

were retested in duplicate to rule out the presence of PCR inhibitors. Three of them were then found to have no inhibitors, while one had presence of PCR inhibitors.

Conclusions Our results show that although majority of cases studied were due to HSV-2, HSV-1 either alone or as a mixed infection with HSV-2 is not uncommon. PCR was found to be as sensitive as DFA for confirming the syndromic diagnosis, but some false negatives may occur due to presence of PCR inhibitors.

Abstract P5.080 Table 1

HSV1 DFA			
HSV1 PCR	Positive	Negative	Total
Positive	10	1	11
Negative	1	32	33
Total	11	33	44

Abstract P5.080 Table 2

HSV2 DFA			
HSV2 PCR	Positive	Negative	Total
Positive	21	3	24
Negative	5	15	20
Total	26	18	44

P5.081 ANALYTICAL EVALUATION OF THE GENEXPERT® CT/NG, THE FIRST GENETIC POINT OF CARE ASSAY FOR SIMULTANEOUS DETECTION OF NEISSERIA GONORRHOEAEE AND CHLAMYDIA TRACHOMATIS

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Introduction New assays for molecular detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* need to be evaluated for potential false positive and false negative results due to cross reaction with other species, and potential mutations and genetic exchanges with other closely related organisms. Cepheid GeneXpert® CT/NG is the first FDA approved genetic point of care (POC) assay which simultaneously detects *C. trachomatis*, *N. gonorrhoeae* and controls for sample adequacy, in less than 90 minutes.

Method This study evaluated the GeneXpert® CT/NG assay with 372 characterised culture isolates; 111 *N. gonorrhoeae* isolates (including 3 isolates with *N. meningitidis porA* sequence), 223 isolates of non-gonococcal *Neisseria* species, 13 isolates of other species closely related to *Neisseria* and 25 *C. trachomatis* strains of different serovars (including LGV and nvCT strains).

Results All *C. trachomatis* and *N. gonorrhoeae* isolates were detected. A detection sensitivity of 10 genome copies per reaction was obtained with all *C. trachomatis* serovars as well as a representative *N. gonorrhoeae* control strain. Among the 223 non-gonococcal isolates, 4/11 *N. mucosa* and 2/42 *N. subflava* isolates were positive in one of the two *N. gonorrhoeae* targets (NG4), however

the assay flagged all 6 as negative due to requirements of both NG targets being positive for the assay to display an *N. gonorrhoeae* positive result.

Conclusion GeneXpert® CT/NG assay was analytically highly sensitive and specific for detection of *C. trachomatis* and *N. gonorrhoeae*, showing great promise as a POC assay. Detection of two NG targets is highly advantageous for avoiding false positive *N. gonorrhoeae* results.

P5.082 WHAT ARE THE COSTS AND BENEFITS OF IMPLEMENTING POINT OF CARE TESTS FOR CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAEE IN GENITOURINARY MEDICINE CLINICS?

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Background To estimate the costs and benefits of new patient pathways in genitourinary medicine (GUM) clinics that incorporate a point of care (POC) nucleic acid amplification test (NAAT) for chlamydia and gonorrhoea (CT/NG), compared to standard off-site laboratory testing.

Method We modelled 20,000 GUM clinic attendees, based on GUMCAD reported diagnoses for men and women in England (2011). A Markov model with Monte Carlo simulation in Excel was developed. We compared existing standard pathways of testing and treatment using a CT/NG test with a new POC NAAT. Scenario and sensitivity analyses were conducted to evaluate the robustness of the model findings. The primary outcome was incremental cost effectiveness ratio (ICER, £ per QALY) of testing and treatment in GUM clinics. Secondary outcomes included the number of over-treatments for CT/NG, complications and transmissions averted, and change in time from test to treatment.

Results The total cost of using the CT/NG POC NAAT in 20,000 patients was £1.73 million and £1.92 million for standard care. The new POC NAAT pathway dominated (less expensive and increased QALYs, ICER of £4,397/QALY saved). As many as 541 unnecessary treatments could be prevented using POC NAAT. The shorter time to treatment for patients receiving same-day diagnosis and treatment may also prevent a small number of complications (3.4 cases PID) and onward transmissions (31.9 infections).

Discussion Replacing standard laboratory tests for CT/NG with a POC NAAT seems to be cost saving or at least cost neutral, and patients would benefit from more accurate diagnosis and less unnecessary treatment. POC NAATs would effectively eliminate the need for presumptive treatment.

P5.083 WHAT QUALITIES DO PROVIDERS IDENTIFY AS BEST FOR POINT OF CARE STI TESTS AND DO OPINIONS DIFFER BY PRACTISE, REGION AND COUNTRY?

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Background U.S. clinicians identified high sensitivity and low cost as the most desirable characteristics for a Sexually Transmitted Infection (STI) Point Of Care Test (POCT); indicated performance time as major barrier; and chose *Chlamydia trachomatis* as the first choice for POCT development. We determined if POCT priorities, preferred qualities and barriers were similar for practitioners globally.