Background In low-risk women, *in vitro* inhibition of E. coli by genital tract secretions is associated with Lactobacillus crispatus and jensenii proteins. However in at-risk populations, HIV seroconversion was associated with greater E. coli bactericidal activity and inflammatory immune mediators. We therefore analysed the relationship between inflammation, E. coli bactericidal activity, and microbiota in vaginal swabs from participants in a safety study of VivaGel®.

Methods Swabs were collected before and after product use from subjects randomised to vaginal VivaGel® (n = 66), VivaGel® placebo (n = 65), or hydroxyethylcellulose (HEC) placebo (n = 54). Cytokines were quantified by multiplex proteome array and lactoferrin and SLPI by ELISA to generate a cumulative inflammatory score using principal components analysis. E. coli bactericidal activity in swab supernatants was quantified by a colony reduction assay. Vaginal bacteria were characterised by quantitative cultures. Generalized estimating equations controlling for product use were used for analyses.

Results Higher inflammatory score was associated with detection of Gardnerella vaginalis (OR 1.5; p = 0.02) and anaerobic gramme-negative rods (OR 1.4, p = 0.03), a trend towards diminished hydrogen peroxide-producing lactobacilli (OR 0.7, p = 0.1), and increased E. coli bactericidal activity (p < 0.001). The combined presence of group B streptococcus, E. coli, S. aureus, and enterococcus (potential pathogens) was associated with decreased E. coli bactericidal activity (p = 0.06). However these results were modified by gel type. Higher inflammatory score was associated with greater E. coli bactericidal activity only in the placebo arms (VivaGel® p < 0.001; HEC p = 0.002), while pathogenic bacteria were associated with decreased E. coli bactericidal activity in the VivaGel® arm (p = 0.001).

Conclusion Mucosal inflammation was associated with E. coli bactericidal activity in women using placebo gels, which could contribute to the previously observed link between bactericidal activity and HIV seroconversion. However bactericidal activity in women using VivaGel® was influenced by pathogenic bacterial populations, which may reflect an altered genital mucosal milieu.

P3.364 DOES TENOFOVIR GEL - OR DO OTHER VAGINAL MICROBICIDE PRODUCTS - AFFECT DETECTION OF BIOMARKERS OF SEMEN EXPOSURE?

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Background Prostate Specific Antigen (PSA) and Y chromosome are used as biomarkers of semen exposure. There is currently no information on whether vaginal products evaluated in microbicide trials, in particular, tenofovir gel (TFV), UC781 or the universal HEC placebo (hydroxyethylcellulose) affect the detection of these markers.

Methods Dilutions of TFV, UC781, and the universal HEC placebo, combined with semen, were tested for PSA using both the Abacus ABAcard semi-quantitative and the Abbott Architect quantitative assay. Y chromosome DNA was determined by real-time polymerase chain reaction (real-time PCR).

Results Tenofovir gel and the universal HEC placebo adversely affected PSA detection using the ABAcard, but not the Abbott Architect PSA assay. UC781 affected PSA results by ABAcard and, at all dilutions, caused invalid results for Abbott Architect assay. None of the products substantially affected the Y chromosome PCR assay's indication of presence of Y chromosome DNA, but the quantitative results varied by product.

Conclusions These *in vitro* results indicate that the Abbott Architect assay, rather than the ABAcard, should be used for PSA detection when tenofovir gel or the universal HEC placebo might be present. The Y chromosome PCR assay when used qualitatively to indicate presence of Y chromosome is not affected by any of these products, but the quantitative results should be used cautiously as the values are affected by microbicide products. *In vivo* confirmation of these findings is recommended to further optimise detection of semen biomarkers when microbicide products may be used.

P3.365 TENOFOVIR VAGINAL FILM: SAFETY ASSESSMENT IN THE MACAQUE MODEL

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Background Tenofovir, a nucleoside reverse transcriptase inhibitor (NRTI), has been formulated as a vaginal film for topical microbicide development. To help inform studies to be conducted in a human population, we assessed safety factors in the pigtailed macaque model.

Methods The use of monkeys on this protocol was approved by the Institutional Animal Care and Use Committee at the University of Washington. Animals were handled humanely, and experiments were performed within the National Institutes of Health's animal use guidelines, in compliance with the *Guide for the Care and Use of Laboratory Animals* and the Animal Welfare Act. Six pigtailed macaques underwent a three-arm cross-over design protocol comparing two doses of tenofovir films (40mg; 20mg) to a placebo film. Films used were 1/3 the size intended for human use. The drug content of macaque-sized test films was 11.2 ± 0.4 and 5.1 ± 0.3mg tenofovir/film. We administered the vaginal films to pigtailed macaques daily for five days one week, followed by four days the next week. Safety of repeated, daily exposures was measured by repeated colposcopic assessment, vaginal pH, vaginal smear and microbiology tracking.

Results Colposcopy revealed similar tissue appearance in all three study arms. There were no indications of product induced tissue disruption to vaginal or cervical mucosal surfaces. Vaginal microbiology assessments revealed similar shifts in flora prevalence across both the tenofovir formulations and the placebo study arm. Vaginal pH fluctuated similarly across all three study arms. Polymorphonuclear cell counts determined from Gram stained vaginal smears increased somewhat with exposure to the higher dose tenofovir formulation compared to the lower dose tenofovir and the placebo arms.

Conclusions Quick dissolving vaginal films, formulated to deliver tenofovir as a topical microbicide, are a promising alternative to gel formulations. Well designed clinical assessments of tenofovir film safety, pharmacokinetics, pharmacodynamics and product dispersal are warranted and ongoing.

P3.366 CHLAMYDIA SCREENING IN EDUCATIONAL SETTINGS: A SYSTEMATIC REVIEW OF STRATEGIES AND OUTCOMES

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Background Low *Chlamydia trachomatis* (CT) testing rates in primary-care (5–20%) in many countries have encouraged screening programmes in non-clinical settings. We describe the strategies and outcomes of screening programmes in educational settings.

Methods We systematically reviewed English-language studies reporting on CT screening programmes in educational settings (school/college/university) published between 2005 and 2011. We classified programmes into groups on the basis of screening strategies and report the median testing rate (number invited/screened) and CT positivity from studies where data were available.
Results We identified 28 studies describing 32 screening programmes in America/Canada (n = 13), Europe (n = 8), Australia/New Zealand (n = 7) and Asia (n = 4). Most targeted both male and female students (71%). Programs were in secondary schools (n = 14), post-secondary schools (n = 16) and both secondary and post-secondary schools (n = 2). Across all programmes, 55369 tests were conducted. The highest testing rates were in programmes involving screening students in class rooms (four programmes), opportunistic screening of students undergoing routine health examinations (six programmes), and opportunistic screening of students visiting school-based health centres for other reasons (six programmes), with median testing rates of 66%, 54% and 46% respectively. Lower testing rates were found in programmes involving screening in other school locations e.g. canteen/study stall (four programmes) with a median testing rate of 30%. The median CT positivity was 4.7% (range:1.3–18.1%); 4.1% in males, 5.8% females.
Conclusion The review demonstrated that education facilities can be used for CT screening. Testing programmes were established in a range of educational facilities, in a variety of countries, and accessed large numbers of males and females. The CT positivity supports educational institutions as a setting to conduct screening. Targeting students in classrooms and opportunistic screening at school clinics and routine health examinations appears to achieve high testing rates in the school setting.

P3.367 SERO-PREVALENCE OF SEXUALLY TRANSMITTED DISEASE (HIV, SYPHILIS, HEPATITIS-B AND HEPATITIS-C) IN VOLUNTEER DONORS OF GAOL INMATES AND STUDENT COMMUNITY IN PUNJAB PROVINCE OF PAKISTAN

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Objective Cohort studies of prisoner and student community volunteer blood donors recruited in 2007–2012 in 30 gaols and 30 educational institues of Punjab province. In Punjab, there are 32 prisoners gaol that are nearly three times overcrowded with 62500 prisoners (undertrial, convict and condemned prisoners). A number of studies indicate that even in prisons of developed countries prevalence of transmission of sexually transmitted infections and HIV is high.
Methods Ten thousand-5000 each fromjail and educational institutes) apparently healthy donors were assessed for the sero-prevalence of human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) and syphillus (RPR) using a commercially available Enzyme Linked Immunosorbent Assay (ELISA)-based kit. Information was obtained for risk factors using structured questionnaire.
Results Out of the 5,000 samples screened in each community, 337 (6.74%) in student community and 1424 (28.48%) in prisoner community were sero-positive. Subjects aged 15–45 years recorded 2.20% HBV, 4.12% HCV, 0.42% RPR and no HIV positivity in students while in prisons 5.28% HBV, 12.32% HCV, 0.18% HIV and 10.70% RPR positivity was recorded. Subjects aged 15–25 years are more HBV positive (2.51%) and (7.94%) while subjects aged 25–35 years were more HCV positive (4.88%) and (14.18%) in student and prisoner community respectively. Unfortunately, sero-prevalnce rate is high in prisoner community as compared to student community.
Conclusion Overcrowding, poor hygienic and close living conditions stake prisoners at a very high risk for acquisition of sexually transmitted infections as compare to student community. Public awareness and vaccination programme should be improved in the community on urgent basis.

P3.368 STD CLINIC PATIENTS' PREFERENCES FOR HIV PREVENTION STRATEGIES

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Background More information is needed to understand how the newer HIV prevention methods should be positioned and which mix of prevention methods should be offered and promoted within the at risk populations. This study sought to obtain data about the preferences for effective biomedical interventions by individuals from the diverse ethnic and racial backgrounds that comprise the STD clinic populations in Miami
Methods A cross sectional survey was used to assess knowledge and preference of traditional (condoms) and new biomedical methods to prevent HIV (Circumcision -C-, Pre-exposure prophylaxis -PreP and microbicides -M) in STD clinic patients. After an initial assessment, the study coordinator provided basic simple descriptions of three new methods of HIV prevention by pamphlets and/or recorded video. The relative preference for each of all the prevention strategies was re-assessed information was provided.
Results Thirty five participants are reported in this interim analysis; 55% were female; 58% were African American; 25% were Hispanic and 12% were Haitians. Most of the participants were not aware of the efficacy of C (68%), PreP (77%) or M (79%) in decreasing the risk of acquiring HIV infection. At baseline, participants described as their preferred method to prevent HIV the use of male condoms (77%) and had marginal preference for the newer methods C (3%), M (6%) and PreP (3%). After the information about the new methods was provided, most of the participants reported to be aware of these methods (80%) and although male condoms was still the first choice for most of the participants (46%) a higher percentage of participants preferred M (20%) and PreP (14%).
Conclusions STD clinic patients who participated in this study had very limited knowledge about the new biomedical strategies to prevent HIV infection. A brief informational session can increase their willingness to use the newer HIV preventive strategies.

P3.369 ACCEPTABILITY OF HPV TETRAVALENT VACCINE AMONG MALES ATTENDING THE STD CLINIC OF MILAN - THE IMPORTANCE OF THE COSTS FOR PATIENTS

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Background HPV infection is usually transmitted by sexual contact and represent the most prevalent sexually transmitted infection all over the world. The clinical spectrum of HPV infection varies from the asymptomatic status to benign genital lesions to the development of virus associated tumours. There is no direct antiviral drug for HPV and all available therapies are aimed to the destruction of lesions or to the enhancement of the immune response.

In recent year a vaccine for prevention of infection has been developed and used for the vaccination of young adolescent girls and later of young women. The quadrivalent vaccine directed against HPV types 6, 11, 16 and 18 has shown efficacy on the incidence of genital warts not only in the vaccinated population but also in the male population of comparable age. Further researches