

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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**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.

## 0.10 – 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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**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 (7.3/1000; 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 PAPILOMAVIRUS (HPV) VACCINATION TRIAL OF VACCINATION STRATEGY

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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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