Review Submission

Submitted

Below is a summary of your completed submission. Any sections that are still required to be completed for submission are noted in red.

First clinical evaluation of a 30-minute point-of-care-test for Chlamydia trachomatis and Neisseria gonorrhoeae infection in UK sexual health clinics

Background:
As part of a programme of work seeking to facilitate adoption of multi-STI POCTs in English sexual health services (SHS), we implemented an approach to facilitate adoption of the binx health io CT/NG Assay ("binx POCT"). This included supporting analysis and interpretation of data following clinical validation and routine use of the binx POCT as implemented into clinical care, prior to SHS adoption decisions.

Methods:
binx POCT diagnostic accuracy was compared to locally-used laboratory-based nucleic acid amplification tests (NAATs) and expressed as positive (PPA) and negative percentage agreement (NPA), with 95% confidence intervals (95% CI). Individual SHS reported turnaround time (TAT) from sample collection to patient receipt of results, before and after binx POCT implementation.

Results:
Three SHS participated, and were a mix of high, medium and low-throughput in south England. Of N=417 patients across all services, n=396 (195 women and 201 men) were successfully tested with both the binx POCT and SHS routine NAATs. CT: male PPA 92.5% (79.6-98.4), NPA 99.4% (96.6-100.0); female PPA 82.1% (63.1-94.0), NPA 98.2 (94.8-99.6). NG: male PPA 91.7% (61.5-99.8), NPA 100% (98.1-100.0); female PPA 90.9% (58.7-99.8), NPA 100% (2.0-100.0). Median TAT decreased from 5 days (IQR 3-7.25) pre-implementation, to 1 day (1=same-day (IQR 1-2)) during implementation; p <0.000001.

Conclusion:
binx POCT PPA and NPA, as compared to participating SHS routine NAATs, were largely within expected ranges of the diagnostic evaluation conducted in the United States for FDA approval, and there was significant decrease in TAT time across all services. The binx POCT was not available for purchase directly following the programme's end, however, local data gave confidence to SHS to use the test in routine care, and all indicated interest in adoption. Providing services the ability to test new POCTs in local settings prior to purchase could help facilitate their wider implementation.

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