

EVALUATION OF REDUCED POOLED URINE VOLUME TO IMPROVE TEST SENSITIVITY FOR MOLECULAR POINT-OF-CARE DETECTION OF CHLAMYDIA AND GONORRHOEA – PRELIMINARY RESULTS

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Background: This study aims to evaluate the sensitivity of pooled self-collected urogenital, pharyngeal and anorectal specimens, using a revised pooling methodology, compared to individual samples for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) at the point-of-care (POC).

Methods: Consenting clients (≥16 years) attending urban, peer-led community testing services are offered CT/NG molecular POC testing of three self-collected specimens (urine, pharyngeal and rectal swabs) using GeneXpert (Cepheid, Sunnyvale, CA). If any specimen provides a detected result, all three specimens are pooled using the revised method and retested. Pooled test results are compared against individual test results to determine agreement.

Results: To date, 161 participants have provided three anatomical specimens. CT was detected at one or more anatomical site for 26 (16.1%) participants; for NG 30 (18.6%). Pooling failed to detect one CT (urine) and three NG (pharyngeal 2; rectal 1) infections. Overall sensitivity, negative predictive value and Cohen's kappa of pooling compared to individual specimen testing for CT is 96.2% (95%CI 78.4%; 99.8%), 99.3% (99.3%; 95.4%) and 0.977 (0.931; 1) respectively; for NG, 90.0% (95%CI 72.3%; 97.4%), 97.6% (92.6%; 99.4%) and 0.935 (0.863; 1). Samples with low microbial loads (cycle threshold ≥ 35.0) are less likely to be detected on pooling.

Conclusion: A reduction in urine volume used in pooled samples has improved sensitivity for CT detection compared to the previous method (96.2% versus 90.0%). Thus far, the revised pooling method has not improved false-negative NG results (89.7% versus 90.0%). This ongoing study (estimated completion five months) enriches available evidence on pooling. The value of pooling should also be considered in respect of available resources, local epidemiology and anatomical site-specific treatment regimens. Further studies, including confirmatory laboratory testing, in different geographical and clinical settings are warranted to strengthen this evidence. Service delivery implications will be discussed.

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