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RAPID POINT-OF-CARE TESTS FOR THE DETECTION OF GENITAL CHLAMYDIA INFECTION IN WOMEN AND MEN: IS IT A COST-EFFECTIVE OPTION FOR NHS?

Background

The current practice of testing for Chlamydia with UK involves the use of nucleic acid amplification tests (NAATs). These tests are very accurate, but are laboratory dependent, creating a delay between testing and receipt of diagnosis, caused by the time it takes to transport the test sample to the laboratory and process the result. This delay is problematic, as a number of infected patients will not return for treatment, following their positive diagnosis. There are point-of-care test methods available which can provide results within hours after the tests are carried out. This can help to allow infected patients to be treated immediately. Besides, the recent sexual partners of those infected can also be immediately notified and can be tested for infection earlier. Currently, point-of-care methods are not recommended for use in the NHS because they are less accurate than methods used in current practice, but if new point-of-care tests reported improved accuracy or increased the uptake of testing, they could potentially become an effective alternative to laboratory testing. The *Chlamydia* Rapid Test is a point-of-care test (POCT) that has reported improved accuracy.

KEY MESSAGES

1. Current practice which involves the use of nucleic acid amplification tests (NAATs) for detection of genital Chlamydia performed better in terms of number of true positives identified, and hence the number of true positives treated compared with the point of care tests
2. When effectiveness is considered in terms of people correctly diagnosed and notifying partners of the true cases, and treating them, the Chlamydia Rapid Test performs better than current practice with a marginal increase in costs
3. Point-of-care testing could become a viable alternative if uptake rates for testing were increased

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Objectives

A study[1] was conducted to assess whether or not a new *Chlamydia* Rapid Test could improve detection of genital Chlamydia, and whether it was more effective than current practice using NAAT, in terms of the number of cases of Chlamydia that are detected and treated, and the proportion of partners identified and treated. This study also sought to establish the incremental cost-effectiveness of the *Chlamydia* Rapid Test (compared with current practice), and patients' own preferences for Chlamydia testing services. This briefing paper presents the cost-effectiveness study.

Methods

A review of published and unpublished studies that considered randomised controlled trials (RCTs) on diagnostic accuracy and effectiveness, direct head-to-head studies for the review of diagnostic accuracy, was conducted. The tests considered were the *Chlamydia* Rapid Test and other comparator point-of-care tests identified, using a NAAT as a reference standard. The results of the individual studies were tabulated and sensitivity, specificity, positive and negative likelihood ratios, and diagnostic odds ratios (DORs) were calculated to obtain potential values of the effectiveness of the tests.

For cost-effectiveness analysis, a simple decision model was used to show that patients attend different screening facilities and are faced with the choice of accepting or not accepting the test offer and providing the sample for the test. Effectiveness was measured in terms of the absolute numbers of true positives, false positives, false negatives (and other positive cases missed) and true negatives detected. Costs were considered from the health services perspective. Incremental cost-effectiveness ratios were used to examine the relative cost-effectiveness and values of the major parameters of the models were varied in a sensitivity analysis. A cohort modelling approach was used to reflect the prevalence of Chlamydia in a population of people presenting or a specified sub-group presenting for testing. The target population considered is sexually active adolescent and adult men and women, suspected of, or being tested for Chlamydia infection. The time horizon of the model only covers the period of initial diagnosis and subsequent treatment for Chlamydia infection.

Screening options evaluated

The *Chlamydia* Rapid Test (CRT) was compared to other relevant POCT and one non-POCT (current practice assumed to involve - NAAT). The two POCTs considered for the decision model were Clearview and the *Chlamydia* Rapid Test. The comparator test considered was polymerase chain reaction (PCR), which is the most frequently NAAT used in current practice. The settings considered for the reviews of test performance and effectiveness is a Family Planning Clinic. The different strategies were compared in terms of the number of Chlamydia cases detected, diagnosed and treated in index patients and contacts, and the costs of the different strategies used to detect Chlamydia. The model compares three basic strategies: screening A (the Clearview POCT); B (CRT POCT); and C (current practice – PCR). The model describes the pathway of individuals covering the period of offer of screening, testing and the costs and consequences of any subsequent short-term outcomes.

The assumed pathway of the model

When a test is offered, a proportion of the target population are assumed to accept the offer, and a proportion of those who do not take up the offer, will have Chlamydia that remains undetected. The health service incurs the costs of offering the test. Of those who do decide to take up the test it is possible that a proportion may not be able, or willing, to provide a suitable sample for testing. Those, for whom samples were not obtained, remain undiagnosed and untreated. For those who do provide a sample some will test positive and some will test negative. The proportion of people in each group will depend upon the prevalence of infection and the diagnostic performance of the test. Those people with a positive result, which might have been a true or a false positive result, are expected to be treated and their partners are notified. The model assumes that all those who test negative (true or false) are not treated, and for these people no contact tracing is performed. The model also assumes that a certain proportion of partners of those who test positive are contacted.

Results

Cost-consequences analysis

Current practice performed better in terms of number of true positives identified, and hence the number of true positives treated compared with the point of care tests. It also resulted in fewer false negatives and hence missed fewer people with Chlamydia. The

current practice and the Clearview test would result in a similar number of false positives (who would then receive unnecessary treatment and have contacts treated unnecessarily). Among the two point of care tests, the *Chlamydia* Rapid Test performed better in terms identifying more true positives, fewer false negatives, more true negatives, more partners of true positive cases notified, and fewer of partners notified amongst those falsely identified as positive (Table 1).

Table 1: Performance of the different test strategies*

	Current Practice (PCR)-C	Clearview (POCT)-A	*Chlamydia* Rapid Test (CRT-POCT)-B
Number of False Positives	5.123	5.123	1.708
Number of False Negatives	1.156	6.934	2.889
Number of False positives treated	4.867	4.867	1.622
Number of True Positives	13.291	7.5125	11.558
Number of True Negatives	165.649	165.649	169.065
Number of True Positives Treated	12.627	7.137	10.979
Number of Partners Reported for True Positives	18.712	10.577	16.272
Number of Partners Reported for False Positives	7.213	7.123	2.404
Total costs of offer, screening and treating index patients and their partners	7070	7170	7180

* Numbers refer to number of events in a cohort of 1000 people offered testing and assuming a prevalence of Chlamydia in this cohort of 7.8%

Cost-effectiveness analysis

The results of the cost-effectiveness analysis using the two different outcome measures are shown in Table 2. If effectiveness is measured in terms of the number of true positives identified and treated and their partners are notified, then current practice performs better than the two point of care test considered in our model. If effectiveness is measured in terms of the number of people that the test correctly diagnoses (i.e. true positives and true negatives) including notifying the partners of the true positive, and treating the positive cases where necessary, then the *Chlamydia* Rapid Test performs better than current practice with a marginal increase in costs.

Table 2: Costs, effectiveness and cost-effectiveness of three screening tests for a population cohort of 1000

A. Effectiveness measured as number of true positive cases identified, treated and their partners notified

	Total costs (£)*	Total effectiveness**	Incremental cost-effectiveness ratio
Current Practice (PCR)	7070	12.63	
Clearview (POCT)	7170	7.14	**Dominated**
***Chlamydia* Rapid Test (CRT-POCT)**	7180	10.98	**Dominated**

B. Effectiveness measured as number of cases correctly identified and treated if necessary and partners of positive cases notified.

	Total costs (£)*	Total effectiveness**	Incremental cost-effectiveness ratio
Current Practice (PCR)	7070	178.27	
Clearview (POCT)	7170	172.79	**Dominated**
***Chlamydia* Rapid Test (CRT-POCT)**	7180	180.05	**62.18**

Notes: * Total cost of offering testing to 1000 people, ** Total number of cases out of a cohort of 1000 people

For a hypothetical cohort of 1000 people, using current practice of polymerase chain reaction (PCR) testing would result in 12.63 people who were offered testing, being correctly treated and having their sexual partners contacted, at a cost of £7070 (for the whole cohort). For the *Chlamydia* Rapid Test, the number being correctly treated would be 10.98, at a cost of £7180. For the Clearview Chlamydia test, the number correctly treated would be 7.14, at a cost of £7170. Both point-of-care tests were therefore more costly and less effective than current practice.

Discussion

Current practice was found to be less costly and more effective for detection of positive cases, although there were circumstances under which point-of-care testing could become a viable alternative (i.e. if uptake rates for testing were increased using this point-of-care method). When effectiveness is considered in terms of the number of people correctly diagnosed as true positives or true negatives, and notifying the partners of the true positive cases, and treating them where necessary, then the Chlamydia Rapid Test performs better than current practice with a marginal increase in costs.

The limited evidence available suggests that NAATs are still the most accurate and cost-effective method for diagnosing Chlamydia infection. There may be circumstances where point-of-care tests could be provided in addition to existing NAAT services (e.g. where this might increase uptake rates or reduce non-return rates for treatment) but there is currently little evidence on point-of-care methods in such settings. Research on this would be useful, along with research on the acceptability of point-of-care testing. Robust evidence of the diagnostic accuracy of point-of-care tests for different types of samples is also still required, as are studies comparing clinical effectiveness outcomes for these tests in comparison with NAATs.

Reference

1 Hislop J, Quayyum Z, Flett G, Boachie C, Fraser C, Mowatt G. Systematic review of the clinical effectiveness and cost-effectiveness of rapid point-of-care tests for the detection of genital Chlamydia infection in women and men. *Health Technol Assess* 2010; 14(29).

Research Team

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