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ADVANCING SCIENTIFIC EFFORTS TO CONTROL HPV-RELATED CANCERS

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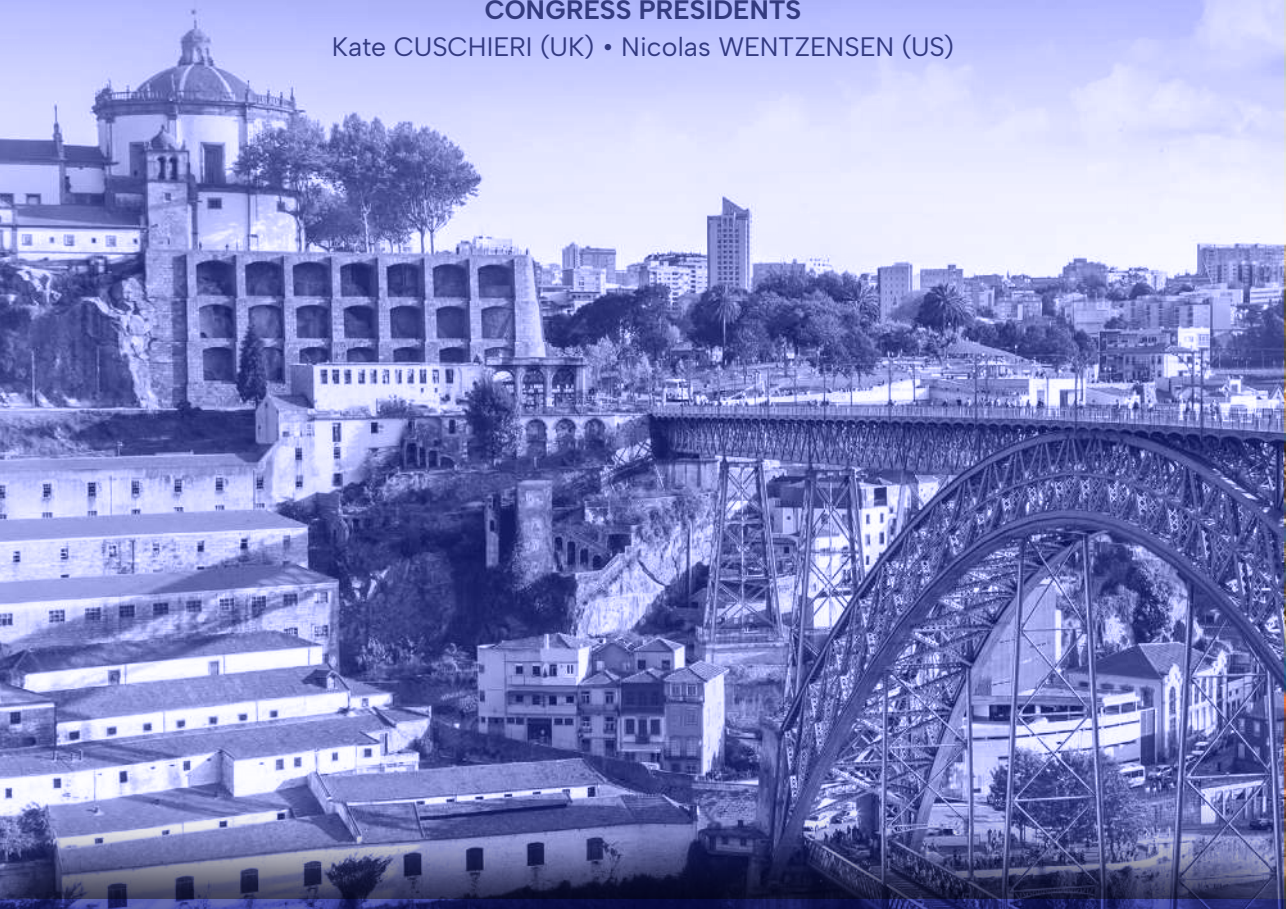

ABSTRACTS

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#8650

P06-07 | Investigation of HPV vaccination status and Influencing factors among primary and secondary school girls in Ganzi, Aba, and Liangshan regions of Sichuan Province

06 - HPV prophylactic vaccines

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Background/Objectives: This study aimed to investigate the HPV vaccination coverage rate for primary and secondary school girls and related policies in the Ganzi-Aba-Liangshan (GAL) areas, which have poor economic levels and health services, in Sichuan Province. It also analyzed the factors influencing parents' willingness to vaccinate their daughters against HPV. The findings can assist the government in establishing strategies for HPV vaccination, which will increase the HPV vaccination rate in areas lacking health resources in western China, and help prevent and control HPV-related diseases.

Methods: A multi-stage stratified sampling method was employed to respectively select 10 vaccination-related staff and health department leaders from the Ganzi-Aba-Liangshan (GAL) areas including Health Commission and CDC leaders and staff, and immunization personnel from community or township health centers. Focus group or face-to-face interviews were conducted with these individuals. Additionally, 15 parents of primary and secondary school girls from each district were surveyed to assess HPV vaccination coverage rates and influencing factors.

Results: The HPV vaccination coverage rate among girls in the three regions remained low. In Ganzi and Liangshan areas, the vaccination rate among eligible girls was below 10%. Before the implementation of free HPV vaccination, Aba Prefecture also had a low vaccination rate. However, following the initiation of free vaccination this year, the vaccination rate among girls increased rapidly. The primary issues in these regions included: 1.Insufficient Vaccine Supply and Limited Vaccination Sites. Before 2024, there was a widespread shortage of vaccines across all three regions. Although the supply of the bivalent vaccine has stabilized since 2024, the supply of the quadrivalent and nine-valent vaccines still cannot meet the demand. Public institutions, government departments, and wealthier parents in these regions were willing to vaccinate their children with the quadrivalent and nine-valent vaccines. However, these vaccines remained in short supply. 2.Poor Economic Conditions. Approximately 70%-80% of families in these regions could not afford vaccination. Implementing government-provided free vaccines can enhance parents' willingness to vaccinate their daughters significantly. 3.Lack of Awareness Among Parents. Many parents, especially in remote rural regions, were unaware of HPV vaccines. Some economically capable parents avoided vaccination due to concerns about side effects. Government-organized and subsidized programs offering free vaccines could rapidly increase the HPV vaccination coverage rate in these areas. Government-sponsored programs offering free vaccines significantly improved vaccination coverage. For instance, the implementation of the "Free Bivalent HPV Vaccination for Girls Aged 9-14" policy in Aba Prefecture significantly raised parents' awareness of the HPV vaccine and their willingness to vaccinate their daughters, greatly increasing the vaccination rate among primary and secondary school girls.

Conclusions: HPV vaccination rates among primary and secondary school girls in GAL areas remains low, and parents' knowledge about HPV is insufficient. However, parents generally hold a positive attitude towards HPV vaccination. Reducing the cost of HPV vaccines and ensuring their supply are key issues. Government financial support and policies to lower HPV vaccination costs would help improve the vaccination rates among these girls.

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P15-02 | Molecular signature of miRNAs to predict high-grade cervical intraepithelial neoplasia using liquid-based cytology

15 - Molecular markers

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Background/Objectives: Cervical cancer (CC) ranks as the fourth most common cancer among women globally and the risk factor for its appearance is HPV (Human Papillomavirus) infection in basal epithelial cells. Early diagnosis of cervical intraepithelial neoplasia (CIN) is crucial for improving patient outcomes, making the development of minimally invasive biomarkers through molecular analysis a promising approach. Among these, miRNAs have emerged as valuable non-invasive biomarkers, offering the potential for personalized treatment and early detection of CC through liquid-based cytology (LBC). However, ongoing research is essential to identify miRNA signatures that can be effectively translated into clinical practice, particularly for early detection. In this study, we aimed to identify a specific miRNA molecular signature in high-grade cervical intraepithelial neoplasia (CIN 2/3) using LBC samples and to explore their interactions with molecular pathways associated with CC in a prospective study.

Methods: The study was approved by the Research Ethics Committee of the Barretos Cancer Hospital (approval no. 3.926.525). We analyzed 96 LBC cervical samples from women aged between 25 and 64 years. The participants were divided into two groups: a case group consisting of women diagnosed with CIN 2/3 and positive for HPV (n = 48), and a control group of women without cervical precursor lesions and negative for HPV (n = 48). miRNA expression profiling involved the nCounter® miRNA Expression Assay (NanoString Technology), evaluating 800 targets. Functional and enrichment analyses were performed using mirDIP and Cytoscape (Reactome plugin), respectively.

Results: We identified 66 differentially expressed miRNAs between the case and control groups ($p \leq 0.05$). We selected three miRNAs (miRNA A and B downregulated, and miRNA C upregulated), considering a fold change ≥ 1.5 and an FDR-corrected p-value of ≤ 0.01. In a multivariate logistic regression model combining these miRNAs with contraceptive use and smoking, the underexpression of miRNA A (OR = 49.2, 95% CI = 6.28 - 628.0, $p < 0.001$) and overexpression of miRNA C (OR = 0.06, 95% CI = 0.01 - 0.24, $p < 0.001$) significantly predicted CIN 2/3. It is important to highlight that miRNA B was removed from the model due to a very high degree of correlation with miRNA A ($r = 0.931$). The signature (miRNA A and miRNA C) had a predictive value with an AUC of 0.84. Furthermore, we found 16 miRNA target genes associated with CC for the two selected miRNAs, mainly related to pathways in cancer, the p53 signaling pathway, Polymerase II transcription, human papillomavirus infection, and cell cycle.

Conclusions: This study hypothesizes that miRNA A and miRNA C may be useful non-invasive biomarkers in LBC samples to identify patients with HPV infection who could develop CIN 2/3, while also being involved in regulating key molecular pathways associated with the onset of carcinogenesis.

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P39-03 | Understanding HPV vaccine initiation and intention among Central American immigrant parents: The role of HPV vaccine literacy and healthcare provider recommendation

39 - Public health

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Background/Objectives: Latinos represent the largest minority group in the United States (U.S.), with a growing proportion of Central American immigrants. Understanding factors influencing HPV vaccine uptake and intention is crucial, particularly among immigrant populations with historically lower vaccination rates. This study explores the relationship between HPV vaccine literacy and vaccine initiation and intention among Central American immigrant parents in the U.S.

Methods: Cross-sectional study with 168 parents of children aged 11 to 17 years in the U.S. Logistic regression analyses assessed factors related to vaccine initiation and intention to vaccinate within the next 12 months.

Results: Among participants (53.8% mothers, 46.2% fathers), only 20% of children had received at least one dose of the HPV vaccine, with mothers reporting higher vaccination rates (27.0%) compared to fathers (12.7%). A significant disparity in health care provider (HCP) recommendations was noted, with only 27.4% of parents receiving a recommendation for HPV vaccination; mothers were more likely to receive recommendations (39.3% vs. 13.9%; $p < 0.001$). Older parents and those with longer U.S. residence were more likely to have initiated vaccination, but increased length of residence correlated with lower intentions to vaccinate. Among unvaccinated children, 23.1% of parents expressed intention to vaccinate within the next 12 months, with mothers showing higher intention (32.3%) than fathers (14.5%; $p = 0.02$). HPV vaccine literacy revealed a moderate understanding among parents, with an average correct response rate of 50% on literacy questions. Higher HPV vaccine literacy was linked to increased vaccine initiation and intention; parents of vaccinated children had higher literacy scores (0.66) than those whose children were unvaccinated (0.46; $p < 0.001$). Similarly, parents intending to vaccinate their children within the next 12 months also had higher literacy scores (0.52 vs. 0.44, $p = 0.05$). Receiving information from HCPs was the most critical factor influencing vaccine initiation, with recommended parents 92 times more likely to initiate the HPV vaccine series (OR = 92.23; $p < 0.001$). Additionally, parents of U.S.-born children reported a higher likelihood of vaccination intention (OR = 10.47; $p < 0.01$), while longer U.S. residence was associated with lower vaccination intentions (OR = 0.84; $p < 0.01$).

Conclusions: In conclusion,findings highlight the critical roles of healthcare provider (HCP) recommendations and HPV vaccine literacy in shaping vaccine initiation and intention among Central American immigrant parents. With only 20% of children vaccinated, improving HCP communication and training is crucial. Tailored communication strategies and enhanced provider-patient interactions can significantly boost vaccine uptake. Moderate vaccine literacy and differences in uptake and intention stress the need for targeted, culturally sensitive education, including community outreach and accessible resources to address specific knowledge gaps. While mothers often play a key role in decision-making, efforts should also focus on increasing fathers' HPV literacy and encouraging their active involvement in vaccination decisions. A comprehensive approach—including improved education for both parents and HCPs, proactive vaccine recommendations, and addressing cultural perceptions—can increase HPV vaccine uptake and reduce HPV-related diseases in these population groups.

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P34-01 | Effect of vaginal microbial infections on the efficacy of 5-aminolevulinic acid-mediated photodynamic therapy for vaginal intraepithelial neoplasia

34 - Conventional therapies

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Background/Objectives: Vaginal intraepithelial neoplasia (VAIN) is a precancerous condition with significant potential for malignant transformation. 5-Aminolevulinic acid photodynamic therapy (5-ALA-PDT) is considered to be a novel approach to treat VAIN. Recent studies have shown that an imbalance in the vaginal microbiota can affect the progression of VAIN. Thus, the effect of imbalanced microbiota on the efficacy of 5-ALA-PDT for treating VAIN needs to be determined.

Methods: Sixty-five female patients diagnosed with VAIN were recruited. 5-Aminolevulinic acid was applied topically to the vaginal wall, followed by red light with a wavelength of 635 nm at intervals of 7-14 days. Cytological inspections, high-risk human papillomavirus (HR-HPV) genotyping, vaginal colposcopy examinations, histopathology and culture, and identification of the vaginal microflora were performed before and after treatment.

Results: Among the 65 patients, the complete remission rate (CRR) of vaginal wall lesions was 84.6%, and the clearance rate of HR-HPV was 61.5%. In the balanced vaginal microbiota group, the CRR of vaginal wall lesions reached 97.2%, with the clearance rate of HR-HPV being 75.1%. In the imbalanced vaginal microbiota group, the CRR of vaginal wall lesions was only 65.5%, with the clearance rate of HR-HPV being 48.3%. There was a trend of improved clearance of lesions and HR-HPV when the vaginal microbiota was balanced ($p = 0.002$ and $p = 0.038$, respectively). During the process of clinical treatment and the 1-year follow-up period, all patients experienced minimal adverse reactions.

Conclusions: The findings of this study demonstrate that 5-ALA-PDT is a clinically effective and safe treatment for VAIN, and the vaginal microbiota's status is a key factor affecting the efficacy of 5-ALA-PDT for VAIN.

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#8882

P13-05 | Detection of HPV in self-sampling vaginal samples stored on cellulose filter paper

13 - Self-sampling

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Background/Objectives: Cervical cancer is associated with the persistence of the human papillomavirus (HPV), making the detection of HPV essential for effective prevention. Investing in secondary prevention through screening programs provides critical opportunities for early diagnosis. HPV testing can be performed using self-sampling vaginal samples, which may improve adherence to screening programs. A method for storing these samples involves the use of filter paper, such as FTA card, but these are relatively expensive (around US$57 per unit). There is a need for more economical filter papers, such as cellulose filter paper (commonly known as coffee filter paper), which is a low-cost alternative (around US$0.15 per unit) and has demonstrated similar efficacy. Acceptable methods to enhance women's adherence to screening programs include self-sampling and the use of cellulose filter paper for storage. Although still little explored, this approach may improve access to screening, especially in resource-limited or hard-to-reach areas. This study aims to evaluate the acceptability and viability of detecting HPV in self-sampling vaginal samples stored on cellulose filter paper.

Methods: Patients from the Barretos Cancer Hospital units in Barretos, Campo Grande, Rio Branco, Boa Vista, and Macapá, who had indications for excision of the cervical transformation zone, colposcopy due to Pap smears abnormalities, and screening Pap smears were included. Two samples were collected from each patient: the first was a self-sampling vaginal sample stored on cellulose filter paper, while the second was a cervical sample collected by a healthcare professional and stored in SurePathTM. Before the first collection, each patient received the PAF Kit, developed specifically for this study, which cost approximately $9. This kit included an informational leaflet with a QR code to access the video explaining how to perform self-sampling, a Viba-Brush® for self-sampling, a cellulose filter paper for storage, and an envelope for transportation. The samples were stored on cellulose filter paper for up to 30 days and then sent to Barretos for analysis. Both samples were tested for HPV using the Cobas® platform. The study also evaluated the impact of temperature, humidity, and long-distance transportation on sample integrity. Concordance and positivity rates were analyzed using the Kappa coefficient, positive predictive value, negative predictive value, sensitivity, specificity, and accuracy of HPV detection through the ROC curve.

Results: A total of 315 of 1,486 women were included. The HPV positivity rate in samples stored in SurePathTM was 62%, while it was 50% for samples stored on cellulose filter paper. The concordance rate between the two storage methods was 87% (Kappa < 0.001). Samples stored on cellulose filter paper demonstrated high accuracy, with an area under the curve (AUC) of 0.89 (95% CI: 0.86 to 0.92). The positive predictive value was 99%, and the negative predictive value was 75%, with sensitivity and specificity rates of 79% and 98%, respectively.

Conclusions: Preliminary results indicate that self-sampling and storage of vaginal samples on cellulose filter paper is a viable and low-cost method that can increase women's participation in screening programs, especially in remote areas and among populations resistant to conventional methods, thus contributing to a reduction in the incidence and mortality rates of this neoplasia.

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Flowchart - Priscila Pedrão

Duvlis Sotirija
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#8944

P04-01 | Association of several host gene variants with HPV-positive cervical intraepithelial lesions and cervical cancer

04 - Pathogenesis

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Background/Objectives: Genetic variants in tumor suppressor genes and genes responsible for HPV viral clearing are crucial in defining susceptibility to cervical intraepithelial lesions (CINs) or cervical cancer (CCa). Cancer susceptibility genes confer structural modification of the proteins that interfere with HPV proteins resulting in lowering or enhancing their function. The study aims to find the effect of variants of 4 different genes on HPV-positive CINs. The study group consisted of 113 cases (HPV-positive women with CINs or CCa) and 134 controls (HPV-negative women without cervical lesions or CCa).

Methods: The single base nucleotide polymorphism (SNP) at p53 Pro72Arg (rs1042522), MDM2 309 (rs2279744), IL-4RI75V(rs1805010), TNFa-238(rs361525) and TNFa-308 (rs1800629) were analyzed using SNaPShot analysis for finding their association with different cervical abnormalities.

Results: The results showed AA genotype of rs1805010, had a significantly lower frequency in CIN1 (25.0%) compared with the CIN2+ group (30.8%) (p=0.03, OR=0.39, 95%CI: 0.14- 1.11) after the stratifications of the cases in low grade and high grade with CCa as separate groups. No significant difference between cases and control was found in either genotype or allelic frequencies for rs1042522 and rs2279744. Still, the stratification of cases based on lesion grade revealed the lower frequency of CC genotype and C allele of rs1042522 and TT genotype and T allele of rs2279744 in CIN2+ and CCa compared to CIN1 [GG vs CC; p=0.001, OR=0.4; CG vs CC; p=0.04, OR=0.03 and CG+ GG vs CC; p=0.004, OR=0.2].

Conclusions: In conclusion, the IL-10-592 A/AA variant indicates a protective role in cervical cancer development, and the GG genotype of IL-4RI75V, conferred protection against progression of CIN1 to CIN2+ or CCa. Oppositely the Arg variant of rs1042522, and the T allele/TT genotype of rs2279744 are associated with the progression of CIN1 to higher lesions. The results should be confirmed on a larger scale of analysis.

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#9082

P13-02 | Women's perceptions and preferences toward HPV self-sampling in France: A qualitative study within the French CapU4 trial

13 - Self-sampling

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Background/Objectives: In France, 3,000 women develop cervical cancer and 1,000 die from it annually. Despite organised screening efforts since 2020 targeting under-screened women, cervical cancer screening coverage remains moderate (60%). The target age for HPV-based screening is women aged 30 to 65. Vaginal self-sampling (VSS) has recently been introduced for women who have not been screened. The current study assesses women's perceptions and preferences toward HPV self-sampling among women enrolled in the CapU4 trial.

Methods: CapU4 is a randomised controlled trial with two experimental arms (mailing either a urine (USS) or VSS kit) and a control arm (mailing of a conventional invitation letter). The trial invited 15,000 women aged 30-65 years, who had no screening test recorded since more than 4 years and who did not respond to an invitation letter within 12 months before. Half of the women in each arm of the study were randomly selected to receive a supplementary questionnaire together with the self-sampling kit or conventional invitation letter. Women in each arm were randomly selected to receive this questionnaire in March 2023, and responses were collected until the end of August 2023.

Results: A total of 682 completed questionnaires were analysed (overall response rate of 9.1%). The majority of participants found self-sampling instructions clear (VSS 87.4%, USS 90.7%) and procedures easy (VSS 85.9%, USS 90.3%). Performing VSS was experienced as more unpleasant by 23.5% of users and 4.9% of USS users. Although some discomfort and pain were reported, particularly with VSS, confidence in correctly executing the sampling was high (VSS 81.8%, USS 86.6%). Approximately 80% of participants in both self-sampling arms indicated that taking a specimen themselves at home was more convenient than going to a health care professional for taking a cervical specimen. The women responded that they would prefer to use a self-sampling kit to collect a sample for their next cervical cancer screening rather than visiting a health care professional, with a preference in the USS arm (VSS 82.6%, USS 89.1%). A high proportion of participants would recommend both self-sampling devices to friends or family, with the USS device receiving more recommendations (VSS 69.9%, USS 79.1%). Among women who only received the conventional invitation letter, 56.6% expressed a willingness to make an appointment with a health care professional for future cervical specimen collection following the invitation.

Conclusions: Self-sampling appears to be a well-received alternative to conventional sampling methods in women not attending routine cervical cancer screening programme.

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#9090

P06-06 | Willingness to get HPV vaccination and its influencing factors among caregivers of primary and secondary school girls in Western Sichuan, China

06 - HPV prophylactic vaccines

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Background/Objectives: The HPV infection rate in Sichuan, China, is higher than the national average, and the Sichuan provincial government plans to promote HPV vaccination programs across the province, including in impoverished areas such as the Ganzi, Aba, and Liangshan (GAL) prefectures. The coverage of adolescent HPV vaccination is closely related to the vaccination willingness of their caregivers. This study aims to investigate the knowledge and attitudes of caregivers of primary and secondary school girls in the GAL areas towards HPV vaccines and to analyze the factors influencing their willingness to vaccinate their daughters against HPV.

Methods: A cross-sectional survey was conducted from September 2023 to April 2024 using a multistage stratified cluster sampling method in the Ganzi, Aba, and Liangshan prefectures of Sichuan Province, China. The participants of this study were caregivers of primary and secondary school girls under the age of 15. The primary outcome was the caregivers' willingness to vaccinate their daughters against HPV. Chi-square tests, Mann-Whitney U tests, and binary logistic regression analyses were used to identify the factors influencing caregivers' willingness to vaccinate their daughters against HPV.

Results: A total of 2,584 caregivers participated in the survey, of whom 2,397 (92.8%) completed valid questionnaires. Among them, 1,421 (59.28%) caregivers had heard of HPV, and 1,669 (69.63%) knew about the HPV vaccine. The proportion of caregivers willing to vaccinate their children against HPV was 92.12%. The reasons given by caregivers willing to vaccinate their daughters included believing that the HPV vaccine effectively prevents cervical cancer (56.39%) and that the vaccine is safe (34.74%). The reasons for unwillingness included insufficient knowledge about the vaccine (30.69%) and concerns about side effects (28.04%). The caregivers' relationship to the girl, marital status, awareness of HPV and the HPV vaccine, knowledge level and scores, willingness to cover the cost of vaccination, personal willingness to receive the HPV vaccine, history of receiving all scheduled and recommended vaccines for both themselves and their children, as well as any history of vaccine refusal for themselves or their children, showed statistically significant differences in their willingness to vaccinate their daughters against HPV (all $p<0.05$). Binary logistic regression analyses showed that caregivers who were parents, willing to pay for HPV vaccination, personally willing to receive the HPV vaccine, and had never refused a vaccine were more likely to vaccinate their daughters against HPV (all $p<0.05$).

Conclusions: In this study, caregivers of primary and secondary school girls in GAL areas generally held a positive attitude towards HPV vaccination. The study identified four factors associated with caregivers' willingness to vaccinate their daughters against HPV. Enhancing parental knowledge, ensuring the safety and efficacy of vaccines, and reducing the cost of HPV vaccination may help increase vaccination rates in areas with limited healthcare resources in western China.

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#9124

P25-03 | Role of cyclooxygenase-2 (COX-2) expression as a prediction of persistent cervical Low grade Squamous Intraepithelial Lesion (LSIL)

25 - Cervical neoplasia

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Background/Objectives: Primary objective was to determine the association of cyclooxygenase-2 (COX-2) expression and persistent cervical low grade squamous intraepithelial lesion (LSIL). Secondary objective was to determine baseline characteristic between patient with persistent LSIL and spontaneous regressive LSIL patients.

Methods: The cross-sectional study was performed. The patients who had previous histological diagnosis of CIN1 at least 12 months prior to follow up date and scheduled for follow up at King Chulalongkorn Memorial Hospital (KCMH) from May 16, 2019 to April 30, 2020 were enrolled. All participants underwent pelvic examination and cervical cytology (Pap smear, liquid-based method) at the time of follow up. They were divided into 2 groups, spontaneous regression and persistent group by the follow up cervical cytology results. Colposcopic biopsies and Pap smear results at first diagnosis were reviewed and confirmed by two gynecologic pathologists to confirm the diagnosis of CIN 1. The previous cervical biopsy slides were reviewed, and the selected paraffin blocks were used to perform immunohistochemistry for COX-2 expression. The immunohistochemical slides were evaluated and reported base on Allred score. Clinical risk factors, cervical cytology, HPV genotype and Allred score were obtained and analyzed.

Results: One hundred sixty-one patients were recruited which comprised 132 participants in regressive group and 29 patients in persistent group. The overall prevalence of COX-2 expression in both groups was 83.8 %. One hundred and ten patients from 132 patients of regressive group and 25/29 of persistent group were positive for COX-2. Median Allred score in both groups were similar. There was no correlation between COX-2 expression Allred score and persistent LSIL (p= 0.663). The correlation between Allred score, high risk HPV infection and high-risk HPV status were no statistical significance (p = 0.66 and p = 0.80). HPV infection at follow up and persistent high-risk HPV detection/infection were significant risk factors for persistent LSIL (p= 0.001) in univariate analysis. However, when multivariate analysis was performed, there was no statistical significance.

Conclusions: Neither Cyclooxygenase -2 expression nor HPV is a good marker to predict a persistent disease. Further investigation should be performed to identify a good predictor for persistence CIN1.

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#9130

P29-02 | LINE-1 methylation in oropharyngeal cancer: The interplay of HPV-infection and TP53 mutation

29 - HPV and oropharynx / Head and neck cancer

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Background/Objectives: Background. We have recently demonstrated that LINE-1 hypomethylation represents a negative prognostic factor in oropharyngeal squamous cell carcinoma (OPSCC) in both HPV16-negative and HPV16-positive patients. Furthermore, HPV16-negative patients presented a lower level of LINE-1 methylation compared to the HPV16-positive ones. p16 over-expression is notoriously used as a surrogate marker for HPV infection, however there is a subset of patients with discordant HPV status and p16 immunostaining results, such as p16-/HPV+. Generally, HPV-positive OPSCC is associated with the presence of wild-type TP53, although mutations of this gene have been reported in a small subset of these patients, as opposed to HPV-negative OPSCC where TP53 mutations are a common feature. Despite these findings, the correlation between LINE-1 methylation and the status of HPV, p16 and TP53 is still largely unknown in OPSCC.

Methods: Methods. Since 2019, an ongoing prospective study has been enrolling patients with OPSCC in nine cancer centers in Northern Italy. HPV genotyping was performed by real-time PCR to detect single genotyping of 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) and 14 low-risk HPV types (6, 11, 26, 40, 42, 43, 44, 53, 54, 61, 69, 70, 73, 82). LINE-1 methylation was evaluated by methylation-specific quantitative real-time PCR. TP53 exon mutations were analyzed by NGS.

Results: Results. We evaluated 95 patients (23 women/62 men; mean age: 65 years) for HPV subtype, p16 over-expression, LINE-1 methylation, and TP53 mutational status; 66 patients were ever smokers and 53 were ever drinkers. The majority of cancers were diagnosed in the tonsil (n=48, 50.5%) or base of tongue (n=31, 32.6%). Results demonstrated that 21 patients (22.1%) were p16-/HPV-, 13 (13.7%) were p16-/HPV+, and 60 (62.2%) were p16+/HPV+; one p16+/HPV- case was not considered thereafter. Notably, in p16-/HPV+ patients, HPV was detected at a mean cycle threshold (CT) of 38.2 (min-max: 32.1-42.3) compared to a mean ct of 24.7 (17.2-32.2) among p16+/HPV+ ones. Among p16+/HPV+ patients, HPV16 was the most frequent genotype (n=52, 86.7%), whereas co-infection of HPV16 with HPV33 or HPV35 was detected in additional 5 cases (8.3%); HPV33, HPV35, and HPV58 were reported in one case each (1.7%). TP53 mutation was found in 34 patients (35.8%), being more frequent in p16- patients (88.2%) than in in p16+ ones (6.6%, $p<0.01$). Mean LINE-1 methylation was 30.5% in p16-/HPV- patients, 35.2% in p16-/HPV+, and 56.3% in p16+/HPV+ ($p<0.01$). No differences were found according to HPV genotype. Hypomethylation was reported in patients carrying TP53 mutation (31.0%) compared to wild type (56.6%; $p<0.01$), with no difference according to mutation type. Interestingly, TP53 mutation exerted an hypomethylation effect in p16- patients (mean LINE-1 methylation: 28.4% and 61.8% in mutated and wild type patients, respectively; $p<0.01$), but not in p16+ ones (50.2% and 56.2%, $p=0.47$).

Conclusions: Conclusion. This study identifies a remarkable fraction of p16-/HPV+ patients; however, HPV was detected at very high CT, suggesting that HPV was not casually involved in the etiology of these tumors. Both p16 status and TP53 mutations were associated with LINE-1 methylation, but TP53 mutations seems to have a role in LINE-1 methylation only in p16- OPSCC. Once the study will be mature enough for survival analysis, the role of these markers on cancer prognosis will be evaluated.

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#9135

P03-04 | Viewing cervical cancer risk disparities in Mozambican HIV-positive women through the lens of vaginal microbiota: Preliminary results from a pilot study

03 - Epidemiology and natural history

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Background/Objectives: Dysbiosis on the cervicovaginal microbiota often characterized by low Lactobacillus species have been implicated in cervical microenvironment changes [1] which contribute to persistent HPV infection [2] and cervical cancer [1,3]. Yet, there is a paucity of data on the vaginal cervicovaginal microbiota in Mozambican women. Here, we aimed to elucidate the relationships between microbiota and persistent high-risk HPV infection, to better understand an increased cervical cancer risk among Mozambican women living with HIV.

Methods: In this pilot and ongoing study, we recruited 72 participants (All Mozambican native women; HIV-positive, n= 60 vs HIV-negative, n= 12) and examined for persistent high-risk HPV infection, in the DREAM Sant'Egidio HPV-Cervical Cancer Screening Program, in Maputo, Mozambique. All participants have previously examined for high-risk HPV status and cervicovaginal microbiota composition. HPV detection was performed using a commercial HPV DNA assay, and microbiome analysis was performed with commercial kits for the detection of 10 typical cervicovaginal bacteria by PCR, with 16S rRNA gene sequencing (V1-V2 region).

Results: Overall, we found persistent high-risk HPV infection in 34 (47,4%) women (HIV-positive, n= 29 vs HIV-negative, n= 5), with most infections related to other high-risk HPV types than HPV 16/18. On the baseline microbiota testing, the profiles were dominated by a mixture of bacterial vaginosis-associated bacteria, CST IV (11.1% for CST-A, and 65.3% for CST-B), and Lactobacillus crispatus, CST I associated with vaginal health (23.6%). Only 8.3% of women with persistent high-risk HPV infection exhibited L. crispatus dominance, compared to 38.9% who exhibited a mixture of bacterial vaginosis-associated bacteria, CST IV (4.2% for CST-A, and 34.7% for CST-B). Women with HIV also had more frequently CST-IV vaginal dysbiosis profile.

Conclusions: This study sheds light on the interplay between HPV, cervicovaginal microbiota, and host defense, which may play a role in the cervical cancer disparity among Mozambican women. Thus it highlight the need for comprehensive microbiota studies in the country, to further potentially consider the cervicovaginal microbiota testing for the identification of women at risk for HPV-dependent cervical cancer among Mozambican populations.

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#9142

P09-05 | Long-term distribution of HPV infections in male patients: A call for enhanced vaccination and screening efforts

09 - HPV testing

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Background/Objectives: The clinical laboratory at a local hospital plays a crucial role in population health surveillance, performing analyses on both inpatients and critical patients, as well as serving as a reference point for health check-ups. Timely diagnosis is essential for effective treatment of infectious diseases, which often present with severe symptoms. Human papillomavirus (HPV) is one of the most commonly diagnosed sexually transmitted infections globally, affecting men as well as women. In fact, 1 in 3 men is infected with HPV, and 1 in 5 men carries a high-risk strain (1). In Italy, vaccination efforts have primarily targeted women, but extending vaccination to men could significantly reduce HPV cases.

Methods: Between 2018 and 2022, we conducted 7,362 HPV tests using DNA extraction (QiaSimphony) and real-time Multiplex PCR (SeeGene 28 strains).

Results: Out of the 7,362 HPV tests, 3,762 were positive for one or more HPV strains. Women, who are generally more proactive about prevention, comprised most of our sample, with 6,499 tests conducted, of which 3,331 were positive. In contrast, 863 tests were performed on men, with 431 testing positive with an important prevalence of positive seminal fluid and anal infections. Among HPV-positive male patients, infections in seminal fluid showed a consistent distribution across age groups, except as expected in the older age group. On the other hand, even if anal infections are most prevalent in the older population, they were present across all age groups, with a concerning peak in the 18 to 22 age group. Overall, more than 50% of the 7,529 tests conducted from 2018 to 2022 detected high-risk viral strains (5,231), approximately half of which (2,781) are preventable with the monovalent HPV vaccine covering strains 6, 11, 16, 18, 31, 33, 45, 52, and 58.

Conclusions: Our first observation was the significant gender disparity in testing, with 6,500 samples from women and only 890 from men (13,6%). Among the male population, 50.6% of seminal fluid samples and 63% of anal samples were tested positive for high-risk HPV. We also found that anal infection, even if more common in older age, is spread among all age classes, especially the youngest one. Despite the HPV vaccine being free and recommended for both sexes in Italy since 2017, only 45% of 12-year-old boys were vaccinated by 2021. Since retrieved strains comprehend the high-risk ones targeted by vaccines, our findings underscore the need to enhance vaccination and screening efforts among men, overcoming societal taboos that delay diagnosis and treatment.

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#9149

P33-02 | Prevalence of human papillomavirus in prostate tissue of patients undergoing robot-assisted radical prostatectomy

33 - Sexually transmitted diseases and HIV infection

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Background/Objectives: Human papillomavirus (HPV) is associated with various types of malignant tumors, including cervical cancer. While the external genitalia are widely accepted as sites of HPV infection in men, HPV has also been detected in semen and urine samples1). To elucidate the sites of HPV infection in the urogenital tract, we investigated HPV infection in resected specimens from Japanese prostate cancer patients who underwent robot-assisted radical prostatectomy.

Methods: 157 patients who underwent RARP at our institution between July 2017 and February 2020 were enrolled. HPV DNA was extracted using the PinpointTM Slide DNA Isolation System. ß-Globin was amplified by PCR to confirm DNA extraction, and HPV DNA was evaluated by nested PCR (MY09/11, GP5+/6+). Genotyping was performed using the flow-through hybridization method (Hybri-MaxTM), and immunohistochemistry for P16INK4a and in situ hybridization for HPV DNA were conducted to examine HPV-DNA status in the prostatic tissue.

Results: HPV was detected in 9.6% (15/157) of prostate cancer patients. The detected genotypes were 31, 44, 52, 58, and 66. In situ hybridization demonstrated that HPV DNA was observed in the nuclei of cells in the prostatic urethra, prostate cancer, and normal prostate tissue in some HPV-positive cases. On the other hand, no HPV infection was confirmed in the seminal vesicles. In the HPV-positive cases in the prostate cancer area, P16INK4a immunostaining was negative, suggesting no potential relationship between HPV infection and carcinogenesis.

Conclusions: HPV prevalence in prostate cancer patients was 9.6%, and HPV infection was detected in the prostate and prostatic urethra, whereas was not observed in seminal vesicle.

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#9150

P29-01 | HPV genotyping from fine needle aspirations of neck lymph nodes with metastatic squamous cell carcinoma: Comparison of HPV detection methods and correlation with histology

29 - HPV and oropharynx / Head and neck cancer

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Background/Objectives: The incidence of oropharyngeal squamous cell carcinoma (OPSCC) is increasing in the Western world, with a majority of cases being HPV-related (HPV-OPSCC). HPV-OPSCC differs from the HPV-unrelated OPSCC in terms of biology, epidemiology, clinical presentation and treatment response. Therefore, it is recommended to routinely test all FNAB samples from enlarged lymph nodes with squamous cell carcinoma metastases and an unknown primary origin. The aim of the study was to compare different methods for HPV detection.

Methods: We conducted a small case study of patients who underwent fine needle aspiration biopsy (FNAB) because of an enlarged neck lymph node and were diagnosed with OPSCC. DNA was isolated from all FNAB samples with automatized system Seeprep32 and STARMag 96 ProPrep plates/tubes (Segeene), and afterwards HPV genotyping was performed with real-time PCR assay and high-risk Anyplex II HPV HR Detection test (Seegene). The results were later compared with the histological diagnosis and clinical data.

Results: HPV genotype analysis was performed on 24 FNAB samples from enlarged lymph nodes. Ten samples were HPV positive. The majority of them (N=8) were HPV16+ while the rest were HPV18+ (N=1), and HPV58+ (N=1). One case was misdiagnosed and was EBV-positive nasopharyngeal carcinoma.

Conclusions: We concluded that HPV presence can be reliably detected in cytological samples of neck lymph nodes of patients with metastatic OPSCC, and the specific HPV strain can be accurately identified. Additionally, we recommend testing these samples for the presence of EBV, as these tumors may show morphological overlap with OPSCC and can also be HPV16+.

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#9153

P26-02 | Vulvar paget's disease: A 10-year experience in a reference gynecologic oncology center

26 - Vulvar diseases and neoplasia

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Background/Objectives: Vulvar Paget's disease (VPD), the most common form of extramammary Paget's disease (EMPD), represents 1-2% of vulvar neoplasms. EMPD is a rare cutaneous malignancy in apocrine gland-rich areas, with the vulva as the primary site in 60-80% of cases. Primary VPD originates from the vulvar epithelium, while secondary VPD arises from metastasis or local extension of malignancies such as colorectal or bladder cancer. Although usually confined to the epithelium, 10% of cases may progress to invasive disease. VPD primarily affects postmenopausal women and presents as erythematous or eczema-like lesions, often misdiagnosed. Despite a favorable prognosis, local recurrences post-surgery are common. Recent studies suggest Imiquimod, an immune response modifier, as a promising non-surgical treatment for selected patients. This study reports our center's experience in managing VPD.

Methods: A retrospective study was conducted, including women with histologically confirmed VPD, evaluated at a gynecologic oncology reference center over a 10-year period (2013-2023).

Results: Nine patients (n=9) were included, with a median age of 77 years (range 49-92), all Caucasian. Most (n=7) had comorbidities, including hypertension (n=7), dyslipidemia (n=2), diabetes mellitus (n=1), hypothyroidism (n=1), and vitiligo (n=1). None were current smokers; one (n=1) was a former smoker. Most patients (n=7) were postmenopausal. Eight patients (n=8) were symptomatic, with pruritus being the most common complaint (n=7). On examination, most (n=8) had labia majora involvement, four (n=4) had labia minora involvement, and three (n=3) had clitoral involvement. Two patients (n=2) had extragenital lesions, affecting the genitocrural folds (n=1) and perianal region (n=1). Histology confirmed the presence of invasive carcinoma in two cases (n=2). None of the patients had an associated underlying malignancy, confirming all cases as primary VPD. Three patients (n=3) received neoadjuvant Imiquimod, including a 49-year-old patient with extensive genital involvement, affecting the clitoris and perianal region. Eight patients (n=8) underwent surgery. Of these, seven (n=7) had at least focal margin involvement, with one case (n=1) having a margin less than 1 mm. One patient (n=1) underwent surgery for margin enlargement. No cases of regional lymph node metastasis or distant metastasis were identified. Three patients (n=3) experienced disease recurrence, with a minimum interval of 1 year and a maximum of 4 years, all of whom underwent surgical excision. Five patients (n=5) remain under surveillance at our institution, one (n=1) is followed at another institution, and one (n=1) was discharged after 10 years of follow-up. Two patients (n=2) died during the study period, including the patient who did not receive surgery.

Conclusions: Our sample is demographically consistent with existing literature on VPD, suggesting broader clinical applicability. Our 10-year experience highlights the challenges of surgical treatment, particularly with margin involvement, which remains common. Despite the generally favorable prognosis, the risk of recurrence underscores the need for careful long-term follow-up. Non-surgical treatments, such as Imiquimod, show promise as viable alternatives, especially for patients with extensive disease or those unfit for surgery due to comorbidities. Further studies are needed to refine treatment strategies, particularly to optimize non-surgical approaches and better manage recurrent disease.

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#9169

P39-11 | Prevalence and genotype distribution of high-risk human papillomavirus in a screening cohort of Czech women

39 - Public health

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Background/Objectives: The prevalence of high-risk human papillomavirus (hrHPV) types varies internationally, underscoring the importance of assessing prevalence through national data. However, information on hrHPV prevalence in the Czech Republic remains limited. This study, ClinicalTrials.gov Identifier: NCT04133610, aimed to estimate the prevalence of different hrHPV types within a representative screening group of Czech women aged 30 to 65 years, using both clinician-collected cervical and self-collected cervicovaginal samples.

Methods: A total of 1,026 eligible participants were assigned to two groups. Group A utilized the digene® HC2 DNA Collection Device for both self-collected and clinician-collected cervical samples. Group B used the Evalyn Brush for self-sampling and the Cervex Brush for clinician-collected samples. All samples underwent hrHPV testing via the digene® HC2 High-Risk HPV DNA Test, followed by genotyping with the PapilloCheck® HPV-Screening assay.

Results: Overall hrHPV prevalence was 14.8% based on combined positive results from both cervicovaginal and cervical samples. HrHPV positivity rates were 10.8% for clinician-collected cervical samples and 11.8% for self-collected cervicovaginal samples. The most frequently detected genotype in clinician-collected samples was HPV16, followed by HPV31, HPV68, HPV56, HPV52, and HPV39. In self-collected samples, the predominant genotypes were HPV56, HPV68, HPV31, HPV16, and HPV39.

Conclusions: The study revealed a lower hrHPV prevalence in the Czech screening population compared to other Central and Eastern European regions. Furthermore, the most prevalent hrHPV types, except for HPV16, showed a distribution pattern that differs from those in other reports. This study was supported by a project at the National Institute for Cancer Research (Programme EXCELES, ID Project No. LX22NPO5102) funded by the European Union (Next Generation EU), by EATRIS-CZ (LM2023053), by MH CZ—DRO (FNOL, 00098892), and by the Cancer Research Foundation CR. The funding agencies were neither involved in the design of the study nor data collection, analysis, and interpretation or the writing of the manuscript.

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#9171

P30-01 | Multiple and recalcitrant warts of the hands completely cured after intake of oral magnesium

30 - HPV and associated skin diseases

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Background/Objectives: Non-genital warts are benign cutaneous tumors caused by human papillomavirus (HPV) infection of keratinocytes. They usually affect children but can also be found in adults at any age. The face, the hands and feet, as well as the palms and soles are common sites of involvement. Although various treatment modalities have been suggested, warts can prove to be resistant and recalcitrant. Moreover, patient compliance and cure are limited by treatment-associated side effects like pain and local irritation. We present a case of a 46-year-old male with hand warts resistant to multiple, topical and destructive, therapies who was finally cured with a 20-day course of oral magnesium supplementation.

Methods: In July 2022, a 46-year-old male, teacher, was diagnosed with flat and periungual warts, affecting both of his hands. Patient's medical history was unremarkable. Additionally, he denied any self-picking habits or activities that involve excessive hand usage in moist environment. Over the course of two years, the patient had received three monthly sessions of cryotherapy, three monthly sessions of CO2 laser ablation and a session of bleomycin injection (bleopuncture technique). All the above methods had led to a quick relapse and subsequent scaring (image 1), preventing the patient from seeking any further treatment. In February 2024, he received oral magnesium for post-training muscle cramps. Twenty days after daily 243mg magnesium aspartate and citrate combination, he reported complete clearing of the warts (image 2) and with no recurrence ever since.

Results: This is the first case reporting the use of oral magnesium for the treatment of warts. Our patient had received three standard therapies that were unsuccessful and was finally cured with oral magnesium prescribed for muscle cramps relief. Other systemic agents like oral retinoids (isotretinoin) and H2 receptor antagonists (cimetidine) have been suggested but their efficacy is limited by the absence of robust data. Recent studies have shown that Magnesium transporter 1 (MAGT1) significantly contributes to the proper function of the cell- cycle as it appears to have a similar role with the TUSC3 tumor-suppressor candidate 3 protein. Deficiency of MAGT1 or reduced magnesium levels at the MAGT1-dependent glycosylation, result to lack of immune glycoproteins and incorrect expression of immune-related genes. These findings indicate that a relation between magnesium levels and immune diseases such as warts caused by HPV is highly possible.

Conclusions: The use of oral magnesium as a therapeutic alternative for the treatment of recalcitrant warts constitutes an attractive option as it has a good safety profile, and it is also painless and inexpensive. However, double-blind studies are needed to support our finding and to better clarify the link between magnesium and HPV infection.

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#9178

P16-01 | Detection of transformation zone cells in liquid-based cytology and its comparison with conventional smears

16 - Screening methods

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Background/Objectives: Although conventional cytology is an effective screening method for cervical cancer, its drawbacks should be recognized, particularly the low sensitivity of the test [1]. Thus, liquid-based cytology emerged as a novel method to improve test sensitivity due to better cellular visualization, because of less overlapping of blood and inflammatory cells. The easier preparation of slides offers an advantage and represents an important advance in the prevention of cervical cancer. So, the objective of the present study was to compare differences between liquid-based and conventional cytology in respect of the detection of transformation zone cells (glandular cells and metaplastic cells), mainly by age group and to assess test performance by correlating results with cytological abnormalities.

Methods: A retrospective study assessing the results of cervical-vaginal cytology smears collected at a private laboratory in São Paulo (Brazil) between January 2010 and December 2015 was performed. The study was approved by the local research ethics committee of the institution.

Results: A total of 1,030,482 cytology tests were performed; of these, 3,811 (0.36%) unsatisfactory samples were excluded. Cytology sampling in the patients studied was performed using the conventional technique in 394,879 (38.5%) cases and the liquid-based techniques in 631,792 (61.5%) cases. The proportion of samples with transformation zone cells for interpretation was 73.2% (288,956 samples) in conventional cytology and 52.7% (333,115 samples) in liquid-based cytology ($p<0.001$). The presence of transformation zone cells rate declined in both groups with age, but was consistently lower for liquid-based cytology ($p<0.001$). The presence of endocervical and metaplastic cells was associated with higher high-grade squamous intraepithelial lesion (HSIL) detection rates. We hypothesize that metaplastic and glandular cells, given they are smaller, may be lost in the filter of liquid-based cytology, whereas larger abnormal cells are retained and do not affect detection rate. Another supposition is that when transferring cells to the liquid-containing vial, the professionals performing the sampling fail to ensure that cells detach from the spatula or brush, resulting in the absence of endocervical and/or metaplastic cells.

Conclusions: Low representation of the transformation zone was found in the samples collected using the liquid-based cytology technique, particularly in the over 50 age group. Conventional cytology was associated with a higher rate of detection of high-grade lesions.

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#9179

P29-04 | Ethical issues related to HPV liquid biopsies

29 - HPV and oropharynx / Head and neck cancer

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Background/Objectives: Liquid Biopsy is an umbrella term used to describe the testing of bodily fluids to detect the presence of cancer either as part of screening or surveillance programs. Plasma circulating tumor HPV DNA (HPV ctDNA) is a promising liquid biomarker in head and neck cancer for both determining treatment response and monitoring for recurrence. Several such tests are now commercially available for routine clinical use and are being employed widely. However, their use highlights myriad regulatory, methodological, and ethical concerns.

Methods: Normative analysis with literature review

Results: There are methodological issues affecting HPV ctDNA assay reliability including false positives and false negatives, and the potential variation in performance metrics across different tests. These assays have also not been validated prospectively across diverse patient populations and disease states, so the key question regarding lead time persists. Despite their reported robust predictive capability, no test has been advanced to a clinical utility trial to assess its ability to improve or alter patient outcomes. In the United States, FDA has oversight over HPV ctDNA assays, as part of its jurisdiction over Laboratory Diagnostic Tests (LDTs). However, in current practice, LDTs have relatively little oversight given FDA enforcement discretion. In addition, insurance coverage for these assays remains variable, and thus patients are potentially burdened with unexpected out-of-pocket costs that may recur with serial testing. These issues are only magnified globally, given vastly different regulatory and coverage standards and, for example, variations in European Union guidance compared to its member nations. Despite the absence of adequate regulation and methodological limitations, HPV ctDNA assays are currently used and their results routinely influence critical healthcare decisions. There is concern that widespread and disparate use of a clinically available and expensive diagnostic test that is unproven may not significantly impact patient outcomes while also contributing to increased invasive interventions, expenses, and contributing to patient distress.

Conclusions: There is an urgent need to establish data-informed practice standards for the clinical use of HPV ctDNA that is informed by an ethical framework involving informed consent, education and training, patient-physician communication, and equal access to resources.

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#9181

P10-03 | Transitioning to HPV primary screening: Factors that influenced British Columbia's (BC) implementation strategy

10 - HPV screening

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Background/Objectives: Jurisdictions need to consider local factors, e.g. ability for the system to absorb year over year screening volume differences, colposcopy capacity, patient and provider readiness for change, when determining HPV primary screening implementation strategies.

Methods: BC developed a Markov chain forecast model to assess two implementation strategies: (1) A transition all at once to offer self-collected HPV testing and triage of all liquid based cytology samples for HPV testing (sharp transition) and (2) HPV implementation with a stepped down approach to cytology volume (smooth transition). A self-screening pilot ran in BC from 2022-2024 which informed the model and provided information on the potential uptake of self-screening. In this pilot, women due and overdue for screening in four communities were offered self-screening.

Results: Model 1 (sharp transition) showed an average of 163K screens every 6 months for 3 years, 102K screens for years 4 and 5 and then an increase to 151K in years 6 and 7. Colposcopy volumes would rise to 45% above historical baseline 3 years after implementation and would stabilize in year 8 at 40% above historical baseline. Model 2 (smooth transition) showed HPV screening volumes would stabilize with more similar year over year volumes starting at 60K HPV screens in the first 6 months and steadily increasing to 139K screens by year 8. Colposcopy demand would increase gradually to 39% percent above historical baseline by year 8. In the BC self-screening pilot communities, a maximum of 42% of patients due to screen chose cervix self-screening, even when self-screening kits were mailed directly to them. Never and under-screened patients returned up to 30% of self-screening kits, both opt in and opt out strategies were trialled. Patients from non-pilot communities regularly reached out to the program to request self-screening, often citing historical trauma or other factors affecting their ability or willingness to access a provider-collected sample for screening. During the pilot, clinics serving Indigenous people, Trans individuals, newcomers to Canada and low income areas sought participation in the Cervix Self-Screening pilot to improve access to the populations they served.

Conclusions: Model 2 showed that HPV implementation with stepped down cytology volumes would provide more consistent annual screening and colposcopy referral volumes going forward. A more gradual increase in colposcopy referrals allows more time for the system to prepare for the expected increase in colposcopy demand (space, equipment and colposcopist training). The BC Cervix Self-Screening experience demonstrated that there are people across the population who would prefer and who would benefit from a self-screening option. The factors that influence someone's need or preference for self-screening are not identifiable at a population level. While self-screening is desirable for many patients, others continue to prefer an interaction with their provider and provider collected sampling. Offering choice for patients and providers to identify the collection method best suited for the patient provides the opportunity to reach all eligible people interested in self-screening while retaining some patients on cytology screening for one more round. This approach takes advantage of the natural adoption pattern observed in technology change to smooth out year over year screening volumes and gradually increase colposcopy demand.

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#9185

P06-03 | Seropositivity 1-2 years after a single dose of 9-valent human papillomavirus vaccine among boys and girls

06 - HPV prophylactic vaccines

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Background/Objectives: In the 2022 update of the World Health Organization Position Paper on human papillomavirus (HPV) vaccines, assessing HPV antibody persistence after a single dose of the HPV vaccine was identified as a research priority. An ongoing, open-label Phase 3 study (V503-069; NCT04708041) is underway to assess the immunogenicity and safety of extended-interval 2-dose regimens of the 9-valent (9v) HPV vaccine among girls and boys. Immunogenicity after dose 1 was assessed as an exploratory analysis.

Methods: Immunogenicity was assessed after dose 1 of the 9vHPV vaccine among girls and boys receiving 2-dose regimens 12 months apart (Cohort 1; aged 9-14 years; n=101) or 24 months apart (Cohort 2; aged 9-13 years; n=101). Anti-HPV geometric mean titers (GMTs) and percent seroconversion for 9vHPV vaccine types were measured using a competitive Luminex immunoassay 1 month (Cohorts 1 and 2), 6 months (Cohorts 1 and 2), 12 months (Cohorts 1 and 2), and 24 months (Cohort 2) after dose 1. Seropositivity was defined as an antibody titer above the serostatus cutoff (SSCO) of the assay.

Results: Initial anti-HPV responses were induced at 1 month after dose 1. Seroconversion at 1 month after dose 1 ranged from 83% to 100% depending on the 9vHPV vaccine type. A decreasing trend in the proportions of participants who were seropositive was observed, ranging from 64% to 96% at 6 months after dose 1, 39% to 87% at 12 months after dose 1, and 31% to 74% at 24 months after dose 1. GMTs starting at 1 month after dose 1 decreased over time through 24 months after dose 1.

Conclusions: At 1 month after dose 1 of the 9vHPV vaccine, incomplete seroconversion for some HPV types and declines in GMTs and seropositivity rates over time were observed. These findings highlight the importance of thoroughly assessing long-term effectiveness of HPV vaccination as a single dose. The short-term efficacy of single-dose HPV vaccination is being assessed in several ongoing trials. Further investigation of the persistence of immune responses following dose 1 of HPV vaccination is also needed.

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#9186

P06-04 | Immunogenicity and safety of 2-dose 9-valent Human Papillomavirus (HPV) vaccine regimens administered 1 or 2 years apart among boys and girls

06 - HPV prophylactic vaccines

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Background/Objectives: Two-dose regimens of the 9-valent (9v) HPV vaccine given 6 or 12 months apart are approved for children aged 9-14 years. The immunogenicity and safety of extended-interval 2-dose regimens given 1-5 years apart are being investigated in pre-/young adolescents (aged 9-14 years) in an ongoing, open-label, Phase 3 study (V503-069; NCT04708041).

Methods: An interim analysis was performed to evaluate 2 doses of the 9vHPV vaccine given 12 months (Cohort 1; aged 9-14 years; n=101) or 24 months (Cohort 2; aged 9-13 years; n=101) apart to girls and boys. Serologic responses to vaccine-targeted HPV types were measured using competitive Luminex immunoassay 1 month after the last vaccination dose. Noninferiority of anti-HPV geometric mean titers (GMTs) at 1 month after the last dose in Cohort 1 versus Cohort 5 (young women aged 16-26 years who received 3 doses of the 9vHPV vaccine, n=103) or in Cohort 2 versus Cohort 5 was tested by ANOVA modeling of the GMT ratio (girls and boys or women). The success criterion for noninferiority required that the lower bound of the 95% CI of the GMT ratio be >0.67 for each vaccine-targeted HPV type. Adverse events (AEs) through Day 15 after vaccination and vaccine-related serious AEs (SAEs) were assessed throughout the study.

Results: At 1 month after the last dose, GMT ratios ranged from 1.81-5.04 (lower bounds of 95% CIs ranged from 1.38-3.81) for Cohort 1 versus Cohort 5 and 1.71-5.58 (lower bounds of 95% CIs ranged from 1.32-4.26) for Cohort 2 versus Cohort 5 across the vaccine-targeted HPV types. GMTs for the 2-dose regimens were both noninferior to GMTs of the 3-dose regimen. Injection site reactions were the most frequently reported AEs through Day 15 after vaccination (67.3%-73.3% of participants; mostly mild to moderate); no vaccine-related SAEs were reported.

Conclusions: At 1 month after the last dose, GMTs in girls and boys who received 2-dose regimens of the 9vHPV vaccine given 12 or 24 months apart were noninferior to GMTs in young women who received the standard 3-dose regimen (the population in which vaccine efficacy was established). These findings are consistent with immunobridging results that supported approval of 2-dose regimens given 6 or 12 months apart in adolescents. All regimens were generally well tolerated.

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#9188

P03-03 | HPV pre and post vaccination prevalence in Inuit women of Nunavik, Northern Quebec, Canada

03 - Epidemiology and natural history

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Background/Objectives: Following the introduction of the province-wide Human Papilloma virus (HPV) vaccine program with the quadrivalent HPV 6/11/16/18 vaccine in 2008, HPV vaccination coverage in the 12-13-year-old girl population has since reached over 80% in Quebec, with nearly the same rate within the circumpolar Inuit population of Northern Quebec. We compared current HPV prevalence to the rate obtained in the pre- vaccination era to assess the impact of vaccination on circulating HPV.

Methods: Methods: 125 Inuit women aged between 25 and 65 (mean 37.5 years) were recruited in Kuujjuaq, Nunavik, Quebec between July 2022, and May 2024. Self-collected cervico-vaginal HPV sampling was performed under the systematic guidance of a registered nurse and analysed using real-time PCR Cobas 4800 HPV test to detect HPV16, HPV 18, and 12 other high-risk HPVs (HPV31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68). The results were compared overall and by age group to prevalence collected in 473 participants (mean age 35.5 years) within the same population from 2002 to 2007.

Results: Results: Overall HPV prevalence for the pre-post vaccination period increased significantly from 15.9% to 24.8%, strongly driven by the statistically significant increase in the 40+ age group of the other high-risk HPVs from 5.8 % to 23.1%. Overall HPV16/18 prevalence showed a non statistically significant increase from 4.0% to 5.6% although post vaccination prevalence showed a decrease in the 25-29 age group. No HPV 16/18 infections were detected among those vaccinated. There were 3 mixed infections none of which were vaccinated.

Conclusions: Conclusion: We showed a statistically nonsignificant overall increase of HPV16/18 since the implementation of the quadrivalent HPV vaccination program in Nunavik although prevalence of vaccine types 16/18 decreased among the age group prioritized for vaccination. The overall and type specific prevalence will need to be monitored as the nonavalent HPV6/11/16/18/31/33/45/52/58 vaccine has been introduced in 2016 with a gender-neutral vaccination policy.

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#9191

P16-03 | Accuracy of PAX1 gene hypermethylation as a biomarker for cervical cancer screening: systematic review and meta-analysis

16 - Screening methods

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Background/Objectives: The global incidence of cervical cancer is 13.3 cases per 100,000 women, with human papillomavirus (HPV) being a necessary but insufficient factor for the development of this cancer. Currently, the gold standard for diagnosing cervical cancer is histopathological examination; however, it has certain limitations that need to be addressed to ensure an early and accurate diagnosis. HPV has the ability to induce epigenetic changes, specifically gene hypermethylation. Thus, hypermethylation assessment has emerged as a promising screening tool for cervical cancer, with the Paired Box 1 (PAX1) gene, involved in cell cycle control processes, being one of these relevant genes. Therefore, the objective of this study was to evaluate the accuracy of PAX1 gene hypermethylation as a biomarker for cervical cancer screening.

Methods: A systematic review and meta-analysis were conducted. The search strategy was implemented using the terms "cervical cancer" and "PAX1 transcription factor," along with their synonyms, in major databases such as MEDLINE, Embase, LILACS, the Cochrane Library, and gray literature. The screening and selection of studies, as well as data extraction, were performed in duplicate. Statistical analysis was conducted using MetaDisc software (version 1.4).

Results: A total of 229 studies were found in the databases, with nine articles published between 2014 and 2023 included. The meta-analyses provided the following results: specificity of 84% (95% CI: 82% - 86%), sensitivity of 78% (95% CI: 73% - 82%); Diagnostic Odds Ratio (DOR) of 39.37 (95% CI: 16.06 - 96.70), and Area Under the Curve (AUC) of 0.9298.

Conclusions: The assessment of PAX1 gene hypermethylation shows promise as an alternative for cervical cancer diagnosis. However, this assessment should be interpreted with caution given the limited evidence available in the literature. Therefore, further studies on this topic are recommended.

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#9199

P13-01 | Diagnostic accuracy of the Daye diagnostic tampon compared to clinician-collected and self-collected vaginal swabs for detecting HPV: A comparative study

13 - Self-sampling

Background/Objectives: Well-accepted and validated collection devices that can support HPV testing are of increasing importance given the increased use of self-sampling for cervical screening, and the global consensus that cervical cancer could be eradicated within our lifetime through a combination of regular screening and vaccination programs. The Daye Diagnostic Tampon (DDT) is an innovative self-collection device that utilises the menstrual tampon familiar to many women and individuals assigned female at birth (AFAB) for HPV screening through vaginal and cervical fluid collection. This study aimed to assess the diagnostic accuracy of DDT and vaginal self-swabs (VSS) for detecting high-risk HPV infection, compared to clinician-collected swabs (CCS).

Methods: A total of 262 patients provided CCS, VSS, and DDT samples for HPV testing, the population was enriched for patients with a (recent) HPV-positive result. Samples were tested with an HPV assay that detects 14 high-risk HPV types; sensitivity, specificity, positive predictive and negative predictive value of the DDT and VSS for HPV detection was evaluated using the CCS as a reference gold standard. All devices were assessed using a collated method where an additional gold standard where the correct result was classed as that where at least two out of the three devices gave a consistent result. The invalidity rate (HPV negative and internal control negative) was measured for the different collection devices.

Results: When compared to CCS, DDT demonstrated a sensitivity of 82.9% (95% CI: 72.4-89.9%), specificity of 91.6% (86.4-94.9%), and overall accuracy of 89.0% (84.4-92.4%). Using the collated results as the reference, DDT exhibited a sensitivity of 92.5% (83.7-96.8%), specificity of 96.0% (92.0-98.1%), and overall accuracy of 95.1% (91.6-97.2%), performing on par with the CCS. Invalidity rate - The proportion of conclusive results varied between sampling methods: CCS (90.8%), DDT (99.2%), and VSS (94.7%).

Conclusions: The DDT demonstrates encouraging accuracy for detecting HPV infection, with performance comparable to CCS. The ease of use and potential to increase screening accessibility make DDT a promising tool for enhancing cervical cancer prevention. Further, complementary research should focus on assessing the clinical performance of the DDT for the detection of HPV associated with the disease.

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#9201

P06-05 | Identifying future needs for reducing missed opportunities for HPV vaccination in a large, urban community health system in Los Angeles

06 - HPV prophylactic vaccines

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Background/Objectives: In the United States, human papillomavirus (HPV) vaccination rates among adolescents remain suboptimal, with only about 55% receiving the recommended doses. Addressing HPV vaccination missed opportunities (MO) during adolescent healthcare visits is one strategy to increase uptake. While evidence-based strategies (EBS) to improve HPV vaccination in clinical settings exist, few studies have focused their impact specifically on MO, particularly among medically underserved adolescents seeking care in community health clinics.

Methods: As a part of a larger mixed methods implementation study focused on HPV vaccine initiation as the primary outcome, we assess the impact of a multi-component HPV vaccine EBS intervention (provider communication training, staff education, audit-and-feedback) within a large, urban community health system on missed opportunities (secondary outcome). An HPV vaccine MO was defined as a clinic visit when an adolescent (ages 9-12) received other vaccines (e.g., Tdap, MCV4, flu) and was eligible for, but did not receive, a dose of the HPV vaccine. Using electronic health records from July 2021-February 2024, we examined the frequency of MO and performed a Difference-in-Difference analysis to examine change in proportion of MO visits between intervention and comparison clinics prior to and following EBS implementation. Guided by RE-AIM and the Practice Change Model, survey and qualitative interviews were conducted among providers and clinic team members to examine implementation determinants and outcomes. Interviews transcripts were inductively and deductively coded for barriers and facilitators to addressing HPV Vaccine MO.

Results: Among adolescents eligible for initiating (n=15,308) and completing (n=4,049) the HPV vaccine during the 18-month study period, frequency of MO visits reduced significantly from pre-intervention to intervention periods in both demonstration (initiation: 56% vs. 40%, $p<0.01$; completion: 78% vs. 66%, $p<0.01$) and comparison clinics (initiation: 56% vs. 41%, $p<0.01$; completion: 70% vs. 57%, $p<0.01$). Change in MO between pre- and post-intervention between demonstration and comparison clinics were not significant. Surveys showed increase in offering HPV vaccines during sick visits between baseline (58%) and 12-month follow-up (68%). Baseline interviews revealed system-level strategies, including vaccine clinics where patients can receive multiple vaccines in one clinic encounter and ongoing CareGap alerts for due vaccines that are accessible in the electronic health records, as facilitators to reducing MO. However, variation in use of standing orders and not starting the HPV vaccine early enough to meet quality metrics contributed to MO. By 12-month follow-up interviews, providers and clinic team members mentioned offering HPV vaccines in urgent care visits as well as other sick visits.

Conclusions: We observed a similar reduction in HPV vaccine MO between demonstration and comparison clinic sites. These findings could be explained by other system-level changes to adolescent HPV vaccination co-occurring with our study period and that the EBS did not target MO specifically but rather HPV vaccination in general. However, prevalence of MO among adolescents in this community health setting after EBS implementation still ranged between 40-66% and suggests more targeted efforts to address MO reductions are needed in future research.

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#9202

P39-10 | Ensuring inclusivity in recruitment and data collection strategies to establish a multiethnic cohort of cervical cancer survivors: Implications for understanding and addressing structural inequities in cancer care

39 - Public health

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Background/Objectives: Cervical cancer (CC) is preventable, yet over 4,000 people continue to die each year in the United States (US), particularly Hispanic/Latinx and non-Hispanic Black women. As such, these inequities cannot be comprehensively addressed without closely examining the social, political, and environmental contexts of CC treatment and how these factors contribute to inequitable CC outcomes. Few studies have systematically examined how multilevel factors - including indicators of racism at the micro-, mezzo-, and macro-levels - impact CC treatment and survival, and the partnership- and community-engaged processes required to rigorously evaluate these pathways.

Methods: The Assessing Cervical Cancer Healthcare Inequities in Diverse Populations (ACHIEVE) Study empowers CC survivors to share their experiences about treatment and survivorship. Guided by the National Institute of Minority Health and Health Disparities Research Framework and Intersectionality Framework, ACHIEVE is recruiting CC survivors from the New Jersey State Cancer Registry and the Los Angeles Cancer Surveillance Program—to establish a diverse, multiethnic cohort of approximately 900 invasive CC cases diagnosed in 2021-2024. Between October 2023-May 2024, a team of multidisciplinary investigators (e.g., cancer epidemiology, health services research, gynecologic oncology, and demography) and diverse, multilingual research team and community advisory board (CAB) members, engaged to develop the baseline survey in an iterative, adaptive process. The survey was then translated to be available in English, Spanish, Chinese, and Haitian Creole to represent target populations.

Results: The baseline survey included measures on CC care, health care access, medical mistrust, discrimination, neighborhood perceptions, social and unmet needs, and patient centered communication, among other topics. Items related to immigration status and experiences with policing or incarceration (i.e., encounters with law enforcement) were removed from previous versions of the survey due to institutional ethics reviews, input from the CAB, and considerations about survey length. The final survey was translated into all target languages by a certified translation service. Bilingual researchers and CAB members then reviewed the translations to ensure accuracy, appropriate terminology, and cultural sensitivity. After incorporating feedback, a matrix style document was generated to compare the translated terminology against the recommendations. Between June-July 2024, a meeting was held for each language to resolve any differences and adapt questions to be understood by participants from diverse backgrounds.

Conclusions: Adaptations for recruitment and linguistic and cultural relevance to data collection materials, conducted through team science and community-participatory approaches, are required to promote justice, equity, diversity, and inclusivity in research focused on addressing structural drivers of cancer inequities. Thoughtful balance between assessment of comprehensive lived experiences, such as those related discrimination, policing, medical mistrust, and intersectional identities, and avoiding questions that may be viewed as too sensitive requires further refinement in inclusive research practices. Findings from the ACHIEVE Study will inform the development of effective strategies to address inequities in CC care and outcomes.

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#9206

P13-06 | Perceptions, knowledge and attitudes regarding vaginal self-sampling for diagnosis of human papillomavirus in women from Boyacá, Colombia

13 - Self-sampling

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Background/Objectives: DNA testing for human papillomavirus (HPV) on samples taken either by health personnel or by vaginal self-sampling has been included in the Colombian program guidelines for more than a decade.However, self-sampling has not been implemented. In order to promete its implementation and aligned with de WHO 90-70-90 strategy we conduced a study to explore the perceptions on this technology and on the barriers that could hinder the optimal use of self-sampling for HPV testing in programmes for the early detection of cervical cancer (CC).

Methods: A mixed methods study was conducted with 50 women from three municipalities in the department of Boyacá. All participants were administered a socio-demographic questionnaire and self-sampling test for HPV-DNA. Pre-test focus groups were conducted with a subgroup of women (n=26). The focus groups explored perceptions and opinions about the self-sampling test. These were recorded, transcribed and analysed on the N-VIVO platform by two researchers.

Results: Quantitative Component: The median age of the participants was 43.5 years (IQR 37.25 - 51.75). The majority of participants were of middle and low socioeconomic status. All except one had a PAP smear done in the past. Of all participants, 30 % (15/50) were positive for HPV. The most frequent genotypes detected were Group 1 (Genotypes 33/58) and Group 2 (Genotypes 56/59/66) corresponding to 46.2 % and 33.3% of the positive samples, respectively. Four women were positive for more than one high-risk genotype and 13 with HPV detected underwent colposcopy, of which 7 required biopsies. In the biopsies one high-grade CIN, one low-grade CIN and one nongrading dysplasia were found. Qualitative Component: The perceived advantages of self-sampling test most often expressed were: the practicality and ease of self-sampling, the fact that women do it themselves and it is not necessary to access the health system or a professional to have it done. Although the perceived disadvantages were very few, there was mention the possibility of errors during sampling, problems regarding contamination, transport or loss of the sample that would require repetition

Conclusions: There is a positive perception of self-testing by the study participants, highlighting aspects such as practicality and ease of collection. All samples were adequately collected by the participants, allowing HPV detection at an expected frequency, and referral to colposcopy. Our findings suggest that self-sampling HPV-DNA testing is an acceptable and feasible strategy for increasing coverage and adherence to cervical cancer screening programmes.

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#9209

P25-04 | Association of Dietary Intake and risk of developing cervical cancer: A population-based study recruiting 1380 cases

25 - Cervical neoplasia

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Background/Objectives: Cervical cancer is one of lethal cancers in women. Due to the role of diet/nutrition factors for cancer, the aim of the present study was to determinate the impact of 100 nutrition/vitamin factor and 100 non nutritional factors on cervical cancer and HPV.

Methods: Population samples of 2088 healthy subjects and patients with cervical cancer were used. 182 factors (e.g. Vitamin E, B1, B6, breakfast, fruits) were investigated. Here, Regularization regression models and correlation were used for modeling. We comparatively evaluate the performance of three regularized linear regression methods. R3.6.8 and EVIEWS11 software were utilized for Implementation.

Results: Among the models Elastic Net had high R square and less MSE.The result of Elastic Net shows that the Phase, sexmate_patient_2group, smear_2g, residient_place, hpv_sign_cat and Education_status variables have the greatest effect more than the other on cancer. Our findings indicated that Tot.N2g, fat.g, cho.g, energy.kcal, energy.kj starch.mg, dietaryfiber, polyfat.g, k.mg, mg.mg, p.mg, fe.mg, zinc,Vitamin E , B1.mg, B3.mg , B6.mg and folat have the most significant impact in reducing the risk of cervical cancer in Iranian women, as well as main _meal, breakfast, Dinner, Salt_at_table and Nutritional_suppliment Were identified as high risk factors(pvalue <0.05). Also Special_diet, breakfast, Dinner, Salt_at_table and Nutritional_suppliment have high risks for HPV. Among results correlation between Menstrual_disorder and Suffering_cancer, Financial status and Suffering_cancer, Doing_vaccination and phase are noticable.

Conclusions: The results show that the Elastic Net regression method outperforms the other methods such as LASSO and Ridge regression in terms of prediction performance. A diet and rich nutrition can be helpful for prevention of cervix cancer and may reduce the risk of disease. Additional research about the role of other nutritional factor in cervical cancer is necessary

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#9214

P15-01 | Genetic variation linked to the extracellular matrix (TGF-ß1 and HPSE1 genes) and the development of cervical lesions in HPV-infected women

15 - Molecular markers

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Background/Objectives: HPVs attach predominantly to the extracellular matrix. TGF-β1 plays a central role in the maintenance, remodelling and regulation of the extracellular matrix. It promotes the synthesis of collagen and other components, regulates their degradation by the metallo-proteinases, activates fibroblasts and myofibroblasts. Heparanase (HPSE1 gene) releases the virus from the matrix. For each gene, specific polymorphisms were selected to evaluate their contribution to the development of the gynecological disorder under study. Considering TGF-β1, two variants were selected, rs1800469 and rs1800470; for HPSE1 the selected polymorphism was rs4693608. The main objective of this work is to find associations between HPSE1 and TGF-β1 and cervical lesions in HPV infection women.

Methods: Genotype distribution of an HPV-infected women population presenting cervical lesion was compared with a population without the disease. PCR-RFLP was used to genotype TGF-ß1 and End Point was used to genotype HPSE1. Statistical analysis was performed with the SPSS 28.0 software.

Results: RegardingTGF-ß1-rs1800469, the dominant genetic model, as well as the allelic model revealed a protection effect of the variant (OR=0.353, CI-0.146-0.850 and OR=0.498, CI-0.260-0.954, respectively). TGF-ß1-rs1800470 showed a protection effect of having the variant allele (OR=0.525, CI-0.282-0.976). An epistatic interaction between TGF-ß1-rs1800469 and HPSE1 - rs4693608 exposed a higher protection effect (OR=0.298, CI-0.106-0.838).

Conclusions: TGF-ß1 and HPSE1 genes are associated with the development of cervical lesions in HPV infected women.

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#9223

P39-06 | How important is the HPV vaccine? Do young people need to be made aware of this?

39 - Public health

Background/Objectives: To assess students' knowledge about the Human Papillomavirus (HPV), its forms of transmission, consequences and the importance of vaccination against the HPV virus.

Methods: Young people between the ages of 9 and 14, students from public schools in Valença - RJ, Brazil, were invited to participate in a survey, in which they were asked if they knew what the HPV virus is, its forms of transmission, if they had already been vaccinated against the virus, if they knew how to protect themselves from STIs and if they knew the main cause of cervical cancer. After the survey was administered, a lecture was given on HPV, its forms of transmission and prevention, emphasizing the importance of vaccination.

Results: A visit was made to 2 schools in our city, in which we managed to get 128 students to answer the survey and attend the lecture, being 57 boys and 71 girls, aged between 12 and 20 years. Among the participants, 65.6% said they knew what the HPV virus is, 63.2% of whom were boys and 67.6% of whom were girls. 58.6% of the participants said they knew how it is transmitted, 57.9% of whom were boys and 59.1% of whom were girls. The majority had already been vaccinated, with 64.8% reporting having received the vaccine, 59.9% of whom were boys and 70.4% of whom were girls. In addition, 86.7% of the students said they knew how to protect themselves against Sexually Transmitted Infections (STIs), with 87.7% of the boys and 85.9% of the girls answering affirmatively. However, only 14% said they knew the main cause of cervical cancer, 15.8% of whom were boys and 12.7% of whom were girls.

Conclusions: Based on these results, we identified that a slightly higher proportion of girls declared they knew what the HPV virus is and how it is transmitted. Furthermore, the data reveal that the vaccination rate among girls was 11% higher than that of boys, indicating the need to intensify vaccination efforts among young people, especially boys, since they can transmit the virus to multiple unvaccinated partners. Most students reported knowing how to protect themselves against STIs, with a slightly higher percentage of boys reporting having this knowledge. Regarding the understanding of the main cause of cervical cancer, we had an alarming result: few boys and girls knew how to answer, with a slight advantage for boys, which surprised the researchers, since girls were expected to have more information on the subject. Overall, the responses of boys and girls were quite similar, except regarding to vaccination, where there was a small discrepancy in favor of girls. The project succeeded in disseminating crucial information about health and prevention, making the topic more accessible and generating a positive impact among adolescents. We believe that this awareness is possible and necessary, by teaching and educating about the importance of vaccination in the school environment.

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#9224

P39-07 | Social and structural drivers of cervical cancer inequities: A systematic review of the associations between measures of racism across the cancer continuum

39 - Public health

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Background/Objectives: Structural racism in the United States is a fundamental cause of cancer health inequities. However, associations between specific measures of structural racism and cervical cancer (CC) care across the continuum remain poorly understood. This systematic review aimed to examine associations between structural racism and CC screening, diagnosis, treatment, survivorship, and palliative care.

Methods: The review followed PRISMA guidelines and was registered on PROSPERO. Searches were conducted in PubMed, CINAHL, Web of Science, and Embase for English-language, peer-reviewed studies published from 2012-2022, using keywords related to structural racism (per five domains of social determinants of health [SDOH] from Healthy People 2030) and CC. Articles were screened, reviewed, and assessed for risk of bias (ROB) using Joanna Briggs Institute (JBI) Critical Appraisal Checklists. ROB was categorized as low, intermediate, or high.

Results: Database searches identified 8,924 articles; 4,383 duplicates were removed, and 4,541 underwent title and abstract screening. After excluding 3,701 irrelevant articles, 840 were screened for eligibility. Ultimately, 208 studies were included in the synthesis. Most (99%) were assessed as low ROB, with 1% as intermediate ROB. Various structural racism measures were examined, including racial discrimination, justice system involvement, and immigration status. Studies also addressed healthcare and education access, community context, economic stability, and neighborhood environment. Of the studies, 60% (n=125) compared CC outcomes by race and ethnicity, often used as proxies for upstream racism measures. Key findings included lower CC screening rates among Asian American and Pacific Islander women and higher rates among Black and Hispanic women, compared to White women. Barriers to healthcare access were linked to delayed follow-up care among Black and Hispanic women. Further, Black and Hispanic women, and those residing in low-SES neighborhoods, were more often diagnosed at later stages. Black women were consistently found to receive sub-optimal care and had poorer survival outcomes than their White counterparts.

Conclusions: Overall, our findings support associations between race and ethnicity and related SDOH variables with CC outcomes across the care continuum. Notably, more than half of the studies focused solely on differences in CC outcomes by race and ethnicity, rather than evaluating more upstream measures of structural racism. Future research should prioritize enhancing the measurement of upstream social and structural drivers of health - including concrete measures of racism - to allow for more rigorous approaches to understanding the impact of structural racism on CC across the care continuum.

Figure 1. PRISMA flow diagram of study selection

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#9226

P39-08 | Sex differences in parental reasons for lack of intent to initiate HPV vaccination among adolescents ages 13-17 years: National Immunization Survey - Teen 2019-2021

39 - Public health

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Background/Objectives: This study aimed to evaluate parents' main reasons for lack of intent to vaccinate their adolescent against human papillomavirus (HPV) from 2019-2021 and to examine changes in these main reasons stratified by sex of the adolescent.

Methods: NIS-Teen data from 2019-2021 were used. Parents who had not vaccinated their adolescent aged 13-17 against HPV and had no intent to do so in the next 12 months were asked the main reason behind this decision. Reasons were grouped into eight domains. A multinomial logistic regression model stratified by sex was used to assess changes in the likelihood of each domain for 2020 and 2021 in comparison to 2019.

Results: A significant interaction between the reasons for lack of intention to vaccinate against HPV and year by sex was documented ($p<0.001$). For males, the odds of parents reporting vaccine misinformation (ORadj: 1.30, 95% CI: 1.26, 1.35), safety and effectiveness concerns (ORadj: 1.08, 95% CI: 1.05, 1.12), systemic barriers (ORadj: 2.57, 95% CI: 2.48, 2.66), lack of knowledge (ORadj: 1.44, 95% CI: 1.39, 1.49), sociocultural barriers (ORadj: 3.20, 95% CI: 3.09, 3.32), already UTD (ORadj: 2.48, 95% CI: 2.39, 2.56), and handicapped/special needs/illness (ORadj: 1.88, 95% CI: 1.79, 1.97), were significantly higher in 2021 compared to 2019. Whereas for females, the odds of reporting vaccine misinformation (ORadj: 0.48, 95% CI: 0.46, 0.50), safety and effectiveness concerns (ORadj: 0.32, 95% CI: 0.30, 0.33), systemic barriers (ORadj: 0.55, 95% CI: 0.52, 0.58), lack of knowledge (ORadj: 0.32, 95% CI: 0.31, 0.34), sociocultural barriers (ORadj: 0.44, 95% CI: 0.42, 0.46), already UTD (ORadj: 0.55, 95% CI: 0.53, 0.58), and handicapped/special needs/illness (ORadj: 0.28, 95% CI: 0.26, 0.30), were significantly lower in 2021 compared to 2019.

Conclusions: The main domain reported was vaccine misinformation. Parents of males were more likely to report all domains in 2021 compared to 2019, the inverse of females. These can be addressed through public health interventions such as launching media campaigns to combat vaccine misinformation tailored to parents of male adolescents.

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#9227

P03-06 | HPV latency: Frequency and genotypes in women from Fortaleza, Brazil

03 - Epidemiology and natural history

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Background/Objectives: Lower genital tract infection by Human Papillomavirus (HPV) can occur in a clinical latent form, where there is no lesion, but the DNA-HPV is detected by molecular biology. We aim to demonstrate the prevalence of latent HPV and the genotypes identified among women with normal exams from private clinics.

Methods: We studied samples from 1,350 women between 2024 April and October who underwent colposcopy, which resulted in negative results (absence of inflammatory changes and lesions) and simultaneously with negative liquid-based cytology for malignancy and without cytological signs of inflammation or dysbiosis. An aliquot was removed from the samples collected for liquid-based cytology and processed for polymerase chain reaction (PCR) testing on a multiplex platform to identify 28 HPV genotypes (AnyplexTM II HPV28, Seegene do Brasil, Contagem, Brazil). Considering a 95% confidence interval, Fisher's exact test and Student's t-test were applied. The ethics committee (Unichristus) approved the study under number 4,256,021.

Results: The average age of women was 46.5 (standard deviation [SD]: 1.5) and the mode was 43. There were an average of 1.5 (SD:1.4) pregnancies, and the mode was zero. We identified HPV DNA in 115 (8.5%) cases. Latent HPV was more frequent in women under 45 years of age (11%) ($p=0.001$). Infections with more than 1 type of HPV were also more frequent among women under 45 years of age (39%) than in older (23%) ($p=0.02$). The frequency of latent infection decreases with age, starting at approximately 16% in those under 25 to approximately 5% in those over 65. The most frequent genotypes in general were the types HPV 52 (13.9%), HPV 53 (13.9%), HPV 58 (13%), and HPV 16 (10%). This frequency repeated in women less than 45 years old, but in older, the more frequent types were HPV 16 (13.9%), HPV 52 (11%), HPV 53 (11%), and HPV 35 (9%). The only type that had a significantly different frequency was type 58, which occurred more in women under 45 years of age (18%) ($p<0.05$).

Conclusions: Latent HPV has a frequency of around 8%, being higher among younger women. It often presents with infection by a single genotype, of which the most frequent are HPV 52, HPV 58, and HPV 16. However, HPV16 tends to be more frequent in women over 45 years of age.

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#9242

P25-02 | Heterogeneity in epithelial neoplasia of the cervix - a Romanian tale of cells and viruses

25 - Cervical neoplasia

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Background/Objectives: In 2023, cervical cancer ranked as the third most frequent cancer among women in Romania and the second most common cancer in women aged 15 to 44 years.

Methods: Our study aimed to determine the predominant HPV genotypes and examine their correlation with cervical pathology and epidemiological data. We provide comprehensive data on the distribution of HPV genotypes in patients diagnosed with cervical lesions, both squamous and glandular, who were admitted to our institution. A consensus cytologic and histopathologic review of the cases was conducted, classified using a simplified scheme based on the Bethesda system and WHO classification.

Results: HPV16 was identified as the most prevalent high-risk genotype, significantly associated with high-grade squamous intraepithelial lesions (HSIL) and invasive cervical cancer. HPV18 and HPV45 were frequently associated with glandular lesions and contributed significantly to invasive cases. Other high-risk genotypes, such as HPV31, HPV52, and HPV51, were associated with HSIL and cervical intraepithelial neoplasia grade 2/3 (CIN2/3). Although these genotypes were less prevalent, they still played a role in the progression of cervical lesions.

Conclusions: Multiple HPV infections were common in lower-grade lesions but tended to decrease in higher-grade lesions, where single high-risk HPV infections predominated. Globally, the prevalence and genotype distribution of HPV infection vary significantly, along with their association with different histological subtypes. Despite the implementation of cancer control strategies and vaccination programs, a high number of HPV-related cancers remain poorly characterized.

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#9244

P05-01 | The role of HLA-G polymorphisms in HPV serological responses

05 - Immunology

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Background/Objectives: Human Leukocyte Antigen G (HLA-G) alleles play a crucial role in regulating immune responses, particularly in promoting maternal-fetal immunotolerance. While associations between HLA-G and the natural course of the human papillomavirus (HPV) infections and related pathologies have been previously studied, no research has focused on the serological aspect. This study was aimed to assess the potential associations between HLA-G alleles and genotypes with serological HPV outcomes in unvaccinated women.

Methods: This study utilized data from the Finnish Family HPV cohort, conducted at Turku University Hospital and the University of Turku, Finland. A total of 265 mothers were included. HLA-G alleles and genotypes were determined with direct DNA-sequencing, while HPV serology for L1 antigen of HPV types 6, 11, 16, 18 and 45 were measured through multiplex serology at baseline and at 12-, 24- and 36- month follow-up visits. The impact of HLA-G polymorphisms on HPV-specific seropositivity, serodecay, and seropersistence was analyzed using logistic regression.

Results: Six different alleles and six different genotypes were identified. The heterozygote HLA-G allele 01:01:01 significantly increased the likelihood of persistent seropositivity for HPV16 (OR 2.99, 95% CI 1.13-7.91). The HLA-G 01:01:03 in its heterozygote form was linked to an increased likelihood of seropositivity for HPV11 (OR 3.93, 95% CI 1.49 - 10.39) and persistent seropositivity for HPV11 (OR 4.42, 95% CI 1.56-12.49), while the heterozygous HLA-G 01:04:01 allele decreased the likelihood of HPV11 seropositivity (OR 0.43, 95 % CI 0.20 - 0.91). HLA-G genotype 01:01:01/01:01:03 also increased the likelihood of HPV11 seropositivity (OR 3.76, 95% CI 1.39 - 10.13) and persistent seropositivity for HPV11 (OR 4.57, 95 % CI 1.51 - 13.00).

Conclusions: HLA-G alleles and genotypes significantly influence HPV serological outcomes, particularly persistent seropositivity, in unvaccinated women. These results suggest that further studies with larger cohorts are needed to better understand the role of HLA-G in HPV-related serological responses and its potential implications for disease progression.

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#9249

P18-01 | Mollicutes and bacteria that are associated with cervicitis. What is the relationship with bacterial vaginosis?

18 - Microbiome

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Background/Objectives: Bacterial vaginosis (BV) is a complex dysbiosis condition that may be correlated with agents present in the cervix that can potentially cause cervicitis. Chlamydia trachomatis (Ct), Trichomonas vaginalis (Tv), and Neisseria gonorrhoeae (Ng) are agents that are often associated with cervicitis and appear to be associated with vaginal dysbiosis. More recently, Mycoplasma genitalium (Mg) has been studied. However, there are still doubts about Ureaplasma urealyticum (Uu), Ureaplasma parvum (Up), and Mycoplasma hominis (Mh). We aim to demonstrate the frequency of Ct, Ng, Tv, Mg, Mh, Uu, and Up in women with bacterial vaginosis compared to women with normal cytological findings.

Methods: 450 women diagnosed with bacterial vaginosis by cytological criteria (>20% of "clue cells") and 462 women with normal liquid-based cytology were studied. All of them had normal colposcopy. An aliquot was removed from the samples collected for liquid-based cytology and processed for polymerase chain reaction (PCR) testing on a multiplex platform to identify seven microorganisms (Ct, Ng, Tv, Mg, Mh, Uu, Up) (AllplexTMSTI Essential Assay, Seegene do Brasil, Contagem, Brazil). Considering a 95% confidence interval, Fisher's exact test was applied. The ethics committee (Unichristus) approved the study under number 4,256,021.

Results: The mean age of women with BV was 38.4 (+10.9), and of women with normal cytology was 38.4 (+10.9). The mean number of pregnancies was 1 (+0.8) and 1.5 (+1.2) for the vaginosis and normal groups, respectively. Among women with BV, cervicitis agents were identified in 311 cases (69%) versus 132 (28.6%) in the normal group ($p<0.05$). Specifically evaluating the microorganisms, it was observed in the BV and normal groups, respectively: Ct in 11 (2.4%) and 3 (0.6%) ($p<0.05$); Ng in 2 (0.4%) and 0 (p NS); Tv in 2 (0.4%) and 0 (p NS); Mg in 7 (1.6%) and 1 (0.2%) ($p<0.05$); Mh in 184 (40.7%) and 9 (1.9%) ($p<0.05$); Uu in 72 (16%) and 15 (3.2%) ($p<0.05$); Up in 210 (46.7%) and 120 (25.9%) ($p<0.05$).

Conclusions: Due to the small number of cases, it was impossible to establish a relationship between Ng and Tv with BV. However, the others (Ct, Mg, Mh, Uu, and Up) had a significant association with bacterial vaginosis.

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#9252

P39-09 | Understanding the association between initiating HPV vaccination at age 9 and 10 and the overall trend in proportion of children vaccinated in Iowa, US

39 - Public health

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Background/Objectives: HPV vaccination uptake in the US remains low: in 2023, only 46% of adolescents aged 13 years had completed the series. There has been recent interest in encouraging vaccination at ages 9-10, however little is understood about current vaccination behavior at this age. Immunization registry data is one method for exploring this. Furthermore, given the recent evidence regarding the efficacy of one dose of the HPV vaccine, assessing initiation rates rather than completion rates may be more relevant. We aim to understand trends in age groups initiating vaccination by using data from the Iowa Immunization Registry Information System (IRIS).

Methods: Data from IRIS inclusive of children vaccinated at age 9 or greater from 2017 to 2023 in Iowa were used. The proportion of children who received one dose of the HPV vaccine each year in three age groups (age 9-10, age 11-12, and age 12 and over) was calculated. The Mann-Kendall test was used to detect whether there was a monotonic trend in the proportion of children vaccinated over time in each age group. This test was conducted for each age group. We report Kendall's correlation coefficient (T) and corresponding p-values.

Results: Our sample included 228,187 children who initiated vaccination. The average percent who initiated vaccination each year was 2.6% for 9-10-year-olds, 65.3% for 11-12-year-olds, and 32.5% for those aged 12 and over. Over time, there was a general decline in the proportion of 9-10-year-olds vaccinated ($T = -0.33$, $p < 0.001$) and the proportion of 11-12-year-olds vaccinated ($T = -0.88$, $p = <0.001$). The proportion of those 12 and older vaccinated increased over time ($T = 0.88$, $p < 0.001$).

Conclusions: In our sample, over time, there was a decrease in the proportion of children initiating the HPV vaccine at age 9-10 and 11-12, while the proportion of children older than age 12 initiating the vaccine increased. These trends may be due to barriers to accessing healthcare imposed by the COVID-19 pandemic, forcing parents to "catch up" on vaccinations at an older age. Future studies comparing changes in proportions of age groups being vaccinated from year-to-year may help to elucidate reasons for these trends.

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#9262

P39-02 | Annual reports for the Slovenian cervical cancer screening program providers in the context of the quality assurance framework

39 - Public health

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Background/Objectives: Since the introduction of the Slovenian national cervical cancer screening programme (ZORA programme) in 2004, the reports for screening providers have helped to maintain a high standard of cervical cancer screening. Over the years, these reports have evolved to include up to five Key Performance Indicators (KPIs) per field, as specified in the Programme Guidelines. The KPIs and other indicators included in the reports are defined in detail in the Methodological Guidance for ZORA Indicators. In gynecology, the KPIs focus on timely sample transport and compliance with national guidelines, particularly for follow-up after low-grade abnormalities and post-treatment surveillance. Meanwhile, KPIs for laboratories emphasize minimum workload requirements, turnaround times, and consistency of results compared to national averages, including longitudinal CIN2+ detection rates. By incorporating programme KPIs, the reports have become an integral part of the quality assurance framework and support the structured external review protocol of the ZORA programme. This overview explains how these reports are produced and their role within the broader quality assurance framework of the ZORA programme.

Methods: The reports are based on data from the population-based screening registry (ZORA registry), which employs rigorous data quality controls to ensure accuracy and completeness at a national level. The reports are produced using a reproducible reporting system and are based on the R programming language, Markdown syntax, supported by the Quarto framework. Initial calculations are performed for specific levels (e.g. individual gynecologists, laboratories, cytoscreeners, etc.), which are then processed using R scripts that perform the required calculations and generate tables, plots, and textual interpretations and compiled into reports in HTML format. The reports are automatically generated and distributed electronically, improving accessibility and reducing the potential for manual errors.

Results: Reports are generated for all (over 400) gynecologists (smear takers), eight cytology and eleven histology laboratories, for each of the last five years. The reports contain interactive visualizations, tables, and interpretations of the results. The results from the screening providers are benchmarked against national averages and set target values. The interactive nature of the reports allows for an in-depth review of results, facilitating a better understanding of performance indicators and areas needing improvement. The annual expert review involves inspecting these reports to identify significant deviations from the recommended standards. Any provider with notable deviations may be subject to additional analysis or further review.

Conclusions: The annual reports for ZORA programme providers serve as an important tool for programme quality assurance and as a feedback mechanism for screening providers, identifying clinically significant deviations and highlighting potential improvements for the screening programme.

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#9264

P24-02 | Discrepancies between cytology, colposcopy and histology: How to act?

24 - Colposcopy

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Background/Objectives: Cervical cancer is the fourth most common cancer among women worldwide, and Human Papillomavirus(HPV) is responsible for more than 95% of these. In Portugal, organized cervical cancer screening is based on HPV test, combined with reflex cytology(if HPV not 16/18). In case of a positive screening, the performance of colposcopy and directed biopsy helps to complement patient's assessment and define therapy. However, some cases pose greater complexity, especially when there's a discrepancy between cytology, colposcopy and results from biopsies. Several factors may contribute to this, although evidence is often contradictory. Additionally, the approach to these cases varies significantly among colposcopists, leading to unequal management. The primary objective of this study was to evaluate the outcomes and therapeutic strategies established for patients with some type of cytological-colposcopic-histological discordance(CCHD). The secondary objective was to assess the variables potentially associated with the presence of these discrepancies.

Methods: An observational retrospective cohort study was conducted on patients that entered Cervical Cancer Screening on the region of Lisboa e Vale do Tejo, in Portugal, and were referred for consultation at Instituto Português de Oncologia de Lisboa, in 2022. Descriptive and comparative statistical analysis were performed using SPSS.

Results: A total of 257 women were evaluated, with an average age of 44.3 ± 9.4 years. Of these, 48.8%(n=125) were smokers, 84.8%(n=218) were multiparous and 21.4%(n=55) used combined hormonal contraception (CHC). Only 3.4%(n=8) were vaccinated por HPV. Among all patients, 19.4%(n=73) had some form of CCHD. The comparative study revealed that women with CCHD were more frequently multiparous (p=0.04;OR 2.4(95%CI 1.1-6.1)) and used more CHC (p=0.02; OR 2.2 (95%CI 1.2-4.1)). Regarding HPV genotypes, cytological changes, and colposcopic findings, statistically significant differences were only observed between groups in the latter variable (p<0.0001), with fewer normal colposcopies in the discordant group (p<0.0001;OR 5.2(95%CI 2.9-9.7)) and more colposcopies with grade 1 (p<0.0001;OR 2.9 (95%CI 1.6-5.1)) and grade 2 findings (p=0.03;OR 2.9(95%CI 1.4-5.8)) compared to women in the non-discordant group. Furthermore, more biopsies were performed in the group of women with discrepancies (p<0.0001; OR 4.4 (95% CI 2.5 - 8.0)). Regarding the decision between monitoring versus treatment, a statistically significant difference was also found, with a higher number of women in the CCHD group undergoing conization (p<0.0001;OR 6.5(95%CI 3.5-12)). Of these, nearly a third presented low-grade lesions or no dysplasia in the specimen, compared to only 10% in the comparison group. At one-year follow-up, 46.7%(n=86) of women in the control group were sent back to screening, versus only 24.7%(n=18) in the CCHD group (p=0.0001).

Conclusions: In summary, this study found that multiparity and use of CHC seem to be associated with greater CCHD. Also, women who present with any kind of discrepancy are more frequently subjected to biopsies, more surgical treatments and stay longer in hospital follow-up likely due to the difficulty in discerning which cases are of greater severity. In the event of discordance, it is essential to integrate all clinical and histopathological data of each patient in order to maximize the treatment of those indicated and avoid overtreatment and unnecessary morbidity.

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P33-01 | HPV and cervicovaginal bacterial co-infections in women with cervical Squamous Intraepithelial Lesions

33 - Sexually transmitted diseases and HIV infection

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Background/Objectives: Together with persistent hrHPV infection, virulent cervical inflammatory changes (either in the context of immune-mediated chronic cervicitis or resulting from bacterial pathogen infections) are intrinsic in the development of cervical precancerous lesions, especially in younger individuals. While recent research has mostly focused on alterations of vaginal microbiome and related microecology as triggers of hrHPV related carcinogenesis, the influence of cervical bac-terial STI co-infections on cervical precancer natural history is often overlooked. We aimed to investigate HPV-DNA positivity rates and possible co-infections with other sexually transmitted bacterial pathogens [Chlamydia trachomatis (CT)-Mycoplasma Hominis (MH)-Ureaplasma Urealyticum (UU) & Ureaplasma Parvum (UP)], in a population of women of reproductive age undergoing colposcopy mainly due to abnormal cytology. We also studied the co-variation of the above parameters with the histological grade of corresponding cervical biopsies.

Methods: Clinician obtained Thin-prep cervical samples were evaluated with LBC and underwent HPV DNA detection & genotyping (both LR- & HR-HPV's) as well as common STIs (Ct-Mg-Mh-Up-Uu) detection using NAATs. All women underwent colposcopically-guided cervical biopsies; full demographic and sexual history data have been also recorded.

Results: In this ongoing study, 222 women have been so far enrolled; with an average age of 33.1 years; only 36.7% had received the anti-HPV vaccine. Positivity rate for HR-HPV was 73.3%. Interestingly, all individuals with cytological HSIL tested positive for HR-HPV. Allarmingly, 56.6% of the study population tested positive for STIs. One hundred seven women (48.2%) tested positive for UP/UU, while other pathogens (CT/MH/HSV-1) were detected in only 19 women. In 142 women histology documented a low-grade lesion (CIN1) and in 72 individuals (32.4%) a high-grade lesion (CIN2+); chronic cervicitis has been documented in most of the remaining specimens.

Conclusions: The high prevalence of STIs commonly found in hrHPV-positive women referred for colposcopy who are per definition at elevated risk of developing cervical disease, indicate that comprehensive screening for genital infections in these populations may be justified. With ongoing research in anti-STI vaccines currently under development, a possible co-administration with the HPV vaccine might emerge as a cost-effective public health intervention. Furthermore, the potential for hrHPV and STI co-detection in vaginal or urine self-sampling material could eventually represent a ground-breaking strategy.

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P37-03 | Engaging 2SLGBTQ communities in HPV vaccination in Canada

37 - Health education

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Background/Objectives: HPV is a significant cause of cervical, anal, penile and oropharyngeal cancers in Canada. While HPV can affect individuals of all genders, immunization campaigns across Canada predominantly focus on women and the prevention of cervical cancers. These campaigns and communication strategies have resulted in prevailing misconceptions that the HPV vaccine is only for women and that HPV's association with cancer is limited to cervical cancer, resulting in lower rates of HPV vaccine uptake among men and 2spirit, lesbian, gay, bisexual and queer (2SLGBTQ) communities. Recognizing the limitations of prior campaigns and framings around HPV immunization, in 2020 Alberta, a province in Canada, expanded eligibility for people of any gender identity up to the age of 26 to receive publicly-covered HPV vaccines. However the proportion of LGBTQ people who report receiving an HPV immunization is still much lower compared to the general population. Studies show that gay and bisexual men have higher rates of HPV and a higher risk of anal cancer and other diseases related to HPV compared to heterosexual males. Similarly, there is a dearth of literature outlining the impact of HPV on 2 spirit communities in Alberta and their rates of HPV-related cancers. The lack of tailored information for 2SLGBTQ communities has resulted in lower HPV vaccine knowledge and immunization rates among this population. This community-based project brings together a team of public health professionals, researchers and 2SLGBTQ-serving organizations to increase HPV awareness in Alberta's 2SLGBTQ communities and support service providers in vaccination discussions.

Methods: Participants from across Alberta, a province in Canada, are being recruited Between November 2024 - January 2025 through organizations who serve 2SLGBTQ communities to participate in focus groups and interviews. The focus group guide was developed with community partners and tailored based on a literature of existing barriers and facilitators to HPV vaccinations for these populations. Focus groups will range in size from 6-10 participants. Eligible participants will be English speaking, over the age of 18, and reside in Canada. Transcripts from the focus groups will be thematically analyzed using an inductive thematic analysis approach and be used to codesign recommendations for tailored education.

Results: Results from this study will include themes related to barriers and facilitators to HPV vaccinations for 2SLGBTQ communities. Themes will be segmented by different subpopulations to provide a more nuanced understanding of the current perspectives of HPV vaccinations for queer communities and recommendations for resource tailoring aiming to support 2SLGBTQ communities with HPV vaccine education. These recommendations will also provide clarity about how to adapt Alberta Health Services' existing HPV Vaccine Decision Tool (http://hpvtool.healthiertogether.ca/) to be more gender inclusive.

Conclusions: Findings from this project will inform the development and dissemination of tailored, evidence-informed educational materials for 2SLGBTQ communities and service providers. These resources will result in a greater awareness of HPV vaccinations in 2SLGBTQ communities, thereby increasing vaccine uptake for queer communities in Alberta and supporting knowledge translation across Canada.

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#9280

P21-01 | Higher diagnostic accuracy of an artificial intelligence model for colposcopy compared to conventional and digital colposcopic evaluation

21 - Artificial intelligence - Big data - Machine learning

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Background/Objectives: Colposcopy is a subjective visualization of features that could indicate potential dysplasia on the cervix. The pattern recognition involved during colposcopy has the potential to be assisted by artificial intelligence (AI). Using previously collected colposcopy images with precise mapping of four biopsy locations and the corresponding histological diagnoses on each separate biopsies we have created an AI model, Cervix-AID-Net. This model is developed to correctly identify colposcopy images into the two categories: low-grade disease (less than cervical intraepithelial neoplasia (CIN) grade 2) and high-grade disease (CIN grade 2 or above). The study aimed to compare the performance of the Cervix-AID-Net AI colposcopy model to the performance of the DySIS colormap and colposcopists´ interpretations in correctly identifying low-grade and high-grade cervical disease.

Methods: All included colposcopy examinations were performed at Randers Regional Hospital, Denmark between February 2017 and September 2020, using a DYSIS colposcope Version 3. Colposcopists marked the biopsy site they considered most abnormal before the DYSIS map was revealed. The area identified as the most abnormal by the DYSIS map was marked as the second biopsy site. If these two sites overlapped, only one biopsy was taken from that area. A total of four biopsies were taken per examination, as recommended by the Danish national guidelines on colposcopy. All biopsies were analyzed separately. Additionally, colposcopists provided their interpretation of the cervix, as normal, low-grade or high-grade disease. A total of 3153 colposcopy images were included from 178 women. These images were annotated with the biopsy location and histological diagnoses of each biopsy and used to develop the Cervix-AID-Net model. We used 80% of images for development and 20% for testing of the algorithm. Sensitivity, specificity, positive and negative predictive value, and accuracy were calculated with 95% confidence intervals (CIs).

Results: In this study, we found that the newly developed AI model, Cervix-AID-Net, had a diagnostic accuracy of 99.8% (95% CI 99.6-99.9) to classify colposcopy images into low-grade and high-grade dysplasia categories correctly. The diagnostic performance was significantly higher than the accuracy of the DySIS color map (58.8%, 95% CI 51.1-66.1) and the accuracy of the colposcopist's visual impression of the cervix (55.1%, 95% CI 47.2-62.5%).

Conclusions: This first version of the Cervix-AID-Net AI colposcopy model demonstrated superior diagnostic accuracy compared to the evaluation provided by the colposcopist and the color-coded map of the DYSIS digital colposcope. The results need confirmation in a prospective clinical trial.

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P22-05 | Detection of HPV in pulmonary interstitium through bronchoalveolar lavage

22 - Diagnostic procedures / management

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Background/Objectives: The presented summary addresses a relevant study on the detection of Human Papillomavirus (HPV) in bronchoalveolar lavage (BAL) samples from patients with suspected interstitial lung diseases. This is an important research area, as the diversity of lung diseases represents a diagnostic challenge, and BAL has proven to be a valuable tool for molecular analyses (1,2), including the investigation of the role of HPV in lung carcinogenesis.

Methods: The study followed a cross-sectional analytical approach, with the collection of 132 BAL samples. After microscopic confirmation of the presence of epithelial cells and alveolar macrophages, 46 samples were selected for molecular analysis. DNA was extracted using a commercial kit, and the detection of HPV-DNA was performed by Nested-PCR, using the MY09/11 and GP5/6 primers. DNA extraction was confirmed by spectrophotometry and amplification of the ß-globin gene as an endogenous control.

Results: Of the 46 analyzed samples, 4 (8.69%) were positive for the presence of HPV. These positive samples were from patients without malignant lesions, but with suspected interstitial lung diseases, the majority being cases of hypersensitivity pneumonitis. The mean age of the patients with positive samples was 60.5 years, with 2 smokers and 2 non-smokers. Cytologically, the positive samples presented neutrophilia (>3%) as the only similar characteristic.

Conclusions: The presence of HPV in lung tissue has been reported since the late 1970s (3), but most studies use histological samples. Despite the recognition of the versatility of BAL, few studies have explored its use for the molecular analysis of HPV. This study demonstrates that the use of BAL for the prospection of HPV in the lung is feasible, as it is a sample that is easy to obtain and provides valuable molecular information. The detection of HPV in benign lesions can provide new insights into the action of this virus in non-gynecological tissues, especially in the lung, as its pro-carcinogenic activities are not yet well elucidated. Additionally, the early detection of HPV, combined with an inflammatory profile, may indicate the formation of a pro-viral infection microenvironment and, consequently, a predisposition to malignant transformation (4). Conclusion: In conclusion, this study presents relevant and innovative results, demonstrating the feasibility of using BAL for the detection of HPV in the lung. These findings may contribute to a better understanding of the role of HPV in the pathogenesis of lung diseases, opening new perspectives for the diagnosis and management of these conditions.

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#9301

P29-03 | HPV-related oropharyngeal cancer: Circulating and salivary DNA-based biomarkers for early diagnosis and recurrence monitoring

29 - HPV and oropharynx / Head and neck cancer

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Background/Objectives: Background: The incidence of oropharyngeal squamous cell carcinoma (OPSCC) has surged worldwide in recent decades. In the Czech Republic, annual OPSCC cases have more than tripled over 30 years, with nearly 800 new cases diagnosed in 2021, surpassing cervical cancer. OPSCC is now predominantly HPV-related, with about 25% of patients experiencing recurrence within five years. Liquid biopsies (plasma and saliva) are being investigated for their potential in diagnosis, treatment monitoring, and recurrence detection through DNA-based biomarkers.

Methods: Methods: HPV tumor status was assessed in newly diagnosed OPSCC patients and those in remission using HPV DNA detection in primary tumor tissue and p16 immunohistochemistry. Only cases positive for both HPV and p16 were classified as HPV-related OPSCC. HPV testing was conducted on liquid biopsies (gargle lavage, oropharyngeal swabs, and plasma) before and after treatment, with regular follow-up sampling.

Results: Results: A total of 151 OPSCC patients were enrolled in the study, with 81.8% classified as HPV-related, predominantly involving the HPV16 genotype (98.9% of cases). Pre-treatment analysis in liquid biopsies showed high sensitivities: 91.7% in gargle lavage, 96% in oropharyngeal swabs, and 95.8% for circulating tumor HPV DNA (ctHPV DNA) in plasma. Among recurrent HPV-related OPSCC cases, ctHPV DNA was detected in 75% (3/4) of cases, with 50% (2/4) also testing positive for oral HPV DNA.

Conclusions: Conclusion: This study seeks to validate liquid biopsy collection and DNA-based biomarker detection for early diagnosis and recurrence monitoring in HPV-related OPSCC patients. Preliminary results are promising, showing potential for early detection, even in early-stage OPSCC, and its clinical applicability. Supported by the Internal Grant Agency of Palacky University (IGA LF UP 2024_007 and IGA LF 2024_15), the project National Institute for Cancer Research (Programme EXCELES, ID Project No. LX22NPO5102) - Funded by the European Union - Next Generation EU, EATRIS-CZ (LM2023053), and MH CZ - DRO (FNOL, 00098892).

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P39-04 | Understanding attitudes and motivators for HPV vaccination among Canadian young adults: Insights from five national focus groups

39 - Public health

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Background/Objectives: Unvaccinated young adults (18 to 26 year-olds) are a high risk group for contracting an HPV infection. However, public health communication about Canada's HPV vaccine catch-up programs (e.g., for those who missed the vaccine during childhood) is inconsistent and inadequate for promoting uptake among this age group. To drive young adults towards HPV vaccination, a tailored approach to communication is required, including an in-depth understanding of this demographic's risk perception, awareness, and motivation to receive the HPV vaccine. Thus, to advance these efforts across Canada, the objectives of this qualitative study were to: (1) Identify current HPV awareness and knowledge gaps among Canada's young adult population; (2) Understand the barriers and facilitators for young adults accessing HPV vaccines in Canada; (3) Identify strategies for improving HPV awareness and vaccine uptake among young adults.

Methods: Participants from across Canada were recruited through a national polling panel to participate in a 90-minute virtual focus group. A focus group guide was developed by the research team using the Capability Opportunity Motivation Model of behaviour change (i.e. COM-B Model) [1], to understand barriers and facilitators for young adults in accessing the HPV vaccine in Canada. The target sample size for each focus group was 6-8 participants. Eligible participants were English speaking, aged 18-26, and residents of any province in Canada. No restrictions were placed on HPV vaccination status. The focus groups were conducted on Zoom, and were recorded and transcribed verbatim. The transcripts were subsequently analyzed using an inductive thematic analysis approach to identify common themes across the dataset . The research team collaboratively developed a codebook of common topics, and one researcher independently coded the dataset using Microsoft Excel. Two researchers then independently conducted a thematic analysis of the coded dataset, and agreed on a final list of analytical themes.

Results: Five national focus groups were conducted, with 32 participants (n=15 female, n=17 male). Six major themes were identified: (1) Participants' low personal risk perception for HPV infections is driven by low awareness about the virus and presumed safe sexual behaviours; (2) Young adults' vaccination choices are strongly shaped by parental influence and familial habits; (3) Fears about HPV's associated cancer risks are a major motivator for vaccine uptake in this age group; (4) Participants feel there is a lack of useful information available on HPV including provincial HPV vaccine eligibility and cost - which poses a major barrier to receiving the vaccine; (5) Participants are highly trusting of vaccine communication from "official sources', and would be encouraged to get the HPV vaccine if they saw tailored communication from these groups; and, (6) Participants are more likely to resonate with messages that balance fear appeals with actionable HPV vaccine information.

Conclusions: The results of this study can be used to inform future public health and HPV vaccine communication efforts to better meet the needs of young adults. Given the high motivation of this age group to protect themselves against HPV and HPV-related cancers, there is a clear opportunity to use tailored communication strategies to increase awareness and drive HPV vaccine uptake among Canada's young adult population.

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P22-01 | Efficacy of a multi-ingredient Coriolus versicolor-based vaginal gel on High-risk HPV clearance: final results from the PALOMA 2 Clinical Trial

22 - Diagnostic procedures / management

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Background/Objectives: High-risk (HR)-HPV infection is a critical precursor to cervical cancer. The PALOMA 2 Clinical Trial was designed to assess the efficacy of a Coriolus versicolor-based vaginal gel in facilitating HR-HPV clearance as one of the secondary endpoints.

Methods: Randomised, multi-centre, prospective, open-label, parallel-group, clinical trial with a watchful-waiting control group. Unvaccinated HR-HPV positive women between 30-65-year-old, with ASCUS/LSIL cytology and concordant colposcopy were randomised (1:1:1:1) into 4 groups with different Coriolus versicolor-based vaginal gel treatment regimens: A) Standard regimen: once daily for one month, followed by every other day for five months; B) Intensive regimen: once daily for three months, followed by every other day for three months; C) Very Intensive regimen: once daily for six months; D) Control group: watchful waiting approach. The study assessed HR-HPV clearance after six months, categorized as complete (negative HR-HPV test or no detectable baseline genotypes) or partial (disappearance of at least one genotype with normal cytology and concordant colposcopy). Ethical approval was obtained, and all participants gave informed consent. Results of arm A, B and C vs D on HR-HPV clearance after 6 months of treatment are presented.

Results: Of the 164 randomised patients, 124 with a mean age of 41.13 years were evaluated for efficacy. Of these, 46.8% were current or former smokers, with an average of 9.52 cigarettes smoked per day, with no significant differences between the groups. From the 109 patients (A=26; B=26; C=29; D=28) who completed the 6-month treatment, 53.8% (A), 88.5% (B), 75.9% (C) and 46.4% (D) obtained HR-HPV clearance (pAvsD=0.5860, pBvsD=0.0011 and pCvsD=0.0225). A subgroup of 56 patients positive for HPV 16 and/or 18 and/or 31 (A=14; B=15; C=14; D=13) with a mean age of 42.52 years was analysed and 57.1% (A), 93.3% (B), 64.3% (C) and 30.8% (D) experienced clearance after the 6-month treatment (pAvsD=0.1682, pBvsD=0.0011 and pCvsD=0.0816).

Conclusions: Viral clearance is particularly challenging in the studied population due to factors such as HPV genotype, age, and smoking status. Our findings indicate that the Coriolus versicolor-based vaginal gel, particularly when administered under the intensive regimen, significantly enhances HR-HPV clearance compared to watchful waiting approach. These results highlight the Coriolus versicolor-based vaginal gel as a proactive management option for HR-HPV positive women with low-grade cervical lesions.

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#9341

P09-01 | Development of an External Quality Assessment for the Detection of High Risk HPV Using Molecular Methods.

09 - HPV testing

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Background/Objectives: Since the introduction of human papillomavirus (HPV) testing using molecular methods, there has been much interest in its utility as a primary screening tool for cervical cancer. More and more healthcare systems are beginning to make the transition from Papanicolaou (Pap) test cytology, which has been the most prevalent screening method since the beginning of cervical cancer screening. The International Agency for Research on Cancer classifies 12 High-Risk HPV (hrHPV) genotypes (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, and 59) as Group I carcinogens1. The detection of hrHPV in cervical swabs using molecular techniques has been part of the Belgian social security system since 2009. To benefit from reimbursement, laboratories performing HPV testing must be accredited under the ISO15189 standard2 and participate in the External Quality Assessment (EQA) organized by Sciensano, the Belgian Institute for Health. This work aimed to develop proficiency testing for hrHPV following the ISO17043 standard3 in collaboration with the National Reference Centre (NRC) for HPV.

Methods: The samples included leftovers from the national cervical cancer screening stored in the NRC biorepository. Firstly, the samples were diluted in a transport medium and rigorously tested for homogeneity and stability. Secondly, samples were tested 4 times using the same method to evaluate reproducibility. The samples with reproducible results were considered homogenous. Thirdly, the homogenous samples were sent to expert laboratories examining 7 different molecular methods. Finally, only samples with concordant results were included in the Core panel. A sample with only one discrepancy was considered an educational sample. Based on these criteria 10 core samples and 4 educational samples were selected. The participants were licensed Belgian medical laboratories (n=46). The samples were sent to the participating laboratories at room temperature with instructions to analyze them as soon as possible and online encode the results within 15 days after the shipping date. The requested data included information about the presence or absence of hrHPV and detected genotypes. Nevertheless, the genotyping was not mandatory. Two weeks after the result encoding deadline, a preliminary report with expected results was available online for the participants. The results were discussed within the NRC and an expert committee to finally produce a global report with detailed insights.

Results: In total, 59 datasets (seeing that one laboratory could encode more than one dataset) were encoded representing 826 results. The core panel consisted of 8 positive samples, one negative sample, and one invalid sample (no DNA). Out of these 590 encoded core results, 584 (99%) were correct. The educational samples consisted of 4 positive samples but with low target concentrations. Out of these 236 educational results, 220 (93.2%) were correct. When all encoded results were considered, out of the 826 results, 804 (97.3%) were correct.

Conclusions: To conclude a unique, highly stable EQA panel was created composed of cervical samples covering a broad spectrum of hrHPV types, as well as covering real life scenarios. The proficiency testing was proven to be well organized, demonstrating a high degree of concordance between the participating laboratories. Future efforts should concentrate on making the EQA more applicable to different molecular techniques.

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#9345

P22-02 | Efficacy of intensive regimen of a multi-ingredient Coriolus versicolor-based vaginal gel in HR-HPV clearance: pooled results from the PALOMA 1 and PALOMA 2 clinical trials

22 - Diagnostic procedures / management

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Background/Objectives: PALOMA 1[1] was the first clinical trial demonstrating the efficacy of a Coriolus versicolor-based vaginal gel in repairing low-grade cervical lesions related to HPV. An intensive regimen proved to be effective on HPV clearance, a secondary outcome. Building on this, PALOMA 2 exclusively focused on a high-risk (HR)-HPV positive cohort, aiming to assess the efficacy of a Coriolus versicolor-based vaginal gel intensive regimen in promoting HR-HPV clearance, as a secondary outcome.

Methods: Randomised, multi-centre, prospective, open-label, parallel-group clinical trial with a watchful-waiting control group. Unvaccinated HR-HPV positive women aged between 30-65 with ASCUS/LSIL cytology and concordant colposcopy were randomized (1:1:1) into 3 groups with different Coriolus versicolor-based vaginal gel regimens: A) Standard regimen: once daily for one month, followed by every other day for five months; B) Intensive regimen: once daily for three months, followed by every other day for three months; C) Control group: watchful waiting approach. This analysis presents pooled results focusing on HR-HPV clearance at six months for the intensive regimen versus control. HR-HPV clearance was classified as either total clearance (defined as a negative HPV test or the disappearance of all species detected at baseline) or partial clearance (defined as the disappearance of at least one HPV genotype present at baseline, along with normal cytology and concordant colposcopy observations). All patients signed informed consent, and studies were approved by centralised IRBs.

Results: Data from 101 patients has been evaluated, 48 from the Coriolus versicolor-based vaginal gel group (PALOMA 1= 22; PALOMA 2= 26) and 53 patients from the control group (PALOMA 1= 25; PALOMA 2= 28). Significant increase of HR-HPV clearance was shown in the group treated with the Coriolus versicolor-based vaginal gel vs control group (85.4% vs 43.4%, p= 0.0024). The analysis of the sub-group of patients positive for HPV 16 and/or 18 and/or 31 at baseline also showed statistically significant results: 82.6% experienced HPV clearance in the Coriolus versicolor-based vaginal gel group, while only 37,0% in the control group (p= 0.0328).

Conclusions: These findings suggest that the intensive posology of a Coriolus versicolor-based vaginal gel significantly enhances HR-HPV clearance, highlighting it as a valuable clinical tool for managing HR-HPV infections compared to watchful waiting approach.

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#9349

P39-01 | PERCH guide for the development of national HPV communication strategy

39 - Public health

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Background/Objectives: Human Papillomavirus (HPV) vaccination is a critical component of cancer prevention, yet vaccination coverages across European Member States (MS) vary significantly due to differences in national health policies, public awareness, and communication strategies. To address these disparities, Project PERCH (PartnERship to Contrast HPV) has initiated efforts under Work Package 2 (WP2) to develop a PERCH Guide for the development of National HPV Communication Strategies. The guide aims to enhance the capacity of MS to design, implement, and evaluate effective HPV communication campaigns. By leveraging shared knowledge, experiences, and best practices across MS, the initiative seeks to support sustainable increases in HPV vaccination coverage throughout Europe.

Methods: The guide is being developed collaboratively under the leadership of the Institute of Oncology Ljubljana (Slovenia) and experts from the Norwegian Institute of Public Health, with input from communication and HPV vaccination specialists from 18 participating countries. The WP2 group, also known as the HPV Vaccination Guild, consists of over 70 members, with at least two representatives (one HPV expert and one communication expert) from each country. Regular online meetings and in-person workshops, facilitated the exchange of insights and refinements to the guide. The initiative also aligns with other EU-funded projects and NGO's focusing on vaccination.

Results: The guide presents a structured framework for creating National HPV Communication Strategies that can be adapted to the different needs and resources of each MS. Effective communication tactics such as "presumptive announcements" are emphasized. This approach helps frame HPV vaccination as a routine part of adolescent care. It involves healthcare providers assuming vaccine acceptance by presenting it as the standard or expected action. Instead of asking parents whether they want the vaccine for their child, providers might say, "Today your child is due for the HPV vaccine. HPV vaccine protects your child against HPV-related cancers." and "HPV vaccine is widely used in childhood vaccination programmes around the world. The vaccine is efficient and well tolerated. The vaccine is administered in the arm." This framing, which minimizes uncertainty or hesitation, has been shown to increase vaccine uptake. The guide also highlights best practices for combining multiple adolescent vaccines, including HPV, into a single healthcare visit to streamline the process for families. Currently, seven countries—Croatia, Czech Republic, Estonia, Hungary, Lithuania, Romania, and Slovenia—are piloting the guide. Recommendations included in the guide draw from successful national practices, facilitating knowledge exchange among MS.

Conclusions: The development of the PERCH Guide for National HPV Communication Strategies represents a significant step towards harmonizing HPV vaccination efforts across Europe. By fostering cooperation and knowledge-sharing among MS, the guide empowers each country to address the unique challenges they face in promoting HPV vaccination. This process has demonstrated the strength of collaborative networks, highlighting the importance of sustained partnerships beyond the project's duration. The guide is expected to be a valuable resource for MS, enhancing their communication efforts and contributing to higher HPV vaccination coverage, ultimately reducing the incidence of HPV-related cancers across Europe.

References: Project PERCH webpage: Home - PERCH Project (projectperch.eu)

Schematic diagrams

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#9367

P10-02 | Association of Human Papillomavirus (HPV) with genital microbiota and infections, in the general female population of Split and Dalmatia County: a prospective study

10 - HPV screening

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Background/Objectives: Human papillomavirus (HPV) infection is the main cause of cervical cancer (CC) and it can be proven in 99.7% of all cases of this cancer. The types that are most often associated with cervical cancer, called oncogenic or high-risk types (hrHPV), are: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68. Genotypes HPV-16 and HPV-18 have the highest oncogenic potential and are the cause of about 70% of all cervical cancer cases worldwide. The presence of HPV is necessary but not sufficient cause for CC development. The development of HPV-induced cancer is associated with some co-factors, like other sexually transmitted infections (STIs) and even the presence of a high diversity in the cervico-vaginal microbiota (CVM) The aims of the present study were: to determine the prevalence of HPV and HPV genotypes distribution in the general female population of Southern Croatia (Split and Dalmatia County, SDC), to detect the presence of other microorganisms in the lower part of the female reproductive system (either as part of the normal CVM or as causative agents of genital infections) and their possible influence on the frequency of HPV infection.

Methods: Data were collected during routine check-ups from four gynecological practices in different parts of the County, that were unaffiliated with the study. Selection bias was eliminated because the gynecologists sent samples of all women who came for regular gynecological examinations on specific predetermined days over a period of one year. All participants were examined by a gynecologist, and cervico-vaginal scrapings/swabs were collected, for cytological (Pap smear) and microbiological (for bacterial growth, genital mycoplasmas, chlamydia, and HPV) analysis. Informed consent was obtained from all participants with the accompanying structured questionnaire. The study has been approved by the Ethics Committee.

Results: A total of 1,050 asymptomatic women aged 17-74 years living in SDC participated in the study during a one year period, and 107 of them (10.2%) had HR-HPV infection. Among positive samples, the following genotype distribution was detected: HPV-16 in 35.5% of women, HPV-18 in 6.5% of cases, while the other HPV types were established in 83% of cases. Multiple HPV infections were found in 25% of positive specimens (27/107). We found that the presence of some bacteria (Ureaplasma, Chlamydia and Gardnerella) in the lower part of the female genital system has a positive correlation with the frequency of HPV infection and, consequently, a possible influence on faster progression to cervical dysplasia caused by HPV.

Conclusions: Data from this study on the prevalence and distribution of HPV genotypes in the general female population of southern Croatia could be valuable for the better organization of HPV-based cervical cancer screening and vaccination programs in this region and in Croatia. We consider that the inclusion of screening for sexually transmitted infections as monitoring in women with HPV infection could help identify women at risk of cervical cancer progression.

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#9374

P24-01 | AI-enhanced mobile colposcopy: Improving cervical screening accuracy and training for medical workers in LMICs

24 - Colposcopy

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Background/Objectives: Cervical cancer remains a leading cause of mortality among women in low- and middle-income countries (LMICs), largely due to limited access to specialized diagnostic tools and trained clinicians. The Swede score is a widely recognized scoring system for colposcopic evaluation of cervical abnormalities, but accurate scoring requires specialized expertise that is often scarce in LMIC settings. To address these challenges, we are developing an Artificial Intelligence (AI)-powered system to integrate the Swede score into our mobile colposcope. Our goal is to support medical workers, including nurses and midwives, by offering a dual-function tool that provides real-time diagnostic assistance and training. This AI system is designed to deliver high accuracy and is explainable, ensuring that users understand its recommendations and can build their diagnostic skills over time.

Methods: The AI model was developed using a large dataset of annotated colposcopic images rated according to the Swede score. Data augmentation and deep learning techniques were employed to improve model robustness, while explainable AI (XAI) methodologies were integrated to make the system's recommendations transparent and interpretable. The AI was trained to identify and grade colposcopic images across the Swede score's five criteria, offering automated scoring suggestions and visual cues that highlight specific cervical features relevant to the scoring system. This approach aims to enable users to gain insights into colposcopic image assessment, promoting learning while supporting accurate clinical decisions. Validation studies were conducted to assess the model's accuracy, focusing on the alignment of AI-generated scores with those of experienced colposcopists.

Results: Initial validation demonstrates that the AI achieves high accuracy, closely mirroring expert scores with high agreement rate across the Swede score categories. Importantly, the explainability component was positively received by medical workers, who reported a greater understanding of the Swede score criteria and improved confidence in interpreting colposcopic findings. In simulated use cases, the tool reduced diagnostic variability and provided consistent training reinforcement, highlighting its potential as a scalable solution for cervical screening. Pilot testing in an LMIC context confirmed that the AI's real-time guidance improved user decision-making, particularly among nurses and midwives with limited prior colposcopy experience.

Conclusions: Our AI-enhanced mobile colposcopy system demonstrates substantial promise in supporting cervical cancer screening in LMICs by empowering local medical workers with an accessible, effective, and educational tool. Through high diagnostic accuracy and an explainable interface, this AI tool addresses the dual need for diagnostic assistance and skill-building in resource-constrained environments. Future directions include larger-scale field testing and further refinement of the explainability features to optimize user engagement and educational impact. This innovation represents a significant advancement in equitable cervical cancer prevention and highlights the potential of AI in supporting sustainable health solutions in LMICs.

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#9378

P23-01 | Single versus multiple-genotype human papillomavirus infections and its association with high-grade cervical lesions

23 - Risk management

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Background/Objectives: Human papillomavirus (HPV) infection is the primary cause of cervical cancers and their precursor lesions. Understanding the pathophysiology of HPV is essential for enhancing screening methods and clinical surveillance. We aim to compare single and multiple-genotype HPV infections, regarding histological-type cervical intraepithelial lesions.

Methods: This observational retrospective study included 409 women with HPV infection referred to the Cervical Cancer Screening Appointment in a tertiary hospital, between January 1st and December 31st, 2022. Our sample was divided into two groups: single-genotype and multiple-genotype HPV infection. Clinical information was gathered from hospital records, and statistical analysis was conducted using SPSS® version 27, employing the χ^2 test.

Results: Single-genotype HPV infection was the most common, occurring in 245 women (59.9%), compared to 160 women (39.1%) with multiple-genotype infections. There were no differences between the two groups, in terms of age, parity, number of sexual partners, smoking, menopause, and vaccination history. HPV 16 was the most prevalent genotype in both single and multiple-genotype groups (83/245, 33.9% vs 61/160, 38.1%, p-value > 0.05). Histological analysis revealed no significant differences in the types of cervical intraepithelial lesions, except for CIN2 (23/245, 9.4% vs 28/160,17.5%, p-value<0.05), which was more frequent in the multiple-genotype HPV group.

Conclusions: In our study, HPV-16 was identified as the most prevalent genotype in both single and multiple-genotype HPV infections. The impact of multiple-genotype HPV infections on the histological types of cervical intraepithelial lesions appeared limited, likely due to the predominant presence of HPV-16 in these cases.

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#9382

P10-04 | Human Papillomavirus in men: screening in spanish high-risk populations and genotype profile

10 - HPV screening

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Background/Objectives: Although the routine use of human papillomavirus (HPV) screening techniques may not be necessary in the general male population, recent research findings suggest that the incidence and prevalence of HPV infection are higher among high-risk populations, specifically men who have sex with men (MSM) and HIV-positive men. This evidence supports the adoption of additional screening measures. Persistent genital or oral infection with oncogenic HPV types, primarily HPV-16 and -18, is the primary etiological agent in squamous cell carcinoma of the anus, tonsils, and base of the tongue. This work studies the prevalence of anal and pharynx HPV infections in at-risk populations (MSM and HSM) and their relation to clinical.

Methods: We studied 104 men from the Dermatology (54, 51,4%), Infectious Diseases (45, 42,9%), and Otorhinolaryngology (6, 5,7%) clinics. Patients suspected of having sexually transmitted infection (STI) underwent anal and pharyngeal swab sampling. In those patients with dermal or mucosal lesions, samples were taken from the lesions and pharyngeal or oral exudates. MSM in infectious diseases were offered HPV vaccination. All samples were studied to detect HPV infection using a real-time PCR technique, which allowed us to differentiate between the genotypes of high and low risk. This technique was performed using the AllplexTM HPV28 Detection kit (Seegene). A total of 19 high-risk and probable high-risk genotypes (16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 73, 82) and 9 low-risk genotypes (6, 11, 40, 42, 43, 44, 54, 61, 70) were studied, along with an internal control.

Results: The mean and the median age was 40 and 39 years, respectively. Of these, 54 (51,4%) were MSM and four are people living with HIV. The reason for consultation was to request PrEP medication (40), and in other cases, due to findings of dermal or mucosal lesions in the genital, anal or other areas of the body. We found 29 patients with condyloma (12 anal and 18 genital), 5 with squamous cell carcinomas (nasal, labial, and cutaneous), and one penile intraepithelial neoplasia (PeIN), pharyngeal squamous cell carcinoma, inguinal angiosarcoma, and oral/pharyngeal papillomatosis. We detected a total of 80 HPV-positive cases among all the samples studied. Among MSM, the most frequently detected oncogenic genotypes in rectal exudates are 51 (12), followed by 16 (11), 31 and 59 (8 both) and 18 (5). Among the low-risk genotypes, the most frequent is 6 (11). Most patients have more than one genotype (27) in the same sample. Only 9 cases of them presented clinical signs of anal condyloma. Among heterosexuals (HSM), in whom dermal lesions were biopsied, only 4 cases VPH-16 were detected (one penile intraepithelial neoplasia and another squamous cell carcinoma), one with VPH-18, and 3 with other oncogenic genotypes. HPV-6 was detected in 19 cases and HPV-11 in 5. In all these cases, the diagnosis was condyloma. In our study, 41 patients (39%) were vaccinated with the recombinant HPV nonavalent vaccine at the time of healthcare attendance.

Conclusions: It is important to conduct HPV infection screening in individuals with high-risk sexual practices to understand the most prevalent infections in our environment. It is essential to genotyping all lesions suspected of infection to determine the implications of different genotypes in oncogenesis. We advocate for the vaccination of men, to prevent oropharyngeal, anal, and penile cancers.

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#9387

P14-04 | Change in prevalence of High-Risk HPV genotypes Our experience in the Lazio Region cervical cancer screening

14 - Genotyping

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Background/Objectives: To prevent cervical carcinoma, molecular screening of the 14 High-Risk (HR) genotypes of the Human Papilloma Virus (HPV) is performed in our centralized reference laboratory. Epidemiological studies carried out both in Europe (1-2) and in the United States have shown that genotype 16 was the most detected. The prevalence data are different in Asia and in Africa where the genotypes 52 and 58 are reported as the prevalent followed by 16 and 18. Due to the effect of vaccination campaigns and migratory flows, the distribution of HR genotypes may have undergone modification in recent times. The aim of this work is to evaluate the distribution of the different HR- HPV genotypes in the last three years.

Methods: In this work we analysed data obtained from January 1st to October 31st of the years 2022 (24,423 cases), 2023 (48,000 cases) and 2024 (47,556 cases). Nucleic acid isolation was performed using the automated extraction and PCR setup platform STARlet IVD (Seegene), coupled with the Vial Cap Management System (VCMS, Hamilton) and the STARMag 96 x 4 Universal Cartridge extraction Kit (Seegene). This assay allows the detection and genotyping of 14 HR-HPV subtypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. Interpretation results were automatically achieved via the Seegene Viewer.

Results: In the first 10 months of 2022, due to restrictions related to COVID-19 pandemic, 24,423 samples were analysed, with 3,850 HR-HPV genotypes identified: 675 (17.53%) 16,156 (4.05%) 18, 478 (12.41%) 31, 131 (3.40%) 33, 81 (2.10%) 35, 212 (5.51%) 39, 176 (4.57%) 45, 270 (7.01%) 51, 303 (7.87%) 52, 276 (7.17%) 56, 241 (6.26%) 58, 198 (5.14%) 59, 292 (7.60%) 66, 361 (9.38%) 68. In the relative 10 months of 2023 48,000 were processed and the HR-HPV detected were 9,488: 1266 (13.34%) 16,419 (4.42%) 18, 1162 (12.25%) 31, 335 (3.53%) 33, 255 (2.69%) 35, 468 (4.93%) 39, 490 (5.16%) 45, 668 (7.04%) 51, 748 (7.89%) 52, 735 (7.75%) 56, 633 (6.67%) 58, 505 (5.32%) 59, 764 (8.05%) 66, 1040 (10.96%) 68. From January to October 2024 47,556 samples were examined and 10,290 HR-HPV were detected: 1286 (12.50%) 16,431 (4.20%) 18, 1300 (12.64%) 31, 374 (3.64%) 33, 309 (3.00%) 35, 492 (4.78%) 39, 452 (4.39%) 45, 755 (7.33%) 51, 739 (7.18%) 52, 789 (7.67%) 56, 744 (7.23%) 58, 608 (5.90%) 59, 872 (8.47%) 66, 1139 (11.07%) 68.

Conclusions: Our data shows that the global prevalence of HR-HPV detected has remained substantially unchanged but the analysis of the prevalence of the different genotypes detected shows a decreasing trend for HPV 16, which has been overcome by genotype 31. These data are probably linked to vaccination campaigns. Furthermore, the data regarding the progressive increase of genotype 68 is interesting, considering that is not present in the nine-valent HPV vaccine and is in third place in prevalence after genotypes 31 and 16.

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#9388

P22-04 | Persistence of high-grade cervical lesions and HPV in women with positive margins post-LEEP: A retrospective study

22 - Diagnostic procedures / management

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Background/Objectives: Cervical intraepithelial neoplasia (CIN) is primarily driven by persistent high-risk HPV infection. Loop electrosurgical excision (LEEP) is commonly employed to treat high-grade lesions; however, positive margins post-procedure increase the risk of residual disease, and have higher likelihood of persistent HPV and high-grade lesions, yet optimal follow-up strategies remain unclear. This study aims to investigate lesion and HPV persistence in women with positive margins after LEEP.

Methods: This observational retrospective analysis included women referred to a tertiary hospital's Cervical Cancer Screening Appointment in 2022, who underwent LEEP with confirmed positive margins. Outcome measures included the persistence of high-grade lesions and high-risk HPV, assessed through cytology and HPV testing at the first follow-up within one year post-LEEP. Clinical data were extracted from hospital records, and statistical analysis was performed using SPSS® version 29, applying the χ^2 test to evaluate associations between variables.

Results: Twenty-six women with positive margins following LEEP were included in the study. Cervical cytology before LEEP revealed that 17 women (65.4%) had low-grade lesions (including NILM, ASCUS, ASCH, and LSIL) and 9 women (34.6%) had high-grade lesions (HSIL, squamous cell carcinoma, or adenocarcinoma). HPV typing showed that 9 cases (34.6%) were positive for HPV 16, 2 cases (7.7%) for HPV 18, 9 cases (34.6%) for other types excluding 16 and 18, and 6 cases (23.1%) for both HPV 16 and other types. The distribution of transformation zone types was as follows: TZ1 in 13 women (50%), TZ2 in 5 women (19.2%), and TZ3 in 7 women (26.9%). Post-LEEP histology indicated CIN2 in 8 cases (30.8%), CIN3 in 14 cases (53.8%), squamous cell carcinoma in 2 cases (7.7%), and adenocarcinoma in 2 cases (7.7%). Regarding margin status, 13 women (50%) had positive internal margins, 8 (30.8%) had positive external margins, and 6 (23.1%) had both positive internal and external margins. Seven women (26.9%) required re-conization, while 19 women (73.1%) maintained follow-up despite positive margins. High-grade lesion persistence was observed in only 1 woman (3.8%, HSIL), while the remaining cases displayed low-grade lesions. Persistent HPV infection was noted in 5 women (19.2%). Notably, no statistical association was found between margin type and the persistence of high-grade lesions or HPV ($p>0,05$).

Conclusions: This study reveals that despite having positive margins following LEEP, many women maintained low-grade lesions, indicating that an expectant approach with careful follow-up may be a viable strategy instead of immediate re-conization. Persistent high-risk HPV was found in a minority of cases, primarily types 16 and 18. These findings underscore the importance of individualized monitoring for this population. Further research is needed to optimize follow-up protocols and enhance patient outcomes.

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#9392

P09-03 | Automated technology implementation for high-risk HPV genotype detection: Validation and analytical performance

09 - HPV testing

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Background/Objectives: This study evaluates the implementation of robotic technology for high-risk Human Papillomavirus (HPV) genotype detection using two approaches: a technical validation of the AnyplexTM II HPV HR Detection (Seegene) system against the routine Clart HPV system and an analysis of analytical sensitivity and specificity relative to cytology.

Methods: In the first approach, 400 samples were processed with the Clart HPV system and subsequently with the Seegene system to validate its accuracy following routine processing. Samples were prepared by rehydration in liquid phaseand aliquoted using COPAN's UNIVERSE station; nucleic acid extraction and PCR were then automated on the STARlet-AIOS platform. Of the 400 samples, 85 were positive with Clart HPV; of these, two samples were undetected in Seegene's 14-genotype panel but were identified through a 28-genotype extended kit, highlighting the importance of broader coverage. Among initially negative samples, two were positive with Seegene and confirmed by a third technique, underscoring the sensitivity of Seegene's system in detection.

Results: The second approach focused on the study of sensitivity and specificity of the robotic technology compared to cytology. In this analysis, 1,450 samples were included, classified by cytology into risk and negative categories. The robotic technology detected 98 positive samples without morphological lesions, demonstrating its efficacy for early detection. In ASCUS-classified samples, a slight decrease (<5%) in HPV detection with the new kit was observed in low-risk cases, while in high-risk lesions (CIN3 and CIN4), only two false negatives were recorded. These differences may be attributed to both the limited coverage of Seegene's 14-genotype panel compared to Clart HPV's 35-genotype panel and sample preservation factors. Moreover, the robotic technology significantly optimizes technical intervention time: while manual processing with Clart HPV requires 90 minutes of hands-on working time, for 48 samples, the automated UNIVERSE-STARlet system (COPAN-SEEGENE-WERFEN) reduces this time to less than 15 minutes for complete plates of 96 samples, owing to continuous processing integration.

Conclusions: The implementation of this robotic technology represents a robust and efficient alternative for HPV screening programs, with substantial potential to enhance preventive strategies against cervical cancer.

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#9393

P03-05 | Survival in HPV-positive oropharyngeal squamous cell carcinoma: An analysis of competing risks based on smoking and alcohol consumption

03 - Epidemiology and natural history

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Background/Objectives: Oropharyngeal squamous cell carcinoma (OPSCC) is associated with tobacco use, alcohol consumption, and lower fraction of human papillomavirus (HPV) infection[1],[2]. Kaplan-Meier (KM) is widely employed to estimate survival probabilities in cancer research; however, caution is warranted when assessing, outcomes may be affected by various causes of death. Competing risks occur in situations where multiple causes of failure exist[3]. Objectives: To estimate the cumulative-risk (CR) and death-probability (DP), considering the presence of competing risks in patients with HPV-positive (HPV+) OPSCC stratified by smoking/drinking status.

Methods: Retrospective cohort study at a single center in Brazil, enrolling patients with OPSCC, with data on sociodemographic, clinical, and lifestyle factors. Participants were classified as smokers/drinkers (including former smokers/formers drinkers) and non-smokers/non-drinkers. CR was estimated using KM up to 8 years, while DP was determined using the Cumulative Incidence Function (CIF). CIF calculates the probability of an event occurring while accounting for competing risks. The analyzed competing risks included death from cancer and death from other causes, with analyses performed based on smoking/drinking status.

Results: Among the 303 patients with HPV+ OPSCC, 124 (42.7%) were smokers/drinkers and 91 (31.4%) non-smokers/non-drinkers. A total of 58 (19.1%) patients experienced the event of interest, comprising 35 deaths attributable to cancer and 23 deaths from other causes. The CR for all causes in 5 and 8 years was 18% and 42% for smokers/drinkers, 24% and 33% for smokers/non-drinkers. For cancer deaths, the CR for non-smokers/non-drinkers was 7.9% and 10.0% at 5 and 8 years, respectively, DP was 7.6% in 5 years and 9.6% at 8 years. The smokers/drinkers group had a CR of 20.0% and 30.0% at 5 and 8 years, corresponding to a DP of 19.5% and 28.4%. Regarding death from other causes, CR for non-smokers/non-drinkers was 5% over 5 years with a DP of 4%, while smokers/drinkers exhibited a CR of 10.0% at 5 years and 16.0% at 8 years, with corresponding DP of 8.0% and 13.5%, respectively. Other results by CIF indicated that the 5-year DP for cancer was 3% for smokers/non-drinkers and 3% for non-smokers/drinkers, with 21% and 7% probabilities for death from other causes at the same time points.

Conclusions: Smokers with HPV+ OPSCC exhibit a higher CR compared to non-smokers, regardless of their drinking status. However, when stratified by cause of death, smokers/drinkers demonstrate the highest CR, followed by non-drinkers/non-smokers. Notably, while the highest CR/DP for death from cancer was observed in smokers/drinkers, the CR/DP for death from other causes was higher in smokers/non-drinkers. The results suggest that the coexistence of risk factors, such as alcohol and tobacco consumption, in HPV+OPSCC patients may lead to an increased risk of cancer-related mortality, emphasizing the impact that alcohol consumption may have on survival.

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#9395

P10-05 | A pilot implementation of a cervical cancer screening platform in Cantabria (Spain): Early detection through self-sampling and integrated health systems

10 - HPV screening

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Background/Objectives: The present study introduces the pilot test conducted by the General Directorate of Public Health of Cantabria, aimed at implementing a Cervical Cancer Screening Platform for early detection among women across various regions.

Methods: Between June and September 2024, the General Directorate of Public Health of Cantabria conducted a pilot test to implement a Cervical Cancer Screening Platform aimed at early detection of cervical cancer in women from Santander, Laredo, Torrelavega and Reinosa. A total of 3,002 invitations were sent via SMS, resulting in a 37% acceptance rate. Once the invitation was accepted, each patient received a self-sampling device, which they delivered to their primary care center for referral to the molecular biology reference center.

Results: The platform relies on the interconnection of various applications and IT systems within the SCS, enabling fast and accurate data transfer. Participant data is integrated into the Primary Care systems, alongside the Ticares scheduling platform and the Gestpath pathology system, which processes screening and colposcopy reports, data were exchanged through HL7 messaging protocols. The target population is updated in real-time via the DYANA system, facilitating centralized registration, follow-up, and appointment scheduling of clinical data. The pilot workflow begins with an invitation to undergo an HPV test. Negative results conclude the process, with retesting every five years, while positive results lead to an evaluative cytology conducted after consultation with a midwife. In cases of suspicious findings, colposcopy and anatomopathological analysis are performed to identify possible lesions. A comprehensive evaluation is subsequently conducted to decide between clinical intervention or monitoring. Samples were processed at the Pathology Department of the Marqués de Valdecilla University Hospital, where automated equipment was used to hydrate, resuspend, and aliquot samples. PCR extraction and analysis were conducted on the STARlet-AIOS platform using the AnyplexTM II HPV HR Detection kit (Seegene), detecting 14 high-risk genotypes (commercialized by Werfen). Results showed an 8% positivity rate for high-risk HPV, which were automatically integrated into health information systems for interpretation and management (figure 1). The platform incorporates automated data validation checkpoints and reminders to optimize participant retention. The pilot test enabled adjustments tailored to each region's needs, with improvements planned, including comprehensive colposcopy reports and anatomical pathology data.

Conclusions: This screening model is replicable and offers an efficient, accessible approach to early cervical cancer detection, with potential for adoption in other public health programs.

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#9398

P39-05 | State and territory immunization program activities and their association with human papillomavirus vaccine initiation in the United States of America: A multilevel approach

39 - Public health

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Background/Objectives: This study evaluates the association between state and territory immunization program (IP) activities aimed at increasing HPV vaccination among adolescents and their impact on HPV vaccine initiation.

Methods: Our data sources are: (i) 2016 AIM Annual Survey and (ii) 2019 National Immunization Survey - Teen. We estimated the prevalence of HPV vaccine initiation using a Poisson model with a multilevel approach, combining state-level IP data and individual characteristics of adolescents. We calculated the prevalence ratio (PR) of HPV initiation among adolescents to compare the effects of all the IP activities, adjusting for state of residence, age, sex, education attained by the mother, and ethnicity.

Results: A total of 17,390 teens aged 13 and 17 were evaluated. Findings showed that states with school-based adolescent coverage rates and/or exemptions available to the public (activity D, PRw, activity Dadjusted: 1.08, 95% CI: 1.02, 1.14), as well as those that expanded the number of pharmacies entering HPV vaccination data (activity N, PRw, activity Nadjusted;1.06, 95% CI: 1.02, 1.10) in Immunization Information Systems (IIS), had higher HPV vaccine initiation rates compared to states that did not implement these strategies. When stratifying, these findings were present in the younger age group (13-15 years, PRw, activity D adjusted: 1.10, 95% CI: 1.01, 1.18; PRw. activity N adjusted: 1.10, 95% CI: 1.05, 1.16), but not in the older group (16-17 years, PRw, activity D adjusted: 1.05, 95% CI: 0.95, 1.15; PRw. activity N adjusted: 1.00, 95% CI: 0.94, 1.06). States that expanded the number of school-located programs entering HPV vaccine records in IIS (activity E, PRw, activity Eadjusted: 1.08, 95% CI: 1.01, 1.15) were associated with higher vaccine initiation prevalence in the younger age group but not in the older age group.

Conclusions: Limitations include a lack of operational definitions for IP activities, potential biases in the NIS-Teen survey, and reliance on provider-reported HPV vaccination histories. Nonetheless, these results highlight specific immunization activities that support national efforts to increase HPV vaccine uptake and inform public health programs on effective approaches for promoting the HPV vaccine.

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#9401

P29-05 | Detection of antibody subclasses IgA, IgM and IgG against HPV L1 in HPV-positive oropharyngeal squamous cell carcinoma patients

29 - HPV and oropharynx / Head and neck cancer

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Background/Objectives: Up to 25% of patients with HPV-positive oropharyngeal squamous cell carcinoma (OPSCC) will suffer from recurrence within the first 5 years despite prognostic superiority. In a prospective observational study, we aimed to investigate the dynamics of HPV-L1 capsid protein specific antibody (AB) subclasses IgA, IgM, and IgG in HPV-positive OPSCC patients under therapy.

Methods: Serum samples from HPV-positive OPSCC patients, identified by positive p16-immunohistochemistry, were collected before and during tumor-specific therapy and 3 to 6 months during follow-up. They were analyzed for the presence of HPV-L1 AB subclasses IgA, IgM, and IgG using an HPV-L1-specific immuno-assay. Additionally, a PCR-based HPV-DNA detection from the tumor tissue was performed.

Results: Altogether, 33 patients with a mean follow-up of 55 months were included. Analysis of a total of 226 serum samples revealed that the most common L1-AB-subclass pattern was characterized by IgG > > IgA > IgM without significant fluctuation during the course of disease. Patients with excessive IgG levels tended to higher tumor stages and three out of three patients with disease recurrence showed increasing IgG AB titers beforehand. Seven patients showed an IgA dominance at diagnosis, which was associated with a better disease-free survival.

Conclusions: Despite limited cases, our prospective observational study revealed promising trends in HPV L1 AB subclasses and may contribute useful information for future risk stratification and post-treatment monitoring in HPV-positive OPSCC patients.

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P38-03 | Cervical cancer screening preferences: A discrete choice experiment in Cambodia, Ethiopia, and Uganda

38 - Low resource settings

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Background/Objectives: Cervical cancer is one of the leading causes of cancer mortality among women in low- and middle-income countries (LMICs). Despite advances in screening technologies and the development of alternative approaches like self-sampling and community-based screening, little is known about how women in these regions prefer to be screened. Understanding these preferences is critical for designing culturally acceptable, accessible, and effective cervical cancer screening programs that can improve participation rates and reduce disease burden. This study aims to explore women's preferences for cervical cancer screening attributes, including sampling method, location, type of health staff, and result communication method, in order to better tailor screening services to the specific needs of women in Cambodia, Uganda, and Ethiopia.

Methods: To identify the screening preferences of women in Cambodia, Uganda, and Ethiopia, we conducted a Discrete Choice Experiment (DCE) with 600 participants in each country. In the DCE, women were presented with hypothetical scenarios featuring varied attributes of screening services. Key attributes included screening location, type of sample collection, type and gender of health staff, choice between drop-in visits or scheduled appointments, and method of receiving results. These attributes and their levels were determined through formative research by local teams to ensure they reflected the cultural and healthcare context of each country. Questionnaires based on these tailored attributes were developed in R. By asking participants to choose their preferred option across scenarios, we quantified women's preferences and assessed the importance of each attribute. Responses were analyzed using the Mixed Logit Model in R.

Results: The DCE findings reveal notable patterns in screening preferences across Cambodia, Uganda, and Ethiopia. In Cambodia, there was a borderline significant preference for self-sampling. Cambodian women also showed a preference for screening at health facilities, for female providers, and for receiving their results in person. In Uganda, women showed a significant preference for self-sampling, particularly when offered by a female doctor, and favored in-person result communication over phone notifications. Similarly, in Ethiopia, women significantly preferred self-sampling at health centers with female doctors as providers. Across all three countries, the option between scheduled appointments and drop-in visits did not significantly influence preferences.

Conclusions: The DCE findings underscore the need to align cervical cancer screening programs with women's preferences in Cambodia, Uganda, and Ethiopia to enhance participation rates. Key preferences include self-sampling, access to female providers, and receiving test results in person. While self-sampling may offer increased privacy, many women still prefer to be screened within health facilities rather than at home or in the community, likely for the reassurance and perceived quality of care in formal healthcare settings. Additionally, there is a preference for doctors over community health workers or nurses as providers. These insights suggest that screening programs incorporating self-sampling options, female providers, and in-person result communication could better meet women's needs. Tailored screening initiatives have the potential to reduce the cervical cancer burden in these regions.

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#9414

P22-03 | Colposcopic and morphological correlations in cervical intraepithelial lesions

22 - Diagnostic procedures / management

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Background/Objectives: Cervical cancer remains a significant global health challenge, particularly in low and middle-income countries, where the burden is disproportionately high. The literature reveals critical insights into the epidemiology, prevalence, and healthcare responses to this disease, highlighting the urgent need for effective strategies to reduce the force of its impact. The main cause of cervical carcinoma is persistent infection with high-risk strains of the human papilloma virus. Carcinogenesis is long-term, characterized by the appearance of precursor lesions, which can be detected by the cytological screening method and which, for the most part, regress spontaneously without treatment. Colposcopy is a critical diagnostic tool for evaluating cervical lesions, providing real-time visual assessment of cervical pathology. Accurate classification of these lesions is essential for effective management and prevention of cervical cancer progression. However, the effectiveness of this system in predicting various grades of cervical lesions, particularly in distinguishing between low-grade and high-grade squamous intraepithelial lesions (LSIL, HSIL), remains a key area of investigation. Accurate identification of these lesions through both clinical and morphological evaluations is crucial for early intervention and prevention of cervical cancer progression. By examining the relationship between clinical presentation, colposcopic findings, and histopathological results, a more precise diagnosis can be achieved. This study aims to explore the effectiveness of these correlations in enhancing diagnostic accuracy, particularly in the detection and classification of cervical intraepithelial lesions.

Methods: This is a retrospective study that includes 698 patients who referred to an Obstetrics-Gynecology Clinic for cervical cytological evaluation and HPV testing, between 2000-2024. In addition to Pap smear and HPV testing, diagnostic and surgical methods included biopsy, conization, or LLETZ, depending on cytodiagnosis and genotyping. Sections from the specimens were paraffin embedded and stained by the classic hematoxylin-eosin (H&E) staining method.

Results: Depending on the lesion grade, 65.7% of cytodiagnostics showed low-grade lesions (ASCUS + LSIL) and 35.4% presented high-grade lesions (ASC-H + HSIL). HPV DNA testing detected HPV16 in 111 patients (27 %), HPV18 in 33 patients (7.9%), combined HPV16 and HPV18 in 33 patients (7.9%), HPV 31 in 19 patients (11.1%) and other strains in 168 patients (40.9%). The colposcopic examination performed in 594 of the patients presented the following gradings: G0 in 22 patients (6.6%), G1 in 368 of the cases (61.9%), G2 or G1-G2 in 214 (36%) of the patients. Excision techniques were performed in 494 patients, as follows: conization in 284 (57.4%) cases, peripheral LLETZ in 103 (27%) cases, central conization with peripheral LLETZ in 70 (19%) of patients. The histopathological examination revealed the following lesions, diagnoses that corresponded the colposcopic aspects: high-grade lesions (HSIL/CIN3) in 182 cases (30.6%), low-grade (LSIL/CIN1) or combined lesions (LSIL/CIN1 and HSIL/CIN2) in 296 cases (49.8%).

Conclusions: The study revealed a very good correspondence between the colposcopic examination and the histopathological diagnosis, demonstrating an effective correlation between these methods, with an essential impact on the therapeutic management of cervical intraepithelial lesions.

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#9416

P26-01 | Vulvar melanoma - about a case report

26 - Vulvar diseases and neoplasia

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Background/Objectives: Vulvar melanomas (VMs) account for 1% of all melanomas in women and 5-10% of all vulvar malignancies. The median age at diagnosis is 68 years, and many cases are diagnosed at an advanced stage, which may partly be explained due to the location of the tumor and the lack of symptoms in an early stage. The prognosis is usually poor, due to a high metastatic potential. There is, however, still an absence of standardized guidelines for treatment of vulvar melanoma.

Methods: Description of a clinical case of a vulvar melanoma in an 86-year-old patient, presenting at an advanced stage, with a poor prognosis.

Results: We report an 86-year-old patient with a medical history of breast cancer, high blood pressure, early dementia, and osteoarticular pathology, referred to our department of cervical pathology due to an asymptomatic nodular vulvar lesion, with a length of 3,5x4cm in the internal part of the small right vulvar labia, extending into the clitoris at 1,5cm of the urethral margin. Peri-urethral and urethral melanocytic lesions were also seen. No inguinal adenomegaly was palpated. A biopsy was performed, with histology report of vulvar melanoma, 1,26mm in thickness, with no ulceration in the specimen. The patient was then referred to an oncologic reference hospital for further investigation and treatment, having guidance from the Onco-Gynecology and Dermatology departments. After staging exams, radical excision of the vulvar lesion and excision of sentinel right and left lymph nodes were performed. The histology result was of a nodular, ulcerated tumor, with12mm in thickness and 4x3,5x1,2 cm in length, with free surgical margins and negative sentinel lymph nodes, with a classification of the tumor of pT4bN0M0. As decided by the therapeutic decision group appointment, the patient has no indication for systemic therapy, only for follow-up.

Conclusions: Vulvar melanomas are rare and present as a challenging pathology for diagnosis and management, with a poor overall prognosis. Like in our case, in which the patient presented with a big lesion at the first appointment, many patients don't acknowledge their lesion due to a probable embarrassment from the location and a lack of symptoms, contributing to an increased stage at presentation.

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#9426

P03-02 | Difference in Human Papillomavirus genotyping after 16 years of vaccination

03 - Epidemiology and natural history

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Background/Objectives: In Andalusia, the human papillomavirus (HPV) vaccine was added to the vaccination schedule in 2008 for 14-year-old girls, aligning with Spain's national vaccination strategy. Initially, either bivalent or quadrivalent vaccines (Cervarix and Gardasil) were administered, which protected against the most oncogenic HPV genotypes, specifically HPV-16 and HPV-18. In subsequent years, Spain introduced the nonavalent vaccine (Gardasil 9), extending protection to five additional high-risk genotypes. Our objective is to highlight any changes in HPV genotypes detected in endocervical samples from women at the beginning of the vaccination implementation in our autonomous community's schedule, compared to those detected in women 16 years after the program's initiation.

Methods: We analyzed 887 endocervical samples collected from women attending opportunistic screening consultations in 2010, of which 475 (53.6%) were under 35 years old and 412 (46.4%) were 35 years or older. Similarly, 2,965 endocervical samples were examined in the same screening program in 2024, with 116 (3.9%) from women under 35 and 2,849 (96.1%) from those 35 or older. All samples were tested for HPV detection using real-time PCR techniques, targeting the most prevalent high-risk genotypes. The 2010 samples were analyzed with Anyplex HPV28 (Seegene), while the 2024 samples were analyzed using Allplex HPV14 (Seegene), following protocol.

Results: In 2010, among women under 35 years of age (average of 26 years), 321 samples were positive (67.6%) with a total of 522 genotypes identified. Only 120 samples had a single genotype. The most predominant genotype was HPV-16 (21.4%), followed by HPV-31 (10.3%), HPV-52 (9.2%), HPV-58 (9%), HPV-45 (8.6%), with other genotypes found in lower proportions. In the group of women aged 35 and older (average of 47 years), 175 samples were positive (42.5%). The predominant genotype was also HPV-16 (17.3%), followed by HPV-31 (12.1%), HPV-52 (9.8%), HPV-58 (8.9%), and HPV-68 (8.4%), with lower proportions for the remaining genotypes, and only 62 samples presented a single genotype. In 2024, among women under 35 years of age (average of 29.8 years), we detected 61 positive samples (52.6%). The most prevalent genotype was HPV-52 (14.1%), followed by HPV-56 (12.8%), HPV-39 (11.5%), and both HPV-16 and HPV-58 at 10.3%. Notably, no HPV-18 genotypes were detected in this group. In the group of women aged 35 and older, 366 samples were HPV positive (12.8%), with HPV-16 being the most prevalent (15.8%), followed by HPV-31 (12.8%), HPV-52 (10.4%), and HPV-56 (7.5%), with other genotypes found in lower proportions. A single genotype was detected in 220 samples (60.1%).

Conclusions: In 2010, genotype HPV-16 was the most frequently detected strain in both age groups, corroborating findings in the existing literature. The distribution of genotypes demonstrated significant similarity across the two age group. By 2024, in the cohort of women under 35 years old, the detection frequency of genotype HPV-16 has decreased, with HPV-52 emerging as the most prevalent, followed closely by HPV-56 and HPV-39. In contrast, the genotype distribution among women aged 35 and older has remained consistent with that observed in 2010. Our findings suggest that the distribution of HPV genotypes is evolving as a result of the vaccination program implemented for women 16 years ago. It is imperative to evaluate the implications of these changes on the histological lesions we are currently identifying.

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P06-02 | HPV vaccine uptake and completion among Hispanic adults in Kentucky, USA

06 - HPV prophylactic vaccines

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Background/Objectives: The incidence rates of two HPV-related cancers, cervical and penile cancers, are higher for Hispanics compared to non-Hispanics in the United States. However, little data exists on HPV vaccination among Hispanic adults. This study examined self-reported uptake and completion of the HPV vaccine among Hispanic adults in Kentucky and potential associations with age, gender, country of birth, English proficiency, educational attainment, income, and health insurance status.

Methods: An observational cross-sectional survey was collected with a convenience sample of 471 self-identified Hispanic men and women (ages 18+) living in Kentucky in 2023 and 2024 as part of a Hispanic cancer needs assessment. Participants responded to the survey in Spanish (n=428) or English (n=43). The current analysis was conducted on the subsample of vaccine-eligible adults aged 18 to 45 (n=355). Bivariate analysis was performed using crosstabulations and Chi-square tests.

Results: HPV vaccine uptake (at least one dose) among Hispanic adults was 26.7% for 18-26-year-olds and 21.9% for 27-45-year-olds, although not significantly different. Completion of all recommended doses of the HPV vaccine was lower than uptake and was higher in the younger group (13.1% for 18-26 years vs. 4.6% for 27-45 years, P =.007). Women had higher uptake than men (27.5% vs. 14.9%, P=.025), but completion did not show a significant gender difference. Uptake differed by country of birth (41.5% born in the U.S., 25.0% born in Mexico, 17.2% born in other countries, P =.003) and was positively associated with English proficiency (34.8% speak English very well, 30.2% well, 23.0% not well vs. 10.6% not at all, P=.003). Additionally, English proficiency was positively associated with completing the recommended HPV vaccine doses (17.7% speak English very well, 7.3% well, 3.8% not well vs. 3.6% not at all, P=.001). Uptake appeared to be higher among those with health insurance than those without (30.0% vs. 20.4%, P=.053), but was not statistically significant, while completion of the recommended HPV vaccine doses was significantly associated with health insurance (13.8% vs. 4.0%, P=.001). Uptake was higher among those with a high school degree or higher compared to those without a high school degree (30.1% vs. 14.8%, P <.001), as well as completion (10.2% vs. 2.5%, P=.005). Income was not significantly associated with HPV vaccine uptake or completion.

Conclusions: Hispanic adults ages 18-26 in Kentucky had lower HPV vaccination rates than recent national estimates for adults of this age (39.9% uptake, 21.5% completion, CDC 2018). Uptake among Hispanic adults ages 27-45 was also lower than a recent national estimate for this age (11.9%, Rincon et al., 2024); national estimates are not available for completion among this age group. The findings provide insights into the social determinants of health contributing to low HPV vaccine uptake and completion among adult Hispanics in Kentucky.

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#9451

P10-01 | Review of the national organized HPV-based cervical cancer screening in Montenegro - establishment of new improved platform

10 - HPV screening

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Background/Objectives: The organized cervical cancer screening program in Montenegro, based on the detection of 14 High Risk (HR) HPV genotypes, was implemented on February 1, 2018 at the national level in all health centers in Montenegro, for women from 30 to 50 years old. During the COVID-19 pandemic, cervical cancer screening was stopped from March 2020 to November 2022, after which HPV testing was established with improved Abbott Alinity m platform and high risk HPV test (approved for use as a first-line primary screening test for cervical cancer). Detection of high risk HPV genotype identifies women who have an increased risk of developing cervical cancer (95% of invasive cervical cancers found are associated with 14 HPV genotypes) or the presence of cervical high-grade lesions. The objective of this review was to analyze the prevalence of the 14 HR HPV genotypes within primary screening of women in Montenegro during period November 2022 to October 2024.

Methods: During the period from November 2022 to October 2024, within the organized cervical cancer screening program, total number of 20 838 cervicval samples were received and tested for presence of 14 high risk HPV genotypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) using the Abbott Alinity m High Risk (HR) HPV assay. The assay specifically identifies HPV genotypes 16, 18, and 45 while reporting the simultaneous detection of the other high-risk genotypes (31, 33, 52, 58 - Group A) and (35, 39, 51, 56, 59, 66, 68 - Group B).

Results: The overall prevalence of 14 HR-HPV genotypes was 13.72%, with the dominance of high-risk HPV genotypes from Group B (31,53%), followed by HPV genotypes from Group A (25.17%), while HPV genotypes from both Group A and Group B were present in 4.44% of HPV positive samples. The presence of HPV genotype 16 was found in 20%, HPV genotype 18 was found in 5,06% and HPV genotype 45 was found in 4,72% of all HPV positive samples. Co-infections with HPV genotypes 16, HPV genotype 18 and HPV genotype 45 were detected in less than 1% HPV positive samples (0.86%). Infection with multiple HR HPV genotypes was found in 69,3% of the HPV infected samples.

Conclusions: Our results indicate that HPV genotype 16 and high-risk HPV genotypes from Group B (35, 39, 51, 56, 59, 66, 68) were the most prevalent HR-HPV genotypes in cervical samples tested within the organized cervical cancer screening program in Montenegro followed by HPV genotypes from group A (31, 33, 52, 58). The possibility of detection and reporting of separate HPV genotypes 16, 18, and 45, as well as two groups of HR HPV genotypes allows a better risk stratification and identification of infections with multiple HPV genotypes.

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P37-02 | Bridging knowledge to action: Evaluation of the ACCESS-HPV clinical trial training program for HPV and cervical cancer prevention in Nigeria

37 - Health education

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Background/Objectives: Cervical cancer is the second most common cancer among women in Nigeria, with approximately 12,000 new diagnoses and nearly 8,000 deaths each year (WHO,2022). A well-organized HPV vaccination and screening initiative could dramatically reduce both the incidence and mortality rates of cervical cancer in Nigeria, yet there are few widespread cervical cancer prevention programs available. To address this critical gap, the Actions for Collaborative Community-Engaged Strategies for HPV (ACCESS-HPV) program was developed with a mission to increase HPV vaccination and screening among Nigerian girls and women by leveraging community relationships, specifically the bond between mothers and daughters. This study evaluates the effectiveness of the ACCESS-HPV Clinical Trial Training, aimed at training early-stage and healthcare professionals in HPV/Cervical Cancer landscape in Nigeria, good clinical practice competencies, human subjects research, recruitment and engagement strategies, sample handling and delivery, implementation science strategies, and specifics of the ACCESS-HPV project. The program was designed to prepare research facilitators and supervisors to carry out the clinical trial with a high degree of fidelity and ethical responsibility.

Methods: The ACCESS- HPV Clinical Trail Training was a week-long online program that provided training and informational support to early-stage and healthcare professionals in Nigeria. The training was designed to give participants the necessary skills to easily and effectively perform the ACCESS-HPV randomized controlled study among girls and women in Nigeria. Pre and Post evaluation surveys were administered to assess the effectiveness of the training.

Results: The ACCESS-HPV Clinical Trial Training included a total of 54 participants varying between physicians, nurses, midwives, professors, students (master's, medical, and postdoctoral), and community health workers, with a majority of them being female (n = 37; 73%). The participants' roles in the clinical trials varied between the research facilitator (n = 32; 63%) and supervisor (n = 19). The median (IQR) score of the ACCESS-HPV project competency was 36 (25-41) in the pre-survey, compared to 52 (45-55) in the post-survey; clinical science and public health competency score was 32 (27-36), compared to 37 (33-40); and implementation support competency score was 24 (21-26), compared to 25 (24-28). The median score differences between pre- and post-survey were significant ($U = 342$; $p < .001$), ($U = 648$; $p < .001$), and ($U = 888.5$; $p = .026$), respectively.

Conclusions: The ACCESS-HPV Clinical Trial Training was effective in increasing participants' knowledge and understanding of HPV and cervical cancer within the Nigerian context, and critical competencies for the ACCESS-HPV project, clinical science and public health, and implementation support. The results emphasize the critical role of comprehensive planning and implementation to achieve successful outcomes in clinical trials and public health initiatives. The training contributes to the global effort to eliminate cervical cancer by 2030 by underscoring the value of structured culturally tailored training, immediate action, and sustained implementation of preventative strategies in Nigeria and similar settings.

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#9458

P03-01 | Sequential acquisition of Human Papillomavirus infection between anogenital anatomical sites in men

03 - Epidemiology and natural history

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Background/Objectives: Robust evaluation of the global incidence of sequential human papillomavirus (HPV) infection between different anogenital sites among men has not been conducted.

Methods: Sexually active heterosexual men (HM; aged 16-23 years) who participated in a global 4-valent (4v) HPV vaccine trial (V501-020; NCT00090285) were included in the evaluation. Sequential anogenital infection for 9-valent (9v) HPV vaccine types (6/11/16/18/31/33/45/52/58) was defined among those who are naïve to the relevant type at baseline (HNRT) as a type-specific, incident anogenital HPV infection at 1 post-baseline timepoint, followed by a type-specific infection at a different anogenital site detected ≥6 months after incident infection. Among those with a type-specific prevalent anogenital HPV infection at baseline (Day 1), a sequential infection was defined as acquiring a new type-specific anogenital infection at a new anogenital site detected ≥6 months after baseline. Infections that progressed from penile/scrotal to perineal/perianal sites or vice versa were considered separately. Infections were grouped into low-risk (HPV6/11) or high-risk (HPV16/18/31/33/45/52/58) types; HPV16 was reported alone, in addition to being reported as one of the high-risk types.

Results: There were a total of 4065 men in the full-analysis set (FAS) and 1871 in the HNRT set, a subset of the FAS.Among the HNRT population, incident infections of low-risk types, high-risk types, and HPV16 alone were detected in 21.5% (124/577), 76.1% (337/443), and 18.6% (106/569) of HM at penile/scrotal sites, and 2.1% (12/577), 7.4% (33/443), and 0.9% (5/569) of HM at perineal/perianal sites. The risk of type-specific sequential infections from penile/scrotal to perineal/perianal sites was 14.5% (18/124) for low-risk types, 22.8% (77/337) for high-risk types, and 21.7% (23/106) for HPV16 alone. The risk of type-specific sequential infections from perineal/perianal to penile/scrotal sites was 16.7% (2/12) for low-risk types, 27.3% (9/33) for high-risk types, and 60.0% (3/5) for HPV16 alone. Among those with a prevalent baseline infection, the risk of sequential infections from penile/scrotal to perineal/perianal was 19.0% (8/42) for low-risk types, 28.5% (39/137) for high-risk types, and 32.7% (16/49) for HPV16 alone. The risk of type-specific sequential infections from perineal/perianal to penile/scrotal sites was 50.0% (1/2) for low-risk types, 14.3% (1/7) for high-risk types, and 0% (0/2) for HPV16 alone.

Conclusions: Among HM, the risk of sequential 9vHPV infections was high for both directions and all types, but highest for high-risk 9vHPV vaccine types. These findings highlight the importance of vaccinating men against HPV infection.

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#9460

P14-01 | Risk stratification for CIN2+ using extended high-risk HPV genotyping

14 - Genotyping

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Background/Objectives: High-risk human papillomaviruses (hrHPV) are the primary cause of cervical cancer, typically progressing through pre-cancerous cervical intraepithelial lesions (CIN). Although HPV screening programs have significantly reduced cervical cancer incidence, the risk of progression to CIN2+ varies by HPV genotype, impacting management strategies. This study aimed to quantify the two-year risk of CIN2+ associated with specific HPV genotypes and assess cumulative risk patterns over time.

Methods: We performed the Hybrid Capture 2 (HC2) triage test to detect women with hrHPV DNA. Samples from HPV-positive women were further genotyped with the Allplex HPV28 Detection assay, identifying 19 different hrHPV genotypes. A longitudinal analysis was conducted on a cohort of 330 HPV-positive women to track genotype-specific CIN2+ progression over two years. Kaplan-Meier estimates were used to calculate cumulative CIN2+ risk for each HPV genotype, focusing on high-risk types.

Results: Our findings indicate that HPV16 and HPV51 confer the highest risk for CIN2+ development, with cumulative two-year risks exceeding 30% and rapid progression within the first-year post-infection. Moderate-risk genotypes, including HPV35, HPV33, HPV18, and HPV52, showed cumulative risks of 10-15% over two years, with slower progression patterns. Due to the relatively small study group, confidence intervals for each genotype did not reach statistical significance, except for the statistically significant difference observed between HPV16 and HPV45. In contrast, HPV66 was not associated with any cases of CIN2+, supporting recent reclassification of HPV66 as no longer high-risk. HPV-negative individuals showed almost negligible risk for CIN2+.

Conclusions: This study underscores the importance of HPV genotype in assessing CIN2+ risk. As is widely recognized, the high-risk genotype HPV16 requires closer surveillance. The findings support genotype-specific risk stratification to optimize patient management.

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P27-01 | High-resolution anoscopy referral rates if adopting IANS consensus guidelines for anal cancer screening in men who have sex with men living and not living with HIV

27 - Anal neoplasia

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Background/Objectives: The International Anal Neoplasia Society (IANS) has included MSM living with HIV (MSM-LWH) ≥35 years and MSM-noHIV ≥45 years in the Risk Category A, i.e., they are at increased risk for anal cancer and should be prioritized for the screening (1). According to IANS recommendations, different screening tests may be used, but screen-positive individuals should be in any case referred to high-resolution anoscopy (HRA) with directed biopsy, the gold standard for identification of anal precancer (2). Unfortunately, HRA availability is still limited in Europe, so that the adoption of IANS guidelines is challenging. We conducted a retrospective study with the aim of estimating the potential HRA referral rates that our STI/HIV centre would have in the routine clinical practice if adopting IANS guidelines to screen MSM.

Methods: We retrieved the results for anal cytology (liquid-based, interpreted following the Bethesda system, blinded to the HPV test result) and the Linear Array HPV Genotyping test for all MSM who attended the STI/HIV centre of the San Gallicano Dermatological Institute (Rome, Italy) between May 2009 and March 2023 and participated in the Surveillance Program of Anal Intraepithelial Neoplasia (SAIN project) (3, 4). The analysis included findings for MSM-LWH ≥35 years and MSM-noHIV ≥45 years who had a valid result for both cytology and HPV testing. We estimated HRA referral rates for seven screening strategies, and five additional strategies that should be adopted in settings with insufficient HRA capacity (i.e., HRA beyond 6 months from the referral test): cytology as a standalone test or with hrHPV triage; hrHPV (with/without HPV16 typing) as a standalone test or with cytology triage; co-testing with cytology and hrHPV (with/without HPV16 typing).

Results: Out of the 1,400 MSM who attended our centre during the study period, 307 MSM were included in the analysis. Of these, 244 were LWH (79.5%), the majority of which were on cART (231/244, 94.7%; 200/231, 86.6% had undetectable HIV-RNA]. MSM-LWH had a median age of 45 years (IQR: 40-51); the median time since HIV diagnosis was 6.5 years, (IQR: 2.8-12.9); median nadir and baseline CD4+ were 308 (IQR: 201- 400) and 610 cells/mm3 (IQR: 441-804), respectively. Sixty-three MSM-noHIV were also included in the study (median age: 48 years, IQR: 46-52). None of the subjects of both study groups had been vaccinated for HPV. HrHPV as a standalone test led to the highest referral rate (MSM-LWH: 74.6%; MSM-noHIV: 55.6%). Strategies with triage resulted in the same and lowest referral rates (44.3% in MSM-LWH and 27.0% in MSM-noHIV). In settings with insufficient HRA capacity, only ASC-H/HSIL (4.9% and 9.5% for MSM-LWH and MSM-noHIV, respectively) and HPV16+ MSM (27% and 20.6%, respectively) would be referred to HRA.

Conclusions: The workload for HRA services would be the highest if using hrHPV test alone, would decrease using cytology alone and would be the least if using triage strategies. Although hrHPV test has a higher sensitivity compared to cytology (5), the high referral rate of the hrHPV test alone implies that the ability to focus the assessment efforts on those with the highest anal (pre)cancer risk would be very limited, particularly in MSM-LWH. The optimal tradeoff between resource utilization and disease detection needs to be found, but it is becoming increasingly important to expand providers trained in HRA to offer appropriate screening programs to the populations with the greatest anal cancer risk.

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P25-01 | Management of a Woman with SMILE Lesion

25 - Cervical neoplasia

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Background/Objectives: Stratified Mucin-producing Intraepithelial Lesion (SMILE) is a rare and distinct cervical lesion with both squamous and glandular characteristics. It is categorized as a premalignant lesion associated with high-risk human papillomavirus (HPV) infection, particularly HPV types 16 and 18, which are known to contribute to the development of cervical intraepithelial neoplasia (CIN) and adenocarcinoma in situ (AIS). (1, 2, 3)

Methods: Case report:

Results: This case report describes the diagnostic and therapeutic journey of an asymptomatic 46-year-old woman with a complex sequence of cervical lesions. The patient initially presented with a PAP smear result of II NILM and HPV 16 positive result, prompting further evaluation with colposcopy. Colposcopic examination revealed a large complex lesion consisting of a coarse mosaic and dense acetowhite epithel on the posterior lip of the cervix, raising suspicion of high-grade cervical intraepithelial neoplasia. To confirm the diagnosis, a targeted cervical biopsy was performed. Histopathology of the biopsy sample confirmed a SMILE lesion. Given the findings, the patient underwent cold-knife conization to better delineate the extent of the disease. Histological examination of the cone biopsy revealed multifocal AIS with positive resection margin and multifocal HSIL, underscoring the need for further definitive management. Immunohistochemistry finding showed Ki67+, p16+, p53-, CK7+, PAX8+, CK 20-, ER+, PR+, CDX2-, mECA+, CAIX- phenotype. Magnetic resonance imaging (MRI) of the pelvis revealed no evidence of lesion inside or outside the cervix. Due to the multifocality of the AIS, positive resection margin and the associated risk of recurrence or progression to invasive carcinoma, total hysterectomy was performed to eliminate any residual disease. The post-hysterectomy pathology report showed multifocal AIS and negative resection margins. PAP smear and HPV test checkup was performed 6 moths after the surgery to rule out any remaining or occult pathology. PAP smear result of II and hrHPV negative result confirmed that there there were no residual lesions or abnormalities.

Conclusions: While the natural history of SMILE is not fully understood due to its rarity, it is often found alongside multifocal lesions, such as HSIL and AIS, emphasizing the importance of thorough diagnostic workups like cervical biopsy, conization, and HPV testing. However, cases with multifocal involvement or recurrence may require more radical interventions like hysterectomy, particularly for patients who are at high risk for progression or have completed childbearing. Long-term follow-up will be essential to monitor for potential recurrence or the emergence of new lesions, especially in patients with complex intraepithelial pathology.

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#9474

P17-01 | FAM19A4 and miR124-2 methylation status in HPV-driven and HPV-negative oropharyngeal squamous cell carcinomas

17 - Methylation

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Background/Objectives: Changes in DNA methylation may contribute to HPV-induced carcinogenesis. The interest in the evaluation of methylated host genes in several HPV-driven cancers has been rapidly growing. The possible role of methylation markers has been investigated in cervical cancer screening as well as in the identification of anal (pre)cancerous lesions. Methylation of two tumor suppressor genes, i.e., FAM19A4 (also known as TAFA4) and miRNA124-2 (miR124-2) has been identified as a promising biomarker for cervical oncogenesis. Less is known regarding methylation of these genes in oropharyngeal squamous cell carcinomas (OPSCCs). We aimed to investigate: i) the methylation status of the promoters of FAM19A4 and miR124-2 in HPV-driven [HPV(+)], HPV-negative [HPV(-)] OPSCCs and cancer-free controls; ii) whether the methylation status of these markers differed between OPSCCs and controls, and between HPV(+) and HPV(-) OPSCCs.

Methods: The analysis included formalin-fixed, paraffin-embedded (FFPE) tissues obtained from consecutive patients diagnosed with primary HPV(+) [i.e., HPV-DNA+ by PCR with SPF10 primers followed by reverse hybridization and p16+ by immunohistochemistry using E6H4 clone] and HPV(-)OPSCC at the Regina Elena National Cancer Institute (Rome, Italy) between 2014 and 2022. Only cases with nucleic acid extracts sufficient for the analysis of the methylation status were selected. FFPE tissues from oral/oropharyngeal squamous cell papillomas and oral rinse-and-gargles (ORGs) from subjects without clinically evident oral/oropharyngeal lesions were used as a control. Methylation of the target genes was evaluated using a commercial assay based on multiplex real-time methylation specific PCR starting from bisulfite-converted DNA. Hypermethylation for each target was expressed as negative/positive based on the delta delta Ct (ddCt), as well as with the ddCt ratio (2-ddCt).

Results: A total of 173 specimens were analysed: 70 HPV(+)OPSCC (of which 66 HPV16+, 94.3%), 71 HPV(-)OPSCC, 12 papillomas, and 20 ORGs. Out of the 153 FFPE samples, six (3.9%) showed invalid results [1 HPV(+)OPSCC, 4 HPV(-)OPSCC and 1 papilloma] and were thus excluded from the analysis. Among the 69 valid HPV(+)OPSCC, 55 were hypermethylated for at least one target (79.7%). The corresponding figure was 36 out of 67 valid HPV(-)OPSCC (53.7%; p=0.0013). None of the papillomas nor ORGs resulted hypermethylated. Considering the ddCt ratio, the HPV(+)OPSCC showed a significantly higher methylation level compared to the HPV(-)OPSCC for both the investigated markers (FAM19A4 median ratio: 11.95 vs. 5.49; p=0.0001; miR124-2 median ratio: 15.65 vs. 8.27; p<0.0001).

Conclusions: Our findings show that up to 10 year-old FFPE tissues can be employed for the analysis of the methylation status of FAM19A4 and miR124-2 using the method of the present study. Hypermethylation of their promoters was only observable in malignant tissues, since neither benign lesions nor samples from lesion-free subjects showed any methylation. Additionally, methylation levels in HPV(+)OPSCC were significantly higher compared to those in HPV(-)OPSCC. Further studies are needed to investigate the possible significance of FAM19A4 and miR124-2 hypermethylation, especially in terms of prognosis.

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#9475

P39-13 | Pancreatic neoplasia in Brazil: A longitudinal study (2008-2023)

39 - Public health

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Background/Objectives: Pancreatic neoplasia encompasses a heterogeneous group of tumors originating in the pancreas. Ductal adenocarcinoma is the most common type, characterized by high aggressiveness and frequently late diagnosis. Symptoms are nonspecific and mortality is high. Risk factors include smoking, diabetes, and advanced age. Treatment depends on the stage of the disease and may involve surgery, radiation therapy, chemotherapy, and targeted therapy. Research is seeking new approaches to improve the diagnosis and treatment of this challenging disease. This study aims to analyze morbidity and mortality from pancreatic neoplasms and their prevalence in hospitalizations in the public health system between 2008 and 2023.

Methods: Retrospective, descriptive, and quantitative study using secondary data from the Ministry of Health's Hospital Information System (SIH/DATASUS) on hospitalizations for pancreatic neoplasms in the public health system between 2008 and 2023. Variables used include region/federative unit, sex, age, race/ethnicity, costs, and deaths, excluding variables that did not meet the predefined criteria

Results: The period from 2008 to 2023 witnessed a continuous and alarming growth in the number of pancreatic neoplasm cases in Brazil, totaling 155,401 cases. The distribution showed significant disparities, with the Southeast region concentrating the highest number of cases (752,740), followed by the Northeast (244,560), North (45,750), South (41,229), and Midwest (9,867). Regarding demographic characteristics, the white population was the most affected (49.12%), with a higher prevalence in the age group between 60 and 69 years (31.45%), but with records in all other ages. Males also showed a higher incidence (50.43%). The high mortality rate associated with pancreatic neoplasm, estimated at 23.91%, reflects the aggressiveness of the disease and the difficulty of early diagnosis. Additionally, the average length of stay and total hospital cost, estimated at R$ 250,051,474.39, demonstrate the significant economic impact of the disease on the health system

Conclusions: The study results highlight the urgent need for coordinated and multidisciplinary actions to prevent, early diagnose, and treat pancreatic neoplasms in Brazil. The heterogeneity of the Brazilian population, with an emphasis on the male population, especially in the age group of 60 to 69 years, and the white population, demands a comprehensive approach that encompasses health promotion, early detection of risk factors, development of new therapies, and optimization of palliative care. The complexity of the disease, coupled with the high cost of treatments, significantly impacts the health system. Continuous training of healthcare professionals, translational research, and integration of health services are fundamental pillars to improve patient prognosis and quality of life, as well as contributing to the reduction of associated costs.

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P06-09 | Rumors and fears about the HPV vaccine: Perceptions of adolescent girls in Addis Ababa, Ethiopia

06 - HPV prophylactic vaccines

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Background/Objectives: Cervical cancer (CC), caused by the Human Papillomavirus (HPV), is the fastest-growing cancer worldwide, particularly affecting women of reproductive age (CDC, 2024). This disease disproportionately affects women in low-and middle-income countries (LMICs), with Sub-Saharan Africa experiencing the highest rates of CC related deaths (WHO, 2024). Despite being largely preventable through HPV vaccination and screening, the prevalence of cervical cancer continues to rise, with 660,000 new cases reported globally in 2022 (WHO, 2018). The prevalence of cervical cancer (CC) in Ethiopia is notably high. Additionally, CC is the second leading cause of cancer-related mortality in Ethiopia, with low awareness and HPV vaccine uptake being significant contributing factors. Therefore, this study aims to investigate these perceptions to identify challenges and factors affecting vaccine uptake. The goal is to enhance vaccine uptake, ultimately contributing to the reduction of cervical cancer in the country and supporting the collaborative effort towards the Sustainable Development Goal (SDGs) 3, which aims to reduce cervical cancer mortality.

Methods: Research Design This study employed a qualitative research design using focus group discussions (FGDs) to collect data. FGDs were chosen as the primary data collection method to allow adolescent girls to openly discuss and share their experiences with HPV vaccination. The study received the ethical approval from the Addis Ababa Health Sciences College Institutional Review Board (IRB) Ethiopia and the Etikprövnings myndigheten insert nr. Parents made an informed decision, and written consent was collected from parents/guardian and assent from the participant girls. Braun and Clark thematic analysis was used to analyze the data (Braun & Clarke, 2006a). NVivo 14 was employed to support data analysis. Two data analysts conducted blinded descriptive coding. The data was visualized using a coding tree and a table to summarize the analysis.

Results: Four themes were identified, participants were concerned about potential side effects, indicating a significant fear of adverse effects. Influences from family, friends, and the community played a major role in the girls' vaccination decisions. Wube et al. highlighted that family perceptions of the vaccine play a significant role in shaping girls' decisions to vaccinate. Communication gaps were noted, with issues in how vaccine information was shared among different groups. Additionally, students' involvement in vaccine decision-making was overlooked and they were often treated as passive recipients.The student's role in vaccine decision-making was an important theme. Students played a pivotal role in the HPV vaccination process, both in their own vaccination and those of their peers. They acted as facilitators and obstacles to other students' vaccination, demonstrating their significant influence and autonomy in the decision-making process. Despite encouragement or discouragement from teachers and family, students were independently deciding whether to get vaccinated.

Conclusions: Adolescent girls in this study were identified as being inadequately informed about the HPV vaccine, and the vaccination program lacks a collaborative effort from various stakeholders. To improve vaccine uptake and reduce cervical cancer morbidity and mortality, it is crucial to enhance communication strategies and actively involve and empower girls in the vaccination process.

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#9481

P28-01 | Extended genotyping (human papillomavirus-HPV) in oropharynx of HIV-infected population: Clinical and cytological findings

28 - Oral HPV infection

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Background/Objectives: High-risk human papillomavirus (HPV) genotypes (VPHar) 16 and 18 are associated with different types of cancer (1-4). The association of HPV infection, genotypes, clinical and cytological findings in the oropharynx of the studied population is described.

Methods: A cross-sectional study was conducted in a group of patients with HIV infection at the Hospital Universitario San Ignacio, Bogotá Colombia South America in 2023. The test used was liquid-based cytology (Surepath® system).

Results: The oropharynx of 221 patients was studied. 210 males (95%). The median age was 31 years for men (18-63) and 36 years for women (18-65). Abnormal clinical findings are nonspecific. Genotyping was positive in 4 patients (1.8%), 2 men and 2 women. Three of them with more than 1 genotype. Liquid-based cytology in the oropharynx was normal in 159 patients (72.0%); ASC-US 22.6%, ASC-H 1.3%; LSIL1.8% and HSIL 0.4%.

Conclusions: The prevalence of oropharyngeal VPHar infection in HIV patients was low, but there is coinfection. The frequent abnormal cytological findings of this test may suggest that screening should start with cytology as in the anus. Further studies are required in immunocompromised patients to determine clearance or persistence in the oropharynx, as well as the description of clinically significant premalignant mucosal lesions.

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P12-02 | Performance of DNA methylation analysis and p16/Ki-67 dual-staining as triage tests for HR-HPV positive women

12 - Triage of HPV positive women

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Background/Objectives: Management of HR-HPV-positive women in cervical cancer screening differs in individual countries and the optimal strategy of triage is being searched. Currently, most advocated triage strategies for colposcopy referral include repeat Pap cytology and HPV genotyping. Molecular markers such as p16/Ki-67 dual-staining or methylation analyses are supposed to further increase the effectiveness of triage. In the setting of Czech cervical cancer screening, the only molecular marker allowed for triage is p16/Ki-67 dual-staining. P16/Ki-67 dual-staining should mark cells with a transforming HR-HPV infection and therefore increase the test specificity for high-grade lesion detection. However, it may not accurately reflect a high short-term risk of progression to cancer, potentially leading to overtreatment, especially in younger women. A methylation analysis of a host cell DNA from cervical scrapes evaluates epigenetic changes associated with long-term HR-HPV infection. It is supposed to be a marker of so-called advanced cervical lesions which should be immediately treated. This study aimed to compare the performance of p16/Ki - 67 dual-staining and methylation analysis in paired liquid cytology and biopsy samples from HR-HPV-positive women from the Czech cervical cancer screening program.

Methods: Methylation analysis of FAM19A4/mir124-2 and p16/Ki-67 dual-staining were performed on archived liquid cytology samples from 44 HR-HPV-positive women. Test results were compared to follow-up biopsy findings and evaluated in relation to clinical data, including age and HPV genotype.

Results: High-grade cervical lesions (HSIL, AIS) were present in 53% (23/44) of biopsies; while 47% (21/44) showed only low-grade lesions or no lesions. P16/Ki-67 dual-staining was positive in 64% (28/44) of samples, and methylation was positive in 43% (19/44). High-grade lesions were positive for p16/Ki-67 dual-staining in 87% (20/23) and for methylation in 65% (15/23). Discrepancies between the two markers were observed in 32% (14/44) of cases, notably in women aged 35 and younger with high-grade lesions, who were often positive for p16/Ki-67 dual-staining and negative for methylation. HPV types 16, 18, or 45 were present in 36% (16/44) of samples; of these, 75% (12/16) were methylation-positive, and 69% (11/16) showed p16/Ki-67 positivity.

Conclusions: In this study, p16/Ki-67 dual staining demonstrated high sensitivity for high-grade lesions, but moderate specificity, as it also identified over one-third of cases with no or low-grade lesions on biopsy. Methylation analysis generally yielded more negative results, leading to lower sensitivity for histologically confirmed high-grade lesions, particularly in younger women. However, these lesions may represent biologically early stages that carry a low short-term risk of progression to cancer. Excluding women with such early lesions from the immediately treated cohort could help reduce overtreatment among those with pending parenting plans. This speculation needs to be verified by long-term studies.

References: The study was supported by a grant: FNPl 00669806/Ministry of Health of the Czech Republic

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#9488

P09-02 | Comparison of clinical management of partial genotyping results from four commercially available HPV assays in a South African setting

09 - HPV testing

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Background/Objectives: In 2024, the South African (SA) National Department of Health (DOH) introduced primary HPV DNA screening in the SA public health sector, recommending the "screen, triage and treat" approach for any HR HPV positive results. However, provincial DOHs in SA could adapt the national algorithm based on provincial expert recommendations and resource availability. Some provinces elected to "screen and treat" HPV 16/18/45 positive patients. HR HPV negative patients would be followed up in 3-10 years dependent on HIV status. The National Health Laboratory Service (NHLS), the SA public sector laboratory service, leverages HPV testing on the Abbott Alinity m and Roche cobas platforms used for HIV testing. Their HPV assays report different partial genotyping profiles suggesting that patients could be managed differently based on provincial algorithm and assay used. We, therefore, compared the hrHPV partial genotyping and clinical performance of these two assays and two additional assays available in SA.

Methods: Residual liquid-based cytology samples (N=60) obtained from an NHLS cytology laboratory were tested on the Alinity m HR HPV(Alin), cobas HPV(cobas), BD Onclarity HPV(BD) and Xpert HPV(Xpert) assays. The squamous intraepithelial lesion (SIL) status of the samples was stratified as: 25 negative (NSIL), 17 low-grade (LSIL) and 18 high-grade (HSIL). Results were cross-tabulated, and concordance evaluated.

Results: Valid results were obtained for 51 samples across all assays. Positive for any HR HPV was reported for 43.1% (n=22). Four patients would have been treated based on the alternative algorithm and 14 triaged if tested on any assay. The remaining four patients would have different clinical management interventions (Table 1). Negative concordance for any HR HPV across assays was 39.2 % (n=20) and 17.6% (n=9) were discordant. Notably, the Alinity HR HPV assay reported negative results for seven discordant results, these patients would have been recommended for rescreening at an interval determined by HIV status but would have had further clinical management if tested on one or more of the other assays (Table 1). Four of the seven patients were concordant for treatment (n=1) and triage (n=3) eligibility according to the other three assays. In total, 25.4% (n=13) would have received different clinical management recommendations. Finally, there were minimal differences in cytology grading across assays (p = 0.998) with HSIL predictably associated with highest hrHPV positivity. Table 1 Summary of discordant treatment recommendations for any HR HPV positive and discordant any HR HPV results across all assays Nominal Sample no. Clinical Management according to adapted algorithm BD Alin cobas Xpert Any HR HPV positive samples 1 treat triage triage treat 2 triage triage triage treat 3 treat triage treat triage 4 triage triage treat triage Discordant any HR HPV results 1 triage treat rescreen treat 2 triage rescreen triage triage 3 triage rescreen triage triage 4 treat rescreen treat treat 5 triage rescreen triage triage 6 rescreen rescreen triage triage 7 triage rescreen rescreen triage 8 rescreen rescreen treat rescreen 9 treat treat treat rescreen

Conclusions: Using different provincial testing algorithms and assays in laboratories could result in different clinical management recommendations with implications for individual patients and monitoring and evaluation of national program performance.

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#9508

P09-04 | HPV-prevalence at first, second and third cell-sample in Danish women HPV-vaccinated as girls: data from Trial23 cohort study

09 - HPV testing

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Background/Objectives: Denmark has a high background risk of cervical cancer, which has, over the past 50 years, increasingly been controlled by cytology screening. Since 2008, human papillomavirus (HPV)-vaccination has been offered to girls aged 13-15, and from January 2009 to all girls turning 12. In Denmark, women under the age of 30 are still being screened with cytology screening, and women over 30 are screened with HPV-testing. Cohorts of women where upto 90% were vaccinated with the 4-valent HPV-vaccine as girls have entered screening age sense 2016. In our study, we wish to evaluate the impact of vaccination on the risk of development of precancerous lesions. Therefore our aim is to track the long-term effect of vaccination by HPV-testing of residual material in three consecutive cell-samples collected when the women were 22-30 years.

Methods: From February 2017 to February 2024, residual material from cytology-analyzed cervical cell-samples collected in SurePath liquid-base medicin was HPV-tested with Cobas 4800/6800 in three-and-a-half out of five Danish regions. For women with HPV-tested cell-samples, our primary outcome was the prevalence of HPV-infection in the first, second, and third cell-sample of the subgroups detectable by Cobas 4800/6800: 1) HPV-positive for any type; 2) HPV16/18-positive; 3) HPV-positive for any HR HPV type other than HPV16/18; and 4) HPV-negative. To distinguish between new ("incident") and old ("persistent") infections, we further stratified the prevalence at second and third samples by previous infection status. Prevalence estimates were reported together with 95% Copper-Pearson confidence intervals (CI). Furthermore, we compared prevalence, persistence and incidence among vaccinated and unvaccinated women by estimating relative risks (RR), obtained through Poisson regression models using a sandwich variance estimator.

Results: Over seven years, 8659 women had at least one cell-sample, 5835 women at least two, and 2461 women at least three. In vaccinated women, HPV16/18-prevalence was 0.4% (95% CI 0.2-0.5) in first, 0.3% (95% CI 0.1-0.4) in second, and 0.2% (95% CI 0.0-0.4) in third cell-sample. Prevalence of other high-risk (HR) HPV was 32%, 28%, and 31%, respectively. In unvaccinated women, HPV16/18-prevalence was 6% (95% CI 5-8), 5% (95% CI 3-8), and 6% (95% CI 3-10), respectively, and for other HR HPV 27%, 24%, and 29 %, respectively. Persistence of HPV16/18 was 40-50% and 50-60% of other HR HPV, with no difference between vaccinated and unvaccinated women. Incidence of HPV16/18 was very low in vaccinated women and statistically significantly lower than in unvaccinated women. The incidence of other HR HPV was higher in vaccinated compared unvaccinated women, 10-14% and 7-8%, respectively.

Conclusions: We analyzed presence of HPV-infections in up to three consecutive cell-samples from women aged 22-30 and vaccinated with the 4-valent HPV-vaccine as girls. Our study provided solid, real-world evidence of a stable, very strong protection against HPV16/18. A high proportion of the few HPV16/18-infections in vaccinated women remained persistent, reflecting that the vaccine is not therapeutic. The small group of unvaccinated women had one-third of the HPV16/18-prevalence seen in previous cohorts, indicating herd immunity. Across the three rounds of cell-sampling, the prevalence of other HR HPV remained high in both vaccinated and unvaccinated women.

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P16-02 | Performance of cytology in HPV-positives by endocervical cell-(EC) status in the national cervical cancer screening program in the Netherlands

16 - Screening methods

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Background/Objectives: Since 2017, the Dutch national screening program for cervical cancer has used primary human papillomavirus (HPV) testing with cytological triage of HPV positives. The performance of cytological triage is currently debated for smears without both endocervical cells and squamous metaplastic cells (EC-negative smear tests), being representative for the transition zone. In 2023, a preliminary evaluation of the Dutch screening program showed increasing occurrence of EC-negative tests and lower detection rates for CIN2, CIN3, and cancer in EC-negative smears compared to EC-positive smears, suggesting a decreased effectiveness of the screening program.

Methods: We used comprehensive nationwide HPV, cytological, and histological data from the Dutch screening program over the period 2017-2024 to assess the performance of cytological triage by EC-status over two rounds of HPV-based screening. Firstly, we evaluated the association between Pap-score and EC-status by calculating relative risks (RR) and examining correlations between baseline and repeat cytology within the same round. Additionally, we tested whether EC-status affects Pap-score in the subsequent screening round. We also examined the effect of EC-status on referral rates and the risk of CIN2+. Finally, for participants not referred in the first round, we used histological examination results in the second round to evaluate the impact of missed referrals due to EC-negative smears on increased detection of CIN3 and cancer in the second round.

Results: The proportion of EC-negative smears was 17.1% across all cytology tests in 2017-2024 and 31.2% in baseline triage cytology, with an increasing trend in recent years, reaching almost 40% in 2024. The RR of an EC-negative versus EC-positive baseline smear was 2.1 for an EC-negative repeat smear and 1.6 for an EC-negative smear in the second round. EC-negative smears had a significantly lower chance of cytological HSIL (Pap3a2+) compared to EC-positive smears (2.3% vs. 5.5%, $p<0.001$), were associated with fewer referrals (25.1% vs. 40.8%, $p<0.001$), and showed a decreased risk of CIN2/3 after referral (45.3% vs. 54.6%, $p<0.001$). Baseline EC-negative smears in round 1 did not result in an increased risk of abnormal cytology (Pap3a2+) or more severe histological diagnoses when referred in round 2.

Conclusions: The proportion of EC-negative smears is high in baseline cytology following HPV-positivity, and this has increased in recent years. The lower Pap-scores and referral rates associated with EC-negative compared to EC-positive smears suggest under-detection and could therefore be cause for concern. However, EC-status in baseline cytology is not associated with more severe cytological or histological outcomes in the subsequent screening round. Therefore, at present, there is no direct evidence to support the notion that EC-negative smears cause under-detection with consequential worse clinical outcomes, but continued investigation is needed to safeguard the effectiveness of the Dutch cervical cancer screening program.

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#9514

P14-02 | Prevalence, genotyping and coinfection of human papillomavirus and sexually transmitted infections: A representative study of the city of Antofagasta, Chile

14 - Genotyping

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Background/Objectives: In Chile, 2 women die every day from cervical cancer, 99% of them are related to Human Papillomavirus (HPV), according to studies by the Public Health Institute of Chile, in Santiago, the 14% of women between 15 and 69 years old are infected with HPV and 45-61% of them are infected with more than one genotype 1. The most prevalent genotypes associated with 70% of invasive carcinomas are genotypes 16 and 18 2. In Antofagasta city, cervical-uterine cancer has the first place of cancers that have an explicit health guarantee and that exceed the Adjusted Mortality Rate (AMR) in women, with a rate of 9.6, according to indicates the National Cancer Plan 2018-2028, Chile. The risk of acquiring this infection is determined by sexual behaviors and includes sexual initiation at an early age and a high number of sexual partners. Nevertheless, the incidence of infection with this virus is low, with only a small percentage of those infected developing cervical cancer. It is estimated that 90% of HPV infections are usually transient, that is, controlled by the immune system, and disappear spontaneously in approximately two years. The precise factors that determine whether an infection persists and progresses to cervical cancer remain unclear. However, there is evidence to suggest that certain risk factors may play a role, these include tobacco use, immunosuppression, multiparity, and the presence of other sexually transmitted infections 3. Sexually transmitted infection caused by the human papillomavirus (HPV) is associated with 570,000 cases of cervical cancer in 2018, and over 311,000 deaths from cervical cancer each year 4.

Methods: A cross-sectional study was carried out in 390 apparently healthy, non-pregnant women, aged 25 to 64 years. The participating women signed a prior informed consent and answered an epidemiological survey. A cervical-vaginal swab was performed considering a sample of simultaneous collection of ectocervical and endocervical cells with a single device. HPV DNA was identified by PCR was performed for 28 genotypes of HPV, in addition to the identification of 4 STI pathogens (PCR): C. trachomatis, N. gonorrhoeae, M. genitalium, T. vaginalis.

Results: The global prevalence of HPV was 36.9% (144 samples), 54.9% (79 samples) of the positive samples had high-risk genotypes (HR HPV), and a mixed infection of genotypes was observed in 26.4% (38 samples). The most frequent HR HPVs were genotype 16 (26 samples), genotype 58 (21 samples), followed by genotype 39 (20 samples), genotype 31 (18 samples) and genotype 66 (14 samples). The most common low-risk HPVs (LR HPV) were genotype 6 (22 samples), genotype 42 (17 samples), genotype 43 and genotype 54 (11 samples) and genotype 61 (10 samples). A total of 46 samples had infection with multiple HR HPV genotypes (2 to 6 genotypes), 12 samples had infection with multiple LR HPV genotypes (2 to 4 genotypes). Regarding the Sexually Transmitted Infections investigated, 24 positive samples were found, of which 17 were positive for HPV.

Conclusions: The prevalence of HPV in the female population of the city of Antofagasta was 36.9%, the prevalence of STIs in the female population was 6.2%, mainly due to Chlamydia trachomatis. The presence of STI is a relevant factor for HPV, being 70.8% more likely to have HPV if you already have an STI infection. The most frequent high-risk HPV genotypes were 16, 31, 39, 58 and 66. The most frequent low-risk genotypes were 6, 42, 43 and 54.

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#9516

P14-03 | Development and validation of an HPV E6/E7 multiplex real-time PCR assay

14 - Genotyping

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Background/Objectives: The HPV E6 and E7 oncogenes are rarely lost during host chromosomal integration events and cancer development, making them suitable targets for HPV detection in high-grade lesions and cancer. As part of the Norwegian vaccine surveillance program, we use singleplex real-time PCR targeting E6/E7 as one of three methods for HPV genotyping. To save time and valuable sample material, we are currently developing a multiplex assay for E6/E7-targeted HPV genotyping to replace our current method.

Methods: The E6/E7 assay will detect 14 high-risk types, HPV16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68. It will include 4-5 separate PCR reactions, each targeting a maximum of 4 HPV types, using short primers (18-22 bp) with melting temperature (Tm) ranging between 55-60 °C. The amplicon length is between 70-150 bp. The probes will have a Tm 8-10 °C higher than the primers and a length of approximately 15 bp, ensuring high binding specificity. To increase Tm, allowing for shorter and more specific probes, the attachment of minor groove binders (MGB) to the probes will be considered. "Primer3" and "Geneious Prime" will be used for primer/probe design and quality control. The assay will be tested first as individual reactions for each HPV type before multiplexing, and run on an AriaDx real-time PCR instrument (Agilent) containing six optical modules, including FAM, ROX, HEX, CY3, CY5, and ATTO425. The assay's performance will be assessed on E6/E7 DNA plasmids and validated on cervical cell samples and FFPE-patient material.

Results: Preliminary results and insights from the assay development will be presented. This includes primer design, the final combination of different HPV types included in each multiplex reaction, as well as the assay's detection limit and analytical sensitivity.

Conclusions: Our current singleplex E6/E7 assay has contributed to identifying HPV types that would otherwise remain undetected due to integration events and subsequent sequence loss. Establishing a multiplex real-time PCR method will provide a more efficient workflow in our lab and will also save valuable sample material.

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#9519

P13-03 | Human papillomavirus genotype diagnosis in self-sampling women at a primary care center near Lisbon

13 - Self-sampling

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Background/Objectives: Early detection and treatment of cervical precancerous lesions can reduce the burden of cervical cancer. In Portugal, some population does not have a general practitioner or access to the screening program; Self-sampling strategies could be an option to increase the number of women who undergo cervical screening in Portugal.

Methods: Women visiting health centers were invited to participate in a self-sampling screening for HPV. Self-samples were collected by swab by the women themselves, and HPV genotyping was performed by the AllplexTMHPV28 Detection (Seegene Inc., Korea).

Results: Between May 2022 and October 2024, 2027 (mean age 43.9) women were screened. HPV was detected in 40.7% (825/2027) of the women. Of those, 58.0% (479/825) corresponded to the high-risk (HR) genotypes, with HPV 31 (9.5%) the most frequent, followed by HPV 52 (8.9%). HPV 16 and 18 were detected in only 7.5% and 4.4% of the cases, respectively. Low-risk genotypes were detected in 48.9% (395/825) of the positive women, with HPV 54 being the most common (14.4%) followed by HPV 42 (10.7%). Possible HR-HPVs were detected in 34.9% of the positive cases, with HPV 53 (13.6%) being the most frequent. The Probably HR-HPVs, HPV 68, was detected in 12.4% of the positive women. Almost half of the positive women, 47.4% (391/825), had mixed HPV infections.

Conclusions: In our self-sampling population, the frequency of HR-HPV is high. Without this sampling strategy, these women will be excluded from cervical cancer screening. Our results reinforce the importance and viability of self-sampling in achieving the goal of eliminating cervical screening in Portugal and show that healthcare policies should take this type of sampling into consideration.

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#9522

P06-01 | Developing HPV vaccination profiles among men who have sex with men to inform targeted public health interventions

06 - HPV prophylactic vaccines

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Background/Objectives: Men who have sex with men (MSM) experience disproportionately high rates of HPV-related conditions, with anal HPV prevalence estimated at over 60%, and exceeding 80% among HIV-positive MSM. This population faces up to 17 times higher risk of anal cancer compared to heterosexual men. Despite elevated risk, only 32-50% of MSM report having received at least one HPV vaccine dose, with significant racial/ethnic disparities, particularly among Hispanic, Black, and Asian MSM. Key factors affecting vaccine uptake include disclosure of sexual orientation to healthcare providers, recent healthcare service use, age, metropolitan residence, income, and health insurance. This study aims to use Latent Class Analysis (LCA) to identify vaccination profiles within the MSM population, thus guiding interventions to improve HPV vaccine uptake and series completion.

Methods: Methods. This cross-sectional study will recruit 1,000 MSM, ages 18-45, from Los Angeles County (LAC), one of the nation's most diverse regions. LCA will classify participants into distinct vaccination profiles based on vaccination history, healthcare access, HIV status, and sociodemographic factors. Subsequently, a subset of 30-50 MSM from each profile will participate in qualitative, semi-structured interviews, exploring profile-specific facilitators and barriers to HPV vaccination. We will also conduct a pile-sort activity in which participants prioritize motivators for HPV vaccination; this information will inform intervention targets aimed at improving patient-provider communication and HPV series completion. Vaccination status will be verified through the California Immunization Registry (CAIR2), ensuring data accuracy.

Results: Results (Anticipated). We expect LCA to reveal multiple unique vaccination profiles, with distinct motivators and barriers for each. Profiles are anticipated to highlight differences by racial/ethnic background, HIV status, and healthcare access, providing actionable insights for public health strategies. These profiles will support targeted interventions to address specific needs, such as reducing racial/ethnic disparities and improving access to HPV vaccines among at-risk subgroups.

Conclusions: Discussion. LCA represents a novel approach by going beyond conventional demographic analysis to identify underlying, unobserved subgroups—or "latent classes"—within the MSM population. Methodologically, LCA assigns individuals to classes based on shared response patterns across variables, revealing nuanced vaccination profiles that reflect meaningful variations in health behavior. This granularity allows us to develop tailored interventions that resonate with each group's unique motivators and barriers. By isolating these nuanced profiles, LCA enhances public health strategies, ensuring that messages and resources are customized to the diverse needs within this high-risk population. This approach has broader implications for improving vaccine uptake in other marginalized communities, as it allows for precision in understanding and addressing specific behavioral drivers within complex populations.

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#9527

P38-01 | Impact and cost-effectiveness of implementing cervical cancer screening in sub-Saharan Africa: A systematic review

38 - Low resource settings

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Background/Objectives: Cervical cancer remains in the top five most common cancers in women worldwide, with there being nearly 700,000 new cases in 2022 as reported by the WHO. Much of this burden disproportionately exists in sub-Saharan Africa where incidence and mortality rates are among the highest globally, making cervical cancer one of the leading causes of cancer-related deaths in the region. Nearly all cervical cancers are caused by human papillomavirus (HPV), a preventable infection with effective vaccines and screening methods. If detected early, cervical cancer is one of the most treatable forms of cancer.Despite this, there still remains high incidence rates in women in sub-Saharan Africa and barriers such as limited access to screening, a shortage of trained health workers, and cost constraints all contribute to the inequities seen in addressing cervical cancer in sub-Saharan Africa. Therefore, it is essential to create and implement effective programs that are specifically tailored to the challenges present within the region. Given there is a lack of evidence on the impact and costs of these tailored strategies, our objective is to synthesize the existing evidence on the impact, cost and effectiveness of strategies to implement cervical cancer screening programs.

Methods: The initial literature search was performed in 2021, followed by an updated search in 2024. We searched PubMed, Embase, Scopus, CINAHL (Ebsco) and Global Health using MeSH terms and Boolean operators to identify relevant articles published between 1994-2021. Our inclusion criteria are 1) study population of women in sub-Saharan Africa, 2) interventions involving cervical cancer prevention programs, implementation programs, or scale-up of screening programs using visual inspection with acetic acid (VIA) or human papillomavirus test (HPV), and 3) outcomes evaluating the intervention and/or program cost information. Two reviewers conducted independent screening on title and abstract, followed by full-text review, with conflicts being resolved by a third reviewer. Studies meeting all inclusion criteria after full-text review were imported into Excel for data extraction and analysis.

Results: A total of 21,226 articles were identified from the database searches with 14,724 removed as duplicates. The remaining 6,502 articles were screened and 207 proceeded into the full text review stage. After final screening, 98 articles are currently included in the study and in review. The results will report on implementation strategies used across various sub-Saharan African countries and populations, along with some costing information. Key themes and categories identified for extraction include country and site location, clinical setting, study population, screening sample collection strategies, methods for results notification, treatment for precancer, post treatment follow up, innovations, primary outcomes, funding/payment sources and economic evaluations used.

Conclusions: Evidence from this review will inform policy and the development of sustainable cervical cancer programs in sub-Saharan Africa.

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#9529

P39-12 | Examining opportunities to improve HPV vaccination coverage through policy change

39 - Public health

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Background/Objectives: Policies are the basis for decision-making on multiple levels. HPV vaccination policies serve to support or hinder myriad factors related to HPV vaccination coverage. Our overarching policy research seeks to understand and examine public policy decisions and other factors that drive HPV vaccination coverage across the United States (U.S.). We have examined multi-levels of drivers of HPV vaccination coverage and regulatory conditions influencing HPV vaccination delivery.

Methods: Multiple analyses were conducted to examine the relation between HPV vaccination with regard to key factors using existing data sources and peer-reviewed literature. A cost savings analysis was performed to project increased HPV vaccination coverage and reduced HPV cancer incidence resulting from addressing key policy actions to reduce national direct health care spending. Engagement with subject matter experts enhanced interpretation of quantitative results. Regulatory conditions were evaluated using existing data sources.

Results: The following five recommendations were identified as being critical to HPV vaccination improvements: Leverage meningococcal conjugate vaccination; Expand health care provider training to strengthen and routinize HPV vaccination recommendations; Improve efforts to recruit and enroll in the federal VFC program; Expand resources available to improve HPV vaccination data through state IIS; and Engage in efforts to preserve and expand eligibility for Medicaid. Additional policy recommendations for Medicaid expansion (importance of setting the federal poverty level to 200% in every state), the southeastern U.S., and provider vaccination reimbursement levels were developed. Projected increased HPV vaccination series initiation and reduced HPV cancer incidence that would result from addressing four of these five factors could reduce national direct health care spending by nearly $19 million in the U.S. In addition, the increased HPV vaccination series completion and reduced HPV cancer incidence could reduce the two-year national direct health care spending by more than $24 million in the U.S. Regulatory examination of HPV vaccination reimbursement in the U.S. revealed discrepancy by provider type with family physicians reimbursed at the lowest levels relative to other provider types, rural serving providers received lower reimbursement overall compared to urban providers, and rural serving family physicians have the lowest reimbursement.

Conclusions: HPV vaccination is cancer prevention. Increasing HPV vaccination coverage will reduce the incidence of HPV cancers. Increasing HPV vaccination coverage will save millions of dollars for our nation's health care system. To realize the full potential and promise of the HPV vaccine, we must pursue policy change to address systemic barriers to HPV vaccination coverage in the U.S. Policy-level changes on proximal and national levels offer permanence to modify and establish facilitative structures for HPV vaccination and also may serve to shift social norms to the importance and value of HPV vaccination for cancer prevention. Large-scale policy efforts may face opposition but remain viable options for improvements in the U.S.

References: Study results are summarized and full report available at stjude.org/hpv-policy-summary, including a complete list of references.

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#9532

P13-07 | Urine high risk human papillomavirus testing as an alternative cervical screening strategy: The ACES Studies

13 - Self-sampling

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Background/Objectives: Urine human papillomavirus (HPV) testing shows promise for cervical screening and may improve uptake. Our aims were to determine the clinical performance of urine HPV for CIN2+ detection in colposcopy and general screening populations; and ascertain its acceptability to current attendees of cervical screening.

Methods: We tested matched cervical and urine samples for high-risk HPV using Roche cobas-8800 at cervical thresholds. Colposcopy clinic attendees were randomised to provide a first-void urine sample using the Colli-Pee® device (Novosanis;10mls+preservative) or a standard-pot. Primary care attendees collected their urine using the Colli-Pee device. The colposcopy arm informed diagnostic test sensitivity (detection of CIN2+) and the general screening arm informed diagnostic test specificity (CIN<2). We assessed concurrent acceptability of self-sampling in trial participants using a questionnaire.

Results: 465 colposcopy and 1517 primary care attendees provided matched samples (total=1982). Colposcopy participants were balanced in age (median;32vs34 years) and ethnicity (79%vs81% white ethnicity) and referral screening results (44%vs44% high grade; 43%vs43% low grade/borderline; and 11%vs12% persistent hr-HPV+/cytology-negative) in Colli-Pee and pot arms, respectively. Primary care participants had a median age of 37 (IQR 30-45), 69.7% were of white ethnicity with an HPV positivity rate of 13.5%. In the Colposcopy study, urine HPV sensitivity for CIN2+ detection was higher with Colli-Pee (90.3%;95%CI=83.7-94.9) than pot-collected urine (73.4%;95%CI=64.7-80.9;p=0.0005). Overall, Colli-Pee urine sensitivity for CIN2+ detection was 91.3%(95%CI=85.5-95.3) vs 98.7%(95%CI=95.2-99.8;rel.sens=0.93) in cervical samples and specificity was 85.2%(95%CI=83.3-86.9) vs 87.8%(95%CI=86.0-89.4;rel.spec=0.97). 72.8% of colposcopy and 69.5% of primary care attendees stated they somewhat or strongly agreed that they would be happy to use only a urine sample for screening.

Conclusions: HPV tested Colli-Pee-collected urine shows similar test accuracy for CIN2+ detection compared to routine cervical screening. Improved test accuracy could be achieved with urine-specific thresholds for HPV positivity. Urine is broadly acceptable to current attendees of cervical screening programmes, however some still prefer clinician sampling, making a choice of sampling methods important in future cervical screening programmes

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#9549

P37-01 | A nationwide survey on knowledge, attitude and practice regarding human papillomavirus (HPV), HPV-related disease and HPV vaccine among adolescents and their parents in China

37 - Health education

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Background/Objectives: This cross-sectional survey aimed to assess the knowledge, attitude, and practice (KAP) towards HPV, HPV-related disease, and HPV vaccine among adolescents and their parents. Additionally, the study further explored factors associated with their KAP, with a particular focus on the influence of adolescent parents on their children's willingness of taking HPV vaccine.

Methods: Adolescents aged 9-17 years and their parents were recruited between July and August in 2024 from seven administrative regions of mainland China based on multi-stage non-randomized sampling. Eligible participants were approached in person and asked to complete an electronic self-administrated questionnaire, in which their socio-demographic characteristics, knowledge and attitude towards HPV and HPV vaccine, willingness and practice towards HPV vaccination, and perceived barriers of receiving HPV vaccination were assessed. The term "adolescents" includes both boys and girls; however, HPV vaccines are not indicated for males in China. Descriptive analyses were conducted to summarize the KAP of the target population, and multivariate regression analyses were used to identify the associated factors.

Results: Participants: Data from 1,000 adolescent-parent pairs were analyzed. The mean (SD) age of adolescents was 13.5 years, and parents' mean age was 39.5 years. Among parents, 57.3% were female, 75.7% had education beyond high school, and 31.2% reported monthly incomes exceeding 6,000 RMB. Adolescents: Only 34.2% had heard of HPV, and 43.9% had heard of the HPV vaccine. Their mean knowledge scores were 2.4/5 for HPV and related diseases and 3.2/6 for the vaccine. Vaccination coverage was 12.5%, though 49.2% of unvaccinated adolescents expressed willingness to receive it. The 9-valent vaccine was most common in regions without free vaccination programs, while the 2-valent vaccine dominated in areas with free programs. Parents: Awareness was higher, with 61.0% knowing about HPV and 68.0% knowing about the HPV vaccine. Their mean knowledge scores were 5.2/10 for HPV and related diseases and 7.5/12 for the vaccine. Among parents, 17.6% had been vaccinated, and 56.6% were willing to vaccinate their unvaccinated adolescents. Influential Factors: Adolescents' willingness to vaccinate was influenced by sex, education, knowledge, and attitudes toward HPV and related diseases. No significant association was found between parental KAP and adolescents' willingness. Fathers' willingness to vaccinate adolescents was influenced by education, vaccine knowledge, and frequency of physical exams, while mothers' willingness was linked to knowledge of HPV and the vaccine, as well as prior HPV testing experience.

Conclusions: Despite the reinforcement of awareness and knowledge of HPV and HPV vaccine in the recent years, the low uptake of HPV vaccine among adolescents remains a vital issue, which underscored the necessity of tailored health education campaigns targeting this population.

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#9553

P13-04 | Comparative analysis of HPV genotyping, methylation and microbiome profile in uterine cervix samples obtained by urine, self-collection and healthcare professionals

13 - Self-sampling

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Background/Objectives: Cervical cancer represents a serious public health problem in countries with low socioeconomic index, including Brazil. In fact, some regions of Brazil such as the state of Amazonas, has one of the highest incidences of cervical cancer in the world. Nowadays, high-risk HPV DNA testing is an attractive strategy for the prevention of this disease, particularly using self-collected samples. In these particular settings, where women have limited access to the healthcare system and screening programs, introduction of self-collecting strategies may contribute to reduce cervical cancer incidence. In this study we aim to compare the performance of commercial HPV-DNA tests, as well as investigate the microbiota and DNA methylation, in samples collected by three different methods.

Methods: To determine the value of self-collection in our settings we designed a cross-sectional study involving 100 women over 21 years of age referred to the colposcopy service for presenting CIN2+ cytology alterations. We analyzed HPV-DNA in urine, cervical self-collection and professional collection. All samples were obtained at the same visit and each one was analyzed for the presence of HPV-DNA using four different commercial tests. Microbiome analyses and sexually transmitted diseases (STI) were tested in all samples. A Methylation test for human genes was also performed. An explanatory video was created in order to guide patients during self-collection steps. This video could be accessed at any time by the patients using a smartphone.

Results: Self-collection approach was well accepted by the majority of the patients, in particular after watching the explanatory video. Urine collection was the most accepted technique, followed by vaginal self-sampling collection. Analyses of HPV-DNA, methylation and microbiota were compared between the three paired samples from each woman in order to determine concordance, sensibility and specificity.

Conclusions: The use of the educational video was approved by 100% of the participants, underscoring the importance of the use of this visual tool in health services. The majority of the participants found self-collection procedure an easy, secure and comfortable way to collect cervical samples. We observed high level of agreement of HPV types detected across all sample collection techniques. For most microbiome components, including STI, we found high concordance among the collecting strategies. Results from methylation analyses will be presented.

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#9554

P15-03 | MIEN1 promotes oral cancer progression and implicates poor overall survival

15 - Molecular markers

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Background/Objectives: Oral squamous cell carcinoma is a highly malignant tumor with the potential to invade local and distant sites and promote lymph node metastasis. Major players underlying the molecular mechanisms behind tumor progression are yet to be fully explored. Migration and invasion enhancer 1 (MIEN1), a novel protein overexpressed in various cancers, facilitates cell migration and invasion.

Methods: In the present study we investigated the expression and role of MIEN1 in oral cancer progression using an in vitro model, patient derived oral tissues and existing TCGA data. Expression analysis using immortalized normal and cancer cells demonstrated increased expression of MIEN1 in cancer.

Results: Assays performed after MIEN1 knockdown in OSC-2 cells showed decreased migration, invasion and filopodia formation; while MIEN1 overexpression in DOK cells increased these characteristics and also up-regulated some Akt/NF-κB effectors, thereby suggesting an important role for MIEN1 in oral cancer progression. Immunohistochemical staining and analyses of oral tissue specimens, collected from patients over multiple visits, revealed significantly more staining in severe dysplasia and squamous cell carcinoma compared to mildly dysplastic or hyperplastic tissues. Finally, this was corroborated with the TCGA dataset, where MIEN1 expression was not only higher in intermediate and high grade cancer with significantly lower survival but also correlated with smoking.

Conclusions: In summary, we demonstrate that MIEN1 expression not only positively correlates with oral cancer progression but also seems to be a critical molecular determinant in migration and invasion of oral cancer cells, thereby, playing a possible role in their metastatic dissemination.

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#9570

P12-03 | HPV-based screening and colposcopy among socially vulnerable women in Brasilia, Brazil

12 - Triage of HPV positive women

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Background/Objectives: Cervical cancer is the third most common cancer among women in Brazil and a serious global public health problem. HPV testing for cervical cancer screening was included into the Unified Health Care System (SUS) in March 2024. However, new screening and management guidelines are to be developed. The objective is to describe the HPV screening findings and clinical follow-up among women recruited into the Management of Cervical Cancer Risk (MARCO) project in Brasilia, part of the HPV-Automated Visual Assessment (PAVE) consortium.

Methods: Women aged 30 and 49 were recruited between August 2023 and August 2024, in socially vulnerable areas, in Brasília. Self-collected samples were tested for HPV using ScreenFire HPV risk stratification assay (Atila, Biosystems), which assigns each sample to the highest risk stratum based on genotype (HPV16, HPV18/45, HPV31/33/35/52/58 and HPV39/51/56/59/68). HPV positive women attended a second visit with collection of cervical images after acetic acid application and of exfoliated cervicovaginal cells for conventional cytology (CC). Subsequently, HPV+ participants were referred for colposcopic evaluation. Histopathological findings were compared to CC and analyzed according to HPV risk stratification.

Results: During the first 13 months of the study, 3,972 women were recruited. A total of 953 were HPV+ (24.0%); of them13.9% were classified as HPV16+, 14.0% as HPV18/45+, 35.7% as HPV 31/33/35/52/58+ and 36.4% as positive for HPV 39/51/56/59/68 group. Of the HPV+, 883 (92.7%) have cytology results, 66 (8.0%) showed abnormal reading (HSIL+). The hierarchical risk group distribution was 25.8% HPV 16+, 10.6% HPV18/45+, 43.9% HPV 31/33/35/52/58+ and 19.7% HPV 39/51/56/59/68+. 812 HPV+ women (85.1%) attended a colposcopic evaluation and 268 (33.0%) had cervical biopsies collected and 14 (1.7%) were immediately treated without collecting biopsies (see and treat). Regarding the histopathology readings of biopsies, 56 (20.9%) were classified as CIN2+. Of these, 47.2% belonged to HPV16+ women, 15.8% to HPV18/45+, 22% HPV31/33/35/52/58+ and 9.5% HPV39/51/56/59/68+. Of 56 CNI2+ biopsies, 29 have already been treated. In addition, of the 14 see and treat, 8 showed histopathological findings that were CIN2+. Among these, 35.7% corresponded to HPV16+ women, 7.1% to HPV18/45+, 50.0% to HPV31/33/35/52/58+ and 7.1% to HPV39/51/56/59/68+. Thus, 57.8% of women with CIN2+ were treated.

Conclusions: The results highlight the importance of switching to HPV testing with risk stratification into routine cervical screening protocols, enabling early detection of precursor lesions with more efficient colposcopy clinics. These findings reinforce the need to implement HPV testing screening in SUS screening program and to formulate the new screening and management guideline for SUS. This guideline should take into account the various Brazilian realities and reinforce early and continuous screening.

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P24-03 | Risk stratification by genotype group and colposcopic findings in women attending colposcopy clinics in Brasilia and Manaus, Brazil

24 - Colposcopy

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Background/Objectives: HPV testing has been recently approved to be included into the Unified Health System (SUS) cervical cancer screening program in Brazil. Currently, SUS continues to use conventional cytology as the screening test. This study describes the HPV genotype distribution from self-collected samples, colposcopic findings and cytology results among women attending 7 colposcopy clinics in the cities of Brasilia and Manaus, Brazil.

Methods: Women aged 24 to 65 years, who attended the selected colposcopy clinics for diagnosis or treatment were approached to participate in the study, from April 2023 to November 2024. Before undergoing colposcopic examination, participants performed self-collection of cervicovaginal samples (FLOQSwab, Copan). Samples were tested for HPV at the MARCO project laboratory using ScreenFire HPV Risk Stratification (RS) assay (Atila, BioSystems), which assigns each sample to the highest risk group based on genotype (HPV16, HPV18/45, HPV31/33/35/52/58, and HPV39/51/56/59/68). The colposcopy findings and the results from the referral cytology or histopathological test were collected.

Results: A total of 617 women were enrolled in the study. Of them, 379 were HPV+ (61.4%), 22.7% were HPV16+, 8.6% for HPV18/45, 21.4% for HPV31/33/35/52/58 and 8.8% only for the HPV39/51/56/59/68 group. The ages with the highest prevalence of HPV positivity were 25-34 (78,2%), followed by 35-44 (65,5%), 55-64 (59,1%) and 45-54 (41,8%). A total of 613 referral cytology results were recovered, of which 79.4% were read as HSIL or worse. Of these 66.5% were HPV+ and 40.1% and belongs to HPV16+. In relation to the diagnostic colposcopies, 556 (88,2%) were considered satisfactory. The colposcopic impression suggested that 42.3% high-grade lesions, 40.6% normal, 15.1% low-grade lesions, 0.5% were cancer and 8 (1.4%) suggestive of cancer. All cases 3 cancer and 8 suggestive of cancer found during colposcopy showed HPV+ results and corresponded to HPV16 (54.5%), HPV18/45 (18.2%) and HPV 39/51/56/59/68 (27.3%). Out of high-grade lesions colposcopic impression suggested, 34.9% were diagnosed as HPV 16 positive, 11.1% HPV 18/45+, 29.4% HPV 31/33/35/52/58+ and 6.6% HPV 39/51/56/59/68+. In this diagnostic consultation, biopsies were collected from 31.0% participants and 14.7% realized LEEP without previous biopsy collection (see and treat). Also, 54.3% women did not collect a biopsy or see and treat during the diagnostic consultation, of which 48.1% were HPV-.

Conclusions: Women attending diagnostic colposcopy, had a low HPV positivity rate (60%, this excess of referrals was particularly high among those referred due to ASC-US or LSIL cytology readings (include here the % HPV+ for this group). The increased carcinogenic potential of HPV16 is highlighted by the higher proportion of HPV16 positivity with increasing disease severity.

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P12-01 | Risk stratification for cervical precancer in women attending primary screening: A retrospective cohort study

10 - HPV screening

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Background/Objectives: We evaluate the effect of hybrid capture based human papillomavirus (HPV) partial genotyping and age-specific risk assessment in cervical cancer screening.

Methods: A total of 7263 women (21-71 years) were included, and a final analysis of the 3-year longitudinal data was performed on 5840 women. The residual samples at baseline were retested with DH3, which detects 14 high-risk HPV (hrHPV) with 16/18 genotyping based on hybrid capture technique, and Hybrid Capture 2 (HC2) assay after 3-year follow-up. Assay results were compared with each other and to histology.

Results: The overall agreement between DH3 and HC2 was 99.2%. At baseline, the sensitivity of DH3 in identifying CIN2+ and CIN3+ was 98.67% and 97.78%, respectively; the corresponding specificity was 91.43% and 91.05. After 3-year follow-up, the sensitivity of DH3 for CIN2+ and CIN3+ was 95.49% and 95.95%, respectively; the corresponding specificity was 92.01% and 91.12. When used in primary screening strategy, the DH3 assay would yield an immediate sensitivity of 92% for CIN2+. Among 5840 women completed 3-year follow-up, the cumulative CIN3+ risk was 25.56% for HPV16/18 and 8.22% for the other hrHPV. Women with an DH3 HPV-negative result had very low cumulative 3-year CIN3+ risk (0.06%), which was about one-tenth of women with normal cytology at baseline (0.62%). We also found a slightly varied prevalence of hrHPV in different age, with highest in women under 30 years old. However, the prevalence of cytology abnormalities peaked in age 30-39 years. Younger women (21-48 years) had a higher 3-year CIN2+/CIN3+ risk than older women (49-71 years).

Conclusions: These findings suggest that hybrid capture based HPV partial genotyping without PCR performs well in cervical precancer risk stratification. DH3 HPV has a potential advantage in primary screening strategy due to HPV16/18 genotyping and can be considered as a primary cervical cancer screening option.

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P06-08 | Evaluating the public health and economic impact of switching from bivalent to nonavalent HPV-vaccination in Finland

06 - HPV prophylactic vaccines

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Background/Objectives: In Finland, a bivalent human papillomavirus (HPV) vaccine is currently being used as part of the national immunization program and is available for girls and boys aged 10 to 12 years, with a catch-up cohort program up to 17 years. However, a nonavalent vaccine providing broader HPV-type protection is also licensed in Finland. This study aims to assess the public health and economic impact of a potential switch from a bivalent to a nonavalent HPV vaccination strategy by accounting for all vaccine-preventable HPV-related cancers (cervical, vaginal, vulvar, anal, penile, head and neck) and diseases (genital warts [GW] and recurrent respiratory papillomatosis [RRP]) in Finland.

Methods: A previously published dynamic transmission model of HPV natural history infection and related diseases was adapted to the Finnish setting. The model was calibrated and populated using Finland's epidemiological and sociodemographic data. The model was used to estimate the number of cases of HPV-related diseases, subsequent number of deaths, and the economic burden of HPV-related diseases under the current standard of care. Only direct medical costs were accounted for and public list prices for vaccines were used. As there is no current list price for the bivalent vaccine, the list price from 2017 was indexed to 2023, leading to a nonavalent price premium of 39.74€ to the bivalent. The time horizon for this analysis was 100 years. Costs and outcomes were discounted at 3%. Incremental cost-effectiveness ratio was estimated.

Results: Over a 100-year time horizon, nonavalent vaccination strategy averted 1592 additional cases of HPV-related cancers, 525 398 cases of GW, 7802 cases of RRP, and 800 HPV-related deaths when compared to bivalent vaccine. A switch to nonavalent vaccination resulted in an incremental cost-effectiveness ratio of 2 611€ per QALY versus bivalent vaccination. Total costs were higher for the nonavalent strategy due to the higher vaccine price compared to the bivalent vaccination. Although a switch to nonavalent vaccination from bivalent cost an additional 137.4 million €, it resulted in a 79.3 million reduction in treatment costs, estimating the net cost of vaccination to be 58 million €.

Conclusions: Using a dynamic transmission model and incorporating the full range of HPV-related cancers and diseases, the nonavalent vaccination strategy is likely to be cost-effective given previously accepted willingness to pay QALY-thresholds in Finland for publicly funded vaccines (20 000€). The benefits were particularly significant for genital warts, as the current bivalent vaccine does not provide direct protection. Our base case model showed that over half million cases of genital warts could be prevented with nonavalent vaccination compared to bivalent vaccination. Despite the relatively low treatment cost for genital warts, the large number of cases averted led to expected savings of 36.9 million € in discounted costs. Whereas preventing RRP cases resulted in savings of 2.6 million €.

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P03-07 | Prevalence of Anal HPV Infection Among Young Adults in Brazil: POP-Brazil Study

03 - Epidemiology and natural history

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Background/Objectives: The rising incidence of anal cancer is concerning, with over 90% of cases attributable to human papillomavirus (HPV) infection. However, limited data are available regarding the prevalence of anal HPV in young adults. Therefore, this study aimed to evaluate the prevalence of anal HPV infection among sexually active young adults aged 16 to 25 years in Brazil.

Methods: Cross-sectional study conducted between 2020 and 2023 in 24 state capitals and the Federal District. Participants were recruited from public health units and the surrounding community. All participants answered a structured questionnaire with sociodemographic and behavioral questions. Men were instructed to insert a swab from Digene Female Swab Specimen Collection Kit 3 cm into the anal canal and rotate it 360 degrees. In women, anal samples were collected by health professionals, using the same collection kit. All samples were processed in a certified central laboratory (WHO HPV LabNet) using Anyplex II HPV 28 detection (Seegene®). Sampling weights were applied to data from the convenience sample in each capital to estimate the prevalence of HPV.

Results: A total of 5,208 participants were genotyped for HPV. Among these, 2,921 (52.1%) tested positive for overall HPV, and 42.3% were positive for high-risk HPV. Women showed a significantly higher prevalence of overall HPV (63.2%) and high-risk HPV (52.5%) compared to men, whose prevalence was 36.8% and 29.0%, respectively ($p < 0.001$). Vaccinated individuals had a higher prevalence of overall HPV compared to unvaccinated individuals (55.6% vs. 49.1%; $p < 0.001$) but a lower prevalence of the HPV types covered by the quadrivalent vaccine (3.1% vs. 10.9%; $p < 0.001$). Regarding HPV types strongly associated with cancer, 4.1% (CI 3.5 - 4.6%) of the sample were positive for HPV 16, and 2% (CI 1.6 - 2.4) for HPV 18. The most prevalent types were HPV 51 [8% (CI 7.3 - 8.7)] and HPV 53 [8.7% (CI 8.0 - 9.5)].

Conclusions: This is the first national study to evaluate anal HPV infection, offering valuable insights into its prevalence and revealing significant disparities based on sex and vaccination status. The high prevalence of HPV infection emphasizes the need of public health strategies to reduce the burden of high-risk HPV infections and associated diseases.

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P34-02 | Identification of anti-HPV and anti-tumor small molecule inhibitors using 3-dimensional tissue systems

34 - Conventional therapies

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Background/Objectives: Management of HPV diseases for the majority of people alive today is based on screening, diagnosis and treatment of persistent HPV infections, pre-cancers and cancers. 2024 global incidence includes 12.5 million high-grade cervical pre-cancers, 886 K incident cancers at HPV-susceptible anatomical sites in women and men, and 2.4 M people living with HPV cancers who need safe, effective, durable, available and affordable treatments no matter their geographic and economic circumstances. Without comprehensive treatments as the safety net for anyone already having persistent high-risk HPV or who will acquire such infections absent vaccination, the 2023 WHO HPV Cancer Elimination Document warns of 40-60 million deaths over the next 95 years.

Methods: We developed 3D tissue models to examine virus-host cell interactions in organotypic epithelial raft cultures supportive of robust recapitulation of the full HPV infection cycle and to model pre-cancerous dysplasias. We examined the interactions of HPV oncoproteins E6 with p53 and E7 with p130/pRB, and the functions of E1 replicative DNA helicase and E2 transcription/replication/DNA segregation regulatory protein in their natural context of stratifying, differentiating squamous epithelia. Viral and host proteins and cell cycle regulatory pathways were identified as promising targets for small molecule pharmaceutical inhibitors. Additional testing models include cervical cancer organoids and patient-derived xenografts in mice for further validation. HPV-positive tissues can be efficiently and economically exchanged among these experimental systems for optimizing dose, dosing frequency and combinatorial drug delivery.

Results: Essential to inhibitor discovery and characterization are development of complementary molecular and in situ tissue assays based on informative biomarkers of HPV and cell DNA replication, gene-specific RNAs, proteins and their post-translation modifications, and on histologic toxicities. It is impractical to develop HPV type-specific inhibitors. Accordingly, our lab identified cell proteins and pathways on which LR and HR HPV genotypes depend for genome maintenance, gene expression, replicative amplification and virion production. We optimize for topical delivery to HPV lesions to avoid systemic toxicities and "re-purpose' inhibitory agents of different target classes that are effective against HPV infections and cancers at various stages of progression. These include synthetic lethal deoxynucleoside analogues, modulators of protein phosphorylation and acetylation, agonists of DNA damage and replicative check points, inhibitors of mRNA stability, the cell cycle, mitotic spindle fibers and centrosomes, and induction of oxidative stress and macromolecular nitrosylation.

Conclusions: Our Lab discovers and characterizes compounds that target host cell proteins and regulatory pathways with key roles in HPV pathogenesis, from infection to cancer. We are defining combinations of inhibitors that synergize effectively at lower doses than single agents. High-tech clinical management of HPV precancers and cancers is unattainable in most LMIC settings, whereas cryo- and thermo-ablative procedures are more practical. Nonetheless, recurrence rates of neoplastic diseases are unacceptable due to incomplete elimination of HPV carrier cells by ablation. Alone or in combination with surgical treatments, topical small molecule inhibitors can and will provide primary or supplemental inhibition at all stages of HPV lesions.