years, p < 0.05). None of the Chlamydia-positive clients tested positive on the subsequent STI tests. Testing at the clinic takes three times more time of the nurse.

Conclusions Young people prefer a home collection kit to a test at the clinic. Furthermore, offering home collection kits is time and cost saving. Because clients who test negative are not seen at the clinic, more time is left for high-risk groups. In conclusion, Chlamydia home collection kits optimise care efficiency at the STI clinic.

009.6 CD4 BELOW 500: INCREASE OF ART PATIENTS AND THE FINANCIAL IMPACT IN BRAZIL

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F Viegas Neves da Silva, A Guimarães, R Hallal, D Greco. *Department of STD, AIDS and Viral Hepatitis - Ministry of Health of Brazil, Brasília, Brazil*

Background In 2012 the Brazilian Ministry of Health began discussing early treatment for patients with CD4 from 350 to 500. This recommendation aimed to increase the quality of life for PLVIH in Brazil. One of the concerns was the financial impact and the increased number of patients that would access the health system.

Methods To identify the number of PLVIH eligible we extracted from SISCEL's (a Brazilian centralised Laboratory Exams Control System) databank data of the patients with at least one CD4 test (in 2010, 2011 and 2012) between 350 and 500. SISCEL only includes patients on follow up within the public network of laboratories (currently 100 CD4 Laboratories). Around 75% of patients are on follow up in SISCEL. Additionally, to remove patients already on ART we crossed 2 databanks - the SISCEL with the SICLOM (a Brazilian centralised Drugs Control Logistic System). On the other hand, to identify the cost of initial ART, from the total of 1.395 currently dispensed, we selected the seven most used(AZT/3TC+EFV; AZT/3TC+LPV/r; TDF+3TC+EFV; AZT/3TC+ATV+RTV; AZT/3TC+NVP; TDF+3TC+ATV+RTV; TDF+3TC+LPV/r) that represent 91.5% of the initial treatment regimens.

Results There is a cumulative number of approximately 35.221 patients that are eligible for the new recommendation that are being monitored with a potential increase of up to 25% of the patients that are not in SISCEL. The proportional increase in the annual expenditure of ARVs would be of around 43 million dollars (10% increase in the total annual budget for ARVs of around 415 million dollars).

Conclusion From the data above we can conclude that a 10% increase in budget is a small expenditure in comparison to the potential benefits of early ART such as avoiding opportunistic infections, improving quality of life, diminishing costs of hospitalisation, increasing survival rate and diminishing risk of transmission.

O.10 – HPV: genital tract malignancy and vaccination

010.1 AGE SPECIFIC ROUND 1 RESULTS OF A CERVICAL CANCER SCREENING TRIAL: HPV FOCAL

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[1]**G Ogilvie**, [1]M Krajden, [2]D vanNiekerk, [2]T Ehlen, [1]R Martin, [1]L Smith, [2]S Peacock, [1]G C E Stuart, [3]E L Franco, [2]A J Coldman. *[1]University of British Columbia, Vancouver, BC, Canada; [2]BC Cancer Agency, Vancouver, BC, Canada; [3]McGill University, Montreal, QC, Canada*

Background HPV FOCAL Study is a randomised trial evaluating the efficacy of high risk-HPV DNA (hr-HPV) testing, with Liquid Based Cytology (LBC) triage testing of hr-HPV positives, compared to LBC testing alone (with triage hr-HPV testing for ASCUS positives) in an organised screening programme. Round 1 age specific results comparing differences in screen detection rates between women < 35 yrs vs ≥ 35 yrs are presented.

Methods Between January 2008 and May 2012, 25,243 consented women aged 25 to 65 were randomised to receive either: primary hr-HPV testing (HPV arms) or primary LBC testing (Control arm). Samples obtained with ThinPrep® LBC. HPV testing performed with Qiagen Hybrid Capture 2® High-Risk HPV DNA Test.

Results Data is presented for 21,985 participants enrolled as of July 1, 2011 who had completed Round 1 follow-up procedures by February 20, 2012. Overall, detection rates for CIN3+ were not statistically different between the HPV arm (7.8/1000; 95% CI: 6.1, 9.6) and the control arm (4.9/1000; 95% CI: 3.3, 6.5) when women of all ages were evaluated. In women ≥ 35yrs, the overall detection rate for CIN2+ and CIN3+ were both significantly higher in the HPV arm compared to the control arm (CIN2+: 9.9/1000 vs. 5.1/1000 respectively)(CIN3+: 4.4/1000 vs. 2.0/1000 respectively). For women < 35 yrs, HPV testing detected more CIN2+ and CIN3+ than LBC, but this did not achieve statistical significance. Overall, colposcopy referrals were higher in the HPV testing arm vs. control arm (59.1/1000, vs. 31.5/1000). HPV testing in < 35 yrs referred significantly more women to colposcopy than cytology (153.2/1000 vs. 73.3/1000).

Conclusion HPV screening with cytology triage detects significantly more CIN2+ lesions in women ≥ 35 years than LBC alone in the first round of screening. In women < 35, there was no difference in detection rates, but overall, HPV primary screening resulted in higher colposcopy rates.

010.2 A COMMUNITY-RANDOMISED PHASE IV HUMAN PAPILLOMAVIRUS (HPV) VACCINATION TRIAL OF VACCINATION STRATEGY

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J Paavonen. *Department of Obstetrics and Gynecology, University Hospital, Helsinki, Finland*

High-risk human papillomavirus (hrHPV) is the 2nd leading cause of cancer in women Bivalent Cervarix™ vaccine is highly efficacious against hrHPVs and associated precancers. Mathematical models disagree about the best vaccination strategy. Thus, we established a community randomised phase IV trial (CRT) to assess effectiveness of different vaccination strategies. During two school years (2007–8 and 2008–9) 80 000 1992–1995 born boys and girls were invited to participate in a CRT in a total of 33 communities in Finland. In 11 arm A communities 90% of girls and boys received HPV16/18 vaccine, in 11 arm B communities 90% of girls received HPV16/18 vaccine and boys received hepatitis B-virus (HBV) vaccine, and in 11 arm C communities both girls and boys received HBV vaccine. Effectiveness of the vaccination strategies in terms of reduction of hrHPV rates was assessed in vaccinated and unvaccinated 18.5 year-old girls. Recruitment resulted in equal enrolment of four birth cohorts (born 1992–95) comprising altogether 32 176 (approximately 40% response) adolescents, including 22 514 girls (> 50% response per birth cohort and arm) and 11 651 boys (20–30% response per birth cohort and arm). Already completed follow-up of 3 614 and 3 256 1992 and 1993 born girls at the age of 18.5 years prove that cervical samples from 350 vaccinated and 85 unvaccinated girls by community will be available. Assuming 80%–95% vaccine efficacy and 30%–50% effectiveness we have 80%–90% power to identify differences between vaccination strategies. In conclusion, this phase IV CRT augments decision making how to implement HPV vaccination programmes.

010.3 PREDICTORS OF WOMEN'S INTENTIONS TO RECEIVE CERVICAL CANCER SCREENING WITH PRIMARY HPV TESTING

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[1]**G Ogilvie**, [2]L Smith, [2]D van Niekerk, [2]F Khurshed, [3]S Greene, [3]S Hobbs, [2]A Coldman, [4]E Franco. *[1]University of British Columbia, Vancouver, BC, Canada; [2]BC Cancer Agency, Vancouver, BC, Canada; [3]University of North Carolina, Chapel Hill, Chapel Hill, NC, United States; [4]McGill University, Montreal, QC, Canada*

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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S Gupta, L Dar, P Kumar, V Sharma, K Verma, S N Dwivedi. *All India Institute of Medical Sciences, New Delhi, India*

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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[1,2]**A M Cornall**, [3]J Roberts, [1,4,2]S M Garland, [5]R J Hillman, [6]M Poyten, [6]F Jin, [6]A E Grulich, [1,4,2]S N Tabrizi, on behalf of the SPANC study team. *[1]Regional HPV Labnet Reference Laboratory, Department of Microbiology and Infectious Diseases, The Royal Women's Hospital, Parkville, Victoria, Australia; [2]Murdoch Children's Research Institute, Parkville, Victoria, Australia; [3]Cytology Department, Douglass Hanly Moir, Macquarie Park, New South UK, Australia; [4]Department of Obstetrics and Gynaecology, University of Melbourne, Parkville, Victoria, Australia; [5]The Western Sydney Sexual Health Centre, University of Sydney, Westmead Hospital, Westmead, New South UK, Australia; [6]HIV Epidemiology and Prevention Program, The Kirby Institute, University of New South UK, Sydney, New South UK, Australia*

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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L Kizima, A Rodriguez, J Kenney, M Hsu, **N Derby**, O Mizenina, R Menon, T Zydowsky, M Robbiani, J Fernandez-Romero. *Population Council, New York, NY, United States*