
Detailed report: Portsmouth pilot site

Prepared by:
The Chlamydia Research Office – Ella Gordon Unit,
St Mary’s Hospital Portsmouth
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1. Summary

- A central co-ordinating office proved very useful in advising health professionals and in the management of positive patients. This reduced the workload of GPs and Family Planning health professionals.
- The urine test was very acceptable to both patients and health professionals.
- The time taken to introduce screening must not be underestimated.
- Young people did not expect their test to be positive, although they were advised about this in advance. Pre-screening counselling about the significance of a positive test needs to have more impact.
- Adequate laboratory facilities and staff are mandatory, as using the urine test will doubtless increase the number of Chlamydia tests undertaken.
- A decision needs to be agreed as to whether all positive patients need to have a full sexual screen for other STIs. If all patients do need to have these extra tests, it will increase the workload for GUM.
- GUM workload is likely to increase because the LCR test is more sensitive and so more positive patients will be detected. This will increase the amount of contact tracing that needs to be undertaken.
- A robust IT system needs to be in place.
- Each area needs to decide how it will contact screened patients with their result. This study found that no single method was satisfactory.

2. Introduction

The Portsmouth district comprises the area of Portsea Island and South East Hampshire. It has a population of 550,696 with the number of 16-24 year old women being 33,241. As not all of this age group would be sexually active [using data from the National Survey of Sexual Attitudes and Lifestyles], the target population was calculated as being 30,000 with a 50% anticipated uptake. The number of samples from this group was therefore estimated to be 15,000 over the 12 month period. The total number of samples to be tested was increased to 17,500 to take into account the small number of men who were to be screened at Sex Sense and GUM and also repeat tests.

The pilot required that opportunistic screening take place in all general practice [GP] surgeries, family planning [FP] clinics, young people’s sexual health services [Sex Sense in Portsmouth], genito-urinary medicine [GUM], gynaecology and antenatal clinics [ANC]. This equated to 143 different sites [110 GP surgeries, 10 FP clinics, 5 Sex Sense sessions for young people, 3 GUM clinics, 8 ANCs and 5 gynaecology sessions]. The actual number was reduced to 113 in total with only 83 surgeries and 5 ANCs taking part. Men were only offered screening in GUM and Sex Sense.

The screening sites were supported by the local PHLS laboratory, which to date had been offering chlamydia testing with swabs using the EIA technique. The number of swab tests was 9,333 in 1997/8, rising to 11,460 in 1998/9. In the first five months of 1999/2000 5,416
were tested. Since the pilot was completed, Portsmouth and Wirral have begun the Re-infection Study.

3. Project Initiation

A local steering group was formed, comprising the local study co-ordinator as the chairman and representatives from general practice, GUM, the laboratory, public health, family planning and finance. Membership of the group is listed at the end of this document. A chlamydia pilot office was established with a secretary and two part time research nurses. The office was situated within the GUM department which meant there could be close liaison between the research nurses and GUM staff.

The steering group initially met in June 1998, as screening was due to commence in August 1998. The actual start date was 1st September 1999. This delay was because many of the issues arising with setting up the study had not been addressed or finalised. The protocol had to be written, ethical approval acquired, patient and professional information packs devised and printed and a request form and unique uri-pot designed. The Department of Health (DH) also wanted a survey undertaken of patients’ knowledge and views about Chlamydia and the screening pilot. The first survey was undertaken prior to the pilot commencing. Views from the participating professionals were also gathered during the 12 months. A new computer package [CPS] was devised, but unfortunately this was implemented late and resulted in some delays. Finally, a remuneration package had to be agreed with the participating sites and discussions with the general practitioners were lengthy.

The two pilot areas worked well together in splitting many of these tasks. Portsmouth was responsible for the patient information, which comprised leaflets, posters & credit card sized advertisements. The Wirral undertook to design the request form and the uri-pots.

3.1 Professional Information

Each pilot site wrote their own manual for the different professionals taking part. This contained a copy of the protocol, responsibilities for the different team members, anticipated questions that patients may ask with appropriate answers, copies of the patients’ booklet and general information on Chlamydia.

3.2 Patient Information

Portsmouth agreed to write the patient information. A booklet was designed which described the study, the reason for screening, the significance of a positive or negative result and how the result would be made available. The Health Education Authority assisted by arranging to pilot the booklet in Oxford, as it was important that any information was assessed outside the screening areas. The final booklet was agreed and to compliment it were posters and credit card sized reminders. (Appendix 1).

3.2 Introduction of Screening

At the commencement of the pilot, the two sites introduced screening in very different ways. Portsmouth followed the protocol and started all the screening sites at the same time. This
ensured that there was complete coverage of the district from the beginning so that prevalence could be measured. This decision resulted in several problems:

- The logistics in arranging for each clinic to receive the equipment needed to commence screening was a major problem. Over 150 boxes needed packing and distributing and finding the space to undertake this was extremely difficult. Finally an empty ward in the nearby psychiatric hospital was utilised.
- Enthusiasm amongst the screeners was very high, resulting in the second major hurdle, in that over the first few weeks the laboratory was swamped with samples. This led to a delay in processing the results and caused some anxiety for patients.
- The two research nurses were kept busy in the initial weeks answering queries from screening sites and patients, without the support of the computer package.
- Because more women were tested than anticipated, a greater than expected influx of positive patients presented to GUM. Extra staff were needed.

The Wirral phased in screening over quite a long period, so did not have these problems.

4. Laboratory Report

The laboratory expected to receive 60 urine samples per working day. From this they estimated their needs would comprise:

- Laboratory space for receiving, unpacking and testing the samples. The study coincided with the integration of two separate laboratory serology departments, which released the usable space in three separate, dedicated areas to reduce cross-contamination.
- One or two Ligase Chain reaction (LCx) machines. Each could process three batches of 20 samples per day, and initially one was obtained on a reagent-rental agreement. The company (Abbott) also provided training for lab staff.
- Short contract laboratory staff to help over the period of the study. One full work-time equivalent (wte) BMS was assigned to the work, being replaced by temporary staff for the year. One part-time Medical Laboratory Assistant increased her hours by 0.5 wte to assist with specimen reception and computer registration.
- Refrigerators and freezers for storage of specimens and test reagents.
- Office space for computer registration, form processing and filing was split between the new reception area and the existing laboratory office. Short contract office staff for these processes were employed (0.5 wte). As well as the documentation of tested samples, data was also entered for persons refusing tests and for persons who accepted tests at the first interview, took containers home, but did not subsequently send specimens. 30,311 entries were made on the patient database, 17,341 on the specimen database.
- Training on and testing of, the bespoke data processing package. A few anomalous features were discovered; for example, there were no means for checking and correcting wrongly entered data. For this, an authorisation stage after the primary data entry stage was requested. In addition, functions which worked during development did not work over the hospital intranet, largely due to the increased security framework necessary for work with patient data. This resulted in a piece-meal implementation of the provided
package, and necessitated use of the existing LIMS, with subsequent double entry into the CPS system, of the first 11,188 samples.

The study started in September 1999, with one LCx machine. Instead of the anticipated 300 samples per week, the following numbers were received in the first six weeks: 401, 827, 779, 905, 1016 and 813, with a subsequent slow diminution. The resultant shortfall in personnel was ameliorated by overtime working, transfer of staff from other parts of the laboratory and employment of extra, agency staff on a short-term basis. It was obvious that one LCx machine was inadequate for the numbers received, but there were no unused machines in the country at the time. A graph of the number of specimens received per month and associated events are shown in Figure 1.

The result was an unacceptable but unavoidable delay between receipt of the specimen and issuing of the final report. The consequence was sending out a positive result some weeks after the specimen had been received. Some clinicians decided that if the patient was suspected of active Chlamydial infection, then the usual swabs were also taken alongside the pilot study urine. As the swab results were available within one week this led to many patients early in the study being falsely reassured that they were chlamydia negative and then being recalled weeks later because the urine result was positive. This continued until the eventual arrival of two more machines and a decrease in the numbers of specimens being received, achieved by FP clinics and GPs being asked to reduce the number of samples they sent in. The laboratory was then able to catch up.

Later in the pilot there was a short period when a large number of equivocal results were reported by the laboratory and patients were required to produce further samples, sometimes on several occasions. This led to great patient concern as to the reliability of the screening procedure and their actual chlamydia status. This was resolved by attention to the testing technique and redefining the cut off level for a positive result.

In all, 17,292 specimens were processed during the 12 month period, all having at least one LCR test. 3,367 had a second LCR and 464 a confirmatory PCR. Over the year the number of samples sent from general practice fell, whereas those sent from FP and GUM remained constant. In the last four weeks of the study specimens averaged 150 per week.

5. Research Nurses’ Report

The two nurses were exceptionally busy prior to the start of the pilot. Their main role before the study could commence involved the education of the professionals at the screening sites. Professional updates continued throughout the study and a regular newsletter was issued. The research nurses also had to deal with the logistics of arranging for the equipment to be delivered to all the participating sites and find suitable storage space for the remaining equipment.
After the study had started, the nurses found that numerous queries about the study from professionals had to be dealt with each day. The ‘day sheets’, which were a record of eligible patients attending screening sites, caused a particular problem in that they were time consuming to complete and the data required was not always easily available. The protocol required that patients be asked to take part every time they visited one of the screening sites. For some patients this may have been several times over a short period. The nurses had to deal with complaints from health professionals that patients did not like being asked to participate on repeated occasions.

Once results were received from the laboratory, an enormous amount of manual administration and double entry of patient details was required, due to the fact that the CPS database was not in use until after the study had commenced. As discussed in the laboratory section, the delay in processing the results, especially the positive ones, led to complaints from health care professionals and unnecessary anxiety among patients. The CPS system assisted with sending out the results to the patients, but was never implemented to its full potential. This resulted in a manual system being maintained until the end of the pilot. A decision was made not to mount a large public education campaign due to time constraints and to reduce the impact on the laboratory, but large numbers of tests were performed even without a big promotion. A proactive approach was taken within the local Further Education Colleges and University, with several health promotion days with screening offered at these venues. Outreach work was undertaken at sites where young people congregated, for example shopping centres and the sea front.

The major part of the research nurses role after the start of the programme was dealing with the patients. Positive patients were contacted via letter or ‘phone and chased up if they did not reply. The nurses were based in GUM and all positive patients were encouraged to attend there for treatment and contact tracing. Knowing that they would see the same nurse they had been talking to was a great help in encouraging attendance to GUM. If the patient did not want to attend GUM, then arrangements were made for her to be seen by the research nurse at an alternative venue; often a FP clinic.

6. GUM Report

Approximately 2000 extra female patients and 1500 male contacts attended Portsmouth GUM as a direct result of the screening pilot increasing annual attendances from around 22000 to 26000. The majority of patients found to be positive were willing to notify or provide details of their traceable partners. It became clear that the pilot had increased awareness of chlamydia among the local population. Patients from GP surgeries not participating in the pilot or outside the study age group accessed the department and also FP clinics specifically requesting chlamydia tests. Furthermore, patients previously screened made appointments for sexual health screening because they had changed their sexual partners.
In GUM dual sampling was undertaken [urine LCR and swab EIA] to compare the two methods. In Portsmouth using a urine LCR rather than a swab led to approximately 30% more women and 45% more men being diagnosed with chlamydia. All participants found to be chlamydia positive were treated with Doxycycline or Azithromycin unless pregnant when Erythromycin was given. Azithromycin is taken as a single dose, allowing for directly observed therapy and ensuring treatment compliance. Among this young age group, doubts about adherence to a 7-day course of treatment or worries about being seen with medication led to many being given Azithromycin.

Positive patients were offered the opportunity to be screened for other infections. 1247 positive women and 490 positive men were seen by GUM. Of these, 390 women [31%] and 54 men [11%] had a co-existing infection, which included bacterial vaginosis, but not candidiasis. 34 women and 5 men had more than 1 co-existing infection. This information needs to be further evaluated in order assess which patients presented with symptoms and had a co-existing infection. This may help with future discussions as to whether all positive patients need screening for other STIs.

In Portsmouth the high percentage of chlamydia positive patients attending GUM was achieved as stated earlier by having the research nurses located within the department and also by offering immediate access to all GUM services whenever patients were seen by the research nurses to discuss results and arrange treatment. Accompanying partners were also seen at the same time. This was possible because of triage by senior nurses in a previously established system.

It was possible to manage the large number of study patients because the department offers a flexible service and has adaptable, highly skilled clinical staff. It was essential that all these staff understood the study requirements and that the nurses in particular possessed the skills, knowledge and competence to assess, diagnose and treat patients according to departmental group protocols. To achieve this all staff attended multidisciplinary team meetings. These identified how the pilot study would work in practice from initial patient contact to test of cure. Decisions were carefully monitored and revised during the study period.

6.1 Confidentiality and Insurance

The NHS Trusts (Venereal Disease) Directions 1991 describe confidentiality requirements in departments of GUM. Although pilot participants had given informed consent for the test initiator to receive their chlamydia result, it was confirmed that the results of further tests undertaken within GUM could not be disclosed. To overcome any possible breach of confidentiality a separate database of GUM details was set up using identification by confidential clinic numbers with no link to the pilot database using patient names. Collation of data from these two systems at the end of the study was unsatisfactory and time consuming. In roll out patients and their doctors must understand the long established confidentiality relating to STIs. Informal reassurances had been received from the Association of British Insurers that a positive result found on routine chlamydia screening, if disclosed by the patient, will not result in loading of life insurance premiums. This statement should be confirmed prior to a national screening programme.
Since the pilot, new Venereal Disease Directions have been published: The NHS Trust and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000, the 1991 Directions are revoked. The New Directions are being discussed fully by the DoH in order to encompass the issue of confidentiality in GUM, contraception clinics and General Practice, as increasingly with the Sexual Health strategy, more STI testing will take place outside GUM.

7. General Practice Report

All 110 practices were notified about the study and representatives from three practices joined the steering group. Initially little thought had been given to how the sites would be remunerated for the extra work in carrying out the pilot screening. Therefore, both Wirral and Portsmouth met with their respective LMC representatives to discuss this issue. It was decided that whatever scheme the GPs chose would also be used for the other screening sites so as to reduce administration costs. Following the discussions, the two sites developed different models with Portsmouth agreeing to pay a higher cost per test initially whereas Wirral opted for the original concept of a capitation fee. The Portsmouth model meant that all screening sites received £25 per test for the first 6000 tests, after which the payment was reduced to £10 per test. Very few practices actually stopped screening once the payment was reduced.

Each practice received a folder with general information on chlamydia, clear guidance on how to undertake screening with the inclusion and exclusion criteria and some examples of questions and answers on contentious issues. The research nurses made themselves available to answer queries.

Practices adopted different approaches as to how they recruited clients; but most involved the receptionist identifying the patient and giving her information to read on arrival. It was thought that lack of privacy and concerns about confidentiality in the waiting room would be a problem, but this was not an issue. The nurse or doctor would then recruit the patient to the study. Many staff found that the whole process actually took less time than they thought it would and most found that they speeded up as the year progressed.

Staff found that discussing the test brought up other issues and that sexuality could be more easily addressed. The opportunistic approach was not the problem everyone thought it might be. Both the health care staff and the patients found the urine test far more acceptable than the vaginal swab.

8. Family Planning (Contraception and Sexual Health) Report

This includes the Sex Sense clinics for young people.

This service screened approximately 4,000 clients including the eligible females aged 16 – 24, but also young people under 16 and men at Sex Sense clinics and under 24s attending the TOP service which is a part of the Family Planning Service department. This represented a
significant increase in workload in a department that already sees over 60,000 clients per year.

All staff were made aware of the pilot study and several meetings were organised to discuss how the study would be implemented. Receptionists were required to check the patient’s age and hand out the information for the woman to read whilst waiting in the clinic. Their most onerous task was having to check extra specimens with the nurse at the end of a busy clinic and then to have to complete the ‘day sheet’ (as explained earlier in section 4). Other clerical staff then had the job of filing all the results as they came back.

The request form was designed so that the patient filled in their own demographic details and where the result was to be sent. The young people were quite happy to fill in these sections themselves. As the pilot progressed, clients were encouraged to provide an address for their result rather than a mobile number or stating that they would return to the clinic. Few of the latter returned when they should have done so and problems were encountered contacting some patients. Interestingly, in the re-infection study we have not encountered the same problems with mobile phones and in fact they have become an important means of contacting patients.

Some patients were unable to provide a specimen whilst they were at the clinic but agreed to take the bottle home and drop it off at an arranged place some days later. Unfortunately many of these patients did not bother to do the sample and this resulted in extra work for the laboratory that had to enter their details on the data base. This option was not offered in the re-infection study.

Under 16s from the Sex Sense clinics who were deemed “Frazer” competent were offered screening. The number of positive tests in this young age group was of concern. It was a pleasant surprise to know how knowledgeable this population was. Most had heard of Chlamydia and understood the reasons for being tested, however, it transpired that many had not thought through what it would mean if they were positive and this is an area that will need to be addressed if screening continues. Overall, the nurses and doctors in all clinics found the experience easier than they thought.

9. Screening at other sites

Unfortunately screening at the other sites was not as great as was hoped. From the results, it appears that screening in colposcopy and ANC would be worth while.

10. Financial Aspects

Obviously, the pilot budget covered most of the costs in undertaking the project. However, as it was also a research project, some costs were incurred which would not be necessary for a straight forward screening programme. As screening is to be continued in a further 10 sites, then this will be an important issue for discussion. Items for consideration will include:

- Increased cost of LCR against EIA.
• Laboratories will require LCR testing machines.
• Probability that more tests will be performed than done previously.
• This together with the increased sensitivity will result in more positive patients needing treatment, more contact tracing, more clients attending GUM.
• Staff costs in laboratory and GUM.
• Possible need to remunerate screeners.
• Cost of recall if introduced.
Figure 1 Number of Specimens received per week.

Portsmouth Public Health Laboratory - Chlamydia Pilot Trial
Number of specimens received per week from 1 September 1999

- Senders requested to reduce numbers of tests
- Senders advised payment reduction
- Xmas & Easter holidays
- GP returned to full screening
- Family planning returned to full screening