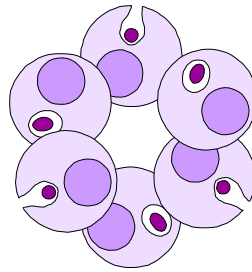


Chlamydia Screening Study



CLASS

Chlamydia Screening Study

Case Control Study Protocol

This document acts as a detailed protocol for the Case-Control study.

CASE-CONTROL STUDY

1. OBJECTIVES

- To identify demographic and behavioural risk factors for genital *Chlamydia trachomatis* infections in a general community sample of men and women aged 16-39 years identified from a community prevalence survey.
- To define risk profiles that could potentially be used to assign risk status in a selective screening programme.

2. PLAN OF INVESTIGATION

2.1 Sample Testing

- 2.1.1 At PHLS samples will only be examined if accompanied by an informed consent form (Appendix 1). Samples returned without an informed consent form will be frozen and a repeat signed consent form requested from the participating study subject. The fact that samples are frozen will be documented in the Laboratory Form (Appendix 2).
- 2.1.2 Analysis of samples will be carried out in accordance with the Laboratory Studies Protocol. Stamped laboratory forms with sample results from Bristol and Birmingham PHLS will be returned to the co-ordinating office and data entry for use in identifying positive and negative cases.

2.2 Case Identification And Selection Of Controls

- 2.2.1 All individuals testing *Chlamydia* positive in the prevalence survey will become cases in the case-control study. Once identified, each case will be matched to two controls. These will be the next two *Chlamydia* negative individuals of the same sex, age-band and practice on the day of selection i.e. on a specific date.

3 CASE-CONTROLSAMPLE

3.1 Case (Positive Sample Result)

3.1.1 All cases will be sent the following:

- **A covering letter** - this will be printed on practice headed paper and signed by the nominated GP (Appendix 3). It will invite the patient to take part in the second part of the Study by attending their practice for an appointment with the named Practice Nurse when they will receive their test result (this will be the Practice Nurse who has attended the ClaSS training days). The letter will provide the patient with an appointment date and time and will stress that recall does not mean that they have *Chlamydia*. The letter will also stipulate which practice to attend for the appointment as some practices are based on more than one site (branch practices). An appointment card with the name of the Practice Nurse, surgery, date and time of appointment will also be included (Appendix 4).
- **Self-administered Risk Marker Case Control Questionnaire** - Potentially useful behavioural and demographic risk markers are taken to be those identified in the report of the expert advisory committee to the Chief Medical Officer. The questionnaire (Male and Female Versions, Appendices 5a and 5b) will cover marital status, education and employment status, sexual orientation, the number of partners in the past year, new partners in the past six months, history of sexually transmitted diseases, pregnancy termination, the presence of genitourinary symptoms, smoking behaviour and alcohol use. Questionnaires are derived from instruments used in the National Survey of Sexual Attitudes and Lifestyles². Participants are asked to bring the completed questionnaire placed in a sealed envelope provided, when attending the practice for their appointment. The nurses will not read the questionnaire unless the subjects request specific advice on questions.
 - **Repeat Specimen Sample Pack** - including urine sample container (male and female), absorbent roll, elastic band and swab container (females only), instructions for specimen collection (male and female), sample collection sheet (Appendix 6) and return pre-paid envelope.

3.2 Control (Negative Sample Result)

- 3.2.1 Participants identified as *Chlamydia* negative **not** selected as controls will be sent a "negative test result" letter - this will be printed on practice headed paper and signed by the nominated GP (Appendix 7). It

will inform the patient of their negative test results, thank them for taking part and inform them that for the majority they need not do anything further. For a small number, as the study rolls out, some participants may be contacted to participate in the Social Research arm of the study. The timing of this will be decided upon following completion of data collection from the pilot practices. (See Social Research Workstream protocol).

- 3.2.2 Participants selected as controls will be sent an invitation letter and risk marker questionnaire as described under "cases" above (3.1.1) and a repeat sample pack for a repeat specimen, which they will be asked to take as they had done previously in the Prevalence Study.

3.3 Practice Appointments

- 3.3.1 Two lists (one for reception and one for the Practice Nurse) of practice appointment times (Appendix 8) will be posted recorded delivery to the surgery on the day the appointment letters are sent to the patients together with a result envelope for each patient and a sheet of unique identifier barcodes attached. A confirmation telephone call will be made to the Practice Nurse from the study centre for receipt of the appointments lists. See Detailed Prevalence Protocol Section 2.2.4 for details on *Chlamydia* clinics.
- 3.3.2 If the patient is unable to attend the appointment date and time given they will be instructed on the covering letter to telephone the practice to speak to their Practice Nurse/Receptionist to arrange another appointment. The Practice Nurse will be responsible for updating the appointment times where necessary and informing the relevant study centre of any changes. The appointments list will be faxed back to the study centre and relevant GU clinic at the end of each ClaSS Research Study Clinic.
- 3.3.3 An individual Case Report File (CRF) for each patient will be used to record procedures carried out during the practice consultation. (Appendix 9)

3.4 Sample Size Considerations And Statistical Analysis

- 3.4.1 Table 1 shows the number of cases assuming a higher response rate among women (60%) than men (40%). The number of cases is calculated based on the prevalences shown in Table 1 and the 2:1 sampling strategy for participants aged 16-25 years and 26-39 years.

3.4.2 The data will be analysed both taking the matching into account and ignoring it. Results will be compared and if no indication of bias is found in the unmatched analysis the latter will be used. Conditional and unconditional logistic regression analyses will be performed in Stata for this purpose.

Table 1 - Detectable odds ratios in women and men

No of female cases	Detectable odds ratio in women			No of male cases	Detectable odd ratio in men		
	Power 80%	Power 90%	Power 95%		Power 80%	Power 90%	Power 95%
170	1.89	2.06	2.20	114	2.16	2.39	2.59
220	1.75	1.89	2.00	146	1.98	2.18	2.33
280	1.65	1.76	1.86	197	1.81	1.96	2.09

Based on a 2-sided significance level of 0.05 (univariate analysis ignoring matching, frequency of exposure in controls 20%)

REFERENCES

- 1 CMO's Expert Advisory Group. Chlamydia trachomatis. London: Department of Health 1998.
- 2 Johnson AM, Wadsworth J, Wellings K, Field J. Sexual Attitudes and Lifestyles. Oxford, Blackwell:1994.

