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 *Neisseira 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

[1]Janneke Van De Wijgert*, [1]Allessandra Gill, [1]Alistair Darby, [2]Helen Kelly, [3]Admire Chikandiwa, [4]Sinead Delany-Moretlwe, [5]Marijn Verwijs, [6]Suzanna Francis, [6]Philippe Mayaud. *[1]University of Liverpool, Liverpool, UK; [2]London School of Hygiene and Tropical Medicine, London, UK; [3]Wits RHI, University of the Witwatersrand, Johannesburg, South Africa; [4]University of the Witwatersrand, Wits RHI, Johannesburg, South Africa; [5]University of Liverpool, Institute of Infection and Global Health, Liverpool, UK; [6]London School of Hygiene and Tropical Medicine, London, UK*

10.1136/sextrans-2019-sti.883

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

Shibo Jiang*. *Fudan University, School of Basic Medical Sciences, Shanghai, China*

10.1136/sextrans-2019-sti.884

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.