Conclusion Syphilis proficiency testing in rural facilities carried out by non-laboratory personnel using DTS is feasible. Initial training with on-site monitoring is important to detect any testing problems.

O3-S1.06 DIAGNOSTIC ACCURACY OF RAPID POINT-OF-CARE TESTS TO DETECT SYPHILIS: A META-ANALYSES

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Background The World Health Organization estimates that in 2006, there were 12 million new cases of syphilis. In developing countries, there is a lack of proper screening due to limited laboratory services and long distances from clinics. In developed countries, there is limited access to care among hard-to-reach populations. In this context of disconnect with the health care system, point of care (POC) tests have proven to be an invaluable resource, yet their accuracy needs to be established in order to justify their use.
Method Electronic databases were searched from 1 January 1980 to 24 September 2010 for articles evaluating syphilis POC tests. Data were extracted and a second reviewer independently reviewed a subset of the articles. Subgroups were made according to the index test, the sample tested, and reference standard employed. Pooled sensitivity and specificity were calculated using Hierarchical Summary Receiver Operating Characteristic Curve. Adjustments were made to account for imperfect reference standards.
Results 30 (47%) from 64 full text articles assessed articles were included in the meta-analysis. The most common kits evaluated were Determine, Bioline, Syphicheck, and Visitect in whole blood and sera samples. Using a Treponema Pallidum (TP) specific reference standard, in sera, the Determine test was the most accurate with a pooled sensitivity of 98.43% (96.03, 99.94) and a specificity of 97.74% (96.38, 98.92). In whole blood, Bioline was the most accurate with a sensitivity of 87.70% (84.78, 90.58) and a specificity of 99.07% (98.50, 99.59). The sensitivity of Determine and Visitect were lower when using whole blood than when using serum. When we adjusted for imperfect reference standards, the pooled parameters of accuracy improved when compared to pooled accuracy under the assumption of a perfect reference standard.
Conclusions Determine with high sensitivity and Bioline with high specificity appeared to perform the best of the tests studied. Higher accuracy in serum warrants the use of serum rather than whole blood wherever possible. Confirmation with non-TP specific reference standard are required to confirm whether the infection is active or treated.

Clinical sciences oral session 2: Genital Human Papillomaviruses & Trichomoniasis

O3-S2.01 LONG-TERM EFFICACY OF HUMAN PAPILLOMAVIRUS VACCINATION AGAINST CIN3 AND INVASIVE CERVICAL CARCINOMA: A REGISTRY BASED PASSIVE FOLLOW-UP OF THE PHASE III TRIAL (PATRICIA)

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Background While phase 3 trials have shown that vaccination against human papillomavirus (HPV) types 16 and 18 prevents persistent HPV type 16 and 18 infections and most high-risk HPV type positive cervical intraepithelial neoplasia (CIN) grade 2+ lesions, long-term follow-up of the phase 3 cohorts is needed to demonstrate that HPV16/18 vaccination prevents CIN3 and invasive cervical carcinoma (CIN3+).
Methods We used data from the Finnish Cancer Registry for passive follow-up of cluster (age-cohort) and individually randomised cohorts of women born in 1984–1989 to assess incidence rates of CIN3+ in HPV16/18 vaccinated Finnish cohort of the bivalent HPV 16/18 vaccine PATRICIA trial participants (N=2404) and a reference cohort (N=7049) enrolled from the same communities. Six months after the Phase III trial was closed in 2009 the cohorts were linked with the Finnish Cancer Registry.
Results and Conclusions A pilot study in 2009 showed that the baseline incidence of CIN3+ was 41 per 100 000 women years in the reference cohort. Knowing that CIN3+ incidence rapidly increases as the cohorts age, the baseline incidence yields 80% power to show 70% vaccine efficacy against CIN3+ in just 5 years. The phase 3 trial included intensive clinical follow-up and thorough health education and counselling which may have modified subsequent risk of cervical neoplasia in all study participants, the incidence rates of CIN3+ need to be validated in a cohort not exposed to any clinical intervention. Preliminary data from such comparison of the incidence rates during passive follow-up the PATRICIA study participants (comprising 50 000 women years) and the reference cohort will be reported.

O3-S2.02 LONG-TERM EFFICACY OF HUMAN PAPILLOMAVIRUS VACCINATION AGAINST CIN3 AND INVASIVE CARCINOMA: REGISTRY BASED FOLLOW-UP OF A PHASE III TRIAL (FUTURE II)

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Background Human papilloma viruses (HPV) 16/18 are known to cause approximately 70% of cervical cancers. Phase III clinical trials of HPV vaccination have demonstrated >95% efficacy against persistent HPV type 16/18 infections and associated cervical intraepithelial neoplasia (CIN) grade 2+ lesions, and up to 90% efficacy against all CIN3+ lesions. A long-term follow-up is, however, needed to confirm the protective efficacy against cervical carcinoma.
Methods Phase III clinical trial (FUTURE II) consisted of intensive clinical 4-year follow-up including health education and counselling. The intervention potentially affects the incidence of neoplasia also in the placebo group. To increase power of the long-term follow-up and to determine the impact of the clinical intervention as such, a population based reference cohort of similarly aged women not exposed to any intervention was enrolled at the same time from the same communities. The HPV vaccine cohort and placebo vaccine cohort of 16–17-year-old women from the Finnish FUTURE II trial (N=1749) and a reference cohort of 18–19-year-old women (N=15 744) were linked with the Finnish Cancer Registry to determine the incidence of CIN3 and cervical cancer (CIN3+) during the passive follow-up, starting 6 months after the clinical follow-up of the phase III trial was completed.
Results & Conclusions Currently the incidence of CIN3+ at the age of 20–24 years is 95 per 100 000 person years in Finland (http://www.cancer.fi). The incidence doubles in 5 to 10 years as the cohorts age. Thus, in less than 10 years the cumulative incidence yields 80% power to demonstrate 90% vaccine efficacy against cervical CIN3+. During the first 2 years this passive registry-based follow-up identified no CIN3+ cases in the HPV vaccine cohort,

two cases in the placebo vaccine cohort, and 21 cases in the unvaccinated reference cohort suggesting that the vaccine efficacy translates into efficacy against cervical cancer. The passive follow-up continues and new cases emerging in future will be monitored by redoing linkage with the population-based cancer register at specific time intervals in the future, which will effectively add up person years to our follow-up study. In conclusion, valid comparisons between the vaccine and placebo recipients (excluding cross-vaccinated placebo vaccine recipients) and the reference cohort not exposed to intervention are feasible, and will be critical to define more definitively the long-term protection provided by HPV vaccination against the hard endpoints.

03-S2.03 THE SPECTRUM OF GENITAL HPV INFECTION AMONG MEN ATTENDING A SWEDISH STI CLINIC: HPV TYPING AND CLINICAL PRESENTATION

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Background Some Swedish studies on HPV typing in men exist. Most earlier studies have used less sensitive HPV typing techniques. The purpose of this study is to see if the HPV types in genital HPV associated lesions have changed since the 80ies, and to describe the lesions in detail.

Methods Between 2004 and 2007, male patients attending the STI clinic of Karolinska Hospital with genital HPV induced lesions planned for surgery, were asked to participate in the study. All men exhibited multiple lesions—men with solitary lesions were excluded. Two clinically identical lesions on the same genital site, were collected by punch biopsy or by scissor excision. One sample was put in formalin for histopathological routine preparation, and the other sample was frozen in −70°C for PCR analysis using a highly sensitive nested PCR technique, detecting 24 different HPV types. The macroscopic morphology of the lesions was classified in acuminate, papular, macular and seborrhoeic keratosis like. The colour of the lesions and the location were recorded. Data on previous therapy and how long time the patients had been afflicted with genital symptoms/and or warts was also noted.

Results Totally 303 men were included in the study. Of these, 47 men (16%) exhibited lesions of PIN and have been described previously. The remaining 256 men had benign lesions and are described here. Acuminate lesions dominated, occurring in 106 (41%) of the men, followed by papular lesions found in 88 (34%) men. The penile shaft, the pubic area and the foreskin were the most common locations for the HPV induced lesions, afflicted in 36%, 29% and 25% of the men, respectively. Pink and brown were the dominating colours of the leions. HPV was detected in 233 (91%) lesions. Low risk HPV types only, were found in 75% of the lesions. On the other hand, 7% of the lesions contained only high risk HPV types, and 9% had a mix of low- and high risk HPV types. Multiple HPV types were found in 13%. HPV 6 was the most common HPV type (70% of the lesions were positive for HPV 6 only). Duration of genital symptoms and/or warts was mean 24 months and 211 of the men had previously been treated.

Conclusion Using a highly sensitive PCR technique, a high HPV detection rate of 91% was found. As in earlier studies, HPV 6 was most common, but also other HPV types including high-risk types were detected. As expected, most of the benign lesions were acuminate, but the morphology as well as the genital location varied.

03-S2.04 CERVICAL ECTOPY IS NOT ASSOCIATED WITH ACQUISITION OF HPV INFECTION

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Background HPV infection and cervical cancer are often found at the cervical transformation zone. High rates of HPV in adolescents have been attributed to their greater extent of "cervical ectopy", defined as areas of columnar and metaplastic epithelium visible on the ectocervix. The study aim was to examine associations between the extent of cervical ectopy and incident HPV infection in healthy adolescents.

Methods Sexually active young women were enrolled as part of a prospective HPV Natural History Study. Women were eligible if they were 13–21 years old, sexually active (5 years maximum), and had no history of cervical intraepithelial neoplasia, cervical procedures, or immunosuppression. At 4-month interval visits, we performed colpophotography to document the epithelium, HPV testing for 37 types by Roche Reverse Line Blot assay, and interviews to assess behaviours. This study selected women (N=147) who had negative HPV results at the first two consecutive visits. Epithelial areas of interest were measured in the digitised colpophotographs by using computerised planimetry to produce pixel counts. The extent of ectopy was measured as a percentage of the total cervical face. Cox proportional hazards models examined ectopy as a predictor for incident HPV, defined as the first positive HPV result following the initial two negative results, adjusted for the number of new sexual partners. Outcomes included incidence of any HPV type; α-9 HPV types (defined as 16, 31, 33, 35, 52, 58, 67); and a-3/15 HPV types (defined as 61, 71, 72, 81, 83, 84, 89).

Results The 147 women attended a total of 545 visits. The mean age at baseline was 17.2 years, mean age of menarche was 12.8 years, and mean age of first sex was 15.4 years. Self-reported race/ethnicity was 35 (24%) Asian, 14 (10%) African-American, 43 (29%) Caucasian, 52 (35%) Latina, and 3 (2%) Other. The median ectopy measurement from the 545 visits was 14% (interquartile range 6–32%) of the total cervical face. Incident HPV of any type was found in 42 (29%) women. The extent of ectopy was not significantly associated with incidence of any HPV type (HR 1.004, p=0.63); α-9 HPV types (HR 0.99, p=0.43); or α-3/15 HPV types (HR 1.02, p=0.18). Results were unchanged when adjusted for new sexual partners in the past 8 months (HR 1.9, p<0.01).

Conclusions When measured quantitatively, the extent of cervical ectopy is not a risk factor for the acquisition of HPV infection in healthy adolescent women.

03-S2.05 PREVALENCE OF *TRICHOMONAS VAGINALIS* AND CO-INFECTION WITH *CHLAMYDIA TRACHOMATIS* AND *NEISSERIA GONORRHOEA* IN THE USA AS DETERMINED BY THE APTIMA *TRICHOMONAS VAGINALIS* NUCLEIC ACID AMPLIFICATION ASSAY

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Background *Trichomonas vaginalis* (TV) is the most common curable sexually transmitted infection worldwide. True prevalence of TV infection is not well characterised as previous studies mainly used