NCCHTA

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1. **Title of the project:** The clinical effectiveness and cost-effectiveness of rapid point of care tests for the detection of genital chlamydia infection in women and men: systematic review and economic evaluation

2. **Research Question:** What testing strategies, using the new *Chlamydia* Rapid Test, for detecting genital chlamydia infection will increase the number of infections effectively treated in index patients and contacts, and be cost effective compared with current detection practice?

3. Aberdeen (HSRU) TAR team

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4. Plain English Summary

Genital chlamydia is the most common bacterial sexually transmitted disease in the world. In the United Kingdom, more than 100,000 cases of chlamydia are diagnosed each year.[1] The number of people with the disease may actually be even higher, as 70% of infected women and 50% of infected men do not show any signs of having the disease[2] and so may not seek testing. Chlamydia is easy to treat, but if left untreated it can cause severe health problems, including pelvic inflammatory disease (PID), ectopic pregnancy and infertility in women, and inflammation of the testicles, and arthritis caused by infection, in men.[3] To reduce the number of people with these conditions and to reduce the spread of infection to others, diagnosing and treating chlamydia quickly and effectively is important.

The current method of detecting the disease from specimens taken from patients, involves sending the specimens to a laboratory, with patients receiving their test results at a later date, and (if they have the disease) having to make a return visit to start treatment and provide contact details for all their recent sexual partners to be told that they may also have the disease. However, recent technological advances have led to the development of Point-of-Care tests (POCTs), where the test result is provided immediately after the test has been carried out. There are numerous potential benefits, as treatment can also start immediately (and there is no longer a risk that a patient might not come back for treatment after receiving a positive test result), patients can have the support of a trained health professional with them when they find out they have the disease, and all their recent sexual partners who may also be at risk of having the disease, can be contacted more quickly.

In addition, as POCT specimens do not need to be sent to a laboratory, the variety of chlamydia testing venues could be expanded, which might make testing more convenient and acceptable for those who may feel embarrassed about attending traditional sexual health treatment facilities, thus potentially increasing the number of infections effectively treated.

Despite this, point-of-care tests are rarely used in clinical practice because research has found them to be less accurate than the current testing method for detecting cases of chlamydia. However, recent research suggests that a new point of care test, the *Chlamydia* Rapid Test, has improved detection capabilities compared with other POCTs, which could enable it to become more widely used in the NHS.

This review will assess the performance of the new *Chlamydia* Rapid Test in detecting chlamydia and its effectiveness and cost-effectiveness compared with current practice in terms of the number of chlamydia cases detected and treated, the proportion of partners identified and treated, and the cost-effectiveness of testing, as well as considering patients' own preferences for treatment.

5. Decision Problem

Genital chlamydia is the most common bacterial sexually transmitted disease in the world. Within the UK, more than 100,000 cases of chlamydia are diagnosed in Genito-Urinary Medicine (GUM) clinics each year.[1] This figure is likely to underestimate the true prevalence of chlamydia within the population, as most of those infected will be asymptomatic of the disease (70% of infected women and 50% of infected men)[2] and consequently will not seek testing and therefore will remain undiagnosed. Although chlamydia is easily treated, if left untreated it can cause pelvic inflammatory disease (PID), ectopic pregnancy and infertility in women and epididymo-orchitis and reactive arthritis in men.[3] Reducing the incidence of these conditions requires effective diagnosis and treatment of asymptomatic chlamydia in advance of the onset of the above conditions.

Currently no universal screening programme exists in the UK for chlamydia detection,[4] but opportunistic case detection services for chlamydia are provided in a wide variety of healthcare and community settings. The recent CLaSS study[5] found sexual behaviour (e.g. more than one sexual partner per year) to be the most important determinant of risk of chlamydia infection, and 56% of women aged 16-24 years old were found to have had a new sexual partner in the previous year. Therefore, providing services for this age group, in as wide a

range of settings as possible, is paramount to reducing the prevalence of chlamydia, and strategic opportunistic case detection of this risk group has been developed in England through the National Chlamydia Screening Programme (NCSP).

Current practice in the detection and treatment of chlamydia involves analysing specimens provided from case detection services by using nucleic acid amplification tests (NAATs), with individuals receiving their test results at a later date and having to make a return visit for treatment to be initiated and for contacts to be identified. In recent years, however, technological advances have led to the development of point-of-care tests (POCTs). These tests are "undertaken by a member of the healthcare team or by a non-medical individual in a setting distinct from a normal hospital laboratory".[6] Unlike the tests used in current practice, POCTs would allow for those individuals testing positive to have treatment initiated during the same session in which testing is carried out, thereby offering several potential advantages. They may increase the proportion of positively diagnosed individuals receiving treatment, by circumventing the problem of individuals not making return visits for scheduled treatment following receipt of a positive test result.[7] Because of this, even if POCTs were found to have slightly lower sensitivity than tests used in current practice, their use could still potentially lead to more people with a positive diagnosis receiving treatment than is the case at present. An additional benefit is that the test results would be provided in the test setting by health care professionals who would also be in a position to provide additional advice and support at that time, as opposed to a situation in which positively diagnosed individuals are notified of their test results at a later date.

In addition, the potential further spread of infection by positively tested individuals within the interim period between diagnosis and commencement of treatment would be prevented, and contact tracing could also begin more rapidly, and would no longer be dependent on whether the diagnosed individual returns for treatment or not. The variety of testing venues could be expanded to improve access to testing, further improving the acceptability of testing for those who may attach a stigma to attending traditional sexual health treatment facilities, thus potentially increasing the number of infections effectively treated.

The reason that POCTs are not widely used in clinical practice is due to their reduced sensitivity and specificity when compared with current NAAT methods for chlamydia detection. However, the new *Chlamydia* Rapid Test developed by the Diagnostics Development Unit at the University of Cambridge, reports improved sensitivity and specificity to the extent that it could perhaps become widely used, both in clinical and community care.[8]

This review will assess the performance of the *Chlamydia* Rapid Test in detecting genital chlamydia and its effectiveness and cost-effectiveness compared with current practice in terms of the number of cases detected and treated, the proportion of partners identified and treated, as well as considering patients' own preferences for treatment.

6. Methods for the synthesis of evidence of clinical effectiveness and preferences

In the event that a suitably large, high quality randomised controlled trial of the *Chlamydia* Rapid Test compared with current practice is identified that reports relevant outcomes in terms of test performance, effectiveness, or preferences,

then information on these aspects would be derived from the RCT rather than by undertaking separate reviews of diagnostic performance and preference. However, we anticipate that this is unlikely in which case the methods described below will be used to synthesise the evidence on clinical effectiveness and preferences.

6.1 Nature of existing evidence base and justification of approach taken

No existing syntheses of evidence have been identified that evaluate the use of the *Chlamydia* Rapid Test for detecting chlamydia infection, although several HTAs evaluating screening for chlamydia, have been identified.[5,9-11] Systematic reviews of (a) test performance, (b) effectiveness and (c) preferences will be undertaken following the general principles recommended in the QUOROM statement.

Individuals may have strong preferences not just for the outcomes of testing but also about how such a service might be organised. There is at least one study that has used a discrete choice experiment (DCE) methodology to compare alternative strategies for organising a screening service.[12] In this DCE services are compared in terms of where testing takes place, the type of test used (i.e. is it a urine test, a perineal swab or a full pelvic examination), the risk of developing pelvic inflammatory disease and the type of information and support available when the test results are given. Also included is a cost attribute which allows a monetary value for alternative ways of organising a service to be estimated. The study was not specifically designed to look at a point of care testing option and the description of the alternative services provided by the set of attributes may not fully capture the advantages and disadvantages of a POCT compared with standard practice.

6.2 Population

The population considered in the reviews of test performance and effectiveness will be sexually active adolescent and adult men and women, suspected of or being tested for chlamydia infection. If sufficient evidence is available, subgroup analysis will be undertaken on the following high risk groups:

- Those aged under 25 years old
- Men who have sex with men (MSM)
- Sex workers
- High-risk African populations

The settings considered for the reviews of test performance and effectiveness will be GUM clinics, primary care and chlamydia screening programme venues.

The review of patient preferences will consider studies conducted in the same population (i.e. relevant to a UK health setting), as it has been argued that economic measures of preference based on population values are of most relevance to priority setting.

6.3 Intervention

For the reviews of diagnostic accuracy the intervention (index test) considered will be the *Chlamydia* Rapid Test, a new 'rapid' point of care test developed by the Diagnostics Development Unit at the University of Cambridge, for the detection of genital chlamydia infection.

The above intervention will also be considered by the review of effectiveness.

In the review of patient preferences the interventions considered will be alternative methods of opportunistic testing or screening for chlamydia. At least one of the methods compared should be representative of the above intervention.

6.4 Comparator

For the review of test performance the comparator test(s) considered will be:
(i) non-POCTs that are used in current practice, i.e. nucleic acid amplification microbiological tests (NAATs). This is equivalent to a comparison with the reference standard detailed in Section 6.5.
(ii) other POCTs. These could be any alternative POCTS, and may include Clearview (Unipath), Quickview (Quidel), Surecell (Kodak), BioStar OIA (Inverness Medical), Handilab Chlamydia C or NPT Gold, for comparison with the index test.

For the review of effectiveness the comparator(s) will be those tests used in current practice.

For the review of patient preferences at least one of the comparator options should be representative of current practice.

6.5 Reference standard

The reference standard test(s) considered will be those nucleic acid amplification tests (NAATs) used in current practice. Relevant NAATs identified so far include:

- Polymerase Chain Reaction (PCR)
- Ligase Chain Reaction (LCR)
- Strand Displacement Amplification (SDA)
- Transcription Mediated Amplification (TMA)

Specific NAATs will only be included following advice from our clinical advisors of their continued relevance to clinical practice.

6.6 Outcomes

Included studies must report relevant and interpretable data.

The following outcomes will be considered:

Review of test performance:

- Sensitivity and specificity. Studies reporting test performance must report the absolute numbers of true positives, false positives, false negatives and true negatives, or provide information allowing their calculation.
- Acceptability of the tests.
- Interpretability of the tests.

Review of effectiveness:

- Numbers of chlamydia cases detected.
- The number of infections diagnosed that are treated (including return/non-return rates for treatment in different settings and locations throughout the UK, following diagnosis associated with non-POCTs).
- The proportion of people completing treatment once treatment is initiated.
- The proportion of partners identified and treated.
- Acceptability of the tests.
- Interpretability of the tests.

Review of patient preferences:

- Willingness to pay estimates for alternative methods of testing for chlamydia.
- Alternative numeraires for strength of preference such as utilities, willingness to wait, etc will be used if they can be used to form judgements about preferences for methods of testing.
- Marginal rates of substitution between the different dimensions that might be used to define alternative methods of testing for chlamydia.

6.7 Search Strategy

For the reviews of test performance, and effectiveness extensive and sensitive electronic searches will be conducted to identify reports of published and ongoing studies on the clinical effectiveness of the *Chlamydia* Rapid Test and other POCTS for detecting chlamydia. The search strategies will be designed to retrieve: a) diagnostic test accuracy studies of POCTs; and b) randomised and non-randomised studies that assess the clinical effectiveness of POCTs. Both full text papers and recent conference abstracts will be sought without publication date restriction. Potentially relevant non-English language studies will be excluded and listed in an appendix to the review, unless the English language evidence base is deemed to be insufficient in which case they will be included. Databases to be searched will include: Medline, Medline In-Process, Embase, Science Citation Index, Biosis, Health Management Information Consortium and the Cochrane Controlled Trials Register. A preliminary Medline search strategy is provided within the Appendix, and will be adapted for use in the other databases.

A search for systematic reviews and other background publications will also be undertaken. Sources will include the Cochrane Database of Systematic Reviews, Medion, HTA Database and DARE.

Current research registers, including Current Controlled Trials, Clinical Trials and WHO International Clinical Trials registry will be searched. Recent conference proceedings of key clinical microbiology and sexual health organisations will also be screened and will include the British

Association for Sexual Health and HIV (BASHH); American Sexually Transmitted Diseases Association (ASTDA); American Association of Clinical Chemistry and European Society of Clinical Microbiology and Infectious Diseases.

In addition, an Internet search using Copernic Agent will be undertaken and will also include key professional organisations and manufacturers of POCTs for chlamydia.

Scoping searches of the MEDLINE and EMBASE databases, have already been undertaken to locate potentially relevant studies (RCTs and non-randomised evidence) for the reviews of effectiveness and diagnostic accuracy. Titles and abstracts were screened and of the 243 hits found, 3 RCTs and 88 non-randomised trials were identified as being potentially relevant.

For the review of patient preferences, highly sensitive search strategies will be developed to retrieve studies that use the relevant economic methods to assess preferences for opportunistic testing or screening for chlamydia. The databases to be searched will include: Medline, Medline In-Process, Embase, Science Citation Index, Health Management Information Consortium, CRD NIHR Economic Evaluation Database, HTA Database and RePEc. Searches will be restricted to English language papers without publication date restriction. A preliminary Medline search strategy is provided within the Appendix, and will be adapted for use in the other databases.

6.8 Inclusion Criteria

Review of test performance:
The following types of studies will be included:

- Randomised controlled trials (RCTs) in which people are randomised to the index and comparator test(s) and all receive the reference standard test.
- Direct (head-to-head) studies in which the index test, comparator test(s) and reference standard test are done independently in the same group of people.

If there is insufficient evidence from direct or randomised studies, we may consider indirect (between-study) comparisons by meta-analysing studies that compare the index test or the identified and relevant comparators with the reference standard test, and making comparisons between meta-analyses of the different tests. However, this type of study design is less reliable than direct studies as differences in diagnostic accuracy are susceptible to confounding factors between studies.

Review of effectiveness:
For assessing The *Chlamydia* Rapid Test in terms of effectiveness outcomes we will focus on RCTs. If there is deemed to be insufficient evidence from RCTs we may then consider non-randomised comparative studies.

Review of patient preferences:
We will consider UK relevant studies that have used economic methods such as a willingness to pay (WTP) exercise or a discrete choice

experiment (DCE) to explore strength of preference for alternative ways of organising a service. These studies may have been conducted as part of RCTs or other comparative studies considered eligible for inclusion into the review of effectiveness or stand alone surveys of the UK general population or relevant client groups.

6.9 Exclusion Criteria

Review of test performance and review of effectiveness:

- Studies published in languages other than English
- Narrative reviews, editorials, letters and opinions
- Animal models
- Preclinical and biological studies
- Case reports
- Abstracts published before 2006
- Reports investigating technical aspects of a test

Additionally, the review of patient preferences will exclude:

- Studies where the population surveyed may not represent the UK population or a relevant UK client group
- Studies investigating preferences but not using discrete choice experiment or willingness to pay methodology.

6.10 Data Extraction Strategy

For all three reviews, citations identified by the search strategy will be screened on the basis of the title and, where available, the abstract. Full-text copies of all potentially relevant reports will be obtained. One reviewer will assess studies for inclusion and extract data using data extraction forms to be developed as part of this review. Any uncertainty will be resolved by discussion with a second reviewer and any disagreements will be resolved by arbitration by a third party. The reviewers will not be blinded to authors, institutions or publications. Where there is insufficient information in the published report, no attempt will be made to contact the authors for clarification because of time constraints.

For the review of test performance, data will be extracted on study design, participants, setting, index, comparator and reference standard tests and test performance outcomes as specified above.

For the review of effectiveness, data will be extracted on study design, participants, setting, intervention and comparator tests and effectiveness outcomes as specified above.

For the review of patient preferences, the data extraction form will seek to describe the population and methods used to elicit preferences. Also extracted will be information on the response rate to the DCE or WTP questions, the results of the analysis including the outcomes specified above. Information will also be recorded on year of publication; source of funding, characteristics of participants; characteristics of the comparisons made including how the description of the comparisons compared in the DCE or WTP exercise was developed.

6.11 Quality Assessment Strategy

Review of test performance:
The QUADAS[13] quality assessment tool, developed for use in systematic reviews of diagnostic studies will be used to assess the quality of all included diagnostic studies. The QUADAS tool will be adapted to make it more applicable to assessing the quality of studies of tests for detecting chlamydia.

Review of effectiveness:
Consideration of study quality of included RCTs will be assessed using the Delphi criteria list adapted from Verhagen and colleagues.[14]

Review of patient preferences:
Consideration of study quality will be made against current recommendations for best practice in the design and analysis of DCE and WTP exercises. Several of the project team have experience of working with these methods but we will be able to draw upon acknowledged world experts from the Health Economics Research Unit (HERU), University of Aberdeen, to aid in the critical appraisal of any identified studies.

6.12 Methods of analysis/synthesis

Review of test performance:
The results of the individual diagnostic studies will be tabulated and sensitivity and specificity calculated.

Summary receiver operating characteristic (SROC) curves will be produced for each test where three or more diagnostic studies report sufficient data. Where studies report 2x2 data for a number of different cut-off values then the most frequently used cut-off value across studies will be chosen. Meta-analysis models will be fitted using the hierarchical summary receiver operating characteristic (HSROC) model[15] in SAS 9.1. A symmetric SROC model will be used. This model takes proper account of the diseased and non-diseased sample sizes in each study, and allows estimation of random effects for the threshold and accuracy effects. The SROC curves from the HSROC models will be produced on the corresponding SROC plots. Summary sensitivity, specificity, positive and negative likelihood ratios and diagnostic odds ratios (DORs) for each model will be reported as a median and 95% confidence intervals

Sensitivity and specificity will be pooled using the weighted average method[16] if there is no evidence of a threshold effect. Pooled likelihood ratios and DOR will be calculated using the DerSimonian and Laird random effects method.[17] Where a study has an empty cell, a correction of 0.5 will be added to all four cells. These analyses will be carried out using Metadisc software.[18] Heterogeneity will be assessed using the I^2 statistic, which describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error. A value greater than 50% may be considered to represent substantial heterogeneity.[19]

Review of effectiveness:
For relevant outcomes, where appropriate, meta-analysis will be employed to estimate a summary measure of effect. Dichotomous

outcome data will be combined using the Mantel-Haenszel relative risk (RR) method and any continuous outcomes will be combined using the inverse-variance weighted mean difference (WMD) method. For the estimates of RR and WMD 95% confidence intervals (CIs) and p-values will be calculated. The results will be reported using a fixed effects model. Chi-squared tests and I-squared statistics will be used to explore statistical heterogeneity across studies. Possible reasons for heterogeneity will be explored using sensitivity analysis. Where there is no obvious reason for heterogeneity, the implications will be explored using random effects methods. Where a quantitative synthesis is considered to be inappropriate or not feasible, a narrative synthesis of results will be provided.

Review of patient preferences:
Formal evidence synthesis of different studies will not be attempted. Rather consideration will be given to the direction and magnitude of effect between studies in a narrative review. Consideration will also be given to establishing similarities and differences between studies and potential explanations for any differences.

Within this review consideration will be given as to how data from a WTP study or a DCE might be incorporated into the decision model. Published examples of how this might be done are rare but we would intend developing techniques previously used in an HTA of Hernia Surgery.[20] Should relevant data be identified that cannot be formally incorporated into the decision model we propose to develop we would still attempt to use the information to aid in the interpretation of the model results. If several different studies are identified that might be incorporated into the economic model then attempts will be made to do this as part of sensitivity analysis.

7. Report methods for synthesising evidence of cost-effectiveness

Given the number of relevant comparators a formal systematic review of existing economic evaluations will not be attempted as it is highly unlikely any economic evaluations will have been conducted that will have considered all comparators from the perspective of the UK NHS. Also an initial search of the NIHR Economic Evaluation Database did not identify any cost-effectiveness studies of rapid point of care testing for chlamydia infections.

We will develop a decision analytic model to compare the *Chlamydia* Rapid Test with other relevant POCTs and current practice (which involves NAATs) to assess the relative efficiency of the use of the *Chlamydia* Rapid Test in the testing of patients who may have or already have chlamydia and to identify the number of diagnosed infections that are treated. This model will display the temporal and logical sequence of the clinical decision problem. The model will describe the pathway of individuals covering the period of testing and the costs and consequences of any subsequent short-term outcomes. The structure of the economic model will be based upon care pathways developed in consultation with our expert advisors and will describe alternative ways in which a service for chlamydia testing may be organised.

The economic model represents a further level of evidence synthesis that will integrate information on the relative effectiveness of diagnostic tests derived from the systematic reviews along with information on the costs of testing, subsequent

treatment and contact tracing derived using the methods described below. The economic model will compare the alternative tests considered for a hypothetical cohort of patients presenting with suspected chlamydia for opportunistic case detection. This cohort will reflect the average population of people presenting with chlamydia or a specified sub-group. This cohort of people will be followed up in the model for a short term horizon as the focus will be on the diagnostic performance of the tests and treatment.

The results of the diagnostic tests are either true positive, true negative, false positive, or false negative. The model will describe the short term outcomes of these tests such as the number of patients correctly diagnosed, the number of patients that receive treatment, the number of partners identified and treated and number of cases missed and the impact on the spread of chlamydia infection in the population. The parameters for the model including disease prevalence, sensitivity and specificity of the POCTS, and incremental patient return rates will be derived from the discrete systematic reviews specified in Section 6.

With respect to the cost data required the primary perspective for the costing will be the NHS and Personal Social Services. Cost data, therefore, will include the direct health service costs associated with each test option and subsequent patient management. The quantity of resources utilised will be identified from consultation with experts, primary data from relevant sources and the reviewed literature. We anticipate that unit cost data will be extracted from the literature or obtained from other relevant sources (e.g. manufacturer price lists, NHS reference costs).

The results of the model will be presented in terms of a cost-consequence analysis (e.g. costs, number of cases correctly diagnosed, number of cases wrongly diagnosed, etc). Depending on the availability of data a cost-effectiveness analysis will be conducted, where the results are presented in terms of an incremental cost per unit change in a natural measure of outcome such as incremental cost per case rightly diagnosed. If data from a WTP study or a DCE which are suitable for incorporation into the model are identified then the economic evaluation will be extended into a cost-benefit analysis.

Sensitivity analysis will be conducted to explore parameter and other forms of uncertainty. The sensitivity analysis will identify thresholds at which the adoption of rapid POCTS would become cost-effective compared with current practice. This will be accomplished using one-way, two-way and multi-way sensitivity analyses. In the latter the impact of simultaneous changes in a variety of input parameters will be performed. Where appropriate, costs and outcomes will be discounted at 3.5%.[21]

8. Expertise in this TAR team

Several members of this TAR team (Graham Mowatt, Cynthia Fraser, Jennifer Burr and Luke Vale,) are very experienced in conducting reviews of diagnostic and therapeutic interventions in both the clinical and technical aspects required to address the commissioning brief, and all members have been involved in similar studies. In addition, local clinical expertise will be provided by Professor Allan Templeton (Head of Obstetrics and Gynaecology, University of Aberdeen), Dr Ambreen Butt (Consultant in Genito-Urinary Medicine – NHS Grampian) and Dr Gillian Flett (Lead Clinician in Sexual Health – NHS Grampian).

TAR Centre:

The Aberdeen Technology Assessment Group has a track record of producing these types of focussed reports whilst keeping to tight timescales for various policy customers, such as the National Institute for Health and Clinical Excellence (NICE) and the National Institute for Health Research (NIHR). In the last 12 months, several similar studies have been completed. These include reviews looking at:

- Oesophageal Doppler monitoring for critically ill and high risk surgical patients
- Minimally invasive total hip replacement (also conducted for the Canadian Agency for Drugs and Technologies in Health)
- 64-slice or higher computed tomography angiography as an alternative to invasive coronary angiography in the investigation of coronary artery disease

Other systematic reviews currently on-going within HSRU include:

- Surveillance of mammography after treatment for breast cancer
- Non-surgical treatment for stress urinary incontinence in women
- Photodynamic diagnosis and urine biomarker tests in the detection and follow-up of bladder cancer

Team members' contributions:

Jenni Hislop, Research Fellow, will be technical lead on this project and will be responsible for the day-to-day running of the review, as well as undertaking the reviews of test performance and effectiveness, and will be supervised by Graham Mowatt, Research Fellow. Zahidul Quayyum, Research Fellow will conduct the synthesis of cost-effectiveness evidence, supervised by Luke Vale, Professor of Health Technology Assessment. Dr Jennifer Burr, Senior Clinical Research Fellow, will provide additional supervision, methodological advice and comments on drafts of the review. Cynthia Fraser, Information Officer, will develop and run the search strategies and will be responsible for obtaining papers and reference management. Charles Boachie, Statistician, will provide statistical advice and support. Professor Allan Templeton, Head of Obstetrics and Gynaecology, University of Aberdeen, Dr Ambreen Butt, Consultant in Genito-Urinary Medicine in NHS Grampian, and Dr Gillian Flett, Director of Sexual and Reproductive Health in NHS Grampian will provide clinical support and advice to the team.

In addition we will seek additional epidemiological expertise on the modelling of the transmission of genital chlamydia in the population.

9. Competing interests of authors

None.

10. Timescale/milestones

Draft protocol submitted: By 11th July 2008.
Final protocol to be submitted: To be agreed.
Review to be submitted: The review has been valued at 0.67 TAR Unit and will be submitted as agreed at the end of March 2009.

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Appendix

Preliminary Medline Search Strategy for Reviews of Effectiveness and Test Performance

1 chlamydia infection/
2 chlamydia trachomatis/
3 chlamydia.tw
4 "Point-of-Care Systems"/
5 point of care.tw
6 POCT$.tw.
7 near patient$.tw.
8 (rapid adj1 test$).tw.
9 (clearview or surecell or quickvue or biostar or oia or handilab or nptgold).tw.
10 1 or 2 or 3
11 or/4-9
12 10 and 11
13 "sensitivity and specificity"/
14 roc curve/
15 predictive value of tests/
16 sensitivity.tw.
17 distinguish$.tw.
18 differentiate.tw.
19 identif$.tw.
20 detect$.tw.
21 diagnos$.tw.
22 (predictive adj4 value$).tw.
23 accura$.tw.
24 comparison.tw. (2
25 or/13-24
26 12 and 25
27 exp clinical trial/
28 randomized controlled trial.pt.
29 controlled clinical trial.pt.
31 randomly.ab.
32 trial.ab.
33 groups.ab.
34 (chang$ or evaluat$ or reviewed or baseline).tw.
35 comparative study/
36 follow-up studies/
37 time factors/
38 (compare$ or compara$).tw.
39 cohort$.tw.
40 (prospective$ or retrospective$).tw.
41 or/27-40
42 12 and 41
43 26 or 42

Preliminary Medline Search Strategy for Review of Preferences

1 chlamydia infection/
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3 chlamydia.tw.
4 "Point-of-Care Systems"/
5 point of care.tw.
6 POCT$.tw.
7 near patient$.tw.
8 (rapid adj1 test$).tw.
9 (clearview or surecell or quickvue or biostar or oia or handilab or nptgold).tw.
10 mass screening/
11 screen$.tw.
12 (opportunistic adj1 test$).tw.
13 or/1-3
14 or/4-12
15 13 and 14
16 patient satisfaction/
17 decision making/
18 choice behavior/
19 willingness to pay.tw.
20 willingness to wait.tw.
21 (discrete adj1 choice).tw.
22 standard gamble.tw.
23 ((preference or opinion or choice) adj3 (elicit or measure$ or obtain or technique$)).tw.
24 or/16-23
25 15 and 24