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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Abstracts

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 ANG 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.

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.

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,