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Assessment of the performance of a rapid point of care syphilis test in a London genitourinary medicine clinic

Dear Editors,

We read with interest the paper by Pai et al.[1] who conducted an innovative observational study of screening for syphilis, hepatitis B and HIV with rapid point-of-care tests (POCTs) on pregnant women presenting for antenatal care in rural India. While the prevalence of syphilis infection was only 0.2%, a high level of acceptance was observed.

Whilst data are available from similar populations using syphilis POCTs, there remains paucity of data for use in men who have sex with men (MSM) populations.

The UK is currently experiencing an epidemic of syphilis among MSM. The Health Protection Agency in 2009 reported a resurgence of syphilis in MSM and more diagnosis than in any other year since 1950.[2] Our genitourinary (GU) medicine clinic diagnoses some of the highest rates of sexually transmitted infections in the UK and MSM comprise one of the most important target populations.

Although rapid POCTs are now available for specific *Treponema pallidum* antibodies, clinical trials[3,4] of these tests have been so far mostly limited to resource-poor settings where they have been shown to be an effective strategy. Few data are available from these tests used within the UK.[5,6] Reliable rapid testing might enable quicker diagnosis and treatment on the day of clinic attendance and expedited partner notification.

We undertook a pilot evaluation of the Treponema pallidum (TP) Determine POCT (Alere Medical, Stockport, UK) to assess its utility in a GU medicine clinic setting in London. Gold standard testing for syphilis within our clinic has traditionally relied on (1) dark field microscopy (DFM) examination of suspected infectious lesions, (2) treponemal serological testing (Architect Syphilis chemiluminescence assay [CLIA; Abbott laboratories, Abbott Park, IL, USA]), confirmed with *T. pallidum* particle agglutination test (TPPA; Serodia, Fujirebio Inc., Tokyo, Japan), and (3) non-treponemal serological tests (rapid plasma reagin test [RPR; Omega Diagnostics, Alloa, Scotland, UK]). Between June 2010 and January 2011 whole blood samples were obtained from 92 patients who were already attending clinic for blood tests. Blood was taken via venepuncture into an EDTA tube – blood for the POCT was pipetted from the tube using the device supplied with the Determine POCT. Some patients were undergoing follow-up for previously diagnosed treponemal infection ($n = 48$) while the remainder were attending for routine GU screening, including syphilis testing. The TP Determine POCT was conducted according to the instructions of the manufacturer, with any positive line visible in the test strip interpreted as reactive. Tests were easy to perform and results were read after 20 min by two of the three investigators who agreed on a reactive or non-reactive result.

Of the 92 patients tested, 77 (84%) were men; 65/77 (84%) were MSM. Median age was 34.5 years and 30/92 (33%) were HIV positive. Treponemal antibody positivity by both the CLIA and TPPA tests was confirmed in 46 specimens, and RPR titres were determined for all of these. Of the 46 true-positive samples, 42 tested positive with the POCT; no false positive POCTs were observed in any of the 46 antibody-negative patients. Reassuringly, of the two POCTs performed in patients with primary syphilis, both were reactive and in the one case of untreated secondary syphilis the POCT was also reactive.

In this small pilot study, we report a sensitivity of 91.3% (95% CI 79.2%–97.5%) and a specificity of 100% (95% CI 92.2%–100%) for the Determine syphilis POCT when used in our GU medicine clinic. A previous study of POCTs for syphilis conducted in the Netherlands has shown similar sensitivity although a much lower specificity.[7] Specificity of had also been lower when preformed by Guinard et al.[8] using a dual rapid test (Chembio Diagnostics Systems Inc., Medford, NY, USA). Herring et al.[9] conducted the largest multicentre trial of *T. pallidum* POCTs on archived sera. Nine rapid POCT syphilis tests were evaluated at eight laboratories on different continents. Sensitivities and specificities in their trial ranged between 84.5–97.7% and 92.8–98%, respectively. Whilst our

numbers were small none of the 19 HIV-positive patients showed a falsely reactive result; in previous studies, false-positive POCTs have been reported more frequently in HIV-positive sera;[9,10] Of the four false-negative POCTs, three were from HIV-positive patients and the POCT sensitivity in this population warrants further study. Whilst no high-titre syphilis infection was missed the sensitivity of the POCT appears lower than standard serological testing and we consider this POCT to be insufficient for routine screening in our setting. Of concern was that three of the four false negative POCTs occurred in MSM with recently acquired infections (two of three already treated).

Such studies are needed to determine the POCT's utility for rapid diagnosis of primary and secondary syphilis in our setting. In two patients with DGM-positive primary syphilis faintly reactive POCT results were obtained, suggesting that the POCT might have some use in such clinical scenarios, particularly in settings where DGM is unavailable. Although easy to perform the test did have the potential for inter-reader variability as nine positive POCTs had only a faintly positive line.

We suggest that although the TP Determine POCT was able to be used easily in our GU clinic setting our results suggest the sensitivity is too low to replace standard serologic screening within our service. With a high uptake of POCTs for HIV testing in many clinical settings,[11] potential exists for syphilis screening to be omitted entirely if patients opt to decline phlebotomy. Use of syphilis POCTs adjacent to or in conjunction with HIV POCTs offers reasonable performance and would be preferable to no screening, especially in MSM where an ongoing syphilis epidemic exists. While loss to follow-up occurs infrequently within our clinic, it is sometimes an issue; for patients at high risk of loss to follow-up such a POCT might be more useful. In addition, ongoing high-risk sexual behaviour in the time between testing and treatment is seen frequently in our patients and POCTs might help to reduce the risk of onward transmission in this setting if infections can be diagnosed and treated at the initial visit.

Further studies on the use of syphilis POCTs in GU settings are warranted.

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