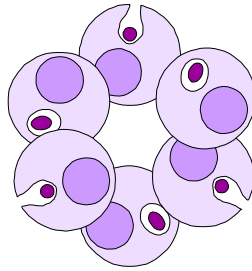


Chlamydia Screening Study



CLASS

Chlamydia Screening Study

Social Research Study Protocol

ClaSS Social Research Study Protocol

INVESTIGATING THE PSYCHOLOGICAL, EMOTIONAL AND SOCIAL EFFECTS OF SCREENING FOR CHLAMYDIA

1.0 BACKGROUND

- 1.0.1 Assessment of whether a population-based screening programme for Chlamydia will do more good than harm must consider the well-being of all of those tested and, because it is a sexually transmitted infection, that of their sexual partners. It will also be important to document the views and experiences of those providing the testing, treatment and follow up. The adverse effects of screening programmes are well documented and these may be compounded by the stigma associated with the unexpected and unsolicited diagnosis of a sexually transmitted infection. People receiving false positive results have been found to experience high levels of anxiety, which have not diminished when subsequent testing revealed no evidence of disease.^{1,2} Furthermore, an invitation to attend for screening, and participating in screening programmes, may lead to increased anxiety^{3,4} and reduced self-perceived health status.⁵ It has also been suggested that those receiving negative screening test results may interpret this as ‘a certificate of health’ and are consequently less inclined to adopt healthy behaviours.⁶
- 1.0.2 This project will use qualitative and quantitative methods to explore the experiences and perceptions of individuals participating in all stages of the screening, diagnosis and partner notification processes. Qualitative interviews will also be conducted with health service staff. A time plan is attached (Appendix 1).

2.0 OVERALL AIM

- 2.0.1 To assess the social, psychological and emotional impact of Chlamydia screening and partner notification.

3.0 OBJECTIVES

- To assess the acceptability of screening and partner notification for genital *C. trachomatis* infection diagnosed in primary health care settings.
 - To assess the effect of screening on the emotional, psychological, and social well-being of those being screened for a sexually transmitted infection.
 - To assess the effect of partner notification on the emotional, psychological, and social well-being of those found to have genital Chlamydial infection.
 - To elicit the views and experiences of primary health care staff involved in testing, treating and partner notification.
- 3.0.1 In order to meet these objectives both qualitative and quantitative methods will be used.

4.0 QUALITATIVE ELEMENT

- 4.0.1 There are three strands to the qualitative element. The first is concerned with the acceptability of the screening process and the impact of being invited, by post, to be screened for a sexually transmitted infection. These issues will be explored through a series of in-depth interviews with those offered screening (i.e. those participating in the community prevalence study).
- 4.0.2 Informants will be purposively selected to ensure a balanced sample of men and women from different ethnic backgrounds and age groups who receive both positive and negative results. Interviews will be conducted with those who have yet to receive their result and with those who have been informed of their result. Up to 40 interviews will be required to ensure thorough exploration and analysis of emergent themes and concepts. Interviews will also be sought with people who decline testing. If themes emerging from the initial interviews require more detailed examination, further theoretical sampling may be used to select interviewees with the particular characteristics. Response rates according to ethnic group and geographic location (urban, peri-urban and rural) will be monitored in the prevalence study. If there are substantial differences in response rates then the reasons behind this will be explored within the social research stream.
- 4.0.3 The second strand of the qualitative element relates to the partner notification trial. An important aspect of the Chlamydia Screening Study (ClaSS) is a comparison of partner notification undertaken in a primary care setting by practice nurses with that undertaken by health advisors in genito-urinary medicine (GUM) clinics. In order to explore possible differences in users' experiences of these two settings up to 20 in-depth interviews will be conducted with those entered into each arm of the trial (if possible some of these interviews will be undertaken with those who were interviewed prior to receiving their results). Some of the sexual contacts traced as a result of partner notification will also be interviewed.
- 4.0.4 Only those who have indicated a willingness to be interviewed as part of the study's consent procedures will be approached (Appendix 2 & 3:p17). These potential interviewees will be telephoned, where possible, to arrange a convenient time and location for the interview to take place (Appendix 4). A letter confirming the details will be sent (Appendix 5). If it is not possible to contact potential interviewees by telephone then a letter will be sent asking them to telephone the researcher (Appendix 6).
- 4.0.5 The final strand of the qualitative element is concerned with describing the views and experiences of the health services staff providing treatment and partner notification for those identified as having a Chlamydial infection. Up to 20 in-depth interviews will be conducted with practice nurses and general practitioners (GPs) participating in the study in Birmingham and Bristol (Appendix 7, 8 & 9).

4.1 Interviews

4.1.1 Interviews will be conducted in the interviewee's home, the interviewer's place of work, general practice, GUM clinic or another suitable setting chosen by the interviewee. Before the interview commences, interviewees will be reminded of the purpose of the interview, assured of anonymity and given the opportunity to ask questions (Appendix 10 & 11). They will then be asked to complete a consent form (Appendix 12 & 13). The interviews will be conducted in a conversational way with interviewees encouraged to relate their expectations, experiences and understandings of the screening process. A checklist of topics will be used to guide the interviews and ensure that primary themes are covered (Appendix 14, 15 & 16). Brief details of the content of these topic guides are given below. As the interviews progress and other themes emerge these will be added to the list of topics to be explored in subsequent interviews.

4.1.2 *Participants in community survey*

The check list of topics for participants in the community survey includes what the term Chlamydia meant; feelings about providing urine and vulvo-vaginal specimens; feelings about being tested for a sexually transmitted infection; reasons for participating or not participating; expectations about test results and reactions to receiving the results; and effects on personal relationships.

4.1.3 *Participants with Chlamydia infection in the partner notification trial*

The focus of these interviews will be on people's feelings about and experiences of the two partner notification strategies but these interviews will also provide additional perspectives on the whole screening and treatment process, from those found to be infected.

4.1.4 *Primary care staff involved in treatment and partner notification*

These interviews will focus on practice staffs' experiences and views of providing follow up for those patients found through screening to have Chlamydia. The interviews will cover the administration of antibiotic treatment on site, providing tracing.

4.1.5 *Case studies*

People who have a positive test result, and a sample of those who do not, will be offered an appointment with the practice nurse at their GP practice. They will be invited to take part in the case control study and complete a questionnaire. Those who have a positive test result will be offered treatment and with their consent entered into the partner notification trial. Practice nurses will keep a log of these consultations (Case Report File). In this log particular problems or special issues which arose in individual consultations can be recorded. In particular, practice nurses have been asked to note cases where people have expressed strong views about the screening process or where the screening seems to have had a deleterious effect (Appendix 3: p19). These logs are returned to the project office in Bristol at regular intervals and we will, using our established procedures, conduct interviews with some of those for whom the Chlamydia screening process has not been

straightforward. Practice staff who express strong views about the screening process or who experience problems may also be treated as case studies.

- 4.1.6 After each interview, informants will be sent a letter thanking them for taking part (Appendix 17 & 18).

4.2 Data collection and analysis

- 4.2.1 Interviews will be recorded on audiotape and fully transcribed. Transcripts will then be studied in detail and a list of common themes and concepts drawn up. Sections of each transcript will be coded according to this classificatory system using Atlas-ti⁷ to facilitate the organisation of the data. Data collection and analysis will run in parallel. The coding index will be added to or refined and coded material regrouped as new themes and categories emerge from subsequent interviews.⁸ Further analysis will employ the constant comparison method of grounded theory in which the textual data are scrutinised for differences and similarities within themes, keeping in mind the context in which themes were mentioned in each interview.⁹ Descriptive accounts will be compiled from these analyses. Members of this work stream will meet on a regular basis to agree on the thematic categories used to index the interview transcripts and to check the plausibility of the data interpretation.¹⁰

5.0 QUANTITATIVE COMPONENT

- 5.0.1 This aspect of the evaluation is concerned with quantifying the impact that the Chlamydia screening process has on a representative sample of those in the prevalence study population. From other studies of screening programmes we know that for the majority, the most likely effect of screening will be that levels of anxiety will be raised, and that when the result is negative these may not return to pre screening levels. Being screened for a sexually transmitted infection may also alter people's sense of self worth. The objective of this element is to assess the impact of an invitation to be screened for Chlamydia on levels of anxiety and depression and on self-esteem using standard instruments.^{11,12} These will be administered from Bristol and Birmingham to the same individuals, by post, at three points in time:
- One month before the invitation to be screened and the screening kit is posted out (Appendix 19 & 20)
 - When the invitation to be screened and the screening kit has been received (measures will be incorporated into the Prevalence Questionnaire - Appendix 21)
 - After negative test results have been dispatched by post (Appendix 22 & 23)
- 5.0.2 Patients who subsequently enter into the case-control study will not be sent a follow-up questionnaire as their experiences will not be typical of people participating in a population based Chlamydia screening programme.
- 5.0.3 Letters sent on practice headed paper and signed by the GP will accompany the questionnaires (Appendix 24 & 25). Reminder letters and a copy of the questionnaire will be sent after one week to those who have not responded (Appendix 26 & 27).

5.1 Sample size

- 5.1.1 For a paired analysis of mean differences in anxiety scores between baseline and receipt of an invitation to be screened, data from a study of breast screening¹³ suggests that we could anticipate a standard deviation of 2.4 in the anxiety score differences. If the mean difference in anxiety scores is 1, then a sample of 355 would result in a 95% confidence interval of 0.75 to 1.25.

Mean difference in anxiety score	Margin of error	Sample size <i>n</i>
2	1	23
2	0.5	89
1	0.5	89
1	0.25	355
1	0.235	400

- 5.1.2 If we anticipate (conservatively) that a measure at all three time points is only achieved for 50% of those approached at baseline, then to obtain complete data on a cohort of 400 we will need to select 800 individuals. To compensate for attrition to the cohort resulting from the exclusion of those subsequently entered into the case-control study, a sample of 1000 will be drawn.
- 5.1.3 Patients in the first two participating practices will not be included in this aspect of the evaluation. This is because the publicity surrounding the study could have an impact on baseline measures of anxiety. The study population for this aspect of the study will therefore contain 16,661 men and women aged 16 to 39 rather than 18,000. An aged stratified simple random sample of 1000 individuals will be selected from the remaining 25 participating general practices in Bristol and Birmingham, using a sampling fraction of 0.060 (1000/16,661).
- 5.1.4 *UPDATE (27-04-01)*: Given that the response rate from the first practice was lower than expected (5/30 after one mailing), we have since decided to increase our sample size. We anticipate a response rate of 25% (after a reminder mailing) and therefore require a sample size of 1600 patients to obtain our target cohort of 400. Excluding the first general practice which has already been sent questionnaires (Knowle), the study population for the remaining 24 practices is 16,147 and thus a sampling fraction of 0.1 (1600/16,147) will be used.
- 5.1.5 *UPDATE (13-08-01)*: Only 15% of patients have so far responded to both baseline and first follow-up questionnaires from the first two practices, although questionnaires are still being returned. We have therefore decided to increase our sample size yet again. To obtain our target cohort of 400, a sample size of 2667 patients is required (assuming 15% response rate across the three waves). Excluding the six general practice that have already been sent questionnaires (Knowle, Tipton, Woodgate, Bartley Green, Quinton &

Southmead), the study population for the remaining 19 practices is 13,838 and thus a sampling fraction of 0.193 (2667/13,838) will be used.

- 5.1.6 *UPDATE (13-11-01)*: To date, the response rates to the baseline and first follow-up questionnaire are low (38% & 17%, respectively) and attrition is high (11% responded to both baseline and first follow-up). We have therefore decided to change the sampling strategy. Instead of following the same patient at three different time points (cohort study), we have decided to adopt a cross sectional study approach and take three independent samples.

Sampling will be conducted with replacement i.e. patients who have been selected at one time point will not be excluded from subsequent sampling populations and so may be selected again. The sampling population at second follow-up (after receipt of negative result by post) will not be a representative sample of patients tested negative as some patients are excluded on the grounds of entering the case control study. The age and sex of the excluded patients will be determined and compared with the age and sex of those in the sampling population at second follow-up. Analyses will be adjusted to take account of any differences detected.

A literature search suggests that it is still appropriate to anticipate a standard deviation of 2.4 in the anxiety score differences.¹³ To detect a difference of 0.4 standard deviations at 90% power, 132 patients are required in each comparison group. Allowing for a 30% response rate, a total sample of 880 patients is needed at each time point.

SD	Power	N in each group	Margin of error	N in each group assuming 30% RR
0.5	80%	63	0.18	210
0.5	90%	85	0.15	284
0.4	80%	99	0.11	330
0.4	90%	132	0.10	440
0.3	80%	142	0.07	474
0.3	90%	190	0.06	634
0.25	80%	252	0.04	840
0.25	90%	337	0.04	1124

This new sampling strategy will be applied to the 12* remaining practices that have yet to receive a baseline questionnaire (Montpelier, Bedminster, St George, Brentry, Cotham, Highgate, Handsworth, Northfield, Shardend, Castle Bromwich, Blakenhall, Pennfields). The study population for these practices is 11457 and thus a sampling fraction of 0.077 (880/11457) will be used.

*NB St John's and Cadbury Heath practices (patients from which had also yet to receive a baseline questionnaire) were excluded from the new sampling fraction calculations as it was unsure at the time if the new or old sampling strategy would be applied. Consequently, the new strategy and fraction was applied. If they had been included in the sampling fraction calculations the study population would be 13225 and thus a slightly smaller sampling fraction of 0.067 (880/13225) should have been used. Given that the study population is a guesstimate (based on estimated practice sizes), the higher fraction of

0.077 will continue to be used to select SR patients from the remaining practices.

6.0 HOW THIS PROTOCOL DIFFERS FROM THE RESEARCH PROPOSAL

- 6.0.1 The short form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI) and the Short-Form-12 Health Survey (SF12) have been replaced with the Hospital Anxiety and Depression (HAD) scale and the Rosenberg Self esteem scale. These are more appropriate scales to measure anxiety and well-being in this study population.
- 6.0.2 Because of changes in the way in which data are being collected in the partner notification trial, it is no longer practicable to administer anxiety scales to participants in the two arms of the partner notification trial, as stated in the original protocol.
- 6.0.3 It was envisaged that we would interview people who are identified as having a false positive or false negative test result, and consider these as individual case studies. However, proposed testing procedures are now such that it is highly unlikely that there will be patients in these categories.

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APPENDICES

- Appendix 1: ClaSS Social Research Workstream Timetable
- Appendix 2: Letter from GP to potential patient interviewees inviting them to take part in an in-depth interview
- Appendix 3: Case Report File: obtaining patient's consent to be contacted for an interview (p17 Section T); comments section (p19 Section W)
- Appendix 4: Invitation to interview patients: follow-up by telephone call
- Appendix 5: Letter to confirm interview with patients
- Appendix 6: Letter to arrange an interview with those who agree to be contacted but who can not be contacted by telephone
- Appendix 7: Letter from lead researcher to potential staff interviewees inviting them to take part in an in-depth interview
- Appendix 8: Invitation to interview staff: follow-up by telephone call
- Appendix 9: Letter to confirm interview with staff
- Appendix 10: To be read to patient prior to in-depth interview
- Appendix 11: To be read to staff prior to in-depth interview
- Appendix 12: Patient consent form
- Appendix 13: Staff consent form
- Appendix 14: Interviews with people who were invited to be screened for Chlamydia
- Appendix 15: Interviews with people participating in the partner notification trial
- Appendix 16: Interviews with staff participating in ClaSS
- Appendix 17: Thank-you letter sent to patients after each interview
- Appendix 18: Thank-you letter sent to staff after each interview
- Appendix 19: Measuring well-being (baseline questionnaire – Bristol patients)
- Appendix 20: Measuring well-being (baseline questionnaire – Birmingham patients)
- Appendix 21: Prevalence questionnaire (incorporates anxiety measures - 1st follow-up)
- Appendix 22: Questionnaire to measure well-being (2nd follow-up - Bristol patients)
- Appendix 23: Questionnaire to measure well-being (2nd follow-up – Birmingham patients)
- Appendix 24: Letter from GP to patients requesting them to complete the baseline anxiety questionnaire
- Appendix 25: Letter from GP to patients who have been mailed negative test results requesting them to complete a follow-up anxiety questionnaire
- Appendix 26: Reminder letter from GP to patients who have not returned the baseline anxiety questionnaire
- Appendix 27: Reminder letter from GP to patients who have been mailed negative test