Accuracy of Two New Point-of-Care Tests for *C. trachomatis*

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Background: Nucleic acid amplification tests (NAATs) are currently recommended to detect *Chlamydia trachomatis* (CT), however are costly and require 2-3 days for results. Accurate point-of-care (POC) tests for CT could increase treatment and decrease loss to follow-up, which is important for young women.
Aims: This study aims to assess the performance (sensitivity/ specificity) of two new POC CT test devices (A or B) on vaginal and cervical samples compared to the gold standard (cervical swab NAAT).
Methods: Women receiving a pelvic exam were recruited. Subjects obtained a vaginal self-swab and the clinician obtained a cervical swab during the pelvic exam. These swabs were tested with either POC device A or B. Results were compared to cervical NAAT (strand displacement assay). For each device, vaginal swabs were compared to cervical swab results. Point estimate and 95% confidence intervals (CI) were generated for test performance measures.
Results: 114 subjects completed testing, 33 with device A and 81 with device B. The mean age of subjects was 18.2 years (range 14-30), and 86% were Black race. Compared to NAAT, device A was 38% (95%CI: 8.5 -77.5) sensitive for both cervical and vaginal samples, while specificity was 73% for cervical and 60% for vaginal swabs. Compared to NAAT, sensitivity of device B was 46% (95%CI: 19.2-75) using cervical and 7% (95%CI: 0.2 -33) using vaginal swabs, with 100% specificity on either sample. For Device A, the self-collected vaginal was 88% sensitive and 82% specific compared to the cervical swab device A result. In contrast, the vaginal sample using device B was 17% sensitive and 100% specific compared to the cervical device B result.
Conclusion: Preliminary results show that both POC devices had poor sensitivity on cervical or vaginal samples, and could not be used for screening. A device with high specificity might be a useful diagnostic tool for symptomatic women, as it would indicate immediate treatment. The poor performance on vaginal swabs would preclude device use in non-clinical settings. A larger sample size is needed to determine reliable estimates of the properties of these tests.