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FROM HPV INFECTION TO CURE

INTEGRATING SCIENCE, CLINICAL CARE AND ARTIFICIAL INTELLIGENCE IN HPV-RELATED CANCER CONTROL

Congress Presidents

J. Palefsky (USA) • M. Poljak (Slovenia) • J. Bornstein (Israel)

ABSTRACTS

POSTERS

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#12248

P39-01 | Health Equity and Human Papillomavirus Interventions for Adolescents: A Systematic Review

39 - Public health

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Background/Objectives: Human papillomavirus (HPV) causes multiple types of cancer and demographic-based inequities in HPV-related cancers persist. Over the past two decades, behavioral interventions have been the focus for increasing HPV vaccination uptake, yet it is unclear how intervention effects vary by demographics. The purpose of this study was to examine if existing HPV vaccine interventions for adolescents have unequal effects on HPV vaccine uptake.

Methods: We developed a search for use in the databases: MEDLINE via PubMed, PsycINFO, CINAHL, Scopus, and Cochrane CENTRAL. The search strategy combined keywords and subject terms for the main concept domains: HPV vaccine, interventions/health promotion, and adolescents. Studies were included in the final analyses if they were peer reviewed, published in the US between 2006-2023, included outcome measures from an evidence-based HPV vaccination intervention, included adolescents 9-17, and demographic variables for age, race/ethnicity, income/SES, or geographic region. The screening and extraction processes were independently performed by multiple reviewers using Covidence software.

Results: Ultimately, 73 articles were included for full extraction. Less than half of included studies used an experimental design (n=32). Examining each study by the HPV Round Table: HPV Vaccination Best Practices Learning Collaborative intervention type, we found that 51 studies had multiple intervention components. Sex was the most common demographic variable analyzed by HPV vaccine (n=38), followed by race/ethnicity (n=15), insurance status (n=11), income/SES (n=6) and geographic region (n=6).

Conclusions: Few HPV vaccination uptake interventions assess whether intervention results differ by demographics. This review included a wide variety of study designs, limiting our ability to uniformly assess study conclusions. Future evidence-based HPV vaccination uptake interventions should assess outcomes stratified by demographic variables, especially demographics with documented evidence of inequitable outcomes in HPV-related disease.

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M., Watson, M., Wilkinson, E. J., Hopenhayn, C., Copeland, G., Cozen, W., Peters, E. S., Huang, Y., Saber, M. S., Altekruse, S., Goodman, M. T., & HPV Typing of Cancers Workgroup (2015). US assessment of HPV types in cancers: implications for current and 9-valent HPV vaccines. *Journal of the National Cancer Institute*, *107*(6), djv086. https://doi.org/10.1093/jnci/djv086

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#12257

P28-01 | Oral and genital high-risk HPV infection in a young male with oral lichen planus: Case report

28 - Oral HPV infection

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Background/Objectives: While the prevalence and risk factors for genital human papillomavirus (HPV) infection are well-documented among young adults, much less is known about oral HPV in this population. However, the simultaneous presence of HPV infection in both oral and genital sites among asymptomatic individuals remains inadequately characterized.This study aimed to investigate the presence of high-risk HPV genotypes in both oral and genital sites of a young male patient presenting with a clinically suspicious oral premalignant lesion.

Methods: We conducted a case study involving a 25 years old male with a suspected oral premalignant lesion of viral etiology. Oral and genital swabs were collected and analyzed for 14 high-risk HPV genotypes using the real-time PCR method. In addition, the oral lesion was surgically excised and subjected to histopathological examination for definitive diagnosis.

Results: Histopathological analysis confirmed the presence of oral lichen planus. Molecular testing revealed the presence of two high-risk HPV genotypes (31, 44) in the oral cavity and six high-risk genotypes (18,31,35,44,73,81) in the genital region.

Conclusions: This case underscores the value of assessing both oral and genital sites for HPV to better understand transmission and cancer risk. Dual-site HPV screening, involving both oral and genital regions, is crucial due to the virus's affinity for stratified squamous epithelium. This is especially important in sexually active youth, to prevent transmission and reduce the risk of HPV-related malignancies.

References:

Brassard Paul
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#12261

P03-01 | HPV prevalence among Inuit women in Northern Quebec, Canada: A pre- and post-vaccination analysis

03 - Epidemiology and natural history

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Background/Objectives: To assess changes in high-risk HPV prevalence among Inuit women in Nunavik following the introduction in 2008 among 12-year-old girls of the quadrivalent HPV vaccine program in Quebec.

Methods: A total of 169 Inuit women aged 25-65 were recruited in Kuujjuaq, Nunavik between July 2022 and December 2024. Participants self-collected cervico-vaginal samples under nurse supervision. HPV DNA testing was performed using real-time PCR (Cobas 4800), detecting HPV 16, 18, and 12 other high-risk types. Results were compared to historical data from 473 Inuit women (2002-2007), using the same genotypic categories. Age-stratified prevalence ratios (PR) were calculated to assess differences over time and odds ratios (OR) for HPV 16/18 detection by vaccination status

Results: Among 148 participants with results, overall high-risk HPV prevalence increased from 15.9% pre-vaccination to 24.8% post-vaccination, driven by a significant rise in other high-risk types among women aged 40+ (from 5.8% to 23.1%; PR = 2.80, 95% CI: 1.16–6.75). HPV 16/18 prevalence showed a non-statistically significant decline among the 25–29 age group (6.8% to 3.3%). Only one vaccinated participant tested positive for HPV 16/18 (OR = 0.29, 95% CI: 0.0062-2.54).

Conclusions: The quadrivalent HPV vaccine has reduced HPV 16/18 prevalence in the targeted younger population. Continued surveillance is warranted, particularly for non-vaccine high-risk types.

References:

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#12330

P39-02 | Acceptance and attitudes towards risk-based cancer screening among general population women: A mixed methods systematic review.

39 - Public health

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Background/Objectives: This mixed-methods systematic review uniquely synthesized women's acceptance and attitudes toward risk-based cancer screening.

Methods: We searched PubMed, Embase, Web of Science, and PsycINFO for English-language primary studies (Dec 2021–Mar 2024) and incorporated 2010–2021 studies from Taylor et al. (2023). Eligible studies reported women's views on risk-based screening across cancer types. A convergent results-based synthesis integrated quantitative and qualitative findings, distinguishing distinguishing attitudes (opinions and feelings toward screening) from acceptance (inclination to follow screening recommendations).

Results: Seventeen studies (eight qualitative, eight quantitative, one mixed methods) from eight countries were included, mainly on breast cancer. Overall, 93% (95% CI 91–94%) accepted risk-based screening and 75% (95% CI 69–81%) expressed supportive attitudes. For more frequent screening of high-risk women, acceptance was 89% (95% CI 87–90%) and supportive attitudes 95% (95% CI 87–100%). For less frequent screening in low-risk women, 39% (95% CI 28–51%) accepted it and 55% (95% CI 48–62%) expressed supportive attitudes. Women valued personalization, citing empowerment and logic, but concerns included anxiety, uncertainty in risk assessment, and inequity. Reduced screening raised fears of missed diagnoses, loss of control, and mistrust in motives for reduction.

Conclusions: Transparent communication that acknowledges women's concerns and supports their confidence and trust in care is essential for successful implementation of risk-based cancer screening.

References:

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#12353

P25-01 | Clinical value of HPV genotyping in women with biopsy-negative or low-grade cervical intraepithelial neoplasia

25 - Cervical neoplasia

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Background/Objectives: The purpose of this study was to investigate whether human papillomavirus (HPV) genotyping could predict the likelihood of disease progression in women presenting with low-grade squamous intraepithelial lesion (LSIL) but without histologic evidence of cervical intraepithelial neoplasia grade 2 or worse (CIN2+).

Methods: We analyzed data from 1986 women enrolled between January 2005 and August 2016, including 1123 cases with LSIL but no histologic abnormality and 863 cases with histologically confirmed CIN1. High-risk HPV (HR-HPV) infection was initially assessed using the hybrid capture II assay (HC2), and specific HR-HPV genotypes were identified with the HPV DNA chip test (HDC).

Results: HR-HPV was detected in 1529 women (77.0%) by HC2 and in 1624 women (81.8%) by HDC, with an overall concordance of 93.2%. During follow-up, 169 women (8.5%) developed CIN2+. The 5-year cumulative incidence of CIN2+ was 11.8% for HPV-16, 9.9% for HPV-18, 16.3% for HPV-31, and 16.1% for HPV-33. Multivariate analysis demonstrated that HPV-16 (HR 1.637, 95% CI 1.064–2.520, p=0.025), HPV-31 (HR 1.845, 95% CI 1.051–3.238, p=0.033), and HPV-33 (HR 2.272, 95% CI 1.235–4.183, p=0.008) were independently associated with CIN2+ progression.

Conclusions: Among women with LSIL, those harboring HPV-16, HPV-31, or HPV-33 face a significantly higher risk of developing CIN2+, highlighting the need for closer surveillance in this subgroup.

References:

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#12367

P15-01 | Circulating plasma miRNA signature associated with HPV-related high-grade cervical intraepithelial neoplasia

15 - Molecular markers

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Background/Objectives: High-risk human papillomavirus (HPV) infection is the main etiological agent of cervical cancer and its precursor lesions. Cervical intraepithelial neoplasia (CIN) grade 2/3 represents a clinically relevant stage in HPV-driven carcinogenesis, for which the identification of reliable biomarkers could enhance detection and molecular characterization. miRNAs are key post-transcriptional regulators that undergo deregulation during HPV-induced cellular transformation. Plasma represents a minimally invasive and clinically useful source of molecular biomarkers, providing access to circulating miRNAs without the need for cervical sampling. In this prospective study, we aimed to identify a plasma-derived miRNA signature associated with HPV-related CIN2/3 to explore its interactions with molecular pathways associated with cervical cancer.

Methods: The study was approved by the Research Ethics Committee of Barretos Cancer Hospital (no. 3.926.525). We analyzed 70 plasma samples from women aged 25 to 64 years old. The participants were divided into two groups: a case group consisting of women diagnosed with CIN 2/3 and positive for HPV (n = 35), and a control group of women without cervical precursor lesions and negative for HPV (n = 35). miRNA expression was performed using the nCounter® miRNA Expression Assay (NanoString Technology), targeting 800 miRNAs. Functional and enrichment analyses were performed using mirDIP and Cytoscape (Reactome plugin), respectively.

Results: We identified 33 differentially expressed miRNAs between case and control groups ($p \leq 0.05$). Three miRNAs (two downregulated and one upregulated) were selected based on fold change ≥ 1.3. In a multivariate logistic regression model combining these miRNAs with contraceptive use, overexpression of miRNA A (OR = 0.11, 95% CI = 0.03 – 0.38, $p < 0.001$) and underexpression of miRNA C (OR = 4.39, 95% CI = 1.32 – 16.9, $p < 0.021$) significantly discriminated CIN2/3 cases. The signature (miRNA A and miRNA C) had a predictive value with an AUC of 0.74. Furthermore, we identified 23 miRNA target genes associated with cervical cancer for the two selected miRNAs, primarily related to pathways in cancer, Polymerase II transcription, the PI3K-Akt signaling pathway, miRNAs in cancer, and human papillomavirus infection.

Conclusions: This study identified a two-miRNA plasma signature that significantly discriminated HPV-related CIN 2/3 from HPV-negative controls. Functional enrichment analysis highlighted pathways related to cancer and HPV infection, emphasizing the biological significance of these circulating miRNAs. Our findings provide evidence that miRNAs from plasma samples may serve as minimally invasive biomarkers for the molecular characterization of HPV-associated with high-grade precursor lesions.

References:

Morshed Rafi Ahammed
Bangladesh

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#12369

P09-01 | Epidemiology, genotypic diversity and age-specific risk pattern of circulating human papillomavirus in Dhaka City, Bangladesh: a five-year study (2020-2024)

09 - HPV testing

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Background/Objectives: Human papillomaviruses (HPV) are highly prevalent DNA viruses that only affect humans. Over 200 HPV genotypes have been discovered, approximately 40 of which infect the vaginal tract.1,2 The situation in Bangladesh is particularly concerning since HPV-related infections remain a serious public health issue. Understanding the local genotype distribution is thus vital for refining vaccine strategies. To address this gap, this study investigates the prevalence and distribution of HPV genotypes in women in Dhaka city from 2020 to 2024.

Methods: The study was conducted with all 2049 patients with their HPV genotypes analyzed at the Ibn Sina Diagnostic and Imaging Centre, Dhanmondi, Dhaka. Cervical swab was collected in a viral transport medium. First, we extracted viral DNA from the cell preservation solution. The DNA purification kit was the QIAamp DSP virus kit. Amplification and detection of HPV DNA were performed using the AmpliSens HPV HCR genotype-titre-FRT PCR kit. The kit detects 14 high-risk HPV genotypes using real-time PCR with fluorescent detection. Four PCR reactions were set up for each sample using different primer/probe mixes to detect different HPV genotype groups.

Results: Among the study participants, 95.99% (1967 women) tested negative for HPV while 4.01% (82 women) were positive. The highest number of positive cases 29 (4.71%) was recorded in 2024. Autumn had the highest number of cases, with a total of 25 (30%). Winter and Autumn showed almost similar numbers, each reporting 24 (29%) and 25 (30%) cases, suggesting that the cooler seasons may correlate with higher case counts. November recorded the highest incidence with 17 cases, indicating a peak in this month. The age-specific distribution of HPV infections highlights those middle-aged adults (35-50 years) represented the largest group, with a total of 37 cases. The predominant genotype combination was HPV 16/31, detected in 55 cases, suggesting a strong presence of these high-risk types.

Conclusions: This study provides novel and context-specific insights into the prevalence, seasonal distribution, and genotype characteristics of HPV infections among women in Dhaka, Bangladesh, from 2020 to 2024. The dominance of high-risk genotypes such as HPV 16/31 and 18/45 suggests substantial potential for oncogenic progression if left unaddressed. The significant prevalence among women aged 35–50 highlights the need to extend screening and vaccination efforts beyond adolescent girls.

References: Clifford GM, Smith JS, Plummer M, Muñoz N, Franceschi S. Human papillomavirus types in invasive cervical cancer worldwide: a meta-analysis. Br J Cancer. 2003;88(1):63-9.Stelzle D, Tanaka LF, Lee KK, Ibrahim Khalil A, Baussano I, Shah ASV, et al. Estimates of the global burden of cervical cancer associated with HIV. Lancet Glob Health. 2021;9(2):e161-9.

Credentials of presenter.

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#12414

P09-02 | Prevalence of High-Risk HPV Genotypes and their Correlation with Cervical Cytology in Georgian Women

09 - HPV testing

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Background/Objectives: Despite the availability of HPV vaccination and screening programs, cervical cancer still remains a major health burden in Georgia. Persistent infection with high-risk human papillomavirus (HR-HPV), particularly types 16 and 18, is the primary cause of cervical intraepithelial neoplasia and invasive carcinoma. However, other HR-HPV genotypes (such as HPV31, 33, 35, 39, 45, 51, 52, 54, 56, 58, 65, and 68) also play a significant role in cervical carcinogenesis and must be considered in epidemiological and clinical studies. This study aims to evaluate the prevalence of HR-HPV genotypes, including HPV16, HPV18, and other oncogenic types, and to investigate their association with cytological abnormalities in Georgian women.

Methods: In a cross-sectional study, 3,000 women aged 21–65 years from urban and rural regions were tested for HR-HPV DNA using PCR-based genotyping (HPV16, HPV18 were analyzed individually, while other high-risk types were grouped as 33/45/51, 35/58/66, 31/39/56, 52/54/68). Cervical cytology was performed and classified according to the Bethesda System (NILM, ASC-US, LSIL, HSIL, suspected invasive carcinoma). Associations between HR-HPV positivity and cytological findings were analyzed using chi-square tests and odds ratios (OR) with 95% confidence intervals (CI). Age-specific prevalence patterns were also evaluated.

Results: Overall, 24.5% (n=736) of women tested positive for HR-HPV. The most frequent genotypes were HPV16 (32%) and HPV18 (25%), followed by 33/45/51 (12%), 31/39/56 (10%), 52/54/68 (6%), and 35/58/66 (12%). Cytology findings were: NILM 32.3%, ASC-US 23.9%, LSIL 28.2%, HSIL 14.7%, and suspected invasive carcinoma 0.9%. HR-HPV positivity increased with lesion severity: 6.3% in NILM, 19.5% in ASC-US, 27.3% in LSIL, 40.0% in HSIL, and 74.0% in suspected carcinoma. Age-specific prevalence peaked in women aged 30–45 years (28.4%), with this group showing the highest rates of LSIL and HSIL. Women >45 years had fewer infections but higher proportions of HSIL and carcinoma, suggesting persistence and progression. HPV16 showed the strongest correlation with HSIL (OR 4.6, 95% CI 3.8–5.5), followed by HPV18 (OR 3.9, 95% CI 3.1–4.9)

Conclusions: This large-scale study of HR-HPV prevalence and genotype distribution in Georgia found, that Nearly one-quarter of women were HR-HPV positive, with HPV16 and HPV18 predominating and strongly linked to high-grade lesions. These findings, once again emphasize the need for integrated screening strategies (HPV testing, cytology, and colposcopy) and expansion of national vaccination programs. Strengthening awareness, prevention, and screening policies is essential to reduce cervical cancer burden nationwide and to improve women's health outcomes in Georgia.

References:

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Organized Data from the study

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#12480

P13-01 | Large-scale paired comparative study on women's preference of self-collection devices and their opinion on self-sampling for cervical cancer screening

13 - Self-sampling

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Background/Objectives: HPV self-sampling is known to improve participation in cervical cancer screening, but device choice may affect user confidence and uptake. We compared women's preferences and user-reported experience for three self-sampling devices in routine screening.

Methods: The study was a program-embedded paired comparative study in the Capital Region of Denmark (April 2024-May 2025). Women eligible for screening (n=1,760) were allocated to one of three study groups: (1) Evalyn vs FLOQSwab (n=518), (2) Evalyn vs SensiGrip (n=657), (3) FLOQSwab vs SensiGrip (n=585). Preferences and 5-point Likert ratings were collected via questionnaire. Preference was tested by χ^2, predictors by logistic regression, user experience by Wilcoxon signed-rank TOST equivalence testing (margin ±0.3).

Results: Overall, 95.7% reported a positive self-sampling experience and 87.3% preferred self-sampling at their next screening. In group 3, SensiGrip was strongly preferred over FLOQSwab ($\chi^2(1)=352.25$, $p<0.001$; 11% vs 89%). In groups 1-2, no significant difference in overall preference was observed between Evalyn and the alternatives ($p>0.05$). On user-experience, SensiGrip was rated higher than FLOQSwab for ease-of-use (mean diff −0.35, ES=0.41) and certainty of correct sampling (mean diff −0.51, ES=0.48), while Evalyn scored highest for certainty versus FLOQSwab (mean diff +0.50, ES=0.38) and versus SensiGrip (mean diff +0.45, ES=0.31). Sampling order influenced preferences in comparisons involving Evalyn; age, prior self-sampling, screening history, and sub-cohort were not associated with preference.

Conclusions: In routine practice, device choice measurably shapes user experience. SensiGrip was preferred over FLOQSwab, while Evalyn showed no overall preference difference vs either comparator but yielded highest confidence in correct sampling. These findings suggest device replacement would be acceptable. Particularly, a shift from FLOQSwab to SensiGrip would be acceptable.

References:

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#12522

P09-03 | Prevalence of different types of Human Papilloma Virus infection in anal samples and impact of co-testing: findings from a public university Greek hospital

09 - HPV testing

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Background/Objectives: HPV infection is the primary cause of anal cancer (>90%) and the overall risk of developing this type is notably increased in individuals with compromised immune systems, such as those living with HIV or undergoing immunosuppressive therapies. The aim of the present study is lying in the understanding of the prevalence of HPV infection and the distribution of the different genotypes among the Greek population of men who have sex with men (MSM) as well as on the evaluation of pathological alterations in the anal test-Pap compared to molecular result.

Methods: Anal samples from HIV-positive and HIV-negative MSM patients (n = 219) received between January 2025 and September 2025 were analyzed in molecular level and 198 of these cases in cytology level as well. In the frame of HPV genotyping, DNA was extracted from anal samples collected in cytological solution vials and a multiplex Real-Time PCR was performed for the detection of 28 HPV genotypes. Moreover, 198 of these samples were analyzed via liquid-based cytology and Papanicolaou staining for the preparation of cytological slides for microscopy (anal Pap-test).

Results: All the samples were derived from the capital. The majority of the examined population was HIV-positive (62.56%) and the mean age of the positive population was 40.18 years, when the mean age of the overall population was 39.81 years respectively. According to our results, in 10.50% of the samples for molecular testing no HPV DNA was detected, when HPV DNA was found in 88.58% and 0.91% of the samples was inadequate for molecular examination. In positive for HPV DNA cases, HPV-16 was the most predominant genotype of the HR-types (27.98%), followed by HPV-31 (23.21%). In HIV-negative samples HPV-16 was the most predominant genotype of the HR-types (37.70%) compared to HPV-31 (24.30%) which was the most common among HIV-positive samples. Furthermore, HPV-53 (47.96%) and HPV-6 (18.75%) were the most common genotypes between the PHR-types and LR-types respectively. Among LR-HPV types, in HIV-negative samples HPV-6 was the most predominant genotype of the LR-types (24.53%) compared to HPV-42 (17.58%) which was the most common among HIV-positive samples. No significant difference was observed in the prevalence of HR-HPV types between HIV-positive (77.54%) and HIV-negative patients (75.31%). Regarding the relevance of cytological diagnosis and molecular testing, in 11.62% of cases where phenotypic cell alterations were observed, a HR-HPV type was detected and HPV-16 was present in 5.56% of those. On the contrary, in 77.78% of the examined samples with negative test-Pap diagnosis and positive HPV test, a HR-HPV type was detected in 65.66% and HPV-16 appeared in 16.67% of those. Finally, patient's HIV profile does not seem to be correlated with the presence of a suspicious cytological diagnosis (HIV-positive 12.90% versus HIV-negative 12.16%).

Conclusions: This data provides important insights into the specific HPV types prevalent in anal samples and the impact of co-testing in monitoring of the MSM population. Further study is necessary to obtain reliable results regarding the correlation between HPV prevalence and HIV profile. The persistent presence of HPV-16 in the positive for HPV population and the existence of cases positive for HR-HPV where cellular alterations are not observed, reflects the importance of studying HPV m-RNA and the conduction of long-term patient follow-up studies.

References:

Pantazi Evgenia
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#12523

P09-04 | Prevalence of different types of vaginal Human Papilloma Virus infection and impact of co-testing: findings from a public university Greek hospital

09 - HPV testing

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Background/Objectives: Persistent infection with high-risk types of HPV is the main etiological factor of cervical cancer in women. The present study focuses on the prevalence of HPV infection and the distribution of genotypes in the Greek population as well as on the evaluation of pathological alterations it the Pap test compared to molecular result.

Methods: To this end, patient's cervical samples (n = 1953) received between January 2025 and September 2025 in the diagnostic cytology department of Attikon hospital were analyzed in molecular level and 1748 of these cases in cytology level as well. In the frame of HPV genotyping, DNA was extracted from cervical samples collected in cytological solution vials and a multiplex Real-Time PCR was performed for the detection of 28 HPV genotypes (including the 14 HR-types). Moreover, 1748 of these samples were analyzed via liquid-based cytology and Papanicolaou staining for the preparation of cytological slides for microscopy (Pap-test).

Results: The samples were derived almost equally from the capital (51.05%) and from other cities of Greece (48.95%). The mean age of the positive population was 39.28 years, when the mean age of the examined population was 45.03 years accordingly. According to our results, in 75.83% of the samples for molecular testing no HPV DNA was detected, when HPV DNA was found in 24.02% and 0.15% of the samples was inadequate for molecular examination. In positive for HPV DNA cases, HPV-16 was the most predominant genotype of the HR-types (12.29%), followed by HPV-31 (10.63%) and HPV-68 (8.97%). Furthermore, HPV-53 (29.63%) and HPV-42 (24.42%) were the most common genotypes between the PHR-types and LR-types respectively. Regarding the relevance of cytological diagnosis and molecular testing, in 72.83% of cases where pathological test-Pap results were observed, a HR-HPV type was detected with HPV-16 appearing in 16.30% of those. However, in 18.23% of the examined samples with negative test-Pap diagnosis, a HR-HPV type was detected in 58.39% and HPV-16 was present in 6.04% of those. Moreover, in 5.15% of the cases with cell phenotypic atypical features, there was absence of any HPV type.

Conclusions: This data provides important insights into the specific HPV types prevalent in cervical samples and the impact of co-testing in monitoring of the female population. The persistent presence of HPV-16 in the Greek population, while the percentage of women vaccinated against the virus is increasing, indicates the need for primary screening. Furthermore, the existence of even a few cases where cellular alterations are observed with negative molecular testing reflects the importance of cytological diagnosis and the ongoing interest in long-term patient follow-up studies.

References:

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#12538

P39-03 | Cervical cancer elimination in Manitoba: An exploration of the current state and opportunities for successful elimination in the future

39 - Public health

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Background/Objectives: Cervical cancer is preventable, and the tools to eliminate it already exist.1 Widespread uptake of the effective human papillomavirus (HPV) vaccine and early detection through organized cancer screening programs are proven strategies to reduce disease burden.1-7 The World Health Organization (WHO) has set a global elimination target of fewer than 4 cases per 100,000 women by 2040, emphasizing prevention, early detection, and equitable access to care.3,8 Yet in Manitoba, Canada, cervical cancer incidence is rising - pushing us further from this goal. This study evaluates Manitoba's progress towards elimination by analyzing trends in HPV vaccination coverage, cervical cancer screening participation, and disease incidence. It also explores disparities across geography, age, sex, rurality, and income, aiming to identify gaps and guide future interventions.

Methods: We examined HPV vaccination coverage, cervical cancer screening participation, and incidence of cervical cancer and its precursors across Manitoba. Data were stratified by region, age group, sex, rurality, and income level. HPV vaccination coverage was defined as the proportion of individuals under universal healthcare coverage who received at least one HPV vaccine dose by age 17. Cervical cancer screening participation was defined as the proportion of individuals aged 21-69 who had a Pap test within each three-year interval through CervixCheck, Manitoba's organized screening program. Test-based results were also included. We calculated incident counts, crude rates, and age-standardized incidence rates (standardized to the 2011 Manitoba population), further broken down by stage at diagnosis using AJCC 7th edition staging criteria. Trends were analyzed using JoinPoint Regression Program (v5.4.0) to estimate annual percent change (APC).

Results: In 2023, about 81% of females received at least one dose of the HPV vaccine by age 17 - a rate that has remained stable over time (+0.16 APC; 2016-2023, $p > 0.05$). Uptake was higher in urban areas (86%) than rural (76%) ($\chi2 = 152.735$, $p < 0.0001$). An income gradient emerged: lower-income quintile had the lowest uptake (Q1 rural: 72%; Q1 urban: 85%) while higher-income quintiles had the highest (Q5 rural: 82%; Q5 urban: 89%), with no significant change over time. Cervical cancer screening participation declined from 2005-2021 (-1.07 APC, $p < 0.05$), but rose to 72% by 2023 (+1.98 APC, $p > 0.05$). Rural residents (65%) especially those in lower-income quintiles (Rural Q1: 58%) were least likely to participate in cervical cancer screening though temporal patterns were consistent across most strata. Cervical cancer incidence increased significantly (+9.14 APC; 2018-2023, $p<0.05$) reaching an age-standardized incidence rate of 9.4 per 100,000 women in 2023.

Conclusions: Elimination of cervical cancer in Manitoba is possible – but only through targeted, data-driven action. Rising incidence rates, coupled with stagnant vaccination and declining screening participation underscore the urgency of strengthening prevention efforts, especially among underserved populations. This study highlights where progress is lagging and where interventions are most needed. Further research should explore the relationship between vaccination and screening behaviours for Manitobans, and identify elimination strategies tailored to Manitoba's unique population. These insights may also inform similar efforts in other jurisdictions.

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#12592

P32-01 | Is there a good statistical correlation between biopsy results and conization outcomes at our center?

32 - HPV transmission

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Background/Objectives: Cervical intraepithelial neoplasia (CIN) is a lesion caused by infection with high-risk human papillomavirus (HPV) and is a precursor to cervical cancer.Cervical conization by diathermic loop or loop electrosurgical excision procedure (LEEP) is the most commonly used excisional treatment in patients with grade 2 or 3 CIN to prevent progression, although it is not free of adverse effects.However, despite clear morphological criteria for the histopathological diagnosis of CIN, histopathological interpretation shows interobserver variability. Accurate diagnostic interpretation of cervical biopsy samples is important to avoid over- or undertreatment of patients.In this study, we analyze whether the histopathological results of previous biopsies and the histopathological results of conizations performed at our center show good correlation.

Methods: A prospective descriptive study was conducted including all patients who underwent conization at our center, Hospital Juan Ramón Jiménez in Huelva, between January 2019 and February 2024. All patients underwent LEEP conization under colposcopic guidance.
Histopathological results of all conized patients and the histopathological results of biopsies prior to conization were analyzed. A comparison and subsequent statistical analysis using the chi-square test were performed to evaluate histopathological concordance between both samples, considering a value statistically significant if p less than 0.005.

Results: The study included a total of n=615 patients who underwent cervical conization, with a median age of 40 years [33-45 years]. After comparing the histopathological results of biopsies with those obtained in conization, good concordance between samples was observed, with a p-value < 0.001.

Conclusions: Despite the good correlation between the histopathological results of prior biopsies and conization specimens obtained at our center, it should be noted that some patients were overtreated, while others were underdiagnosed. In recent years, it has been shown that p16 immunohistochemical staining increases interobserver concordance regarding the presence of a lesion and its grade, reducing under- or overdiagnosis.

References:

- Data obtained from the Hospital Juan Ramón Jiménez, Huelva.
- Spanish Association for Cervical Pathology and Colposcopy (AEPCC) Screening Guidelines.

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#12604

P20-01 | New Biomarker E7 Oncoprotein Detected Using Self-Sampling and Self-Testing E7 Oncoprotein Rapid Test Assay for Cervical Cancer Screening

20 - New technologies

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Background/Objectives: As a new biomarker, E7 oncoprotein can be detected using E7 oncoprotein rapid test assay. This study is to explore the role of E7 oncoprotein self-sampling and self-testing in cervical cancer screening. Screening coverage is one of the key factors to ensure the success and widespread application of cervical cancer screening. Only when more healthy people participate in screening can we find more patients with cervical precancerous lesions and provide them with opportunities for early intervention and treatment. The introduction of self-sampling and self-testing screening methods can play a key role in increasing the coverage of cervical cancer screening. This screening method allows women to collect cervical cell samples using self-sampling brush and self-test at home without going to a medical institution, making it more convenient, easy and feasible, which is conducive to lowering the threshold for cervical cancer screening and increasing screening coverage. High-risk HPV (hr-HPV) is an important factor causing cervical cancer. Its oncogene E7 is integrated into the human genome and expressed as E7 oncoprotein [1]. The latter binds and degrades retinoblastoma protein (pRb), causing the cell cycle of infected cells to lose control, leading to unlimited cell proliferation and mutation. E7 oncoprotein is closely related to the occurrence and development of cervical cancer [2]. This study will explore the advantages of self-sampling and self-testing screening of E7 oncoprotein, as well as the importance of actively promoting this method. This method is expected to play a key role in cervical cancer screening, provide more women early detection opportunities of cervical precancerous lesions.

Methods: A prospective research method of E7 Protein Test Kit (Colloidal Gold Method) was used to analyze the correlation between E7 oncoprotein and cervical precancerous legion and cancer. The detection of E7 oncoprotein is to identify when E7 oncoprotein begins to express. The expression of E7 oncoprotein leads to cervical precancerous lesions, and the stages of precancerous lesions include CIN1-3. The E7 oncoprotein identification of this study starts from CIN1+ cervical precancerous lesions.

Results: 452 participants were enrolled in the study. Histopathological results showed that there were 8 patients with CIN3, 20 patients with CIN2, and 6 patients with CIN1. Therefore, there were 34 cases (7.52%) in the cervical lesion group (CIN1+); and 418 cases (92.48%) in the normal cervical group. In this study, 452 cases were effectively tested for E7 oncoprotein, of which 60 cases were positive for E7 oncoprotein and 392 cases were negative. When predicting cervical lesions (CIN1+), E7 oncoprotein detection had a sensitivity of 76.47% and a specificity of 91.87%. E7 oncoprotein detection of positive and negative predictive values for cervical lesions was 43.33% and 97.96% respectively (see Table 1).

Conclusions: In summary, E7 oncoprotein self-sampling and self-testing can allow more people to self-test at home for cervical cancer screening and have test result in 15 minutes. E7 oncoprotein self-sampling and self-testing can help to timely identify women at high risk and take early intervention measures, making it easier to achieve regular screening and tracking, especially for those at high risk.

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5a53d22e61118d2c003b1eaThe Role of E7 Oncoprotein Self-Sampling and Self-Testing in Cervical Cancer Screening-V3(1)a8b913356

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#12629

P37-01 | Enhancing HPV vaccine acceptance in school-based programs: Assessment of the Immune Patrol Game in Quebec, Canada

37 - Health education

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Background/Objectives: Human papillomavirus (HPV) vaccination is offered in a school-based program (grade 4: ages 9-10) in Quebec, Canada, a predominantly French-speaking province. Vaccine coverage among school-aged children remains suboptimal (80-85%). Non-French-speaking, immigrant, and disadvantaged students have lower HPV vaccine coverage, and these inequalities have persisted since 20081. Among barriers identified in our previous work2, several communication issues regarding the vaccination program were raised. The objective of this project was to evaluate the feasibility of implementing the Immune Patrol online game platform, in school settings across the province.

Methods: *Immune Patrol* is an innovative online digital educational platform developed by the World Health Organization (WHO) Europe Region, aimed at raising awareness among primary school students (target ages of the game: 10-12) about health, immunity, and vaccination3. A qualitative project was conducted in the spring of 2025 to gather schoolteachers' feedback and evaluate the integration of the platform into the Quebec school curriculum. A small number of teachers (n=3) tested the platform, completed observation grids, and participated in a group discussion. Completing all steps required around 5 hours per teacher.

Results: The three teachers who participated in the exploration and evaluation of the platform had many years of experience in primary education (more than 10 years). Most of their teaching careers were spent in the second cycle (3rd and 4th grades). Teachers emphasized the platform's strong educational value, noting its ability to engage students, foster motivation, and support critical thinking and health literacy through diverse, multimodal activities. The flexibility of the activities and the diversity of pedagogical approaches—alternating videos, physical or paper activities, and interactive games—were considered relevant for maintaining attention and supporting learning. Among the key limitations were usability challenges including lack of intuitiveness and navigation difficulties (switching between teacher and student accounts was deemed complicated), content complexity for some younger (ages 9-10) students, and the need for guided implementation due to the sensitive nature of vaccination topics.

Conclusions: Although based on a small sample, this in-depth evaluation highlights the platform's potential to engage students and support teaching on public health, immunity, and vaccination. Teachers valued its educational contribution but noted usability and content-related challenges. Effective integration will require technical improvements, professional support, and official recognition by educational authorities.

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#12651

P29-01 | Socio-demographic Characteristics of People with HPV-Associated Oropharyngeal Cancer in Iowa, US

29 - HPV and oropharynx / Head and neck cancer

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Background/Objectives: Iowa has the highest and fastest rising incidence rate of oropharyngeal cancer (OPC) in the US with HPV-associated OPC driving this rate [1,2]. To better understand why the incidence is rising, it is important to know who is experiencing HPV-associated OPC compared to those who have non-HPV-associated OPC. Thus, the purpose of this study was to assess differences in sociodemographic factors among those with HPV-positive and HPV-negative OPC in Iowa.

Methods: We used data from the Iowa Cancer Registry. US state-based cancer registries include patients residing in that state at the time of diagnosis. Registries collect data on the patient and first-course treatment from medical records. We utilized the following variables: race (white, not white), age (less than 55, 55-64, 65-74, 75 and older), insurance status (private, public, public and private, other, none), sex (female, male), marital status (not married, married or domestic partner), census tract level of rurality (metropolitan, micropolitan, rural). We employed logistic regression using HPV status (HPV-positive, HPV-negative) as an outcome and all socio-demographic variables as predictors. We included patients from 2018-2021 to reflect the time period when data on HPV-associated cancer testing was available. We used data based only on those individuals with cancer HPV status.

Results: Of the 853 people diagnosed with OPC, 826 (97%) had HPV status available. Of these, 607 (73%) were HPV-positive and 219 (27%) were HPV-negative. In the multivariable model, males were more likely than females to be diagnosed with HPV-positive cancer (odds ratio (OR)=2.4, 95% confidence interval (CI)=[1.5,3.7]). Additionally, those who were married or had a domestic partner were more likely than those who were not married to be diagnosed with HPV-positive cancer (OR=1.8, 95% CI=[1.3,2.5]). No other variables were associated with HPV status.

Conclusions: Our findings mirror those of other US-based studies: male sex is associated with HPV-positive OPC [3]. We also found that marital status was associated with HPV-positive OPC. While this study helps to describe the epidemiology of OPC in Iowa, additional individual-level information regarding socio-demographics of patients with OPC are needed to further describe and understand the rising incidence rate of the disease.

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#12664

P22-01 | The additive value of routine endocervical curettage at loop conization for future management of cervical dysplasia

22 - Diagnostic procedures / management

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Background/Objectives: Endocervical curettage (ECC) is a well-established procedure in current practice of cervical clinic, advocated in cases of higher-risk settings (HSIL, Transformation Zone (TZ) type 3, elderly age, or glandular dysplasia). However, in loop conization it is still questionable whether to perform routine ECC as part of the procedure. In our study, we assessed ECC diagnostic yield, concordance with cone pathology and whether ECC results changed clinical management.

Methods: Retrospective cohort study of 272 consecutive patients who underwent loop conization with routine ECC, between January 2022 to September 2023, at a single tertiary center. Patients who underwent loop conization for macroscopic invasive cervical cancer were excluded. We analyzed ECC diagnostic yield, concordance between ECC diagnosis and final cone pathology, associations with margin status (free; ectocervical margins involved—ecto+; endocervical margins involved—endo+; both margins involved—both+), and the effect of positive ECC results on subsequent management (re-excision or additional procedures). Descriptive statistics were used.

Results: ECC was positive in 15/272 cases (Table 1). Positive ECC occurred across all margin categories—endo+ 6, both+ 3, ecto+ 4, free 2—with the majority clustering in endocervical involvement (endo+ / both+); in these cases, ECC positivity may reflect cells scraped from residual endocervical disease rather than a new discordant diagnosis. In the AIS/carcinoma subset, ECC was negative in most cases: AIS cases were ECC-negative, and 1/6 invasive cases had a positive ECC (CIN2–3) with endocervical margins involved by invasive carcinoma. Among cases with negative endocervical margins (Free or ecto+; 6/15), escalation based on ECC was uncommon and low-yield: 2/6 underwent hysterectomy, and both were negative on operative pathology.

Conclusions: Routine ECC at loop conization provides limited incremental value: it rarely identifies higher-grade disease beyond the cone or adds clinically actionable information. When endocervical margins are negative, acting on a positive ECC led to two hysterectomies without pathologic justification, reinforcing a selective, risk-adapted approach-prioritizing ECC when endocervical disease is suspected and deemphasizing routine ECC in clearly low-risk, endocervical-negative scenarios. In the AIS/invasive carcinoma subset, ECC was negative in most cases; the single invasive case with positive ECC (CIN2–3) co-occurred with endocervical margins involved by invasive carcinoma, underscoring ECC's limited added value in this setting. Limitations include the single-center, retrospective design and small AIS/carcinoma numbers; larger studies with longer follow-up are needed.

References:

table 1

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P34-01 | Medical Therapy of Genital Human Papilloma Virus-Related Disease -Case Series and Treatment Approach

34 - Conventional therapies

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Background/Objectives: Introduction: HPV is considered the most common heterosexual and homosexual sexually transmitted infection globally. Although the majority of HPV infections are asymptomatic and resolve spontaneously, persistent infections can develop into anogenital warts, precancers, and cervical, anogenital, or oropharyngeal cancers in women and men.

Methods: Methods: We reviewed the history of four patients diagnosed with HPV-associated cervical lesions. Clinical data was collected, including demographics, working status, sexual history, and smoking status. All of them were treated with *Coriolus-Versicolor* -Based Vaginal gel.

Results: Case report 1
27 old patient, single, Null para, smoker, working as nurse in the hospital, came to regular visit at gynecologist in primary care center. Pap test was done as a regular annual screening and Hpv screening. The result from pap was infection, present Candida and Gardnerella vaginalis. The result from HPV screening was 5 HPV types, (52, 51, 66, 53 and 6). Biopsy was performed.
The result was LSIL (low-grade squamous intraepithelial lesion).
Patient started Coriolus-Versicolor-Based Vaginal gel, receiving the vaginal gel one cannula/day for 21 days (first month)/7-day pause for menstrual cycle + one cannula/alternate days (five months)/7-day pause for menstrual cycle. After the treatment finished pap test, colposcopy and Hpv testing were made.
Pap test was normal, colposcopy findings were normal and Hpv test was negative.

Case report 2
39 years old patient, married, 2 deliveries, works as cosmetician, non-smoker
Annual screening with Pap test and Hpv screening.
Pap was inflammation with presence of Hpv type 16.
Biopsy was done.
Result was LSIl lesion (low-grade squamous intraepithelial lesion).
Patient started Coriolus-Versicolor-Based Vaginal gel, receiving the vaginal gel one cannula/day for 21 days (three months)/7-day pause for menstrual cycle + one cannula/alternate days (three months)/7-day pause for menstrual cycle. After the treatment finished Pap test, colposcopy and Hpv testing was made.
All tests were normal, with absence of HPV.
Case report 3
51 old patient, married, 2 deliveries, smoker, works in a market.
Hpv testing two high risk Hpv viruses (16, 33), pap CIN 1, colposcopy mosaicism.
Biopsy chronic viral cervicitis, intraglandullar squamous metaplasia without atypia. Coriolus-Versicolor-Based Vaginal gel was taken, one cannula/day 21 day (three months) /7 days' pause, + one cannula/alternative days (three months)/7-day pause.
After six months the result was negative Hpv, clear pap and normal colposcopy.

Conclusions: Conclusion

Coriolus-Versicolor-Based Vaginal gel shows promising potential as a supportive treatment in managing HPV infections. Its unique formulation, which includes antioxidant, anti-inflammatory and mucosal repairing agents, may help enhance the local immune response, promote epithelial healing and create an unfavorable environment for viral persistence. Preliminary findings suggest that Coriolus-Versicolor-Based Vaginal gel can contribute to the clearance of Hpv and the regression of low grade cervical lesions when used as an adjunct to standard monitoring protocols.

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#12710

P29-02 | Fibroblast supernatants modulate treatment responses in human papillomavirus positive and negative oropharyngeal cancer cell lines.

29 - HPV and oropharynx / Head and neck cancer

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Background/Objectives: Human papillomavirus-positive (HPV+) oropharyngeal squamous cell carcinoma (OPSCC) has a better outcome than HPV-negative (HPV-) OPSCC, but not all are cured with chemoradiotherapy, so new therapies are required. Recently, we showed that e.g. phosphoinositide 3-kinase (PI3K) and fibroblast growth factor receptor (FGFR) inhibitors reduced viability in both HPV+ and HPV- OPSCC cell lines. Here, to better mimic the in vivo environment, the effects of supernatants of a normal fibroblast cell line on the responses of HPV+/HPV- OPSCC cell lines to various drugs were examined.

Methods: HPV^+(CU-OP-2, CU-OP-20) and HPV^-(CU-OP-17) OPSCC cell lines were treated for 72 h with PI3K (BYL719), FGFR (JNJ-42756493), cyclin-dependent kinase (CDK) 4/6 (PD-0332991) and AKT (AZD-5363) inhibitors as well as cisplatin and docetaxel, with/without supernatants from the normal BJ-hTERT fibroblast, or the cancer-associated fibroblast (CAF) KS35 cell lines. Effects on viability and cell confluence/proliferation were then analyzed.

Results: All drugs abrogated viability and confluence in all cell lines. Combining BJ-hTERT supernatants with BYL719, JNJ-42756493 and PD-0332991 decreased their reduction of viability in some cell lines, while this was not the case for AZD-5363 and cisplatin. Docetaxel efficacy on viability was only slightly affected and only in CU-OP-20. BJ-hTERT supernatants mainly had analogous effects on confluence to those observed on viability. CAF supernatants had more variable results due to the influence of growth factors needed and added to their media and were not pursued further.

Conclusions: Co-administering fibroblast BJ-hTERT supernatants with BYL719, JNJ-42756493 and PD-0332991 had an inhibitory effect on their effects with regard to viability and confluence on some cell lines. This was never the case with cisplatin, and very rarely the case with docetaxel or AZD-5363.

References:

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#12723

P39-04 | Every opportunity counts: Rural-Urban differences in public comfort of dental settings for HPV-related discussions in the United States.

39 - Public health

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Background/Objectives: Oral health providers (OHPs) play an increasingly recognized role in HPV-related cancer prevention through patient education and vaccination advocacy. Despite professional guidance encouraging OHP engagement in HPV prevention [1,2], HPV-related discussions rarely occur in dental settings in the United States (U.S.). Prior studies demonstrate patients' limited comfort discussing HPV with OHPs [3] and providers' uncertainty about role boundaries [4]. In the U.S., rural populations experience lower HPV vaccination rates, fewer provider interactions, and higher oral cancer incidence than in urban settings [5]. Understanding geographic differences in comfort with dental-based HPV education may inform strategies for leveraging nontraditional healthcare settings for HPV prevention in areas with limited medical infrastructure. Therefore, this study examined rural-urban differences in U.S. adults' comfort and preferences regarding HPV-related discussions with OHPS.

Methods: A cross-sectional online survey of 500 U.S. adults (ages 18-45) who had visited the dentist within the past 3 years assessed comfort and preferences for HPV-related discussions in dental settings. Measures included comfort discussing HPV as an oral cancer risk factor and the HPV vaccine with OHPs (5-point Likert scale) and perceived importance of OPHs in HPV prevention. Independent samples t-tests examined differences by residence (rural = 49.8%, urban = 27.6%).

Results: Only 9.6% of respondents reported ever discussing HPV vaccination with a dentist or hygienist. Yet 75.6% expressed at least moderate comfort discussing HPV as a risk factor for oral cancer (M = 4.13) and 71.2% felt comfortable discussing the HPV vaccine (m = 4.02) with an OHP. Two-thirds (68%) agreed they would like OHPs to address HPV on their next visit. However, rural respondents reported significantly lower comfort discussing the HPV vaccine (M = 3.9 vs. 4.20; p = .008; d = .28), lower comfort with dentists recommending vaccination (p = .034; d=.23), and lower perceived importance of OHPs in HPV prevention (p,.001; d = .36 - .44) than urban participants. Despite lower comfort, rural adults also reported fewer prior HPV conversations with any healthcare provider, suggesting limited opportunities for HPV education in traditional settings.

Conclusions: Dental settings represent an underused but acceptable environment for HPV prevention communication. Although comfort with and perceived appropriateness of these discussions are lower in rural areas, these same communities face greater barriers to care and lower vaccination coverage – paralleling challenges in other underserved in the US and beyond. Future interventions should explore communication framing that normalizes HPV prevention in dental care and enhances provider confidence. Integrating HPV messaging into routine dental visits, particularly in areas with limited medical access, could expand vaccine promotion and oral cancer prevention. Rural dental clinics may serve as nontraditional access points for education, referral, or on-site vaccination – supporting a global "every opportunity counts" approach to HPV prevention.

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#12763

P22-02 | HPV RNA and DNA analysis as potential diagnostic tool for nodal metastasis in cervical cancer

22 - Diagnostic procedures / management

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Background/Objectives: Cervical cancer, the fourth most common cause of cancer-related death among women worldwide, is strongly associated with persistent infection by high-risk human papillomavirus (HPV). The detection of HPV DNA and RNA in primary cervical tumors has been well established; however, the presence of viral genomic material within lymph nodes remains less clearly defined. The expression of HPV E6 and E7 oncogenes may represent an early carcinogenic activity in lymphatic tissue that can be overlooked by conventional pathology. Previous studies have shown that up to 15% of pN0 patients eventually develop recurrence or distant metastasis, and some histologically tumor-free sentinel lymph nodes (SLN) were found to be positive for HPV E6/E7 mRNA. Given that lymph node metastasis is the most critical prognostic factor in cervical cancer, this study aimed to evaluate HPV detection in lymph node tissues and to explore its correlation with histopathological evidence of metastasis.

Methods: Inclusion criteria were: HPV-associated Cervical Cancer patient, undergo SLN harvesting or systematic lymphadenectomy, age over 18 years old, no contraindication for SLN biopsy, the patient agrees to participate in the study.
Tumor tissues samples and lymph node materials were taken during cervical cancer surgery. Samples were examined with HPV-DNA PCR test and HPV-RNA test. Results from both tests would be compared with histopathological findings.

Results: This study included 26 patients diagnosed with cervical cancer, with a mean age of 55.4 ± 13.9 years. Among them, 76.9% had squamous cell carcinoma and 23.1% had adenocarcinoma. HPV16 was detected in 61.5% of patients, while HPV18 accounted for 19.2%. The most common FIGO stages were IB1 (34.6%), IIB (26.9%), and IB2 (15.4%).
Ninety SLN and pelvic lymph node samples from 26 patients were analyzed for HPV RNA and DNA. Histopathological examination confirmed 8 metastatic lymph nodes (9.3%).
The HPV-RNA test demonstrated a 100% sensitivity, as all histologically positive nodes were also HPV-RNA positive. The specificity was 77.1% in SLNs and 76.6% when all lymph nodes were considered. The negative predictive value (NPV) of the HPV-RNA test was 100%.
In contrast, the HPV-DNA test showed a sensitivity of only 75.0% but a higher specificity of 93.6% for all lymph nodes. For SLNs alone, sensitivity decreased to 66.7%, and specificity to 91.7%.
Four patients developed recurrence. All four were positive for HPV RNA in lymph node testing, while only one (25%) was positive for HPV DNA and three (75%) had histologically confirmed nodal metastasis.

Conclusions: The HPV-RNA might be, potentially, a prognostic marker to rule out metastasis in cervical cancer and an indicator for future recurrence. Follow-up time is needed to monitor the patient population which has RNA-positive lymph node but pathologically negative.

References:

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#12766

P17-01 | DNA-methylation markers for early endometrial cancer detection in patient-collected urine and vaginal samples - a case control study

17 - Methylation

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Background/Objectives: Testing for DNA methylation markers in self-collected urine and vaginal samples holds promise for the early detection of cervical cancer and could also aid endometrial cancer detection. Endometrial cancer is the most common gynaecological cancer in developed countries [1, 2]. Current diagnostics, transvaginal ultrasound, has a good sensitivity (94.8%) but a low specificity (51%) [3], resulting in unnecessary numbers of invasive and time-consuming endometrial biopsies in women without endometrial cancer. Methylation analysis of self-collected urine and vaginal samples would provide a simple and women-friendly alternative to determine cancer risk. Therefore, this study will determine and compare the test performance of DNA methylation testing in paired patient-collected urine and vaginal samples to differentiate endometrial cancer cases from healthy controls.

Methods: A total of 60 women with endometrial cancer at Aarhus and Odense University Hospital and 60 healthy age-matched controls are included in the study. Participants are asked to self-collect paired full-void urine and vaginal samples at the hospital. Samples will be analysed for two panels of DNA-methylation markers: *GHSR*, *CDH13*, and *SST* (urine) and *CDO1*, *GHSR* and *ZIC1* (vaginal) using quantative methylation-specific PCR (qMSP) [4]. Test performance from women with endometrial cancer will be compared to results from the controls and presented as Receiver-Operating Characteristic (ROC)-curves and quantified by Area Under the Curve (AUC) with 95% confidence intervals.

Results: Patient enrollment started in April 2025 and is ongoing. Currently, 48 cases are included and methylation analysis of urine and vaginal samples is ongoing. Preliminary results will be presented in March 2026.

Conclusions: This study will show if DNA methylation analysis of patient-collected samples effectively can distinguish endometrial cancer cases from controls. This method holds promise for the use in the diagnostic assessment of women with postmenopausal bleeding who are suspected of endometrial cancer. Possibly, it may also be combined with cervical cancer detection. This approach could spare women from unnecessary invasive procedures and reduce health-care costs in the future.

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#12772

P29-03 | Early Detection of Minimal Residual Disease Using Circulating Tumour HPV-DNA in HPV-Associated Head and Neck Squamous Cell Carcinoma

29 - HPV and oropharynx / Head and neck cancer

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Background/Objectives: HPV-associated head and neck squamous cell carcinoma recurs in 10–25% of the patients. Current surveillance methods, including clinical follow-up and imaging have limited sensitivity and specificity. There is a critical need for complementary biomarkers that enable earlier detection of minimal residual disease (MRD). Circulating tumour HPV-DNA (ctHPV-DNA) represents a promising biomarker due to its correlation with tumour burden. This study aimed to evaluate the utility of ctHPV-DNA in a clinical setting and to compare its capacity in detecting MRD against standard surveillance according to national guidelines.Presentation of two-year follow-up data from the CIRCOS multicentre study (ClinicalTrials.gov: NCT05904327).

Methods: This prospective observational study included patients with HPV-positive oropharyngeal cancer or head and neck cancer of unknown primary, who were consecutively enrolled between 2020 and 2023 at three otolaryngology units in Sweden.Plasma samples were collected at diagnosis, at the end of treatment, and during surveillance. Clinical follow-up was conducted in accordance with national guidelines.Tissue or cytology samples obtained at diagnosis were genotyped for HPV. Circulating tumor HPV DNA (ctHPV-DNA) in plasma samples was detected using HPV genotype–specific droplet digital PCR assays. A sample that remained positive at the end of treatment was classified as a slow decline. A molecular recurrence was defined as two consecutive positive ctHPV-DNA. All patients with a molecular recurrence were offered an additional clinical examination. Clinical recurrence was confirmed by biopsy whenever feasible; in cases where biopsy was not possible, radiological assessments were used.

Results: A total of 120 patients with a median age of 62 and a male predominance (76%) were enrolled. A variety of HPV genotypes were detected (HPV 16 (82%), 18, 33, 35, 56, 59). At diagnosis, 91,6% of the patients had detectable ctHPV-DNA. Follow-up after treatment ranged from 5.5 to 54 months.
During follow-up, 20 of 120 patients (17%) developed clinical recurrence. Ten of these twenty patients demonstrated residual disease on evaluating post-treatment PET-CT, accompanied by a correspondingly slow decline in ctHPV-DNA levels. The remaining ten patients developed recurrence at a later stage; in six of these cases, additional clinical evaluation was initiated due to molecular recurrence.
Clinical recurrence was confirmed a median of 3.5 months (IQR 4.75) after molecular recurrence. The first out of two detectable ctHPV-DNA appeared a median of 5 months (IQR 3.25) before clinical confirmation.

Conclusions: ctHPV-DNA is a promising biomarker for MRD in HPV-positive oropharyngeal cancer or head and neck cancer of unknown primary. By adding ctHPV-DNA to standard surveillance, patients at risk or recurrence can be identified at an earlier stage.

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ctHPV-DNA test result during post-treatment surveillance

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#12778

P13-02 | Impact of Home-Based Cervical Cancer Screening on Other Preventive Health Service Utilization: An Analysis of Flu Vaccine Uptake

13 - Self-sampling

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Background/Objectives: Home-based HPV self-sampling is an emerging cervical cancer screening option in the United States (US). However, introducing a home-based healthcare option might reduce uptake of other recommended, in-person preventive services, particularly among those with a history of screening adherence. We explored whether mailed, home-based HPV self-sampling impacted flu vaccine uptake among individuals with a history of cervical cancer screening adherence.

Methods: We conducted a secondary analysis of STEP ("Self-Testing options in the Era for Primary HPV screening for cervical cancer"), a pragmatic, randomized trial conducted from November 2020-January 2022 within a US integrated healthcare delivery system. Individuals (N=12,928) who were due, but not yet overdue, for cervical cancer screening were randomized to one of the following arms: 1) "Usual Care" (UC) (outreach for in-clinic screening), 2) "Education" (EDU) (UC + educational packet on cervical cancer screening), 3) "Opt-in" (UC + EDU + option to request an HPV self-sampling kit be sent by mail), or 4) "Direct-mail" (UC + EDU + HPV self-sampling kit mailed directly to them). Our outcome was flu vaccine uptake within 1 year after randomization. For this analysis, we combined UC and EDU into a single reference exposure group. We fit modified Poisson models to obtain risk ratios (RRs) and 95% CIs, and stratified by randomization month to explore variation by proximity to flu season.

Results: Overall flu vaccine uptake was 52.5%; prevalence varied slightly by randomization month (March-August: 55.5%, December-February: 50.7%, September-November: 50.1%). There were no significant differences in flu vaccine uptake comparing those in Direct-mail (RR: 1.01 (95%CI=0.96, 1.07)) and Opt-in (RR: 0.99 (95%CI=0.96, 1.03)) to UC+EDU. Results did not vary significantly by randomization timing.

Conclusions: We found no difference in annual flu vaccine uptake among those given the option to use home-based HPV self-sampling for cervical cancer screening. It is unlikely that seasonality impacts this relationship. Future work will explore whether offering HPV self-sampling impacts uptake of other preventive services, including breast and colorectal cancer screening, and, among those offered home-based HPV self-sampling, whether those who use self-sampling compared to those who screen in clinic or not at all are more or less likely to subsequently receive other recommended preventive services. These results can help shape messaging around continuing to receive in-person preventive services as HPV self-sampling becomes more available in the US.

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#12793

P09-05 | Ten-Year Results of HPV and Cytological Testing from the National Reference Centre, Zagreb, Croatia

09 - HPV testing

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Background/Objectives: In recent years, HPV testing has been introduced in Croatia as part of the existing opportunistic cervical cancer screening program and within the organised screening program, which is currently in the third year of its pilot implementation. However, the history of HPV testing in Croatia extends much further back. This study presents a decade-long analysis of HPV and cytological testing at the Ministry of Health's Reference Centre for the Diagnostics of Sexually Transmitted Infections, which is part of the Department of Clinical Microbiology at the Dr Andrija Štampar Teaching Institute of Public Health in Zagreb.

Methods: Samples submitted to the Reference Centre Laboratory, which maintains continuous accreditation to the ISO15189 standard, were received based on indications provided by gynaecologists. These comprised specimens obtained through opportunistic screening as well as those collected for other clinical indications. HPV testing was performed using a real-time PCR assay with partial genotyping capabilities, detecting types 16 and 18 separately while providing a pooled result for the remaining 12 high-risk HPV (hrHPV) types. From the same sample, HPV testing and liquid-based cytology (LBC) were performed in selected cases, at the gynaecologist's request. The analysed results cover the period from January 1, 2015, to December 31, 2024. For statistical analysis, the χ^2 test and the Mann-Kendall test were used.

Results: Over the ten-year study period, a total of 49,295 cervical swab samples were tested for high-risk HPV, with at least one hrHPV genotype detected in 17,704 samples (35.9%). In women under 30 years of age, the proportion of positive samples was 49.55%, whereas it was 29.50% in women 30 years of age or older ($p < .001$). Multiple hrHPV infections were more frequent in women under the age of 30 ($p < .001$). A declining trend in the hrHPV prevalence was observed in girls under 21 years of age ($p < .05$). During the study period, 9,230 LBC specimens were processed, with 1,659 also undergoing HPV testing from the same sample. The proportion of hrHPV positive samples in women with normal cytology was 23.40%, while it increased with the severity of the cervical intraepithelial lesion: 35.09% in ASCUS, 63.13% in CIN I, 87.30% in CIN II, and 93.10% in CIN III ($p < .001$). The proportion of cervical lesions attributable to HPV genotype 16 rose significantly with increasing lesion severity (25.07% in CIN I to 66.67% in CIN III, $p < .001$).

Conclusions: HPV testing has undergone rapid technological advancement and widespread implementation over the past decade. It is essential to promptly adopt emerging technologies and continuously monitor the evolving epidemiological landscape, particularly considering the growing proportion of the population that has been vaccinated. In response to anticipated shifts in HPV prevalence and genotype distribution, extended genotyping assays are becoming increasingly important. Furthermore, self-sampling should be introduced as a complementary strategy to enhance both the accessibility and uptake of screening programs.

References:

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#12794

P13-09 | Veil-based self-collected cervicovaginal sampling for site-of-care sexually transmitted infections and primary HPV-based cervical cancer screening: a large-scale pilot feasibility study in Romania

13 - Self-sampling

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Background/Objectives: Veil-based self-collection of female genital secretions for the detection of high-risk HPV (HR-HPV) and pathogens causing sexually transmitted infection (STI) constitutes an attractive non-invasive and easy-to-perform method to increase the participation of women in cervical cancer and STIs screening programs. The feasibility of large-scale use of veil-based self-collected genital specimens for HPV and STIs screening was assessed in real-life in adult female population in Romania, for assessing molecular epidemiology of circulating HPV and STIs pathogens as well evaluating interactions between HR-HPV and STIs pathogens as possible cofactors.

Methods: Adult women (≥30 years) from five gynecologic centers across Romania participated. They used a veil-based self-sampling kit (Vaginal Veil Collector V-Veil Up UP2™ device, V-Veil-Up Production SRL, Pitesti, Romania). Specimens underwent multiplex real-time PCR (Allplex™ assays, Seegene, Seoul, South Korea) to detect 14 HR-HPV types and seven major STIs, including *Chlamydia trachomatis* (*CT*), *Mycoplasma hominis* (*MH*), *Ureaplasma urealyticum* (*UU*), and *Ureaplasma parvum* (*UP*).

Results: Among 950 (98.3%) valid specimens, HR-HPV DNA was detected in 13.8% of participants. The most frequent genotypes were HPV-16 (2.4%) and HPV-68 (2.0%). Non-vaccine HR-HPV types were found in 8.7% of women, exceeding the 7.7% prevalence of Gardasil-9 types. *UP* (24.0%) was the most common STI, followed by *UU* (4.5%) and *MH* (3.9%); *CT* prevalence was 0.9%. The 18–29 age group showed the highest overall HR-HPV prevalence (22.2%), multiple HR-HPV infections, and specific STIs like *CT* (2.3%) and *UP* (34.7%). Women aged ≥30 years had significantly reduced odds of HR-HPV (aOR: 0.41–0.55; p≤0.03). In multivariate analysis, *CT* infection emerged as the strongest, most consistent predictor of HR-HPV: overall HR-HPV, aOR 8.76 (p=0.004); multiple HR-HPV infections, aOR 23.25 (p<0.001); Gardasil-9-targeted genotypes, aOR 13.45 (p<0.001). *MH*, *UP*, and *UU* were also independently associated with overall HR-HPV and, notably, with non-vaccine HR-HPV types (*e.g.*, *UP*, aOR: 2.23; p=0.001).

Conclusions: The veil-based self-collection method was highly effective and community-friendly for broad-based screening, which can significantly improve participation, especially in underserved or harder-to-reach populations. The 18–29 age group emerged as the highest-risk group, showing the highest prevalence for overall HR-HPV (22.2%), multiple HR-HPV infections, and specific high-risk types like HPV-16. The significantly reduced odds of HR-HPV in women ≥30 years (aOR: 0.41–0.55) aligns with known HR-HPV epidemiology. The high prevalence of *UP* (24.0%) highlights the need for better surveillance and management of non-classical STIs. The most critical clinical finding is the extremely strong association between *CT* infection and overall HR-HPV and multiple HR-HPV infections, indicating that *CT* acts as the strongest and most consistent predictor. Screening and treatment for *CT* in cervical cancer screening programs (or *vice versa*) is thus strongly justified. Other STIs, including *MH*, *UP*, and *UU*, were independently associated with HR-HPV, often specifically with non-vaccine HR-HPV types, suggesting that these co-infections may promote the acquisition or persistence of HR-HPV. Taken together, implementation of parallel testing for *CT* and *MH* alongside HR-HPV screening, should be integrate in Romania, especially for women in the 18–39 age bracket.

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#12797

P35-01 | Cost-effectiveness analysis of catch-up HPV-Vaccinations in Austria

35 - Economics and modelling

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Background/Objectives: Human Papillomavirus (HPV) is among the most common sexually transmitted infections, with up to 80% of sexually active individuals infected at least once. Persistent infections can lead to cancers of the cervix, anus, vulva, penis, and oropharynx, as well as genital warts. Austria introduced gender-neutral HPV vaccination for 9–12-year-olds in 2014 and expanded free access to individuals aged 9–21 in 2022. In 2024, the Ministry of Health announced a national catch-up vaccination program for adults aged 21–30. While HPV vaccination has shown to be cost-effective in previous Austrian analyses, no evaluation has yet assessed this new catch-up program.

Methods: A Markov model will be developed to evaluate the cost-effectiveness of the 2024–2026 catch-up program from both healthcare system and societal perspectives. Model inputs will include Austrian registry data (ELGA, Statistics Austria, ÖGK) and published evidence on vaccine efficacy and disease incidence. The model will project HPV-related outcomes, including cancer and genital wart incidence, over 10–40 years. Costs and effects will be discounted at 3% annually. The main outcome measures will be the incremental cost-effectiveness ratio (ICER), life-years gained, and costs averted. Deterministic and probabilistic sensitivity analyses will test parameter uncertainty.

Results: The research project is still ongoing and calculations and modelling are undertaken at the moment. The economic analysis is part of a Master Thesis Project written in the program of Health Economics, Policy and Management at Karolinska Institutet, Stockholm, Sweden. Henceforth, results can only be made available at a later stage.

Conclusions: This study aims to quantify the economic and public health impact of Austria's HPV catch-up vaccination program.

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#12902

P13-03 | Analytical and diagnostic quality of biobanked HPV Self-samples for cervical cancer screening after storage

13 - Self-sampling

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Background/Objectives: Since 2017, human papillomavirus (HPV) self-sampling has been implemented in the Cervical Cancer Screening Program of the Capital Region of Denmark. Reanalysis of HPV self-samples may be required for audit purposes, for example, when women develop cancer between screening intervals. In addition, preservation of clinician samples is necessary for development and improvement of diagnostic technologies for the ultimate effort of cervical cancer elimination. To reliably preserve samples, it is necessary to establish biobanking protocols, however, knowledge regarding the stability and diagnostic reliability of biobanked HPV self-samples over time, is limited. The objective of this study is to assess the analytical and diagnostic quality of biobanked self-collected cervical screening samples over time.

Methods: Biobanking followed established best-practice procedures, whereby 2 mL of the suspended sample in BD cervical brush diluent (BD Integrated Diagnostic Solutions) was transferred to Eppendorf tube and initially stored at −20 °C before long-term storage at −80 °C. The quality of biobanked HPV self-samples was assessed by reanalyzing samples, stored for 3, 5 and 7 years each. Original diagnostic testing and study reanalysis was performed using the BD Onclarity HPV assay on a BD viper platform. The diagnostic outputs from the original and study analysis were compared and Internal control cycle threshold (Ct) values for the human β-globin (HBB) gene were used as a proxy for DNA quantity and compared between original and study analysis.

Results: Samples stored for 7 years (n = 250), mean internal control Ct-values increased from 20.9(SD:1.6) to 22.2(SD: 1.5), with a difference of 1.3 and with an overall diagnostic agreement of 95.6%.
Samples stored for 5 years (n = 248), mean internal control Ct-values increased from 22.0(SD:2.4) to 23.1(SD: 2.3), with a difference of 1.1 and with an overall diagnostic agreement of 96.0%.
Samples stored for 3 years (n = 250), mean internal control Ct-values increased from 21.4(SD:1.9) to 22.5(SD: 1.7), with a difference of 1.1 and with an overall diagnostic agreement of 98.0%.
Analysis of genotype-specific agreement is ongoing.

Conclusions: Our study shows no time-dependent effect on the quality of biobanked HPV self-samples. The shift of approximately 1 Ct in internal control values is uniform across all cohorts. We hypothesize that the minimal deterioration in quality compared to the fresh samples is attributable to freezing–thawing cycle rather than representing a time dependent effect. Diagnostic concordance exceeded 95% in all cohorts, supporting the robustness of current biobanking procedures for HPV self-samples at Hvidovre Hospital and validating their suitability for audit and research purposes.

References:

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#12911

P06-01 | The identification of HPV prevention strategies between oral health and primary care settings in the United States.

06 - HPV prophylactic vaccines

Richman A[1], Maness S[1], Egan K[2], Sanchez L[1], Al-dajani M[1], Torres E[3], Flores A[4]

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Background/Objectives: HPV vaccination prevents most HPV-related cancers, yet vaccine uptake remains low in the United States (US). HPV is linked to an estimated 70% of oropharyngeal cancers (OPCs) and nearly all cases of cervical cancers. Not all OPCs can be detected through routine screening, making HPV vaccination a first line primary prevention strategy. Promoting HPV vaccine in non-traditional locations in the US, like dental offices, may increase HPV vaccine uptake. The American Dental Association encourages dentists to educate patients about HPV-related OPCs and engage in oral cancer screenings, however HPV vaccine education and referrals to community clinics where HPV vaccines can be provided are limited in the US dental setting currently. The purpose of this study is to identify HPV prevention strategies and key infrastructure elements and policies that can be implemented within dental clinics and between dental clinics and nearby community primary care clinics that can be used to increase HPV vaccine uptake in the US.

Methods: Researchers conducted in-depth interviews with directors and semi-structured focus groups with staff (general dentists, dental assistants, dental students) at six dental clinics and with staff (physicians, nurses, administrators) at eight nearby community primary care clinics strategically located across a southeastern state in the US. Interviews and focus groups at dental and community clinics were analyzed by two study team members using thematic analysis with Nvivo software.

Results: A total of 90 individuals participated in all focus groups and interviews (n=14 interviews, 10 focus groups (5–13 participants per focus group). Most participants identified as white (59%) and female (70%), with an average age of 38.5 years. Researchers identified nine key study themes from the data: three specific to the dental clinics' HPV conversations with patients, two related to community clinics' vaccine provision, and four involving the relationship between the dental and co-located/nearby community clinics. Results indicated that dental clinic staff do not currently discuss HPV with patients. They are open to discussing HPV with patients but anticipate barriers that require preparation and education to overcome them. Community clinics have demonstrated previous success with HPV vaccination, but patients over the age of 18 face financial barriers to vaccination. Community clinics and dental clinics report that they do not currently have existing referral networks between the two clinics but are open to the development of a referral system between practices if infrastructure is put into place to support it.

Conclusions: Our findings indicate that there is interest in, and potential for, increased discussion of HPV with dental patients and collaboration between dental and community clinics for HPV vaccination referral. The results of this investigation have informed a subsequent project which will test the feasibility of an intervention strategy to increase HPV vaccination through referral networks between dental clinics and nearby community primary care clinics. Ultimately, this work can reduce HPV-related cancers, serve as a model for US dental practices, and could influence US public health policy.

References:

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#12925

P11-01 | Self-sampling for cervical screening in the transgender and non-binary community: a qualitative study

11 - Screening for women difficult to reach

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Background/Objectives: People from the transgender masculine and non-binary (TMNB) community have reduced cervical screening uptake. Self-sampling methods, including a novel urine test for high-risk human papillomavirus (HPV), may overcome some universal and community-specific cervical screening barriers. These methods could be an attractive option for the TMNB community, enabling higher cervical screening rates, narrowing the current health inequity gap.

Methods: This was a UK wide qualitative study involving 16 transgender male and non-binary individuals. Data were generated using semi-structured qualitative interviews and after transcription a thematic analysis was employed. The Candidacy Framework and Sekhon's Theoretical Framework of Acceptability were drawn on as sensitising frameworks to understand the data and inform recommendations.

Results: Known barriers to cervical screening persist for TMNB people who describe negative interactions with healthcare and the speculum examination. Positive cervical screening episodes centred around choice, advocacy and power balance between participant and healthcare provider. Self-sampling methods for cervical screening, including a vaginal swab and urine, were positively received with pros and cons listed for each sampling method, highlighting the need for all sampling methods to provide personalised healthcare provision through enhanced choice. Home-based self-sampling options would likely improve uptake by removing most barriers through choice of location and sampling method.

Conclusions: Barriers to current cervical screening are endemic for TMNB people, although some gave positive examples of inclusion within cervical screening advertisement and healthcare interaction. Home-based self-sampling methods are preferred by TMNB people and would empower individuals to be screened and ultimately close the health inequity gap within this marginalised community. Future research should explore concurrent acceptability of self-sampling for cervical screening within the TMNB community.

References:

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#12952

P22-03 | Application of vaginal gel with Coriolus versicolor after operative treatment of cervical intraepithelial neoplasia - case series

22 - Diagnostic procedures / management

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Background/Objectives: Background: HPV infection is the most common sexual transmitted disease, therefore the cervical intraepithelial neoplasia are very common among female population in reproductive age. As far as, there is no screening program in our country, most of them are diagnosed once they come to the outpatient department

Methods: Methods: All three patients were treated with Worldwide accepted techniques for cervical dysplasia treatment (thermic ablation and excision-LLETZ).
Case reports: 1. 31 years old patient, non-smoker, infertility over 3 years. Persistent LSIL, (3 PAP smears in two years). HPV PCR-type 31. Biopsy was performed and histology finding was LSIL (cervical intraepithelial neoplasia, low grade) solely on the ectocervix. She was advised by infertility physician to eliminate the HPV, before the IVF cycle. Ablation of the cervix was performed and after that, she was prescribed a Coriolus versicolor based vaginal gel to be applied 3 months in a row for 21 days, one cannula per day, 7 days pause for the menstrual cycle. After 3 months, both PAP smear and HPV PCR were negative. After that, she had an IVF cycle and she delivered healthy baby at therm. 2. 27 years old patient, one term vaginal delivery, non-smoker. PAP smear-HSIL, HPV PCR types-16, 18 and 31. Two years ago she had a biopsy and histology was HSIL (both ecto and endo cervicaly), and she wasn't treated. The newly performed biopsy came carcinoma in situ, and LLETZ procedure was done. The margins were clear. She was prescribed a Coriolus versicolor based vaginal gel to be applied 3 months in a row for 21 days, one cannula per day, 7 days pause for the menstrual cycle. After 3 months she came for a check-up, the PAP smear was clear, but the HPV PCR-16. She was again prescribed to use the gel but every other day except during the menstrual cycle. After 3 months, the HPV PCR came negative. 3. 35 years old patient with two term cesarean section deliveries, smoker (20-30 cigarettes per day). Came to the outpatient department because of bloody discharge after sexual intercourse. PAP smear – HSIL, HPV PCR types-31, 56, microbiological smears – Trichomonas vaginalis. Firstly she was prescribed a course of antibiotics (her partner also). Control microbiological smears came negative. Biopsy was performed and it came HSIL. After 6 weeks, she had a LLETZ procedure. The margins came clean. She was prescribed a Coriolus-versicolor based vaginal gel to be applied 3 months in a row for 21 days, one cannula per day, 7 days pause for the menstrual cycle, following 3 months every other day. After 6 months, both her PAP smear and HPV PCR came negative.

Results: Results: In all three cases, patients are treated with, both operative techniques. After treatment, they were advised to use supportive therapy with vaginal gel that improves epithelization and enhances the immune response. After 6 months of treatment, all 3 patients were negative for high risk HPV.

Conclusions: Conclusion: It can be clearly seen, that post-treatment application of the Coriolus versicolor gel helps the epithelization of the cervix and enhances the clearance of HPV. Key words: HPV, LSIL, HSIL, LLETZ, Corisolus-Versicolor-Based vaginal gel

References:

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#12954

P25-05 | Early up-regulation of ROMO1 in cervical intraepithelial neoplasia: evidence of HPV-driven oxidative stress in precancerous lesions

25 - Cervical neoplasia

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Background/Objectives: Persistent infection with high-risk human papillomavirus (HPV) triggers a multistep process leading from normal cervical epithelium to cervical intraepithelial neoplasia (CIN) and, eventually, invasive carcinoma. Oxidative stress is a central driver of this transformation. ROMO1 (Reactive Oxygen Species Modulator 1), a mitochondrial membrane protein that regulates intracellular ROS, has been implicated in early HPV-induced mitochondrial reprogramming. Our recent study showed that HPV E5/E6/E7 oncoproteins disrupt mitochondrial homeostasis and enhance oxidative stress via ROMO1 activation (Cells 2024, 14, 1629). This study aimed to characterize ROMO1 expression in healthy cervix and CIN, testing whether oxidative imbalance is already evident at the precancerous stage.

Methods: Immunohistochemical analysis of ROMO1 was performed on formalin-fixed, paraffin-embedded cervical samples. The study cohort included histologically normal cervical tissues (n = 30) and cervical intraepithelial neoplasia (CIN I–III; n = 41). ROMO1 expression was assessed qualitatively and classified as positive or negative.

Results: ROMO1 expression was completely absent in all normal cervical samples (0/30; 0%) but present in all CIN lesions (41/41; 100%). These findings demonstrate a clear binary distribution: ROMO1 is inactive in normal epithelium but universally upregulated in precancerous lesions.

Conclusions: ROMO1 is uniformly absent in healthy cervix but strongly expressed in CIN, suggesting that HPV-driven mitochondrial dysfunction and ROS accumulation are early events in cervical carcinogenesis. The lack of ROMO1 in normal epithelium likely reflects intact antioxidant control, whereas its strong induction in CIN mirrors HPV E6/E7–induced oxidative imbalance. ROMO1 immunostaining could complement p16 as an early biomarker for distinguishing high-grade CIN from benign lesions.

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#12964

P06-02 | Impact of HPV Vaccination on the Distribution of HPV Genotypes in Women Attending a University Hospital in Buenos Aires, Argentina

06 - HPV prophylactic vaccines

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Background/Objectives: Background:Human Papillomavirus (HPV) is the leading cause of cervical cancer. In Argentina, HPV vaccination was introduced in 2006 and incorporated into the National Immunization Program in 2011 for girls aged 11 years, later extended to boys in 2017. Continuous surveillance of circulating genotypes is essential to evaluate the vaccine's long-term impact.Objective:To determine HPV prevalence and genotype distribution among women attending a university hospital in Buenos Aires, Argentina.

Methods: Methods:
Cervical samples from women aged between 25 and 65 were studied between January and May 2025 using complete real-time PCR genotyping, identifying 19 high-risk (HR) and 9 low-risk (LR) HPV types.

Results: Results:
516 women participated in the study. HPV was detected 156 samples (30.2%). HR-HPV was detected in119 samples (23%). Single HR-HPV infections accounted for 14.1%, multiple HR-HPV infections for 3.3%, and mixed HR/LR infections for 5.6%.
The most frequent HR-HPV genotypes were HPV 31 (13.4%), 68 (11.7%), 45, and 66 (10%). HPV 16 and 18 were detected at low frequencies (<10%). Among LR types, HPV 54 (27.3%), 42, and 61 (19.7%) were the most common.

Conclusions: Conclusions:
HPV 31 was the most frequent HR type, while HPV 16 and 18 showed reduced circulation, suggesting vaccination impact. In a scenario of changing prevalent genotypes due to vaccination, complete genotyping allows continuous surveillance of HPV type distribution and facilitates follow-up of HPV-positive patients to detect viral persistence enhancing clinical management.

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#12977

P13-04 | Streamlining HPV Screening: UniVerse® Automated Workflow for Self-Collected Vaginal Swabs

13 - Self-sampling

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Background/Objectives: UniVerse® is an automated in vitro diagnostic device for the pre-analytical procedures intended to aliquot liquid or semiliquid microbiological human specimens and/or reagents for microbiological analyses. The system can be optionally equipped with a module for the automatic dispensing of MSwab® medium, enabling the rehydration of dry vaginal swabs. The objective of the two studies presented was to assess the sample recovery efficiency of UniVerse® when processing self-collected dry vaginal swabs for human papillomavirus (HPV) screening. Specifically, the studies aimed to evaluate the equivalence between the automated UniVerse® workflow and manual processing in detecting HPV genotypes using molecular biology techniques.

Methods: In the first study, 93 women were enrolled, each providing two self-collected vaginal swabs (labeled A and B). Immediately after co arrival, the tubes were randomized into two processing workflows:

- One set was manually eluted in MSwab® medium, vortexed for 10 seconds at maximum speed, and manually aliquoted into a secondary
- The other set was processed using the UniVerse® automated workflow: swabs were eluted in MSwab® medium, vortexed for 10 second

Sample recovery efficiency was assessed by comparing the total number of HPV genotypes detected, PCR cycle threshold (Ct) values for HPV
A second study was conducted to compare the sample recovery efficiency of UniVerse® automated workflow using MSwab® with a manual v

Results: Scatterplots and Two One-Sided Tests (TOST) for paired data were used to assess the relationship and statistical equivalence between the analytical results obtained from the two workflows. In both studies, the mean differences in PCR cycle threshold (Ct) values for the Sample Adequacy Control (SAC) and HPV targets, along with their confidence intervals, fell within the predefined equivalence bounds of ±2 Ct.
Confusion matrices were generated to evaluate agreement between UniVerse® automated workflow and manual processing, calculating Positive Percentage Agreement (PPA), Negative Percentage Agreement (NPA), and overall agreement:

- First study: PPA = 92.0% (23/25), NPA = 98.5% (67/68), Overall agreement = 96.8% (90/93)
- Second study: PPA = 90.0% (9/10), NPA = 100% (28/28), Overall agreement = 97.4% (37/38)

Conclusions: The high level of agreement between the automated UniVerse® workflow and manual processing demonstrates that UniVerse® is equivalent in terms of sample recovery efficiency. This includes both the number of HPV genotypes detected and the semi-quantitative recovery of human cellular material from self-collected dry vaginal swabs.

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#13071

P16-01 | The evaluation of filter paper as a urine specimen collection method for HPV detection and genotyping

16 - Screening methods

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Background/Objectives: Cervical cancer remains one of the most prevalent cancers among women, accounting for approximately 90% of HPV-related malignancies. Traditionally, cytology-based screening (Pap test) has been used to detect cervical lesions; however, the World Health Organization now recommends DNA-based testing, which offers greater accuracy in identifying high-risk HPV types and precancerous lesions, while reducing diagnostic errors associated with visual interpretation. Self-sampling methods—including self-collected urine—have emerged as key strategies to help achieve the WHO's cervical cancer elimination targets. Due to its non-invasive nature, urine is considered an acceptable and promising specimen for HPV-based screening, with strong potential to improve participation rates and expand access to early detection. Our lab previously developed a filter paper based method of urine sample collection for chlamydia and gonorrhea testing. The drying of urine on filter paper preserves nucleic acid, does not involve the use of preservatives, and was shown to be an accurate method for chlamydia and gonorrhea diagnostic testing and molecular characterization. Here we sought to evaluate the use of filter paper for the collection of urine for HPV detection and genotyping.

Methods: Seventy-eight paired urine and cervical-vaginal swab (CVS) specimens were obtained from the Sex Worker Outreach Program (SWOP) in Nairobi, Kenya. All specimens were collected from women (median age = 31) that had tested positive by cervical swab for high-risk HPV(s). CVS were stored in PreservCyt, no media was added to urine, and all specimens were stored at -80◦C. To prepare dried urine strips (DUS), 1mL of urine specimen was applied to a filter paper, dried overnight, and stored at room temperature for 1 week prior to elution. DNA was eluted from DUS into 1.5mL of Hologic specimen transport medium and was placed on a nutating mixer for 30 mins at 30rpm. DNA was extracted using the MagNA Pure 96 automated system from 1mL of neat urine (n=81), 1mL of DUS eluate (n=81), and 500uL of CVS eluate (n=81). HPV detection of 46 mucosal types was done using a nested-PCR and microsphere-based in-house assay.

Results: HPV was detected in 100% of CVS and 66% of neat urine and DUS. In positive specimens, high-risk HPV types were detected in 100% of CVS and 90% of DUS and neat urine. DUS was in substantial agreement (k=0.7) with neat urine for the detection of HPV (sensitivity = 90.2%, specificity = 77.8%). DUS was in fair agreement (k=0.3) with neat urine for the detection of high-risk HPV types (sensitivity = 87.0%, specificity = 41.7%). HPV types 6, 67, and 90 were genotyped exclusively in urine specimens, while HPV types 33, 43, 59, 71,72, and 82 were typed exclusively in cervical swab specimens. Quantification of HPV 16 by qPCR showed that DUS specimens resulted in a loss of 0.5 - 1 log copies of HPV compared to neat urine, with an LOD of 1.25x101 copies/uL.

Conclusions: The global rise in HPV-related cancers underscores the urgent need to expand HPV testing coverage. The evaluated filter paper based method of urine sample collection was shown to be suitable for HPV detection and genotyping. Urine collection using dried urine strips (DUS) offers a promising, non-invasive strategy to enhance accessibility and facilitate early detection of high-risk HPV types associated with cancer development.

References:

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#13090

P37-02 | Assessing the Impact of HPV 9 in 9: A High-Production Educational Video to Enhance Pharmacist Confidence and Uptake in HPV Vaccination

37 - Health education

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Background/Objectives: Pharmacists in Canada possess an advanced scope of practice that includes independently administering vaccines such as HPV9 and prescribing for minor ailments. Despite this capability, HPV vaccination remains under-recommended in pharmacy settings compared to influenza or pneumococcal vaccines. To address this practice gap, an innovative high-production educational video—HPV 9 in 9—was developed to empower pharmacists with updated HPV knowledge and practical communication strategies to integrate vaccination discussions into routine care.

Methods: *HPV 9 in 9* is a 45-minute accredited educational video (CCCEP) designed in a TED-style format to enhance learner engagement. The program provides a clinical overview of HPV genotypes, transmission, related cancers, and eligible vaccination populations, followed by real-world pharmacy scenarios such as contraceptive prescribing, travel consultations, and minor ailment assessments where HPV vaccination opportunities naturally arise. Post-program questionnaires evaluated learner engagement, perceived relevance, and intention to implement HPV vaccination in practice.

Results: The *HPV 9 in 9* program was completed by over 1,000 pharmacists across Canada. Most participants reported that the content was directly relevant to their daily practice, with 88% indicating it was applicable to their professional context. Nearly all respondents (90%) stated they would recommend the program to their colleagues, and 80% expressed interest in attending a follow-up educational activity on the same topic. Importantly, 93% of pharmacists reported feeling more confident in initiating HPV vaccination discussions and implementing these services within their pharmacy practice after completing the program. The video's innovative production quality and storytelling approach were consistently cited as key factors enhancing engagement and knowledge retention. Reflecting its educational and creative impact, *HPV 9 in 9* was also officially selected for the 2025 CineHealth Film Festival, the world's only international health and wellness film festival.

Conclusions: The *HPV 9 in 9* initiative demonstrates that high-production, narrative-driven video education can significantly enhance pharmacist engagement and confidence in HPV vaccination advocacy. This model highlights the potential of multimedia, storytelling-based continuing education to accelerate vaccine uptake and close implementation gaps within primary care and pharmacy practice.

References:

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#13115

P14-01 | Detection and genotyping of human papillomavirus (HPV) in liquid-based cytology samples from a rural region of São Paulo State (Vale do Ribeira), Brazil

14 - Genotyping

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Background/Objectives: Cervical cancer remains the third most common malignancy among women in Brazil, excluding non-melanoma skin cancers, with an estimated 17,010 new cases per year between 2023 and 20251. Recent national guidelines have shifted cervical cancer screening from cytology-based to molecular testing for oncogenic HPV detection2. This study aimed to determine the prevalence and genotype distribution of HPV in liquid-based cytology (LBC) samples from women screened in the Vale do Ribeira region, São Paulo, Brazil, and to assess associations between HPV positivity, cytological abnormalities, and behavioral and reproductive risk factors.

Methods: This cross-sectional study analyzed 1,502 cervical samples collected from women attending primary healthcare units between September 2020 and December 2022. Participants provided informed consent and completed standardized questionnaires on demographic, behavioral, and reproductive characteristics. Genomic DNA was extracted and analyzed for HPV using multiplex PCR with PGMY09/11 primers, followed by Sanger sequencing for genotyping. Statistical associations were assessed using Pearson's chi-square or Fisher's exact tests.

Results: HPV DNA was detected in 11.1% of samples, with high-risk (HR) genotypes present in 6.5%. Among HR-HPV–positive women, 4.3% had negative intraepithelial lesion or malignancy (NILM), 25.5% exhibited low-grade abnormalities (ASC-US/LSIL), and 40% showed high-grade abnormalities (AGC/ASC-H/HSIL). Of all HPV-positive samples (n=92), 61.7% were cases of HR types. The most prevalent genotypes were HPV-16 (18.8%), HPV-52 (10.7%), HPV-51 (7.4%), HPV-58 (5.4%), and HPV-35 (5.4%). HPV-58 predominated among high-grade lesions (16.7%), whereas HPV-51 was most frequent in low-grade abnormalities (5.3%). HPV-18 was uncommon (2.7%) and mainly detected in NILM or LSIL samples.
Cervical abnormalities were significantly associated with early sexual debut, higher numbers of pregnancies and sexual partners, and lifestyle factors such as tobacco and alcohol use. Younger women showed a higher prevalence of HPV infection. A strong correlation was observed between the presence of high-risk HPV genotypes and cytological abnormalities.

Conclusions: This study provides valuable epidemiological data on HPV infection and genotype distribution in women from a vulnerable, rural area of São Paulo State. The predominance of high-risk HPV types, particularly HPV-16 and HPV-52, and their correlation with lesion severity underscore the need for targeted prevention and early detection strategies. Incorporating HPV genotyping into screening programs may improve risk stratification and inform vaccination and public health policies tailored to underserved regions such as the Vale do Ribeira.

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#13138

P15-02 | Discordant Phenotypes in Penile Squamous Cell Carcinoma

15 - Molecular markers

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Background/Objectives: Penile squamous cell carcinoma (PSCC) is a rare malignancy, affecting fewer than 1 in 100,000 men in Europe. According to the WHO, approximately half of PSCCs are attributed to high-risk human papillomavirus (HPV), most frequently subtype 16. HPV-associated and HPV-independent PSCCs exhibit distinct molecular profiles and prognoses, highlighting the importance of accurate etiological classification. p16 overexpression is widely used as a surrogate marker for HPV-driven oncogenesis; however, rare cases containing HPV DNA but negative p16 staining results pose a diagnostic dilemma. The discordance between p16 staining and HPV DNA presence warrants more investigration using in-situ RNA hybridization.

Methods: DNA was extracted from micro-dissected tumor tissues and analyzed for the presence of HPV genotype-specific DNA using the LCD-Array (CHIPRON). Immunohistochemical overexpression of p16INK4A served as a surrogate marker for a transforming HPV infection. In situ RNA hybridization was performed on FFPE tissue slices using the RNAScope 2.5 (Adanced Cell Diagnostics) with probes to HPV16 and HPV18.

Results: In a previous paper (Ermakov et.al., 2023), we identified 4 of 79 penile cancers which contained HPV DNA but were negative for p16 on immunohistochemical analysis. One SCC contained low risk HPV 6 DNA, but in 2 SCC HPV 16 and in one SCC 18 DNA was detected. In situ RNA hybridization for HPV 16 and 18 were negative in all 3 SCC.
Table 1:

Age
HPV DNA
HPV RNA
p16 Staining
Histological subtypes
Classification
Patient 1
76 years
HPV18
Negative
Negative
Sarcomatoid SCC
HPV Independent SCC
Patient 2
78 years
HPV16
Negative
Negative
Keratinizing SCC in Lichenoid dermatosis
HPV Independent SCC
Patient 3
38 years
HPV16
Negative
Negative
Keratinzing SCC in lichenoid dermatosis
HPV Indepent SCC

Conclusions: The presence of HPV DNA alone does not indicate HVP driven oncogenesis. Together with p16 overexpression as indirect surrogate marker for a transforming HPV infection, however, diagnostic accuracy is high. Rare SCC containing HPV DNA, but lacking p16 overexpression can be further characterized etiologically via demonstration of HPV RNA. In the absence of RNA, they can be classified as HPV-independent SCC.

Table 2: Summary of p16 staining patterns in PSCC

Penile SCC	**Etiology**	**HPV DNA**	**HPV RNA**	**p16 Staining**
HPV Induced	+	+	overexpression	
HPV Independent	-	-	-	
HPV Independent	+	-	-	

References: Ermakov MS, Kashofer K, Regauer S. Different Mutational Landscapes in Human Papillomavirus–Induced and Human Papillomavirus–Independent Invasive Penile Squamous Cell Cancers. *Modern Pathology*. 2023;36(10):100250. doi:10.1016/j.modpat.2023.100250

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#13163

P18-01 | Comparative analysis of HPV genotyping and microbiome profile in uterine cervix samples obtained by urine, self-collection, and healthcare professionals

18 - Microbiome

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Background/Objectives: Cervical cancer remains a major public health concern, particularly in low- and middle-income countries such as Brazil. Persistent infection with high-risk human papillomavirus (HPV) is the central causal factor in cervical carcinogenesis; however, growing evidence indicates that the cervical microbiome influences HPV persistence and progression to high-grade lesions.In this context, molecular HPV testing—especially through self-collection and non-invasive sampling such as urine—represents an important strategy to increase screening coverage. Nevertheless, the impact of the sampling method on both HPV detection and microbiota composition remains insufficiently explored.This study aimed to compare the analytical performance of four commercial HPV DNA assays and to investigate the microbiome profile obtained from urine, vaginal self-collected, and clinician-collected samples, assessing their concordance and biological representativeness.

Methods: A cross-sectional study was conducted among 100 women aged >21 years referred for colposcopy due to histological CIN2+ findings. HPV DNA detection was performed on urine, self-collected vaginal, and clinician-collected cervical samples, all obtained during the same visit and analyzed using four commercial HPV assays (Cobas, Quant_21, Seegene, and Flowchip). Microbiome and sexually transmitted infections (STIs) were evaluated in all samples using a multiplex molecular panel (Microbiome Analysis).

Results: A cross-sectional study was conducted among 100 women aged >21 years referred for colposcopy due to histological CIN2+ findings. HPV DNA detection was performed on urine, self-collected vaginal, and clinician-collected cervical samples, all obtained during the same visit and analyzed using four commercial HPV assays (Cobas, Quant_21, Seegene, and Flowchip). Microbiome and sexually transmitted infections (STIs) were evaluated in all samples using a multiplex molecular panel (Microbiome Analysis).

Conclusions: Comparable HPV genotyping results were obtained across all collection methods, supporting flexible sampling strategies in screening programs. The specific detection of several vaginal microbiota components showed a high level of agreement across different collection methods, highlighting the efficiency of the molecular approach across sampling strategies.

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#13164

P25-02 | Retrospective analysis of the effectiveness of laser vaporization for cervical lesions

25 - Cervical neoplasia

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Background/Objectives: Early detection and timely treatment of cervical precancerous lesions have significantly contributed to the lower incidence of cervical cancer. In Slovenia, the National Cervical Cancer Screening Program ZORA was introduced in 2003. According to ZORA every woman (aged 20 to 64 years) has her preventive cervical smear taken every 3 years . When such a smear indicates pathological changes, a colposcopic examination and biopsy are performed according to guidelines. Based on the type and extent of the changes, further actions are carrised on (monitoring, laser vaporization, LLETZ, conization, etc.).

Methods: We designed a retrospective analysis of patients, who underwent laser vaporization for pathological PAP smears, histopathologically confirmed changes of cervical biopsy, persistent HPV infection, or issues with contact bleeding. We reviewed the documentation of patients treated in the years 2015 and 2016 at the Day Hospital of the Department of Reproductive Medicine of the Gynecology Clinic, University Medical Centre Ljubljana. The aim of the study was to determine the number of treated patients, detected cervical lesions and the number of patients who no longer had recurring issues or pathological smears after the procedure. We wanted to identify, which patients were most suitable for laser vaporization.

Results: We analyzed 232 patients. A total of 111 patients were lost to follow-up. As a control, we have used the results of follow-up PAP smears. In more than 50% of patients, there was regression or improvement. A 100% improvement was detected in cases with contact bleeding, along with a negative PAP smear result. In a patient with atypical glandular cells, we have found progression to AIS (adenocarcinoma in situ).

Conclusions: Laser vaporization with a CO2 lasser is a simple procedure and can be performed as an outpatient procedure. It is suitable for contact bleeding, low-grade cervical squamous lesions and also for high-grade cervical lesions with adequate colposcopic visualisation. However, laser vaporisation is not suitable for glandular changes and squamous changes located in the cevical canal.

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#13200

P13-05 | Self-sampling HPV screening with DH3, a hybrid capture-based HPV test with HPV16/18 genotyping

13 - Self-sampling

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Background/Objectives: This study was aimed to evaluate the applications of DALTONbio DH3 (IVDR 790056), a hybrid capture-based high risk human papillomavirus (hrHPV) test with HPV16/18 genotyping, in self-sampling and cervical cancer screening.

Methods: A total of 400 women were recruited in this multi-center study. We recruited 100 women in Cixi city for the comparative study of self-collected vs physician-collected HPV results (i.e. SVP group). Another 100 women in Xiangyuan county were recruited for the comparison of hybrid capture-based vs PCR-based HPV tests (i.e. HCVP group) using the self-sampling device from Sunvale Tech (Ningbo, China). And 200 women in Shihezi were recruited for the cervical cancer screening of self-sampling HPV test in the remote areas (i.e. RAS group). Self-collected specimens were tested for hrHPV using DH3 assay (DALTONbio, Hangzhou, China) and/or HBRT-H14 assay (Hybribio, Guangzhou, China). The concordance rates were analyzed for the self-sampling vs physician-collection, as well as for two HPV tests.

Results: For the SVP group, two cases were excluded due to incomplete self-collection, and a total of 98 samples were analyzed. The DH3 concordance rate between self-collection vs physician-collection for HPV testing was 87.76%. The positive concordance rate was 87.50%, and the negative concordance rate was 87.78%.
For the HCVP group, a total of 68 self-collected samples were retrieved. The agreement between DH3 and PCR-based HPV test was 92.65% in self-collected samples. In comparison, the corresponding agreement of HPV16/18 and other 12 hrHPV types were 100% and 71.43%, respectively. The positive rate of hybrid capture (14.71%) was slightly higher than that of PCR test (13.24%).
For the RAS group, a total of 180 self-collected samples were retrieved. The positive rate of DH3 was 17.22%. The positive rates of HPV16/18 and other 12 hrHPV types were 4.44% and 12.78%, respectively.

Conclusions: Our study indicated that hybrid capture-based DH3 HPV test with HPV16/18 genotyping is applicable to self-collected samples. Hybrid capture-based HPV assay combined with self-sampling device provides a useful tool for cervical cancer screening, particularly in the resource-limited areas.

References:

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#13201

P23-01 | Heterogeneity of CIN2 diagnosis and risk of progression: a Danish historical cohort study

23 - Risk management

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Background/Objectives: Cervical intraepithelial neoplasia grade 2 (CIN2) represents a diagnostic and clinical grey zone. Our group and others have shown that the risk of CIN2 progression is influenced by age, cytology, and HPV genotype. However, the CIN2 diagnosis is associated with a substantial interobserver variability, highlighting the challenges in reproducible histopathological grading. Understanding how these factors truly affect outcomes is particularly relevant in the context of conservative management, as Denmark applies a watchful waiting strategy for women with CIN2 to preserve fertility, whereas many other countries perform immediate excision. Therefore, this study aimed to assess the risk of persistence and progression according to age, cytology, and HPV type in a Danish population-based cohort of women under active surveillance, including those with expert-verified CIN1, CIN2, or CIN3.

Methods: Through the Danish Pathology Databank (Patobank), we identified women aged 23–40 years undergoing active surveillance for CIN2 in Central Denmark Region during 2000–2010. Tissue specimens at the time of CIN2 diagnosis underwent expert histopathological review by two independent pathologists (and a third in case of disagreement). Cases were classified as expert CIN1 (including normal), expert CIN2, or expert CIN3. Women were followed from date of CIN2 diagnosis until a record of CIN3 or worse (CIN3+), LEEP, hysterectomy, or end of follow-up, whichever occurred first. As some women underwent a LEEP because of persistent disease at the 2-year follow-up visit, we followed women for up to 2 years and 4 months. Using a modified Poisson Regression analysis, we calculated the relative risk (RR) of CIN3+ using expert CIN2 as the reference, adjusting for age, cytology, and HPV type (aRR). Results were reported overall and stratified by age, cytology, and HPV type.

Results: We included 437 women with CIN2. Expert review reclassified 120 (27.5%) as expert CIN1, confirmed 261 (59.7%) as expert CIN2, and upgraded 56 (12.8%) to expert CIN3. Age, index cytology, and HPV type were evenly distributed across groups. Women with expert CIN1 had a significantly lower risk of CIN3 (aRR 0.70, 95% CI 0.53–0.91), while those with expert CIN3 had a significantly higher risk (adjusted RR 1.37, 95% CI 1.08–1.75). Highest relative risks of CIN3+ were observed in women with expert CIN3 who were aged 31-40 (aRR 1.80, 95% CI 1.23–2.63), had an associated high-grade cytology (aRRs 1.43 (1.04–1.97), or were positive for non-HPV16 (aRR 1.61 1.04–2.48).

Conclusions: Our findings demonstrate that community-diagnosed CIN2 encompasses a heterogeneous group with high interobserver variability, as 40% were reclassified after expert review, reinforcing the critical importance of accurate CIN grading to minimize risk of under- and overtreatment. Additionally, risk of CIN3 was significantly influenced by age, cytology, and HPV type, highlighting the multifactorial nature of progression risk. While these precise risk estimates cannot yet be directly applied in clinical practice, the data support the need for integrated, risk-based management of CIN2 rather than decisions based solely on histopathology, particularly in settings applying conservative management strategies.

References:

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#13256

P18-02 | Aerobic Vaginitis Diagnosis Criteria Combining Gram Stain with molecular panel RT-qPCR: a improve aprroach

18 - Microbiome

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Background/Objectives: Background:Aerobic vaginitis (AV) was first proposed by Donders et al. (2002) and is defined as a vaginal infection mainly caused by aerobic bacteria, characterized by a reduction in Lactobacillus spp., the presence of leukocytes or inflammatory reaction, and epithelial atrophy. AV is characterized by yellowish vaginal discharge, mucosal hyperemia, itching, burning sensation, and dyspareunia, and it accounts for 4.2% to 25.8% of all vaginal infections.Currently, the most commonly used method for diagnosing AV is fresh microscopy using a phase-contrast microscope to evaluate the lactobacillary grade (LBG), leukocytes, and the proportion of toxic leukocytes and parabasal epithelial cells (PBC), as well as to assess the background microbiota. A composite AV score based on three of these components confirms the diagnosis of AV. Recently, Gram staining has been validated to follow the same original scoring system for diagnosing AV, and RT-qPCR methods have also been reliably employed.Objective:To evaluate the use of an expanded molecular vaginal microbiota panel (EVMP), which includes bacteria from healthy microbiota, as well as the most prevalent anaerobic and aerobic bacteria found in bacterial vaginosis (BV) and AV, performed after bacterioscopy using Gram staining.

Methods: Methods:A total of 140 results from Gram-stained bacterioscopies and RT-qPCR molecular panels were analyzed. Of these, 54 patients, after Gram evaluation, presented leukocytes, LBG, and background microbiota assessment, and their EVMBP results were further analyzed.

Results: Results:In the Gram-stained evaluations, all 54 patients showed >30 leukocytes per field (x1000). According to LBG assessment, 32 (59.3%) presented Nugent scores of 4–6, classified as intermediate vaginal microbiota (VBM), and 22 (40.7%) showed Nugent scores of 7–10, suggestive of BV. For background microbiota evaluation, classification followed the validated criteria of Dong et al. (2023), modified from Donders (2002): 32 (59.3%) were classified as IIb and 22 (40.7%) as III.The EVMBP analysis revealed 15 (27.2%) with AV, 34 (62.9%) with mixed vaginitis (AV + BV), 4 (7.4%) with BV, and 1 (1.9%) with normal microbiota (L. crispatus and L. gasseri).

Conclusions: Conclusion:Gram staining results were able to identify AV; however, the EVMBP results were more reliable for the identification of AV and could accurately detect the presence of mixed vaginitis (AV + BV), enabling a more precise laboratory diagnosis and targeted treatment for patients.
Key-words: Aerobic vaginitis, mixed vaginitis, molecular panel, GRAM stain, leukocytes

References:

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#13260

P34-02 | The current application status of photodynamic therapy for cervical HSIL in China

34 - Conventional therapies

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Background/Objectives: The World Health Organization's global strategy to eliminate cervical cancer highlights the critical need for effective precancerous lesion management. PDT is a targeted therapy technology that utilizes the synergistic interaction among photosensifiers, light sources of specific wavelengths, and oxygen molecules in tissues to treat HSIL of the cervix. It does not cause the risks of cervical insufficiency, miscarriage, or premature birth, and is suitable for young patients who wish to preserve their fertility or refuse surgery.

Methods: Indications for PDT: complete visibility of the cervical TZ under colposcopy, the upper edge of the lesion does not exceed the visible range. Contraindications: AIS or invasive carcinoma. There are three types of PDT used in China: ①ALA-PDT is used to treat CIN2 and strictly selected CIN3, VaIN, AIN and GW. The interval between each treatment is 7 to 14 days, and 2 to 3 courses of treatment (a total of 6 to 9 times) need to be completed. ②HpD-PDT is used for CIN2/3. Patients must strictly avoid light for 1 to 2 months following treatment. ③HAL-PDT is an automated device containing HAL and a built-in cold light source. During treatment, the doctor inserts the instrument into the vagina with the tip directed at the cervical surface. And removes it after 11-24 h of placement.

Results: Clinical research in China shows that: ① The overall histological response rate of ALA-PDT for CIN2 patients after treatment was over 90%, the complete remission (CR) was 77.8% - 91%, and the recurrence rate within 1-3 years of follow-up was 3.7% - 13.9%②HpD-PDT: In a small-sample study in China, the CR of CIN2 and CIN3 lesions after 12-month follow-up were 100% and 87.2%, respectively. ③ HAL-PDT: An international multicenter, randomized, double-blind, placebo-controlled Phase IIb study conducted in China found that CIN2 patients had a complete remission rate of 95%, with an 83% clearance rate for high-risk HPV16/18. The Phase III results showed a histological regression rate of 47.0% at 6 months, compared to 29.5% in the placebo group ($p < 0.001$).

Conclusions: PDT is a new treatment method for cervical lesions. The characteristics of PDT are that it does not damage the structure of the cervix, does not cause cervical stenosis, and does not lead to miscarriage or premature birth. It is suitable for patients who wish to preserve their fertility or refuse surgery. The results are safe and effective with few side effects. The three photodynamic therapy methods each have their own characteristics, but more prospective large-sample studies are still needed to better guide clinical practice.

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#13275

P10-01 | Patient acceptability of CITOBOT for cervical cancer screening: A mixed-method study

10 - HPV screening

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Background/Objectives: Cervical cancer prevention efforts face major challenges in Colombia related to accessibility, timely diagnosis, and patient discomfort during screening. CITOBOT is a portable, AI-supported device designed for early cervical cancer detection that aims to make screening more efficient, accessible, and comfortable.The objective of this study was to evaluate patient acceptability of CITOBOT in a real-world pilot test as part of a translational research project to refine and prepare the device for clinical adoption.

Methods: This study employed a **mixed-method design** grounded in the **Theoretical Framework of Acceptability (TFA v2)** proposed by Sekhon et al., which supports the evaluation of complex health interventions. The approach integrated both quantitative and qualitative methods to comprehensively assess women's perceptions of the CITOBOT device during its pilot testing phase. Twenty women aged 21–59 were consecutively recruited from a specialized cancer healthcare center in Cali, Colombia, between February and April 2024. Recruitment was conducted via email, social media, and in-person announcements. Inclusion criteria required participants to have a cervix and a history of cytological screening. Selection ensured diversity in reproductive and hormonal conditions (e.g., nulliparous, multiparous, menopausal). Exclusion criteria included pregnancy, menstruation, recent vaginal procedures, allergies, or any condition that could interfere with participation. All procedures were performed by a gynecologist trained with a simulated model. Participants attended a follow-up appointment seven days after the test, where no adverse events were reported.

Results: Quantitative results showed that 75% of participants reported high acceptability of CITOBOT and 25% moderate acceptability, with none reporting low acceptability. Most participants (90%) felt safe during the test, 60% experienced no discomfort, and 55% preferred CITOBOT over the traditional speculum.
Qualitative findings revealed that, retrospectively, participants felt comfortable using the device, perceived it as coherent with its preventive purpose, and did not consider the procedure burdensome compared to conventional cytology. Prospectively, all participants expressed willingness to attend screening if CITOBOT were implemented and stated they would recommend it to others, highlighting its advantages such as faster results, earlier diagnosis, and improved accessibility for underserved women. No adverse effects were reported during the seven-day follow-up period.

Conclusions: In conclusion, this study offers promising evidence of patient acceptability of CITOBOT for cervical cancer screening, aligning with the growing emphasis on patient-centered care and the recognition that acceptability is a critical determinant of intervention effectiveness. By addressing concerns related to discomfort, burden, and timely delivery of results, CITOBOT can potentially improve cervical cancer screening uptake and adherence, particularly among underserved populations. However, continued research and stakeholder engagement is necessary to successfully translate and implement this innovative technology into real-world settings.

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Citobot Portable Device Prototype

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#13316

P03-05 | Long-term risk of gynecologic cancers following HPV testing with Hybrid Capture 2 among women unscreened for over six years: a nationwide cohort study in Taiwan

03 - Epidemiology and natural history

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Background/Objectives: The long-term predictive value of high-risk HPV testing for gynecologic cancers remains insufficiently characterized, particularly among underscreened women. This study evaluated the subsequent of risk of gynecologic cancers following HPV testing with Hybrid Capture 2 (HC2) among women who had not participated in cervical screening for more than six years.

Methods: Between 2010 and 2013, 132,343 women without cervical screening records for at least six years were invited to undergo HPV testing with HC2 using either self-collected or clinician-collected samples. Incident gynecologic cancers, including invasive cervical cancer, carcinoma in situ, endometrial cancer, and ovarian cancer were identified through computerized linkage with the population-based Taiwan National Cancer Registry and followed until December 31, 2023. Cox proportional hazards regression was applied to estimate hazard ratios (HRs) and 95% confidence intervals (CIs) for cancer outcomes according to HPV status. This work was funded by the Health Promotion Administration, Ministry of Health and Welfare (HPA, MOHW). (No. A1131116). The content of this research may not represent the opinion of the HPA, MOHW.

Results: Among 132,343 women tested, HPV positive rate **was 8.1% (n = 10,684). Participants contributed 1,554,973 person-years of follow-up (mean 11.7 years). During the study period, 1,558 gynecologic cancers were identified, including 660 cervical cancers (371 carcinoma in situ and 289 invasive). Compared with HPV-negative women, HPV-positive individuals had significantly higher risks of gynecologic cancers overall (HR = 4.27; 95% CI 3.82–4.78), cervical cancer (HR = 13.62; 95% CI 11.69–15.87), carcinoma in situ (HR = 13.46; 95% CI 10.97–16.50), and invasive cervical cancer (HR = 13.83; 95% CI 10.98–17.43).**

Conclusions: Long-term follow-up demonstrated that HPV testing using HC2 provides strong predictive power for future cervical cancer risk among previously underscreened women. The substantially elevated risk among HPV-positive individuals highlights the importance of integrating HPV-based screening and self-sampling into national prevention programs, together with expanded HPV vaccination coverage, to reduce the population burden of cervical cancer.

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#13323

P15-03 | Association of iron metabolism genetic variants in HFE and TMPRSS6 genes and HPV infection in lung cancer risk

15 - Molecular markers

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Background/Objectives: Iron metabolism plays a crucial role in oxidative stress and carcinogenesis. Hepcidin, the key hormone regulating systemic iron homeostasis, controls intestinal iron absorption and macrophage iron release through degradation of the iron exporter ferroportin. Dysregulation of hepcidin expression can lead to iron overload, promoting the generation of reactive oxygen species and DNA damage that contribute to malignant transformation. Variants in genes involved in the hepcidin regulatory pathway and iron homeostasis, such as HFE and TMPRSS6, may therefore influence cancer susceptibility. This study aimed to evaluate the association between these variants, HPV infection, and lung cancer risk.

Methods: Two polymorphisms were analyzed: HFE (H63D; rs1799945) and TMPRSS6 (rs855791). Genotypic distributions were compared between control and lung cancer populations under different genetic models, adjusted for age and sex. Epistatic interactions between both genes and associations with HPV infection were also assessed.

Results: Under the dominant model, the HFE variant showed a significant association with lung cancer after adjustment ($p = 0.033$). Although the TMPRSS6 variant alone did not reach statistical significance, the combined presence of alleles promoting higher iron levels (HFE-G and TMPRSS6-G) was significantly enriched in cancer cases (adjusted $p = 0.003$), suggesting a synergistic effect. HPV infection alone did not appear to increase cancer risk; however, in the cancer population, the recessive model indicated a specific association between the HFE variant and HPV positivity (adjusted $p = 0.012$).

Conclusions: These preliminary findings suggest that genetic variants regulating iron metabolism, particularly in HFE, may contribute to lung cancer susceptibility and interact with HPV infection. The observed gene–gene and gene–virus interactions support a role for iron-induced oxidative stress in lung carcinogenesis. Further analyses with larger cohorts are warranted to validate these associations.

References:

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#13331

P25-03 | Effectiveness Of A Coriolus Versicolor-Based Vaginal Gel On Cervical Re-Epithelialization, Bleeding And Hr-Hpv Clearance After Excisional Treatment: Preliminary Results

25 - Cervical neoplasia

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Background/Objectives: Excisional treatment for cervical intraepithelial neoplasia (CIN) is associated with postoperative complications such as bleeding and delayed mucosal healing. Moreover, persistence of high-risk HPV (HR-HPV) after excision, particularly in women with involved surgical margins, remains a clinical challenge. In such situations, close follow-up at 3 months is required. These risks are more pronounced in women aged ≥50 years. This study evaluated the effectiveness of a Coriolus versicolor-based vaginal gel in enhancing cervical re-epithelialization, reducing bleeding, and promoting HR-HPV clearance in real-world clinical practice.

Methods: This was an observational, prospective, single-center, controlled study in women ≥18 years with CIN who meet the criteria for excisional treatment. Patients were assigned according to clinical practice: A) treated with a *Coriolus versicolor*-based vaginal gel, B) untreated controls. The gel was applied perioperatively, then once daily for 3 months. Follow-up visits were scheduled at day 21, month 3 (affected margins) or 6 (clear margins). On day 21 post-procedure, cervical re-epithelialization was assessed by colposcopy and rated using a 4-point Likert scale based on the percentage of re-epithelialized surgical bed: score 4 (75–100%), 3 (50–75%), 2 (25–50%), and 1 (less than 25%). Postoperative bleeding was evaluated using a similar Likert scale: 4 (no bleeding), 3 (less than menstruation), 2 (equivalent to menstruation), 1 (more than menstruation). HR-HPV testing (COBAS) was performed at baseline and follow-up (6 months). Viral clearance was defined as a negative test or loss of more than 1 baseline genotypes. Statistical analysis used Chi-square or Fisher's exact test. Ethical approval and informed consent were obtained. Preliminary results show the proportion of patients scoring 3 and 4, and HR-HPV clearance in margin-positive patients.

Results: A total of 66 women were included (treated=35; control=31). Mean age was 42.4 years; 48.5% were smokers, 90.9% had received HPV vaccination (25% before lesion onset), and HPV16 was the most prevalent genotype (50.0%). Histopathology revealed CIN2+ in 83.3%, and 13.6% had type 3 excision. Baseline characteristics were homogeneous across groups. Re-epithelialization was observed in 88.6% of treated vs 74.2% controls (p=0.20). Minimal/no bleeding was reported by 80.0% vs 58.1% (p=0.065). Among margin-positive patients (treated=15; control=8), HR-HPV clearance at 3 months was significantly higher in the treatment group (80.0% vs 25.0%, p=0.0228). Within this subgroup, women aged ≥50 years (treated=4; control=5), showed clearance rates of 75.0% vs 0%, respectively (p=0.0476).

Conclusions: The *Coriolus versicolor*-based vaginal gel showed favorable trends towards better reepithelialization and mild or no bleeding after excisional treatment. In addition, it significantly enhanced HR-HPV clearance in margin-affected patients, including those over 50 years. These findings highlight its potential to accelerate postoperative recovery and reduce the risk of viral persistence, supporting its role as a complementary strategy to optimize outcomes after excisional treatment of CIN.

References:

Vich Gina
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#13336

P25-04 | Efficacy Of A Multi-Ingredient Coriolus Versicolor-Based Vaginal Gel In Hr-Hpv Clearance: Final Pooled Results From The PALOMA 1 And PALOMA 2 Clinical Trials.

25 - Cervical neoplasia

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Background/Objectives: Following PALOMA 1's demonstration of Coriolus versicolor-based vaginal gel efficacy in HPV-dependent low-grade cervical lesions, PALOMA 2 incorporated HR-HPV clearance as a secondary endpoint. We present the pooled results on HR-HPV clearance at 6 months from both trials.

Methods: Randomised, multi-centre, prospective, open-label, parallel-group, watchful waiting-controlled clinical trial. Unvaccinated HR-HPV positive women aged between 30 to 65 years, with Atypical Squamous Cells of Undetermined Significance (ASCUS) or low-grade squamous intraepithelial lesions (LSIL) cytology and concordant colposcopy were randomised (1:1:1) into: 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. This analysis presents pooled results on HR-HPV clearance at six months for the intensive regimen versus control group. HPV clearance was considered as total (negative HPV test or the disappearance of all species detected at baseline) or partial clearance (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 centralized IRBs.

Results: Data from 101 patients were analyzed: 48 in the treatment group (PALOMA 1, n=22; PALOMA 2, n=26) and 53 in the control group (PALOMA 1, n=25; PALOMA 2, n=28). A significantly higher rate of HR-HPV clearance was observed in the treatment group compared with controls (85.4% vs 47.2%; $p<0.0001$; RR=1.81). In the subgroup of patients positive for HPV 16, 18, and/or 31 at baseline, clearance rates were also significantly higher in the treatment group (82.6% vs 37.0%; $p=0.0011$; RR=2.23).

Conclusions: These findings suggest that the intensive regimen 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.

References:

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#13344

P39-05 | "Those who tested positive should be the ones sensitizing others": Socio-Ecological Factors of Loss to Follow-Up among HPV-Positive women in a Door-to-Door HPV self-sampling screening Program in Cameroon

39 - Public health

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Background/Objectives: The Cervical Cancer Screening At Home (CASAHO) trial was designed to assess whether home-based HPV self-sampling could improve cervical cancer (CC) screening uptake in Dschang, Cameroon. The intervention led to an 80% increase in screening coverage among the target population. However, it was accompanied by a substantial loss to follow-up (LTFU), with 41% of HPV-positive women failing to attend further diagnostic care, potentially undermining program effectiveness. This study explored the barriers and facilitators to follow-up care among HPV-positive women and to generate public health recommendations.

Methods: A qualitative study was conducted in the Dschang Health District between June–August 2024 and July 2025. LTFU was defined as non-attendance at the scheduled Visual Inspection with acetic Acid/Visual Inspection with Lugol's Iodine (VIA/VILI) appointment three weeks after receiving three weekly reminder calls. Data were collected through individual interviews with 10 HPV-positive women, 10 male partners, and 9 community leaders, as well as two focus group discussions involving 8 healthcare professionals (HCPs) and 9 community health workers (CHWs) engaged in home-HPV self-sampling screening. Transcripts were coded and analyzed using Atlas.ti software. Barriers and facilitators were categorized according to the Socio-Ecological Model (SEM), encompassing individual, interpersonal, community, organizational, and policy levels.

Results: Barriers were identified at all SEM levels: lack of time and fear of diagnosis (individual), partner influence (interpersonal), stigma and misconceptions (community), poor result communication and distance (organizational), and limited infrastructure and policy integration (policy). Facilitators included contextualized health education, partner involvement, community leader engagement, HPV-positive women as ambassadors, and decentralized screening and treatment services.

Conclusions: LTFU among HPV-positive women in Cameroon is influenced by multiple SEM levels. Enhancing health literacy, engaging men, involving HPV-positive women as role models, and improving service delivery and policy integration are critical. Multi-level strategies are essential to reduce LTFU and strengthen cervical cancer prevention in low-resource settings.

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McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. Health Educ Q. 1988;15(4):351-77.

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#13358

P34-03 | Breaking Down the Barrier: Enzymatic Strategy to Overcome Biofilm-Mediated Resistance in Urogenital Infections

34 - Conventional therapies

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Background/Objectives: Biofilm-associated infections represent a paramount challenge in modern medicine, leading to resistance, chronicity and high treatment failure rates. In the urogenital tract this challenge is particularly critical, as, for example, bacterial vaginosis—a condition characterized by polymicrobial biofilms—significantly increases the risk of acquiring sexually transmitted infections, including HIV, gonorrhea, and chlamydia. The extracellular matrix of biofilms, composed of polysaccharides, proteins, and DNA, forms a formidable barrier that protects embedded microorganisms from antibiotics and the host immune system. This study aimed to investigate the efficacy of an enzymatic strategy using bovhyaluronidase azoximer to disrupt these biofilms and potentiate conventional antimicrobial therapy.

Methods: The anti-biofilm activity was assessed in vitro against mature 48-hour biofilms of clinically relevant urogenital pathogens, including Staphylococcus aureus, Escherichia coli, Enterococcus faecalis, Pseudomonas aeruginosa, and Klebsiella pneumoniae. Biofilms were treated with bovhyaluronidase azoximer (Longidaza®) at concentrations ranging from 1,25 to 3000 IU/mL. The amount of extracellular matrix of biofilms and its integrity was quantified using crystal violet staining and Congo Red depletion assays. Structural changes were visualized via scanning electron microscopy. The synergistic effect with antibiotics (ciprofloxacin, cefuroxime, amoxicillin) was evaluated by assessing the viability of biofilm-embedded cells using MTT-assay, CFU counting, and confocal laser scanning microscopy.

Results: Treatment with bovhyaluronidase azoximer (750-1500 IU/mL) demonstrated potent efficacy against bacterial biofilms, causing a significant reduction in biomass: 50% for E. faecalis and E. coli, and 60% for S. aureus after just 2 hours of treatment. The enzyme effectively hydrolyzed biofilm matrix components, particularly β-polysaccharides, with SEM confirming visible structural disintegration and pore formation in biofilms of E. faecalis, E. coli, and P. aeruginosa. Crucially, the enzyme itself was not bactericidal but significantly enhanced antibiotic efficacy. When combined with ciprofloxacin or amoxicillin, it reduced the bactericidal concentration required against E. faecalis biofilms by 16-fold. Similarly, a 4-fold lower concentration of cefuroxime was sufficient to achieve a bactericidal effect on S. aureus biofilm-embedded cells.

Conclusions: Enzymatic disruption of the biofilm matrix with bovhyaluronidase azoximer presents a highly promising strategy to overcome antimicrobial resistance in urogenital infections. By breaking down the physical barrier, it facilitates the penetration of antibiotics to their targets, thereby restoring their efficacy and allowing for a substantial reduction in therapeutic doses. This adjuvant approach could significantly improve clinical outcomes for chronic, biofilm-associated infections, including bacterial vaginosis and its complications.

References:

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#13438

P12-01 | Between Molecules and Microscopes: Lessons from Romanian Cervical Screening in the Age of Precision Diagnostics

12 - Triage of HPV positive women

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Background/Objectives: As molecular assays and methylation profiling redefine cervical cancer screening, countries with limited resources continue to rely on pragmatic, accessible diagnostic tools. Romania, where cervical cancer remains the third most frequent malignancy in women and second in those under 45, exemplifies this diagnostic crossroad. This study integrates HPV genotyping and p16/Ki-67 dual stain cytology to reassess diagnostic efficiency, identify genotype–morphology correlations, and evaluate the real-world balance between innovation and feasibility.

Methods: A total of 276 cervical smear cases (women aged 25–64) were analyzed using conventional cytology, p16/Ki-67 dual staining, and HPV genotyping. Cytologic and histologic findings were classified according to the Bethesda and WHO criteria. 53 cases had corresponding biopsies. Dual staining was applied to refine the interpretation of equivocal results and to stratify patients by risk category.

Results: Of the 276 cases, 119 (43.1%) were NILM, 52 (18.8%) ASC-US, 26 (9.4%) ASC-H, 36 (13.0%) LSIL, 39 (14.1%) HSIL, and 4 (1.4%) SCC. High-risk HPV-DNA was detected in 146 (52.9%) cases, while p16/Ki-67 dual stain cytology was positive in 122 cases. Positivity rates by category were: 9.2% in NILM, 46.2% in ASC-US, 96.1% in ASC-H, 52.8% in LSIL, and 100% in HSIL and SCC. HPV16 was the predominant genotype, strongly associated with HSIL and SCC, followed by HPV18 and HPV45 in glandular lesions. Multiple HPV infections were more common in lower-grade lesions, decreasing with progression severity.

Conclusions: While p16/Ki-67 dual staining and HPV genotyping substantially enhance diagnostic precision and risk stratification, the Romanian experience highlights a critical reality: basic, affordable screening methods remain indispensable for broad population coverage. High-cost molecular assays, including methylation-based tests, are promising but not yet scalable for nationwide implementation. Combining morphology, immunocytochemistry, and genotyping offers a cost-effective, evidence-based pathway toward equitable cervical cancer prevention—reminding us that innovation must be inclusive to be impactful.

References:

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#13444

P05-01 | Spatial Immune Architecture Predicts Treatment Outcomes in HPV-Positive Oropharyngeal Cancer

05 - Immunology

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Background/Objectives: Background: The incidence of Human Papillomavirus (HPV)-associated oropharyngeal cancer (OPC) has been increasing in recent years. While patients with HPV-positive OPC generally demonstrate more favorable outcomes compared to those with HPV-negative disease, a subset still experiences locoregional recurrence and distant metastasis. These clinical challenges underscore the need for a better understanding of the tumor microenvironment (TME) and its role in modulating treatment response. We hypothesized that the composition and spatial dynamics of the TME differ between complete responders and partial/non-responders, and these differences may serve as predictive biomarkers.

Methods: Methods: This retrospective study included patients with p16-positive OPC treated at two major cancer centers in Montreal between 2010 and 2023. Formalin-Fixed Paraffin-Embedded (FFPE) tissue blocks were retrieved, and tissue microarrays (TMAs) were constructed for high-dimensional immune profiling using imaging mass cytometry (IMC). Immune cell populations were analyzed across treatment response categories (complete vs. partial responders) and treatment stages (pre- vs. post-treatment). Deep learning–based cell segmentation was applied to quantify immune cell subsets, assess spatial architecture, and perform network and neighborhood analyses of the TME to identify potential predictive and prognostic immune signatures.

Results: Results: Tissue specimens were obtained from HPV-positive (p16+) OPC patients, of whom 79.6% were male, with a mean age of 62.5 years. IMC revealed distinct immune landscapes between response groups. In complete responders, treatment induced a robust recruitment of anti-tumor immune cells (e.g., CD8+ T cells and B cells), suggesting an activated immune phenotype post-treatment. In contrast, non-responders exhibited enrichment of immunosuppressive or tumor-promoting cell types following therapy. Spatial co-localization and cell–cell interaction analyses further indicated that B and T cells interactions may contribute to therapeutic success.

Conclusions: Conclusion and Impact: This study provides novel insights into the spatial and cellular remodeling of the immune microenvironment in HPV-positive OPC before and after treatment. Our findings highlight the prognostic potential of IMC-based immune profiling and support the development of predictive biomarkers to guide the selection of patients who may benefit from neoadjuvant chemotherapy or immunomodulatory interventions.

References:

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#13446

P11-02 | Acceptability of urine self-collection for (human papillomavirus) HPV testing among U.S. low-income women

11 - Screening for women difficult to reach

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Background/Objectives: Guideline-based cervical cancer (CC) screening significantly reduces mortality; however, low-income women in the U.S. experience nearly double the mortality rate of CC compared to high-income women. This disparity emphasizes the need for innovative approaches to reduce inequities to allow progress in the elimination of CC. Urine based screening for human papillomavirus (HPV) testing could provide an alternative screening method to women with barriers to conventional CC screening. The current study aimed to (1) evaluate the hypothetical acceptability of CC screening using mailed urine self-collection kits for HPV testing, and (2) identify sociodemographic and psychosocial factors associated with acceptability.

Methods: This U.S. national cross-sectional study included 909 low-income women, defined as having an annual household income less than $50,000, who were recruited from a survey research company, Dynata. Participants were provided written instructions describing urine self-collection for HPV testing and asked: “If self-sampling for HPV testing by a home urine sample were available today, and a kit was mailed to you, how willing would you be to complete and mail back the test?” Responses were dichotomized as “willing” or “not willing.”

Results: The mean age of the participants was 55 years. Overall, 61% of women found urine self-collection acceptable. Variables significant from bivariate analyses, including marital status, provider suggestion of a Papanicolaou (Pap) or HPV test (yes/no), history of an abnormal Pap or HPV result, and health behavior constructs such as perceived barriers and benefits to CC screening, trust in new technologies, perceived importance of CC screening, and HPV knowledge, were entered into a multivariable logistic regression (MLR) model. In the MLR, women who were married (OR=1.58;95%CI= 1.17, 2.13); trusted in new technologies (OR=1.2;95%CI=1.01,1.4); and had higher scores on benefits (OR=1.09;95%CI=1.03,1.16) and HPV knowledge (OR=1.06,95%CI=1.03,1.10) indicated a greater odds in willingness to complete a urine self-collection kit.

Conclusions: This is one of the first U.S. studies to examine hypothetical acceptability of urine collection as a CC screening method. Our findings indicated over half of women found urine self-collection acceptable. Acceptability was positively associated with being married, trusting new technologies, perceived benefits, and HPV knowledge, which could inform implementation if urine collection is approved as a CC screening method in the U.S. A study limitation is that women were asked to imagine a hypothetical scenario rather than complete a urine self-collection kit and may have overstated their willingness to use urine self-collection. Future research should include acceptability and completion of a urine self-collection kit in real-world settings.

References:

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#13447

P04-01 | Hypervirulence through the identification of the genes blaCTX-M-15 and blaNDM in ESBL-producing Klebsiella pneumoniae isolates at the institute of infectious diseases in Libreville

04 - Pathogenesis

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Background/Objectives: Urinary tract infections (UTIs) are the second most common type of infection worldwide after respiratory infections, affecting millions of people each year, of whom 50 % to 60 % are women. Over the past three decades, their incidence has continued to rise, particularly in low- and middle-income countries. In 2021, there were approximately 287,200 deaths associated with antimicrobial resistance (AMR), of which 67,467 were directly attributable to UTIs, placing UTIs fourth globally among causes of AMR-related deaths. Escherichia coli and Klebsiella pneumoniae, two opportunistic Enterobacteriaceae with multiple virulence factors, are the main agents responsible for UTIs and the surge in AMR, notably to cephalosporins, fluoroquinolones and carbapenems. This AMR leads to treatment failures, prolonged hospitalisation and increased healthcare costs. In Africa, several studies have reported the emergence of multidrug-resistant carbapenemase-producing K. pneumoniae strains. In Gabon, very few studies have addressed this phenomenon. This study aimed to characterise the virulence and antimicrobial resistance profiles of urinary K. pneumoniae isolates, and to propose a simplified, cost-effective surveillance model for enhancing the control of AMR.

Methods: We conducted a six-month prospective study in Libreville, Gabon, analysing urine specimens positive on cytobacteriological examination (CBEU). Isolates were identified using morphological, biochemical and cultural methods (API 20E system, BioMérieux). Antimicrobial susceptibility testing was performed with a panel of 14 antibiotics, and results were interpreted in accordance with the 2024 recommendations of the CA-SFM.

Results: A total of 89 patients with positive CBEU were included. The cohort comprised a majority of female subjects (54.3 %) and individuals aged 60 years or older (34.3 %). The most common clinical presentation was urinary (micturition) syndrome (44.3 %). Among the isolates, 45 % were *K. pneumoniae* producing extended-spectrum β-lactamases (ESBLs). Of these ESBL strains: 100 % exhibited full resistance to aminopenicillins; 83.15 % demonstrated high-level resistance to aminopenicillin + inhibitor combinations (amoxicillin/clavulanate); and 54 % were resistant to third-generation cephalosporins. Resistance to carbapenems remained low (1.75 %). The majority of the isolates carried the **blaCTX-M-15** gene; two of them were co-carriers of the **blaNDM** gene and displayed hypervirulence traits.

Conclusions: These findings reveal the dissemination of high-risk clones and the alarming advancement of multidrug resistance in *K. pneumoniae* in Gabon. They underscore the urgent need to establish national-level microbiological surveillance and to implement rational therapeutic strategies aimed at limiting the spread of multidrug-resistant Enterobacteriaceae.

References:

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#13457

P39-06 | Microbiological Profile Of Symptomatic Vaginal Discharge At The Institute Of Infectious Diseases Professor Daniel Gahouma In Libreville, Gabon.

39 - Public health

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Background/Objectives: Background: Symptomatic vaginal discharge represents a major public health problem among women of reproductive age, accounting for between 5 and 10 million medical consultations worldwide each year. Although often trivialized, these conditions are associated with significant morbidity, including pelvic inflammatory disease, infertility, endometriosis, miscarriages, preterm deliveries, and an increased susceptibility to sexually transmitted infections, particularly HIV. With 62.8 % of vaginal discharge cases occurring among women of reproductive age, the issue remains a major concern in Gabon.Objectives: The aim of this study was to characterise the microbiological profile of symptomatic vaginal discharge in Libreville, Gabon.

Methods: Methods: A five-month prospective, descriptive study was conducted at the Microbiology Unit of the Professor Daniel Gahouma Institute of Infectious Diseases in Gabon. Women of reproductive age were included. Vaginal samples were subjected to microscopic examination (wet mount, Gram stain, and Nugent scoring), culture on selective media, biochemical identification, and antimicrobial susceptibility testing (API BioMérieux system). Urogenital mycoplasmas (*Ureaplasma urealyticum* and *Mycoplasma hominis*) were detected and tested using the Mycoplasma IST2 kit.

Results: Results: A total of 73 samples were analysed; 50 (68.49 %) tested positive, indicating a high rate of infection or colonisation. From these, 97 isolates were identified. Mycoplasmas predominated (38.11 %), followed by *Candida* spp. (20.62 %), *Gardnerella vaginalis* and other agents of bacterial vaginosis (15.46 %). Severe dysbiosis (type IV vaginal flora) was present in 59.2 % of infected cases. High levels of multidrug resistance were observed in *Staphylococcus aureus* and *Escherichia coli* for β-lactams (75 %–100 %), suggesting the presence of MRSA and ESBL-producing strains. Fluoroquinolone resistance was also elevated in *E. coli*, while tetracyclines remained partially effective against mycoplasmas. Azole antifungals retained good activity (resistance rates 8 %–20 %).

Conclusions: Conclusion: These findings highlight the urgent need for rational antibiotic use and for systematic antibiotic susceptibility testing to guide treatment. They enrich our understanding of the microbiological landscape of symptomatic vaginal discharge in Africa and support development of context-appropriate therapeutic and preventive strategies in resource-limited settings.

References:

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#13458

P09-06 | Impact of low HPV vaccination coverage on infection rates and cytological findings in women in Bulgaria

09 - HPV testing

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Background/Objectives: Human papillomavirus (HPV) is the most common sexually transmitted infection worldwide. Literature estimates that over 80% of sexually active women and men will be infected at least once during their lifetime. Recent evidence also highlights infection in childhood and adolescence. Despite limited studies on these age groups, the high virulence of HPV makes it clinically and socially significant. Primary prevention, particularly vaccination, is crucial. In Bulgaria, vaccination coverage is low, contributing to rapid viral spread. According to the Ministry of Health, coverage rates dropped sharply after 2015, ranging between 7% and 9% from 2018 to 2023.

Methods: A retrospective study was conducted between January 2024 and January 2025, including 143 women examined at “Hinkomed” Medical Center, Pleven. Data were analyzed using MS Excel 2019 and SPSS Statistics v.28 (IBM Corp., Armonk, NY).

Results: Patients participating in the study ranged in age from 15 to over 58 years. Women aged 15–27 years comprised 35.0% (n=50), and the highest proportion was in the 34–39 age group (20.3%). All participants with atypical colposcopic findings underwent high-risk HPV DNA testing. Thirty-six women (25.2%) tested positive, with the highest proportion among women aged 18–27 years (22.2% of positives). No statistically significant correlation was observed between HPV positivity and age (χ^2=5.531, df=8, p>0.05, Cramer’s V=0.197). Cytology results were compared with HPV status. No cases were interpreted as carcinoma in situ (CIS); the majority of HPV-positive women were NILM (61.1%), followed by LSIL (25.0%). A significant association was found between Bethesda-classified cytology and HPV positivity (χ^2=14.382, df=3, p=0.002, Cramer’s V=0.337), as well as with PAP results (χ^2=11.794, df=3, p=0.008, Cramer’s V=0.305).

Conclusions: Low vaccination coverage increases the risk of HPV infection and rapid viral spread. Abnormal cytological results do not always indicate the absence of pathology. Properly structured screening—including cytology, colposcopy, and HPV testing—is essential, particularly for women of reproductive age.

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#13460

P18-03 | Interactions between human papillomavirus infection and vaginal microbiota imbalance: The role of bacterial vaginosis in cervical dysplasia

18 - Microbiome

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Background/Objectives: The vaginal microbiota plays a crucial role in maintaining cervical epithelial integrity [1, 2]. Bacterial vaginosis (BV), characterized by the depletion of protective Lactobacillus species and overgrowth of anaerobic bacteria, may enhance susceptibility to and persistence of human papillomavirus (HPV) infection [3]. The coexistence of BV and multiple HPV genotypes could potentiate cervical intraepithelial neoplasia (CIN) development [4, 5].

Methods: This observational study was conducted between October 2024 and October 2025 at the University Hospital “St. Marina,” Pleven, Bulgaria. A total of 56 women with confirmed HPV infection were evaluated. BV was diagnosed using Amsel criteria and Nugent scoring. HPV genotyping was performed by PCR-based assays. All participants underwent cytological examination, followed by colposcopy and biopsy when indicated. Descriptive statistical analysis was used to assess the relationship between BV, HPV genotype multiplicity, and cervical abnormalities.

Results: BV was detected in 42 of 56 HPV-positive women (75.0%). Among these, 30 patients (71.4%) had concurrent BV and HPV infection. Of this subgroup, 19 (63.3%) harbored a single HPV genotype, and 11 (36.7%) were infected with multiple HPV genotypes.
In the group with BV and multiple HPV infections, cytological abnormalities (ASC-US) were found in 10 of 11 women (90.9%), and 9 of them (81.8%) had biopsy-confirmed CIN (grades I–III).
In the group with BV and a single HPV genotype (n=19), cytological abnormalities (ASC-US) were identified in 7 women (36.8%), and 2 (10.5%) were confirmed with CIN on biopsy.
Overall, the prevalence and severity of cervical dysplasia were higher in women with BV and multiple HPV infections compared to those with BV and single HPV infection.

Conclusions: In this cohort, BV was highly prevalent among HPV-positive women and was strongly associated with both multiple HPV infections and higher-grade cervical dysplasia. These findings underscore the potential synergistic role of vaginal dysbiosis and multiple HPV infections in promoting cervical neoplastic transformation, emphasizing the importance of microbiome balance in preventive gynecologic care.

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#13464

P06-03 | It's not too late to get vaccinated against HPV - the benefits of vaccinating HPV-positive population and patients with cervical intraepithelial neoplasia

06 - HPV prophylactic vaccines

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Background/Objectives: Human papillomavirus (HPV) infection remains the most prevalent sexually transmitted viral infection worldwide and a major etiologic factor for cervical and other anogenital cancers. Despite the implementation of organized screening and vaccination programs that have reduced cervical cancer incidence and mortality in high-income countries, HPV-related precancerous lesions continue to represent a substantial clinical and epidemiological burden.This prospective, non-randomized study aimed to assess the effect of nine-valent HPV vaccination on viral clearance, genotype distribution, and lesion regression among HPV-positive women unvaccinated in childhood.

Methods: Between January 2020 and August 2025, 461 women presenting with abnormal cytology, positive high-risk HPV tests, or abnormal colposcopic findings were enrolled at a private gynecologic practice in Poland. Participants underwent liquid-based cytology, HPV genotyping, colposcopy, and biopsy or loop electrosurgical excision procedure (LEEP) when indicated. The vaccinated cohort (n = 351) received the Gardasil®9 series (0–2–6 months), while 110 women served as unvaccinated controls. Statistical analyses were performed using *R* software (v4.4.2) with a significance threshold of $\alpha = 0.05$.

Results: Following vaccination, HPV positivity for any genotype was significantly lower in the vaccinated group than in controls (29.3% vs 56.4%, $p < 0.001$). Clearance of Gardasil-specific genotypes occurred in 83.5% of vaccinated women compared with 63.6% in the control group. Complete remission was observed in 70.7% versus 43.6% of participants, respectively. Persistence of identical HPV genotypes was markedly reduced after vaccination (8.5% vs 27.3%). No significant association was identified between patient age and HPV clearance.

Conclusions: Nine-valent HPV vaccination significantly enhanced viral clearance and reduced persistence and recurrence of high-grade squamous intraepithelial lesions (HSIL) among previously unvaccinated HPV-positive women. These findings support extending vaccination recommendations to adult HPV-positive patients as an adjunctive strategy to surgical and cytologic management.

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#13465

P13-06 | Cloud-based Cervical Cancer Screening with High Follow-up Rates: A Scalable Self-sampling Approach in Cambodia

13 - Self-sampling

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Background/Objectives: Reliable follow-up is essential for cervical cancer screening, yet it is one of the biggest challenges, especially in low-resource settings. In Cambodia, we implemented a cloud-based digital system to manage community-level HPV self-sampling, laboratory diagnostics, triage, and follow-up, aiming to evaluate its real-world performance and scalability.

Methods: Women were invited to collect their own vaginal sample for high-risk HPV (hrHPV) testing during community outreach campaigns. Each sample was barcoded and entered into a cloud-based platform that connected field teams, labs, and hospitals. hrHPV-positive women were referred for triage at local hospitals, and their follow-up was tracked through the same digital system.

Results: Out of 7,657 women approached, 7,520 (98.2%) enrolled in the study, and 7,466 (99.3%) provided a sample. Valid results were available for 7,376 women. A total of 352 (4.7% - figure 1) tested positive for hrHPV, and 297 of them (84.4% - table 1) attended their follow-up visit. Reasons for missed follow-up included migration (39%), work-related barriers (17%), refusal (22%), and other logistical challenges. The cloud-based system made it possible to manage a large number of participants, real-time data flow, minimize data loss, and ensure that results and follow-up were handled efficiently across multiple sites.

Conclusions: This study shows that a cloud-powered digital system can effectively manage large-scale cervical cancer screening and follow-up, even in low-resource settings. The high follow-up rate among hrHPV-positive women suggests that this model works, not just technically, but also in practice. With its flexibility and scalability, this approach could be a strong foundation for national screening programs.

References:

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#13467

P03-02 | Prevalence of human papillomavirus infection by anatomical sites of the urinary tract among the cases with radical cystectomy for bladder cancer

03 - Epidemiology and natural history

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Background/Objectives: Although the common site of HPV infection in men is the external genitalia (glans penis and penis), our previous studies have demonstrated that HPV detection in urine samples was a certain frequency. In cases with HPV detection in urine samples, it remains unclear where origin of HPV infection is the urinary tract. In this study, we investigated HPV prevalence by the anatomical sites, including urethra, prostate, and urinary bladder among the cases who received robot-assisted laparoscopic radical cystectomy (RARC) for bladder cancer.

Methods: Sixty-one 61 male patients who underwent RARC at our hospital between 2018 and 2024. Paraffin-embedded sections of the specimens obtained by the surgery were divided into the anterior urethra, prostatic urethra, bladder cancer, and non-tumor bladder areas. The presence of HPV-DNA was investigated in each area using nested PCR. For HPV-positive cases, HPV genotyping was performed using flow-through hybridization. HPV-DNA localization was investigated using in situ hybridization (ISH).

Results: HPV-DNA was detected in at least one site in 8 cases (13.1%). HPV-DNA was detected in 10 specimens: 5 in the anterior urethra, 1 in the prostate, 1 in the bladder tumor area, and 3 in the non-tumor bladder area. HPV-DNA was detected in multiple sites in 2 cases (anterior urethra and non-tumor bladder area; bladder tumor area and non-tumor bladder area). ISH analysis demonstrated that HPV-DNA signals could be observed in 3 cases in the urethra, 1 in the prostate, and 2 in the non-tumor bladder area.

Conclusions: Urinary tract HPV infection occurred most frequently in the anterior urethra, but was also found in the prostate and bladder. In addition, HPV infection was detected in bladder cancer lesions. An etiological role in the development of bladder cancer is an important issue to be required to assess in the future.

References:

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#13470

P39-07 | HPV Genotypes in Women Diagnosed with HSIL+ in Northeastern Brazil: Evaluating the Protective Impact of the HPV Vaccine.

39 - Public health

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Background/Objectives: The Brazilian Ministry of Health has implemented the quadrivalent HPV vaccine as a public health policy, particularly for women under the age of 20. This study aimed to evaluate the effectiveness of this primary prevention strategy by identifying HPV genotypes in cases diagnosed with high-grade squamous intraepithelial lesions (HSIL) and squamous cell carcinoma of the cervix.

Methods: A prevalence study was conducted to examine HPV genotypes in cervical samples from 64 women diagnosed with high-grade squamous intraepithelial lesions and squamous cancer (HSIL+). The samples were collected and preserved in a specific medium suitable for liquid cytology. An aliquot of each sample was then used for HPV genotyping using the HPV28 test (Segeene Brasil®, Votorantim, Brazil). Sociodemographic data and test results were recorded to assess the prevalence of genotypes and their associations. The research ethics committee of UniChristus University Center in Fortaleza, Brazil, approved the study.

Results: The ages of the women in the study ranged from 24 to 69 years, with a mean age of 38.4 years (± 10.7). The number of pregnancies experienced by the participants varied from 0 to 4, with a mean of 1.3 pregnancies (± 1.4). In the clinical history, 26 women (40.6%) underwent screening. HPV was not detected in 7 cases (10.9%), and in 48 cases, only one genotype was identified (70%). The most commonly observed genotype was 16, found in 37 women (57.8%), followed by genotype 45 in 7 cases (10.9%), genotype 18 in 6 cases (9.4%), genotype 33 in 5 cases (7.8%), genotype 31 in 4 cases (6.3%), genotype 58 in 3 cases (4.8%), and genotypes 51 and 53 in 2 cases each (3.2%). Additionally, genotypes 33, 43, 66, and 73 were identified in one case each (1.6%). Genotype associations were observed in only 9 cases (14.1%). (Figure 1).

Conclusions: Precancerous and cancerous squamous cell carcinoma of the cervix primarily affects young women in Northeast Brazil who have had fewer pregnancies. The most prevalent genotype observed was 16, with genotypes 45 and 18 following closely behind. Notably, genotype association was identified in only about 14% of cases. This indicates that the quadrivalent vaccine effectively covers approximately 70% or more of HSIL lesions within this population, emphasizing its critical role in prevention and public health.

References:

Slide1

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#13475

P16-02 | Correlation between HPV testing and histological findings in adult women in Pleven

16 - Screening methods

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Background/Objectives: Human papilloma virus (HPV) infection is considered one of the most common sexually transmitted infections worldwide [1]. There is significant genetic variability among papilloma viruses, with over 200 genotypes identified, of which approximately 50 affect the genital tract [2,3]. Among these, HPV types 16 and 18—classified as high-risk—are responsible for over 70% of cervical cancer cases globally [4].

Methods: Between December 2023 and December 2024, a retrospective study was conducted, including 120 female patients examined at “Hinkomed” Medical Center, Pleven. Data processing and statistical analysis were performed using MS Office Excel 2019 and SPSS Statistics v.28 (IBM Corp., Armonk, NY).

Results: The study included 120 women aged between 18 and over 58 years. All participants underwent HPV DNA testing and colposcopic ex the cervix. The results showed that 25 women (20.8%) tested positive for HPV, while 95 (79.2%) tested negative. Among the total, 19 women presented atypical colposcopic findings, requiring targeted cervical biopsy.
Comparison of histological results with HPV test outcomes revealed the following distribution:

- Among the 10 women (52.6%) with positive HPV DNA tests, histology confirmed viral infection in 4 (40.0%).
- Cervicitis was found in 1 patient (10.0%), CIN I in 3 women (30.0%), CIN III in 1 woman (10.0%), and carcinoma in situ (CIS) in 1 wo

Among the 9 women (47.4%) with atypical colposcopic findings but negative HPV tests, targeted biopsies were also performed. Results indica

- HPV infection in 1 case (11.1%),
- Cervicitis in 2 cases (22.2%),
- Mild dysplasia (CIN I) in 1 case (11.1%),
- CIS in 2 women (22.2%), and
- Invasive cervical carcinoma (Ca colli uteri) in 3 women (33.3%).

These findings indicate that even in the absence of active viral infection, significant histopathological changes may be present. Despite the nea number of HPV-positive and HPV-negative cases undergoing biopsy, a strong and statistically significant correlation was found between the tw approaches (χ^2=25.078, df=6, p<0.001, Cramer’s V=0.457).

Conclusions: This study demonstrates that secondary prevention of HPV-related diseases should not exclude any diagnostic method. Both HPV testing and colposcopy are essential and complementary procedures in early detection and prevention of cervical neoplasia. Their combined application ensures more accurate diagnosis and better patient outcomes.

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#13477

P16-03 | In the era of co-testing, can the LuViva test qualify patients for colposcopy? - a pilot study

16 - Screening methods

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Background/Objectives: Cervical cancer remains a significant public health problem, despite the implementation of organized screening programs. The new recommendations of the Polish Society of Gynecologists and Obstetricians introduce screening every five years to detect cervical intraepithelial neoplasia (CIN) or cervical cancer, based on HPV testing and cytology co-testing. The diagnostic pathway often leads to colposcopy, an invasive and time-consuming procedure associated with patient discomfort, overtreatment, and healthcare burden. Therefore, there is an urgent need for reliable, noninvasive tools that can accurately triage patients for colposcopy and identify those at high risk of developing precancerous lesions.

Methods: The present prospective pilot study evaluated the diagnostic performance of the LuViva device (Guided Therapeutics, Inc., Norcross, GA, USA), which uses multimodal hyperspectral spectroscopy (MHS) combining fluorescence and reflectance spectroscopy. One hundred adult patients referred to the District Public Hospital for detailed cervical diagnostics were enrolled. Inclusion criteria were an abnormal liquid-based cytology (LBC) result, a positive high-risk HPV test, or an abnormal cervical appearance within 120 days before recruitment. Exclusion criteria included pregnancy, active bleeding, menstruation, previous cervical cancer, or excessive discharge. Before undergoing colposcopy, each participant was examined with the LuViva device, and histopathological evaluation following biopsy or LEEP served as the diagnostic gold standard. The study was approved by the Ethics Committee (protocol no. 457/25), and all participants provided written informed consent.

Results: Of the 100 patients examined, approximately one-third had normal LBC results (NILM), while 45% showed ASC-US, LSIL, or AG-US findings, and around 20% exhibited ASC-H or HSIL. The most prevalent high-risk HPV genotypes were HPV 16 (39%) and HPV 31 (18%). The LuViva device correctly classified nearly 97% of histopathologically confirmed HSIL lesions as high risk, missing only three HSIL cases that were categorized as intermediate risk.

Conclusions: These findings indicate that the LuViva test may represent a promising, minimally invasive method for cervical cancer risk stratification. Its painless and rapid nature allows for immediate results, enhancing patient comfort and potentially reducing unnecessary colposcopy referrals and overtreatment. The use of LuViva could be especially beneficial in settings where HPV vaccination coverage is still developing, providing an effective triage option for HPV-positive women. However, larger multicenter studies and longer follow-up are needed to confirm the diagnostic accuracy and clinical utility of this technology in routine practice.

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#13483

P17-02 | Our brief experience with methylation

17 - Methylation

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Background/Objectives: Background Till recently, gynaecologists could not distinguish between patients with CIN2 and CIN3 who will progress in the short term to cancer (and therefore need treatment or other diagnostic procedures) and those who have the potential for spontaneous regression and whose evolution can only be actively monitored. This is why the current medical practice is to treat all CIN 2+ lesions with local excisional surgical procedures, which in special groups (nullipara) may have some risks. Methylation tests may have the potential of solving this classical dilemma.

Methods: We used the methylation marker test in selected cases, due to the still high costs. We tried to identify the potential of aggravation in some risk groups: pregnant patients with modified cytology (ASC-H, HSIL) and negative colposcopy – five cases; nullipara with persistent ASCUS or LSIL and moderate colposcopy findings (eight cases); searching for prediction of evolution in patients with large loop excisions and CIN 3 results (four nullipara and three multipara); nullipara with ASCUS, positive immunocytology CINtec plus, who refused any intervention (four cases).

Results: The result of the methylation biomarkers represents an important argument in the decision of appropriate medical conduct: excision treatment vs. monitoring the evolution of the lesion.
Three out of the five nullipara had negative methylation test, reevaluation was performed eight weeks after birth. Two had LSIL and minor colposcopy, one had ASCUS and minor colposcopy. They were further observed. The two other with positive tests had CIN 3 biopsies during pregnancy and excision procedures six weeks postpartum, which confirmed CIN 3 lesions.
Two out of the eight nullipara with persistent abnormal cytology had positive methylation tests, excisions were performed and confirmed in both cases CIN 3.
The four nullipara with CIN 3 after excision procedures had all negative methylation test and thus were referred to observation. Two out of the three multipara with CIN3 after excisional procedures had positive methylation test and we proposed conization, which was positive for focal CIN 2.
One out of the four nullipara with positive immunocytology test has a positive methylation test and finally accepted a loop excision, which confirmed CIN3.

Conclusions: Patients with positive methylation markers, who present an increased risk of worsening in the short term need appropriate excision treatment. Patients with negative methylation markers, who present a low risk of lesional progression in the short term may be appropriate candidates for surveillance.

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#13485

P29-04 | HPV-Associated Oropharyngeal Carcinomas-a Romanian Institutional Study

29 - HPV and oropharynx / Head and neck cancer

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Background/Objectives: The growing incidence of HPV-driven head and neck squamous cell carcinomas (HNSCC) has transformed the epidemiological profile of these malignancies. In Romania, however, data remain limited. This study aimed to evaluate the prevalence and clinicopathologic features of HPV-associated oropharyngeal carcinomas and to compare their demographic, behavioral, and survival profiles with HPV-negative cases in a single institutional cohort.

Methods: A retrospective analysis was performed on 20 patients diagnosed with ENT carcinomas and monitored for 24 months at Elias University Hospital, Bucharest. HPV status was assessed using p16 immunohistochemistry, which served as a surrogate marker of viral oncogenic activity. Clinical and pathological data were compared between HPV-positive (p16+) and HPV-negative (p16–) groups, focusing on sex distribution, age at diagnosis, smoking status, tumor site, nodal involvement, treatment type, and overall survival.

Results: HPV positivity was identified in half of the cases (10/20; 50%). These patients were younger, with a mean diagnostic age of 53.6 years, compared with 67.7 years in the HPV-negative group. A clear male predominance was observed in both subgroups, though more pronounced among HPV-positive patients (8M/2F).
Smoking history was significantly more common in HPV-negative cases, reflecting the classical exposure pattern of non-viral carcinogenesis.
Regarding tumor site, oropharyngeal localization predominated among HPV-positive patients (8/10), while HPV-negative tumors were more evenly distributed across lingual and tonsillar regions.
In terms of prognosis, HPV-positive patients demonstrated improved survival, with a mean follow-up of 17.6 months, compared to 12.8 months in the HPV-negative cohort. A statistically significant inverse correlation was identified between nodal stage and survival ($p < 0.02$), indicating reduced outcomes in patients with lymph node involvement.

Conclusions: Our study showed the emerging burden of HPV-related oropharyngeal carcinomas in Romania. HPV-positive tumors tend to occur in younger, less frequently smoking men and are associated with better short-term survival compared to HPV-negative cases.
Routine implementation of p16 and HPV testing offers essential prognostic information and may refine therapeutic decision-making. In healthcare systems where access to advanced molecular assays is limited, basic immunohistochemical and genotyping tools remain vital for understanding and managing the shifting epidemiology of head and neck cancer.

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#13487

P03-03 | Epidemiological study of patients undergoing high-frequency cervical surgeries at a University Hospital in Brazil, aged 30 to 60 years.

03 - Epidemiology and natural history

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Background/Objectives: Introduction: Human Papillomavirus is the most common sexually transmitted infection in the world. HPV is known to be the etiological agent of cervical cancer, representing one of the main health problems in Brazil. Through public policies for vaccination and screening, primary and secondary prevention of this pathology can be guaranteed, respectively. In this context, High-Frequency Surgery stands out for the treatment of precursor lesions of cervical cancer, being a safe, low-cost procedure with rapid recovery and a high rate of therapeutic success. Objective: This study aims to outline an epidemiological profile of women between 30 and 60 years old, submitted to High-Frequency Surgery at the Teaching Hospital of Valença - Brazil, in order to analyze the prevalence and evolution data in the studied epidemiological window.

Methods: This is a prospective, quantitative study. Data collection was carried out using a questionnaire, containing 16 questions, directed at 150 patients from the gynecology specialty at the Integrated Medicine Outpatient Clinic of the Teaching Hospital of Valença, who underwent High-Frequency Surgery of the Uterine Cervix. The questionnaire addressed risk factors for cervical cancer, as well as data regarding the diagnosis and histopathological examination of the High-Frequency Surgery of the Uterine Cervix.

Results: 112 responses with sufficient data for analysis were obtained. The data showed that the most affected age group was patients between 30 and 35 years old (37.5%), followed by patients between 36 and 40 years old (23.3%). Furthermore, one of the main risk factors, early sexual debut (sexarche), was confirmed, with 69.7% of patients having started their sexual life by age 18, of which 2.7% started before age 15. The analysis of the number of partners highlights the close relationship with cervical cancer, with 53.6% of patients reporting a number greater than or equal to 4 partners and 8.9% over 7 partners. Cytological examination for cervical screening proved essential for detecting precursor lesions, showing the main lesions found in the studied patients: the most prevalent being HSIL (in 60.7% of patients), followed by ASC-H (in 8.9% of patients). Regarding the histopathology, the most present was CIN II (present in 47.6% of patients), followed by CIN III or Carcinoma in situ (with 38.6%).

Conclusions: Thus, the importance of adequately educating patients about cervical cancer, the initiation of screening, and the risk factors that may contribute to its development is elucidated. Therefore, although the Ministry of Health has well-established protocols for the screening and diagnosis of cervical cancer, high numbers of diagnoses are still observed in young patients. This can be minimized with correct follow-up of patients from the first gynecological consultation, advising vaccination at the appropriate time and also at the beginning of sexual life, warning about the relevance of barrier contraceptive methods, in order to minimize the risks of contamination by the HPV virus.

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age of diagnosis

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#13500

P15-04 | Expression profiles of selected microRNAs as potential biomarkers in cervical lesion progression

15 - Molecular markers

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Background/Objectives: Cervical cancer remains the fourth most common malignancy among women worldwide, despite the availability of vaccination and regular screening programs. Current research therefore focuses on identifying novel molecular biomarkers to improve early detection and risk assessment. MicroRNAs (miRNAs) play key roles in post-transcriptional gene regulation, and their dysregulation can induce pathological changes contributing to carcinogenesis. This study aimed to evaluate the expression of selected miRNAs in cervical swab samples from women with various grades of cervical lesions. The identified miRNAs may be associated with lesion progression and could serve as potential biomarkers for early diagnosis and prognosis in cervical carcinogenesis.

Methods: A total of 72 samples were included in this study, which were divided into groups according to severity: negative for intraepithelial lesion or malignancy (NILM, n=15), atypical squamous cells of undetermined significance (ASCUS, n=12), low-grade squamous intraepithelial lesion (LSIL, n=19) and high-grade squamous intraepithelial lesion (HSIL, n=26). MiRNA expression was quantified by real-time PCR using commercially available miRNA assays.

Results: To assess the relationship between miRNA expression and lesion severity, fold change values were compared to the control group (NILM). No significant differences were observed in the ASCUS group ($p > 0.05$). In contrast, several miRNAs were significantly upregulated in LSIL and/or HSIL groups, indicating their association with lesion progression. Specifically, miR-17-5p, miR-26b-5p, miR-29a-3p, miR-103a-3p, miR-106a-5p, miR-146a-5p, miR-155-5p, and miR-191-5p showed increased expression ($p < 0.05$) compared with controls. The most prominent changes were observed for miR-26b-5p, miR-103a-3p, and miR-146a-5p, with up to a 4-fold increase in LSIL and/or HSIL groups, miR-106a-5p exhibited nearly a 5-fold elevation in HSIL. Overall, the expression patterns demonstrated a gradual increase from low-grade to high-grade lesions, supporting their potential role as non-invasive biomarkers of cervical carcinogenesis.

Conclusions: The observed gradual increase in specific miRNA expression with lesion severity suggests their involvement in cervical carcinogenesis. The identified miRNAs, particularly miR-26b-5p, miR-103a-3p, miR-106a-5p, and miR-146a-5p, may serve as promising non-invasive biomarkers for early detection and monitoring of disease progression. Further validation in larger cohorts is warranted to confirm their diagnostic and prognostic potential.

References: *This work was supported by project No. 09I03-03-V04-00228 from the Call „Fellowships for excellent researchers R2-R4".*

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#13516

P29-05 | Molecular and immunohistochemical annotation of HPV in oropharyngeal cancer: extent and clinical implications of discordance

29 - HPV and oropharynx / Head and neck cancer

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Background/Objectives: HPV status has been clearly demonstrated to be independently associated with prognosis in oropharyngeal carcinoma (OPC) and can be used to tailor supportive clinical management strategies; therefore, robust annotation to confirm "true" HPV status is important. However, there is some ambivalence in the literature as to the optimal method of annotation.Scotland has offered molecular HPV typing for OPC since 2014 centrally at the Scottish HPV Reference Laboratory (SHPVRL) subsequent to p16 testing performed by local pathology laboratories, aligning with guidance from the Royal College of Pathology.The aim of this study was to assess concordance between HPV and p16 status in OPC samples received as part of a national service and identify variables contributing to any discordance.

Methods: Specimens were identified from the SHPVRL database and demographic (health board, age, sex) and test result data (HPV, p16, assay) collated on formalin-fixed paraffin-embedded (FFPE) specimens received between May 2022 – May 2024 for HPV genotyping using an ISO15189:2022 accredited assay.
Specimens were extracted using STARMag Universal Cartridge Kit (Seegene, South Korea) and genotyped using Anyplex II HPV28 Detection Kit (Seegene) up to July 2023, and Allplex HPV28 Detection Kit (Seegene) from July 2023.
p16INK4a immunohistochemistry was performed by each health board according to local procedures.
Cohen's Kappa (κ) was used to assess levels of agreement and McNemar's to evaluate discordance distribution between HPV and p16, stratified by assay. Univariate analysis was performed to assess variables that may contribute to discordance – health board, age, sex, assay. For binary, categorical, and continuous variables, statistical analysis was by comparison or proportions, chi-squared (χ^2), and two-sample t-test, respectively. *p*-values less than 0.05 were considered statistically significant.

Results: A total of 679 oropharyngeal samples were included in the analysis. Two samples were invalid and 12 had no p16 result so were excluded leaving 665 results.
High-risk HPV was detected in 66.2% (448/677) of samples as either single or mixed infections, with HPV16 detected in 91.9% (407/448) of high-risk HPV-positive cases.
Agreement between HPV and p16 status was high (>90%) with both Anyplex and Allplex irrespective of whether equivocal p16 results were included or excluded (Table 1). Kappa values were 0.83 (95% CI: 0.77-0.90) and 0.85 (95% CI: 0.78-0.92) for Anyplex and Allplex, respectively.Distribution of discordant results when equivocal p16 results were excluded was statistically significant in Anyplex tested samples ($p = < 0.001$), but not Allplex ($p = 0.332$), with a greater number HPV-/p16+. Distribution of discordant results was significant when equivocal p16 results were considered positive ($p = < 0.001$ and 0.015 for Anyplex and Allplex, respectively).
In univariate analysis, none of the variables assessed were associated with discordance – health board ($p = 0.146$), age ($p = 0.142$), sex ($p = 0.920$), assay ($p = 0.582$).

Conclusions: Agreement between HPV and p16 status in oropharyngeal cancer specimens was high, at least 90%, irrespective of HPV assay although with a greater likelihood of HPV-/p16+ samples. While the high concordance provides reassurance of using both assays for annotation and prognostication in OPSCC, the origins and clinical relevance of discordant HPV/p16 results requires further investigation given this group may represent a distinct prognostic entity.

References:

EUROGIN 2026 - Table 1

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#13518

P36-01 | Improved Quality of Life and Emotional Well-Being after Diathermy Ablation for Cervical Intraepithelial Neoplasia: a Prospective Study

36 - Advocacy, acceptability and psychology

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Background/Objectives: Cervical intraepithelial neoplasia (CIN) represents a high-grade precursor of cervical cancer, and fertility-preserving treatment is essential for women of reproductive age. Diathermy ablation is a minimally invasive alternative to excision, yet little is known about its impact on patients' quality of life (QOL) and emotional well-being. This prospective clinical trial aimed to evaluate postoperative changes in QOL among patients undergoing diathermy ablation for CIN2/3.

Methods: Forty patients with biopsy-proven CIN2/3 were enrolled between January 2017 and October 2019 at Fujita Health University, Japan. The European Organization for Research and Treatment of Cancer questionnaires (EORTC-QLQ-C30 and QLQ-CX24) were administered preoperatively and at 3 and 6 months postoperatively. Changes in scores were analyzed using the Friedman and Wilcoxon signed-rank tests.

Results: Thirty-nine patients were included in the final analysis (median age: 36 years). Significant postoperative improvements were observed in emotional functioning (p=0.001), body image (p=0.002), symptom experience (p=0.016), and physical functioning (p=0.032). Pairwise comparisons confirmed sustained enhancement of emotional functioning at both 3 and 6 months after surgery (p=0.004 and p=0.001, respectively). Vaginal discharge and abnormal bleeding, components of the symptom experience scale, significantly decreased during follow-up (p=0.004 and p=0.001, respectively). Sexual activity temporarily declined at 3 months but recovered to preoperative levels by 6 months. No major complications were reported. These findings demonstrate that diathermy ablation, while minimally invasive, contributes not only to physical recovery but also to emotional stability and body confidence in women treated for CIN2/3.

Conclusions: Diathermy ablation significantly improved QOL indicators including emotional functioning, body image, and symptom control in patients with CIN2/3. Postoperative sexual activity and overall well-being recovered within 6 months, suggesting a favorable psychosocial outcome. The use of standardized EORTC QOL instruments enables global comparison across different cervical disease treatments and supports the role of minimally invasive, fertility-preserving approaches in enhancing patient-centered care.

References:

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#13522

P17-03 | Methylation status of cell adhesion molecules in early detection of cervical cancer

17 - Methylation

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Background/Objectives: Cervical cancer remains a significant health problem despite the possibility of its early detection. In addition to detecting cytological abnormalities and the presence of HPV infection, scientists around the world are also aiming to detect the methylation status of genes that would allow early prediction of the development of cervical cancer. In our study, we focus on analyzing the methylation status of genes responsible for cell adhesion (ALCAM, CDH1, and CD8A), which could predict morphological changes in cervical cells in an early stage.

Methods: Cervical specimens were collected from 81 patients with normal and abnormal result of cervical cytology. DNA extracted from cervical swabs was subjected to bisulfite conversion, PCR amplification using comercially available assays, and subsequently analyzed using pyrosequencing. Statistical analysis was performed in jamovi and R programme with additional packages.

Results: HPV infection was detected in 49% of women (40/81) with average age of 39 years. We detected a statistically significant higher average methylation (p=0.003) of selected CpGs in the CD8A promoter region in worsening cervical lesions. The methylation status of CDH1 and ALCAM was not significant (p=0.861 and p=0.782, respectively) in high-grade cervical lesions (HSIL). We also compared the methylation status with the gene expression of the CD8A and CDH1 genes. We found a decreasing trend in CDH1 gene expression with worse cervical lesion results, and an increasing trend in CD8A gene expression, but the differences were not significant (p=0.8551595 and p=0.47899 for HSIL lesions, respectively). Other findings showed slightly increased CD8A methylation in HPV 16 and 18 positive cervical samples that was significant (p<0.001). The average methylation in selected CpGs in ALCAM and CDH1 genes was not associated with HPV infection (p=o.741 and 0.128 respectively).

Conclusions: This study's findings indicate a relationship between the methylation status of adhesion genes and HPV infection, as determined by methylation assays. We have demonstrated a correlation between CD8A promoter methylation and disease progression, as well as an association with HPV positivity. Furthermore, a trend was observed for increased CDH1 methylation and a corresponding decrease in its gene expression. Future work will focus on validating these conclusions in a larger patient cohort and in cervical tissue samples. The outcomes of this research could significantly enhance patient prognosis by enabling earlier and more precise disease detection.
undefined

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#13523

P08-01 | Legal aspects of underestimation and overestimation of diagnosis and treatment of precancerous conditions and cervical cancer

08 - Immunotherapy - Immuno-oncology - New treatments

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Background/Objectives: The diagnosis and treatment of precancerous conditions and cervical cancer involve a significant risk of discrepancies between the histopathological assessment and the actual clinical condition of the patient. It is estimated that underestimation or overestimation of the diagnosis may affect up to 20-30% of cases, which may lead to potential legal claims against physicians. The aim of this study is to discuss key principles of conduct that minimize the risk of legal liability for physicians in the diagnostic and therapeutic process of cervical diseases.

Methods: The analysis covered factors contributing to medical-legal disputes, including the method of documenting clinical decisions, the scope of informing patients about diagnostic risks and the importance of continuous professional development of medical personnel.

Results: The most important element of legal protection for doctors is reliable medical documentation, justifying every diagnostic and therapeutic decision. The informed consent of the patient is also of significant importance, including informing them about possible discrepancies between the test results and the actual state of the disease. Regular training and participation in conferences provide additional confirmation of due diligence.

Conclusions: Safe diagnosis and treatment require not only medical knowledge, but also legal awareness. Applying current guidelines, keeping accurate records, and communicating effectively with patients are the basis for minimizing medical liability risk.

References:

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#13524

P16-04 | Vulvovaginitis molecular diagnosis: study of potential etiological agents in a Portuguese cohort

16 - Screening methods

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Background/Objectives: Background: Vulvovaginitis (VV) are the main cause of vaginal dysbiosis, with potential implications for women's reproductive health and psychosocial well-being. Accurate diagnosis remains critical for correct treatment, since clinical VV symptoms often overlap, and the routine microbiology methods are time consuming and have lower sensitivity. Allplex™ Vaginitis Assay (Seegene) is a high-sensitivity method that uses multiplex real time PCR technology, allowing clinicians access to fast and reliable results. It detects bacterial vaginosis and identifies other infectious agents (Candida albicans and non-albicans, Trichomonas vaginalis).Objective: The purpose of this study is to analyse the demographic, clinical and lifestyle data known to influence vaginal dysbiosis, and identify the infectious agents using Allplex™ Vaginitis Assay. This study also aims to evaluate the applicability of this test, and explore the feasibility of integrating VV screening into routine gynaecological care, maximizing diagnostic efficiency and patient comfort.

Methods: It is a Portuguese prospective cohort study, which will enrol 180 female participants aged 18 to 65 years, over 1 month. A vulvovaginal swab sample will be collected from symptomatic and asymptomatic participants, and tested for candidiasis, *Trichomonas vaginalis* and bacterial vaginosis. Each participant will complete a questionnaire covering demographic data, lifestyle, reproductive health, intimate hygiene practices and sexual behaviour. Simultaneously, gynaecologists will complete a separate form documenting clinical history, symptoms, and physical findings of these patients. Data analysis and interpretation it will be done.

Results: The epidemiological data and the VV infection rates will be presented upon completion of analysis.

Conclusions: This study will offer valuable insights into the diagnostic utility of multiplex PCR testing for common VV pathogens, even in routine gynaecological consultations concerning other clinical purposes.

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#13539

P23-02 | Risk factors associated with disease recurrence following cervical conization

23 - Risk management

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Background/Objectives: Cervical conization is currently a widely used method for the treatment of precancerous lesions of the uterine cervix; thus, for the prevention of cervical cancer. The reported incidence of recurrent disease following conization shows substantial regional variation. According to literature data, factors like incomplete excision, age, persistent, coexisting sexually transmitted infection (STI) poor follow-up adherence may all contribute to recurrent disease. ObjectiveTo examine clinicopathological factors related to high-risk cervical disease, and risk factors of persistent infection of patients who underwent conization between 2015-2020 at the Department of Obstetrics and Gynecology, Semmelweis University, Budapest.

Methods: All 1071 patients with a High Grade Squamous Intraepithelial Lesion cytological diagnosis who underwent cervical conization were included in the study.
The following data were recorded from the Semmelweis University and Synlab Hungary files: age at time of conization, number of conizations, margin status, smoking, human papilloma virus (HPV) status, coexisting STI, BMI and parity. Statistical analyses and Kaplan-Meier curve estimation was performed to determine the risks of recurrent disease and the implication of HPV infection and surgical margin status in predicting recurrence.

Results: Of the 1071 patients 639 were tested for HPV. The most frequent HPV types were 16, 31, 52 and 51. The prevalence of HPV 16/18 varied significantly across age groups. HPV 16/18 positivity was more frequent among women <30 years compared to those ≥30 years (47.3% vs. 32.1%; $p < 0.001$). In 21% of the cases reconization was performed. Women with multiple conizations had a significantly higher prevalence of HPV 16/18 compared to those with a single conization (42.5% vs. 33.8%; OR = 1.45, 95% CI: 1.08–1.95, $p = 0.018$). Cone height was significantly lower in patients with multiple conizations compared to those with a single procedure (0.82 cm vs. 1.00 cm; $t = 4.75$, $p < 0.001$; mean difference 0.19 cm, 95% CI: 0.11–0.26. Based on negative vs. positive margin status Kaplan–Meier curve presented marginally significant differences in recurrence free survival (p=0.05). However, based on pairwise comparisons, only positive endocervical margin was significantly associated with worse recurrence when compared to negative margins (p=0.022).

Conclusions: The presence of HPV16/18 was significantly associated with younger age and resulted in multiple conizations. Overall recurrence-free survival showed marginal significance when comparing negative vs. positive margin status, endocervical margin involvement was associated with a higher risk of persistent infection. Careful surgical technique and tailored follow-up are essential to reduce recurrence in cervical lesions.

References:

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#13552

P18-04 | Cervico-vaginal dysbiosis and FAM19A4/miR-124-2 methylation in cervical intraepithelial neoplasia

18 - Microbiome

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Background/Objectives: High-risk human papillomavirus (hrHPV) infection is the primary cause of cervical cancer, but most infections don't progress, implicating co-factors like epigenetic silencing and dysbiotic cervicovaginal microbiota. The aim of the study was to investigate the correlation between cervicovaginal microbiota profile and methylation of FAM19A4 and miR-124-2.

Methods: We analyzed a cross-sectional cohort of 70 women, including hrHPV-positive women with varying grades of cervical intraepithelial neoplasia (CIN1-3) and cancer (SCC), respectively healthy controls (NILM HPV negative). Cervicovaginal samples were collected for both DNA extraction and 16S rRNA gene sequencing for microbiota profiling. Methylation levels of FAM19A4 and miR-124-2 were quantified using an IVD quantitative methylation-specific PCR (qMSP) assay and categorized as methylated (positive) or not (negative) based on a validated clinical cut-off.

Results: To assess the relationship between *Lactobacillus* dominance and disease severity, we categorized samples based on relative *Lactobacillus* abundance into four groups: >80% (dominant), 31-79% (intermediate), <30% (low), and not detected. The distribution of these categories across histological groups was highly significant ($p < 0.0001$, Chi-square test). A clear inverse trend was observed: high *Lactobacillus* abundance (>80%) was strongly associated with normal cytology (NILM). In contrast, the progression from CIN1 to SCC was marked by a progressive loss of *Lactobacillus*, with SCC samples almost exclusively falling into the 'low' or 'not detected' categories. Moreover, while present in pre-cancerous lesions, *Lactobacillus* relative abundance was significantly reduced in SCC compared to CIN1 ($p = 0.0455$) and CIN2 ($p = 0.0124$), indicating a potential exclusion or suppression in the late-stage tumor microenvironment.
We further investigated the shift in microbial community complexity by categorizing samples based on the number of dominant genera present (<3, 3-5, >5). The analysis revealed a statistically significant association between the number of dominant species and histological diagnosis ($p = 0.0485$). While the NILM group was predominantly characterized by a low number of dominant species (<3), consistent with *Lactobacillus* dominance, the pre-cancerous and cancerous lesions (CIN1-SCC) exhibited a trend toward a higher number of co-dominant genera (3-5 and >5), indicating increased microbial diversity with disease severity.
The methylation status of FAM19A4 and miR-124 revealed distinct and significantly correlated cervicovaginal microbial consortia, underscoring a direct link between the microbiome and specific epigenetic events in cervical carcinogenesis. We identified a universal, foundational dysbiosis involving *Gardnerella and Prevotella.* A *Bifidobacterium*-high signature was characteristic of miR-124 positive samples, while *Streptococcus* and *Mycoplasma* were linked to FAM19A4 positivity. Most notably, samples negative for both methylation markers were characterized by a dysbiotic (non-specific BV-like) profile, including species as *Atopobium, Clostridia, and Fusobacterium.*

Conclusions: Our findings link distinct cervicovaginal microbial profile signature to specific epigenetic pathways in cervical carcinogenesis. This model positions the microbiome as a key disease regulator and highlights its potential as a biomarker for precision risk stratification and prevention.

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#13554

P39-08 | Effectiveness of trainings for healthcare professionals to human papillomavirus (HPV) vaccination

39 - Public health

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Background/Objectives: Healthcare professionals (HCP) play an important role in increasing HPV vaccination coverage. Within the Joint Action PERCH (Partnership to contrast HPV, 11/2022-08/2025) need based trainings to HPV vaccination for HCP were implemented in 11 countries during the year 2024. The trainings were online (self-paced e-course or webinar), face-to-face, or combined (face-to-face and online). The objective was to support HCP in vaccine communication.

Methods: The evaluation followed a pre-post-test design to measure two key indicators: (1) improved knowledge about HPV and HPV vaccination, and (2) enhanced communication skills regarding vaccine-related discussions. In addition, perceptions and beliefs on HPV vaccination and feedback on the trainings were assessed. A training evaluation questionnaire was developed and implemented in 11 countries, with some variations in data collection due to local adaptations. The data from over 21.500 healthcare professionals were collected and analysed. Of those, 1.289 cases (8 countries) could be included in the pooled analysis.

Results: The majority of participants (71%) demonstrated improvements in knowledge post-training. The proportion of participants scoring high on knowledge increased from 62% to 91%. 38% out of 1.289 participants had low to moderate knowledge in the pre-knowledge-test (up to 11 correct answers out of 16 items). Of those, 88.7% improved their scores after the training.
The trainings also enhanced self-perceived communication skills: 55% reported increased competencies in the post test. High confidence in discussing HPV vaccination improved from 56% to 90% post training. 44% out of 1.289 participants had low to moderate confidence (self-perceived communication competencies) in the pre-test: They were not rather or very confident in all 9 communication items. Of those, 89.8% felt more confident in an increased number of communication items after the training. The most notable improvements were in responding to parental concerns about vaccine safety and efficacy. Participant satisfaction was very high: 95% of participants were satisfied with the training, 92% would recommend it to colleagues.

Conclusions: The training evaluation demonstrates that structured educational programs significantly enhance healthcare professionals' knowledge and self-perceived communication skills regarding HPV and HPV vaccination. The high level of participant satisfaction and willingness to recommend the training indicate the trainings' usefulness. However, remaining knowledge gaps suggest possibilities for further refinement.

References:

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#13589

P09-07 | HPV biomarkers in oral derived body fluids in oropharyngeal cancer patients

09 - HPV testing

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Background/Objectives: Background: Human papillomavirus (HPV) is increasingly recognized as a key etiologic factor in oropharyngeal cancers (OPC). Saliva may serve as a convenient, non-invasive specimen for HPV detection.Objective: To determine the presence of HPV DNA in saliva samples and assess its potential as a screening tool.

Methods: Methods: Saliva samples, along with detailed clinical data and follow-up exceeding 18 months, were collected from 120 study participants by oral gargles. Each participant rinsed by swirly in oral cavity with 15 ml of sterile saline solution (0.9%: 9 g NaCl in 1000 ml of sterile water) for 15 seconds and the rinse was collected in a 50 ml sterile falcon tube. Samples were analyzed for HPV DNA using Real Time PCR-based assays (HPV PLUS ELITe MGB® Kit). The prevalence and genotype distribution of HPV were evaluated.

Results: Results: HPV DNA was detected in a subset of saliva samples, indicating variable prevalence among individuals. Detected genotypes included only high-risk HPV types.

Conclusions: Conclusion: The detection of HPV DNA in saliva supports its utility as a non-invasive method for HPV screening for risk for OPC. These findings underscore the potential role of salivary testing in HPV surveillance and early detection strategies.

References:

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#13592

P18-05 | Anal microbiome in MSM living with HIV: correlation with HPV16 infection and High-grade Squamous Intraepithelial Lesions

18 - Microbiome

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Background/Objectives: High-risk human papillomaviruses (HPVs) cause the large majority of anal squamous cell carcinomas (ASCCs), particularly among men who have sex with men living with HIV (MSMLWH), who show the highest ASCC incidence. HPV16 is the most prevalent genotype in ASCCs. Given that only a subset of HPV16-positive (HPV16+) individuals ultimately develops ASCC, additional cofactors are likely to contribute to the development of pre-neoplastic and neoplastic lesions. Emerging evidence suggests that the anal microbiome may play a role in this process, although data in this regard are still limited. This study characterized the anal microbiome of MSMLWH to assess potential microbial alterations associated with HPV16 infection and the presence of High-Grade Squamous Intraepithelial Lesions (HSILs).

Methods: Cell pellets from anal swabs, stored at -80°C, were retrospectively selected among those collected from MSMLWH participating in the SAIN project, conducted by the STI/HIV Unit of the San Gallicano Dermatological Institute (Rome, Italy). Demographic, clinical and laboratory data (HIV-related parameters, HPV testing by the Linear Array HPV genotyping test and liquid-based cytology) were retrospectively retrieved. DNA was extracted using the DNeasy PowerLyzer PowerSoil kit, and the 16S rRNA gene (V3-V4 region) was amplified and sequenced on the MiSeq platform. Sequencing data were processed and analysed using the QIIME 2 platform to evaluate alpha and beta-diversity and differential microbial composition. Analyses compared i) HPV16+ vs. HPV-negative (HPV-) individuals and ii) HPV16+HSIL vs. HPV16+Negative for Intraepithelial Lesion or Malignancy (NILM).

Results: A total of 109 individuals were included (median age: 42 years, IQR: 34-49). Significant differences in both alpha (Shannon and Chao-1 indices) and beta diversity (Jaccard and unweighted UniFrac distance) were observed between HPV16+ (n=84) and HPV- individuals (n=25). Specifically, HPV16+ samples displayed significantly higher alpha diversity. No significant differences in alpha diversity were found between HPV16+HSIL (n=9) and HPV16+NILM (n=28), whereas Jaccard distance analysis indicated a significant difference in beta diversity between these groups. Differential abundance analysisidentified 7 genera and 12 species with significant differences between HPV16+ and HPV- samples. At the genus level, *Fusobacterium*, *Dorea*, *Ruminococcus* and *Succinivibrio* were significantly enriched in HPV16+ subjects. At the species level, *Granulicatella elegans* was enriched, whereas *Prevotella stercorea* (one of the most prevalent and abundant species in the healthy human gut), *P. bivia* and *Bacteroides fragilis* were depleted in HPV16+ subjects. Compared with HPV16+NILM, HPV16+HSIL showed an increased abundance of Actinomycetota (phylum) and *Veillonella* (genus).

Conclusions: HPV16 infection in MSMLWH is associated with distinct alterations of the anal microbiome, characterized by increased alpha and beta diversity, enrichment of potentially pathogenic bacteria (e.g., *Fusobacterium*, implicated in colorectal carcinogenesis), and depletion of commensal *Prevotella spp.* The observed depletion of *P. bivia* and enrichment of *Granulicatella spp.* have already been reported in samples from individuals with histologically confirmed anal precancerous lesions. Our data suggest that distinct anal microbiome profiles are associated with HPV16+ infection and HPV16+HSIL in MSMLWH.

References:

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#13594

P13-07 | Incidence of cervical cancer in Sweden after switching to HPV-based self-sampling in general screening

13 - Self-sampling

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Background/Objectives: Over the past decade, the cervical cancer incidence in Sweden has fluctuated around 550 cases annually. The 2015 national guidelines mandated HPV testing as the primary screening method and in 2017 self-sampling for HPV was recommended for non-attenders. During the COVID-19 pandemic, self-sampling was allowed for all women because clinician-based screening was disrupted. In 2022 there was a permanent national guideline that self-sampling could be used for screening of all women. To assess the impact of self-sampling on cervical cancer incidence, data on test coverage, HPV testing volume, self-sampling uptake, and cancer rates were compared.

Methods: Data on coverage, number of HPV- tests and self-samples were collect from the Swedish National Cervical Screening Registry. Data on cervical cancer incidence were retrieved from the Swedish Quality Registry for Gynecological Cancer.

Results: From 2016 to 2021 there were no major changes in number of incident cervical cancer cases (fluctuating between 550-570 cases/year), but from 2022 and onwards a clear decrease in incident cervical cancer cases is reported with only 418 cases in 2024. The proportion of HPV tests that were self-samples was very small (between 1-8%) during the first 4 years (2017-2020) but increased dramatically during 2021 to 49% of all HPV tests when clinician-taken sampling was disrupted due to the COVID-19 pandemic and has stably remained at about half of all HPV tests since (48% in 2025).

Conclusions: Self-sampling has greatly facilitated cervical screening in Sweden. The rapid introduction of self-sampling in 2021 was, starting in 2022, followed by a rapid decline in invasive cervical cancers.

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#13595

P18-06 | Longitudinal assessment of vaginal microbiome composition and HPV clearance among women in Nairobi, Kenya

18 - Microbiome

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Background/Objectives: The vaginal microbiome is a key determinant of reproductive tract health and may shape susceptibility to sexually transmitted infections, including HPV. In healthy reproductive-age women, Lactobacillus-dominant communities generally protect against pathogen colonization. In contrast, a shift toward diverse anaerobes—characteristic of bacterial vaginosis—has been linked to adverse reproductive outcomes. Although associations between vaginal microbiota and HPV have been reported, it remains unclear whether microbiome shifts predispose individuals to persistent HPV or whether HPV disrupts microbial homeostasis. Longitudinal studies of these dynamics are scarce, particularly in African populations. We assess 12-month changes in relative and absolute vaginal microbial abundance alongside HPV status among participants with high-risk HPV at baseline.

Methods: We enrolled female sex workers from the Sex Worker Outreach Program (SWOP) in Nairobi, Kenya. Participants were >18 years of age, non-pregnant at baseline, asymptomatic for CIN, and had no recent history of cervical intraepithelial neoplasia treatment. The primary outcome was HPV clearance, defined as a change from positive to negative for specific HPV genotypes using 46-plex microsphere-based genotyping. At each visit, cervicovaginal swabs were preserved in RNA Later for microbiome analysis. Vaginal microbiota were characterized by 16S rRNA gene sequencing (V3–V4 region, Illumina NextSeq) and 16S rRNA qPCR to assess both relative and absolute bacterial abundance. Sequence data were processed using DADA2, with species-level classification via vSpeciateDB and community state typing through VALENCIA.

Results: Analyses include 54 participants sampled at 351 visits. Overall, HPV clearance was observed in 17/32 visits (53%) where optimal *Lactobacillus*-dominated community state types (CSTs I,II,V) were present, compared with 29/209 visits (14%) with non-optimal CSTs. Multivariable models using generalized estimating equations (adjusted for repeated measures, HIV status, age, and HIV–age interaction) demonstrated that optimal *Lactobacillus* CSTs were significantly associated with HPV clearance (aOR = 1.47, 95% CI 1.14–1.91, p = 0.003). Higher total *Lactobacillus* load was also independently associated with clearance (aOR = 1.15/log10 copies, 95% CI 1.08–1.24, p < 0.001). Conversely, greater *Gardnerella vaginalis* abundance was associated with reduced odds of clearance (aOR = 0.86, 95% CI 0.75–0.99, p = 0.037). Similar trends were observed for *Prevotella* genus (aOR = 0.94, 95% CI 0.88–1.00, p = 0.044). HPV persistence was nominally associated with specific anaerobic taxa, including *Mobiluncus mulieris*, *Atopobiaceae*, *Aerococcus*, *Berryella*, *Fannyhessea*, *Megasphaera*, and *Streptococcus* (all p < 0.001).

Conclusions: In this longitudinal analysis, *Lactobacillus*-dominant CSTs and higher total *Lactobacillus* load, were associated with higher odds of HPV clearance, while *Gardnerella*, *Prevotella*, and a few BV-associated anaerobes were associated with HPV persistence. These data suggest that absolute abundances of optimal *Lactobacilli* favour clearance of HPV in a population of female sex workers from Nairobi, Kenya. Further identification of non-*Lactobacilli* that promote virus persistence could identify novel interventions to prevent cervical cancer in women with established HPV persistence. Clinical trials that robustly restore optimal Lactobacilli are required to confirm a causal role for this observation.

References:

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#13606

P39-09 | Impact of HPV Vaccination on Cervical Preneoplastic Lesions in Colombia: Analysis of National Health Databases

39 - Public health

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Background/Objectives: Persistent high-risk human papillomavirus (HPV) infection is the main cause of cervical intraepithelial neoplasia and cervical cancer. Colombia introduced HPV vaccination in 2012 for girls aged 9–16 years. Evaluating its population-level impact is essential to inform prevention policies.

Methods: We conducted a retrospective analysis of national health data (health services provision and capitated payments database, Ministry of Health vaccination records, and official population projections) between 2010 and 2019. Diagnoses were identified using ICD-10 codes for cervical lesions: D06X (cervical carcinoma in situ/CIN3), N86X (erosion and ectropion), N870 (mild dysplasia/CIN1), N871 (moderate dysplasia/CIN2), N872 (severe dysplasia/CIN3 but not in situ carcinoma), and N879 (unspecified dysplasia). Potential exposure to HPV vaccine through the Expanded Program on immunization was defined by birth cohort: vaccinated (born 1996–2003) vs unvaccinated (1982–1995). Incidence trends and consultation rates by sex, age, and department were analyzed. Incidence rate ratios (IRR) comparing vaccinated vs unvaccinated cohorts were estimated using negative binomial models with a log link and offset for population/time at risk.

Results: A total of 911,678 cases were identified in women. Mild dysplasia (N870/CIN1) was most frequent (58.7%), followed by unspecified dysplasia (15.6%) and moderate dysplasia (10.1%). Lesions clustered in women aged 25–39 years, with marked geographical variability. Vaccinated cohorts showed lower lesion rates across ICD-10 categories. Estimated IRRs (vaccinated vs unvaccinated) for the different outcomes were: CIN3/in situ carcinoma 0.60 (95% CI 0.52–0.69; $p<0.05$), erosion/ectropion 0.84 (0.68–1.04; $p=0.12$), CIN1 0.78 (0.74–0.82; $p<0.05$), CIN2 0.68 (0.63–0.73; $p<0.05$), CIN3/not in situ carcinoma 0.64 (0.59–0.70; $p<0.05$), and unspecified dysplasia 0.80 (0.76–0.84; $p<0.05$). Thus, vaccinated cohorts had 22%–36% lower rates for CIN1–CIN3 outcomes and 40% lower rates for carcinoma in situ; the reduction for N86X (erosion/ectropion) was not statistically significant.

Conclusions: HPV vaccination in Colombia is associated with substantially reduced incidence rates of cervical preneoplastic lesions spanning CIN1, CIN2, CIN3, and carcinoma in situ, among vaccinated birth cohorts. These real-world findings support the effectiveness of the national vaccination program and the need to achieve and sustain high vaccine coverage alongside screening strategies.

References:

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#13607

P14-02 | Optimizing Cervical Cancer Screening: The Value of HPV Testing in West Algeria

14 - Genotyping

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Background/Objectives: Cervical cancer, predominantly caused by persistant high-risk Human Papillovairus (HR-HPV) infection, remains a major public health concern in Algeria. This study aimed to assess the clinical value of Amplicor HR-HPV test in cervical cancer screening and to compare the performance of three different HPV assays: INNO-LiPA, Cobas and Amplicor.

Methods: A total of 76 cervoco-vaginal samples were collected from women in the Wilaya of Tlemcenusing ThinPrep liquid-based cytology. All samples underwent cytological examination and were tested with INNO-LiPA and Cobas assays. Additionally, 18 of these samples were also analysed using the Amplicor method. Results were compared to determine concordance between HPV tests and correlated with cytological findings to evaluate the clinical relevance (sensitivity and specificity) of each method. Statistical analysis was performed using IBM SPSS 21.

Results: The Amplicor HR-HPV test revealed HR-HPV presence in 17,1% of the 76 screened patients from Tlemcen. Its integration facilitated: referral for colposcopy only for cytologically abnormal and HPV-positive cases; extended follow-up intervals (3 to 5 years) for normal, HPV-negative smears; reducion of cytology-alone overdiagnosis; and a decrease in unnecessary colposcopies. Comparison of the three tests showed variable concordance: low agreement between INNO-LiPA and Cobas ($\kappa = 0.116$; $p = 0.001$), moderate agreement between INNO-LiPA and Amplicor ($\kappa = 0.556$; $p = 0.125$), and better agreement between Cobas and Amplicor ($\kappa = 0.667$; $p = 0.250$). Notably, INNO-LiPA demonstrated higher sensitivity but lower specificity compared to Cobas.

Conclusions: The integration of HPV testing into the diagnosis and follow-up of cervical abnormalities in the studied population highlights its potential for significant public health impact, particularly when combined with HPV vaccination. Furthermore, understanding the analytical and clinical performance of various HPV tests is crucial: while some optimize clinical management, others, owing to their high sensitivity, are more suitable for research and epidemiological studies.

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#13608

P36-02 | Cervical cancer: Main determinants of delayed diagnosis and ways to eliminate them

36 - Advocacy, acceptability and psychology

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Background/Objectives: The purpose of the study. Identifying the main causes of advanced cases of cervical cancer, in particular cases delayed by doctors, and developing proposals aimed at eliminating them.

Methods: Materials and methods. The study included 80 women with advanced stage of BPH. Distribution by clinical stage: IIA–B — 40%, IIIA–B — 56%, IVA — 4%. Data are recommended by the World Health Organization (WHO),Data were collected in the form of a questionnaire using the RedCap application, adapted to local conditions. The analysis was conducted on the dimensions of “delay in first presentation”, “delay in diagnosis” and “delay in treatment”. In this thesis, the main focus is on the results on “delay in diagnosis”.

Results: • Which specialist did the patient refer to when the first symptoms appeared? 72% are gynecologists, 5% are general practitioners, 12% are private doctors, 2% are pharmacists, 2% are doctors, and 7% are secondary medical workers.
• How many times did you see a doctor before starting treatment:
86% did not apply at all, 14% applied three or more times.• What was the doctor's recommendation before the final diagnosis was made: Instrumental examinations and biopsy - 68%, later re-application -9%, taking medications -23%.
• Was the patient informed about the treatment process before starting treatment: 58% — "yes", 42% — "no".• The degree of freedom of communication with the doctor about the patient's illness: 40% - "yes", 60% - "no".
• The patient's attendance at the doctor's appointment with his/her relatives: 59% - never, 23% - once, 10% - twice, 8% - three or more times.• Institution where the diagnosis was made: 70% - public hospitals, 30% - private medical institutions.
• Whether the patient was given another diagnosis before the final diagnosis of cancer: 60% - “yes”, 40% - “no”.
• Did the patient have to wait more than 4 weeks to get the biopsy results: 30% - “yes”, 70% - “no”.

Conclusions: Conclusion. The results of the analysis show that the late detection of BLS is greatly influenced by “delayed diagnosis”. The main problems are: 1) General practitioners do not have sufficient knowledge and awareness about the disease.2) Lack of explaining to the patient about the seriousness of the disease, establishing a trusting relationship, and providing psychological support. 3) Obstacles to timely referral of patients to a gynecological oncologist. 4) Deontological problems in the patient-doctor-diagnostic chain.Retraining general practitioners, improving their communication and dental skills, and referring patients to oncology hospitals with urgent referrals are important steps in overcoming these problems.This, in turn, will reduce deaths from CHD, increase treatment effectiveness, and improve women's quality of life.

References:

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#13612

P14-03 | Analysis of high-risk HPV infection trends in women triaged with Anyplex II HPV HR assay and SG STATS platform

14 - Genotyping

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Background/Objectives: Cervical cancer is the fourth most common cancer in women, but its incidence can be effectively reduced through screening and vaccination. Although HPV genotyping is not yet part of the Slovenian National Screening guidelines, it can provide valuable information for gynecologists. The aim of this study was to analyze the results of full high-risk HPV genotyping in Hybrid Capture 2 (HC2)-positive women enrolled in the Slovenian National Screening Program and triaged at the Institute of Oncology Ljubljana (IOL).

Methods: HC2 samples from women triaged at the IOL between January 2023 and October 2025 were included in this study. An aliquot of 300 µL was used for full genotyping (HPV16/18/31/33/35/39/45/51/52/56/58/59/66/68) using the Anyplex II HPV HR Assay (Seegene, South Korea). Statistical analyses of HPV prevalence were performed using the SG STATS platform (Seegene, South Korea).

Results: In total, 1700 samples were included in the analysis, covering the Slovenian regions Gorenjska, Goriška, Jugovzhodna, Obalno-kraška, Osrednjeslovenska, Podravska, Pomurska, Savinjska, and Zasavska. The average number of HPV tests per month was 51, with no significant variation across months or years analyzed. The average annual HPV positivity rates were 85%, 86%, and 86% in 2023, 2024, and 2025, respectively. HPV16 was the most prevalent genotype in all three years, with an average positivity rate of 20.2%, followed by HPV31 at 17.6%. The prevalence of HPV18 and HPV45 remained consistent at 5.1% and 6.2%, respectively, while other HPV types showed a slight increase over time. Approximately half of HPV16-positive cases were single infections (49.5%) and half co-infections (50.5%). However, HPV18 single infections increased over time (44.1%, 51.8%, and 64.0% from 2023 to 2025), while the co-infections decreased (55.9%, 48.2%, and 36.0%, respectively). HPV31 and HPV45 maintained a similar distribution of single (≈40%) and co-infections (≈60%) across the years analyzed.

Conclusions: Analysis of high-risk HPV genotypes provides valuable information on infection trends in women residing in the analyzed regions of Slovenia and can improve future screening and prevention strategies.

References:

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#13617

P39-10 | Empowering Communities for Cervical Cancer Elimination: A Contextual Prevention Model from Rural Namibia

39 - Public health

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Background/Objectives: Despite global progress towards cervical cancer elimination, rural women in Namibia continue to face significant barriers to prevention and early detection. Low screening uptake, limited HPV vaccination coverage, and constrained health system capacity hinder progress towards the WHO 90-70-90 targets. This study sought to develop a context-specific, community-based prevention model for cervical cancer management in the Ohangwena and Kavango West regions of Namibia.

Methods: A sequential explanatory mixed-methods design was employed in four phases. Phase I involved a cross-sectional survey (n = 228) that assessed community knowledge, attitudes, and practices regarding cervical cancer prevention. Phase II explored women's health-seeking behaviours through focus group discussions and in-depth interviews. Phase III examined systemic constraints using the WHO's six health system building blocks. The findings from all phases were synthesised using Chinn and Kramer's theory-generation framework to construct a comprehensive, community-driven prevention model.

Results: Quantitative results revealed that while 94.6% of respondents had heard of cervical cancer, only 41.1% were aware of HPV, and 30.2% knew of the HPV vaccine. Knowledge of risk factors was fragmented, with only 28.9% recognising multiple sexual partners and 11.6% early sexual debut as key risks. Screening uptake remained critically low, with 79.7% of women never screened. Qualitative findings illuminated deep-rooted barriers, including misconceptions that cervical cancer is caused by witchcraft, fear of diagnosis, long distances to health facilities, male partner disapproval, and inadequate outreach. Health-system analysis exposed shortages of trained personnel, weak referral pathways, and irregular supply of screening materials. These insights informed the development of the "Empowerment-to-System Ring Model," which connects systemic enablers (policy, financing, governance, research), immediate enablers (trained workforce, resilient supply chain, digital HIS), and community facilitators (people-centred care, peer support, and traditional-leader engagement) to drive prevention and early detection.

Conclusions: The proposed model provides a structured framework for empowering communities and strengthening local health systems to achieve equitable cervical cancer prevention. Its integration into Namibia's primary healthcare and school health programmes could accelerate progress towards the WHO elimination strategy and offer a scalable approach for other low-resource settings in sub-Saharan Africa.

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#13618

P15-05 | Evaluation of Torque teno virus (TTV) as a potential biomarker of immune status in relation to high-risk HPV infection in cervical samples

15 - Molecular markers

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Background/Objectives: Torque teno virus (TTV) is a small, non-enveloped DNA virus belonging to the human virome and increasingly investigated as a marker of immune status[1-3]. Its replication level has been associated with systemic immunosuppression, but its relationship with mucosal viral infections such as human papillomavirus (HPV) remains unclear. This study aimed to evaluate whether the presence and relative level of TTV DNA in cervical samples were associated with high-risk HPV (HR-HPV) infection, infection multiplicity, or cytological abnormalities.

Methods: A total of 197 cervical samples were retrospectively selected based on HR-HPV results previously obtained in routine testing with the Allplex™ HPV28 assay (Seegene). DNA extracts were subsequently used for TTV quantification with the TTV R-GENE® kit (bioMérieux), with albumin amplification used as an internal control. The relative TTV DNA level was expressed as ΔCt (Ct TTV – Ct albumin). Cytology results were available for 125 samples and were classified according to the Bethesda system as NILM (negative for intraepithelial lesion or malignancy) or cytological abnormalities (≥ ASC-US). Statistical analyses were performed using Chi-square and Mann–Whitney tests (GraphPad Prism version 8.4.3).

Results: TTV DNA was detected in 100/197 samples (50.8%), and HR-HPV in 106/197 (53.8%). Co-detection of both viruses occurred in 52 samples, and no association was found between the detection of TTV and HR-HPV ($\chi^2 = 0.27$, $p = 0.61$; RR = 0.93 [95% CI: 0.72–1.21]). Among TTV-positive samples, ΔCt_TTV–Albumin values did not differ between HR-HPV–positive and -negative samples (median 10.26 [IQR 7.68–12.22], n = 52, vs 9.20 [IQR 7.24–10.88], n = 48; $p = 0.12$, Mann–Whitney test). Similarly, ΔCt_TTV–Albumin values were comparable between single (n = 37) and multiple HR-HPV infections (n = 15), with median values of 10.37 [IQR 8.06–11.99] and 9.29 [IQR 6.84–12.30], respectively ($p = 0.61$, Mann–Whitney test). Among TTV-positive samples, cytology results were available for 65 cases. No significant difference in ΔCt_TTV–Albumin was observed between NILM and abnormal cytology (median 10.71 [IQR 8.65–14.22] for NILM, n = 6, vs 9.51 [IQR 6.84–11.75] for abnormal cytology, n = 59; $p = 0.28$, Mann–Whitney test), although the number of NILM samples was limited.

Conclusions: TTV detection and relative DNA levels were not associated with HR-HPV infection, the number of HR-HPV genotypes, or cytological abnormalities. These findings suggest that HPV infection status is not influenced by local TTV replication in the cervix. The role of TTV as a biomarker of local immune modulation in HPV-related disease remains to be clarified. Larger studies combining local and systemic TTV quantification with host immune parameters are warranted to determine whether TTV load reflects mucosal immune competence in the female genital tract.

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#13628

P14-04 | High-Risk Human Papillomavirus (HPV) Genotype-Specific Distribution in HPV-Positive Women from Southern Croatia, using full genotyping

14 - Genotyping

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Background/Objectives: Infection with Human Papillomavirus (HPV) is the main cause of cervical cancer and it can be proven in 99.7% of all cervical malignancies. 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 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. PCR tests of the second generation enable individual genotyping for HPV-16 and HPV-18 and pooled detection of “other hrHPVs”. But nowadays, it is clear that there are significant differences in the importance of individual genotypes that are included in the pool, and that certain HPV genotypes classified in the "other high-risk types" group have a significantly higher risk of developing ≥CIN3 than others in that group. New researches advocate the introduction of extended and full genotyping in additional risk stratification of HPV-positive women. According to the latest knowledge, the results of HPV genotyping can be classified into four groups according to the risk for the development of cervical cancer. In previous studies for our county, we examined the distribution of HPV genotypes only for HPV-16 and -18 and pooled “the others”.The aim of this study was to assess the genotype-specific distribution of high-risk HPV among HPV-positive women from Southern Croatia.

Methods: A retrospective study encompassed a total of 1,211 HPV-positive women residing in Split and Dalmatia County, whose samples were collected in a one-year period between 2023 and 2024 in an outpatient setting at the Teaching Institute for Public Health of Split and Dalmatia County. For HPV genotyping, the Allplex™ HPV HR Detection assay was employed. This multiplex PCR test simultaneously amplifies and identifies individually nucleic acids from 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68), along with an internal control, in a single reaction.

Results: In this study, in one-year period, a total of 3,098 women were tested for high-risk HPV, with 1,211 (39.09%) of them being positive. Out of the total number of HPV-positive women, the most frequently detected genotypes were HPV-16, HPV-31 and HPV-51.

Conclusions: This study contributes to better understanding of HPV epidemiology. he results support the expansion of national cervical cancer screening programs to include extended genotyping for high-risk HPV types beyond those covered by current vaccines. The high prevalence of non-vaccine genotypes underscores the need to monitor shifts in genotype distribution that may impact long-term vaccine effectiveness.
Furthermore, extended genotyping is considered to provide clinically important information for further procedures, i.e., implementation of appropriate treatment for the appropriate risk of developing HSIL lesions that a particular HPV genotype has. These findings may help in better organization of cervical cancer screening.

References:

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#13635

P29-06 | Prevalence and genotypic distribution of human papillomavirus (HPV) in the oral cavity of transgender women in Women in Central Brazil

29 - HPV and oropharynx / Head and neck cancer

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Background/Objectives: Transgender women are highly susceptible to sexually transmitted infections, including those caused by the human Papillomavirus (HPV). HPV is responsible for several pathological manifestations and associated with skin and mucous lesions in different sites in the body, including the oral cavity and oropharynx. However, specific epidemiological data for the transgender population are very limited. Objective: The present study aimed to estimate the prevalence and genotypic distribution of HPV in the oral cavity in transgender women and to identify sociodemographic characteristics and behaviors associated with the infection.

Methods: The study was approved by the Research Ethics Committee of the Federal University of Goiás, with decision number 4,633,951. This is a cross-sectional study that evaluated a group of 270 transgender women in Goiânia, Goiás, from 2018 to 2020. Sampling was carried out through Participant Driven Sampling (RDS). All participants were interviewed using a structured questionnaire with questions about sociodemographic characteristics and behavioral sexual risk factors. Oral cavity samples were self-collected by the participants and analyzed for the presence and genotyping of HPV DNA, using the polymerase chain reaction and the commercial Inno-Lipa HPV Genotyping Extra II kit (Fujirebio). Bivariate and multivariate analyzes were performed to identify factors associated with HPV infection, using the Statistical Package for the Social Science (SPSS) and the Respondent Driven Sampling Analysis Tool (RDSAT)

Results: A total of 270 transgender women participated in the study. Their median age was 25 years (interquartile range: 20.5-29.5 years). Most participants were single (85.5%) and had engaged in sex work in their lifetime (58.6%). The prevalence of HPV in the oral cavity of transgender women was 10.8% (95% CI 5.8-17.1 of 95%), high-risk HPV was detected in 4.6% of the cases (95% CI 1.5-8.6%), low-risk HPV in 3.3% (95% CI 0.9-6.7%) and the prevalence of co-infections with multiple genotypes was 5.0% (95% CI 1.1-13.1%). Among HPV-positive cases, the most prevalent genotype was HPV66 (14.8%), followed by HPV16, HPV83, HPV55 and HPV62, with 11.1% each. Multivariate analysis demonstrated that education up to nine years (p=0.002), sexual practices exclusively with men (p=0.038) and history of STI (p<0.0001) were significantly associated with HPV infection in the oral cavity of transgender women

Conclusions: Based on the results obtained, a high prevalence of HPV was observed in the oral cavity of transgender women, highlighting the associations between the infection and low education level, sexual practices exclusively with men and a history of previous STIs. Health interventions are necessary, including educational measures that enable the prevention, diagnosis, and treatment of sexually transmitted infections in transgender women.

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#13637

P03-04 | Prevalence of HPV genotypes in Brazilian women with cervical cancer and cervical intraepithelial neoplasia: A systematic review and meta-analysis

03 - Epidemiology and natural history

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Background/Objectives: Background/objectives: Cervical cancer screening in Brazil is changing, shifting from the Pap smear (cytology) to HPV-DNA test. Understanding regional hrHPV genotype distribution in a continental country as Brazil is essential for evaluating vaccine effectiveness and to monitor population-based screening. The objective of the present study is to estimate hrHPV genotype prevalence in cervical intraepithelial neoplasia (CIN2/3) and invasive cervical cancer (ICC) in Brazilian women, in the last 15 years.

Methods: Methods: This is a systematic review conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines and registered in PROSPERO (International Prospective Register of Systematic Reviews). The search was performed in the PUBMED database, in December 31rst 2024, using the terms: *cervical cancer AND HPV AND Brazil NOT review*. Initially, 526 studies were identified. After screening, 21 studies were selected - 17 studies evaluated invasive cervical cancer (ICC) and 14 investigated CIN2/3, with nine studies addressing both ICC and CIN2/3. The studies were published in 2010 to 2024, and HPV prevalence and genotyping data were combined in a meta-analysis.

Results: Results: The selected studies included 2,498 ICC patients, with a pooled HPV prevalence of 96.0%. In the ICC cases, HPV16 was the most frequent genotype (62.2%), followed by HPV18 (12.9%), HPV45 (4.1%), HPV33 (3.7%), and HPV31 (4.0%). Regarding CIN2/3, 2,230 patients were included in the analysis, and the pooled HPV prevalence was 97.0%. HPV16 was the most frequent genotype (56.0%) in NIC2/3, followed by HPV18 (11.0%), HPV31 (4.8%), HPV33 (3.7%), and HPV52 (2.6%). PCR-based methods were used in all the included studies. A heterogeneous distribution of the studies was observed according to the geographical regions, with only one study in the North region of the country, the region with the highest cervical cancer incidence in Brazil.

Conclusions: Conclusion: Our study corroborates the high prevalence of HPV16 and HPV18 in ICC and CIN2/3 in Brazilian women, however, the proportion of the further three most common genotypes was different in the two conditions, with HPV45 replacing HPV52 in ICC, reinforcing the inclusion of non-HPV16,18 high risk genotypes in cervical cancer screening and vaccination programs. Since the quadrivalent vaccine is adopted by the public health system in Brazil, our findings reinforce the importance of vaccination as a preventive strategy against cervical cancer, with an estimated efficacy of approximately 75.0%. Furthermore, the scarcity of studies on HPV prevalence in certain regions of the country highlights the need for further research in this area.

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#13649

P18-08 | Characteristics of vaginal microbiota in high-grade squamous intraepithelial lesions of the uterine cervix for patients following eubiosis maintenance protocol

18 - Microbiome

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Background/Objectives: Cervical cancer is mainly caused by persistent high-risk HPV infection. However, the mechanisms associated with persistence of HPV infection remain poorly understood and appear to be multifactorial. Notably, Lactobacillus-dominated vaginal microbiota has been associated as protective effect against HPV persistence. This study aims to associate the maintenance of vaginal eubiosis with the evolution or remission of precursor lesions and/or HPV clearance.

Methods: 153 women diagnosed with high-grade squamous intraepithelial lesions and undergone to LEEP have been followed during 6 months, and colposcopy, HPV genotyping and vaginal microbiota analysis was performed. Participants were randomized in 2 groups: Group 1, women who were followed in standard protocol of Prevention Department of Barretos Cancer Hospital; Group 2, women who were followed in maintenance of vaginal eubiosis protocol, including follow-up with gram stain every 2 months, and treatment of any dysbiosis. Molecular analysis of vaginal microbiota content and HPV test were performed for both groups.

Results: Around 25% of patients are smokers for both groups, and no statistical difference in sociodemographics and clinicopathological characteristics were observed. Eubiosis state was analyzed in group 1 by Gram stain, and only 53.8% of participants showed *Lactobacillus*-dominated microbiota. Molecular analysis of vaginal microbiota from 38 patients (19 patients for each group) showed the CST I/II profiles (*Lactobacillus crispatus* or *L. gasseri*-dominated microbiota) in about 20% of patients, and around 45% CST IV (*Lactobacillus*-depleted microbiota) for both groups in initial moment (M0). The detection of HPV 16 showed 50% of the CST IV profile whereas 16.7% of CST I. After 6 months (M6), of those patients who followed the standard protocol, 21.1% were CST IV, and 79% were CST I/II. For group that followed maintenance of vaginal eubiosis protocol, we found 10.5% of CST IV, and 26.4% of CST I/II. At M6, 78.4% of HPV infection was cleared, and it was observed the presence of CST III (*L. iners*-dominated microbiota) in 62.5% and 53.9% of those cases with no HPV detection for group 1 and 2, respectively.

Conclusions: This study showed a population in homogeneity in the initial moment and CST IV dominated, that changed the CST profile 6 months after LEEP. We found higher reduction of CST IV profile in group that followed maintenance of vaginal eubiosis protocol. The impact of eubiosis maintenance in HPV clearance is still ongoing.

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#13668

P06-04 | Safety and immunogenicity of concomitant first dose of 2-dose regimens of 9-valent HPV and mRNA-1273 vaccines in children aged 9-11 years

06 - HPV prophylactic vaccines

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Background/Objectives: This open-label, phase 3 study (NCT05119855) was conducted to evaluate the safety and immunogenicity of concomitant administration of the 9-valent HPV (9vHPV) and mRNA-1273 COVID-19 vaccines in unvaccinated, sexually naive children aged 9-11 years. This is the first clinical study to evaluate the coadministration of a recombinant subunit HPV vaccine and an mRNA COVID-19 vaccine in the pediatric setting.

Methods: Children aged 9-11 years were randomly assigned 1:1 to receive the first dose of both 2-dose regimens of the 9vHPV and mRNA-1273 vaccines concomitantly on Day 1, then the mRNA-1273 vaccine at Month 1 and the 9vHPV vaccine at Month 6, or non-concomitantly (mRNA-1273 vaccine on Day 1 and Month 1, 9vHPV vaccine at Months 2 and 8). Primary immunogenicity endpoints were geometric mean titers (GMTs) of serum antibodies to 9vHPV vaccine-targeted types and geometric mean concentration (GMC) of SARS-CoV-2 spike protein-specific binding antibody 4 weeks after dose 2 of the 9vHPV and mRNA-1273 vaccines, respectively. Antibody responses were assessed at 4 weeks after dose 2 for each vaccine by use of the competitive Luminex immunoassay for the 9vHPV vaccine and an electrochemiluminescence assay to assess SARS-CoV-2 spike antibodies for the mRNA-1273 vaccine. Injection site and systemic adverse events (AEs) were collected for 28 days after each vaccination; serious AEs were collected throughout the study.

Results: Between March 2022 and March 2023, 165 participants were enrolled (concomitant, n = 82; non-concomitant, n = 83). Four weeks after dose 2, GMT ratios (concomitant vs non-concomitant) were 1.20-1.45, with the lower bound of associated 95% CIs ranging from 0.91-1.13 across the 9vHPV vaccine–targeted HPV types; the SARS-CoV-2 spike antibodies GMC ratio was 1.17 (95% CI, 0.99-1.40). Seroconversion was 100% for the 9vHPV vaccine and seroresponse was ≥95% for the mRNA-1273 vaccine in the 2 cohorts at 4 weeks after dose 2. Percentages of participants with injection site and systemic AEs after the first dose were 54.3% and 33.3% for the concomitant group and 56.8% and 44.4% for the non-concomitant group. No serious AEs were observed.

Conclusions: Concomitant administration of the first dose of the 9vHPV and mRNA-1273 vaccines was generally well tolerated and did not impair the antibody response to either vaccine.

References:

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#13676

P23-03 | HPV Test Clearance after LEEP in Women with High-Grade Squamous Intraepithelial Lesions and Its Association with Persistence and Recurrence

23 - Risk management

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Background/Objectives: In Brazil, cervical cancer is the third most common cancer, and its carcinogenesis is associated with persistent infection by oncogenic types of Human Papillomavirus (HPV). The purpose of screening programs is to detect cervical intraepithelial neoplasia (CIN). Patients diagnosed with high-grade squamous intraepithelial lesions (CIN 2, CIN 3, or CIN 2/3) typically undergo a Loop Electrosurgical Excision Procedure (LEEP) and are subsequently followed up to monitor for residual or recurrent disease. HPV detection tests routinely used in screening have also been employed in post-treatment follow-up, underscoring the need to standardize their indications and testing intervals. This study aims to evaluate HPV infection clearance among women who underwent excisional procedures (LEEP) for treatment of precursor lesions and to identify factors associated with disease persistence or recurrence.

Methods: This study is a retrospective cohort including women who underwent LEEP at the Cancer Prevention Department of Barretos Cancer Hospital between 2014 and 2024. Women aged over 25 years who tested positive for high-risk HPV and had a precursor lesion confirmed by LEEP. All patients have at least one HPV DNA test during the follow-up. All data were recorded in the RedCap database.This study is a retrospective cohort including women who underwent LEEP at the Cancer Prevention Department of Barretos Cancer Hospital between 2014 and 2024. Women aged over 25 years who tested positive for high-risk HPV and had a precursor lesion confirmed by LEEP. All patients have at least one HPV DNA test during the follow-up. All data were recorded in the RedCap database.

Results: A total of 1,631 women aged 25 to 77 years were evaluated, the mean age was 39 years and 16.4% were smokers, and 47.7% had HPV16 and/or HPV18 detected (either as single or co-infections). Based on histological classification, 19.6%, 71.7%, and 8.7% of the women were diagnosed with CIN2, CIN3, or unspecified CIN2/3, respectively. The overall rate of persistence or recurrence of precursor lesions after treatment was 6.3%. Among cases with negative surgical margins (66.5%), only 2.86% underwent an additional excisional procedure and CIN2+ detected in 1.38%. In contrast, among the group with positive margins (31.7%), 24.76% underwent at least one additional treatment with CIN2+ detected at 17.02%. Six months after LEEP, 79% showed no detectable HPV infection. Regarding HPV type, CIN2+ was detected in a subsequent treatment in 9.25% of cases initially positive for HPV16 and/or HPV18, whereas only 3.99% of women with other HPV types showed CIN2+ in follow-up procedures.

Conclusions: As previously described in the literature, positive surgical margins and the presence of HPV16 and/or HPV18 are associated with an increased risk of recurrence and persistence. Further analyses to assess the impact of these variables may contribute to clinical practice by influencing the management and outcomes of women with precursor lesions who are followed up after excisional treatment.

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#13696

P11-03 | Urine HPV Testing for Cervical Cancer Screening Among Malaysian Women - Feasibility and Accuracy

11 - Screening for women difficult to reach

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Background/Objectives: Background:Persistent infection with high-risk human papillomavirus (hr-HPV) remains the primary cause of cervical cancer worldwide, including in Malaysia. Although HPV DNA testing offers high sensitivity, screening uptake is hindered by its invasive nature and sociocultural barriers linked to clinician-collected sampling. Urine-based self-sampling presents a simple, acceptable, and non-invasive alternative. This study evaluated the diagnostic accuracy and feasibility of hr-HPV DNA detection in self-collected urine processed using the SEDIPREP® pre-concentration method, compared to clinician-collected cervical samples tested on the Cobas® 4800 HPV platform.

Methods: Methods:
In this cross-sectional study, paired urine and cervical samples were obtained from women referred to colposcopy clinics following abnormal Pap smears. Urine samples were pre-processed using the SEDIPREP® device and both sample types were tested for hr-HPV DNA using the Cobas® 4800 system.

Results: Results:
Of 166 paired samples, 99 yielded valid results. Initial invalid urine tests due to double filtration improved markedly after switching to single filtration. Among valid pairs, urine-based hr-HPV testing achieved 93.9% sensitivity and 95.5% specificity, demonstrating excellent concordance with cervical sampling ($\kappa = 0.887$). ROC analysis showed an AUC of 0.836, confirming strong diagnostic performance.

Conclusions: Conclusion:
Urine self-sampling using the SEDIPREP® method is a highly accurate, feasible, and patient-friendly approach for hr-HPV detection. Its strong agreement with cervical testing and non-invasive nature underscore its potential to transform HPV screening uptake, particularly in culturally sensitive and resource-limited settings.

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P27-01 | Concordance and acceptability of self- vs. clinician-collected anorectal swabs for HPV genotyping in gay, bisexual and other men who have sex with men

27 - Anal neoplasia

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Background/Objectives: Squamous cell carcinoma of the anus (SCCA), linked to high-risk human papillomavirus (HR-HPV) genotypes, is a growing concern among gay, bisexual, and other men who have sex with men (GBMSM) and transgender women (TW), particularly those living with HIV. Early detection of precursor lesions is crucial, yet current screening methods face limitations. Anal self-sampling has emerged as a promising patient-centered alternative. The aSELF-GEN study aims to evaluate the diagnostic accuracy and feasibility of self-collected anal swabs for HPV genotyping compared to clinician-collected swabs among GBMSM and TW.

Methods: We conducted a cross-sectional, multicenter study in STI/HIV and anal screening units at three hospitals of the metropolitan area of Barcelona. GBMSM and TW were invited to participate. Sampling kit (FLOQSwabs®, Smart-eNAT vial, and instructions) was provided to participants for self-collection sampling. Clinicians then collected a second anal sample using an identical kit. Upon arrival at the laboratory, self-samples were divided into two aliquots: one was processed alongside clinician-collected samples, and the other was incubated at 30ºC for 15 days to assess sample stability. HPV-DNA extraction and genotyping were performed using the STARlet-AIOS™ platform and Allplex-HPV28 assay which performs extended genotyping of 28 HPV genotypes. Clinician-collected samples served as the reference standard. Diagnostic performance (sensitivity, specificity) and concordance (overall HPV, HR-HPV, HPV16, HPV18, HPV6/11, and vaccine-types) were evaluated using McNemar's test and Cohen's κ. Feasibility and acceptability of anal self-sampling was assessed with a questionnaire answered by participants after self-sampling. A model with five dimensions (learnability, willingness, suitability, satisfaction and efficacy) scoring from 1 to 5 was used.

Results: A total of 151 participants were enrolled (median age 43 years); 53.0% were living with HIV. Only one invalid self-collected sample was obtained, indicating excellent sample adequacy. Overall HPV detection was similar between self- and clinician- collected samples (89.9% vs. 92.6%). Concordance across HPV groups was moderate to strong (> 88% agreement, $\kappa > 0.69$). Overall HPV agreement reached 96.0% (95% CI: 91.5-98.1), with a κ of 0.75 (95% CI: 0.55-0.94), and no significant differences between methods (p=0.22). For HR-HPV and HPV16, agreement was also high (90.6 (95% CI: 84.8-94.3) and 96.4% (95% CI: 91.8-98.4), respectively), with strong κ values (0.77 (95% CI: 0.65-0.88) and 0.88 (95% CI: 0.78-0.97)), and no significant differences (p=0.42 and p=0.68). For overall HPV detection, sensitivity of self-sampling was 96.4% (95% CI: 91.8-98.4), and specificity 90.9% (95% CI: 62.3-98.4), with similar performance for HR-HPV and HPV16 types. HPV-DNA remained stable after 15 days at 30°C, showing excellent concordance between fresh and incubated self-samples (agreement 95.0-98.6%; $\kappa = 0.87$-0.96). Participants rated self-sampling very positively across all domains, with mean scores ranging from 4.4 to 4.8 on a 1–5 scale, resulting in a total score of 23.2/25.

Conclusions: Anal self-sampling shows high accuracy and strong feasibility, supporting its use as a viable and user-friendly strategy to enhance HPV screening in key populations at risk for SCCA.

References:

aSELF-GEN

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#13776

P11-04 | Structured Implementation of Cervical Cancer Screening & Dysplasia Treatment in Ghana: Implementing Sustainable care in a low-resource setting

11 - Screening for women difficult to reach

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Background/Objectives: Cervical cancer remains a leading cause of mortality among women in low-income and middle-income countries (LMICs) (1). Effective prevention requires sustainable models of clinical interventions with robust organization (2). The CARCISCAN project in Ghana, integrates high-risk HPV (hrHPV) self-sampling with midwife-led colposcopy for cervical cancer screening (3).

Methods: A structured, phase implementation model was developed at Holy Family Hospital, Techiman. A coordination unit linked local gynaecology, public health, and laboratory services. In 2024 (February-October) 1,000 women (30–65 years) were invited to perform self-sampling using COPAN© FLOQswabs (hrHPV 16, 18, and 45). HPV-positive women are referred for colposcopy and retested in 6 months, while HPV-negative women are retested after 3 years. Community engagement and patient input shaped communication tools and educational materials.

Results: Key organizational steps included:
Preparation (July 2023): Site assessment, needs analysis, team assembly, financial planning, community engagement, crowdfunding, and equipment procurement.Regulatory & Training Phase (February 2024): Ethical approval secured; room setup; 8-week intensive colposcopy training with medical superivisionClinic Launch (March 2024): Introduction of hrHPV self-sampling kits, PCR equipment, opening of the outpatient screening clinic – including a questionnaire, capturing socio-demographics, gynecologic history, prior screening and treatment, vaccination status, contraception, and acceptability of self-sampling.Pilot Screening (April 2024): Recruitment of 1,000 women for hrHPV self-sampling. Positive cases were referred to midwife-led colposcopy with – if needed – immediate thermocoagulation (“see and treat” algorithm). Ongoing patient tracking and data registration.October 2025: LLETZ/LEEP-excision teaching introduced to expand treatment capabilities. Outreach in 3 different villages in the Region offering free hrHPV Self-Sampling to 1500 women, mobile colposcopy and counselling to more than 300 women in 5 days. Key organizational features supporting sustainability included integration within existing health infrastructure and targeted midwife training, which enabled independent performance of colposcopy and ablation without reliance on specialists. The delegation of responsibility and establishment of a dedicated midwife-led department enhanced staff motivation and operational focus. Integrated patient tracking ensured timely laboratory turnaround, adherence to follow-up, and data linkage across services. Community engagement and the development of patient-centered education improved acceptability, reinforcing the program’s long-term sustainability.

Conclusions: The CARCISCAN project demonstrates that a structured, phased, and locally coordinated implementation model can sustainably integrate hrHPV self-sampling and midwife-led colposcopy into low-resource health systems. By detailing operational timelines, training strategies, workflow design, and community engagement, it provides a replicable blueprint for prevention programs in similar contexts. Sharing these insights contributes to the scientific community’s understanding of how targeted interventions can be effectively and sustainabily embedded within existing health structures, accelerating progress toward the WHO 2030 elimination goals for cervical cancer (4).

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P09-08 | Novel HPV Reference Materials Representing Normalized Viral Load for Use in Assay Validation

09 - HPV testing

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Background/Objectives: Quantifying HPV DNA copy number is a critical metric for understanding viral dynamics, genome integration, and oncogenic risk. However, reliable reference materials for validating second-generation assays remain scarce. This study evaluates prototype reference materials with normalized HPV copy number (QUANTDx) designed to mimic distinct infection stages—Latent (1 copy/cell), Medium (10 copies/cell), and Productive (100 copies/cell)—to ensure accurate risk stratification and reproducible assay performance across platforms1,2,3.

Methods: Methods Three QUANTDx prototypes with HPV52 and human cells representing Latent, Medium, and Productive infection states were prepared and further diluted in ThinPrep PreservCyt (for internal testing) or BD SurePath (for external testing) to simulate specific clinical cellularity profiles: 1:10 (poor), 1:100 (low), and 1:1000 (extremely low).
Internal Testing: DNA was extracted using the MagMax™ Viral/Pathogen Kit. Detection was performed on the Seegene Allplex™ HPV28 platform (L1 target + human housekeeping gene).
External Validation: Samples were tested using the BD Onclarity™ HPV assay on the BD ViperLT™ platform (E6/E7 target+ human housekeeping gene).

Results: Both assays demonstrated high sensitivity for detecting different HPV 52 infection stages. Medium and Productive stages were resolved down to extremely low cellularity. Latent infection was consistently detected at low cellularity (1:100) but dropped at extremely low levels (1:1000), confirming the expected viral-to-cell ratio in the sample. Notably, both assays exhibited no cross-interference between targets or infection stages, confirming consistent performance and independent titration of HPV52 and HBB markers.

Conclusions: QUANTDx HPV 52 normalized reference materials provide a robust framework for benchmarking assay performance across diverse disease states and sample qualities. By validating the co-detection of housekeeping genes (HBB) and HPV 52 targets at predefined ratios, these reference materials define essential criteria for sample adequacy and establish the minimum quality and quantity required for reproducible results. This enables refinement of target cut-offs for identifying true negatives, thereby strengthening diagnostic confidence, enhancing clinical triage accuracy, and improving patient management.

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P11-05 | Participation after Implementation of Self-sampling in Cervical Cancer Screening among Long-Term Non-Attenders (LTNAs) with Severe Mental Illness in Stockholm

11 - Screening for women difficult to reach

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Background/Objectives: Cervical cancer prevention depends on high participation in organised screening. Long-term non-attenders (LTNAs) remain at increased risk, and women with severe mental illness diagnoses (SMIDs) tend to participate less in screening and HPV vaccination (Hu et al., 2023, 2024). Self-sampling was introduced in Sweden in 2019 to improve LTNA participation. This study examined whether self-sampling reduced participation disparities between LTNAs with and without SMIDs, and whether associations differed across individual psychiatric diagnoses.

Methods: A cohort study was conducted using linked data from the Swedish National Cervical Screening Registry, National Patient Register, and Total Population Register (2000–2023). LTNAs aged 33-70 with no screening test in the previous 10 years were included if invited to self-sample between 2019-2022. SMIDs were identified using ICD-10 codes and analysed as an overall exposure and as individual diagnoses. The primary outcome was participation following invitation. Logistic regression estimated associations between SMIDs and participation, adjusting for age, education, and birth region. Kaplan-Meier curves assessed participation timing.

Results: The cohort included 51,177 LTNAs, of whom 8,546 (17%) had at least one SMID. Overall participation was 14%. LTNAs with SMIDs had lower odds of participating than those without (13% vs 14% adjusted OR 0.90, 95% CI 0.84-0.97). Increasing SMID burden was associated with reduced participation (from 12.9% to 8.3%, adjusted OR per additional SMID 0.95, 95% CI 0.91-0.98). Associations varied across diagnoses: schizophrenia showed markedly lower participation (8.1%, adjusted OR 0.55, 95% CI 0.45-0.67), and bipolar disorder and intellectual disabilities also showed reduced odds. No significant differences were seen for depression, substance use disorders, ADHD, borderline personality disorder, or antisocial personality disorder. Participation timing was similar between groups until approximately two months post-invitation, after which participation declined more rapidly in the SMID group.

Conclusions: Self-sampling was associated with increased engagement among LTNAs, but participation remained lower among women with SMIDs, particularly schizophrenia, bipolar disorder, and intellectual disabilities. When SMIDs were grouped together, effect sizes were small, yet diagnosis-specific differences were substantial. These findings highlight the need for targeted strategies addressing the distinct barriers faced by different SMID groups to reduce inequalities in cervical screening and support cervical cancer elimination efforts.

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The Isala project and beyond: vaginal microbiome patterns and preliminary mechanistic insights into Lactobacillus-mediated HPV protection

18 - Microbiome

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Background/Objectives: The relationship between the human vaginal microbiota and HPV infection remains insufficiently understood. Epidemiological evidence increasingly suggests that Lactobacillus-dominated communities are linked to reduced HPV acquisition and more efficient viral clearance, whereas alternative microbial profiles are associated with viral persistence and elevated cervical cancer risk 1,2. Early interventional studies further indicate that Lactobacillus-based probiotics may support HPV clearance and promote a protective microbiome 3, although the underlying mechanisms remain unclear, partly due to limitations of existing animal models. This work aims to characterize vaginal microbiome diversity at population scale and to identify microbial mechanisms that may influence HPV infectivity.

Methods: Through the Isala platform in Belgium, launched in 2020, we profiled the vaginal microbiome of 3,345 healthy women 4. Community composition was assessed to identify dominant taxa, co-occurrence patterns, and microbial modules. Associations with HPV vaccination status were evaluated. In parallel, culturomics was used to isolate *Lactobacillus* strains for mechanistic studies 5. Genetic engineering enabled the construction of a capsular saccharide mutant to investigate the role of exopolysaccharides (EPS) in host–microbe interactions (Croatti et al., in review). Functional assays were performed using vaginal and cervical cell models, with future evaluation planned in advanced cervico-vaginal systems, including optimized vagina/cervical-on-chip platforms.

Results: More than 75% of samples were dominated by *Lactobacillus* taxa, primarily *L. crispatus* and *L. iners*. Co-dominance of these species in 15% of participants suggests a continuum of community states rather than discrete clusters. Microbial taxa grouped into modules dominated by *L. crispatus*, *L. iners*, *Gardnerella*, *Prevotella*, *Anaerococcus*, and gut-associated species. HPV vaccination correlated with reduced abundance of the *Gardnerella* module, highlighting unresolved questions regarding the directionality between HPV infection and vaginal dysbiosis 4. Culturomics yielded candidate *Lactobacillus* strains, and EPS-deficient mutants demonstrated that EPS modulates bacterial adhesion and immune balance in vaginal cells, enhancing chemotaxis and reducing tissue degradation, features potentially counteracting HPV infection and immune evasion (Croatti et al., in review). Preliminary experiments further indicate that lactobacilli can suppress expression of HPV oncogenes *E6* and *E7* in cervical cells.

Conclusions: Isala constitutes the largest population-based dataset on vaginal microbiome diversity to date. By integrating community profiling, strain isolation, and functional modeling, this work advances understanding of microbiome-mediated mechanisms involved in HPV clearance. These insights will support the development of *Lactobacillus*-based diagnostics and therapeutic strategies for persistent HPV infections.

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#14256

P03-06 | Long-term hormonal contraceptive use and risk of high-grade cervical lesions in women with high-risk human papillomavirus: a retrospective cohort analysis

03 - Epidemiology and natural history

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Background/Objectives: While high-risk human papillomavirus (HPV) is the main cause of cervical intraepithelial neoplasia (CIN), cofactors influencing progression to high-grade disease remain poorly identified. This study aimed to investigate the association between long-term oral contraceptive use and the risk of high-grade CIN (grade 2/3) in a high-risk HPV positive referral population.

Methods: A retrospective analysis was conducted on the records of 684 women screened at a specialized gynecologic oncology clinic (2019-2024). Data on oral contraceptive use (≥5 years), high-risk HPV status, age, and smoking history were extracted. The primary outcome was CIN grade. To mitigate bias from sparse data, Firth-penalized logistic regression was used to calculate adjusted ORs (aOR) for the association between long-term oral contraceptive use and CIN grade.

Results: Long-term oral contraceptive use was reported by 5.6% of the cohort. After adjusting for confounders, long-term oral contraceptive use was strongly associated with a 16.8-fold increased odds of high-grade CIN (aOR 16.79, 95% CI 3.82 to 73.70, $p <$ .001). However, the wide CI indicates significant statistical uncertainty in the magnitude of the effect. Conversely, oral contraceptive use was associated with significantly lower odds of low-grade CIN (aOR 0.04, 95% CI 0.01 to 0.15, $p <$ .001).

Conclusions: In this high-risk population, long-term oral contraceptive use is a significant independent risk factor for high-grade cervical lesions, while paradoxically being associated with a lower risk of low-grade disease. This suggests an important role for hormonal factors in the progression of cervical neoplasia. Clinicians might consider long-term oral contraceptive use a key risk indicator in HPV-positive women and incorporate this modifiable factor into patient counseling.

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#14349

P13-08 | Maintaining Continuity of Community HPV Self-Sampling and Result Tracking in Disrupted Operating Environments

13 - Self-sampling

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Background/Objectives: Cervical cancer prevention is acknowledged as a global public health priority by WHO in 2018. Support and international funding was secured for a community HPV self-sampling project in the Amharic North Zone of Gondar in Dec 2019. The project implementation faced diverse challenges due to health and socio-political emergencies as well as bureaucratic barriers. We here describe the impact on the follow-up examination and solutions.

Methods: Trained study field workers paired with health extension workers to systematically visit the homes of 25 to 64 years old women in 6 kebele (neighborhood) of Gondar. Self-collected HPV samples using Evalyn brush were analyzed on cobas 4800 platform at EPHI laboratory in Addis. Study data were captured and managed on cloud-based digital information system which included contact details. HPV results were communicated by phone and if unsuccessful by home visits facilitated by GPS location taken on sampling visit. HPV positive women are currently invited for triage examination using colposcope, LBC sample, and treatment preceded by biopsy.

Results: Between 02 June and 16 Jul 2022 3146 self-samples were collected and sent to EPHI laboratory. In Dec 2024 -after 30 months-HPV test results were released which contained 283 positive HPV tests. 113 (40%) of HPV positive women were contacted by phone of which 81 scheduled a triage examination. Between Oct and Nov 2025 176 women were visited at their home based on GPS of which 103 were scheduled for a triage examination. All together, at follow-up 30-40 months after enrollment 85 women had an outdated contact information and additional 43 women did not have a study triage examination, mainly due to change of residence or having been tested elsewhere. Only 8 women refused triage. Currently triage examinations are in progress expected to be completed by January 2026

Conclusions: Home-based HPV self-sampling is an effective and well-accepted cervical cancer screening method. Timely triage examination of HPV positive women is essential and when phone contact failed, GPS-recorded sampling location enabled successful follow-up to deliver results even after three years.

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#14436

P09-09 | Analytical Agreement Between the SD Biosensor STANDARD M10 Hr-HPV Assay and the RIATOL qPCR Genotyping Test Applied to Channel-Specific hrHPV Detection

09 - HPV testing

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Background/Objectives: High-risk human papillomavirus (hrHPV) testing is central to cervical cancer screening. The SD Biosensor STANDARD M10 Hr-HPV assay is a novel, fully automated cartridge-based molecular test designed for broader accessibility, including decentralized settings. The STANDARD M10 Hr-HPV assay allows detection of 14 HR-HPV types, organized into eight subgroups: HPV16, HPV18, HPV45/59, HPV33/52/58, HPV31/35, HPV39/68, HPV56/66, and HPV51. This design provides a high level of genotyping detail, facilitating precise identification of clinically relevant HPV infections.This study aimed to evaluate the analytical performance of the STANDARD M10 Hr-HPV assay against the established RIATOL real-time qPCR HPV full genotyping assay. The primary objective was to assess analytical agreement between assays for overall hrHPV detection and across individual genotype-specific channels.

Methods: Residual cervical samples previously tested with the RIATOL assay were reanalyzed using the SD Biosensor STANDARD M10 Hr-HPV assay. For each detection channel—including HPV16, HPV18, and grouped hrHPV genotypes—2×2 contingency tables were constructed. Positive, negative, and overall percent agreement were calculated. Cohen's kappa coefficients with 95% confidence intervals were used to assess agreement with standard thresholds. McNemar's test was applied to evaluate systematic discordance between assays.

Results: For overall hrHPV detection, the SD Biosensor assay demonstrated almost perfect agreement with RIATOL, with a Cohen's kappa of 0.88. Genotype-specific analysis showed perfect agreement for HPV16 (κ=1.00) and almost perfect agreement for HPV18 (κ=0.86). Among grouped channels, agreement remained high: G2 (HPV33/52/58) and G3 (HPV31/35) both showed kappa values of 0.93, while G1 (HPV51) and G4 (HPV45/59) also demonstrated almost perfect agreement (κ=0.81 and κ=0.92, respectively). Substantial agreement was observed in G5 (HPV39/68) and G6 (HPV56/66), with kappa values of 0.62 and 0.73, respectively, primarily due to additional positives detected by SD Biosensor. McNemar's test did not indicate significant systematic bias in most channels. Overall percentage agreement (OPA) was consistently above 96% both for the full STANDARD M10 Hr-HPV test, as well as channel-specific measurements.

Conclusions: The SD Biosensor STANDARD M10 Hr-HPV assay shows high analytical agreement with the RIATOL qPCR assay for overall hrHPV detection and for genotype-specific channels. Concordance was particularly strong for HPV16 and HPV18, as well as for channels G1-G4. Selected channels (G5-G6) suggest genotype-specific sensitivity differences, still rendering substantial agreement. These findings support the SD Biosensor assay as a reliable molecular alternative for hrHPV detection, with potential utility in both centralized and decentralized screening environments.

References:

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#14437

P20-02 | Bridging and Diagnostic Evaluation of the HPV PLUS ELITe MGB® Kit from the ELITe InGenius to ELITe BeGenius Sample to Result PCR System

20 - New technologies

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Background/Objectives: The HPV PLUS ELITe MGB® Kit is a multiplex real-time PCR assay designed for the qualitative detection and identification of 14 high-risk (HR) HPV genotypes. Detection is done in multiple channels, allowing individual identification of HPV16, HPV18, HPV31, and HPV45, and grouped measurement of remaining HPV genotypes in HR1 and HR2 channels. Currently, the test is used with the ELITe InGenius sample-to-result system, which enables fully automated extraction, amplification, and result interpretation. The ELITe BeGenius instrument, developed based on the ELITe InGenius platform, provides enhanced throughput, capable of processing up to 24 samples per run – versus 12 with the ELITe InGenius – combined with improved sample and reagent traceability and stability. This equivalence study aimed to demonstrate that the analytical and diagnostic performance of the HPV PLUS ELITe MGB® Kit on the ELITe BeGenius is equal to those obtained on the ELITe InGenius, supporting successful instrument bridging and regulatory-marking compliance.

Methods: The evaluation focused on analytical performance equivalence between the two instruments. Key parameters assessed were the limit of blank (LoB), limit of detection (LoD), clinical cut-off validation, intra- and inter-session repeatability, and inter-instrument and inter-batch reproducibility. Experiments were performed using clinical cervical samples collected in ThinPrep® and SurePath™ media, including specimens with normal, CIN1, CIN2, or CIN3 histological diagnoses, previously characterized as HR-HPV negative or positive using the AML RIATOL qPCR Assay and the Abbott RealTime High Risk HPV Assay. Additional studies employed spiked controls and WHO reference standards. Cycle threshold (Ct) values, variability (CV%), and concordance with reference methods were statistically analyzed using ROC curve analysis and Cohen's kappa to confirm robust analytical and diagnostic performance equivalence.

Results: All analytical performance criteria were met, confirming equivalent results between the ELITe BeGenius and ELITe InGenius systems across both ThinPrep® and SurePath™ matrices. The limit of blank (LoB) showed ≥98% negativity for all targets, according to Linnet et al. (2004). The limit of detection (LoD) was 202 cells/mL for HPV16 (SiHa) and 56 cells/mL for HPV18 (HeLa), and confirmed at >87% positivity rates with WHO reference standards on both instruments. Intra- and inter-session repeatability showed CVs <5%, confirming high precision, while inter-instrument and inter-batch reproducibility demonstrated consistent performance. Using clinically validated Ct cut-offs, both assays achieved 100% relative sensitivity and 116% specificity versus the reference method, with strong inter-method agreement (Cohen's kappa ≥0.87).

Conclusions: Bridging validation data confirm that the HPV PLUS ELITe MGB® Kit, along with the control and dedicated consumables, assay protocols and cervical specimens establish equivalent analytical and clinical performance on ELITe BeGenius, comparable to ELITe InGenius. The transition between platforms does not affect assay performance and ensures continued diagnostic validity in compliance with applicable regulatory requirements.

References:

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#14446

P06-05 | Final Results of a 5-Year Immunogenicity and Safety Study of the 9-Valent Human Papillomavirus Vaccine in Chinese Females Aged 9-45 Years

06 - HPV prophylactic vaccines

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Background/Objectives: Study V503-024 (NCT03903562) was a phase 3, non-randomized, open-label, multi-site 2-stage study to investigate the immunogenicity and safety of the 9-valent human papillomavirus (9vHPV; HPV6/11/16/18/31/33/45/52/58) vaccine in Chinese females aged 9-45 years. In stage I, 9vHPV vaccine-induced antibody response was non-inferior in Chinese females aged 9-19 and 27-45 years versus those aged 20-26 years, and the 9vHPV vaccine was generally well tolerated. Here, we present results from stage II, which evaluated the persistence of immune responses induced by the 9vHPV vaccine and safety in females aged 9-19 years.

Methods: In stage I, Chinese females received a 3-dose regimen of the 9vHPV vaccine at day 1, month 2, and month 6. Those aged 9-19 years of age who received all 3 doses of the 9vHPV vaccine during stage I were eligible to participate in stage II and were followed up to the month 60 visit (54 months after dose 3). No vaccinations were administered during stage II. Serum samples obtained from participant visits at months 12, 24, 36, 48, and 60 were assessed to determine HPV antibody responses by competitive Luminex immunoassay (cLIA) and IgG Luminex immunoassay (IgG LIA). Anti-HPV geometric mean titers (GMTs) and seropositivity percentages were summarized descriptively. Serious adverse events (SAEs; regardless of causality), pregnancy outcomes, and potential autoimmune disorders were collected throughout stage II.

Results: A total of 1990 females (690 females aged 9-19 years, 650 females aged 20-26 years, and 650 females aged 27-45 years) were enrolled in stage I. All females aged 9-19 years who completed the 3-dose regimen of 9vHPV vaccine entered stage II (n = 682), and 645 (94.6%) completed stage II. Anti-HPV cLIA GMTs to all 9vHPV vaccine-targeted HPV types decreased sharply from the peak at month 7 to month 24 and slowly from month 24 to month 60. Seropositivity rates by cLIA and IgG LIA were 100% for all 9vHPV vaccine-targeted HPV types at month 7 and ranged from 89.7% to 98.9% for cLIA and from 97.5% to 100% for IgG LIA at month 60 depending on HPV type. There were no deaths during stage II. Ten participants (1.5%) experienced 11 nonfatal SAEs; all SAEs resolved and none were considered related to the 9vHPV vaccine by the investigator. Three pregnancies were reported by 3 participants; there were no congenital anomalies or other abnormalities in infants. Two potential autoimmune disorders were reported (1 case each of immune thrombocytopenia and arthritis); neither was considered to be vaccine-related by the investigator.

Conclusions: In Chinese females aged 9-19 years, a 3-dose regimen of the 9vHPV vaccine induced antibody responses to the 9vHPV vaccine-targeted HPV types that generally persisted through 5 years since the first vaccination was received. The 9vHPV vaccine was generally well tolerated.

References:

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#14542

P12-02 | The Impact of Bisulfite Conversion Method on FAM19A4/miR124-2 Methylation Testing in Cervical Samples with Low-DNA Input

12 - Triage of HPV positive women

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Background/Objectives: Methylation of the FAM19A4 and hsa-miR124-2 gene promoters represents a promising triage marker for HPV-positive women, particularly in self-sampling settings where cytology is not applicable. While the clinical performance of methylation testing is well documented, limited data exist regarding the technical impact of bisulfite conversion when applied to previously isolated and stored DNA samples with low DNA input. This pre-analytical step may critically influence test outcomes. The aim of this study was to compare two bisulfite conversion methods using the same methylation assay on archived DNA samples from Hybrid Capture 2 (HC2)-positive women routinely managed in a national triage setting.

Methods: A total of 134 HC2-positive women were included. Cervical samples underwent immediate DNA isolation and were stored at −30 °C until bisulfite conversion. Two kits were evaluated: the 96-well plate–based EpiTect Bisulfite Kit (Qiagen) and the single-column EZ DNA Methylation Kit (Zymo Research), following the manufacturers' instructions with recommended elution volumes of 70 µL and 10 µL, respectively. Methylation analysis was performed using the QIAsure Methylation Test (Qiagen). Results were correlated with initial DNA concentration, and Spearman correlation was used to assess the association between DNA input and invalid results.

Results: The median age of the women was 42 years (range 22–84 years), with a median DNA concentration of 6.06 ng/µL (range 0.139–141 ng/µL). Using the EpiTect kit, 48/134 samples yielded valid results (30 methylation-positive, 18 negative), while 86/134 samples were invalid (64%). Lower DNA concentration showed a significant correlation with invalid results (Spearman $\rho = -0.717$, $p < 0.001$). In contrast, the Zymo kit produced valid methylation results in 124/134 samples (66 positive, 58 negative), with only 10/134 classified as invalid (7%), indicating a low invalid rate and good assay performance.

Conclusions: Efficient bisulfite conversion is crucial for obtaining valid methylation assay results when analyzing FAM19A4 and hsa-miR124-2 promoter genes in cervical samples with low DNA input. The Zymo kit yielded a substantially higher proportion of valid results compared with EpiTect. However, validation in larger cohorts with correlation to clinical outcomes is required to define the optimal pre-analytical workflow for methylation-based HPV triage.

References:

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#14671

P13-10 | Validation of a novel first-void urine collection device

13 - Self-sampling

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Background/Objectives: The ability to easily obtain appropriate and reliable biological samples is critical to advancing public health. Non-invasive self-collection methods offer clear advantages in terms of user acceptability, implementation and scalability. Urine is a valuable clinical sample as it contains a broad range of biomarkers that reflect physiological processes and changes in health status. The initial fraction of each urine flow, called first-void urine (FVU), is particularly enriched in biomarkers originating from the urogenital tract, as it washes away exfoliations and secretions1. For cervical cancer screening, comprehensive studies have shown comparable clinical sensitivity and specificity in FVU samples compared to clinician-collected cervical samples as well as vaginal self-samples for HPV testing2–5. User preference data further highlights the importance of offering urine-based self-sampling methods: 53% of Belgian women would choose urine collection over vaginal swabs (38%)6, while women who provided both vaginal and FVU self-samples in rural India indicate a 98% preference for urine sampling7. Beyond HPV detection, its applications extend to detection of sexually transmitted infections, other urogenital conditions and monitoring of vaccine effectiveness. Effective FVU collection requires a device that captures the initial urine fraction and facilitates proper mixing with a preservative. The objective of this study is to evaluate the ability of a novel FVU collection device to capture human DNA and HPV16-specific antibodies.

Methods: The novel device called Ini-Stream incorporates a passive flow-control geometry that uses fundamental fluid dynamics to automatically capture the initial stream of urine while allowing the user to continue urinating. By making use of 3D-printed prototypes and proto-moulded polymer prototypes, we performed verification and validation tests through a combination of controlled bench simulations and a pilot study involving real user testing.

Results: Simulated bench testing showed robust volume capture across various flow rates and angles. The collected volume as well as the capture of analytes of interest such as human DNA and HPV16-specific antibodies, were further evaluated in a pilot study conducted with 25 HPV-vaccinated volunteers. The volunteers were asked to use the novel collection device as well as two versions of an FVU collection device already on the market. This pilot study showed equivalent capture of GAPDH in comparison to the already available 10mL collection device, while the 20mL variant of the already available collection device captured lower concentrations of GAPDH. HPV16-specific antibodies were captured at comparable levels by all included collection devices. Wash-out was tested by the addition of spike DNA to the preservation buffer in the collection tube before collection. Detection of spike DNA in the subsequent stream, which was collected by the volunteers by holding a standard urine cup at the outlet of the FVU collection devices, was rare, showing minimal wash-out.

Conclusions: Our findings demonstrate that the novel Ini-Stream device reliably captures first-void urine and key analytes. These results support the device's potential for application in diagnostic workflows, including HPV testing and broader urogenital health monitoring.

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