Usability and acceptability of a novel rapid lateral-flow self-test for the detection of active syphilis infection

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Background: There are no point-of-care or self-tests that accurately discriminate active and past-treated syphilis. We developed a rapid lateral-flow self-test that reliably distinguishes active from past-treated syphilis, with results in 15 minutes. In a laboratory setting, the test has 100% sensitivity for detecting active syphilis (reactive RPR), 99% specificity in those never infected, and differentiates active syphilis in 4/5 past-treated (>3 months post last infection) cases. We conducted a first in-human study assessing self-test usability and acceptability among people at risk of syphilis.

Methods: Clients attending a community-led HIV/STI testing service were asked to perform the self-test under observation and without assistance across two iterative implementation phases. In Phase 1, participants received paper-based instructions for use (IFU) prior to testing, with optional access to a video IFU. Based on Phase 1 observations, in Phase 2 participants were required to view the video IFU. Observers recorded user errors. Participants completed a survey assessing usability, acceptability, and willingness to use.

Results: Among 120 participants (mean age 36 years; 30% with a history of prior syphilis), 109 (91%) successfully completed the self-test; completion rate was higher in Phase 2 compared with Phase 1 (96% vs 78%). Among the 11 participants who did not complete the test successfully, errors included producing insufficient blood (n=3), premature inversion of the collection tube to test strip (n=5), failure to prick finger (n=1), and failure to release the buffer (n=2). Most participants reported that the test was easy to use (88%), felt confident performing the test alone (93%), would recommend it to a friend (85%), and would use syphilis self-testing if available free of charge (91%) or at a cost under AUD$30 (57%).

Conclusions: High usability and acceptability of our novel active syphilis self-test support the feasibility of syphilis self-testing and expanding access to timely syphilis diagnosis in at-risk populations.

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