Background Condoms decrease sexually transmitted infection(STI) transmission, good evidence supports this, if used correctly. This study investigates individuals understanding of the correct use of male latex condoms.
Methods Random individuals completed a questionnaire and were requested to conduct an observed demonstration of condom application, marked against criteria from British Association for Sexual Health and HIV(BASHH) guide for condom use and Centers for Disease Control and prevention(CDC) Condom fact sheet.
Results 127 responders, 45 participants in the observed demonstration(57%males, 46%females, age 12–66) 100% believed they used condoms correctly, 68% were self taught. 100% knew condoms were barrier contraception. 67% indicated condoms protection against all STIs and 5% indicated no STI protection: 11% gonorrhoea and Chlamydia only, 10% HSV and warts only and 7% HIV only. 7% felt condoms decreased STI transmission during oral sex and 10% during anal sex(100% of men who have sex with men) During observed demonstration, 33% correctly applied a condom. Mistakes: not squeezing air from condom, unrolling before applying and condom contact when opening. Factors stated to increase latex condom splitting: 25% penis size, 22% sexual vigour, 7% certain lubricants, 46% unsure(25% admitted to doubling condoms once since coitarche, all unaware of risk) 38% believed condoms not required throughout intercourse, 100% of these believed STI transmission was decreased if worn at the end.
Conclusion Perceived good condom technique, however, practical adherence to guidance is poor(particularly younger cohorts) Inadequate heterosexual awareness of STI transmission and prevention during oral and anal intercourse. Poor understanding of condom STI prevention, risks for condom splitting and timing of condom use. Good quality sexual education to include male condoms is important. Age of education is crucial capturing individuals before and timely to coitarche. Self teaching is common and requires quality accessible material. Opportunistic teaching is required, condom use competence should not be assumed.

P3.361 MALE INVOLVEMENT IN THE VOICE MICROBICIDE TRIAL AT KAMPALA SITE UGANDA - A WORTHWHILE VENTURE

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Background Makerere University-Johns Hopkins University research collaboration (MU-JHU) conducted a VOICE study which was a phase 2B safety and effectiveness study of Tenofovir 1% gel, Tenofovir tablet and Truvada tablet for the prevention of HIV infection in women. The study encouraged women to disclose to their partners for support while using study products.
Methods Before and during recruitment, need for male involvement was emphasised. At screening and follow up visits, participants were informed about the importance of disclosing their participation to partners. Women were encouraged to invite their spouses to the clinic to know about the study and also receive HIV and syphilis testing. Men were invited verbally through their spouses; given reading materials to give to their partners before inviting them. Later, an invitation letter was developed inviting male partners to the clinic but given to those who opted for it. Male partners who came to the clinic were periodically invited for meetings to brainstorm issues about the study and general health.
Results Out of 322 participants, 140 accepted to take letters, 67men turned up to the clinic, and 52 men tested for syphilis and HIV. 5 male partners' meetings were held and many concerns, which rotated around safety and effectiveness, were resolved, among which; whether it is safe for them to stop using a condom since their partners are on study products and whether the products will not affect their manhood.
Lessons learnt Male Partners who turned up to the clinic were very supportive in reminding their partners clinic appointments and product use for better adherence. Increased disclosure among discordant couples, and helped treating sexually transmitted infections.
Conclusion Male Involvement in microbicide studies is of utmost importance. Men need a proactive approach to get involved in clinic activities to support spouse in adherence and avoiding STD/STI re-infection.

P3.362 MICROBICIDE USE DURING PREGNANCY: ACCEPTABILITY FOR PREVENTION/TREATMENT AND THE ROLE OF PARTNERS

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Objectives To explore pregnant women's acceptance of microbicides for reproductive tract infections (RTIs).
Methods To date, we have analysed interview transcripts of 15 women in their third trimester who participated in a qualitative study on microbicide acceptability for treatment and prevention of bacterial vaginosis (BV) and role of partners in decision-making regarding product use. Interviews were coded for relevant themes. Women (mean age = 25.5; range = 21–30) were recruited from a clinic serving an inner-city minority population.
Results While few women reported BV history, most did not spontaneously provide specific BV knowledge. Most participants strongly endorsed treatment of any infection during pregnancy, however, responses to prevention ranged from ambivalence to strong support. Many women would make a decision based on perception of risk/benefit to the baby. Other themes included: (1) side effects; (2) effectiveness; (3) perceived personal risk for RTI; (4) general investment in personal health. Some women seemed to have difficulty understanding prevention, and many felt greater clarity about microbicide use for treatment. Many viewed barriers (i.e., leakage, remembering, inserting) as easy to manage since they already used panty-liners, thought product use could be incorporated into daily routines and thought partners could help. Treating an active infection trumped barriers; this was less clear for prevention use. The decision regarding product use was viewed as belonging to the woman; partners were perceived as supporting what is best for the baby.
Conclusions Women in a NYC pre-natal clinic enthusiastically support the use of microbicides for RTIs. In order for this enthusiasm to lead to adoption, women need to be well-informed about the RTI, its consequences and risk/benefit of use. As barriers are likely to be greater in the absence of a current infection, a greater understanding and emphasis of the need versus the risk will be required for prevention use.

P3.363 INFLAMMATORY SOLUBLE IMMUNE MEDIATORS AND PATHOGENIC VAGINAL BACTERIA IMPACT E. COLI BACTERICIDAL ACTIVITY IN FEMALE GENITAL TRACT SECRETIONS

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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 gramnegative 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.