case of the Scottish data that revealed 77% of syphilis cases there to be type 14d.

O3-S1.03 PERFORMANCE OF REVERSE SEQUENCE SYPHILIS SCREENING IN JAMAICA

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Background Algorithms for syphilis serologic testing traditionally have relied on screening with a non-treponemal test, such as the rapid plasma reagin (RPR) test or the toluidine red unheated serum test (TRUST) followed by confirmation using a treponemal test, such as Treponema pallidum particle agglutination (TP-PA). To reduce time, material and labour costs, many laboratories, including at the Comprehensive Health Centre in Kingston, Jamaica, have reversed the sequence testing first with a rapid treponemal test followed by non-treponemal testing of reactive sera.
Methods In a survey of STIs among men who have sex with men (MSM) in Jamaica, syphilis serologic testing is currently conducted using an initial rapid treponemal SD Bioline Syphilis 3.0 test followed by TRUST for reactive sera. Discordant sera that are Bioline-positive and TRUST-negative, or sera with TRUST titres < or =8 undergo supplemental testing by TP-PA. SD Bioline was previously validated in the field and reference laboratory in Jamaica and is 95.2% sensitive and 93.5% specific compared to TP-PA. Here we report the results from sera obtained from 135 MSM in Kingston between December 2010 and February 2011.
Results Among 135 sera evaluated using the reverse syphilis screening sequence, 13 (9.6%) had a positive rapid treponemal test. Among these 13 reactive sera, 6 (46.2%) were nonreactive with TRUST. All discordant sera were also reactive by TP-PA, indicating that initial rapid testing did not produce false-positives in this setting. The proportion of discordant syphilis test results was similar among HIV+ and HIV- men. The prevalence of primary syphilis detected by concordant positive treponemal and non-treponemal tests in this survey was 5.2%, compared to 5.3% in a previous survey conducted in this population during 2007–2008 using the traditional screening sequence.
Conclusions The prevalence of primary syphilis among MSM in Kingston has not changed since the previous survey. In the current survey using the reverse screening sequence, nearly half of sera that were reactive with the treponemal test produced discordant results with the non-treponemal test. Such results are consistent with previous syphilis infection, treated or untreated, or early primary syphilis in which non-treponemal antibodies have yet to develop. Distinguishing these possibilities requires detailed history and clinical assessment in addition to serologic test results.

O3-S1.04 PERFORMANCE CHARACTERISTICS OF BIOPLEX 2200 SYPHILIS IGG AND LIAISON TREPONEMA AUTOMATED ASSAYS FOR DETECTION OF ANTIBODIES TO *TREPONEMA PALLIDUM*

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Background Serological testing continues to be a crucial tool for syphilis diagnosis and control. The commonly accepted syphilis screening algorithm is screening with non-treponemal tests such as RPR or VDRL, and confirming with treponemal tests such as TP-PA. Recently, automation has been introduced whereby serological screening using treponemal tests has resulted in reduced labour time and removal of the subjectivity associated with the traditional testing algorithm. The objective of this study was to compare the performance characteristics of two FDA approved automated tests, the BioRad BioPlex 2200 Syphilis IgG and the DiaSorin LIAISON treponemal assays, with known predicate tests. The BioPlex 2200 syphilis IgG is a multiplex test that utilises three analytes (15-, 17-, & 47-kDa) to detect specific IgG antibodies, whereas the LIASION treponemal assay uses only one analyte (17 kDa) in a single step sandwich method to detect both syphilis IgG and IgM antibodies.
Methods A total of 1086 commercially obtained sera tested in this study consisted of: 430 from pregnant women, 409 from HIV positive individuals, and 111 from known syphilis patients of various disease stages. Characterised syphilis samples (n=140) were also obtained from the CDC serum repository. All samples were screened by the Bioplex IgG, Liaison, RPR and TP-PA tests. Any indeterminate results were repeated at least once.
Results Of the 1086 samples tested, the syphilis reactivities were the following: 551 (50.7%) by BioPlex IgG, 528 (48.6%) by LIAISON, and 509 (46.9%) by TP-PA. The sensitivity and specificity when compared to TP-PA for LIASION was 98.8% and 90.5% respectively. The BioPlex IgG sensitivity and specificity when compared to TP-PA was 85.1% and 80% respectively. Overall, 443 (40.8%) samples were found to be reactive and 450 (41.4%) non reactive to both LIAISON and BioPlex IgG. All three tests agreed on 877 (81%) samples. On the 209 discordant samples TP-PA agreed with LIAISON 85.2% (n=178), BioPlex 7.2% (n=15), but disagreed with both tests 7.7% (n=16).
Conclusion Both tests have high throughput, walk-away capability, and would be useful in low prevalence settings. There was good agreement between the LIAISON and the BioPlex IgG in 893 (82%) samples (Cohen's κ=0.64). The LIAISON had higher sensitivity most likely due to its detection of both IgG and IgM, while the BioPlex detected only IgG antibodies. Both tests show significant promise in the future of syphilis serology.

O3-S1.05 QUALITY ASSURANCE OF SYPHILIS TESTING IN A RURAL HEALTH FACILITY USING DRIED TUBE SPECIMENS (DTS)

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Background Assuring the quality of a diagnostic test is important in healthcare. For syphilis testing, this includes proficiency testing of previously well characterised serum samples by health workers blinded to the results of characterisation. As part of a study on the feasibility of using a Point of Care (POC) rapid test devise for syphilis testing in rural antenatal settings, proficiency testing material prepared in a referral laboratory using Dried Tube Specimens (DTS) was sent for testing by the nurses/midwifes in these rural settings.
Methods Five well characterised DTS (one high RPR reactive, three low RPR reactives and one RPR non-reactive) were sent for on-site testing in eight rural antenatal facilities in Eastern Ghana. Training of nurses/midwifes in reconstituting the DTS and their testing and reporting was previously carried out. An instruction leaflet was enclosed in each batch of the DTS. Four rounds of the testing were carried out at monthly intervals.
Results Seven out of the eight facilities correctly reported results of the DTS for all the rounds. One facility however reported all specimens as negative at the first round. On-site investigation showed that the nurse running the antenatal clinic who normally wore reading glasses had lost them. On replacing her glasses and going through an on-site re-training, she obtained 100% in subsequent rounds of testing.

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,