An early evaluation of clinical and economic costs and benefits of implementing point of care NAAT tests for *Chlamydia trachomatis* and *Neisseria gonorrhoea* in genitourinary medicine clinics in England


**ABSTRACT**

**Objectives** To estimate the costs and benefits of clinical pathways incorporating a point of care (POC) nucleic acid amplification test (NAAT) for chlamydia and gonorrhoea in genitourinary medicine (GUM) clinics compared with standard off-site laboratory testing.

**Method** We simulated 1.2 million GUM clinic attendees in England. A simulation in Microsoft Excel was developed to compare existing standard pathways of management for chlamydia and gonorrhoea with a POC NAAT. We conducted scenario analyses to evaluate the robustness of the model findings. The primary outcome was the incremental cost-effectiveness ratio. Secondary outcomes included the number of inappropriate treatments, complications and transmissions averted.

**Results** The baseline cost of using the point of POC NAAT was £103.9 million compared with £115.6 million for standard care. The POC NAAT was also associated with a small increase of 46 quality adjusted life years, making the new test both more effective and cheaper. Over 95 000 inappropriate treatments might be avoided by using a POC NAAT. Patients receive diagnosis and treatment on the same day as testing, which may also prevent 189 cases of pelvic inflammatory disease and 17 561 onward transmissions annually.

**Discussion** Replacing standard laboratory tests for chlamydia and gonorrhoea with a POC test could be cost saving and patients would benefit from more accurate diagnosis and less unnecessary treatment. Overtreatment currently accounts for about a tenth of the reported treatments for chlamydia and gonorrhoea and POC NAATs would effectively eliminate the need for presumptive treatment.

**INTRODUCTION**

In England, there were 1 258 706 sexual health screens performed in genitourinary medicine (GUM) clinics in 2011, including tests for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoea* (NG). This resulted in 100 647 diagnoses of chlamydia and 20 964 of gonorrhoea. Epidemiological treatment, in which partners of confirmed index cases are given treatment, was reported for 13 125 cases of chlamydia and 2162 cases of gonorrhoea. This represents 12% and 9% of all treatments, respectively, assuming that all of those diagnosed received treatment. A glossary of terms is given in box 1. Management of patients with symptoms indicating possible chlamydia or gonorrhoea infection usually includes presumptive treatment for chlamydia prior to confirmed diagnosis (also called syndromic management). However, symptoms can be non-specific and may also be due to other infections, for example, *Mycoplasma genitalium*, resulting in unnecessary or potentially less efficacious treatment.

Inappropriate or incorrect treatment can result in (1) unnecessary costs of treatment, (2) continuing symptoms or progression to sequelae with associated consultation and treatment costs, (3) selection for the evolution of drug resistance and (4) delayed appropriate treatment.

Asymptomatic infection is also common and patients remain untreated until the laboratory diagnosis is available. Individuals unaware of their infection may continue to infect partners and risk developing complications during the delay between test and treatment.

Under current best practice, results from off-site laboratories (standard care) should be available to clinicians within 7 days or less. A BASHH audit in 2011 surveyed the proportion of GUM clinics that received chlamydia results within 7 days, the target being 100%. However, a quarter of clinics reported that they received 25% of results after 7 days. There was also variation within and between clinics, for example, due to laboratory capacity or clinic opening times. Once the clinic receives the test result, the patient is contacted and advised how to obtain treatment. The National Chlamydia Screening Programme audit target is that 50% of chlamydia-positives should be treated within 14 days; however, 16% of trusts in 2010 failed to meet this target, primarily due to difficulties in recontacting patients after their test or non-attendance. Infections may therefore remain untreated if patients cannot be contacted or choose not to return.

There are various technologies employed by point of care tests (POCTs) including antibody detection and DNA based methods. Early POC chlamydia/gonorrhoea tests based on antibody/antigen binding detection had limited application due to lower sensitivity and specificity compared with nucleic acid amplification tests (NAATs) performed in laboratories. However, new generation POC NAATs for chlamydia and gonorrhoea use PCR technology to detect DNA and are reported to have equivalent performance characteristics to standard laboratory NAATs. The Cepheid Xpert CT/NG (Cepheid, Sunnyvale, California,
USA) is one such test, providing results within 90 min of specimen collection. It is simple to use, does not require highly skilled staff and requires only a small space in the clinic.

The clinical and economic costs and benefits of POC NAATs have not yet been fully evaluated for the UK. We present an early, pragmatic decision analysis of introducing a POC NAAT for chlamydia and gonorrhoea into GUM clinics compared with current practice in England. We compare the complete pathway costs of current practice estimated in four diverse GUM clinics against a new pathway incorporating a POC NAAT test. The pathways include testing and treatment costs. This information can aid services in deciding whether to adopt this new technology. We also estimate the number of unnecessary treatments for chlamydia and gonorrhoea that could be prevented if test, diagnosis and treatment are available on the same day. We consider the potential indirect effects of reducing the time between test and treatment on preventing onward transmission and progression to pelvic inflammatory disease (PID).

METHODS

Model structure

We developed a decision analytic model in Microsoft Excel 2010 simulating patient pathways to estimate the costs and benefits of implementing standard care pathways and POC pathways including a chlamydia/gonorrhoea POC NAAT.

The model cycle length was 1 day with an overall length of 28 days. The primary outputs were total costs, quality adjusted life years (QALYs) and incremental cost-effectiveness ratios (ICER).

Description of patient flow through the model

Patient flows are illustrated in figure 1 and a sample patient flow is calculated in online supplementary appendix table A1. The arrows represent the possible transitions at the end of each model cycle.

All index patients in the model enter the testing pathway. Under standard care, a proportion of symptomatic patients are treated presumptively for chlamydia or gonorrhoea at the time of sexually transmitted infection (STI) screening. The remaining infected but untreated and/or asymptomatic patients wait on average 10 days before obtaining treatment at a second visit. Some treated individuals remain positive due to treatment failure. Progression to PID and onward transmission to uninfected partners may occur in positives on days between test and treatment or following treatment failure. In the POC pathways, all patients are tested and receive their result plus appropriate treatment on the same day. As there is no delay between test and treatment, patients in the POC pathway only develop complications or transmit to a partner if they fail treatment.

Asymptomatic partners of chlamydia or gonorrhoea positive index cases who attend GUM for treatment enter a simplified standard care pathway including treatment and test (symptomatic partners would be treated as index cases). In the POC pathway, partners are tested and only positives treated.

Key model assumptions

We assume equivalent test performance for the POC compared with standard tests. The new generation POC NAATs appear to fulfill this requirement. Others have previously investigated the trade-offs between reduced loss to follow-up versus lower sensitivity or specificity and willingness to wait, so we do not consider these here. We assume that all tests are in individuals attending for a new episode and the sample obtained is appropriate (eg, urine, vulvo-vaginal swab or rectal swab).

Epidemiological and clinical parameters

We modelled a cohort of 1.2 million index patients to simulate the annual number of STI screens performed at GUM clinics in England. Epidemiological parameters were based on data from the Genitourinary Medicine Clinic Activity Dataset 2011 (table 1). We estimated baseline positivity in men and women of 8.6% and 7.4% chlamydia and 2.6% and 0.9% gonorrhoea, respectively. We then estimated the distribution of infections between symptomatic and asymptomatic pathways using a detailed study of GUM attendees from the MISTIC study. We assumed that all patients reporting symptoms would enter the symptomatic pathway, regardless of whether their symptoms were indicative of a chlamydial or gonorrhoeal infection.

We synthesised several aspects of current symptomatic patient management to make credible estimates of presumptive treatment of positive and negative attendees (see online supplementary appendix table A2). Available data were used to estimate the number of contacts attending GUM who would be given epidemiological treatment in the absence of symptoms.

We estimated the potential for onward transmission of infection from asymptomatic GUM attendees in the time between
test and treatment based on the frequency of unprotected intercourse (2/week), transmission probability (5% chlamydia, 10% gonorrhoea per unprotected sex act) and one partner per index case and adjusted for the probability that partners were already infected.\(^1\)\(^2\)\(^3\) The per day risk of progression from untreated chlamydia to PID was calculated from a recent evidence synthesis estimate of the overall risk by Price \(^1\)\(^9\).

Costs and utilities

We take the perspective of a National Health Service (NHS) GUM clinic deciding whether to implement a chlamydia/gonorrhoea POC NAAT test. Costs and utilities are summarised in table 2. POC pathways represent an alternative streamlined pathway to standard care, based on same-day diagnosis and treatment; details of both types of pathways are given in Adams et al.\(^2\)\(^0\). The average total cost
for standard care testing pathway was £79.77/£99.38 and for the new POC testing pathway £75.50/£92.43 in asymptomatic and symptomatic patients, respectively.\textsuperscript{20} This includes an assumed acquisition cost of £13.35 for the standard NAAT and £19.71 for the POC NAAT, including the sample collection kit for both. The total testing pathway costs include laboratory time and clinic staff time to administer and process the test result. The total management pathway cost includes clinic staff time and treatment costs.

We only considered clinic running costs and excluded any additional costs of implementing a change in pathway such as staff training costs or additional quality assurance for performing tests on-site (eg, lab accreditation).
Utility estimates were obtained from published literature or expert opinion of the authors if no data were available (table 2). We assumed at baseline that patients did not have any disutility associated with anxiety while waiting for test results or from negative results.

Outcome measure
The primary outcome is the total cost per QALY gained, expressed as an ICER between standard care and POCT pathways \(\text{ICER} = \left(\frac{\text{cost}_{\text{POCT}} - \text{cost}_{\text{standard care}}}{\text{QALY}_{\text{POCT}} - \text{QALY}_{\text{standard care}}}\right)\). The secondary outcomes were number of overtreatments prevented, onward transmissions prevented and PID cases prevented.

Scenario and sensitivity analyses
We conducted scenario analyses to evaluate the robustness of the model findings in which we varied different key parameter values. We considered five primary scenarios which would tend to favour standard care ((1) shorter time to treatment, (2) no progression to PID or onward transmissions, (3) lower baseline prevalence, (4) higher POCT test acquisition cost) or where an uncertain parameter estimate could potentially have a large effect ((5) patients experience disutility while awaiting test results). Additional scenarios are detailed in online supplementary appendix table A3. We performed a univariate sensitivity analysis, varying the POCT NAAT acquisition cost.

RESULTS
The POCT pathway was £11.7 million cheaper and increased QALYs by 46 compared with standard care at baseline, shown in table 3. Since the POCT NAAT pathway dominates, the ICER is not meaningful and is not presented. The total cost of providing chlamydia/gonorrhoea testing and treatment for 1.2 million GUM attendees in standard care is £115.6 million and for the POCT pathway is £103.9 million. The POCT NAAT pathway could prevent 17 561 onward transmissions, 189 cases of PID and more than 95 000 overtreatments per year under baseline assumptions (table 3). If the acquisition cost of the POCT NAAT is more than £10 higher than baseline (ie, £29.73 instead of £19.73) then the POCT pathway becomes more expensive than current standard care (see online supplementary appendix figure A1).

In scenario 1, standard care is assumed to deliver treatment to all patients in 4 days. This reduces the number of outcomes averted, but does not influence the costs. In scenario 2 the POCT has lower cost, but does not result in prevention of sequelae or transmission. If prevalence is lower than currently assumed then the POCT test prevents more unnecessary treatment but the overall difference in costs is reduced (scenario 3). If the POCT NAAT is more expensive (scenario 4) then standard care is cheaper overall, but POCT still reduces overtreatment. In this case, the total cost of the POCT pathway is £116.1 million compared with £115.6 million for standard care. The total cost of testing varies linearly with increasing POCT NAAT test cost (from £9.73 to £39.73, baseline £19.73), shown in univariate sensitivity analysis in online supplementary appendix figure A1. If patients experience anxiety during the wait for results then the POCT NAAT compared with standard care can result in 2536 QALYs gained compared with 47 in the baseline scenario (scenario 5).

Additional scenarios are given in the online supplementary appendix table A3. If the underlying prevalence is higher, or fewer true infections are treated presumptively, the POCT test is more cost-effective (scenarios 6 and 7). Similarly, if there is more overtreatment or more preventable transmissions or sequelae this also favours the POCT NAAT (scenarios 8–11).

If 40% of partners are infected, then 60% of partners treated presumptively receive unnecessary treatment. Epidemiological treatment of partners under standard care costs £1.7 million and POCT costs £0.95 million (see online supplementary appendix table A4). Infection positivity among partners does not affect the cost of the standard care pathway (since all are treated) but the cost of the POCT pathway increases with

<table>
<thead>
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<th>Table 2 Model input parameters: costs and utilities</th>
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<td>Symptomatic testing*</td>
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<tr>
<td>Chlamydia management, additional</td>
</tr>
<tr>
<td>Gonorrhoea management, primary</td>
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<td>Complications</td>
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<tr>
<td>Infection negative</td>
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*All testing pathways include an acquisition cost of test and sample collection kit: standard care costs £12 for the test plus £1.35 for the sample collection kit; POCT costs £18 for the test plus £1.71 for the sample collection kit.

GUM, genitourinary medicine; PID, pelvic inflammatory disease; POCT, point of care test; SC, standard care.
increasing positivity, due to increased treatment costs. The greatest difference in cost between the POC and standard care pathways occurs when the proportion infected of those epidemiologically treated is lowest.

**DISCUSSION**

In the baseline model scenario, the POCT pathway dominates the standard care test pathway and will save an estimated £11.7 million annually in GUM and gain 46 QALYs overall. The POCT pathway includes a more expensive test, but less clinician time. Even making pessimistic assumptions that the POC will not prevent any overtreatment, complications or transmissions, the POCT pathway dominates. Same day diagnosis and treatment could prevent over 95,000 unnecessary treatments per year.

The strengths of this paper are that the pathway costs are based on a recent study and patient infection characteristics and management derived from national data. The model and cost estimates are for England, where patients typically have to wait to see a clinician, and tests and treatment are provided free of charge by the NHS.

We considered costs from an NHS GUM clinic perspective and did not consider patient costs, for example, returning for treatment. Additional costs may also be incurred by clinics in changing between pathways, for example, developing new testing protocols, staff training and laboratory accreditation; these are not considered here. We did not consider the potential effect of large changes in clinic demand due to the availability of a new POCT test as the impact is not yet known. Qualitative research is required to assess the likely impact on clinic attendance for example, testing more ‘worried well’ or increasing testing in hard to engage groups. The evidence for patient experience of waiting for GUM test results in the UK setting is not well characterised. One study of chlamydia screening, the Class study, reported a reduction in anxiety on receipt of a negative test for women and on submitting a sample for testing for men. In our model, if waiting for 10 days is associated with anxiety (0.95 utility) then there could be a much greater QALY gain from early diagnosis of 2,536 QALYs. Studies are required to evaluate the potential impact of POCT NAAT tests on patient experience.

Some model parameters are not well estimated in the literature. A detailed breakdown of current patient management was not available from national data to link initial presentation and management with test results. The estimates of presumptive treatment are consistent with data on the number of diagnoses of non-specific genital tract infection, non-gonorrhoeal/non-chlamydial PID or epididymitis (see online supplementary appendix table A2). However, this leads to an overestimate of overtreatment if these related diagnoses were not presumptively treated for chlamydia. Conversely, other presenting conditions might also be treated presumptively leading to underestimation of presumptive treatment. Treatment regimens for chlamydia have previously been considered effective against other infections, but recent findings suggest that alternative treatments may be preferable if chlamydia and gonorrhoea can be ruled out initially.

We only considered the immediate complication of PID in women as this has been shown to have the greatest effect on cost and may occur in the time period considered in our analysis. Other complications may also result from infection with chlamydia or gonorrhoea, for example, epididymitis in men. If earlier treatment prevents other complications (not the immediate PID complications), the cost-effectiveness of POCT may be improved.

### Table 3

The cost, quality adjusted life years, transmission to partners, PID cases and overtreatment in standard care compared to point of care tests for chlamydia and gonorrhoea in genitourinary medicine clinics in the UK: baseline and scenario analyses results.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>See tables 1 and 2 for full baseline parameter list</th>
<th>Rx time=4 days (baseline: 10 days)</th>
<th>Cost</th>
<th>QALY</th>
<th>PID</th>
<th>Overtreatment</th>
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<td>QALY</td>
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<td>184,012</td>
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<td></td>
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<td>8811</td>
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<tr>
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<td>132</td>
<td>119</td>
<td>–</td>
<td>–</td>
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<tr>
<td></td>
<td>Overtreatment</td>
<td>95,382</td>
<td>95,382</td>
<td>100,278</td>
<td>95,431</td>
<td>95,382</td>
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<td>POCT</td>
<td>Cost</td>
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<td>£103,873,872</td>
<td>£101,452,506</td>
<td>£103,868,307</td>
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<td>184,084</td>
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<tr>
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<td>Transmissions</td>
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<tr>
<td></td>
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<td>34</td>
<td>17</td>
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<tr>
<td></td>
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<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
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<tr>
<td>Difference (POC-SC)</td>
<td>Cost</td>
<td>£11,754,015</td>
<td>£11,739,481</td>
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<td>–95,382</td>
<td>–100,278</td>
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</table>

CT, Chlamydia trachomatis; NAAT, nucleic acid amplification test; NG, Neisseria gonorrhoea; PID, pelvic inflammatory disease; POC, point of care; QAly, quality adjusted life year; Rx, treatment; SC, standard care.
just PID, this would increase the POC NAAT cost-effectiveness.

Cost implications may be different in countries with other healthcare models. Huang et al also found that in the USA, a POCT was cost-effective in comparison with standard care, even without including additional indirect benefits such as reduced overtreatment and reduced transmission potential. They found that POCT sensitivity, proportion of women willing to wait for test results and the POCT costs were the most influential parameters in the model. In contrast, we assumed that all patients are willing to wait for a result, and a recent UK study found that 75% of women were prepared to wait between 30 min and 2 h and 18% were prepared to wait over 2 h.28

We assumed that both the standard care and the POCTs had equivalent performance characteristics. If this is not achieved in practice then not all the benefits of early diagnosis are realised. POCTs test characteristics have been previously modelled extensively, showing that sensitivity is a key factor.15 Gift et al have demonstrated that test sensitivity could be balanced against return rates for treatments. A systematic review was conducted in 2010 and others have concluded that a chlamydia/gonorrhoea POCT with sufficiently good performance for routine clinical use was not currently available.9 10 22 However, these papers did not include new generation POCT NAAT tests. The chlamydia/gonorrhoea POC NAAT developed by Cepheid has shown equivalent performance to standard NAAT tests in early trials.11 12 27 It has received CE marking and FDA approval, and is being marketed for use in Europe, North America, the Middle East and Africa. Several other tests will likely emerge in the near future. The new generation POC NAAT tests need to be evaluated in independent randomised controlled trials, compared head to head in routine practice and included in an updated systematic review.

This study indicates that introducing a chlamydia/gonorrhoea POC NAAT could be cost saving, subject to our assumptions about the data and clinical pathway. The introduction of such tests to GUM clinics may also benefit patients by providing a more accurate and timely diagnosis with potentially better treatment outcomes and fewer unnecessary treatments. The study highlights that many symptomatic men and women currently receive treatment using an antibiotic primarily intended for treating chlamydia when this infection may not be present, and for which better treatments may be available. Additional national guidance will be required to enable clinics to make informed choices about whether and how to implement new pathways with chlamydia/gonorrhoea POC NAATs in the future. Once up and running, POC NAATs for chlamydia and gonorrhoea in English GUM clinics could save the NHS money.

Contributors PH and EJA conceived the study idea, EJA and KMET conceived the study design, supervised the model development and parameter collection, and analysed and interpreted the model results. PH commented on the likely clinical implications. KMET wrote the first draft, contributed to the model development and undertook the parameter estimates and model analyses. JR developed the economic model. AD assisted with data collection and literature review. PH and JM provided expert opinion on the parameter choices and guidance on the structure of the model. SG provided expert knowledge regarding the use of point of care tests from a microbiological context. PH, JM and SG contributed to the study design. All authors critically reviewed the paper for content and approved the final submitted version.

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Competing interests EJA has received funding from Cepheid, Bristol University, the National Chlamydia Screening Programme, the Office for Sexual Health, Pathway Analytics, Atlas Genetics and Hologic for consultancy and lectures relating to chlamydia and gonorrhoea; PH has received funding from HEFC, NHS, BASHH, the Bristol University, Imperial College London, the Crown Prosecution Service Hologic, Cepheid and Rib-x for his salary, consultancy, lectures, patents and providing evidence; KT has received funding from for NIH for a personal fellowship, and from NHS Bristol Hospitals Health Trust, the Office for Sexual Health and NICE for consultancy. SG has received funding from Cepheid for travel and accommodation for work not related to this submission. SG, AD, Bristol University (PH, JM, KMET), and JR received funding from Aquarius Population Health for this work. KMET is grateful to NIH for fellowship funding. PDF-09-02-055. Cepheid provided funding to Aquarius Population Health to conduct the study and estimates of the cost of their proprietary Point of Care Test. Other similar tests are, or are soon to be, commercially available. The results presented could be applicable to any other point of care test with similar performance, cost and usability. We do not make any recommendation as to which test, if any, a clinic should use.

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Key messages

- Point of care test pathways could be implemented in genitourinary medicine clinics with minimal increases in cost or could be cost saving once established.

- Presumptive or epidemiological treatment of chlamydia and/or gonorrhoea accounts for a large number of suboptimal and unnecessary antibiotic prescriptions.

- Additional national guidance is required to enable clinics to make informed choices about whether and how to implement new pathways in the future.

Handling editor Jackie A Cassell

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