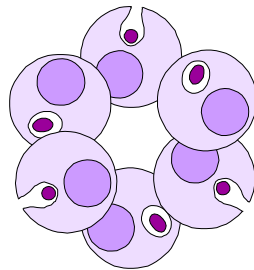


# Chlamydia Screening Study



**CLASS**

Chlamydia Screening Study

## Economic Evaluation Protocol

This document acts as a detailed protocol for the Economic Evaluation.

## **ECONOMIC EVALUATION**

### **1 OBJECTIVES**

- To determine the cost effectiveness of different screening strategies for detecting and treating Chlamydia Trachomatis.
- The economic objective is to determine the relative cost effectiveness of the two strategies under comparison in the Partner Notification Trial:
  - Nurse led partner notification strategy carried out in GP surgeries
  - Referral to GUM clinics for partner-notification undertaken by health advisors.
- To determine the relative cost effectiveness of the different laboratory tests for Chlamydia, namely enzyme linked immunoassays (EIA); Roche Cobas Polymerase Chain Reaction (PCR); and a new Strand Displacement Amplification (SDA).

### **2 PLAN OF INVESTIGATION**

The economic evaluation has three main sections:

#### **2.1: Systematic review of the economic literature and construction of initial model**

2.1.1 A systematic review of economic studies will be used to collect all relevant cost and cost effectiveness evidence that is currently available.

2.1.2 A preliminary decision model will be constructed to represent the design of the overall study. The effectiveness data for the preliminary model will be taken from secondary sources (such as the report of the Expert Advisory Committee on Chlamydia Trachomatis ). Where relevant data are unavailable these will be supplemented as necessary with expert opinion from team members based on their knowledge. A systematic review of the clinical evidence is not being carried out. The cost data from the literature review will be used to provide preliminary estimates of cost-effectiveness in the model.

2.1.3 The preliminary model will provide the basic framework for the economic evaluation and the economic data collection. It will highlight the main areas of uncertainty, gaps in current evidence and provide an insight into the most critical areas of cost data collection. The data collected in the literature review will also prove useful when comparing the screening strategies in the study with other screening strategies, such as opportunistic screening, which are not assessed as part of the current primary study.

**2.2 Collect cost, prevalence and effectiveness data that will feed into and revise the model**

**2.3 Evaluate the cost and cost effectiveness of alternative screening strategies based on this model**

### **3 DATA COLLECTION**

#### **3.1 Data collection from Community Prevalence Study**

3.1.1 Potential participants will be contacted at home by post. Women and men will be asked to provide a first void urine sample (FVU). Women will also be asked to provide a vulvo-vaginal swab (VVS). An instruction leaflet will be enclosed in the study pack. Samples returned to PHLS with consent form will be tested.

3.1.2 The following cost data will be collected:-

*NHS costs will include:-*

- Cost per study pack
- Cost of postage
- Cost of reminder
- Cost of follow up telephone call (if reminder not successful)
- Cost of test
- Cost of researcher
- Any other cost data that is deemed relevant

*Societal costs:-*

- Cost incurred by patients

3.1.3 The results of the prevalence study will feed into main economic model.

#### **3.2 Data Collection from the Case Control Study**

3.2.1 For each participant with a positive test, two with a negative test will be selected. Positives and non-infected controls will be invited to re-attend their surgeries. All patients attending will have completed a lifestyle questionnaire in a sealed envelope and will hand this over to the nurse/counsellor. Treatment will be provided (free of charge) – in the form of a single dose of azithromycin. Appropriate alternatives will be provided to any individual known to be azithromycin sensitive.

3.2.2 The following cost data will be collected:-

*NHS costs will include:-*

- Cost of treatment i.e. staff time for a session in the surgery, the drug and its administration (*the Nurse will record time in and out of session*)
- Cost of side effect (eg. Anaphylactic shock)
- Cost of counselling (for positive cases)
- Cost of training counsellors (cost of the training days) and any others
- Cost of repeat test for positives
- Any other cost data that is deemed relevant

3.2.3 All the index cases that attend the surgery will be given a patient cost questionnaire (see appendix 1) . The time patients arrive in the clinic will be recorded on the top of the patient cost questionnaire, by a staff member who will give out the questionnaires when patients arrive in surgery. The time of the session with the nurse will be recorded by the nurse. The patient cost questionnaire will collect the following information:-

- Time spent in surgery
- Paid or unpaid time off work – how much
- Childcare whilst attending surgery (paid or unpaid – how much)
- Mode of transport
- Cost of transport

3.2.4 The results of the case control study will feed into main economic model.

### **3.3 Data collection in alongside the Partner notification trial**

3.3.1 Participants with positive screening tests will be randomised centrally to the two different partner notification strategies. The unit of randomisation is the individual.

3.3.2 In the nurse led scheme, prior to the study the designated nurse in the practice nurse led scheme will receive training. The nurse will interview the index case in the Case Control Study (described above) at the same time that treatment is administered etc. For the group randomised to the Nurse led partner notification strategy, the interview will include advice about the importance of partner notification and abstinence until both partners are treated. An information leaflet and uniquely numbered contact slips for partner notification will be provided. Index cases will be advised that partners should present themselves at the GUM clinic where they would receive treatment and investigation for chlamydia and other sexually transmitted infections.

3.3.3 In the referral to GUM clinic arm index cases are referred to the GUM clinic for partner notification. At the GUM clinic they will be given the study contact slips

and specially designed study form to present to the clinic on arrival. Attendance of the index cases at the genitourinary clinic will be confirmed either through the presentations of the special study form or through daily clinic records. These index cases are likely to have a shorter interview at the GP surgery in the Case Control Study because they won't have received partner notification advice there. All times will be recorded and coded so it will be possible to separate out those who had partner notification in practice and those that did not.

3.3.4 All index cases will be sent sample containers and a prepaid envelope and will be asked to provide a non-invasive repeat sample 4 weeks after treatment and partner notification. Repeat test results will be sent to the study centre. At 6 weeks index cases will be contacted by telephone and interviewed by a health advisor or research assistant who is unaware of the treatment allocation. Numbers of contact slips handed out will be documented together with the outcomes of partners if known. Index cases will be asked to return any contact slips that were not handed out. Index cases whose repeat chlamydia test is positive will be asked to attend the GU clinic for treatment and routine partner notification.

3.3.5 The following cost data will be collected:-

*NHS Costs will include:*

- Cost of training practice nurse in counselling re: partner notification
- Costs of time for sessions involving partner notification by practice nurse to be compared with cost of session for those being referred directly to GUM clinic for partner notification
- Cost of repeat sample package (same as cost of package in Prevalence study)
- Cost of repeat test
- Cost of re-treatment for positive cases
- Costs of partner notification for repeat positives, treatment of repeat positives partners and partners etc (the numbers involved here may need some modelling input)
- Cost of re-infected patients turning up for treatments (same as for initial round)
- Knock on costs associated with identifying and treating partners and partners of partners being treated (if considered relevant and feasible would need to model this)

3.3.6 Partners who turn up at some of the GUM clinics will be offered a full set of tests with treatments, whilst others will simply get treatment with no tests.

3.3.7 Co-infections will be recorded and there are data on this

3.3.8 Patient cost questionnaires will not be administered to partners as index patient costs can be used as a proxy. One of the few differences that may exist is the travel cost difference of turning up to the GP, which is local

may be less than the travel cost of turning up to GUM clinic which is usually less local. Published data are available on this.

*Societal costs will include:-*

- Cost of turning up to CSS (already collected with patient cost questionnaire)
- Cost of index case turning up to GUM clinic for PN
- Cost of partner turning up to GUM clinic
- Childcare whilst attending surgery (paid or unpaid – how much)
- Mode of transport
- Cost of transport
- Any other cost data that is deemed relevant

3.3.9 The primary economic outcome is the relative cost per index patient for number of partners treated. As there is a comparator in the partner notification trial the information will be used to assess the most cost-effective way of notifying partners. But all the information collected will also feed into the main economic model.

#### **3.4 Data collection associated with the laboratory tests in the sample evaluation study**

3.4.1 During the testing if possible there will be pooling of samples, if in a pool there are any positives all samples will be tested. If all negative - no further tests required implies pooling will save money.

3.4.2 Alternative strategies for testing will be modelled. EIA is more labour intensive and could provide equivocal results and all these would need to be re-tested. PCR and SDA are automated and more sensitive. Testing in the labs during study period will require steady flow of samples to be constant. An appropriate time for carrying out a cost study for the testing of the samples will be ascertained.

3.4.3 The following cost data will be collected.

Cost of each different test: For this we intend to time typical session in the laboratory – collecting data on things such as the throughput of swabs and urines tested in a typical session for each of the tests. What resources are required to carry out each test and maintain specimens in appropriate environment whilst awaiting test?

*NHS costs include:-*

- Equipment
- Staff
- Disposables
- Overheads
- Staff training

- Any other cost data that is deemed relevant

*Societal costs*

None

*Consequences*

None

3.4.4 Laboratory results will provide estimates of sensitivity and specificity that will be used in the economic model. The incremental cost per positive case of Chlamydia Trachomatis identified will be estimated. As more than one test is being evaluated the information will be used to assess the most cost effective way of testing for Chlamydia Trachomatis in a separate sub-study in addition to the information feeding into the main economic model.

### **3.5 Data collection associated with the psychological, emotional and social effects.**

3.5.1 Costs associated with the psychosocial aspects of the study are not being collected directly. The report will include a review of the current literature on quality of life issues relevant to long-term outcomes associated with Chlamydia Trachomatis, such outcomes include: pelvic inflammatory disease, infertility and ectopic pregnancy. If the literature search identifies studies that have constructed quality of life indices or utilities that can be used to formulate Quality Adjusted Life Years (QALYs) then our study will undertake a cost utility analysis alongside the cost effectiveness analysis.

## **4 MODELLING**

### **4.1 Additional data requirements**

4.1.1 The model will also be used to compare a strategy of screening against a no screening strategy. To do this the model will be extended beyond the endpoints of the study using the Swedish database, which will link outcomes in the study to longer-term outcomes such as PID, infertility etc.

4.1.2 The economic approach will as far as possible adopt a societal perspective including both costs incurred by the NHS and private individuals.

4.1.3 The longer-term analysis provided by the extended model will be a cost effectiveness study in the first instance. A cost utility analysis is an objective if the appropriate published data are available. This will be determined by our review.

**Appendix 1. Patient cost questionnaire**

**Questionnaire for measuring costs to patients of attending for treatment**

**Thinking about your visit today:**

1. What would you have been doing today if you were not attending the clinic?

- Paid employment
- Looking after children or relatives
- Studying at school/college
- Other  *Please*

*specify* \_\_\_\_\_

**If you are in paid employment, please answer question 2, if not go to question 3**

2. What arrangements did you make to take time off work? *(Please tick one box)*

- Paid absence from work
- Unpaid absence from work
- Will make the time up
- Came to clinic outside work time
- Took holiday
- Other arrangements  *Please*

*specify* \_\_\_\_\_

3. a) Did you travel here today by:

- Walking
- Bicycle
- Private car
- Public transport
- Other  *Please specify*

\_\_\_\_\_

b) If you came by private car, were you given a lift by someone else?

- Yes  No

c) If you came by private car, how much was paid in car park fees ? \_\_\_\_\_

d) If you came by public transport how much did it cost ? £ \_\_\_\_\_ p \_\_\_\_\_  
*(write down the single fare; if given a return fare, halve it)*

4. How long did the whole journey take? \_\_\_\_\_ minutes

5. Did anyone come with you to hospital,  
**and wait** for you while you received your care ? Yes  No   
  
**If yes**, did they take time off work ? Yes  No   
  
*If more than one person, please specify* \_\_\_\_\_

6. Have you been advised to take time off work after today's visit ? Yes  No   
**If yes**, how long ? \_\_\_\_\_ days

9. What money income, if any, are you losing today by coming to the clinic?  
None  £\_\_\_\_\_ p\_\_\_\_\_

10. If you have children or other dependants,  
Have you paid someone to look after them ? Yes  No  Not Applicable   
  
If yes, how much has it cost ? £\_\_\_\_\_ p\_\_\_\_\_  
or  
Has someone taken time off work to look after them ? Yes  No