O02.2 OPERATIONAL PERFORMANCE OF A NEW MOLECULAR-BASED POINT-OF-CARE TEST FOR DIAGNOSIS OF *CHLAMYDIA TRACHOMATIS* AND *NEISSERIA GONORRHOEAE* INFECTION: CONCORDANCE WITH CONVENTIONAL LABORATORY TESTING

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Introduction New molecular-based point-of-care (POC) tests for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) infections are being used for the first time by trained Aboriginal health workers/practitioners, registered/enrolled nurses and medical officers in regional/remote health services in Australia as part of TTANGO (Test, Treat ANd GO). We assessed the operational performance of the GeneXpert®CT/NG assay (Cepheid) POC test using conventional laboratory tests as the reference standard.

Methods TTANGO, a randomised cross-over control trial of CT/NG POC testing, commenced June 2013. To date, 12 services have implemented GeneXpert testing on-site as routine practice, with specimens still sent to jurisdictional laboratories for conventional nucleic acid amplification testing (NAAT) as usual. We assessed the concordance of GeneXpert performed by health service staff with conventional laboratory NAAT. We also present selected details of discordant specimens.

Results Among 1995 GeneXpert tests performed, CT and NG were detected in 182 and 127, respectively, by the jurisdictional laboratory. CT concordance was 99.4% (95% CI: 99.0 – 99.8) and NG was 99.9% (99.6–100.0). The fourteen discordant results (eight urines, six lower vaginal swabs) were identified in seven services and five laboratories (two use Cobas 4800, three use Aptima). Discordant results were predominantly CT (n = 12) and most (n = 10) were positive POC/negative laboratory results. The median POC test crossing point among CT discordants was 37.2 (IQR: 31.6–37.7) with five of nine (55.6%) having crossing points >35, compared to 29.2 (IQR: 26.3–32.6) among CT concordants with 10 of 179 (5.5%) having crossing points >35. The two NG discordant results were both positive POC/negative laboratory results.

Conclusion The performance of GeneXpert in the hands of trained health service staff is excellent and consistent with previous laboratory and field evaluations. Higher crossing points of discordant results most likely indicates low organism loads close to test detection threshold and seem unrelated to service, laboratory, specimen type or reference assay. Overall, results show the GeneXpert method is suitable for routine detection of CT and NG.

Disclosure of interest statement No conflicts of interest declared. No financial support was received by Cepheid. Cepheid has provided GeneXpert devices on loan for the duration of TTANGO and test cartridges at a reduced rate.

O02.3 ARE RAPID POINT-OF-CARE TESTS FOR SYPHILIS USEFUL IN OUTBREAK SETTINGS IN REMOTE AUSTRALIA? – AN EXPERIENCE FROM THE NORTHERN TERRITORY

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Introduction A rapid point-of-care test (PoCT) for syphilis was used in two community-wide screens as part of an outbreak response in remote Northern Territory (NT) in 2014. This paper reports the results and evaluation for using PoCT as a tool for outbreak management.

Methods A community-wide screen for people aged 12–30 years was conducted in two remote communities in the NT with high numbers of new cases and contacts, using the OnSite Syphilis Ab Combo Rapid Test. Preparatory work included devising a screening protocol, community engagement, clinical staff training and mobilisation of resources.

Results The two screens were conducted in September to December 2014 in the two communities. The combined population of residents in the targeted age group was 545. A total of 326 individuals (including 57 non-residents) were tested with the PoCT (44.5% males and 55.5% females). The age range was from 12 to 30 years (median: 18, interquartile range: 14–23). Of these, 30 tested positive (13 males and 17 females), giving a combined prevalence among those tested of 9.2% (9.0% in males, 9.4% in females). All positive PoCT results were confirmed positive by normal syphilis serology tests, with 14 and 10 of them categorised as confirmed and probable infectious syphilis cases respectively. Treatment was given on the spot for these cases and contact tracing initiated immediately. Of the 296 tested negative, 5 (1.7%) were found to be false negative later due to past history of infection. Staff reported excellent acceptability of the test method for specimen collection.

Conclusion With prior community engagement, updated population lists, screening protocols, and staff training, using PoCT for syphilis can be an effective for case detection in an outbreak setting in remote Indigenous communities in Australia. However, given the reported sensitivity of the PoCT used, retesting in 3 months is important.

Disclosure of interest statement No potential conflicts of interest are identified.

O02.4 FIELD EVALUATION OF STANDARD DIAGNOSTICS DUO HIV AND SYPHILIS TEST AMONG FEMALE SEX-WORKERS IN JOHANNESBURG

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Introduction Point-of-care tests (POCT) for STI/HIV provide immediate results with the opportunity for same day treatment,

counselling and partner notification. Combination POCTs for HIV and syphilis are particularly beneficial for pregnant women and key populations as treating these infections early reduces vertical and community transmission.

Methods We evaluated Standard Diagnostics' Duo HIV and Syphilis Test (SD bioline) among female sex-workers (FSW) in the inner-city of Johannesburg. SD bioline was conducted on-site using whole blood according to manufacturer's instructions and compared to Genscreen HIV 1/2 V2 – 3rd and Vironostika Ag/Ab – 4th generation assays for HIV and to the *T. pallidum* particle agglutination (TPPA) test for syphilis. A Rapid Plasma Reagin (RPR) test was conducted in the laboratory to assist with classification of treponemal disease. Sensitivity, specificity, positive predictive values (PPV) and negative predictive values (NPV) were calculated

Participants with HIV were referred to HIV services and those with syphilis were managed according to national guidelines. The study received ethics approval.

Results We recruited 263 FSW, 14 (5.3%) declined an HIV test and were excluded. Among the remaining 249 FSW 187 (75.1%) women were HIV positive and 51 (20.5%) had evidence of syphilis with 7 (2.8%) having active syphilis. For HIV sensitivity was 98.9% (95% CI: 95.8–99.8), specificity was 100% (95% CI: 92.7–100), PPV was 100% (95% CI: 97.5–100%) and NPV was 96.9% (95% CI: 88.2–99.5). For treponemal antibody detection, sensitivity was 66.7% (CI: 52.0–78.9), specificity was 98.0% (CI: 94.5–99.3), PPV was 89.5 (CI: 74.3–96.6) and NPV was 91.9% (CI: 87.2–95.1). Sensitivity increases to 85.7% for active syphilis (RPR > 1:4).

Conclusion Although the SD bioline performs well for HIV diagnosis, the assay has lower sensitivity for syphilis detection in our field setting compared to published laboratory evaluations. Using the test in screening programmes will detect both HIV and active syphilis but will result in overtreatment for syphilis.

Disclosure of interest statement The study was funded by USAID/PEPFAR and AIDS Fonds. SD bioline tests were provided by SD diagnostics.

O02.5 EVALUATION OF FIVE RAPID POINT-OF-CARE TESTS FOR SYPHILIS: TWO TREPONEMAL ONLY, AND THREE DUAL TREPONEMAL/HIV ASSAYS

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Background Traditional syphilis and HIV screening strategies require laboratory capacity which is often limited in resource-poor settings. Affordable rapid point-of-care tests (RPOCT) with high sensitivity and specificity would allow same-day testing and referral for treatment of syphilis and HIV in pregnant women. This would allow a decrease in adverse outcomes as a result of mother-to-child transmission (MTCT). We compared test performance of two RPOCT treponemal tests and three combination treponemal/HIV tests for detection of treponemal antibodies in sera; and we also examined test performance of the three RPOCT treponemal/HIV tests for detection of HIV antibodies in sera.

Methods We tested banked sera previously characterised for syphilis (n = 1186), from San Francisco Department of Public Health, Kaiser Permanente Northern and Southern California, and 437 known HIV-positive samples (CDC HIV), according to manufacturer's insert with 3 dual HIV/Syphilis RPOCT: SD BIOLINE HIV Syphilis Duo (Standard Diagnostics), Multiplo TP/HIV (MedMira) and DPP HIV-syphilis Assay (Chembio), and 2 treponemal-only tests: SD Syphilis 3.0 (Standard Diagnostics), Determine SyphilisTP (Alere). Positive agreement across tests was determined and RPOCT results were compared to prior test results.

Results The 5 assays had concordant positive result of 84% (1362/1623) for treponemal antibodies, and 96.6% (1569/1623) for HIV antibodies. Compared to previously reported results, treponemal tests had sensitivities and specificities of; SD 3.0 – 72%, 97.2%; SD DUO- 72.2%, 97.2%; Multiplo- 80.7%, 88.7%; Chembio – 82.5%, 96.4%; DetermineTP- 89.3%, 97.5%. The 3 treponemal/HIV assays sensitivity was100% for 437 known HIV-positives compared to standard assays.

Conclusion Positive agreement was greater for HIV antibodies than for treponemal antibodies; Using banked sera could have affected performance of treponemal assays. Further prospective studies need to be performed in the field to better characterise performance of RPOCT treponemal tests. Findings from this study will provide data to guide countries' selection of RPOCTs for syphilis and HIV screening.

Disclosure of interest statement The reagents/kits for this study, were donated by the various manufacturers (Standard Diagnostics, MedMira, Chembio, and Alere).

O02.6 A LOW-COST MOBILE NAAT PLATFORM FOR *CHLAMYDIA TRACHOMATIS*

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We report the development of a low-cost mobile nucleic acid analysis platform (mobiLab) utilising a smartphone-enabled microfluidic device for streamlined analysis of biological samples. Using magnetic particles as a mobile solid phase for nucleic acid capture and transport, fluidic processing is simplified to particle translocation on a robust and scalable cartridge.

Process integration facilitated by Bluetooth-enabled microcontrollers enables full control of the instrument by the user with a smartphone application. Each cartridge costs less than $2 using off-the-shelf reagents and materials, an order of magnitude cheaper than $9.98/test for a GeneXpert cartridge. The instrument utilises a microcontroller which controls the rotary bead manipulator, thermal incubation and Bluetooth-based communication with the smartphone application. Each assay consumes approximately 10% of the battery capacity, allowing up to 10 assays to be performed consecutively without access to a power outlet.

We designed a single-stream loop-mediated isothermal amplification (LAMP) assay to operate in tandem with the mobiLab platform. We tested the single-stream assay using plasmid targets and were able to capture and amplify 10^3 copies of gene targets. Absence of cross-reactivity with human genomic DNA or other vaginal flora was verified.