Department of Health


Detailed report: Wirral pilot site

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1. Summary

- Very little medical input is required in offering chlamydia screening. Developments in the pilot all contribute to efficiency and reducing the burden on health professionals and increasing acceptability to clients. These include adequate interesting and varied information, self-completed request forms, a variety of drop-off points, personal contact and troubleshooting.
- A central management point for screened positive people by community health advisers is innovative. It removes the direct burden of responsibility from individual health professionals in tracking results and people and therefore reduces the likelihood of disparate management.
- The non-GUM services finding the most cases of chlamydia were family planning clinics (40% including the Brook clinic) and GP (26%).
- Many young people move addresses and/or do not want correspondence or communication. In trying to reduce chlamydia, opportunistic screening reaches many of them, whereas call/recall may not.
- The profile and understanding of chlamydia and other sexual health issues in the public was raised dramatically as the programme with its publicity developed.
- Collaboration between all involved to plan effectively is vital - in this case particularly clinical and laboratory aspects of the project.
- Sufficient time for consultation and troubleshooting is essential in developing any computer system to support such a programme and to utilise and interact with existing and planned systems in the NHS.
- It has been privilege to be involved with this project, with its common goal and multidisciplinary approach, engendering positive collaboration and extreme goodwill in both health professionals and the public.

2. Planning the pilot on Wirral

2.1 Background considerations.

In order to develop chlamydia screening we first considered other screening programmes especially the National Health Service Cervical Screening Programme (NHSCSP) and we related this to our experience in chlamydia testing. We thought that there were many issues in common which we could use in planning, though there are inherent differences/problems likely to arise from offering screening for an overt sexually transmitted infection.

One decision in common with the NHSCSP was to send results to all those tested; one difference was the decision not to send a copy of results to general practitioners if they had not initiated the test.
We thought that any national programme must be planned and be delivered effectively and equitably, taking into account existing population and health services, so we intended that the two pilot sites would develop identically, having identified background differences. Wirral is a peninsular with a relatively static population, high unemployment & few ethnic communities compared with Portsmouth, a city with a university & naval base & therefore a migratory population. Other differences between the pilot sites were in delivery of their existing genitourinary medicine services and in availability of diagnostic tests for chlamydia. However, despite our best efforts there were some unavoidable differences in delivery.

2.2 Preparation

Preparation was essential to ensure that the appropriate infrastructure was in place. Key questions addressed included:
- Is there backing from local health professionals?
- Are there appropriate information, education and support in place for them and for the community?
- Can the testing sites cope and should there be payment for their involvement?
- Does the laboratory have enough of the relevant equipment and personnel to carry out tests? (Support services are often overlooked in clinically driven projects).
- Are there computer links and expertise to enable local monitoring of tests both for any planned payments and for disease surveillance and for management of the programme?
- How will those tested receive their results?
- And of course, can people screened positive be managed appropriately and effectively and with minimal harm?

As the basis for addressing these questions on Wirral, an estimate was made of the maximum number of tests possible and the likely numbers of screened positive cases throughout 12 months of testing. There were 20,000 women in the target age range and using data from National survey of Sexual Attitudes and Lifestyles (NATSSAL) to estimate the levels of sexual activity in the population this gave a likely 12,000 women eligible for screening. Recognising that some would be offered tests on more than one occasion including "tests of cure" and resolution of equivocal results and following the decision that tests could be offered to men in a few settings, planning was based on a maximum of 15,000 tests.

Meetings with all services likely to be involved were held to plan the programme many months before testing began and the final details of the main protocol developed in the light of input from these. Staff from each service then wrote individual simplified protocols appropriate for their staff in order to develop shared ownership of the project.
On Wirral, a capitation fee (£3) for each patient registered with a service in the 16-24 age group was paid at the outset to each participating service as recognition of time involved in education and information visits. This was intended to be seen clearly to represent payment related only to the study aspect of the programme. It was agreed that payments per test initiated would be £10 for the duration of the pilot in all services, to cover costs incurred in pre test counselling, administering the tests and filing results etc. All services agreed to this. Supplies and treatment were funded centrally by the pilot. Target payments were considered though rejected.

3. Implementation.

3.1 Samples:

We had used Urikones (Rocket) in a previous study and found these to be more acceptable than a simple bottle for samples. Further, they were easily identifiable as related to the chlamydia test. We had them made in the "chlamydia colours" for the pilot and provided paper bags to put them in, as discretion was difficult in some waiting rooms. Storage was a problem and we used a shed at Cammel Lairds shipyard for some time. We do not believe this has contributed to their current crisis!

3.2 Request forms

See section 4 for more detailed information. These were to have a pivotal multipurpose role in the pilot, providing information, requesting the test, enabling results to be sent, and collecting most of the relevant data in one step\(^1\). They were designed in the light of our previous work. The intention was that the offer of a test should be as simple as possible, reflecting any future opportunistic screening programme, rather than being perceived solely as a research project which may have had different acceptability and therefore requiring different evaluation.

3.3 Information and involvement for health professionals

This included information sheets, distribution of the protocol, meetings in each individual service, four conferences, presentations at postgraduate meetings, regular newsletters, local steering group meetings. We also developed a Web site during the Pilot (www.WOW.nhs.uk). There was easy contact with the pilot office, with its phone number readily accessed on request forms, mugs, coasters, pens, notelets etc.
3.4 Information for public:

Posters and booklets were the same on both sites. Locally designed postcards, two designs of condom holders etc (enclosed) were distributed by the team in health outlets, buses, discos etc. These were rolled out through the pilot both to maintain interest and to enable people who may not have accessed information through health care to receive it in other ways. The local HealthWise helpline provided an additional phone number for information on these items.

To reduce the risk of blame in relationships we took the step of introducing the term "sexually shared infection"

“You may not know you have it” was our other catch phrase.

3.5 Pilot administration:

This involved the enormous support function, including packing and distributing the "battle boxes", sending of all results and management of screened positive people. It was intended that a computer system would facilitate this. In Portsmouth the central administration for the pilot was sited in the department of GUM with the clear advantage that there was seamless transfer of care of screened positive clients to the department. On Wirral, there was limited space in the Department for this purpose and on balance it was decided to have a community based centre outwith the District General Hospital and close to the Well Woman centre and Wirral Brook service. A further factor in this decision was previous finding from others, and ourselves that many people do not attend GUM for a variety of reasons. We planned to give those who tested positive the choice of venue for management. Nurses were appointed to work as research nurses who became community health advisers, based in the pilot office and working closely with their colleagues in the Department. They had the medical support of JJH and prescribed according to Patient Group Directions, which we devised in conjunction with the pharmacy department. Partner notification and treatment was also carried out at the Chlamydia pilot office.

3.6 Results

People should receive their results without delay so implementation of the testing was planned so that there would be no backlog. Letters were generated in the pilot office after downloading from the laboratory. (Further details are in the laboratory section). We received no queries/criticisms arising from the results system. Every positive person had a case note made and kept in the pilot office so that treatment and partner notification could be recorded. If there was no response, every effort was made to trace the client. The health advisers were able to be entirely flexible and could visit people at any convenient place.
3.7 Management of screened positive people

Assuming a maximum positivity of 10%, 1500 screened positive women with their partners could need to be managed during the pilot. For planning purposes we made the assumption that all would attend the department of genitourinary medicine.

3.8 Computer support and data collection

We already had long term data through the laboratory Telepath system with Epi info. We envisaged that for the pilot this would enable us to link with the FHSA and develop a system similar to the NHSCSP and we had several constructive meetings to develop this. However, it was decided to develop a new data collection system (CPS) for both sites and it is this that delayed implementation of the pilot and gave us most unscheduled work throughout. For the duration of pilot testing it was a flat file so that we could not link sequential or dual tests on the same patients. We did not have monthly data to enable us to refine testing and others have documented further problems. Concerns about confidentiality led us to devise the use of sequential numbers in addition to all the other safeguards and they have in fact been useful in tracking people without use of names of other accessible identifiers.

4. Development of the request form for the pilot chlamydia screening programme

4.1 Main body of form

![Request form diagram]
4.2 Unique features

*Tear off strip for recording data*
*Self completion facility*
*Detachable information sheet*

We planned that everyone having a chlamydia test as part of the Chlamydia Pilot would receive their result in the way they chose. Self administered tests are possible, so with this in mind there is a shaded area which clients/patients can complete with or without assistance and which can be signed. Results letters could be sent to a home address or a relative or friend’s address. Alternatively they could be collected at the site where the test was initiated. An additional option was to give a phone number (or mobile phone number) for contact. E-mail contact is also a possibility though was not used in the pilot.

A second report is forwarded to the Chlamydia Pilot Office to check against the electronic report incorporated into the letter informing the patient of the test result. A box on the request form is completed to give details of other chlamydia tests taken in addition to the urine test, as it was planned that the screening result would not be sent until all results were available, in case there were discrepant results. However, the computer system was unable to deal with this.

The test initiator's address is required to allow a result report to be sent there.

Some concerns were expressed by young peoples’ services with regard to the level of privacy in the data collection. After consultation with the services involved, it was decided to separate the essential information (likely to be required in a national programme) from the study data. We examined ways of removing the latter, leaving only numbered tick boxes, which would be unidentifiable in transit or by anyone not closely involved with the pilot. Methods examined included having a fold over section, rub/scratch information, but in the end we decided on a tear off strip. This information is clearly defined as belonging to the study.

In order to enhance partnership in health care and to document that testing is about risk reduction rather than health guarantees, information is attached to the front of the request form explaining what the test is for, the limitations of a test and how the results will be obtained. There is space to write in the test date and who to contact if no result is obtained, together with a reference number. This sheet is detached and given to the client.
Detachable information leaflet - to be retained by patient

A previous development was to include in the result, management guidelines for those testing positive. We decided that this would not be helpful in the pilot as consistent management was planned.

We also rejected as unethical the idea of sending copies of positive results from all health care settings to a department of genitourinary medicine.

Familiar items on the test request form such as 'date' were consistently completed, but less familiar items such as 'reason for attendance' were not completed in approximately 14% of forms (though this overall figure does not demonstrate the improvement found as the pilot progressed.)

5 Laboratory report

Diagnostic tests on Wirral are carried out using ELISA. Historically, those from GUM are tested at Liverpool PHLS (confirmatory PCR) and all others at Clatterbridge Hospital microbiology department (confirmatory IFA). We thought that there would be considerable overlap between use of swabs for diagnostic purposes and urine for screening (please see section 9). Liverpool PHL already carried out LCR tests, and Dr Mallinson, Principal Microbiologist there and Dr Hopwood had worked together on chlamydia for fourteen years. All these issues led to the decision to transfer all testing to Liverpool PHLS, so that by using the same request form we could monitor both diagnostic and screening tests on Wirral for the duration of the pilot. Funding was
required to sort and transport samples to PHLS and to ensure retention of staff to return to the previous system after the pilot.

In order not to flood the laboratory with urine samples (!) community testing was phased in over the first few months by the evolving publicity programme and by bringing in general practices gradually. As the programme developed, practices were asking to be involved rather than being persuaded.

Decisions were taken in relation to equivocal results, to discrepant results (when swabs were taken at the same time as the urine test) and to quality assurance.

Liverpool PHLS Laboratory provided in addition to testing the database management for the CPS computer at the Wirral Chlamydia Pilot office. Various other computer solutions were also developed to address functions of the CPS computer system, which were missing or late in development.

Organisation to provide laboratory services and data collection at Liverpool PHL had to take account of several features of pilot design particular to the Wirral site.

- The Chlamydia Pilot System (CPS) computer was installed within the Pilot Office using hardware and networking support from the local Trust but the Database management and housekeeping support was provided remotely from Liverpool PHL.

- Electronic transfer was used to pass results from Liverpool PHL to the Pilot Office CPS computer.

- To facilitate collection of data on all chlamydia testing activity across Wirral and to cross-check consistent management of Pilot patients having both type of investigation, ALL chlamydia samples (Diagnostic Swabs and Pilot Urines) were transported to and processed at Liverpool PHL for the duration of the Pilot. Results of Swab testing were returned electronically to the local Microbiology Laboratory computer system and reported from there to maintain the continuity essential after the pilot.

- The local Microbiology Laboratory at Clatterbridge Hospital dealt with the increased level of testing for concurrent ‘other infections ‘ in chlamydia positive patients.

Chlamydia LCR testing was already in place using a single installation of the Abbott LCx system (one microcentrifuge, one heater block, one thermocycler, one LCx anylyser). A Grade ‘A’ Clinical scientist, with some prior experience of LCR testing, was recruited and cover for illness/ leave arranged from existing MLSO staff. Abbott arranged an extra
service visit for the equipment and two extra on-site training days for all PHL staff to be involved. It was agreed that a second set of LCx equipment would be available on standby in case of breakdown at either the Liverpool or Portsmouth site. Also a second LCx system would be installed when throughput reached more than 40 LCR tests per day. In the event, there was delay in this when Portsmouth required more than the anticipated number of LCx machines.

Specimen reception and preparation was situated in a room dedicated to LCR processing. The existing LCR amplification room already contained the required refrigerator and was large enough to hold the second LCx equipment.

An arrangement was agreed that Roche COBAS PCR would be performed within PHLS North West Group (Manchester PHL) when results of initial LCR and repeat confirmatory LCR were discrepant.

A Quality Assurance scheme was developed in conjunction with the PHLS genitourinary Infection Reference Laboratory, Bristol. Initial LCR evaluation of a range of titrated aliquots of chlamydia DNA allowed a range QA samples to be defined. The QA process was repeated twice during the Pilot.

5.1 Specimen testing, workload and reporting

Urine LCR tests were, according to the manufactures recommendation, considered reactive, positive with test/cut-off (T/C) value >= 1.0. For the purposes of the Pilot, urine LCR tests were also consider reactive, equivocal with (T/C) value > 0.5 but <1.0. Initially reactive urines were repeated/confirmed by repeating LCR following re-extraction of the raw urine. Samples showing discrepant initial and repeat LCR results were further tested by PCR.

Over 19,000 transactions were completed (including 2927 Request Forms without a sample as required for evaluation of acceptance of the offer of a test. There were 8006 swabs of which 7.8% were EIA reactive and confirmed positive by LCR or PCR. Urine testing involved 9549 LCR tests (8398 initial tests and 1151 repeat tests) and 88 PCR tests. Overall, 917 (10.9%) urines were reported as ‘Chlamydia trachomatis detected’, 17 (0.2%) were reported as ‘equivocal results, please repeat’, 7414 (88.3%) were reported as ‘Chlamydia trachomatis not detected’. 50 (0.6%) had initially positive LCR but negative confirmatory tests and were also reported as ‘Chlamydia trachomatis not detected’. There is some evidence from repeat samples received, that some of these 50 patients (?20-30%) may have been true positive cases.
6. Experiences of Chlamydia screening at Wirral Brook

Approximately 1500 people were tested during the Pilot and both young men and women were really enthusiastic about being screened. It has also given staff wide opportunities to discuss matters of sexual health and STI awareness within consultations. Brook is an ideal location for testing as we receive approximately 10,000 visits a year from young people and clients have clearly welcomed the opportunity to access advice about both contraception and infection testing in one setting.

The Pilot has also raised our profile in the community and the potential for extending our range of services to include those not traditionally within the Brook forte.

However whilst the benefits of screening are obvious, various other issues arose during the Pilot:

- Young people can feel judged and over-scrutinised with regard to their sexual history. Some resent being asked what they perceive as invasive questions.
- If the test is positive, young people can feel ‘contaminated’. What impact will this have on their confidence and self-esteem?
- A positive test raises issues for clients about infidelity in a relationship, even if the infection could relate to a previous relationship. Counselling is important.
- A client leaving with a positive test result may be returning home to a potentially violent relationship, made worse by the result. Some clients have reacted badly to a positive result for fear of their partner’s reaction. How can we offer further support?
- Young women are often labelled if they test positive. It has been so important for the centre to be able to extend the screening service to young men.
- Brook worked in partnership with other agencies during the Pilot. This inevitably raised issues of confidentiality and the sharing of information. Whilst we were prepared to talk with the Pilot team about a client, we felt that it was inappropriate to extend this dialogue to other services taking part in the Pilot.
- Many clients who did not consent to being contacted at home had positive results, which they failed to collect. There was no choice but to wait until they did come back to the clinic for other reasons.

7. Management of screened positive people – Chlamydia Pilot (Wirral)

The management of all individuals who had a positive chlamydia urine test was co-ordinated from a central point. The majority of patients tested in the Department of Genito-urinary medicine were treated there, whilst the majority of patients tested outside of this department were managed by the Chlamydia Pilot Office by a community health adviser in accordance with Patient Group Directions.
We felt that the benefits of community health advisers included:

- A central office design able to 'take the strain' from other services
- A consistent approach to management of the infection with reduced burden on other health professionals.
- A choice of service to suit all client needs
- Less ‘institutional’ service for young client
- Close liaison with other agencies
- A flexible and ‘mobile’ service offering evening cover, home visits or meeting at convenient, local venues

There was a wide range of health professionals, expertise and facilities involved in the Chlamydia Pilot with the potential to lead to disparate management. This was overcome in the pilot by having central administration of results with community health advisers to manage people with infection.
8. Numbers of positive tests

Age group 16 – 24 (incl) for those testing positive with urine test (LCR) from September 1999 - October 2000. 6668 urine samples were collected between these dates, 557 of which were positive (overall positivity rate – 11.7%).

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<th>%age positive</th>
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9. Department of genitourinary medicine at Arrowepark Hospital

Assuming a maximum positivity of 10%, 1500 screened positive women with their partners could need to be managed during the pilot. This figure was used from the outset to plan resources for the department of GUM. A research registrar was appointed both to assist with the data element of the pilot and to help with the added clinical work. There was a designated “chlamydia nurse” at every clinic session to ensure smooth running of the pilot in GUM and an extra part time clerk was employed. Urine LCR tests were available for those attending GUM as a chlamydia screening site. For those with symptoms, current practice was continued using a swab for ELISA testing with confirmation of reactive by DNA amplification techniques on the same sample but during the pilot, these clients were additionally offered urine LCR in order to enhance the diagnosis. It appears that EIA testing misses a considerable number of cases, though more detail shows this to be more conclusive in males than in females.
Preliminary figures show that on Wirral two thirds of clients tested in the community chose to have treatment there, but despite this, attendance in GUM has risen by 15% in the first 6 months of screening. During the first 6 months, 108 female and 65 male chlamydia cases were dealt with in GUM, compared with 50 female and 36 males in the previous year.

Gonorrhoea:
Only one woman testing positive for chlamydia in GUM, attending because of a discharge, was found to have gonorrhoea and no gonorrhoea was found in chlamydia positive clients referred to GUM from the community. Those treated by the community health advisors were offered a gonorrhoea test on their stored, frozen urine sample and a separate form sent to the laboratory confirmed this request. Two asymptomatic women tested positive. Other non-sexually transmitted infections showed similar prevalence to those expected in the population.

### Concurrent genital infections - % of women
10. Conclusion

Our observations, from Wirral are that a central office for treatment, advice and possibly direction to a venue for treatment appears essential if we are not to return to disparate management by different health professionals in different services. This has the added benefit of removing concerns raised about a screening programme if time is required in each service for tracing, treating, counselling and partner notification. Optimal management of those testing positive takes into account many factors including evidence, cost effectiveness, acceptability to clients, availability and accessibility of expertise and services. The necessity of seeking for other less common or less serious infections in asymptomatic people could be deliberated. Where there is a low prevalence of gonorrhoea in a community, it seems to us that the invasive nature and cost of tests and possible stigmatisation by seeking other infections could be balanced against any personal and community benefits from this strategy. However, it may be that it is the practicalities of space, IT links geography and transport in addition to local prevalence of other infections, which will determine policy in each area. Even where an outreach service is provided, as on the Wirral, GUM attendance is likely to increase with screening. GUM expertise is essential and community health advisers enable this to be extended effectively rather than be replaced.

11. References

1 Hopwood J, Gleave T, Mallinson H. What is needed on a laboratory test request form? Communicable Disease and Public Health 2002; 5: 38-42