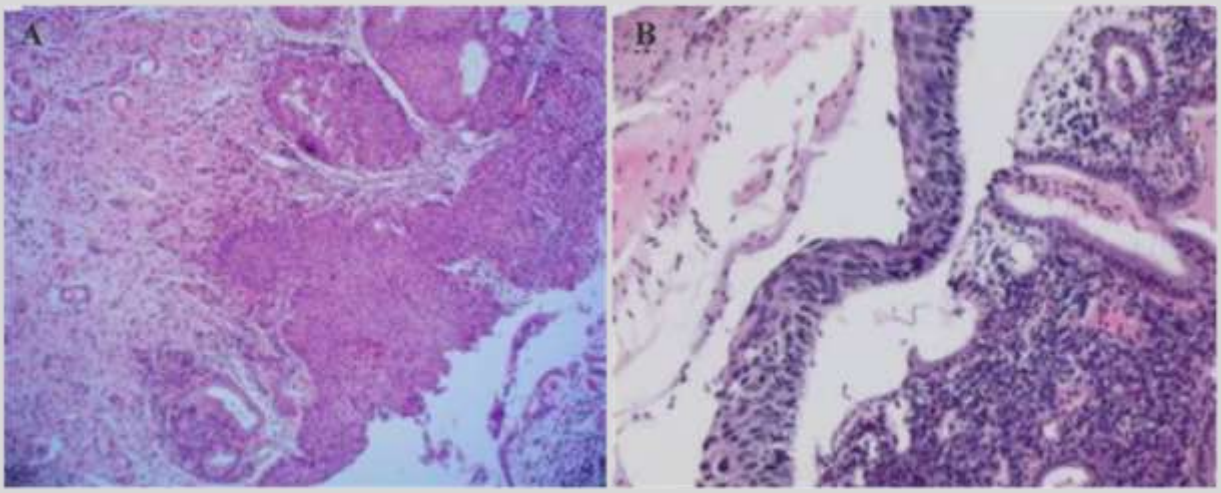

Fig. 2. Pathology images. The left and right column reflects the H&E-stained specimens in cervix. (CIN2) .(A and B)

Conclusions: The results of PDT in the treatment of patients with HSIL(CIN2) demonstrated its few adverse reactions and good efficacy. PDT is not only an effective treatment for HSIL(CIN2) in patients who have fertility requirements, but also can preserve cervical integrity.

VIRTUAL-027 / #1645

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

THE EXTRACTS OF GENUINE CHINESE MEDICINE, JIN-CHUANG-YAO IMPROVES THE DEVELOPMENT OF PATHOGENESIS AND MICROBIOTA OF CERVICAL EROSION

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Introduction: Pathological inflammatory cervical erosion(CE) is a common gynecological disease that affects women's reproductive health. The purpose of this study is to explore the structural characteristics of vaginal microflora in patients with CE, searching cytokine from vaginal microenvironment in wound healing and HPV infection through genuine Chinese medicine (Jin-chuang-yao).

Methods: Vaginal samples from 22 women (12 controls, 10 cervix erosion cases) were analyzed using nanopore sequencing of the full-length 16S rRNA gene before and after treatment with Jin-Chuang-Yao from LangZhongTang (Xiamen) Pharmaceuticals Inc.. We evaluated the level of cytokines in vaginal specimens using 22 multiplexed, bead-based immunoassays. Metabolites were analyzed by non-targeted LC- and MS-based metabolomics. The relationship between cytokines and wound healing or HPV infection, microbiome, and metabolomics were also studied.

Results: Observed differences in the vaginal microbiota structure between healthy and CE women, the latter having higher species diversity and significantly less Lactobacillus spp. At the species level, Candidatus Thioglobus autotrophicus, Bacillus anthracis, Candidatus Thioglobus singularis, Clostridium sp. CT4, and Bacillus thuringiensis were closely related to the CE state. These species may be used as biomarkers for predicting pathological cervical erosion disease status. Cytokines, namely, IL-1β, eotaxin, MCP-1, and IL-4, displayed different expression levels in healthy controls and CE group. We also found that levels of IL-7/8/9, IFN-γ, eotaxin, MIP-1α, IL-1ra, and MIP-1β were significantly different between the HPV(+/-) groups. The levels of biogenic amines in the vaginal microenvironment were higher in cervical erosion patients and HPV+ patients. The levels of local AA were much higher in the healthy and HPV- groups.

Conclusions: We characterize the vaginal microbiota and metabolites from cervical erosion and HPV+ women, as well as cytokines related to wound healing and HPV infection in the vaginal microenvironment by treating Jin-Chuang-Yao, providing a new look for the etiology and treatment of CE.

VIRTUAL-028 / #1344

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

EFFECT OF A CORIOLUS VERSICOLOR-BASED VAGINAL GEL FOR HIGH-RISK HPV CLEARANCE AND CYTO-NORMALIZATION IN A 44-YEAR-OLD PATIENT WITH HR-HPV PERSITENCE OF MORE THAN 10 YEARS

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Introduction: Human papillomavirus (HPV) infection is one of the most frequent sexually transmitted infections and high-risk (HR) oncogenic strains of HPV are behind virtually all cases of invasive cervical cancer. Although prophylactic vaccines are highly effective, they have no therapeutic effect. In this clinical case, a Coriolus versicolor-based vaginal gel treatment was assessed for HR-HPV clearance and cyto-normalization.

Methods: A clinical case of 44-year-old woman, ex-smoker from 2018, who attended for a routine follow-up visit due to a history of persistent infection for 12 years with a HR-HPV strain and both low-grade and high-grade squamous intraepithelial lesions in the cervix and vagina (Fig 1 and 2). The patient was subjected to two excisional therapies (large loop excision of the transformation zone) in 2007 and 2009 and one cervical CO_2 vaporization in 2013, plus another vaginal CO_2 vaporization in 2014 which reduced the extension and grade of the lesions. The follow up of the case showed 4 years of viral persistence and intermittent appearance of HPV-linked cytological alterations. At the time of the visit, she presented low-grade cervical lesions and was positive for HPV type 53. Therefore, a conservative treatment with the Coriolus versicolor based vaginal gel was prescribed (1 cannula/day for 1 month + 1 cannula/alternate days for 5 months) in

2019.

Figures

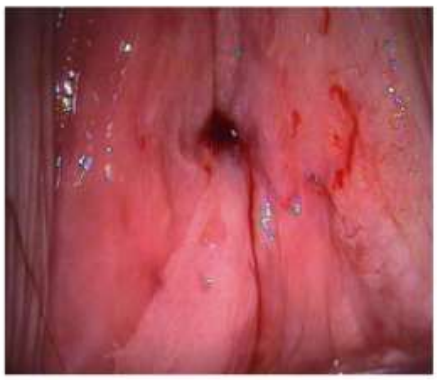

Fig. 1. Colposcopy/vaginoscopy Abril 2013. Transformation zone 3 cervix. Major changes in cervix and left-hand side posterior cul-de-sac and anterior vaginal face. Previous cytology: HSIL, Biopsy: HSIL/CIN and VaIN.

A

B

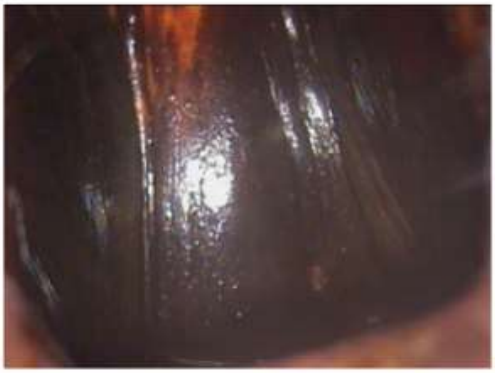

Fig. 2. Vaginoscopy in January 2014. Erased posterior cul-de-sac, major changes in left hand side posterior cul-de-sac, coincident lugol's negative result. Previous cervical cytology: ASCUS. Positive HPV test (Cervista™). Vaginal biopsy vaginal with diagnose of HSIL/VaIN (A). Vaginoscopy in January 2015 without evidence of lugol's negative lesions (B).

Results: After several surgical procedures and a long history of HR-HPV persistency, the patient achieved complete cyto-normalization and HR-HPV clearance with a 6-month treatment period of the Coriolus versicolor based vaginal gel.

Conclusions: This clinical case shows that a conservative non-invasive treatment with a Coriolus versicolor-based vaginal gel can be a valuable therapeutic option to achieve the normalization of cytological alterations and HR-HPV clearance in a patient with a long history (12 years) of HPV persistency after several excisional and destructive treatments.

VIRTUAL-029 / #1360

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

EFFECT OF A CONSERVATIVE MANAGEMENT OF CIN II USING A CORIOLUS VERSICOLOR-BASED VAGINAL GEL: AN OBSERVATIONAL STUDY

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Introduction: Human papilloma virus (HPV) is behind 95% of cervical cancer cases and its precursor lesions. According to the American Society of Colposcopy and Cervical Pathology (ASCCP), 50% of CIN II cases managed conservatively spontaneously regress. The aim of this study was to evaluate the effect of a Coriolus versicolor-based vaginal gel in the conservative management of CIN II lesions.

Methods: A one-cohort, prospective, single-centre, observational study including ≥ 18 years-old women, with CIN II diagnosis were treated with 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months of a Coriolus versicolor-based vaginal gel. Inclusion criteria have been based on the Spanish Society of Colposcopy and Cervical Pathology (AEPCC) guidelines for CIN II conservative treatment: colposcopy image with visible transition zone, completely visible lesion affecting less than 2 quadrants, non-affected endocervix and accepting cytology/colposcopy after 6 months. Baseline and 6-month biopsies were performed.

Results: A total of 44 women 35.5 years-old on average were included. After a 6-month treatment period, 68.2% of them showed a regression by biopsy, 11.4% persisted on CIN II and 18.2% progressed to CIN III. Three patients were considered null and not included in the data analysis because they did not have a biopsy taken after 6 months.

Conclusions: The Coriolus versicolor-based vaginal gel 6-month treatment seems to increase the regression of the lesions compared to spontaneous resolution and could represent a clinical advantage compared to the “wait and see” approach in patients meeting the conservative treatment criteria for CIN II lesions.

VIRTUAL-030 / #1646

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

EFFECTIVENESS OF A CYTOLOGY-BASED ARTIFICIAL INTELLIGENCE SYSTEM FOR THE TRIAGE OF HPV-POSITIVE WOMEN: A CHINESE, CROSS-SECTIONAL AND MULTICENTRE STUDY

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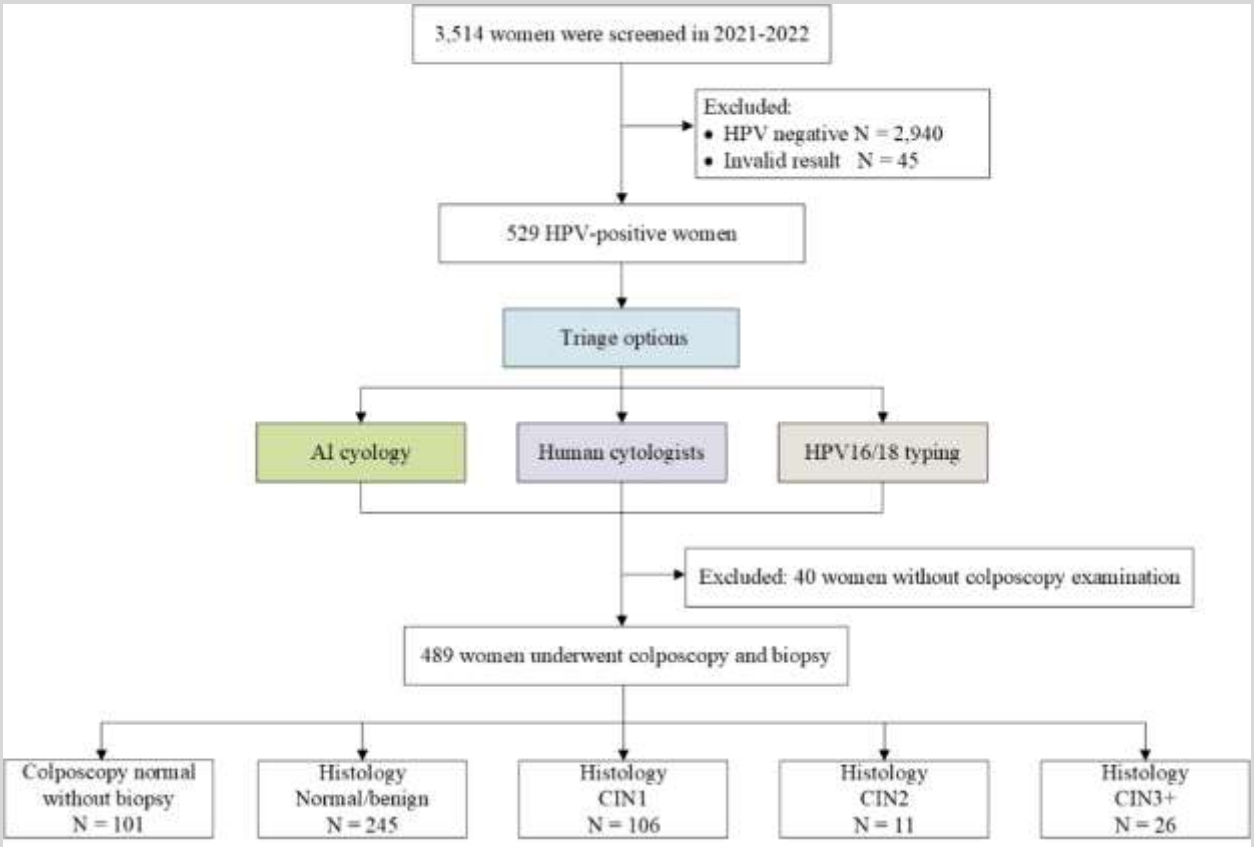
Introduction: The management of HPV-positive women becomes particularly crucial in cervical cancer screening. We investigated whether a cytology-based artificial intelligence system (CAIS) could serve enable effective triaging of HPV-positive women.

Methods:



We used a retrospective dataset of 8,000 digital whole cytological slide images consisting of 5,713 negative and 2,287 positive cases to develop CAIS for the triage of HPV-positive women. A Chinese, cross-sectional and multicentre study was conducted to assess the performance of CAIS from 489 consecutive women diagnosed as HPV positive between 2021 and 2022. HPV positive women received further tests using HPV16/18 typing, and liquid-based cytology slides were interpreted by human cytologists and comparatively with AI cytology. Histological cervical intraepithelial neoplasia (CIN) grade 2 or higher (CIN2+) or grade 3 or higher (CIN3+) were considered the gold standard. Triaging performance

and efficiency of cytology-based AI, human cytologists and HPV 16/18 typing were compared at detecting CIN2+ or CIN3+ in HPV-positive women.

Results: For CIN2+ detection, CAIS had significantly higher specificity than cytologists (51.33% vs 40.93%, p < 0.001), but CAIS had significantly lower sensitivity than HPV16/18 typing (51.33% vs 87.17%, p < 0.001). The sensitivity of CAIS was comparable to cytologists (86.49% vs 83.78%, p = 0.744), but significantly higher than HPV16/18 typing (86.49% vs 54.05%, p = 0.002). Compared to cytologists, CAIS reduced colposcopic referrals significantly (51.53% vs 60.94%, p = 0.003). Similar patterns were also observed for CIN3+ detection.

Table 1. Screening performance of different triage tests for CIN2+ and CIN3+ diagnoses among HPV–positive women

	AI cytology	Cytologists	HPV16/18 typing	P^a	P^b
Detection of CIN2+ (N = 37)					
Sensitivity (%) 95% CI	86.49 (75.47–97.50)	83.78 (71.91–95.66)	54.05 (38.00–70.11)	0.744	0.002
Specificity (%) 95% CI	51.33 (46.72–55.94)	40.93 (36.40–45.46)	87.17 (84.08–90.25)	< 0.001	< 0.001
PPV (%) 95% CI	12.70 (8.59–16.81)	10.40 (6.94–13.87)	25.64 (15.95–35.33)	0.400	0.006
NPV (%) 95% CI	97.89 (96.06–99.72)	96.86 (94.38–99.33)	95.86 (93.94–97.79)	0.716	0.170
Detection of CIN3+ (N = 26)					
Sensitivity	92.31 (82.06–100.00)	88.46 (76.18–100.00)	61.54 (42.84–80.24)	1.000	0.008
Specificity	50.76 (46.20–55.31)	40.60 (36.13–45.08)	86.61 (83.51–89.71)	0.008	< 0.001
PPV	9.52 (5.90–13.15)	7.72 (4.69–10.75)	20.51 (11.55–29.47)	0.450	0.009
NPV	99.16 (97.99–100.00)	98.43 (96.67–100.00)	97.57 (96.08–99.06)	0.660	0.253

Abbreviation: CIN2+, cervical intraepithelial neoplasia grade 2 or worse; CIN3+, cervical intraepithelial neoplasia grade 3 or worse; HPV, human papillomavirus; CI, confidence interval; AI, artificial intelligence; PPV, positive predictive value; NPV, negative predictive value; P^a value indicates the comparison between AI cytology and cytologists; P^b value indicates the comparison between AI cytology and HPV16/18 typing.

Table 2. Performance of AI cytology and cytologists in combing with HPV16/18 typing among HPV–positive women

	HPV16/18 with AI cytology triage of other HR–HPV[a]	HPV16/18 with cytologists' triage of other HR–HPV[b]	*P*
Detection of CIN2+ (N = 37)			
Sensitivity (%) 95% CI	91.89 (83.10–100.00)	91.89 (83.10–100.00)	1.000
Specificity (%) 95% CI	46.02 (41.42–50.61)	36.73 (32.28–41.17)	0.005
PPV (%) 95% CI	12.23 (8.38–16.08)	10.63 (7.25–14.00)	0.537
NPV (%) 95% CI	98.58 (96.98–100.00)	98.22 (96.23–100.00)	1.000
Detection of CIN3+ (N = 26)			
Sensitivity (%) 95% CI	96.15 (88.76–100.00)	96.15 (88.76–100.00)	1.000
Specificity (%) 95% CI	45.36 (40.82–49.89)	36.29 (31.91–40.66)	0.005
PPV (%) 95% CI	8.99 (5.63–12.36)	7.81 (4.87–10.75)	0.603
NPV (%) 95% CI	99.53 (98.60–100.00)	99.41 (98.25–100.00)	0.445

Abbreviation: CIN2+, cervical intraepithelial neoplasia grade 2 or worse; CIN3+, cervical intraepithelial neoplasia grade 3 or worse; HPV, human papillomavirus; CI, confidence interval; AI, artificial intelligence; PPV, positive predictive value; NPV, negative predictive value; [a]Considered positive if HPV16 or HPV18 results are positive, with AI triage of the other 12 high–risk HPV types. [b]Considered positive if HPV16 or HPV18 results are positive, with cytologists' triage of the other 12 high–risk HPV types. *P* value indicates the comparison of AI cytology and cytologists in combing with HPV16/18 typing.

Conclusions: Compared to human cytologists, CAIS has equivalent sensitivity but higher specificity with more efficient colposcopy referrals for triage of HPV-positive women. This is particularly important given the global shortage of skilled cytologists. This cloud-based technology could therefore improve cervical cytology screening programs worldwide.

VIRTUAL-031 / #1105

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

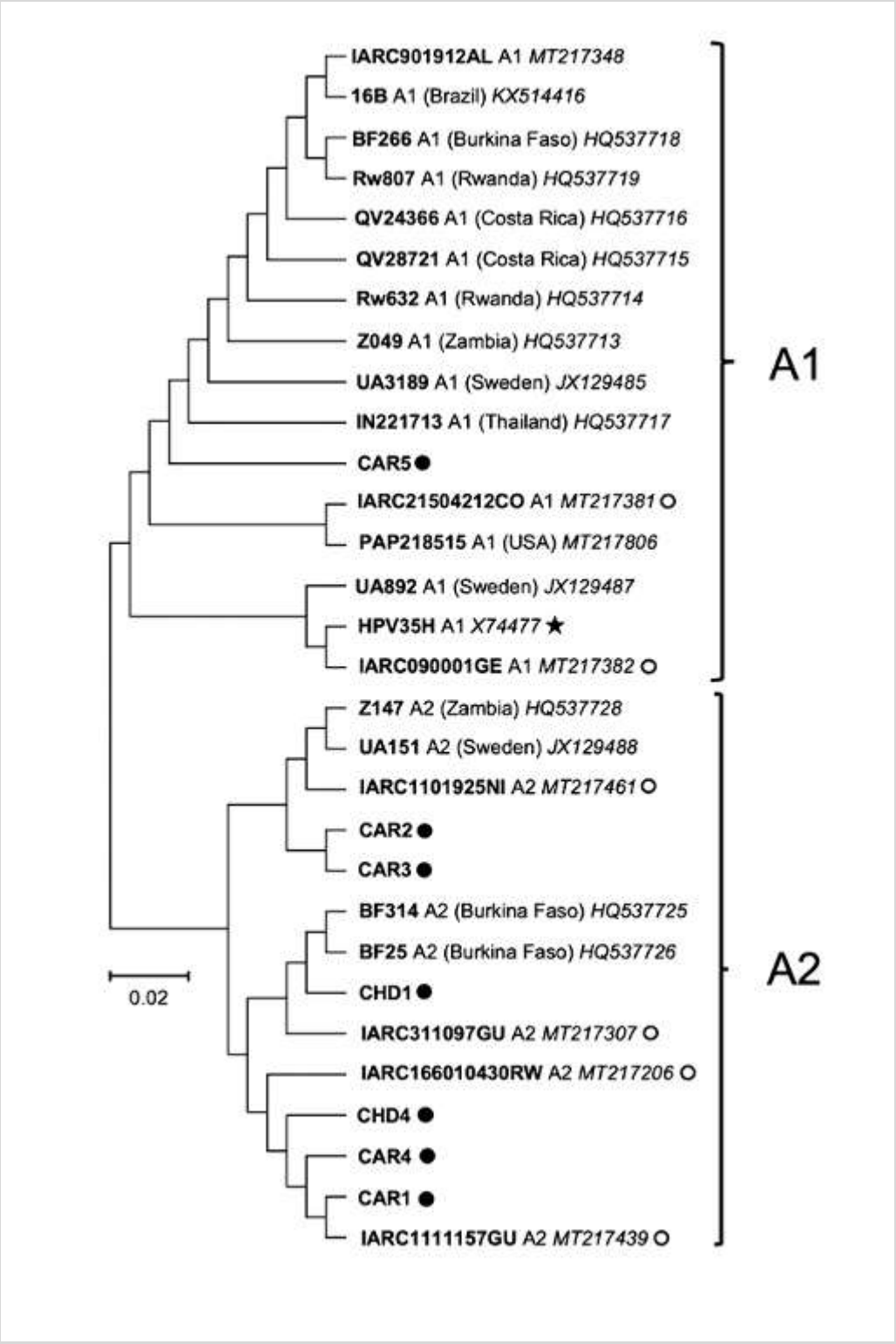
GENETIC DIVERSITY OF HUMAN PAPILLOMAVIRUS 35 FROM HEALTHY HETEROSEXUAL WOMEN LIVING IN CHAD AND HIV-INFECTED MEN HAVING SEX WITH MEN LIVING IN CENTRAL AFRICAN REPUBLIC

N.J. Avala[1], Ralph-Sydney Mboumba Bouassa[1,2], Zita Aleyo Nodjikouambaye[1,3], Christian Diamant Mossoro-Kpinde[4], Gerard Grésenguet[4], David Veyer[2], Hélene Péré[2], Laurent Bélec[2]
[1]Ecole Doctorale d'Infectiologie Tropicale, Infectious Disease-medical Virology, Franceville, Gabon, [2]Hôpital européen Georges-Pompidou, APHP.Centre - Université Paris Cité, Paris, France, Virology (microbiology), Paris, France, [3]Hôpital de la Mère et de l'Enfant, N'Djamena, Service De Gynécologie-obstétrique, N'Djamena, Chad, [4]Université de Bangui, Faculté Des Sciences De La Santé, Bangui, Central African Republic

Introduction: The A2 sublineage of the non-vaccine Human Papillomavirus (HR-HPV)-35 has been linked to a higher risk for cervical cancer in the African population worldwide. We aimed to describe the genetic diversity of HPV35 in Chadian women and Central African men having sex with men (MSM).

Methods: HPV35 DNA was detected using Anyplex™ II HPV28 from cervical and anal swab samples from HIV-negative Chadian women (#CHD) with normal cytology and HIV-positive Central African MSM (#CAR) with abnormal anal cytology, respectively. L1, E2, E6, E7, and LCR were sequenced using the ABI PRISM® BigDye Sequencing technology and analyzed with MEGA 7.1 software.

Results: Most of the HPV35 strains belonged to the A2 sublineage, and only #CAR5 belonged to the A1 sublineage as the prototype (HPV35H) (Figure 1). HPV35 from #CAR tended to have higher L1 variability compared to #CHD (mean number of mutations: 16 and 6, respectively; P=0.113). #CAR5 showed a significant L1 variability of 2.29%, making it likely divergent from HPV35H. The capsid L1 loop domains BC, DE, and EF, remained totally conserved in all specimens, while FG- and HI- loops of #CAR specimens exhibited amino acid variations (Figure 2). #CAR5 also showed the highest LCR variability with a 16bp insertion located at binding sites of the YY1 transcription factor. HPV35 from #CHD exhibited the highest E2 variability (P<0.05). Finally, E6 and E7 oncoproteins remained well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QV28721 A1 (Costa Rica) HQ537715
Rw632 A1 (Rwanda) HQ537714
Z049 A1 (Zambia) HQ537713
UA3189 A1 (Sweden) JX129485
IN221713 A1 (Thailand) HQ537717
CAR5
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PAP218515 A1 (USA) MT217806
UA892 A1 (Sweden) JX129487
HPV35H A1 X74477
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A1
Z147 A2 (Zambia) HQ537728
UA151 A2 (Sweden) JX129488
IARC1101925NI A2 MT217461
CAR2
CAR3
BF314 A2 (Burkina Faso) HQ537725
BF25 A2 (Burkina Faso) HQ537726
CHD1
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A2
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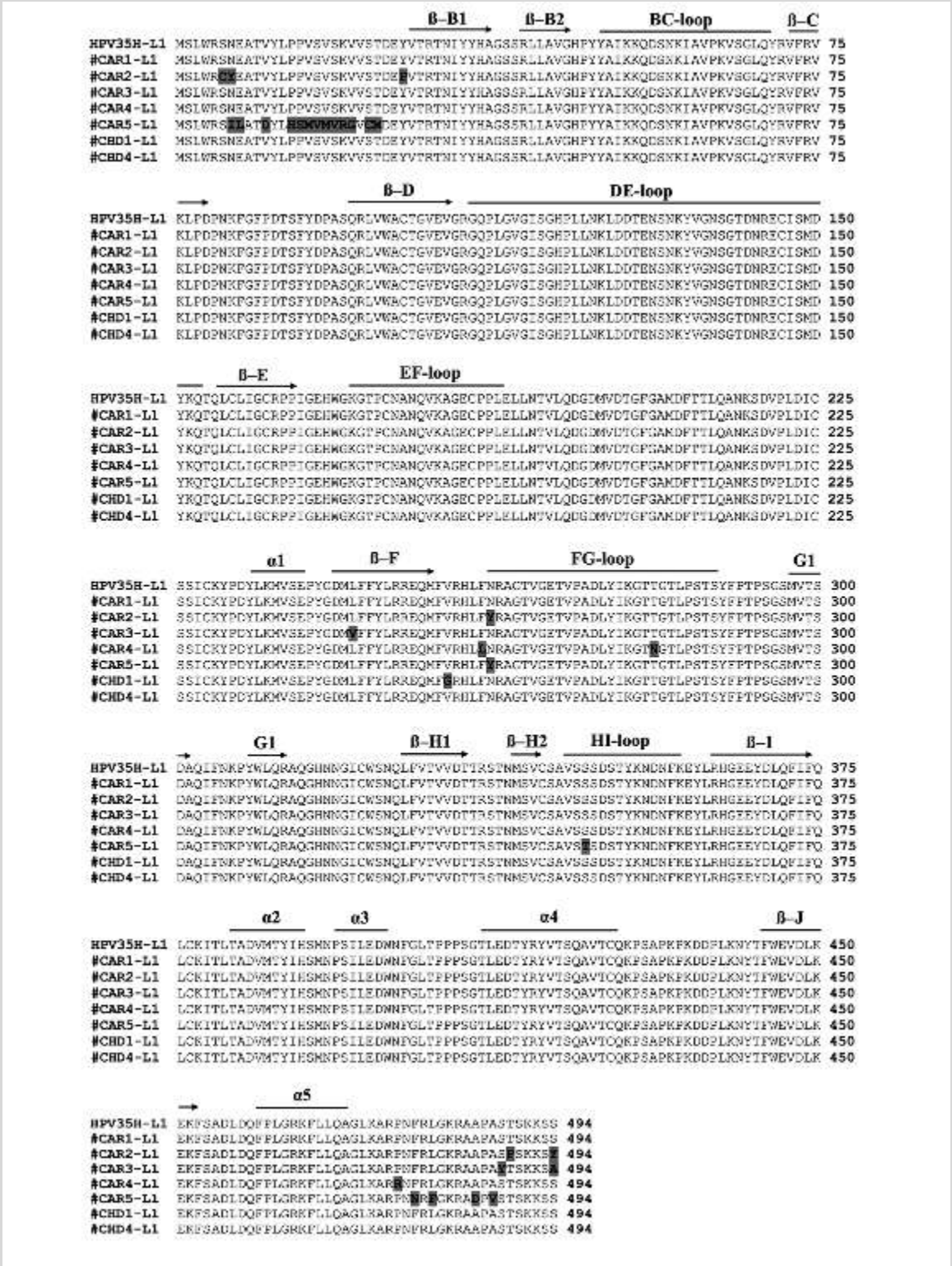
conserved.



Conclusions: There is relative maintenance of a well-conserved HPV35 A2 sublineage within heterosexual women living in Chad and MSM living with HIV in the Central African Republic. It is necessary to elucidate the consequences of such genetic variability within the A2 sublineage, as well as

the likely divergent #CAR5 strain, on the virus-host interactions, in order to better understand the clinical implications that these HPV35 variants could have in the Central African population.

VIRTUAL-032 / #485

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

CYTOLOGICAL STUDY OF URINE IN THE DIAGNOSIS OF PAPILLOMAVIRUS CYSTITIS

Khalid Ibishev, Vahid Mamedov
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Introduction: Human papillomavirus (HPV) with a rare occurrence in the urinary tract and reproductive system, both in men and women. In recent years, the number of patients with recurrent cystitis, in which the etiological disease is HPV, has been increased

Methods: Analysis of the cytological study of 140 patients with chronic cystitis was carried out, which, depending on the etiological disease, were divided into two groups by bacteriological examination (BI) of the urine: group I - 70 patients, according to the BI data, no bacterial pathogen was detected and group II – 70 patients, where various bacterial pathogens were identified according to the BI data. Cytological examination of urine for the presence or absence of pathological specific cells.

Results: Analysis of the cytological study revealed koilocytous transformation of urethelial cells of patients in the group in 34 (48.5%) cases, in the second group it was not checked in any patient. Single koilocytes in group I were in 20 (35.7%) patients, and in group II - 11 (15.7%) (Figure 1.).Signs of hyperkeratosis of the urothelium in group I were detected in 30 (42.8%) patients, and in group II in 5 (7.1%) patients. In addition, 58 (82.8%) patients of group I had an increase in the presence of a large number of lymphocytic cells, 15 (21.4%) patients had a small number of neutrophilic leukocytes. In group II, a small number of lymphocytes in the field of view in the cytological picture was detected in 8 (12.8%) patients, and neutrophils - in 70 (100%) women. Figure 1. Signs of koilocytosis.

Conclusions: Thus, a cytological examination of urine can show the nature of an infectious-inflammatory process.

VIRTUAL-033 / #653

Poster Viewing
VIRTUAL POSTERS
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DEVELOPMENT OF A MULTIPLEX IMMUNOASSAY TO MEASURE ANTIBODY ISOTYPES AND SUBCLASSES TO SEVEN HPV VACCINE TYPES

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Introduction: HPV vaccines given prior to infection are immunogenic and effective at preventing vaccine-type HPV infection and cervical precancers. Three common methods for measuring HPV-specific antibody responses are: HPV pseudovirion-based neutralisation assays (PBNA), competitive immunoassays (CLIA), and the virus-like particle (VLP)-based ELISA. PBNA is low-throughput and time-consuming, while ELISA detects only one antibody isotype per genotype at a time. Therefore, we developed a bead-based Luminex multiplex immunoassay to measure antibody isotypes and subclasses to seven HPV genotypes that cause cervical cancer (HPV16/18/31/33/45/52/58).

Methods: HPV VLPs were produced by transfecting human embryonic cell line (HEK293TT) with L1 plasmid DNA for each HPV genotype. VLPs were purified by ultracentrifugation and verified by SDS-PAGE. Each HPV VLP (16/18/31/33/45/52/58) was then covalently conjugated to carboxylated beads. Type-specific antibody isotypes and subclasses (IgG, IgM, IgA1-2, IgG1-4) were measured by incubating VLP-conjugated beads with human serum and phycoerythrin (PE)-conjugated mouse anti-human secondary antibody. This assay was validated using serum from a cohort study in Fiji, where adolescent girls received 1, 2 or 3 doses of 4vHPV followed by booster 2vHPV six years later.

Results: Using the multiplex assay, we could differentiate antibody responses between vaccinated and unvaccinated individuals. We detected a dose response for IgG (IgG1/IgG3) and IgA1 against 7 HPV types among individuals previously vaccinated with 1, 2 or 3 doses of HPV vaccine and an anamnestic antibody response following a booster dose. HPV16/18-specific IgG antibodies strongly correlated with nAb levels previously measured by PBNA (HPV16: $r=0.75$, HPV18: $r=0.88$, $p<0.0001$), and a moderate correlation was observed with HPV16-specific IgA1 and IgA2 with nAb (HPV16/18: $r=0.53$, $p<0.0001$).

Conclusions: We established a high-throughput immunoassay that has the advantage of measuring multiple antibody features to comprehensively evaluate HPV antibody responses. This assay can be used as an alternative method to existing immunoassays to measure HPV type-specific antibody responses.

VIRTUAL-034 / #586

Poster Viewing
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COMPARATIVE ANALYSIS OF RELATED FACTORS OF POSITIVE MARGIN AFTER CONIZATION FOR CERVICAL GLANDULAR LESION

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Introduction: To explore the possible related factors of positive margin after conization for cervical glandular lesion.

Methods: The clinical pathological characteristics of 78 patients with cervical glandular lesion who underwent cervical conization from January 2012 to April 2022 were reviewed and analyzed.

Results: Among the 78 patients, ① General condition: Age ranges from 25 to 74 years old, median age 38 years old. 37.18% had positive margin; Asymptomatic patients accounted for 69.23% . ② Screening results:41.54% were NILM, and 58.46%were abnormal. The positive rate of HPV was 95.77% and the negative was 4.23% . Single type infection accounted for 82.35% , , HPV 16 was the most common type, followed by HPV 18 . ③ Pathological terms: Only 66.67% of glandular lesions were found by biopsy; after conization, 62.82% were diagnosed as glandular lesions combined with squamous epithelial lesions.The average cone height and diameter of the specimens with positive incisional margin were (1.8 ± 0.7) cm and (2.2 ± 0.5) cm respectively. The negative incisional margin were (1.7 ± 0.4) cm and (2.2 ± 0.7) cm respectively. The positive margin had statistical significance with multifocal of the lesion (c2=15.528; p=0.000). The risk of positive margin is increased by 0.121 times compared with patients with non-multifocal lesions (95% CI: 0.039-0.373). The positive margin had no statistical significance with the patient's age, clinical symptoms, screening results, HPV infection status, pathological diagnosis, the size of specimen, and the modus operation. (P > 0.05).

Conclusions: ① There is an increased risk of positive margin in patients with jumping multifocal lesions. ②Glandular lesions may be present in the form of a squamous epithelium.③ When abnormal signs of squamous epithelial lesions are found by colposcopy, endocervical curettage is recommended for HPV16 and / or 18 positive patients, especially for those with colposcopy impression of HSIL, regardless of the type of transformation zone

VIRTUAL-035 / #1446

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

CATCHING THEM YOUNG TO CONQUER CERVICAL CANCER IN ABIA STATE-NIGERIA: FINDINGS FROM A SCHOOL-BASED ADVOCACY PROJECT

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Introduction: Although cervical cancer is the second most common cancer affecting Nigerian women, most Nigerian women are not aware of this disease nor do they attend screening services, where available. The We-Can, I-Can-Conquer Cervical Cancer Project sought to 1) create awareness about cervical cancer among 2,000 secondary school students and 2) explore the use of cloud computing and essay competition in improving the retention of advocacy messages. It was collaboratively implemented by community partners in Nigeria as a primary prevention intervention.

Methods: Pre-recorded videos in English and Igbo Languages were hosted on OneDrive and presented at various secondary schools in Nigeria using projectors. Volunteer nurses also addressed questions from the students, who were encouraged to participate in a follow-up essay competition. The project was promoted using WhatsApp, Facebook, and Twitter. Printed pamphlets and Facebook Live® interactive broadcasts were used to sustain public engagement. Essay entries were collated and graded by nurses. Data included number of entries, social media impressions, and advocacy event participants.

Results: Fifteen secondary schools and one Junior College hosted the presentations, with a total of 3, 919 participants. The Facebook Live event has 200 views with 10 shares. Eleven non-school community groups (e.g. churches) also hosted the presentations. Fifty essay competition entries were received from eleven secondary schools including Bulgaria, to demonstrate their retention of the content of the advocacy messages. The audience expressed their satisfaction with the cloud-based pre-recorded video presentation.

Conclusions: The project surpassed its target in-person audience by almost 100% (2,000 vs 3,919), excluding the online audience. This approach demonstrated the power of cloud-based video presentations in demystifying cervical cancer among young people in Nigeria. Subsequent projects should invest more resources into media promotions and reaching out to students even when schools are out of session.

VIRTUAL-036 / #1818

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ROLE OF SELF-SAMPLING FOR THE DIAGNOSIS OF HUMAN PAPILLOMAVIRUS IN RURAL AREAS FROM CUENCA ECUADOR: ACCEPTANCE, SENSITIVITY AND SPECIFICITY

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Introduction: Background:.High sensitivity tests for primary screening of HPV are useful for an early detection of cervical pathology. Self-sampling techniques could overcome barriers and increase participation in screening and participation. Objectives 1.- To compare the sensitivity and specificity of urine and vaginal self-sampling test versus clinician sampling test, for HPV diagnosis. 2.- To compare the acceptability of urine and vaginal self-sampling methods versus clinician sampling among rural women

Methods: A diagnostic test study was conducted in a rural parish of Cuenca, Ecuador.. Each participant self-collected urine and vaginal samples and underwent clinician sampling for HPV testing. The latter was considered as the golden standard. All three samples were processed with the same amplification and hybridization protocol.. After sample collection a questionnaire to qualify device and technique and individual acceptability was applied and additional overall preference of three sample tests was evaluated

Results: A total of 120 women participated. Self-sampling sensitivity reached 94.4% , and specificity 92.1%.. Urine sampling had a sensitivity of 88.8% , and specificity 94.1% . The negative predictive value was 98.9% for vaginal self-sampling and 97.6% for urine sampling. Acceptability: Compared with clinician sampling, both vaginal self-sampling OR 20.12 and urine sampling OR16.63 , were more comfortable, granted more privacy: vaginal self-sampling OR 8.07 ; urine sampling OR 19.5 , were less painful: vaginal self-sampling OR 0.07, urine sampling OR 0.01 and less difficult to apply: vaginal self-sampling OR 0.16 urine sampling OR 0.05 . Overall preference has shown an advantage for vaginal self-sampling 4.97

Conclusions: This study shows that vaginal and urine self-sampling methods have similar sensitivity and specificity compared with clinician sampling for the diagnosis of HPV. The correlation between HPV genotypes among the three tests is satisfactory. Self sampling methods have a high acceptance in rural communities. .

VIRTUAL-037 / #1823

Poster Viewing
VIRTUAL POSTERS
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BARRIERS AND FACILITATORS TO CERVICAL CANCER SCREENING AMONG UNDER-SCREENED WOMEN IN CUENCA, ECUADOR: THE PERSPECTIVES OF WOMEN AND HEALTH PROFESSIONALS

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Introduction: In Ecuador, cervical cancer being the most frequent cancer in women, only 58,4% of women of reproductive age have ever been screened for cervical cancer during their lifetime. ObjectivesThe aim of this research is to complement and update previous studies, by assessing the perspectives of under-screened women and health care providers regarding barriers and facilitators of cervical cancer screening in Cuenca, Ecuador

Methods: A qualitative study was performed from April 2020 until March 2021, in Azuay province, Ecuador. Focus group discussions (FGDs) were organized with health staff and under-screened women separately, as this method allows participants to interact with each other which enriches the generated information. Two FGD guides were developed, one for women and one for health personnel. Key topics addressed during the discussions were opinions about or experiences with cervical cancer screening, opinions about national cervical cancer screening practices or programs, barriers that inhibit screening uptake and suggestions to address these barriers

Results: Overall, 28 women and 27 HP participated in the study. Both groups perceived different barriers for cervical cancer screening. For HP, barriers were mainly allocated at the policy level (lack of a structured screening plan; lack of health promotion) and individual level (lack of risk perception; personal believes). Women identified mainly barriers at operational level, such as long waiting times, lack of access to health centers, and inadequate patient-physician communication. Both groups mentioned facilitators at policy level, such as national campaigns regarding cervical cancer screening, and at community and at individual level, including: health literacy and women empowerment

Conclusions: From women's perspectives, access to health services is the main limitation; while for health professionals lack of investment in screening programs and cultural patterns at community level constitute major obstacles. To address cervical cancer prevention integrally, the perspectives of both groups should be taken into account.

VIRTUAL-038 / #922

Poster Viewing
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PREVALENCE OF UTERINE CERVICAL HIGH-RISK HPV (HR-HPV) 16 INFECTION AND ITS CLINICO-DEMOGRAPHIC PROFILE AMONG THE WOMEN OF THE REMOTE ANDAMAN ISLANDS, INDIA

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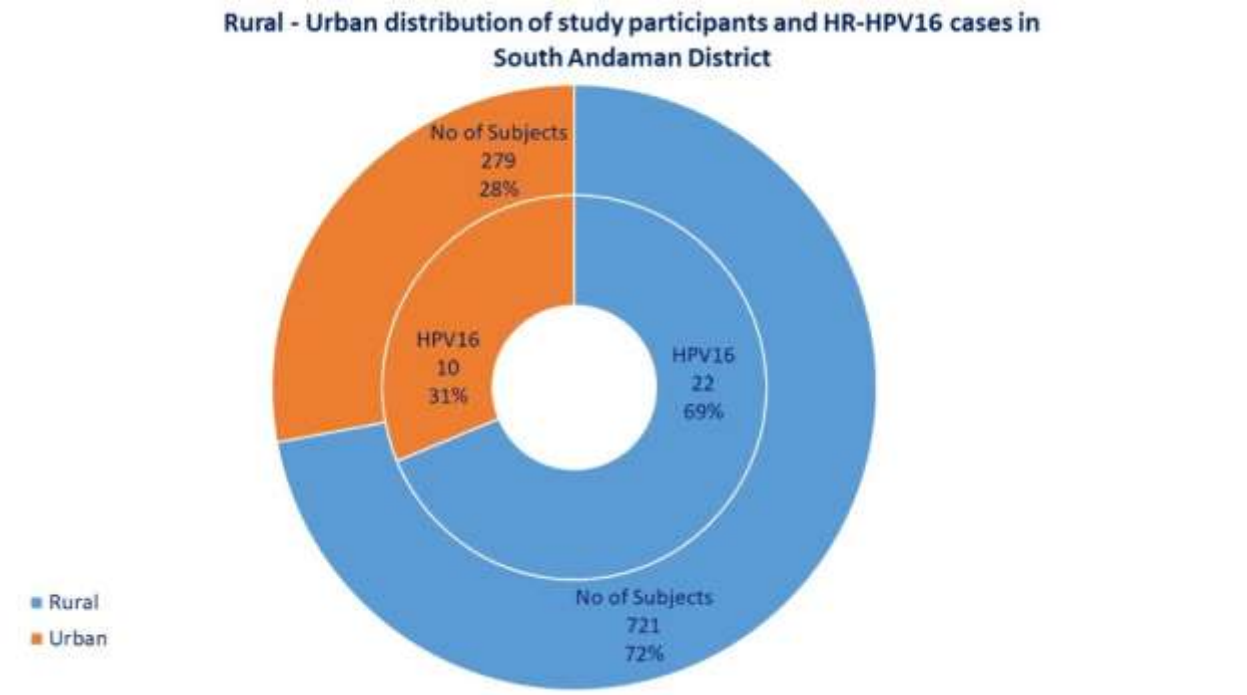
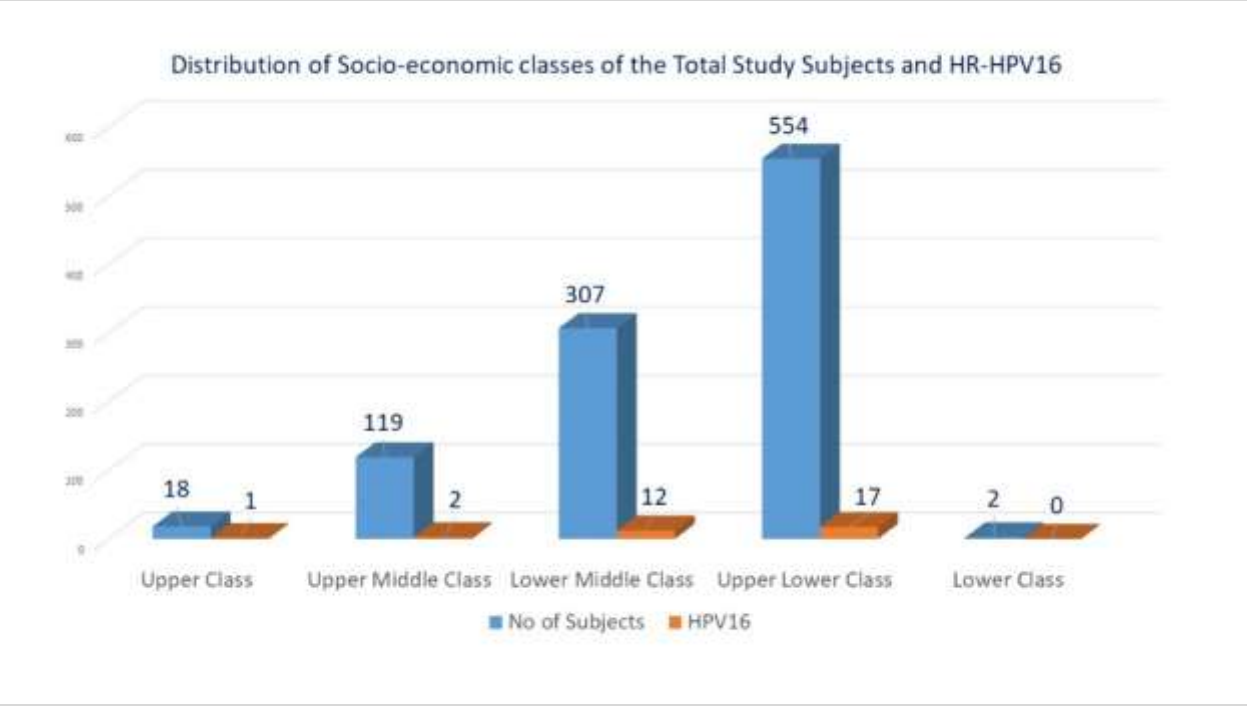
Introduction: Persistent infection with High-risk human papilloma viruses lead to the development of precancerous lesions and cervical cancer. HPV16 accounts for almost half of all cervical cancers. Andaman has a diverse population from different regions of mainland India. The aim of the study was to estimate the prevalence of HR-HPV16 infection and to identify associated clinico-demographic risk-factors among women of this remote island.

Methods: A cross sectional community based study was conducted in the South Andaman district of Andaman Islands, India. Married women of age group 18-59 were screened for High-risk HPV16. Informed consent was obtained from all participants. Cervical scrapings were collected and screened by PCR in accordance with the published protocol using L1 consensus primers for HPV and type-specific primers for HR-HPV16. Clinical and demographic data were also collected in a questionnaire.

Results: A total of 1000 subjects were enrolled in the study and cervical scrapings were collected after obtaining informed consent. Study subject's mean age (SD) was 37.8 (9.24) years. The prevalence of HPV was 5% and prevalence of HPV16 was 3.2%. Chronic vaginal discharge was the most common clinical presentation of the subjects followed by lower abdominal pain and chronic pelvic pain. The mean age (SD) of HR-HPV16 positives was 40.5 (11.9) years Among the 32 identified with HPV16, three had squamous cell carcinoma, one had atypical squamous cells of undetermined significance, 16 had inflammatory pap-smear, and 12 had a normal pap-smear. The prevalence of High-risk HPV 16 was found to be higher among the age group of 36–45 years, rural women and among upper lower socioeconomic
classes.





Conclusions: Prevalence of HR-HPV16 in South Andaman district of Andaman Island was found to be lower than that reported from other parts of India. However due to the availability of vaccines for prevention, awareness on preventive measures need to be strengthened.

VIRTUAL-039 / #1205

Poster Viewing
VIRTUAL POSTERS
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TRANSCRIPTIONAL LANDSCAPE OF RECURRENCE RISK FOR ANAL CANCER AFTER CHEMORADIATION THERAPY IN PATIENTS WITH HIV

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Introduction: Improved chemoradiation therapy (CRT) is the standard of care for squamous cell carcinoma of the anus (SCCA), the most common type of anal cancer. However, approximately one fourth of patients still relapse after CRT. Transcriptomic biomarkers will be useful in predicting anal cancer treatment outcomes.

Methods: In this pilot study, we used RNA-sequencing to characterize and compare the coding and non-coding transcripts in the tumor tissues between 3 recurrent and 12 non-recurrent SCCA patients who underwent CRT. RNA was extracted from SCCA FFPE tissues and linked to clinical data. An initial filter of $log_2FC > 2$ and p-value < 0.05 were used to identify differentially expressed genes (DEGs). Function and pathway enrichment analyses were performed with Metascape and enrichment of gene ontology (GO) was performed with Gene Set Enrichment Analysis (GSEA).

Results: We identified 449 DEGs (390 mRNA, 12 miRNA, 17 lincRNA and 18 snRNA) between the non-recurrent and recurrent. We found a core of upregulated genes in the SCCA tissue from participants with non-recurrent cancer enriched in “allograft rejection” which were highly suggestive of a productive CD4+ T cell driven immune response, such as IL4, CD40LG, and ICAM2 the human leukocyte antigen genes, both HLA-I and HLA-II. Conversely, in the SCCA tissue from participants with recurrent cancer, we determined that the most significant DEGs were enriched in “Epidermis Development,” consistent with the growth of an epidermal malignancy, such as keratin (KRT1, 10, 12, 20) and hedgehog signaling pathway genes. Previous studies showed that mi-R-4316, which we identified as upregulated in non-recurrent SCCA, inhibits tumor proliferation and migration by repressing vascular endothelial growth factors.

Conclusions: Our study identified several key host factors which may drive the recurrence of SCCA after CRT and warrants future studies to understand the mechanism and further evaluate their potential use in personalized treatment of SCCS.

VIRTUAL-040 / #1587

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INCIDENCE, PERSISTENCE, AND CLEARANCE OF ANOGENITAL HUMAN PAPILLOMAVIRUS AMONG MEN WHO HAVE SEX WITH MEN IN TAIWAN: A COMMUNITY COHORT STUDY

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Introduction: Men who have sex with men (MSM) are at increased risk for Human papillomavirus (HPV) infection. This study aimed to assess the incidence, persistence and clearance of anogenital HPV infection among MSM and the correlates in a three-year community cohort study.

Methods: From 2015 to 2019, MSM were recruited and followed up at 6-, 12-, 24-, and 36- months in Taiwan. Questionnaires and anogenital swabs were collected at baseline and each follow-up. Thirty-seven HPV genotypes were detected and genotyped using the linear array HPV genotyping test. Incidence, persistence, and clearance rates of anogenital HPV infection and 95% confidence intervals (CIs) were estimated by Poisson regression. Correlates were examined using a generalized estimating equations (GEE) model.

Results: A total of 201 MSM retained in the cohort study with a median age of 27 years (IQR 24-32) at baseline. Rates of incidence, persistence, and clearance of any anal HPV infection among MSM were 43.6 (95%CI 33.7-55.6), 23.4 (17.7-30.2), and 58.3 (45.1-74.1) per 1000 person-month (pm), respectively. Rates of incidence, persistence, and clearance of any penile HPV infection among MSM were 26.8 (20.1-34.9), 13.4 (8.0-20.9), and 51.5 (37.8-68.5) pm, respectively. MSM who did not consistently use a condom in receptive sex (aOR 2.06, 95%CIs 1.14-3.72) were more likely to acquire any anal HPV infection. Age at recruitment (1.05, 1.01-1.09) were positively associated with any penile HPV incidence. MSM with over one sex partners in receptive anal sex (0.53, 0.30-0.94) were less likely to clear any anal HPV infection. MSM who were unemployed/students (0.55, 0.30-0.98) were less likely to clear any penile HPV infection.

Conclusions: High incidence and low clearance of anogenital HPV infection among MSM in the study serve as a reminder to address HPV vaccination targeting this population. It is essential for MSM to scale up HPV screening and adhere to safe sex.

VIRTUAL-041 / #1820

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A COMPARISON OF ACCEPTABILITY OF HPV SELF-SAMPLING FOR CERVICAL CANCER SCREENING AMONG WOMEN LIVING WITH AND WITHOUT HIV IN LAGOS UNIVERSITY TEACHING HOSPITAL, NIGERIA

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Introduction: Women with HIV infection have higher risk of persistence Human Papillomavirus (HPV) infection and developing cervical cancer compared to women in the general population. As part of self-care interventions, HPV testing with self-collected genital samples and timely follow-up care has the potential to improve the prevention of cervical cancer among women. The aim of this study was to assess and compare the acceptability of HPV self-sampling method for cervical cancer screening among women living with and without HIV in Lagos University Teaching Hospital (LUTH), Lagos, Nigeria.

Methods: A comparative cross-sectional study was conducted and participants were selected using a systematic sampling technique. Data were collected using a semi-structured interviewer-administered questionnaire and analyzed using SPSS. Chi-square statistics was used at the level of significance was set at 5%.

Results: The mean age of the respondents was 42.4 years ± 7.3SD and 64.8% were married. Awareness of HPV infection was low (33.6%) and this was significantly lower among women living with HIV (18.5%) than women living without HIV (50.2%). However after a brief information on HPV infection and cervical cancer, a significantly higher proportion of women living with HIV infection (92.8%) compared to women without HIV infection (83.6%) accepted HPV self-sampling method ($p<0.0001$). Awareness of HPV infection was significantly associated with the acceptance of HPV self-sampling method. Age, marital status, level of education and previous Pap test were not significantly associated with the acceptance of HPV self-sampling among the women in the two groups.

Conclusions: Acceptance of HPV self-sampling method for early detection of high-risk HPV infection and prevention of cervical cancer especially among women with HIV can be achieved by increasing the awareness about HPV infection and HPV self-sampling method.

VIRTUAL-042 / #995

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EVALUATING THE IMPACT AND IMPLEMENTATION OF A STIGMA-RESPONSIVE HPV EDUCATIONAL VIDEO INTERVENTION IN KISUMU, KENYA

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Introduction: Human papillomavirus (HPV) is the leading source of cervical cancer in Kenya. Education and empowerment are crucial in combating HPV stigma and increasing screening uptake. We conducted qualitative and quantitative analyses of an HPV educational video intervention in Kisumu, Kenya to determine its impact by examining women's experience and implementation sustainability factors in the clinic setting. The stigma-responsive video featured a group discussion with an individual describing her experience with HPV, self-testing, and preventive treatment.

Methods: As part of a cluster-randomized control trial, community health volunteers (CHVs) provided standard HPV education at three control clinics and showed the video, augmented with HPV education, at three intervention clinics. We observed factors impacting implementation for six weeks using a survey evaluating client engagement, workflow logistics, and education delivery. Three focus group discussions were conducted with 30 women from intervention clinics, ages 30-65, to explore their experience with the video education delivery, perspectives on HPV and self-sampling, and the feasibility of peer navigation to increase screening and follow-up.

Results: Across 33 clinic data collections, 16.5 women per day at intervention clinics saw the video over 17 days, and 14 women per day heard HPV health talks in the control over 16 days. 182/307 (63%) of the women screened in the intervention sites, compared to 103/224 (46%) who screened after standard health talks at control sites. Women in FGDs felt that the video would decrease fear of testing, increase HPV knowledge, and empower sharing knowledge.

Conclusions: The video education reached more women who followed up with screening, compared to standard education. Women in FGDs found the HPV educational video to be acceptable, stigma-reducing, and empowering. Further research is necessary to determine the viability of sustainably implementing the intervention in a clinic environment with regard to suspected barriers (CHV and women's availability and technological interruption) and implementation facilitators.

VIRTUAL-043 / #1067

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PRACTITIONERS INTENTION TO INTEGRATE A UNIVERSAL OPTION FOR SELF-COLLECTION CERVICAL SCREENING IN AUSTRALIA'S NATIONAL CERVICAL SCREENING PROGRAM: OPPORTUNITIES AND CHALLENGES

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Introduction: In 2017, Australia's long-established National Cervical Screening Program (NCSP) transitioned from cytology to HPV-based screening. This provided the opportunity to introduce the option of screening on a self-collected sample (self-collection), initially only for under-screened or never-screened participants. From mid-2022, self-collection was made available as a choice for all people undergoing screening, overseen by a healthcare professional. This study explored practitioners' perception of a universal option of self-collection, and how they intend to provide it in routine practice.

Methods: Interviews with 30 practice managers, general practitioners, and nurses from 10 practices in Victoria, Australia were conducted between May to September 2022. Interviews were analysed thematically, informed by the Consolidated Framework for Implementation Research.

Results: Participants stated that cervical screening is a key component of the clinical care that they and their practice provides, but their experience with providing self-collection within the previous restricted policy was limited. Most participants supported policy change expanding access to self-collection, reflecting on its potential to increase participation, but reported differences in how they intend to provide it in practice. Most practitioners (n=27, 7 practices) indicated intention to provide self-collection as an option to all potential screening participants. In some cases, whole of practice level changes were considered to support its implementation. Practitioners from three practices were undecided about offering self-collection universally, citing concerns about participants' self-efficacy to collect their sample and the perceived lost opportunity to perform a pelvic examination.

Conclusions: This study was conducted during a time of significant change in Australia's NCSP and, for the first-time, details practitioner's perception of and intention to provide a universal choice for self-collection within routine practice. As implementation continues, communication and education, which addresses key concerns of practitioners, will be critical to ensuring the potential for self-collection to increase participation and accelerate Australia's progression towards elimination of cervical cancer is realised.

VIRTUAL-044 / #1068

Poster Viewing
VIRTUAL POSTERS
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SELF-COLLECTION CERVICAL SCREENING IN THE ASIA-PACIFIC REGION: A SCOPING REVIEW OF IMPLEMENTATION EVIDENCE

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Introduction: While cervical cancer is a disease of inequity, it can be eliminated as a public health problem through vaccination, screening and treatment. HPV vaginal self-collection cervical screening is a high-performance screening test that can increase the reach of screening. This scoping review described the different contexts and models of care used to pilot or implement self-collection within the Asia-Pacific Region, to measure the extent implementation outcome measures are reported and, where available, summarise key implementation findings.

Methods: A scoping review was conducted by searching five databases of the peer-reviewed literature. Two researchers assessed eligibility and extracted data independently relevant to the model of care and the Conceptual Framework for Implementation Outcomes. A mixed-method synthesis was undertaken to report findings.

Results: A total of 57 articles, comprising 50 unique studies from 11 countries were included; 82% were conducted in a trial setting. Ten different models of care were utilised in implementation studies; 80% were delivered through a practitioner-supported model with diversity described in how samples were processed, and treatment was offered. Acceptability (73%) and appropriateness (64%) measures were most frequently reported, followed by adoption (57%), feasibility (48%), and fidelity (38%). Only 7% of articles reported implementation cost or penetration measures and no studies reported sustainability measures.

Conclusions: Self-collection cervical screening can be implemented within most settings in the Asia-Pacific Region and there is clear evidence demonstrating that it is acceptable and appropriate from the user's perspective. Well-designed, high-quality implementation trials and real-world evaluations of self-collection that report on the breadth of implementation outcomes can support activities in the Asia-Pacific region to progress the elimination of cervical cancer.

VIRTUAL-045 / #1185

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

CERVICAL SCREENING IN PRINCESS GRACE HOSPITAL IN MONACO

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Introduction: The aim of this study was the evaluation of HPV research in cervical cancer screening in Princess Grace Hospital, Monaco, in 2021 and 2022 (until August 23rd).

Methods: Our case series was represented by 9666 women from different countries who have been divided in two groups based on their age: the first group was made by women of 30-65 years old, while the second one by women <30 and >65 years old. Patients underwent a first triage, in which the first group of women had been submitted to hrHPV research, while the others had been screened by cytology. In the first group, patients with negative hrHPV testing were recalled after 5 years, while those with positive hrHPV testing were advised to repeat the test after one year (second triage). If hrHPV testing resulted still positive, patients were submitted to colposcopy and eventual treatment; if negative, they returned to routine screening. In the second group, patients with negative cytology were recalled after 3 years, those with cytology ASC-US or more were submitted to colposcopy; those negative for intraepithelial lesion or malignancy were addressed to second triage, with the same protocol as the first group.

Results: are summarized in Tables. Table 1 – Women 30-65 years.

	hrHPV	hrHPV-	hrHPV+	hrHPV+/ASC-US	hrHPV+/ASC-H	hrHPV+/L-SIL	Total positive
2021	4848	3833	676	181	25	133	1015
2022	2762	2141	415	115	18	73	621
Total	7610	5974	1091	296	43	206	1636

Table 2 – Women <30 years and >65 years.

	Cytology	Negative	ASC-US/hrHPV+	ASC-US	Total positive
2021	1228	1001	47	180	227
2022	828	626	51	151	202
Total	2056	1627	98	331	429

Table 3 – Conization.

Conization	SCC	L-SIL

2021	107	1	27
2022	74	1	16
Total	181	2	43

Conclusions: Our study confirms the validity of screening for cervical cancer prevention.

VIRTUAL-046 / #1480

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

SEXUAL RISK BEHAVIORS, SOCIAL VULNERABILITY, AND ANAL CANCER SCREENING AMONG MEN LIVING WITH HIV IN THE DEEP SOUTH

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Introduction: Without standard anal cancer screening guidelines, there is a need to examine screening practices, particularly in the South where HIV incidence remains highest in the U.S. This study describes the first strand of a sequential, explanatory mixed methods research project with the purpose of identifying sexual risk and other social factors associated with screening among men living with HIV (MLHIV) at the University of Alabama at Birmingham's HIV outpatient clinic.

Methods: Patient reported outcomes were analyzed using the Center for AIDS Research Network of Integrated Clinical Systems (CNICS) survey among MLHIV in 2018. Relationships between demographic (i.e.; age, race, sexual identity, social vulnerability), clinical (i.e.; viral load, CD4 count), and sexual risk characteristics (i.e.; number, HIV status, and PrEP use of partner(s)) with screening were examined using t-tests, chi-square tests, and logistic regression analyses.

Results: Among 1,114 men, 52% had received an anal pap screen within one year of the survey. Those who were older or identified as straight had lower odds of being screened. A greater proportion of young black men were screened compared to young white men; older black men living in counties with moderate to high social vulnerability were less likely to be screened. Men with one partner that reported unprotected anal sex were 2 times as likely to be screened compared to those who did not. Men with two or more partners that were not male were 94% less likely to be screened compared to those with two or more male partners.

Conclusions: MLHIV in the South who are older, black, or identify as straight may be less likely to receive secondary preventative care for anal cancer. The results in this study will be used to inform the development of in-depth interview guides among men and their providers to help better explain barriers and facilitators to screening.

VIRTUAL-047 / #1743

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

NONVACCINE ONCOGENIC HUMAN PAPILLOMAVIRUS (HPV)-35: THE MOST PREVALENT HPV GENOTYPE AMONG GABONESE WOMEN

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Introduction: Data on the genotype distribution of human papillomavirus (HPV) is important for cervical cancer prevention and HPV vaccine implementation. In Gabon, little is known about HPV prevalence. The aim of this study was to assess the prevalence of HPV genotypes and the suitability of HPV vaccination in Gabon.

Methods: Cervical samples were collected from women participating in the annual cancer screening campaign at the major hospital of Libreville. Detection and genotyping of HPV was performed by real-time multiplex PCR, and logistic regression analysis was used to determine associated-risk factors.

Results: Among the 358 women recruited, the prevalence of HPV was 17.2% and decreased with age. HPV 35 (3.1%) was the predominant genotype, followed by HPV 16 (2.2%),HPV 18 (2.2%), HPV 52 (1.68%), HPV 58 (1.40%), HPV 53 (0.8%), HPV 59 (0.8%), HPV 81 (0.8%), HPV 6 (0.6%), HPV 33 (0.6%), HPV 66 (0.6%), HPV 56 (0.6%), HPV 82 (0.6%), HPV 31 (0.3%), HPV 39 (0.3%), HPV 45 (0.3%), and HPV 68 (0.3%). Multiple HPV infections were found in 20.9% of women. Parity was the only risk factor significantly associated with HPV carriage. Gardasil9 was the best-suited vaccine, with a predicted vaccine coverage of 73%.

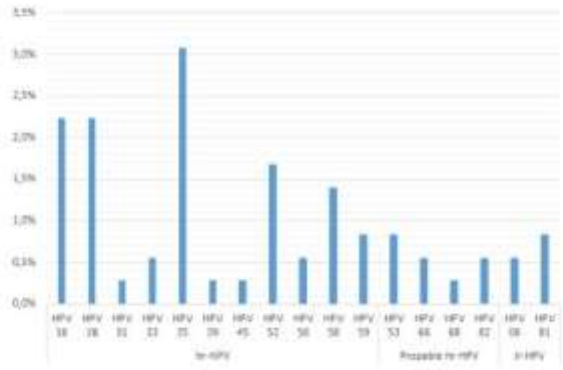

Figure 1: Hierarchical relative positivity rate of hr-HPV, probable hr-HPV and lr-HPV genotypes detected from the 38 randomly selected samples with respect to overall HPV prevalence. Incidence of HPV 16 and 18 is also represented.

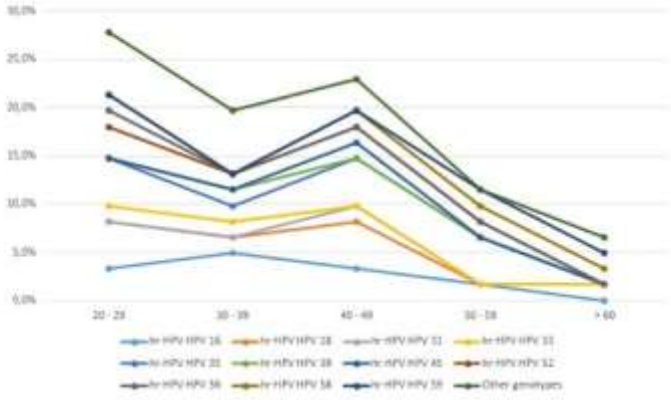

Figure 2: Stacked-line graph of the relative age-specific prevalence of HPV genotypes detected in the study population.

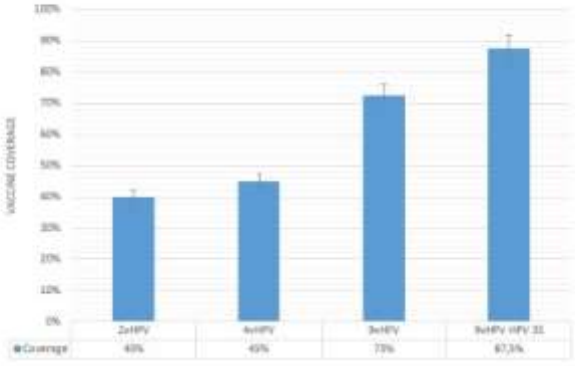

Figure 3: Potential vaccine efficacy of available commercial vaccine with respect to the HPV genotypes detected.

Conclusions: The predominance of HPV 35 in this population deserves particular attention: HPV 35 is not included in current HPV vaccines and is associated with cervical precancer treatment failure in HIV infected women. This study warrants the need for a nationwide epidemiological study to fully evaluate the prevalence of HPV genotypes in Gabon.

VIRTUAL-048 / #616

Poster Viewing
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HUMAN PAPILLOMA VIRUS (HPV) INFECTION OF THE MALE GENITAL TRACT. STUDY OF LOCAL EPIDEMIOLOGY, INDUCED IMMUNE RESPONSE AND ALTERATIONS IN FERTILITY

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Introduction: HPV infection in general male population remain an underexplored field. Although some reports associate HPV with certain seminal alterations, others reported no disturbances. Most of them do not analyze concomitant presence of other STI and their effects. The aim of our study was to evaluate whether HPV alone or coinfecting with other STI is associate with semen inflammation and impaired sperm quality.

Methods: 168 male patients aged 20-61 attending urology clinic were enrolled. Control group was composed by patients without leukocytospermia and negative for all the STI tested. Semen samples were analyzed for HPV by PCR and genotyped by RFLP. The presence of C.trachomatis, U.urealiticum, M.hominis, M.genitalium, T.vaginallis, N.gonorrhoeae, T.pallidum, and HSV was screened by PCR. Seminal quality was evaluated according to WHO guidelines. Semen leukocyte subpopulations, reactive oxygen species and sperm viability were analyzed by flow cytometry.

Results: 39/168 semen samples were positive for HPV, being 49% high risk oncogenic genotypes. The 74% HPV+ samples were co-infecting with at least one of the other pathogens. Patients solely HPV+ did not show leukocytospermia (peroxidase+ cells). No difference in seminal lymphocytes CD4+/CD8+, monocytes or granulocytes were found between HPV+ and control groups. Patients solely HPV infected showed increased sperm necrosis (p=0.048). HPV alone was not associated to significant alterations in semen quality, however, when HPV was coinfecting with certain pathogens (C. trachomatis, M. hominis or T. vaginallis) more seminal parameter alterations were observed with respect to control group. (table I)

and the separate infections.

Table I: Parameters in HPV-positive and HPV-negative semen samples with or without other infections

	Control patients (n=43)	Total HPV+ patients(n=38)	*p* value	Only HPV+ patients (n=10)	*p* value	HPV+ *C.trachomatis*+ (n=6)	*p* value	HPV+ *M.hominis*+(n=4)	*p* value	HPV+ *T.vaginalis*+ (n=3)	*p* value
Sperm Parameters											
Volume (ml/ejaculate)	2,83±1,42	2,82±1,25	0,734	2,82±0,53	0,492	2,63±1,48	0,736	4,05±2,21	0,261	1,7±0,69	0,152
Sperm concentration (million/ml.)	100,2±76,45	107,6±93,15	0,905	87,99±72,7	0,731	23,32±27,61	**0,006**	97,57±55	0,834	177±181,5	0,469
Viability (%)	87,5±5,57	84,3±9,28	0,113	84,7±6,8	0,367	80±8,45	**0,033**	89,5±4,12	0,508	89±3	0,242
Total motility (PR+NP, %)	52,1±14,35	48,9±17,95	0,084	42,8±15,5	0,127	27,17±20,6	**0,007**	59±14,21	0,341	40±1	0,147
Progressive motility (PR, %)	51,8±14,5	43,5±18,04	0,085	42,8±15,5	0,146	26,67±20,33	**0,006**	58,5±14,48	0,359	40±1	0,173
Normal morphology (%)	6,14±3,02	4,63±2,48	**0,035**	4,2±2,86	0,077	4,02±3,98	0,146	6,75±1,5	0,576	2,67±2,52	0,080
Sperm Viability											
Live	57,60±16,40	61,64±15,61	0,336	58,99±19,62	0,656	60,52±9,51	0,94	71,85±15,79	0,215	60,5±13,36	
Early apoptosis	8,48±5,73	5,64±4,83	**0,001**	4,06±3,35	**0,003**	10,75±8,72	0,909	5,36±4,52	0,187	2,79±0,93	**0,006**
Late apoptosis	18,5±9,28	14,02±8,27	**0,032**	12,79±6,81	0,090	16,08±8,44	0,632	11,98±9,04	0,351	14,48±7,17	0,585
Necrosis	10,96±6,86	16,04±11,18	**0,032**	21,04±15,97	**0,048**	12,64±6,47	0,619	5,36±1,86	0,073	22,2±9,85	**0,011**
Inflammatory markers											
Peroxidase-positive cells (10^6/ml)	0,212±0,28	0,28±0,48	0,968	0,075±0,08	0,318	0,08±0,08	0,652	0,04±0,02	0,468	1,282±0,31	**0,0001**
Reactive oxygen species (%)	26,48±15,87	34,83±17,82	0,107	29,78±13,15	0,576	48,9±4	**0,007**	48,28±20,07	**0,044**	12,25±17,04	0,2222

*HPV: Human Papillomavirus. All data are presented as mean ± SD. Total motility is the sum of Progressive motility (PR) and Non Progressive motility (NP, data not shown). **Control patients:** patients without leukocytospermia and negative for all the STI tested. **Total HPV+ patients:** All HPV positive patients with or without coinfections. **Only HPV+ patients:** HPV positive patients without other infections detected. **HPV+*C.trachomatis*+:** Patients only positive for HPV and *C.trachomatis*, without other infections. **HPV+*M.hominis*+:** Patients only positive for HPV and *M.hominis*, without other infections. **HPV+ *T.vaginalis*+:** Patients only positive for HPV and *T.vaginalis*, without other infections. Comparisons were performed between each group and control group and *p* value calculated using the Mann–Whitney test. The differences were considered statistically significant when $p < 0.05$.

Conclusions: Herein we show that HPV infection alone does not associate to semen inflammation or altered sperm quality. Nevertheless, HPV seems to potentiate harmful effects when coinfecting with other STI. Our data contributes to understand the real effect of HPV on male genital tract highlighting the importance of excluding the confounding effects of other not assayed coinfections.

VIRTUAL-049 / #1071

Poster Viewing
VIRTUAL POSTERS
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IMPLEMENTATION OUTCOMES AND HPV PREVALENCE RATES AMONG TRIBAL, RURAL AND URBAN-POOR WOMEN FROM TAMIL NADU, INDIA, FROM AN HPV SELF-COLLECTION STUDY

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Introduction: In view of the need for India to rapidly transition to HPV based screening, there is a need for implementation studies among all vulnerable populations, to ensure equity in screening. This feasibility study reports implementation outcomes and HPV prevalence rates among women from tribal, rural and urban slums in Vellore and Tiruvannamalai districts, Tamil Nadu.

Methods: HPV prevalence was estimated using the low-cost careHPV test on self-collected vaginal samples in tribal (two different distances from follow up testing centre), rural and urban poor areas. The rural area had a long-standing VIA based screening program. Women aged 30-60 years were motivated by health workers, educated in groups using videos, posters, counselled by nurses, over 8 months, and self-collected samples at home. HPV positive women were navigated for follow up (triage with colposcopy/pap smear, followed by thermal ablation).

Results: Implementation outcomes are shown in Table. Programmatic challenges of identifying eligible, education, collecting samples, follow up, were higher for tribal women, requiring adaptations: home education, extra volunteer, honoraria for workers and temporary camps.

implementation outcomes of study

	Nearby tribal villages	Distant tribal	Overall tribal	Urban poor	Rural
Women 30-60 years	800	289	1089	1335	1437
No education	63.4%	96%	75.5%	20.7%	10.5%
Previous screening	4.6%	0.8%	3.2%	3.1%	16.0%
Screening participation (8 months)	27.3% (218)	41.9% (121)	31.0% (339)	26.7% (357)	32.9% (474)
HPV positive	10.1% (22)	15.7% (19)	12.1% (41)	3.1% (11)	5.5% (26)
Triaged (colposcopy/pap)	77.3% (17)	31.6% (6)	56.1% (41)	45.5% (5)	84.6% (22)
Triage positive	3*	1	4	0	2*
Treated (ablation/conisation) among triage positive	2*	1	3 (75%)	0	1-ablation
Biopsy (before treatment)	2-CIN3 1-negative	CIN3			1-inconclusive 1 negative

*2 triage positive: missed ablation, treated based on biopsy

Conclusions: HPV self-collection showed encouraging coverage in various vulnerable groups, in just 8 months, but flexible treatment protocols are needed to ensure treatment.

VIRTUAL-050 / #664

Poster Viewing
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DNA METHYLATION MARKERS IN HPV-BASED SCREENING: WHAT IS THE ROLE IN THE TRIAGE SETTING? A META-ANALYSIS

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Introduction: High-risk human papillomavirus (hrHPV) testing became a gold standard for cervical cancer screening across most of developed countries. HrHPV testing presents a high negative predictive value (NPV) but the specificity is rather low, particularly among young women. Triage markers of hrHPV-positive women are essential to ensure the sustainability of cervical cancer screening programs. Cytology, p16 immunostaining, and/or hrHPV genotyping are currently the most accepted triage strategies however, all present several limitations, such as an increase of women referred for colposcopy. DNA methylation markers have been presented as an alternative for hrHPV-positive women triage. Thus, this work aimed to systematically review the published data on the performance of DNA methylation markers as a triage tool for HPV-positive women.

Methods: Pubmed, Scopus, and Cochrane were searched. Pooled sensitivity and specificity for cervical intraepithelial neoplasia (CIN)2 or worse (CIN2+) and CIN3+ detection were calculated using a bivariate model. Positive predictive value (PPV) and NPV according to disease prevalence were also calculated.

Results: Twenty-three studies were considered for meta-analysis. Most of the studies were conducted in the Dutch population and CADM1, FAM19A4, MAL, and miR124-2 were the most studied genes. Pooled sensitivity detection was 0.67 (CI 95%: 0.63-0.70) and 0.78 (CI 95%: 0.75-0.81) for CIN2+ and CIN3+, respectively. For CIN2+ pooled specificity was 0.80 (CI 95%: 0.74-0.83) and for CIN3+ was 0.77 (CI 95%:0.73-0.80). Moreover, PPV and NPV for CIN2+ detection was 0.620 (CI 95%: 0.601-0.639) and 0.880 (CI 95%: 0.875-0885), respectively.

Conclusions: DNA methylation markers might be an alternative tool in triaging hrHPV-positive women for colposcopy referral in cervical cancer screening programs with higher specificity than reported for cytology and genotyping.

VIRTUAL-051 / #1800

Poster Viewing
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DETERMINANTS OF INTENTION OF NIGERIAN SECONDARY SCHOOL HEALTH TEACHERS TO EDUCATE AND RECOMMEND HUMAN PAPILLOMAVIRUS VACCINATION TO ADOLESCENTS IN SCHOOL SETTING

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Introduction: The World Health Organization identifies the school setting for reaching adolescents for Human Papillomavirus(HPV) education and vaccination, and suggests that this can be most effective if delivered through strategic partnership between health and education sectors. Health science teachers are qualified teachers in charge of health education of school students. The aims of this study were to assess the knowledge and attitudes of health science teachers in secondary schools in Lagos, Nigeria about HPV infection and vaccination and to identify the factors associated with their intention to recommend HPV vaccine to adolescents through HPV education and communication with students and their parents.

Methods: A cross-sectional study was conducted and participants were selected using a multistage sampling technique. Data were collected using an interviewer-administered questionnaire and analysed using SPSS. Chi-square test was used to determine the factors associated with intention to recommend HPV vaccine and the level of sgnificance was set at 5%.

Results: This study found that about half of the health science teachers had low level of knowledge and poor attitude towards HPV infection and vaccination. However, factors associated with the intention of these teachers to recommend the HPV vaccine to adolescents in school settings include the teacher's age, gender, level of education, level of knowledge about HPV vaccine and perceived benefit of HPV vaccine.

Conclusions: There was an insufficient level of knowledge and poor attitude of health science teachers in Lagos, Nigeria about HPV vaccination which affected their intention to recommend HPV vaccine to the adolescent students.These findings suggest a need for a collaboration of the health science teachers with healthcare workers for an organised educational training to increase their understanding of HPV infection and HPV vaccination and this will improve the teachers' confidence to educate their students and the parents about HPV vaccine for appropiate HPV vaccine acceptance and uptake in Nigeria.

VIRTUAL-052 / #1318

Poster Viewing
VIRTUAL POSTERS
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MUSLIM PARENTS' BARRIERS AND WILLINGNESS TOWARDS HUMAN PAPILLOMAVIRUS (HPV) VACCINATION: A QUALITATIVE STUDY

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Introduction: Infection with Human papillomavirus (HPV) is the leading risk factor for the development of ano-genital cancers. Cervical cancer is the fourth most common cancer among women worldwide. Most Arab countries lack both HPV educational programmes and national HPV vaccination programmes.

Methods: This qualitative descriptive study aimed to explore Muslim parents' barriers and willingness towards HPV vaccination. Twenty-seven parents were conveniently invited from two districts in Oman to participate in five single-sex focus group discussions and four in-depth individual interviews. Thematic analysis was conducted to analyse the qualitative data.

Results: Seven major themes were found. The results showed that most parents lacked knowledge about HPV infection and HPV vaccination. Parents were also concerned about the vaccine's safety and side effects and wanted the reassurance of protection against HPV infection. However, the study findings showed that Muslim parents were willing to consent to HPV vaccination for their children if recommended by the healthcare providers, and suggested that both girls and boys should be vaccinated at the school age of 10-14 years. There was almost universal agreement among parents that adolescents should receive HPV education, including HPV infection and prevention methods through school-based HPV education programmes.

Conclusions: This study shows Muslim parents' positive attitudes and willingness towards the HPV vaccination. There is a need to create an HPV vaccination policy within the healthcare system, establish school-based HPV education programmes and public HPV education campaigns, and support implementing a national HPV vaccination programme in Muslim countries for HPV elimination.

VIRTUAL-053 / #56

Poster Viewing
VIRTUAL POSTERS
04-16-2023 1:00 AM - 11:00 PM

URGENT ACTION TO PRIORITIZE ADOLESCENT HEALTH IN SOUTH AFRICA: HUMAN PAPILLOMAVIRUS VACCINATION ALONGSIDE OTHER SCHOOL-BASED HEALTHCARE SERVICES

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Introduction: This study highlights the programmatic successes and challenges of the school-based HPV vaccination programme in South Africa since its inception in 2014, contributing to the evidence base needed to improve programme performance.

Methods: A systematic narrative review approach was best suited to addressing our objectives as it provided a broad perspective on the research focus and allowed for rich speculation on the barriers and facilitators to the South African HPV vaccination programme. A Boolean search strategy was developed to source primary research studies conducted in South Africa between 2010 – 2021. A cross-cutting thematic analysis was performed, and outcomes narratively reported.

Results: 35 articles were included in this review. As of 2020, the proportion of adolescent girls aged 15 years who had received at least one dose of the HPV vaccine at any time between 9 – 14 years was 75%, while 61% had completed the recommended two-dose schedule. Despite this, annual vaccine coverage and dose completion rates have persistently followed a downward trend. Evidence suggests that declining public demand for the HPV vaccine may be a result of weakening social mobilization over time, inadequate reminder and tracking systems, and vaccine hesitancy. The increased risk of cervical cancer amid the high incidence of HIV infection also necessitates rapid scale-up of vaccine coverage. Opportunities exist to strengthen the delivery of HPV vaccines alongside other adolescent health services, and this can be achieved by reinforcing the national Integrated School Health Policy.

Conclusions: Policymakers and immunization programme managers should (i) promote adolescent-led awareness campaigns, (ii) explore interventions to improve vaccine uptake among out-of-school girls, girls attending private schools, and HIV positive adolescent girls, and (iii) leverage school-based platforms to co-deliver other adolescent health services like comprehensive sexual and reproductive health and rights education, deworming, and health screening.

VIRTUAL-054 / #1211

Poster Viewing
VIRTUAL POSTERS
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PERCH: PARTNERSHIP TO CONTRAST HPV (BY CONSORTIUM OF PERCH, GA N. 101075314)

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Introduction: Cervical cancer is a highly preventable disease through HPV vaccination and cervical cancer screening. However it still represents an important public health problem in worldwide. Although HPV vaccines have been available since 2006 both introduction and coverage do not still reach optimal levels. In 2020, the European Region reported a program coverage of the 29%. The European countries require urgent and sustainable actions in order to achieve the WHO 90% HPV vaccination coverage. An European PartnERship to Contrast HPV (PERCH), composed of 19 European countries, has been established with the aim to contribute to the implementation of the Europe's Beating Cancer Plan. Specifically, PERCH will contribute to achieve the first objective of the "90-70-90" WHO strategy among girls, and if possible also boys.

Methods: PERCH GA ws signed in September 2022. The activities planned over 30 months are distributed into 7 complementary and interconnected Work Packages (WPs): WP1 Coordination, WP2 Dissemination, WP3 Evaluation, WP4 Integration and Sustainability, WP5 Monitoring, WP6 Improving Knowledge and Awareness to Increase Vaccine Uptake, WP7 Training and Support in Vaccine.

Results: All the activities planned within PERCH are designed with the aim of achieving sustainable results at short, mid and long-term perspective. The preliminary results will be available at the beginning of 2023.

Conclusions: An Integration and Sustainability Plan will be developed at the end of PERCH with the objective to integrate HPV vaccination in the routine vaccination schedule in countries where this not yet the case and to booster capacities in countries where coverage currently is low. The sustainability plan will include roadmaps for implementation of HPV vaccination adjusted to local needs and recommendations for best practice. Funded by the EU. Views and opinions expressed are those of the author(s) only and neither the European Union nor the HaDEA can be held responsible for them.

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HPV VACCINATION IN A SPANISH RURAL AREA: A PUBLIC HEALTH CHALLENGE

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Introduction: HPV is associated with multiple cancerous and precancerous pathologies. It is a highly preventable disease based on vaccination, for this reason, the WHO designed the 2030 strategy to be able to eradicate cervical cancer from the panel of important public health problems. The main objectives of the study are: 1) to know the vaccine coverage rate (VCR) obtained in the target population, 2) to identify risk subgroups and possible barriers to accessibility to the vaccine.

Methods: This is a multicentre, retrospective, observational and community-based women cohort study conducted in Southern Catalonia since 01/01/2020 to 31/12/2021. Target population: women aged 15-40 residents in the study area. Variables: Dependent variable: HPV Vaccination Status Independent Variables: Sociodemographic variables: Age, region of residence, assigned primary care team; aging index and annual per capita average income. Clinical variables: Number of administered doses, type of vaccine, date of administration, HPV vaccination (G1, public vaccination program funded for target population; G2, funded vaccination according to risk criteria; G3, nonfunded vaccination), cervical screening test and cytology-registered, HPV polymerase chain reaction test (PCR)-registered, and HPV-positive PCR diagnosis. These variables were described by vaccination status. All presented results have been stratified by age.

Results: The included people meant the 94.7% of whole target people in the study area. A total of 23,136 women were included, with a mean age of 26.6 (SD=5.6) years. The average dose number was 1.7 (SD=0.7). The results showed overall vaccination coverage of 17.4% among the target women. This coverage was unequal across regions (16.6–24.5%, $p<0.001$), primary healthcare teams (15.5–24.3%, $p<0.001$), and age groups (56.7% (15–19-year-olds) vs. 3.8% (35–40-year-olds), $p<0.001$), related to accessibility to vaccination and economic–geographical indicators.

Conclusions: Clinical practice guidelines on screening individuals at risk in terms of vaccination access and public vaccination protocols should be implemented in order to improve the vaccination coverage rate.

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HPV VACCINE AND ABORTION: AN UNEXPECTED RELATIONSHIP

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Introduction: Research on possible individual determinants associated with the voluntary interruption of pregnancy (VIP) allows access to knowledge of factors in different territorial areas. Economic, sociocultural, sexual practice and pregnancy factors have been related to accessibility to HPV vaccination, but we do not know the possible relationship between HPV vaccination status and IVE. To find out if there is an association between prevalence and incidence of VIP and HPV vaccination status in a cohort of women between 15-40 years of age.

Methods: Multicentre, retrospective, community-based study of a cohort of women aged 15-40 years in a rural area of Catalonia until December of 2021. Data obtained anonymously from the Institut Català de la Salut (CEI 21/064-P). Dependent variable: VIP. Independent: sociodemographic, clinical, cervical cancer screening (CCV, HPV-PCR), HPV vaccine. Descriptive analysis by five-year age groups, prevalence and total incidence by counties and by Primary Care Team (EAP). Statistical analysis: continuous variables were analysed using the t-Student test; categorical variables, using the $\chi 2$ test or Fisher's exact test.

Results: 23136 women, meaning 94.7% of the censed target population. Total mean age 26.6±5.6 years. Majority group was 35-40 years old (28.9%, $p<0.001$). 1119 abortion [744 Pharmacological abortion (FVIP) 66.4%; 375 Surgical abortion (SVIP) 33.5%, ($p<0.001$)]. 7388 vaccinated women with a mean age of 21.01±5.4 years. The total prevalence of abortion was 4.8%[5.7% non-vaccinated (NoVAC) vs 3.0% vaccinated (VAC),($p<0.001$)], higher in the age group 25-29 years (6.9 %, $p<0.001$). Incidence of abortion: total 3.7/1000/year [95% CI 3.5-3.9], Non-VAC 3.5/1000/year [3.3-3.8] vs VAC 4.9/1000/ year [4.3-5.6]. Odds ratio 1.39 [1.20-1.61($p<0.001$)]

Conclusions: There is a higher incidence of abortion among vaccinated vs. vaccinated non-HPV women, with significant differences by age, district, type of abortion, and EAP. Vaccination was associated with a higher probability of abortion (OR 1.39).

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HUMAN PAPILLOMAVIRUS VACCINATION AND HEAD, NECK AND ANOGENITAL CANCERS: FINDINGS FROM NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (2011-2018)

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Introduction: Human papillomavirus (HPV) infection causes most head, neck, and anogenital cancers (HNAGC). There are some evidence of the associations of HPV with prostate, testicular and ovarian cancers. Experimental studies showed that HPV vaccines are highly efficacious against oropharyngeal and anogenital HPV infections, and cancer precursors. However, there is insufficient evidence on the real-world effectiveness of the HPV vaccine against HNAGC. Our study aim was to examine the association of HPV vaccination with HNAGC in the U.S. adult aged 20-59 population.

Methods: We used cross-sectional data from four National Health and Nutrition Examination Survey cycles from 2011 through 2018. We performed a survey-weighted regression analysis on multiple imputed datasets to explore the association of HPV vaccination with HNAGC. In the survey-weighted regression analysis, we included prior determined confounders in the imputation models, while potential risk factors for the outcome were included based on the AIC-based backward elimination approach and “stacking” all multiply imputed datasets. We also performed a sensitivity analysis using propensity score matching approach. After 20 imputations using the “multiple imputation then deletion” approach, each imputed dataset contained 13,993 participants.

Results: We found a statistically significant association between HPV vaccination and HNAGC (adjusted OR=0.41, 95% CI 0.18; 0.95). The propensity score analysis found comparable effect size estimate with no statistical significance (crude OR=0.42, 95% CI 0.15; 1.15).

Conclusions: Our study findings suggest that HPV-vaccinated adults are at least two times lower odds of developing HNAGC in comparison to not vaccinated. These findings can be used as evidence to further promote HPV vaccination programs, support decision-making about HPV vaccination and encourage eligible individuals to receive HPV vaccine.

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"INTERPRETIVE DESCRIPTION INQUIRY EXPLORES BARRIERS AND FACILITATORS IN THE UPTAKE OF HUMAN PAPILLOMAVIRUS IMMUNIZATION IN IMMIGRANTS AND REFUGEES"

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Introduction: The Canadian Partnership Against Cancer (CPAC) has commissioned the Urban Public Health Network to assess the landscape of Human papillomavirus vaccine (HPVV) coverage, barriers, and opportunities at a sub-provincial level in Canada. CPAC identified immigrants and refugees as underserved in this area, which is widely supported by literature highlighting the disparity in the uptake of HPVV by these subgroups. This work has involved engaging Immigrant and Refugee organizations to uncover high-resolution quality improvement targets for investment.

Methods: In partnership with the Saskatoon Open Door Society (SODS), this project undertook a qualitative inquiry following an Interpretive Description approach based on pragmatic philosophy. Data collection involved a short online survey and one-on-one interviews in understanding barriers and facilitators from immigrant and refugee parents' perspectives regarding HPVV and HPVV school-based programming.

Results: A preliminary analysis of interviews with the following subgroups (very recent immigrants, recent immigrants and refugees) indicates that education about HPVV and awareness regarding HPVV educational activities was low among participants. There was tremendous interest from participants to learn about HPVV; therefore, providing an avenue for partnership with health authorities to assess what type of information these subgroups require would be crucial. Also, it warrants further sub-group analysis with the inclusion of a third category (established immigrants) and subgroup analysis for future refugees.

Conclusions: A multi-component intervention to enhance HPV immunization rates remains instrumental, given the inconsistent uptake of HPVV by these subgroups who voice unique barriers and facilitators. An educational campaign that involves educating parents who consent for their child(ren), the child receiving the needle, and training of staff providing HPVV through school-based immunization programs could help improve HPVV immunization rates among these subgroups.

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EXPLORING PUBLIC-PRIVATE PARTNERSHIPS TO ACHIEVE HPV VACCINATION TARGETS IN LOW-RESOURCE SETTINGS

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Introduction: There is currently no access to the HPV vaccine in Nigeria, neither through the private nor the public sector. Both the private and public sectors are struggling to overcome the challenge of vaccine access in Nigeria with varying degrees of hope for success. We therefore explored areas of collaboration between the public and private sectors towards meeting the 90% HPV vaccination target.

Methods: The proceedings of a virtual meeting on HPV vaccination in Nigeria were transcribed and reviewed for recurring themes. The findings informed the second virtual meeting to explore the role of private sectors in achieving HPV vaccination targets in Nigeria. The recurrent themes from both meetings informed a key informant interview to assess the feasibility of public-private partnership in HPV vaccination in Nigeria.

Results: Two hundred and ninety-five participants attended the first meeting, and 33 stakeholders involved in the HPV vaccine value chain distribution in Nigeria, including representatives of some international stakeholders, participated in the second meeting. HPV vaccine will be available in the public sector by last quarters of 2023 but no definitive date for its availability in private sector. Market dynamics beyond the control of the manufacturers will most likely determine the eventual cost of the vaccine in the private sector. The key informants' interview revealed that policy issues might hinder effective public-private partnerships despite willingness from both sides to partner.

Conclusions: Public-Private Partnership to improve effective HPV vaccination program in Nigeria is feasible and desirable. There are, however, policy and bureaucratic stumbling blocks to effective partnership. We therefore recommend a global framework to guide public-private partnerships to implement or scale-up HPV vaccination in low resource settings.

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EVALUATION OF CERVICAL CANCER STAKEHOLDERS' ATTITUDE TOWARDS HPV VACCINATION IN NIGERIA

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Introduction: The identification of Human papillomavirus (HPV) as a necessary cause of cervical cancer and subsequent development of HPV vaccine has given the world the prospect of cervical cancer elimination. Despite several timelines, like many developing countries, Nigeria is yet to introduce a national HPV vaccination program. A roundtable discussion was held among stakeholders to review the prospect of HPV immunization program in the country.

Methods: A volunteer sampling was done through emails and social media to reach cervical cancer stakeholders in Nigeria. At the roundtable discussion held on an online platform (Zoom) 12th of March 2022, in-program polls were conducted focusing on the thematic areas of access, uptake and willingness to pay out-if-pocket for HPV vaccines. The data were analysed in frequency and percentages.

Results: A total of 432 participants registered for the event while 295 participated (68%). Over 90% were health workers and cervical cancer advocates. Only a fifth of the participants have had their eligible daughters / wards vaccinated. Of the 61% of the stakeholders, who tried accessing the HPV vaccine in the last 6 months, only about 9% were successful. About 5% were willing to pay more than $15 for HPV vaccination which previously costed $28 for two doses.

Conclusions: Even among cervical cancer stakeholders, access to and practice of HPV vaccination is poor. The introduction of HPV vaccination into the national program on immunization, in the last quarter of 2023 as proposed, will be critical to achieving the 90% target of HPV vaccination of eligible girls by 2030.

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EFFECTIVENESS AND COST-EFFECTIVENESS OF HUMAN PAPILLOMAVIRUS VACCINATION STRATEGIES AMONG MEN WHO HAVE SEX WITH MEN IN CHINA: A MODELLING STUDY

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Introduction: The health and economic benefits of human papillomavirus (HPV) vaccination targeted at men who have sex with men (MSM) in developing settings were rarely assessed. This study aimed to evaluate the effectiveness and cost-effectiveness of different HPV vaccination strategies among MSM in China.

Methods: A Markov model was developed to simulate HPV transmission dynamics among MSM. The corresponding natural history included 6 states: susceptible, infected with low-risk subtypes, high-risk subtypes, anogenital warts and anal cancer, and deaths from anal cancer. MSM were divided into three age groups with cut-off points of 26 and 45 years. Alternative vaccination strategies were built by allocating bivalent, quadrivalent or nine-valent vaccine to each of the groups. We generated the prevented infections and deaths by vaccination compared with baseline (no vaccination) and calculated incremental cost-effectiveness ratios (ICERs) to determine the optimal strategy.

Results: The model showed that in 10 years, at baseline, the existing cases of anogenital warts would reach 478,300 (95% CI, 441,600-512,900); that of anal cancer would reach 512 (462-560), resulting in 226 (178-277) deaths. With 50% coverage of nine-valent vaccine, 16.10% (8.23%-23.16%) anogenital warts cases and 40.33% (34.32%-45.99%) anal cancer cases could be prevented. The lowest ICER value (124,700 USD/QALY, 123,200-126,000) was reached when allocating quadrivalent vaccine to each age group. Based on this strategy, when the vaccine coverage increased from 50% to 90%, the deaths could be reduced by 6.19% with no significant change detected in ICER. When the vaccine price decreased by 50%, the ICER was reduced to 37648.88 (37570.14-37726.98), indicating cost-effectiveness taking three times of China's per capita GDP as a threshold.

Conclusions: HPV vaccination can effectively reduce the prevalence of related diseases and deaths caused by anal cancer among MSM in China. However, appropriate adjustment of vaccine price is necessary to further improve the cost-effectiveness.

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BARRIERS AND ENABLERS OF SCHOOL-BASED HUMAN PAPILLOMAVIRUS IMMUNIZATION: EMERGING RESULTS FROM A MIXED-METHODS STUDY IN ALBERTA, CANADA

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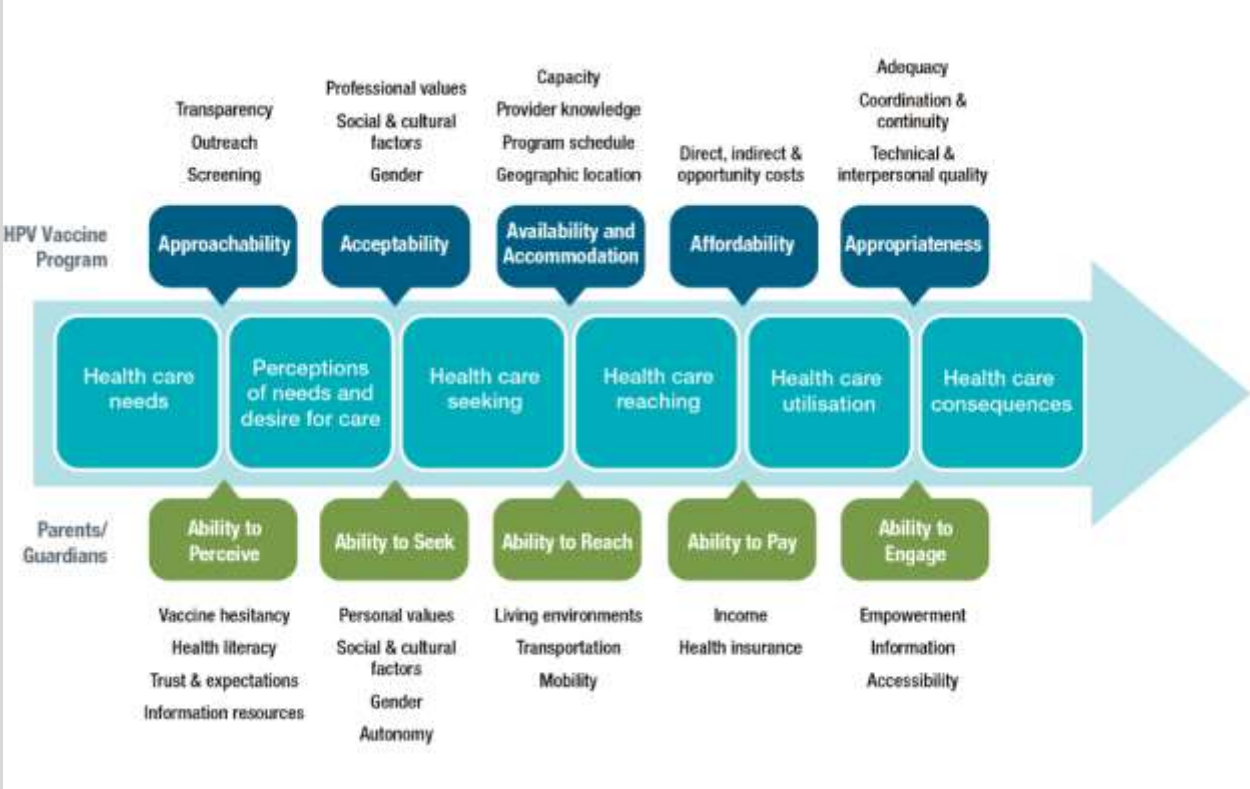
Introduction: Human papillomavirus (HPV) nearly exclusively causes cervical cancer, the fourth most prevalent female cancer globally. Despite widespread availability of the HPV vaccine, most of Canada has immunization rates below our 90% target. In response, the Canadian Partnership Against Cancer commissioned the Urban Public Health Network to coordinate a quality improvement project of Canada's school-based HPV immunization programs. In Alberta, the objective was to determine parent/guardian and program stakeholder perceived barriers and enablers to school-based HPV immunization, and opportunities to increase coverage.

Methods: This study used a mixed-methods sequential explanatory design guided by the Conceptual Framework of Access to Health Care (Figure 1). A sample of Albertans with children aged 11-17 years completed a survey, with a sub-set participating in follow-up interviews. Focus groups were completed with school-based immunization program leaders and providers. Logistic regression was used to investigate if Framework constructs were associated with parents'/guardians' decision to immunize their child(ren). Qualitative data were analyzed using template thematic analysis guided by the

Framework.



Results: Approximately 200 parents/guardians participated in the survey. While 77% of participants immunized their child(ren) with the HPV vaccine, 100% immunized their child(ren) with other childhood vaccines. Parents/guardians who immunized their child(ren) were more likely to “strongly agree” that their family, health provider, and religious community would agree with their child(ren) being immunized. Those who didn’t have sufficient time to review vaccine materials were five times more likely to not immunize their child(ren) (OR=4.80, 95% CI=1.36-17.01) than those who did have time. We anticipate interview and focus group results to impart barriers and enablers related to the Framework.

Conclusions: Study results will enable Alberta’s public health professionals to make evidence-informed decisions to adapt the program for underserved populations, and inform national partners of current realities as they seek to create new policies and programs to reach the 90% coverage target.

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STRENGTHENING HPV VACCINE UPTAKE AMONGST GIRLS AGED 9-14 IN LESOTHO.

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Introduction: In 2009, Lesotho piloted the HPV vaccine (HPVV). The program halted in 2015 due to inadequate financial forecasting. LDHS 2014 states that 11% 0f women of reproductive age have screened for cervical cancer in Lesotho. Lesotho has a high cervical cancer burden to date, in 2020, 541 cervical cancer cases were recorded with a mortality rate of 376. In April 2022, Clinton Health Access Initiative (CHAI) Lesotho supported the Ministry of Health's (MoH) reintroduction of national HPVV. Vaccination campaign to administer HPVV dose1, targeting approximately 130,000 9 – 14-year-old girls.

Methods: A school- based approach was used for the campaign supported by MoET's (Ministry of Education and Training School Health and Nutrition Policy (SHNP). CHAI coordinated the establishment of New Vaccine Introduction technical working group (NVI-TWG), consisting of key stakeholders from MoH, MoET, MoLGC (Ministry of Local Government & Chieftainship) UN partners, NGOs, media, and religious organisations. This strengthens immunisation and introduction of national vaccines. In April 2022, in a national campaign 84% of girls (9-14) were vaccinated. Immunocompromised girls were mobilised for dose1 because 30.4% of women aged 15-49 are HIV positive.

Results: In 2022, the national campaign for dose1 vaccinated 84% of 9–14-year-old girls. 233 immunocompromised girls received dose1. The campaign strengthened relationships between MoET and MoH through the formation of DISCs (District Immunisation Steering Committee) which coordinate vaccinations at district level. 84% coverage was achieved because of the community sensitisation of all key stakeholders like chiefs.

Conclusions: Conclusion The HPV vaccine re-introduction proved that clear communication amongst main stakeholders (MoH and MoET) is vital for a successful campaign. Continuous education about HPVV and cervical cancer is necessary for women in order to combat the prevalence of cervical cancer. HPVV forms part of immunization approach Lesotho is embarking on.

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PROFILING HPV ANTIBODY RESPONSES SIX YEARS FOLLOWING 1, 2 OR 3 DOSES OF QUADRIVALENT HPV VACCINE

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Introduction: The World Health Organisation recently gave a permissive recommendation for HPV vaccine of 1 or 2 doses for females <20 yo. This was based on evidence demonstrating comparable vaccine efficacy between 1 or 2 doses, despite 1 dose inducing lower neutralising antibody levels. Although neutralising activity is thought to be the mechanism of vaccine protection, antibodies have other functions mediated by Fc receptors (FcR). We profiled HPV-specific antibody features including FcR engagement in girls who received 1, 2 or 3 doses of quadrivalent HPV vaccine (4vHPV) six years earlier and their booster responses after bivalent HPV vaccine (2vHPV).

Methods: In 2015, a prospective cohort study was conducted in 200 Fijian girls (15-19 yo) who were previously unvaccinated or received 1, 2 or 3 doses of 4vHPV 6 years prior. Blood was collected pre- and 28 days post-2vHPV. Using a multiplex immunoassay, antibody isotypes and subclasses (IgG, IgM and IgG1-4, IgA1-2) and FcR-binding (FcγRIIa, FcγRIIb, FcγRIIIa) were measured against HPV16/18 and 5 vaccine-related genotypes (HPV31/33/45/52/58) in a subset of participants (N=20/group).

Results: After 6 years, 1-dose 4vHPV recipients had staistically significantly lower HPV16/18 IgG compared to 2- or 3-dose recipients ($p<0.05$). However, HPV16/18 IgG and IgA1 levels in 1-dose recipients were significantly higher than unvaccinated girls ($p<0.05$). Antibody subclass profiles were similar between 1-, 2- and 3-dose recipients, with high IgG1, IgG3 and low IgM, IgA. Post-2vHPV, HPV16/18 antibody responses in 1-dose 4vHPV recipients increased to a similar level and subclass profile as 2- or 3-dose recipients. Vaccine-related genotypes (HPV16; HPV31/33/52/58, HPV18; HPV45) had weaker responses but similar antibody profiles. FcR-binding analyses are ongoing.

Conclusions: A single dose of 4vHPV induced HPV type-specific antibodies of similar subclass profile to 2 or 3 doses which persisted for 6 years. Future work to evaluate Fc-mediated antibody functions will improve our understanding of HPV vaccine immune mechanisms.

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HPV VACCINATION INCREASES ANTI-VLP16 ANTIBODIES IN THE ORAL CAVITY IN MEN WHO HAVE SEX WITH MEN

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Introduction: The rates of HPV-related oropharyngeal cancers are increasing in MSM. Although there is not yet prospective data on the efficacy of HPV vaccination to reduce oral HPV infection, the evidence suggests that HPV vaccination elicits an immune response that results in antibodies in the oral cavity.

Methods: Participants were MSM (n=128) selected from a larger study that aimed to evaluate a strategy of HPV vaccination among key populations at two specialized clinics for the prevention of sexually transmitted infections (STI) in Mexico City. Briefly, participants were enrolled and randomized in three groups, to receive one-dose (n=57, Day1) or two-doses (n=30, Day1 and Month 6) or control that received at least one dose (n=41, Month 12 or 18) of quadrivalent vaccine against HPV-6/11/16/18 at the end of follow-up. Oral samples were provided for antibodies determination and HPV DNA genotyping. We used a self-administered questionnaire at baseline to obtain risk factors associated with oral HPV infection. All participants provided signed informed consent. The study was approved by the institutional review board of the National Institute of Public Health of Mexico.

Results: The control group had the highest baseline prevalence of oral hrHPV, followed by the one-dose and two-dose groups (17.1%, 3.3%, and 5.3%, respectively, p value=0.08). The baseline prevalence of oral HPV16 was zero in the three groups. The control group had lower baseline anti-VLP16 antibodies with a GMT of 23.19 EU/ml (95%CI 13.37, 40.21), compared to the one-dose group 108.52 EU/ml (95%CI 68.18-172.73) and the two-dose group 122.12 EU/ml (95%CI 62.31-239.34).We observed that the one-dose and the two-dose group had a 36% (95%CI 0.04, 0.68; p-value=0.03) and 37% (95%CI:0.03, 0.77; p-value=0.06) increase in the ratio of anti-VLP16 antibody compared to the control group,

respectively.

Table 1. Association between HPV vaccination and anti-VLP16 oral antibodies 12 months after vaccination in men who have sex with men.

	Main analysis[a] n=128			Correcting for selection bias[a,b] n=116		
	Coeff.	*95% CI*	*p value*	*Coeff.*	*95% CI*	*p value*
Control	Ref.	-		Ref.	-	
One dose	0.36	0.04, 0.68	0.03	0.31	-0.04, 0.66	0.08
Two dose	0.37	-0.03, 0.77	0.06	0.42	-0.02, 0.86	0.06

Analysis with a linear regression model. [a]Adjusted for the interaction of baseline log-anti-HPV16 EU/ml and age, the time between first and second sample, HIV status, and baseline hr-HPV prevalence. [b]Selection bias correction using inverse probability weighting.

Conclusions: Our study suggests that vaccination increases antibodies anti-VLP16 in the oral cavity in high-exposed individuals to oral HPV.

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ADAPTATION, IMPLEMENTATION AND EVALUATION OF THE CLINIC-BASED ADOLESCENT VACCINATION PROJECT (AVP): A REPLICATION STUDY

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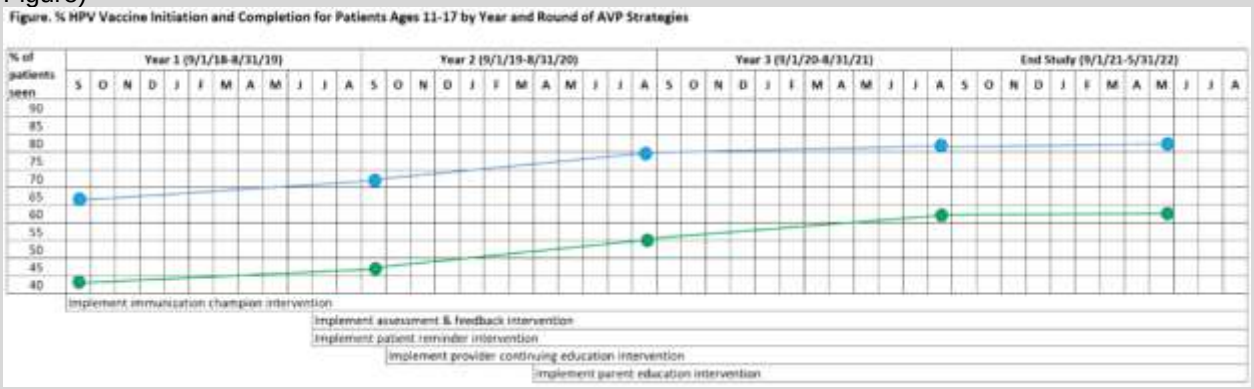
Introduction: Underutilization of HPV vaccination in the United States is a persistent problem. We developed the clinic-based multi-component intervention, the Adolescent Vaccination Program (AVP), which comprises six evidence-based strategies that target clinic systems, providers and parents (See Figure). We previously demonstrated its effectiveness in increasing HPV vaccination initiation and completion in a 51-clinic pediatric network in Houston, Texas. The purpose of this replication study was to adapt and implement the AVP, and evaluate its effectiveness in a 5-clinic pediatric network in San Antonio.

Methods: In 2017, we conducted focus groups and surveys with clinical staff and clinic managers to identify potential new psychosocial factors in patients and providers (e.g. social and cultural norms), and structural factors that affect implementation of AVP strategies. Based on formative work, we adapted the parent education and provider continuing education content. Examination of EHR capabilities also informed adaptation of the assessment and feedback strategy. From 2018 to 2021, we conducted a single group pre- and post- study design to examine the adapted AVP intervention's effect on HPV vaccination initiation and completion rates.

Results: Formative work revealed new implementation barriers, including increased parental use of social media to inform their vaccination decisions and increased demands on providers to engage with hesitant parents in vaccination conversations. Of the 6,438 patients (11-17 years) with clinic visits in the evaluation period, (52% female; 43% Hispanic, 39% NH white, 4% NH African American, and 13% other race/ethnicity), HPV vaccination initiation rates increased from 64.7% to 80.2% ($p<0.05$) and completion rates increased from 43.1% to 60.1% ($p<0.05$). (See Figure)



Conclusions: Clinic rates increased corresponding to AVP rollout, with a leveling of increase occurring once clinic initiation rates reached 80% of patients. Results successfully replicated findings of the original 3-year effectiveness trial, which increased rates from 50% to 80%.

VIRTUAL-067 / #1168

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HPV VACCINATION UPTAKE AND ANOGENITAL WARTS AMONG GAY, BISEXUAL, AND OTHER MEN WHO HAVE SEX WITH MEN ATTENDING SPECIALIST SEXUAL HEALTH SERVICES IN ENGLAND

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Introduction: The national human papillomavirus (HPV) vaccination programme for gay, bisexual and other men who have sex with men (MSM) in England has offered opportunistic vaccination to MSM up to 45 years attending specialist sexual health services (SHSs) and HIV clinics since April 2018, following a successful pilot from June 2016-March 2018. This programme should result in fewer anogenital warts (AWG), and subsequently, HPV-related cancers, among MSM.

Methods: HPV vaccination uptake and rates of first AGW diagnosis (per 100,000) were monitored using the GUMCAD STI Surveillance System (GUMCAD) that receives data from all SHSs in England. MSM eligible for HPV vaccination initiation were defined as those aged up to and including 45 years, attending SHSs, without any prior vaccine doses reported. MSM were defined as men who self-reported as gay or bisexual at any attendance.

Results: From 2016-2021, a total of 262,774 eligible attendances were reported to GUMCAD. Of these, 37.2% (97,762) noted initiation of HPV vaccination, 1.9% (5,011) declined vaccination, and 52.4% (137,786) had no vaccination or decline recorded. 58.3% (57,036) of those initiated received at least two doses, with 9.3% (24,452) of those initiated completing a course compliant with a recommended schedule. Between 2016-2019, rates of first AGW diagnosis among MSM aged 15-45y declined by 10.9%, and from 2016-2021 rates declined by 53.7%.

Conclusions: This national selective vaccination programme is progressing well and declines in rates of first AGW diagnosis since 2016 at the population level likely include some direct protection from MSM-vaccination. However, modest declines in 2016-2019 are probably largely due to indirect protection from the adolescent vaccination programme, whilst declines in 2020-2021 are complicated by disruption due to the COVID-19 pandemic. Further work is exploring reasons for no recorded vaccination, vaccine efficacy against first episode and recurrent AGW, and the distribution of uptake and protection.

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POLICY ACTORS' QUESTIONS ABOUT THE HUMAN PAPILLOMAVIRUS VACCINE PROGRAM IN MOZAMBIQUE THAT CAN BE ADDRESSED USING MATHEMATICAL MODELS

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Introduction: Research products are often defined without detailed understanding of the policy process for public health decision-making. The aim of this study is to firstly identify policy actors' interests and questions around the human papillomavirus (HPV) vaccine program in Mozambique. Secondly, we investigate the feasibility of addressing identified evidence gaps in this context with existing mathematical models.

Methods: Through purposeful sampling and snowballing, twenty-eight semi-structured interviews were conducted with actors in the policy network concerning the HPV vaccine introduction in Mozambique. Study participants are employees at organizations that have or had been engaged in the decision to introduce the HPV vaccine in Mozambique, and/or the program planning. Interviews were conducted either in person or via Microsoft Teams in Portuguese or English, depending on the interviewee's preference, between January and May 2022. Interview data were analyzed inductively. Thereby, emergent themes were identified and translated into research questions. We then reflected on the extent these questions can be modelled given existing methods.

Results: Policy actors were interested in learning about vaccine impact, with interviewees' definition of 'impact' varying from health to wider economic benefits, e.g., financial risk protection benefits. Further, actors were interested in learning about the distributional impact of the vaccine program on cervical cancer prevention across poorer socioeconomic and rural population subgroups. For these purposes, existing mathematical models can be used but need to be extended.

Conclusions: This study can inform how mathematical models can be applied to address policy actors' questions and subsequently inform policy. This study facilitates democratic and participatory evidence production as emerging research is co-designed with evidence end-users. To better address policy needs, mathematical models should be adapted to estimate both narrow and broader vaccine benefits. Yet, extensions with methods such as the Extended Cost-Effectiveness Analysis framework are dependent on the availability of high-resolution data.

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"I HAD NO IDEA WHAT TO CHOOSE": A MIXED METHODS STUDY OF HPV VACCINATION DELAY AMONG CHINESE CAREGIVERS IN CHENGDU, CHINA

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Introduction: Adolescent girls in China have a low HPV vaccination rate (<3%). HPV vaccines are not covered by the national immunisation programme, hence the choice and timing of vaccination is a personal decision. Vaccination delay due to supply shortage and affordability, especially for the 9vHPV vaccine, among other reasons, contributes to the low uptake. This mixed methods study aimed to identify potential factors of delayed HPV vaccine uptake among Chinese adolescent girls.

Methods: Quantitative data about the attitudes and perceptions of HPV vaccination were collected from 100 caregivers of 14–18-year-old girls using an online survey in Chengdu, Western China. The survey data informed a subsequent qualitative study using four focus group discussions with 21 participants. We conducted a descriptive analysis of the survey data and a thematic analysis of the qualitative data. The findings were interpreted using a health behaviour model adapted from the Health Belief Model and the Andersen's Behavioural Model for Health Services Use.

Results: 100 Han Chinese caregivers, the majority of whom were parents, with mothers making up 85% and fathers 15% of the parent population, completed the survey. When asked about their intended course of action if the 9vHPV vaccine was out-of-stock, 74% chose to delay until the 9vHPV vaccine is available while 26% would consider 2vHPV or 4vHPV vaccines or seek alternative methods. Qualitative results found the intent to delay was influenced by systemic barriers such as 9vHPV vaccine shortage, inadequate health communication, and individual-level factors such as a preference for the 9vHPV vaccine, safety concerns, and the belief that adolescents were unlikely to be sexually active.

Conclusions: Caregivers' intent to delay vaccination in favour of 9vHPV vaccine over receiving the more accessible options was influenced by a mix of individual and contextual factors. Health communication strategies and public health messages targeted towards caregivers are needed.

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SAFETY OF THE AS04-ADJUVANTED HPV-16/18 VACCINE: RESULTS FROM A POST-MARKETING SURVEILLANCE STUDY CONDUCTED IN KOREA BETWEEN 2017 AND 2021

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Introduction: Several cancers, including cervix, vulva, vagina, penis, anus, rectum, and oropharynx, are associated with Human Papillomavirus (HPV) infection. HPV immunization with the AS04-adjuvanted bivalent HPV-16/18 vaccine was included in the Korean National Immunization Program in 2016. Vaccination of 11–12 years old girls is recommended for the prevention of cervical cancer. In 2017, vaccine indication was further broadened to include prevention of anal cancer caused by HPV types 16 and 18 and males. This post-marketing surveillance study assessed the safety of the AS04-adjuvanted HPV-16/18 vaccine in Korea.

Methods: This multicenter observational study (NCT03671369) was conducted in males and females aged 9–25 years from 2017 to 2021. Occurrence and intensity of adverse events (AEs), adverse drug reactions (ADRs), and serious adverse events (SAEs) were collected after each dose. Safety analysis included all participants who were vaccinated per prescribing information and completed a 30-day follow-up after at least one dose. Data were collected on individual case report forms.

Results: The total safety cohort included 662 participants, mostly females (n = 639; 96.53%). Subjects median age was 12 years. A total of 220 AEs were reported in 144 subjects (21.75%), and 158 ADRs in 111 subjects (16.77%). The most frequently reported AEs were injection site pain (9.06% [60/662 subjects]; 68 events), followed by injection site erythema (4.68% [31/662 subjects]; 34 events). Fever was the most frequent systemic AE (1.81% [12/662 subjects]; 12 events). Twenty-one unexpected AEs were reported by 15 subjects (2.27%); none were considered vaccine-related by the investigator. No SAEs were reported. Most AEs occurred after the first dose and were injection site reactions of mild intensity that resolved.

Conclusions: Data from the post-marketing surveillance showed that the AS04-adjuvanted HPV-16/18 vaccine was generally well tolerated in the Korean population and no safety concerns were identified.

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INCREASING UPTAKE ON HPV VACCINATIONS AMONG HISPANICS IN THE COVID-19 ERA

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Introduction: HPV vaccinations in the United States have been proven to be safe, effective, and available since 2009. In August of 2021 the FDA approved the first of three COVID-19 vaccines, proving to be effective in reducing hospitalizations and deaths. Unfortunately, misinformation, lack of knowledge, and attitudes about vaccines, fuels health disparities in HPV and other vaccine uptake in the United States.

Methods: We combined data form two vaccine studies (Studies A & B). Study A was a community intercept survey on HPV vaccines. Study B was a qualitative study on COVID-19 vaccines obtained via focus groups, townhall meetings and monthly community advisory committee meetings. Both were compiled in the predominantly Hispanic Boyle Heights area of Los Angeles. Data were examined for patterns and themes.

Results: In Study A, 745 and in Study B, 83 community residents participated. Most were females, and all were Hispanic. In Study A, 60.4% stated they knew about the HPV vaccine. Yet, among women who qualified for the vaccine (18-45 years of age), 57.8% had not received it. Study B revealed lack of trust of government services, vaccine safety and effectiveness concerns, misinformation, logistics of vaccination, costs, being a public charge, insurance, and information overload, resulted in vaccination hesitancy. Social media played an important role in conveying both pro and anti-vaccine sentiments. Parents had a wait-and-see attitude about vaccinations. Taken together, reliable sources of information included pediatricians, family members, churches, and clinics, outdoor media, social media, and public engagement activities via local theater and art exhibits.

Conclusions: Misinformation and a strong anti-vaccine sentiment during COVID-19 pandemic furthered mistrust in HPV and other vaccines. COVID-19 pandemic taught us that creative, socially engaging and culturally specific sources of information proved to be most reliable and unique sources to increase uptake of HPV and other vaccines.

VIRTUAL-072 / #727

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THE ROLE OF LANGUAGE IN INCLUSIVE WOMEN'S HEALTH: STAKEHOLDER PERCEPTIONS ON THE ROLE AND IMPACT OF GENDERED LANGUAGE IN AUSTRALIA'S NATIONAL CERVICAL SCREENING PROGRAM

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Introduction: As a broad medical speciality, 'women's health', including the prevention and control of cervical cancer, has historically been categorised with gendered language as relevant to 'women'. In Australia, however, there is an emerging cultural shift which is questioning the universality of gendered language in recognition that gender identity exists on a continuum. Shifts in language to make 'women's health' more inclusive are currently being negotiated within the Australian National Cervical Screening Program. This study aimed to investigate stakeholders' views and decisions around the use of gendered language in policy and promotion of cervical screening in Australia.

Methods: Semi-structured interviews (n=27) were conducted with stakeholders working in cervical cancer policy and promotion, LGBTIQ+, disability and Culturally and Linguistically Diverse health organisations. Interviews were thematically analysed.

Results: Interviews with stakeholders confirmed the cultural shift surrounding inclusive language in the promotion of cervical screening in Australia, with most recognising that 'women and people with a cervix' is an inclusive phase, at least in the interim. Stakeholders' decisions regarding the adoption and dissemination of inclusive language, however, are made on an ad-hoc basic with little guidance on whether this would resonate with other under screened populations. Stakeholders spoke about the importance of language reflecting both communities' preferences and medical accuracy. Stakeholders were in broad agreement that principles of inclusivity require greater flexibility within the healthcare system, which also need to be aligned with incremental shifts in policy.

Conclusions: This is the first study conducted in Australia which explored stakeholders' views and decisions around gendered language in policy and promotion of cervical screening. Emerging findings point to the importance of inclusive language being tailored to the target audience and policy around cervical screening being responsive to the emergent cultural change in Australia that is moving away from applying overarching gendered language in 'women's health' specialities.

VIRTUAL-073 / #1225

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ACAPELLA MUSIC AS A TOOL FOR CANCER ADVOCACY: AN EXPLORATORY STUDY

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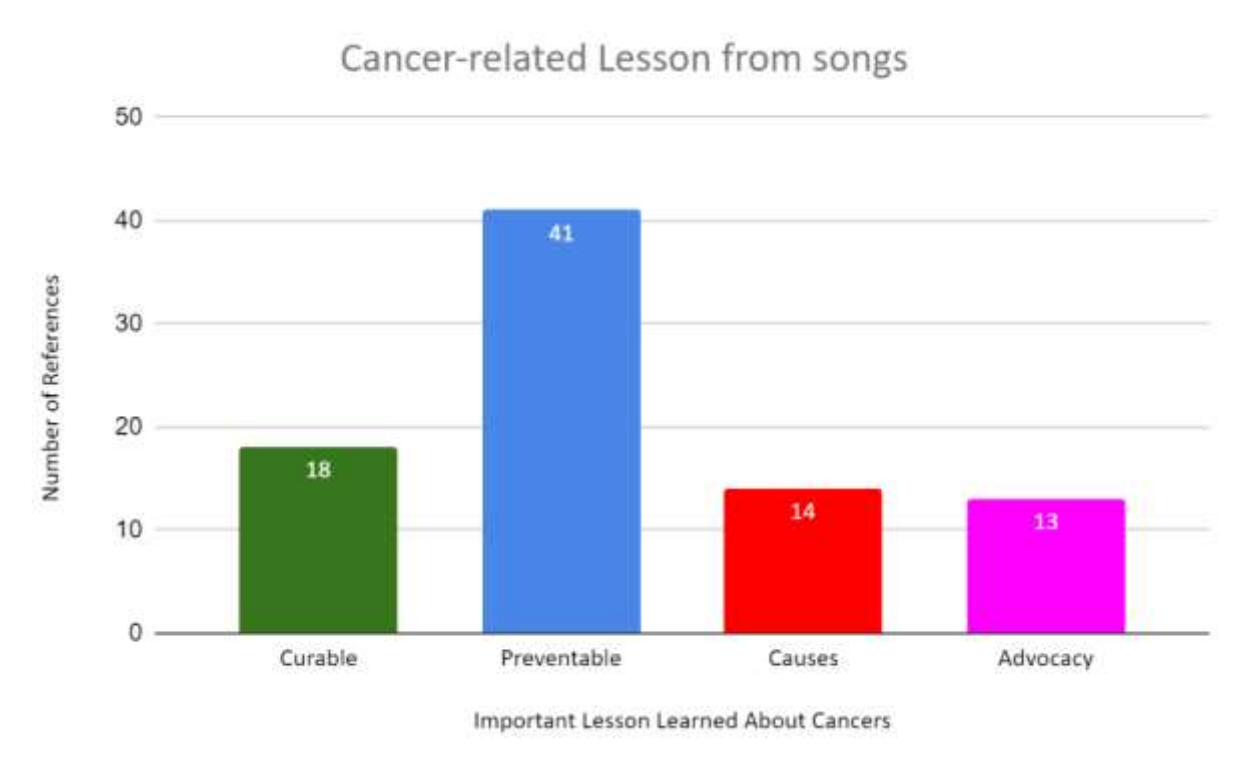
Introduction: Cancer incidence is rising in Nigeria, however, most of the population has limited awareness of the disease spectrum. Most Nigerians have strong religious affiliations and enjoy a variety of music. Religious gatherings have been used to promote cancer awareness through lectures. This research evaluates the use of an annual acapella music concert to raise awareness about cancers in Nigeria.

Methods: Four Nigerian acapella music groups within the Church of Christ fellowship were invited to compose original songs with cancer as a theme, including cervical cancer, breast cancer, and hematological cancers. These songs were performed live during an acapella music concert, as part of a larger 3-day youth seminar. The audience volunteered to share their experience regarding the use of acapella music for cancer awareness, objective knowledge gained from the concert, and lessons learned from each song. Pretest and post-test surveys with open comments were used to evaluate the project. Data analysis involved descriptive statistics, t-tests, and content analysis for comments.

Results:



Out of 120 participants 82 completed the evaluation survey (response rate = 68.3%; 82/120). Most participants were males (52.4%, 43/82). Forty percent (33/82) were undergraduate students with an average age of 24 (±10) years. The average self-reported confidence in cancer awareness was 4/10 (±3.3) before listening to the songs, and 6/10 (±3.7) after the songs; p=0.03 (α=0.05). About 90% of the audience (74/82) recommended the use of acapella music for cancer awareness. Cancer-related themes that emerged from comments about the songs were coded as follows (figure 1): 'preventable', 'curable', 'causes of cancer', and 'advocacy'.

Conclusions: This study showed that acapella music can be an effective tool for cancer advocacy. Further studies are needed to evaluate the long-term knowledge gain and impact on early diagnosis behavior from participation in such concerts.

VIRTUAL-074 / #1488

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TRENDS IN INCIDENCE OF HEAD AND NECK CANCER IN SOLID ORGAN TRANSPLANT RECIPIENTS

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Introduction: Solid organ transplant recipients have an elevated risk of cancer following organ transplantation than the age-adjusted general population. Increased cancer risk could be attributed to higher susceptibility to oncogenic viruses and persistent infection due to chronic immunosuppressive status. Previous studies have reported a disproportionately higher burden of head and neck cancer (HNC), including human papillomavirus (HPV)-associated squamous cell carcinomas in organ recipients. We assessed trends in the incidence of HNC in heart, lung, and liver recipients.

Methods: This retrospective cohort study included 129,164 patients from the United States Scientific Registry of Transplant Recipients (SRTR) who received heart, lung, or liver transplantation between 1991-2010. Patients did not have any prevalent HNC at organ transplantation. Head and neck cancer cases post organ transplantation were identified from SRTR follow-up database. Incidence rates of HNC following transplantation were compared based on organ type and age at organ transplantation.

Results: The majority of patients received liver transplantation (59.32%), followed by heart (28.05%), and lung (12.63%). During follow-up, 6.29% patients developed HNC. Median (IQR) time from organ transplantation to HNC diagnosis was 6.0 (3.0-9.0) years. Overall incidence rate of HNC was 667.03 per 100,000 person-years. Males transplant recipients had higher HNC incidence rate than female recipients (879.42 and 301.38 per 100,000 person-years, respectively). Overall, lung recipients had the highest HNC incidence rate (1674.76 per 100,000 person-years), followed by heart (1048.38 per 100,000 person-years), and liver recipients (349.51 per 100,000 person-years). This trend persisted across all age-groups (Figure 1). An increase in incidence of HNC over time was observed in lung and liver recipients; however, heart recipients showed a decrease in HNC incidence over time (Figure 2).

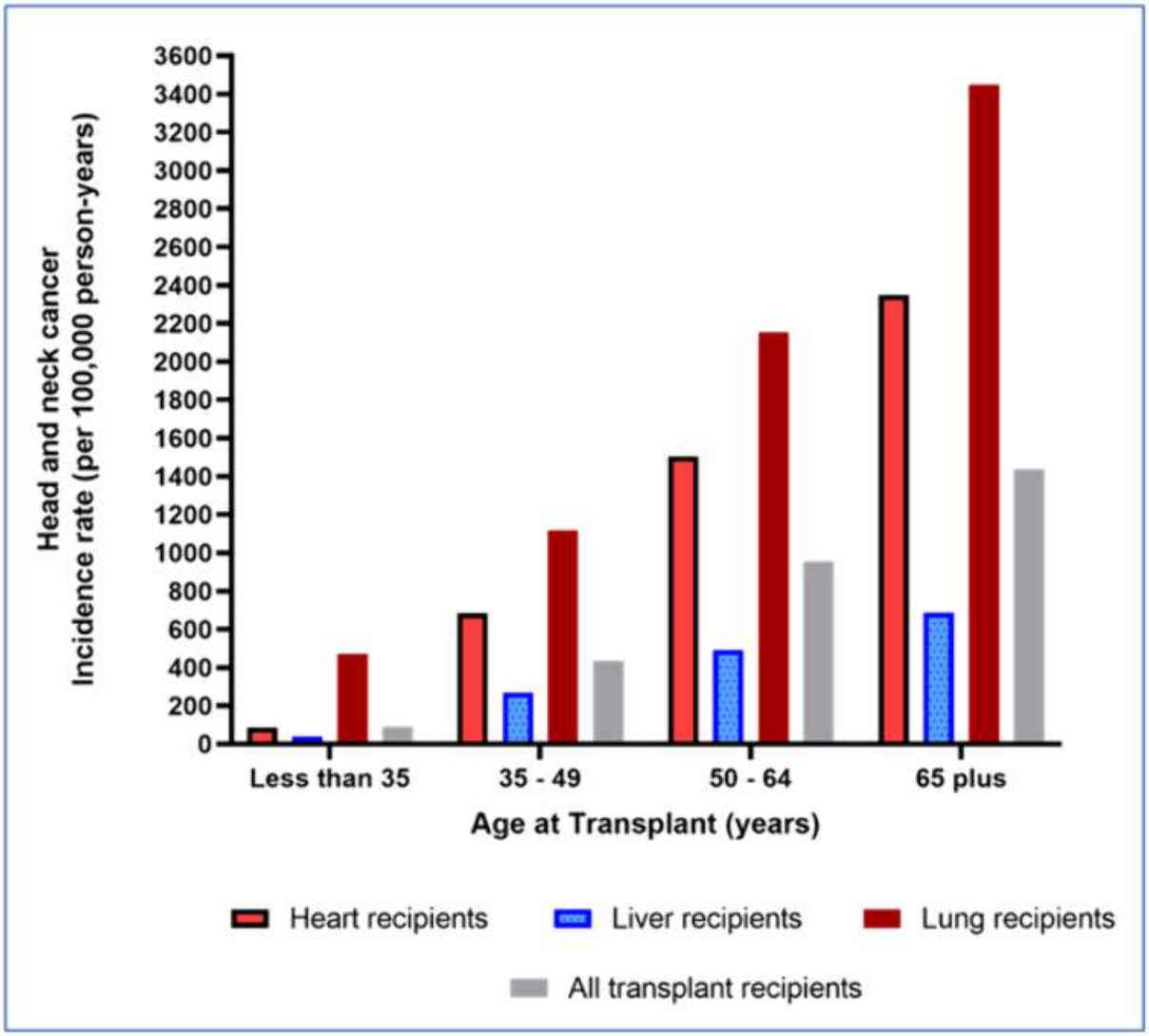

Figure 1: Head and neck cancer incidence in solid organ recipients by age at transplant and organ type

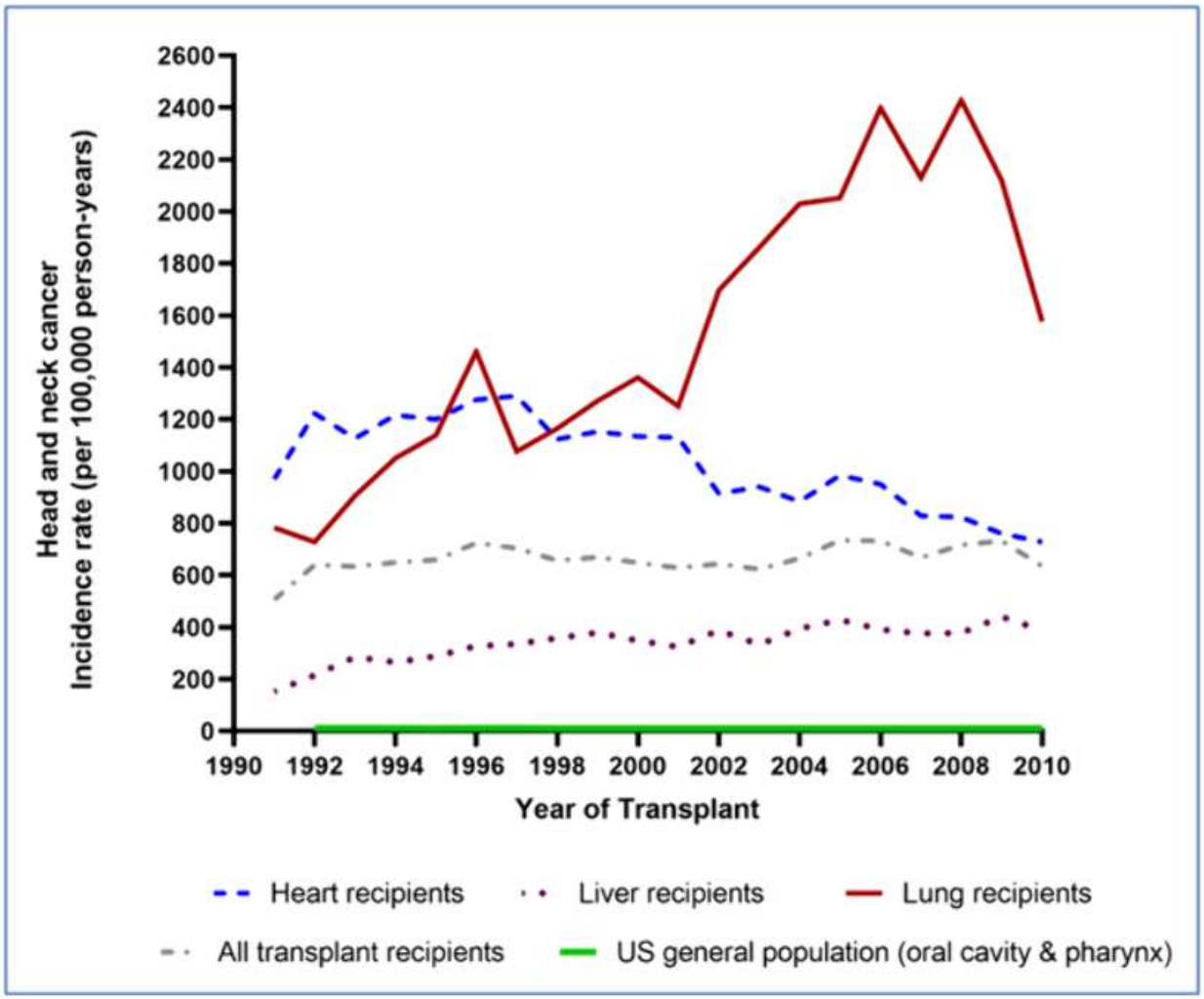

Figure 2: Head and neck cancer incidence in solid organ recipients by year of transplant and organ type

Conclusions: Solid organ transplant recipients have an alarmingly high incidence rate of head and neck cancer following organ transplantation and the incidence varies based on type of organ received.

VIRTUAL-075 / #1411

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CERVICAL CANCER STAGE AND PREVALENCE HR-HPV IN WOMEN ATTENDING A PUBLIC AMAZON ONCOLOGY REFERRAL HOSPITAL

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Introduction: In Brazil, the burden of cervical cancer cases remains a challenging public health problem with high incidence and mortality rates despite having a Universal Health Care System (SUS) that offers free cytology-based screening since 1990 and HPV immunization since 2013. The public system is constrained by many challenges and its performance regarding cervical cancer prevention not fully characterized. This study aimed to describe the Hr-HPV genotypes and CC stage, according to FIGO's 2018 staging system, among women receiving care at the Amazon public oncology referral hospital.

Methods: Women with histopathological diagnosis of CC were recruited at the Foundation Center for Oncology Control of the State of Amazonas (FCECON), Manaus, Brazil. HPV detection and genotyping were performed by in house qPCR targeting HPV 16 and 18 types only. Staging data were abstracted from medical registries and classified as group A if FIGO I or II, or group B if FIGO III or IV. The study was approved by FCECON ethical review board.

Results: 73 women (age 20 to 81) (69.9% with biopsy and 30.1% with surgery) were included. The most prevalent genotype was HPV16 (80.8%), followed by HPV 18 (10.9%) and there were 8.3% not determined. 77.3% of biopsy specimens were from B group patients and 92.1% of surgery specimens were from A group. Because we chose to work with fresh frozen tissue for this study, we observed a greater number of patients with surgical indication and therefore with lower staging. Although most of then arrive with advanced stage II and IV.

Conclusions: Early prevention and early detection of CC are pending tasks in Amazonas, most women with CC are diagnosed in advanced stages with decreasing the chance of treatment success.

VIRTUAL-076 / #82

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THE PREVALENCE AND RISK FACTORS OF ORAL HPV16/18 IN JAPANESE PEOPLE

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Introduction: Recent studies suggest that oral human papillomavirus (HPV) infection is strongly associated with oral cancer development. The aim of this study was to clarify the prevalence of and risk factors for oral HPV16/18 in Japanese people.

Methods: A total of 181 patients (age range: 20–89 years) who visited Hiroshima University Hospital were enrolled in the present study. None of the participants had oral premalignant lesions or oral cancer. Oral rinse samples were collected by asking the participants to rinse their mouths with saline. Real-time polymerase chain reactions (PCR) were performed to detect HPV16/18 DNA.

Results: Twenty out of 181 participants (11.0%) were HPV16 DNA-positive. HPV18 DNA was determined as positive in three participants (1.7%). Participants in their 20s and 60s exhibited greater HPV16 DNA positive rates (22.7% and 21.2%, respectively) compared with other participants. Smokers (n = 23) showed a significantly higher HPV16 DNA positive rate (26.1%) compared with non-smokers (8.9%) (P = 0.03). In addition, current smokers (n = 15) showed a higher HPV16 DNA positive rate (26.7%) compared with others (9.6%), but no significant difference was found (P = 0.07). Female smokers (n = 10) recorded a higher HPV16 DNA positive rate (50%) compared with male smokers (n = 13) (7.7%), but no significant difference was found (P = 0.05). Furthermore, binomial logistic regression analysis revealed that smoking was significantly related to HPV16 DNA (odds ratio 4.11, P = 0.01).

Conclusions: Smoking is an important risk factor for oral HPV16 infection. Tobacco smoke may attenuate the immune response to oral HPV infection by weakening the host immune system, resulting in a high rate of HPV16 infection in smokers. Our results highlight the importance of not smoking as a preventative measure for oral HPV infection.

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HUMAN PAPILLOMAVIRUS DETECTED IN PLACENTAL BIOPSIES AND FACTORS ASSOCIATED WITH PLACENTAL INFECTIONS

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Introduction: Human papillomavirus (HPV) infections are prevalent amongst women in their reproductive years, including during pregnancy. We aimed to describe the prevalence of placental HPV infections at delivery and its associated factors.

Methods: The study population of this study included 557 women with placental biopsies at delivery, from the Preventing Atopic Dermatitis and Allergies in children (PreventADALL) study. Pregnant women (N=2697) were recruited in this Scandinavian, population based, multi-center, mother-child cohort, during their mid-gestation routine ultrasound scan. Human papillomavirus detection was performed on placental biopsies using the in-house real-time PCR protocol on Quantstudio™ 7 Flex Real-Time PCR System and Seegene Anyplex II HPV28 detection kit, detecting High-Risk (HR-HPV) and Low-Risk HPV (LR-HPV) genotypes. Genotyping and semi-quantifying urine HPV infection was determined at mid-gestation using Seegene Anyplex II HPV29 detection kit. Socio-demographic and medical data was collected through electronic questionnaires as well as medical records. We investigated whether the following factors were associated with placental HPV: maternal age, pre-pregnancy maternal BMI, marital status, maternal education, alcohol/nicotine use during pregnancy, and duration of pre-conception relation to child's father as well as high viral HPV load at mid-gestation. Descriptive statistics was used for prevalence and Chi^2 and Fisher's tests for association, P value <0.05 was considered as significant.

Results: Placental HPV was found in 3% (18/557) of women and HR-HPV was found in 2% (11/557). The most common genotypes were LR-HPV42 (4/557) followed by HR-HPV31 (3/557) and HR-HPV51 (3/557). Short duration of relation to the child's father prior to conception (<2 years) and high overall-HPV/HR-HPV viral load in mid-gestational urine samples were associated with placental HPV (p=<0.001); no other factors investigated were associated.

Conclusions: In a Scandinavian general population cohort, we found low prevalence of placental HPV at delivery with few associated factors. Low- Risk HPV42 was the most common genotype detected with unknown clinical significance.

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