Human Papillomavirus (HPV-16/18) AS04-adjuvanted vaccine (Cervarix®) on the serum and cervicovaginal microenvironment, characterizing the TH1/TH2 cytokines profile.

Methods A subset of 20 women between 18 and 40 years old without genital coinfections (bacterial vaginosis, Herpes virus, *Candida* sp *Neisseria gonorrhea* or *Chlamydia trachomatis*) were selected to receive the three doses of the HPV-16/18 AS04-adjuvanted vaccine (Cervarix®). Blood and cervicovaginal samples were collected before the first dose and 30 days after the third dose. TH1 (INF- γ , IL2, IL-12p70, TNF- α , GM-CSF) and TH2 (IL-4, IL-5, IL-10, IL-13) cytokines were determined by Immunology Multiplex.

Results In the blood samples there were no statistically significant differences in the level of cytokines before or after the three doses of the vaccine, except for TNF- α (INF- γ : $p=0.797$; IL2: $p=0.735$, IL-12p70: $p=0.881$; TNF- α : $p=0.011$, GM-CSF, $p=0.721$; IL-4, $p=0.223$; IL-5, $p=0.860$; IL-10, $p=0.473$; IL-13, $p=0.913$). However, for the CVC samples, there was a tendency to decrease the cytokine level after the three doses of the vaccine. This decrease was significant for the INF- γ ($p=0.010$), IL-5, ($p=0.005$), IL-12p70 ($p=0.002$) e IL-13 ($p=0.002$).

Conclusion TH1/TH2 cytokines were detected in serum of women who received the HPV-16/18 AS04-adjuvanted vaccine, but there were no significant differences before and after the three doses. In the vaginal samples there was a significant decrease of INF- γ , IL-12p70, IL-5 and IL-13. Understanding the clinical significance of these modifications is a very relevant issue and future studies that address the network of inflammatory and anti-inflammatory cytokine effects should be considered.

Disclosure No significant relationships.

P838

ASSOCIATIONS OF THE VAGINAL MICROBIOTA WITH HPV INFECTION AND CERVICAL DYSPLASIA IN SOUTH AFRICAN WOMEN LIVING WITH HIV

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Background Fifteen longitudinal studies have shown associations between bacterial vaginosis and high risk human papillomavirus (hrHPV) acquisition and/or persistence, and/or cervical dysplasia. However, few studies assessed the vaginal microbiota (VMB) comprehensively, and none controlled the dysplasia association for persistent hrHPV.

Methods 623 women attending HIV outpatient clinics in Johannesburg, South Africa, were examined for hrHPV (Inno-LipA HPV Genotyping Extra Assay), cervical dysplasia (histology), and vaginal microbiota (VMB; V3-V4 Illumina HiSeq 2x300bp with Swarm OTU-picking) at baseline and endline, a median of 16 months after baseline. VMB research questions were addressed in two nested case-control designs.

Results Hierarchical clustering resulted in seven VMB types: *L. iners*-dominated (Li; $n=214$ samples), *Lactobacillus crispatus* or *L. jensenii*-dominated (Lcj; $n=68$), *Bifidobacterium*-dominated (BD; $n=2$), lactobacilli + bacterial vaginosis (BV)-

anaerobes (L+A; $n=208$), BV-like (BV; $n=303$); BV-anaerobe dominated (AD; $n=56$); and pathobiont-characterised (PB; $n=19$). Women with new or persistent hrHPV during follow-up were less likely to have an Lcj VMB type (compared to Li) at endline, and persistent hrHPV was associated with vaginal anaerobic dysbiosis at baseline (decreased lactobacilli, increased BV-anaerobes, and increased Nugent score). Women who developed CIN2+, compared to women with persistent hrHPV but no CIN2+, were more likely to have vaginal anaerobic dysbiosis at endline (decreased lactobacilli, increased BV-anaerobes, and increased diversity), but not at baseline. These associations persisted after controlling for age, hormonal contraception, and CD4+ count; several additional potential confounders (HIV plasma viral load, antiretroviral therapy, sexually transmitted infections, sexual risk-taking, among others) were evaluated.

Conclusion Frequent hrHPV exposure (and/or increased sexual risk-taking) likely causes vaginal dysbiosis, but a bilateral relationship cannot be ruled out. Women with vaginal dysbiosis are not at increased risk of CIN2+ development when hrHPV status is taken into account, but vaginal dysbiosis does develop when CIN2+ lesions develop. These results should be confirmed in even larger longitudinal studies.

Disclosure No significant relationships.

P839

A CHEMICALLY MODIFIED β -LACTOGLOBULIN (JB01) IS EFFECTIVE IN TREATING HPV INFECTION AND PREVENTING SEXUAL TRANSMISSION OF HIV

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Background More than 90% of the new HIV infection in China occurred through sexual transmission, particularly among the men who have sex with men (MSM). Cervical cancer, the second most common cancer among women, is caused by sexually acquired infection with high-risk types of HPV, such as types 16 and 18. We previously have shown that a chemically modified bovine milk protein, β -lactoglobulin (3HP- β -LG, also known as JB01), is effective against infection by a broad-spectrum of HIV (*Nat. Med.*, 2:230,1996) and HPV entry inhibitor. Therefore, we intended to develop topical formulations containing JB01 against HIV and HPV infections.

Methods A pseudotyped HPV particles expressing HPV L1 and L2 proteins were used for testing the inhibitory activity of JB01. A randomized open-label clinical trial of a JB01 biological dressing (JB01-BD) administered intravaginally was performed to evaluate its *in vivo* safety and efficacy. Both pseudotyped and live HIV-1 strains with different subtypes and tropisms were used for evaluating the *in vitro* efficacy of JB01 and a non-human primate (NHP) model was used for testing the *in vivo* efficacy of JB01.

Results The trial of JB01-BD administered intravaginally demonstrated that JB01-BD is safe and effective. About 60.5% and 13.5% HPV-positive women in the treatment and non-treatment groups, respectively, became HPV-negative ($P < 0.001$). *In vitro* study suggests that JB01 exhibits broad-spectrum antiviral activity against divergent HIV-1 strains, including those resistant to the current antiretroviral therapeutics. Rhesus macaques monkeys pretreated with a topical formulation were protected against rectal challenge with SHIV-SF162P3.

Conclusion JB01-BD is safe and effective against HPV and HIV infections, and was approved by China Food and Drug Administration (CFDA) for treating cervical HPV infection with the potential to reduce morbidity of cervical cancer. A lubricant formulation containing JB01 has recently been approved by CFDA as an auxiliary strategy to prevent sexual transmission of HIV.

Disclosure No significant relationships.

P840

THE HPV SCREENING AND VACCINE EVALUATION (HPV-SAVE) STUDY IN MEN LIVING WITH HIV: EARLY PATHOLOGIC AND ACCEPTABILITY OUTCOMES

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Background Anal cancer caused by oncogenic, high-risk (HR) human papillomavirus (HPV) is emerging as a leading cause of non-HIV-related death in HIV-positive MSM. Anal cancer rates in HIV-positive MSM are up to 100-times higher than the general population. There are no universally-accepted guidelines for anal cancer screening, even in high risk populations, due to a paucity of evidence to support its effectiveness. We assessed the acceptance rate to invitations for anal cancer screening, and describe preliminary pathology results.

Methods The HPV-SAVE Study is an ongoing Canadian study on screening and treatment of anal cancers and pre-cancers in HIV-positive MSM. Participants were invited to have anal cytology and HPV testing in their physician's office. Those with abnormalities were referred for high resolution anoscopy (HRA) and anal biopsies. Cytology was graded as per the Bethesda classification, and histology was described per the Lower Anogenital Squamous Terminology (LAST) nomenclature.

Results Out of 2241 invitations as of 01/2019, 617 men (27.5%) agreed to be screened. Cytology results from 518 satisfactory Pap tests were: 246 negative (47.5%), 62 LSIL (12.0%), 9 LSIL-H (1.7%), 14 HSIL (2.7%), 174 ASCUS (33.6%), and 13 ASC-H (2.5%). In 116 participants referred for HRA, 247 biopsies were done, yielding HSIL in 62 (53.4%) unique individuals, and one invasive carcinoma. In a sample of 127 participants, 111 (87.4%) had any HPV type, 82 (64.6%) had multiple HPV types, 78 (61.4%) had at least one high-risk HPV type, and 39 (30.7%) had HPV-16.

Conclusion MSM living with HIV had moderate acceptance of anal cancer screening invitations, with over half of screened men having abnormal cytology. A majority of those undergoing HRA had high-grade histology diagnosed, and most participants had HPV anal canal infection, with nearly two-thirds having anal canal infection with HR-HPV. These early results highlight the enormous HPV burden in this high-risk population.

Disclosure No significant relationships.

P841

BARRIERS TO HPV VACCINATION AMONG GAY, BISEXUAL, AND OTHER MEN WHO HAVE SEX WITH MEN (GBMSM) IN CANADA: A CIRN STUDY

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Background Internationally, Canada was one of the first countries to offer free HPV vaccination to young gbMSM. The provinces of British Columbia (BC), Ontario (ON) and Quebec (QC) implemented HPV vaccination programs in 2015–2016 for gbMSM aged 9–26. We explored HPV vaccine initiation and among unvaccinated men, potential barriers to uptake.

Methods Engage is a sexual health study among gbMSM aged 16+ in Vancouver BC, Toronto ON, and Montreal QC, the largest urban centres in each province. Men are recruited via respondent driven sampling (RDS). We estimated the proportion that had initiated HPV vaccination and among unvaccinated men, compared proportions to responses on HPV vaccine knowledge and willingness, healthcare access and sexual orientation disclosure by age (eligible for free vaccination: ≤26 and ineligible for free vaccination: ≥26 years old). Proportions were RDS unadjusted.

Results From 01/2017 to 31/12/2018, 2099 men enrolled (542 Vancouver, 378 Toronto, 1179 Montreal). Their median age was 33 years (IQR 27–46). In Vancouver, Toronto, and Montreal, 48.6%, 44.1% and 44.2% of men aged ≤26 and 24.9%, 30.3% and 7.1% of men aged ≥26 had 1+ dose of the HPV vaccine, respectively. Among unvaccinated men, more men aged ≥26 versus ≤26 accessed healthcare (family doctor/sexual health/HIV care) (87.2% vs 78.9%, $p=0.0008$) and disclosed their sexual orientation to their family doctor (86.2% vs 64.4%, $p<0.0001$). A similar proportion of unvaccinated men from each age group had heard of the HPV vaccine (≥26=67.5% vs ≤26=69.0%, $p<0.0529$). Among unvaccinated men aware of the HPV vaccine, more men aged ≥26 versus ≤26 were willingness to get vaccinated if the vaccine were free and required disclosure of same-sex activity (80.3% vs 61.5%, $p=0.0259$).

Conclusion Preliminary analyses indicate that HPV vaccine initiation in this population remains suboptimal. Among unvaccinated gbMSM ≤26, accessing healthcare, not disclosing sexual orientation and willingness to get vaccinated may be barriers to vaccine uptake.

Disclosure No significant relationships.