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Background Primary HPV testing for cervical cancer screening (HPV-CCS) could result in significant CCS programme changes including extended screening intervals, later age to start of screening and use of a test for a sexually acquired infection. We examine the predictors of women's intentions to undergo HPV-CCS compared to screening with Pap smears in different screening scenarios.
Methods Participants from a Canadian trial of primary HPV CCS completed a survey which determined women's intentions to attend CCS in three different models - (a): HPV-CCS conducted annually; (b): HPV-CCS conducted every 4 years; and (c): HPV-CCS conducted every 4 years and starting after age 25. Demographic and health data were assessed, and scales for attitudes about HPV testing (AT), perceived behavioural control (PBC) and direct and indirect subjective norms (SND, SNI) were created. Three logistic regression models were created, to determine predictors of women's intentions to attend HPV-CCS in each scenario.
Results 981 of 2016 emailed surveys were completed. Eighty four percent of women intend to be screened with HPV, which decreased to 54.2% with an extended screening interval, and 51.4% with a delayed start of age 25. Predictors of intention to undergo HPV-CCS screening in Model A were attitudes (OR 1.22; 95% CI 1.15, 1.30), SNI (OR 1.02; 95% CI 1.01, 1.03) and PBC (OR 1.16; 95% CI 1.10; 1.22). In Model B, predictors were attitudes (OR 1.32; 95% CI 1.28; 1.37), and in Model C, predictors were attitudes (OR 1.26; 95% CI 1.23; 1.30), education (OR 0.59; 95% CI 0.37; 0.93), and PBC (OR 1.06; 95% CI 1.02; 1.10).
Discussion Women's intentions to be screened for cervical cancer with HPV decreases substantially with an extended screening interval and delayed screening start. CCS programmes considering primary HPV screening must ensure robust planning to mitigate any negative impact on screening attendance.

O10.4 EFFICACY AND SAFETY OF INTRALESIONAL (IL) INJECTION OF MYCOBACTERIUM W VACCINE VS. IMIQUIMOD CREAM IN THE TREATMENT OF ANOGENITAL WARTS: A DOUBLE BLIND RANDOMISED TRIAL

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Introduction External Anogenital warts (EGW) are associated with poor response to treatment and high recurrence rates. There is a need for development of immunotherapeutic agents for treatment of AGW.
Objectives To compare efficiency and safety of IL injection of killed Mycobacterium w (Mw) Vaccine and Imiquimod cream in complete resolution of EGWs, recurrence rates, and reduction in HPV viral load.
Method 89 patients (71 male and 18 female) with EGW were recruited over a period of 3 years. Patients were randomised in to two Group: Group A Patients (Male 34, Female 10) received Imiquimod cream and IL placebo injection; Group B patients (Male 37 and female 8) received Placebo cream and IL Mw injections. HPV Genotyping was done by reverse line blot hybridization by the Linear Array (Roche) and viral load was done by Real Time quantitative PCR.
Results Mean percentage reduction in Imiquimod and Mw groups were 84.7% and 83.2%, respectively (P > 0.05). Overall, 59% and 66.7% of patients in Imiquimod and Mw groups respectively showed complete clearance. There was no significant difference in adverse events and recurrence rates. HPV DNA was detected in anogenital warts samples in 84 (94.38%) of 89 patients. The predominant types were HPV-6(55%), 11(41.5%) followed by HPV 16(5.6%), 18(4.4%), and others(27.5%). 22(24.7%) showed infection by multiple HPV types. Baseline HPV 6 and 11 DNA load ranges were $1.4 \times 102–2.1 \times 108$ and $2.6 \times 102–2.1 \times 108$ copies/mg, respectively (P value < 0.001). After treatment, there was a significant decline in viral load of HPV 6 in both the groups, but of HPV 11 only in Mw group.
Conclusions There was no significant difference in efficacy and adverse events in both the treatments. HPV viral load declined significantly and correlated with clinical resolution. Further studies are needed to explore whether injection Mw works for patients who do not respond to topical imiquimod.

O10.5 HUMAN PAPILLOMAVIRUS (HPV) GENOTYPES ASSOCIATED WITH PERSISTENT HSIL ISOLATED BY LASER CAPTURE MICRODISSECTION

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Background Anal squamous cell carcinoma (ASCC) is preceded by persistent high-grade squamous intraepithelial lesion (HSIL). A small proportion of HSIL will progress to ASCC; estimates in men who have sex with men (MSM) suggest one in 400 per year in HIV-positive men and one in 4,000 per year in HIV-negative men. There are no tests to predict which HSIL are more likely to persist and potentially progress to ASCC. As MSM are often concurrently infected with multiple anal HPV genotypes, the role of each in progression to ASCC is unclear.
Methods Biopsies of suspected HSIL collected during high-resolution anoscopy from participants enrolled in the ongoing SPANC cohort of homosexual men (Sydney, Australia) between November 2010 and December 2011. Samples taken at 0, 6 and 12 months were formalin-fixed, paraffin-embedded then sandwich sectioned. Sections 1 and 5 were stained (haematoxylin and eosin [H&E]) and section 2 placed on a PEN-membrane slide. H&E sections were reviewed and lesions annotated using Aperio ScanScope software. Annotated abnormal tissue was isolated using laser capture microdissection (LCM), DNA was extracted and HPV genotypes present determined by reverse hybridisation assay (HPV SPF10-LiPA25, Labo Bio-medical Products).
Results From a pilot study comprising 16 men diagnosed with HSIL at one or more visits, 94% were positive for at least one HPV type. HPV16 was the most common genotype detected in HSIL (28%), followed by 45, 18 (each 17%), 58 (11%), 56, 31, 52, 34 and 33 (each 6%). Three participants had HSIL that persisted over three consecutive visits: 2 were positive for HPV16 and 1 for HPV18. An additional 28% of HSIL persisted for 2 consecutive visits, and were positive for HPV58 (40%), 16, 18 or 33 (each 20%).
Conclusion Overall, 10% of HSIL persisted for longer than 12 months with HPV16 being present in majority of these.

O10.6 A POTENT COMBINATION MICROBICIDE GEL INHIBITS SHIV-RT, HSV-2 AND HPV INFECTIONS *IN VIVO*

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Background HIV acquisition is fueled by infection with HSV-2 and HPV. Microbicides that target all three STIs may more effectively limit HIV incidence. We previously showed that a gel containing the NNRTI MIV-150, zinc acetate (Z) and carrageenan (C, MZC) significantly protected macaques from vaginal SHIV-RT challenge, while ZC also protected mice against HSV-2 vaginally and rectally. Here we evaluate a new formulation of MZC optimised for clinical use against SHIV-RT, HSV-2, and HPV.
Methods Toxicity was measured using the HSV-2 increased susceptibility model in mice. Macaques received gels vaginally every day for 14d followed by SHIV-RT (10^3 $TCID_{50}$) 8 or 24h post-last gel or SHIV-RT plus HSV-2 (2×10^8 pfu) 8h post-last gel. Rectally, gels were applied 1h before SHIV-RT. Anti-HSV-2 and anti-HPV16 PsV activities were assessed by vaginally or rectally challenging mice with different viral doses 24h before to 8h after single gel application. Significance was determined by Fisher's exact or Mann Whitney U tests ($P < 0.05$).
Results MZC pretreatment did not enhance HSV-2 infection of mice. MZC protected macaques against vaginal SHIV-RT infection (in the presence or absence of HSV-2) for up to 8h ($p < 0.0001$ vs. C) and rectal SHIV-RT infection (0/5 MZC infected vs. 1/4 C; C barrier effect). While MZC only reduced vaginal HSV-2 infection of macaques by 27% after challenge with 2×10^8 pfu, MZC significantly reduced vaginal ($p < 0.0001$) and rectal ($p = 0.0187$) HSV-2 infection of mice when 10^6 pfu were applied immediately and also when 5×10^3 pfu were applied between 8h before and 2h after vaginal challenge ($p < 0.0021$). Protection of mice against HPV16 PsV was significant ($p < 0.0001$ vs. HEC) for MZC applied up to 24h before and 2h after challenge.
Conclusion MZC provides a durable window of protection against SHIV-RT, HSV-2, and HPV *in vivo*, making MZC an excellent candidate microbicide for clinical use.

0.11 - HIV prevention and lessons learned from trials of HIV pre-exposure prophylaxis

011.1 HERPES SIMPLEX VIRUS (HSV) INFECTION IN THE VOICE (MTN 003) STUDY: PRE-EXPOSURE PROPHYLAXIS (PREP) FOR HIV WITH DAILY USE OF ORAL TENOFOVIR, ORAL TENOFOVIR-EMTRICITABINE, OR VAGINAL TENOFOVIR GEL

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Background In subSaharan Africa, HSV-2 infection is common, and increases risk of HIV transmission and acquisition. Tenofovir gel applied before and after vaginal intercourse provided partial protection from HSV-2 acquisition in the CAPRISA 004 study. We enrolled women in a 5-arm, randomised, double-blind, placebo-controlled trial assessing the safety and efficacy of daily use of oral tenofovir, oral tenofovir-emtricitabine, and 1% vaginal tenofovir gel as HIV PrEP, and assessed characteristics of women with baseline HSV and risk of HSV seroincidence during the study.
Methods From September 2009-June 2011, 12,379 women were screened at 15 sites in South Africa, Uganda, and Zimbabwe. Eligibility criteria included normal renal, hematologic and hepatic function, report of vaginal intercourse in prior 3 months, negative pregnancy test, and willingness to use effective contraception throughout. Testing for HSV-2 type-specific antibody (Focus HerpeSelect EIA) was performed on plasma from enrollment and study exit.
Results Of 5,029 participants, baseline HSV serology was available for 4996 (99.3%). Most were from Durban (62%), followed by Johannesburg (14%), Zimbabwe (13%), Uganda (6%), and Klerksdorp (5.2%). Mean age was 25.3 years; 79% were unmarried. Over follow-up of 5,511 person years, end-of-study retention was 91%. Using a cutoff index value of > 3.5, 46% of participants were HSV-2 and 95% HSV-1 seropositive at enrollment. Country- and age-specific HSV-2 seroprevalence ranged from 32% (Zimbabwe) to 63% (Uganda). Seroincidence of HSV-2 by arm will be presented.
Conclusions In this population of women at risk for HIV-1, seroprevalence of HSV-2 was high, with potentially important differences by age and site of enrollment.

011.2 SEXUAL BEHAVIOUR OF HETEROSEXUAL MEN AND WOMEN RECEIVING ANTIRETROVIRAL PRE-EXPOSURE PROPHYLAXIS FOR HIV PREVENTION: POST-UNBLINDING ANALYSIS OF THE PARTNERS PREP STUDY

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Background Limited data are available to assess the potential for increased sexual risk-taking by persons using antiretroviral pre-exposure prophylaxis (PrEP) for HIV prevention. In July 2011, the Partners PrEP Study, a randomised trial of daily oral tenofovir and emtricitabine/tenofovir PrEP among HIV-uninfected members of African heterosexual HIV serodiscordant couples, demonstrated efficacy of PrEP for HIV prevention and use of placebo was discontinued in the trial. Follow-up of study participants on active PrEP through December 2012 provided an opportunity to evaluate risk behaviour on PrEP after efficacy was announced.
Methods Among participants assigned to active PrEP pre-unblinding who continued follow-up after the placebo arm was stopped, we used zero-inflated negative binomial regression with robust standard errors and adjusted for baseline sexual behaviour, age, gender, and secular changes to compare the frequency of unprotected sex up to 12 months before versus after knowledge of PrEP efficacy.
Results We analysed 54,876 person-months (33,254 pre- versus 21,622 post-unblinding) from 3024 HIV-uninfected subjects (64% male). On average, the observed frequency of unprotected sex with the HIV-infected study partner was 58 per 100 person-months pre-unblinding versus 53 per 100 person-months post-unblinding, reflecting no immediate change or change in trend over time following unblinding ($p = 0.734$ and 0.264, respectively). The annual average total number of unprotected sex post-unblinding was 6 acts versus 5 that would have been expected in the counterfactual situation had unblinding not occurred. There was no significant increase in diagnoses of incident sexually transmitted infections or pregnancy post- versus pre-unblinding ($p > 0.05$).
Conclusion The transition from a blinded, placebo-controlled trial to all participants aware they were receiving active PrEP in the Partners PrEP Study provided a "natural experiment" to evaluate behavioural risk compensation. PrEP, provided as part of a comprehensive prevention package, may not result in substantial changes in risk-taking sexual behaviour in HIV serodiscordant couples.

011.3 USING HCV INCIDENCE TRENDS TO DISENTANGLE THE LIKELY IMPACT OF HIV ANTI-RETROVIRAL TREATMENT ON DECREASING HIV INCIDENCE AMONGST INJECTING DRUG USERS: A MODELLING ANALYSIS

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