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Chlamydia Screening in Ireland: a pilot study of opportunistic screening for genital Chlamydia trachomatis infection in Ireland (2007-2009). Screening Intervention Report

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03

CHLAMYDIA SCREENING IN IRELAND

A pilot study of opportunistic screening for genital *Chlamydia trachomatis* infection in Ireland (2007–2009)

SCREENING INTERVENTION REPORT

REPORT PREPARED BY CHLAMYDIA SCREENING STEERING GROUP

RCSI
NUI Galway
OÉ Gaillimh
Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive
hpsc
HRB
Health Research Board

Screening Intervention Report and Website

This Screening Intervention report outlines the piloting of screening models and test positive follow-up models as part of the Chlamydia Screening in Ireland Pilot Study conducted between 2008 and 2009. Further information including more detail on the methods and results can be found in the following accompanying reports on the Health Protection Surveillance Centre (HPSC) website.[1]

Chlamydia Screening in Ireland Pilot Study. Summary Integrated Report

Chlamydia Screening in Ireland Pilot Study. Background Studies: Acceptability and Feasibility of Screening

Chlamydia Screening in Ireland Pilot Study. Economic Evaluation

Other resources on the website include additional information on the implementation of screening, a toolkit for organising screening in non-clinical settings and links to published articles from the study.

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[1] http://www.hpsc.ie/hpsc/A-Z/HepatitisHIVAIDSandSTIs/SexuallyTransmittedInfections/Chlamydia/Publications/

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Abbreviations and acronyms used in this report

BASHH	British Association for Sexual Health and HIV
ClaSS	Chlamydia Screening Studies Project
CT	*Chlamydia trachomatis*
ESR	Effective Screening Rate
FPC	Family Planning Clinic
GP	General Practice/General Practitioner
GUM	Genitourinary medicine
HEI	Higher Education Institution
HPSC	Health Protection Surveillance Centre
HRB	Health Research Board
HSE	Health Service Executive
ISSHR	Irish Study of Sexual Health and Relationships
MSM	Men who have sex with men
NUI Galway	National University of Ireland Galway
NCSP	National Chlamydia Screening Programme
PID	Pelvic Inflammatory Disease
PIP	'Pee-in-a-pot'
RCSI	Royal College of Surgeons in Ireland
RCT	Randomised Control Trial
RHA	Research Health Adviser
SHU	Student Health Unit
STI	Sexually Transmitted Infection
SOP	Standard Operating Procedure

1. Introduction

This report summarises the findings of the Pilot Screening Intervention conducted in Ireland between 2008 and 2009 as part of the Chlamydia Screening in Ireland Pilot study. The studies aimed to pilot screening models and to evaluate their feasibility and effectiveness.

The study was commissioned by the Health Protection Surveillance Centre (HPSC) and overseen by the Health Research Board (HRB). It was carried out by a team from the Division of Population Health Sciences at the Royal College of Surgeons (RSCI) in Ireland, the College of Medicine, Nursing and Health Sciences at the National University of Ireland Galway, and Consultants in Public Health Medicine from the Health Service Executive (HSE).[2] *Ethical approval* for study components was provided by Research Ethics Committees of the RCSI, NUI Galway and the Irish College of General Practitioners (ICGP).

[2] See *Background Studies: Acceptability and Feasibility of Screening* for Background to the study. All the reports and related publications and other resources can be found at:

http://www.hpsc.ie/hpsc/A-Z/HepatitisHIVAIDSandSTIs/SexuallyTransmittedInfections/Chlamydia/Publications/

2. Screening Study Methods

2.1 Screening studies in clinical settings

2.1.1 Study area and population

For the purpose of the study, primary care settings were categorised as urban and rural based on their location in relation to the local city boundaries. Urban based general practices were located within the Galway city borough (i.e. high population density area) and rural based practices were categorised were located outside the city boundary.



Figure 1. Geographical area (Galway city and county) of pilot screening

In 2007, the total population of young people aged 18-29 in Galway city and county was 41,999, with similar numbers of males (21,259) and females (20,740) [1]. The demographic profile in figure 2 shows the population of young people aged 18-29 in the city and surrounding county where screening project was implemented. High proportions of the city population were in the screening age range.

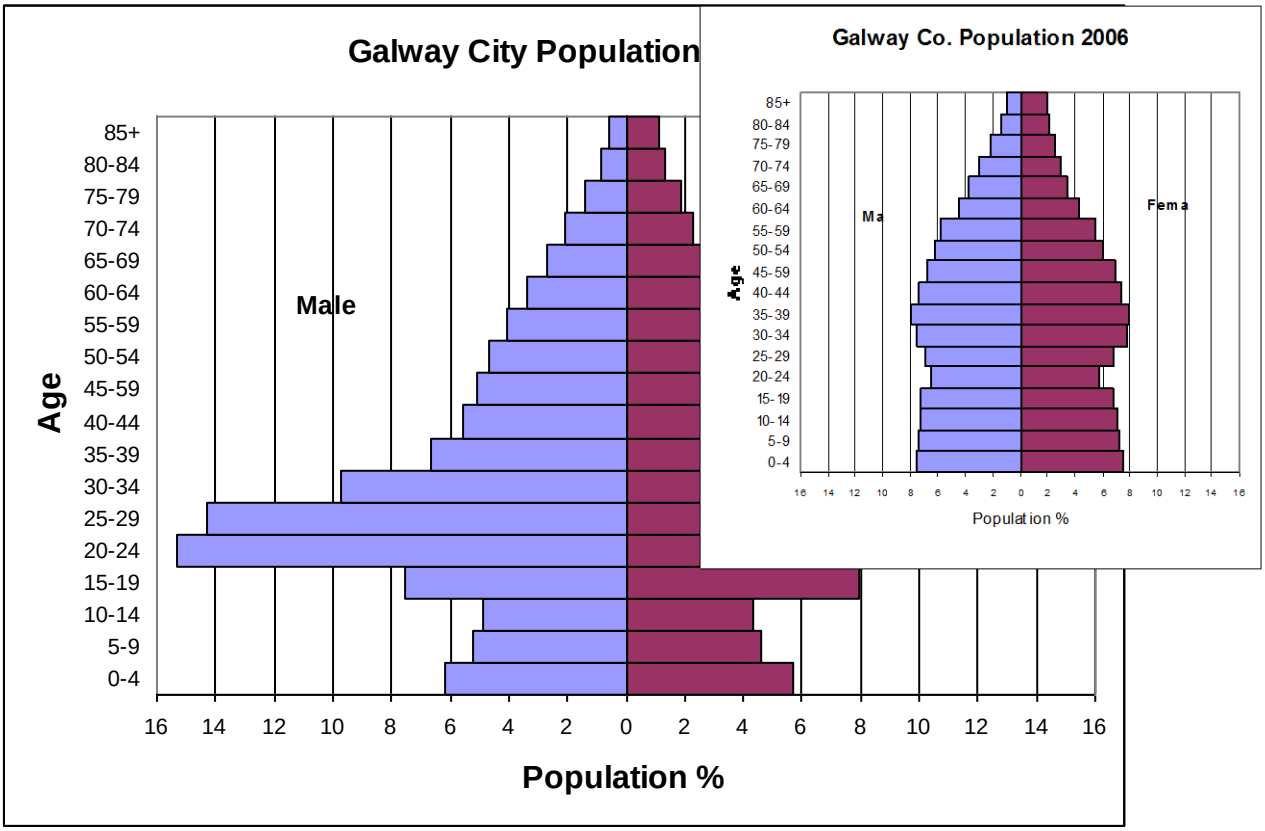


Figure 2. Population of Galway County by age

2.1.2 Recruitment of service providers

A full-time Research Health Adviser (RHA), who was an experienced health adviser with a master's qualification that included training in research methods, was appointed to oversee the implementation of the screening pilot intervention. Following pre-pilot interviews with local service providers on screening design[3] screening activities commenced with the recruitment of general practices. Of thirteen training practices approached initially, seven agreed to participate in the study. Two student health units (SHU), one family planning clinic (FPC) also agreed to participate in pilot screening.

Several months of screening delivered a much lower rate of tests (screened patients) per general practice than had been anticipated. The RHA discussed this with practice staff that raised issues such as lack of time and not remembering to make the screening offer. This led to adaptations in the process such as reminder prompts (computer stickers for providers to remind to offer screening) and adaptations to forms (to reduce the form filling).

With offer rates still low, additional providers were recruited. Letters of introduction (134) were then sent all other GPs and registered GP practice nurses in Galway city and county, followed by a call made by the RHA to discuss potential participation.

[3]See http://www.hpsc.ie/hpsc/A-Z/HepatitisHIVAIDSandSTIs/SexuallyTransmittedInfections/Chlamydia/Publications/

The study was also advertised in local Continuing Medical Education meetings for GPs, an Irish College of General Practitioners conference, and a regional practice nurse meeting.

A further 22 general practices were recruited, leading to a total of twenty nine general practices participating in the study. However, 6 of these practices did not screen any participants and withdrew from the study; leaving a total of 23 general practices in the study.

2.1.3 Opportunistic testing model

The opportunistic testing model required providers to offer chlamydia screening to young people aged 18-29 years attending the clinical setting. Screening was to be offered by either a practice nurse or general practitioner (GP) at the end of a consultation with an eligible patient regardless of the purpose of the visit.

Specimens were urines or cervical swabs where a smear test was being taken. Urine samples were to be taken following a two hour void interval. Use of self-taken vulva-vaginal swabs was explored but not used in the pilot due to concerns over the detection method: at the time it was not validated for vaginal swabs.

A study implementation pack for the Pilot Screening Intervention was designed and distributed to the participating practices/settings. This contained standard operating procedures (SOP) which included algorithms and guidance notes, a supply of microbiology request forms, patient information leaflets, and care management pathways (flow charts).

The contents of the pack drew on or took into account lessons learned from an earlier screening project in an Irish Higher Education Institute (HEI) setting [2], the English National Chlamydia Screening Programme [3] and the British Association for Sexual Health and HIV (BASHH) screening guidelines[4]. Providers had been given the opportunity to review and comment on drafts of materials during the pre-screening interviews, and were consulted regularly throughout the design phase.

Patient leaflets were developed entitled *Free Chlamydia Testing* (Appendix A) and *Receiving Your Result* (Appendix B), which outlined key messages on chlamydia testing. Positive images of young people were used and additional information on locally based sexually transmitted infection (STI) testing services and sexual health support networks were provided on the back of the leaflets.

Several sets of core data were required for recording and test reporting. A coded, anonymous chlamydia request form was developed (Appendix C) that recorded details including date of birth, sex, specimen taker, reason for test (screen or contact of screen positive), specimen type and mobile phone number. Each screening site was allocated a unique combined site/patient code that was pre-printed on the chlamydia request form, the self-administered anonymous questionnaire (see below) and microbiology forms. Participants who accepted the offer of screening were allocated this unique code as no commonly used unique identifier exists within the Irish health services.

Demographic and risk factor data were collected from participants through a short self-administered anonymous questionnaire (Appendix D) in order to evaluate the utility of a risk factor pre-screening approach. Envelopes were provided to ensure confidentiality.

The screening model entailed service providers (GPs and practice nurses) opportunistically offering a test during, or at the end of a general consultation with a patient. Those eligible to participate were given an information leaflet to read and the chance to ask any questions before accepting or declining an offer. If participants agreed to take part in the study, a urine sample was provided by the participant or a cervical swab was taken if a smear test was being done. Consent was implied by reading the leaflet and agreeing to supply a sample.

Providers recorded relevant details and filled out the chlamydia request form, retaining a copy for their records, and filing a copy for the RHA. Specimens were refrigerated immediately and sent to the Microbiology Department at the Galway University Hospital within twenty four hours.

Patients in whom chlamydia was not detected were contacted by their chosen method of communication (SMS text, phone call or letter) and given their result. Participants with a positive result were contacted also by their chosen method by a practice nurse or GP from the relevant screening site, and were invited to return to be given the result and offered treatment and follow-up by the RHA.

2.1.4 Introduction of screening

Screening commenced in July 2008 in the seven initial settings, and subsequently in all twenty nine sites that agreed to participate. The RHA made an introductory visit to each screening site, delivering supplies, introducing the screening to providers, and answering queries.

Each screening site received a screening box with laboratory and treatment supplies, an implementation pack, advertising posters and patient information leaflets, as well as clinical materials. Posters and leaflets were provided to advertise the study in the waiting rooms of health care settings

In the context of this pilot screening study, the providers' participation was optional and largely unremunerated. Each provider received €25 for a positive case detected to cover the treatment consultation, which was free to patients / study cases.

As a support to participating practices and an incentive to participate, all practices were offered the opportunity for a staff member to participate on the Sexually Transmitted Infection Foundation (STIF) course accredited by the British Association for Sexual Health and HIV (BASHH). Participation was not linked to performance targets. Five GPs, seven practice nurses, and one GP trainee completed the STIF course.

The RHA visited sites and communicated regularly with staff during the screening period and was available to provide support and information by mobile phone. Some sites were visited more frequently than others, depending on screening activity. Visits were made to collect research data and to discuss screening with providers.

Initial queries from providers were mainly about operational issues such as form filling and use of codes. As the pilot progressed visits were made only when requested however phone calls to sites were made regularly. Throughout the study letters were sent to providers concerning modifications made to protocols based on feedback received from sites.

Urine specimens were obtained from all participating men and most women, unless a cervical swab was appropriate. These specimens were transported to and processed at a regional university hospital microbiology laboratory.

Results were communicated to the clinician in the clinical settings where the screening had been taken, who took responsibility for case management as is routine practice. Participants were informed of their results by the clinic staff, using the patient's preferred communication method such as text message or phone call.

2.1.5 Management (treatment) of positives cases

The management of participants who tested positive was coordinated by each screening site, following the Standard Operating Procedures (SOP) manual and treatment protocols (Appendix E).

Patients were given the appropriate antibiotic (usually Azithromycin), free of charge and on site, along with the information leaflet *Receiving Your Results* (Appendix B). This provided a detailed explanation of chlamydia infection with particular emphasis on the long term implications for their partners(s). All positive cases were given the option by the providers to speak to the RHA for further counselling and information.

2.1.6 Further STI screening

Further STI testing of all positive cases was recommended, in compliance with standard international practice. A copy of the BASHH Guidelines [4] was distributed to clinical staff at all screening sites for reference and information.

Screening sites also had the options of referring patients to the regional genitourinary medicine (GUM) clinic or to offer further STI testing on site. Providers were requested to provide a referral letter if a patient was referred to the GUM clinic. The referral process to the GUM clinic was two fold: (i) at the treatment consultation, providers discussed with the positive case the need for further STI testing; and (ii) the RHA also followed up and provided support and advice on further STI testing with positive cases. In some cases, appointments for further STI testing at the GUM clinic were made by the research health adviser.

2.1.7 Retesting of positive cases

The US Centre for Disease Control and Prevention [5] recommends rescreening of positive cases at three months. Studies in the US have reported a high prevalence of chlamydia infection in women who were treated for chlamydia in the preceding months. The majority of infections that are detected within three months of treatment are due to re-infection, frequently occurring because the patient's sex partners were not treated, or because the patient has sex with a new partner infected with chlamydia [5].

As there are no Irish data on intervals for screening, participants were offered repeat testing between three months and six months after treatment. This was not a test of cure, but a test to detect re-infection. Participants were given the option to attend for retesting either at their GP or the local GUM clinic.

2.1.8 Partner notification

Partner notification is a key element in the identification, management and control of STIs [6]s. In this process people who are known to have been exposed to a STI are notified and invited to attend STI testing services.

The BASSH guideline for the management of *Chlamydia trachomatis* (CT) genital tract infection [7] was followed for the pilot study. This recommends that, where the index case is asymptomatic, all sexual partners over the previous six months should be contacted. This time period may be extended depending on a participant's sexual history (last previous sexual partner).

Two methods of partner notification were used for the pilot study, patient referral and provider referral, depending on the preference of the patient. Both partner notification systems involved discussions to identify partners at risk and partner follow up.

Patient referral

Patient referral is the method where positive patients are offered the choice of notifying their current and previous partner(s) themselves. Index cases were offered community contact cards (see below) by the providers to give to their previous/current partner(s).

Community contact cards

Community contact cards were designed specifically for the study (Appendix F) and were based on the system used by GUM clinics in Ireland and internationally. The purpose of the community contact card is to give the contact sufficient information to find a service and book an appointment to get tested and treated for chlamydia. It also aims to enable the issuing screening site of the contact to track attendance.

Chlamydia was named on the contact card as a British research study had found that more contacts attended when the infection (chlamydia) was named on the contact slip [8]. Providers were instructed to write the site code/patient ID of the index case on the contact card to link contact cards with index cases and assist in tracking the process.

Provider referral

Provider referral is an alternative approach to partner notification, which is conducted in GUM clinics. It is the process where a health care professional (rather than the patient) informs a contact about their possible exposure to infection while not revealing the identity of the index patient. The partners are then advised they may have been exposed to chlamydia and should attend either a GP or GUM clinic for testing and treatment. The usual process for this is a telephone call.

In this study the community-based RHA was available to conduct partner notification by phone. Providers who did not wish to carry out partner notification referred positive cases to the RHA, passing the mobile phone and other relevant information (i.e. time to call) of the index case to her.

The RHA phoned the index case to discuss the recent diagnosis, partner notification options and preferences, follow-up visit (usually to the GUM clinic) for further STI tests, the need for a later retest, and other relevant sexual health education. A phone-call protocol was devised which allowed the RHA to systematically follow up each patient (Appendix G). Forms for assessing partner risk and partner notification

outcomes were designed (Appendix H). Completed forms and all patient records were stored securely in the RHA's office.

The following information was recorded:

- All actions, including successful and unsuccessful attempts to contact the person by telephone or other method
- The outcome of actions, including whether contact was made, what information was given and the patient's response.
- Discussions on case management and partner notification with member(s) of the multi-disciplinary team.

In addition, the RHA was available to conduct on site training for practice staff where requested and was available to provide support to primary care staff during the study. Two providers (both practice nurses) undertook onsite training for doing partner notification.

Standards and protocols on the following areas were included in the Standard Operating Procedures (SOP) manual to assist providers during the study:

- management of sexual partners
- standards for good practice in partner notification
- standard questions to assess partner risk

2.2 Year 2 β HH-in-a-pRWT creening studies in non-clinical settings

Several non-clinical settings were explored as possible settings for outreach or community based screening, such as an army base, a prison, a hostel for asylum seekers, and an adolescent youth service. It was not feasible to proceed with screening in these sites for logistic reasons, and because of age issues in the youth service. Screening in non-clinical settings in higher education institutions (HEIs), i.e. through offering a 'pee-in-a-pot' (PIP) service during a suitable event, was explored and developed.

Guided by the findings of the focus groups (See Background Studies*: Acceptability and Feasibility of Screening*), and consultation with the Student Health Units in two HEIs, a one week screening program, called a *'pee-in-a-pot'* event, was designed and planned. Each event was held during the annual sexual health awareness week which is a student organised event designed to promote positive sexual health in each of the HEIs.

Planning and preparation

Posters and information leaflets were used to help attract attention to the pilot and were distributed around each campus. Media releases, radio broadcasts, email alerts and newspaper articles were used to publicise the event. A poster competition was held inviting students to design a poster, image and slogan for the event (the winning poster is in Appendix I). This was used throughout the event on all materials including volunteer t-shirts.

Testing packs

Testing packs (comprising small specimen bags containing a 10ml urine container, a pen and an information card) were designed for the study (Appendix J). Testing was

anonymous and each pack was identified through a unique code. Participants who chose to take a test were instructed to read the information leaflet, write their mobile number and date of birth on the urine container, urinate in the specimen container and keep the information card.

Consent for testing was implied through the completion of details on the sample container. Specimen collection boxes were located inside toilet areas where participants were instructed to leave their samples in a sealed specimen bag. Testing packs were made available for three to four hours each day for 7 days in total between both sites. Project researchers collected the specimen bags and transported them to the laboratory services each day.

Peer volunteers

Student (peer) volunteers were recruited to distribute testing packs and information leaflets to potential participants on the two student campuses during the sexual health awareness and guidance (SHAG) week. Thirty five volunteers were recruited who were given training on chlamydia and the background to the research project. Volunteers were given a €25 voucher for their participation (approximately four hours each). Volunteers were dressed informally and were easily identified through cartoon t-shirts with '*Pee-in-a-pot Volunteer'* printed on the back (Appendix K).

Screening approach

The approach used was adapted during the week to maximise privacy for participants. While testing packs were initially distributed in communal areas, as the event progressed male and female toilet areas became the focal point for distribution. Packs were left around sinks, mirrors and inside toilet cubicles, which led to more participants self-selecting for screening.

The most common approach was for students to pick up a pack themselves in the toilet cubicle. Male volunteers were allocated to male bathrooms and other male oriented entertainment venues, such as pool and snooker rooms while female volunteers were allocated to female toilets and other communal areas.

Results notification

Positive results in non-clinical 'pee-in-a-pot' settings were communicated to the Student Health Unit doctors who contacted these persons directly by phone to organise treatment. Those who tested negative received a standard text message from the Research Health Adviser (RHA).

2.3 Interviews with screened participants

Thirteen in-depth interviews were conducted with young adults who had undertaken screening (Appendix L: topic guide). These consisted of seven interviews with 'pee-in-a-pot' participants and six interviews with clinical setting attendees (GP, SHU and FPC). Respondents were recruited either by the RHA during a telephone liaison call or by the individual responding to student intranet advertisements for interview participants. Non-directive semi-structured interviews were conducted to allow respondents to shape their own accounts. Interviews were tape-recorded (with respondents' permission) and fully transcribed. The resulting data was coded and thematically analyzed by a public health specialist using NVivo revision 1.3 (qualitative data analysis software).

2.4 Post pilot interviews with health care providers

At the end of the pilot study, health care providers who took part in the pilot study were invited to participate in a semi-structured interview. The purpose was to discuss providers' experiences of the screening processes and explore their views and recommendations on the feasibility of rolling out a chlamydia screening programme in primary care settings.

Three members of the research team who were healthcare professionals and experienced researchers conducted semi-structured individual face to face interviews. A topic guide was used based on the literature (Appendix L). Interviews were conducted at a time convenient to participants and all took place in participants' place of work. Interview questions were divided into sub-sections which included their experience of: offering the test, sampling, giving results, partner notification and perspectives on feasibility. In addition, overall attitudes to the process and recommendations for future programmes were also discussed.

Interviews lasted from thirty to forty minutes and were digitally recorded and transcribed verbatim. Transcription was conducted by a professional transcriptionist who signed a confidentiality agreement. Transcripts were verified for accuracy by replaying tape recordings while reading transcripts.

Participants were selected based on their screening activity during the pilot and also their geographical location. Twenty-one providers were approached with phone calls inviting them to take part in an interview. While no providers refused, four providers did not return phone calls. One provider was on maternity leave.

Sixteen health care providers from general practices, family planning clinics and student health units were interviewed. One declined to have her voice recorded but still participated. Data saturation was judged to have occurred at sixteen interviews.

Interviewees were directly involved in the screening pilot.

We sought to achieve diversity in participants based on a number of factors: these included setting (family planning, student health, and general practice settings), urban or rural based services, and professional grouping (doctor or nurses). Nine general practitioners and seven practice nurses were interviewed, all of whom were female. While we were keen to capture a diverse gender perspective in this work our attempts to get male health care providers to participate in an interview were unsuccessful. We actively sought to capture the experiences and attitudes of health care professionals who had high, as well as low rates of testing during the chlamydia screening pilot. In addition, we were keen to capture the views of health care providers who were enthusiastic and also those who were less than enthusiastic about the screening process.

Data analysis

Two researchers from the research team were involved in reviewing transcripts and data analysis to ensure reliability. Thematic analysis was used to generate categories and themes related to the aims of the research. The researchers worked independently initially identified emerging themes and then together to decide on categories and finalise main themes.

2.5 Laboratory methods

Qualitative interviews were conducted with staff from the Microbiology Department of Galway University Hospital where the *Chlamydia trachomatis* testing was conducted, after the screening pilot. Interviews were coded and thematically analyzed.

Specimen management

Specimens were frozen for batch testing. The design and costs of the testing process meant that it was necessary to accumulate a sufficient number of specimens to form a batch for testing, particularly in the early stage of the pilot when recruitment was slow.

Specimens were tested with Polymerase Chain Reaction (PCR) testing technology. The test used was the *COBAS® TaqMan® CT Test v2.0* manufactured by Roche Diagnostics, Switzerland.

Management of test result

Electronic and paper copies of test results were sent by the Microbiology Department to the screening sites. A copy of test results was also sent to a medical doctor in the research team to allow for patient follow-up by the RHA.

3. Results

3.1 Overview of Screening Results

The screening intervention commenced in September 2008 and was completed in April 2009. Screening was conducted in three different types of clinical settings (GP, SHU (Student Health Units) and FPC (Family Planning Clinics), and in one type of non-clinical setting (two HEIs) where two one week 'pee in a pot' (PIP) screening interventions took place.

Participation rates

During the pilot 1112 participants were screened: of these 114 (10%) were excluded from analysis:

- 83 were outside the eligible age range (15 were aged less than 18 years, 58 were aged 30 years or older) and eight had no age given
- 23 were excluded because of mislabelling or inadequate identifiers on the specimen container.

Offer rates

Accurate information on offer rates is not available as the total number of people offered screening was not recorded by any provider due to time constraints. Clinical settings reported that up to 30% of eligible people attending clinical settings were offered a screening test for chlamydia.

However, on detailed examination of records from four general practice settings where computerised patient databases were in place, the offer rates ranged from 0.9 - 3% for male attendees and from 2 - 9% for female attendees (refusal rates were utilised). For the two SHUs, the offer rates ranged from 0.08 - 1.3% for male attendees and from 0.3 - 2.8% for female attendees. The FPC did not have the information system required to facilitate do this assessment.

Refusals

Providers in the clinical settings were requested to record refusals to participate. The total number of participants offered screening was not recorded by most providers due to time pressures. Nineteen providers recorded 94 refusals (65 female and 29 males) giving a minimum refusal rate of 7.8%. Interviews with providers estimated that less than 10% of those offered a screen in general practices declined, 33% in SHU, and 20% in FPC.

3.1.1 Study population screened

The study population consisted of 998 eligible persons: 460 in clinical settings (286 GP, 100 SHU and 74 FPC) and 538 (54% of those screened) in non-clinical PIP settings. Of those screened in clinical settings, 29% took place in general practices.

Table 1. Numbers of screened people by settings (percentages out of total n=998)

Setting	GP n(%)	SHU n(%)	FPC n(%)	PIP n(%)	Total n(%)
Total	286 (28.7)	100 (10)	74 (7.4)	538 (53.9)	998 (100)

Tables 1 and 2 summarise the demographic characteristics of population screened. Of the 998 participants, 726 (73%) were women, 248 (25%) were men. Sex was not recorded on 23 (2.3%) persons screened.

Table 2. Description of eligible people screened during the pilot

(percentages out of total n=998)

Age	Female n(%)	Male n(%)	Sex not specified n(%)	Total n(%)
18-19	137 (13.7)	63 (6.3)	2 (0.2)	202 (20.2)
20-24	398 (39.9)	139 (13.9)	12 (.2)	549 (55)
25-29	192 (19.2)	46 (4.6)	9 (0.9)	247 (24.7)
Total	727 (72.8)	248 (24.8)	23 (2.3)	998 (100)

The mean age of participants was 22.3 years (median: 21). In females the mean age was 22.4 years (median: 22, and among males the mean age was 21.6 years (median: 21). Table 3 describes the ages of participants in the different settings.

Table 3. Mean and median ages (years) by settings

Setting (range 18-29)	GP	SHU	FPC	PIP
Mean age	24.3	21.3	24.4	21
Median age	24.5	21	25	21

3.1.2 Screening Processes

Table 4 summarises the types and distribution of specimens by sex taken in each setting: 878 (91%) were urines and 97 (9.7%) were cervical swabs.

Table 4. Specimen type taken by settings (percentages out of total n=998)

	Urine			Cervical	
Setting	Female n(%)	Male n(%)	Sex not specified n(%)	Female only n(%)	Totals N(%)
GP	164 (16.4)	35 (3.5)	10 (1.0)	77 (7.7)	286 (28.6)
SHU	79 (7.9)	18 (1.8)	1 (0.1)	2 (0.2)	100 (10.0)
FPC	51 (5.1)	4 (0.4)	1 (0.1)	18 (1.8)	74 (7.4)
Total (clinical settings)	294 (29.5)	57 (5.7)	12 (1.2)	97 (9.7)	460 (46.1)
PIP	336 (33.6)	191 (19.1)	11 (1.1)	0	538 (53.9)
Total	630 (63)	248 (24.8)	23 (2.3)	97 (9.7)	998 (100)*

*Percentages may not add up to 100% due to rounding

Table 5 describes the ages of those who had cervical swabs taken in clinical settings. Among the 97 cervical swabs processed, 29 (29.9%) were taken from participants who were outside the 25-60 years recommended age interval for cervical smears. The majority of these were done in general practice.

Table 5. Cervical swabs by age group and clinical setting

Age group	GP n(%)	SHU n(%)	FPC n(%)	Total n(%)
18-19	1 (1.0)	0	1 (1.0)	2 (1.0)
20-24	26 (26.8)	1 (1.0)	0	27 (27.8)
25-29	50 (51.5)	1 (1.0)	17 (17.5)	68 (70.1)
Total	77 (79.3)	2 (2.0)	18 (18.5)	97 (100)

Table 6 shows that doctors and practice nurses took equivalent numbers of cervical swabs. In general practice settings, doctors took the majority of specimens. In student health units (SHUs) and in the family planning clinic practice nurses took over 90% of the specimens: in these settings, the majority of patients were triaged by the nurses

and where necessary referred to the doctor. Patients could also make appointments directly with the doctor if they wished.

Table 6. Specimen taker by clinical settings (percentages 100% in each column)

Specimen taker	GP (n%)		FPC (n%)		SHU (n%)		Total
	Urine	**Cervical**	**Urine**	**Cervical**	**Urine**	**Cervical**	
Doctor	159 (76.0)	44 (57.1)	3 (5.3)	3 (16.6)	1 (1.0)	0	210 (45.6)
Nurse	40 (19.1)	32 (41.5)	52 (92.8)	15 (83.3	97 (98.9)	2 (100)	238 (51.7
Missing (taker)	10 (4.7)	1 (1.2)	1 (1.7)	0	0	0	12 (2.6)
Total	209 (100)	77 (100)	56 (100)	18 (100)	98 (100)	2 (100)	460 (100)

The median time for both the doctor and nurse to obtain a urine test was 5 minutes. The median time to take a cervical swab was 5 minutes for a practice nurse and 7 minutes for a doctor. Table 7 demonstrates there were similarities in the time required for completing a test between the settings.

Table 7. Time to take test in clinical settings (in minutes)

Setting	Time to take test (in minutes)
GP	(n=252, 34 missing)
Range	2-20
Mean	6.8
Median	5
SHU	(n=77, 23 missing)
Range	4-15
Mean	7.2
Median	5
FPC	(n=60, 14 missing)
Range	4-15
Mean	5.6
Median	5
Total settings	(n=389, 61 missing)
Range	2-20
Mean	6.7
Median	5

Interval from test date to result date *(in weeks)*

The mean interval from testing to reporting of results was 4.97 weeks (median =5). For a small proportion of tests (7.4%), the interval was longer than 8 weeks. Urine samples were the main specimen type requested during the pilot study. However, the routine tests for chlamydia in the laboratory used in the pilot study are vaginal, cervical and urethral swabs. Routine clinical specimens are reported within a week of submission in almost all cases.

Efficient processing of urine samples within the financial constraints of the study meant that it was necessary to accumulate a sufficient number of urine specimens to form a large enough batch for testing. The issues in relation to the turnaround time and specimen type for this project are entirely related to the practical difficulties of accommodating the extra work of a once–off research project at the lowest practical cost within a laboratory that was not specifically set up for the purpose and which did not have any spare capacity. This is not likely to be an issue in the context of an ongoing screening programme with a structured and resourced laboratory service component.

3.1.3 Screening in clinical settings

Overall, 286 persons (240 females, 35 males and 11 sex not specified) were screened in general practices. One hundred persons (81 females, 18 males and 1 sex not specified) were screened in two SHUs, and 74 (70 female and 4 males) were screened in the FPC.

General practices

Out of the original 29 general practices recruited, 23 provided specimens for testing. The results from these 23 general practices were included in the analysis. The mean number of specimens (urine and cervical swab) per general practice was 12.4 (range: 1-61) median=6. Table 8 summarises the profile of participating general practices.

Table 8. Profile of general practices in screening programme

*Type of practice	n=23
Group practices (>1 GP)	18
Single-handed general practices	5
Training general practices	6
General practices with practice nurse (s)	16
Rural based general practices	10
Urban based general practices	13

*These are non-exclusive categories

The mean number of cases screened was higher in urban practices (15.8 vs. 6.2); group practices (14.7 vs. 4.4) and in training practices (17.8 vs. 10.5). Practices with or without a practice nurse screened the same mean number of participants (12.4). Four practices screened more than 20 people: these were urban group practices with a female clinician who was providing sexual and reproductive health services. Table 9 summarises screening by different participating practices.

Table 9. Specimen type by practice type (percentages by row)

Practice type*		Cervical n(%)	Urine n(%)	Total specimens n(%)
Group practice	Yes	76 (28.7)	188 (71.2)	264 (100)
	No	1 (4.5)	21 (95.4)	22 (100)
Training practice	Yes	23 (21.4)	84 (78.5)	107 (100)
	No	54 (30.1)	125 (69.8)	179 (100)
Practice nurse	Yes	49 (24.6)	150 (75.3)	199 (100)
	No	28 (32.1)	59 (67.8)	87 (100)
Urban general practice		64 (31.2)	141 (68.7)	205 (100)
Rural general practice		13 (16)	68 (84)	81 (100)

*These are not exclusive categories

Between two thirds and three quarters of tests were urine tests, across all types of practices.

3.2 Risk factors of population screened in clinical settings

Risk factor data were collected only from those screened in clinical settings, i.e. not at the 'pee-in-a-pot' events, where students were not requested to complete this form.

Table 10. Risk factors of study population in clinical settings and the Relative Risk for each risk factor, male versus female. (Percentages by column based on total respondents to each question)*

Risk factor	Female n(%)	Male n(%)	Relative Risk for each risk factor (male vs. female) (95% CI)
Number of sex partners			
1	57 (16.5)	3 (6)	1
2-4	120 (34.8)	12 (24)	1.18 (0.90, 1.55)
5-14	142 (41.2)	20 (40)	2.47 (0.76, 8.01)
>14	25 (7.2)	15 (30)	4.13 (2.34, 7.28)
New partner in past 3 months			
Yes	134 (38.1)	31 (60.7)	1.59 (1.23, 2.06)
No	217 (61.8)	20 (39.2)	
Two or more partners in past year			
Yes	126 (35.6)	29 (56.8)	2.37 (1.26, 4.49)
No	227 (64.3)	22 (43.1)	
Unusual discharge			
Yes	49 (13.8)	4 (7.8)	0.57 (0.21, 1.51)
No	306 (86.1)	47 (92.1)	
Pain on passing urine			
Yes	38 (10.7)	13 (25.4)	2.37 (1.36, 4.13)
No	315 (89.2)	38 (74.5)	

*The sum of the categories for each determinant varies slightly because of missing data.

The mean number of life time sex partners was 6.7 (range: 0-60, median = 5). In this population 38.1% of women and 60.7% of men reported having a new sex partner in the three months before the test, and 35.6% of women and 56.8% of men reported having more than 2 sexual partners in the previous year. Males were significantly more likely than females to have had high numbers of sex partners, a new partner in the last 3 months and more that two partners in the last year. In the screened population 13.8% of women and 7.8% of men reported an unusual discharge. Males were significantly more likely to have dysuria (pain on passing urine) (10.7% of women and 25.4% of men).

3.3 Screening in non-clinical settings

During the 6.5 'pee-in-a-pot' (PIP) days 592 urine tests were collected (mean 91 per day). Of these 54 (9%) were excluded from analysis because:

- 45 were outside the eligible age range (9 were aged less than 18 years, 21 were aged 30 years or older)
- 9 had labelling errors.

There were 538 samples eligible for analysis. Table 11 summarises demographic characteristics of those screened in non-clinical settings.

Table 11. Description of participants in non-clinical setting (PIP)

(percentages out of n=538)

Age	Female n(%)	Male n(%)	Unknown sex n(%)	Total n(%)
18-19	93 (17.2)	56 (10.4)	1 (0.1)	150 (27.8)
20-24	214 (39.7)	112 (20.8)	9 (0.1)	335 (62.2)
25-29	29 (5.3)	23 (4.2)	1 (0.1)	53 (9.8)
Total	336 (62.4)	191 (35.5)	11 (2.0)	538 (100)

3.4 Management of positive persons

3.4.1 Positivity rates

Of the 998 people screened 48 (4.8%, 95% Confidence Interval (CI) 3.5-6.1) tested positive. The positivity rate was 4.8% (95% CI 3.3-6.3) in females, and was 5.2% (95% CI 2.5-8.0) in males.

Of the 460 eligible people screened in clinical settings, 27 (5.9%, 95% CI 3.7-8.0) tested positive. Of the 538 persons screened in the non-clinical settings 21 (3.9%, 95% CI 2.3-5.5) tested positive. The following tables provide a breakdown of results by clinical and non-clinical setting (Table 12), age bands (Table 13) and sex and specific settings (Table 14).

Table 12. Chlamydia results by sex in clinical and non-clinical settings.

	Clinical			Non-clinical		
	CT neg n(%)	**CT pos** n(%)	**Total clinical**	**CT neg** n(%)	**CT pos** n(%)	**Total non-clinical**
Female	373 (95.4)	18 (4.6)	391 (100)	319 (95)	17 (5.0)	336 (100)
Male	48 (84.2)	9 (15.8)	57 (100)	187 (97.9)	4 (2.1)	191 (100)
Sex not specified	12 (100)	0	12 (100)	11 (100)	0	11 (100)
Total	433 (94.1)	27 (5.9)	460 (100)	517 (96.1)	21 (3.9)	538(100)

The positivity rate for females in clinical settings (4.6%) was not statistically significantly different to females in non clinical settings (5.0%); whereas for males the rate of positivity in clinical setting (15.8%) was significantly higher than in non-clinical PIP settings (2.1%), Odds Ratio: 8.77 (95% CI 2.33-35.5). Males attending clinical settings were also more likely to be CT positive than females attending clinical settings, Relative Risk: 3.43 (95% CI 1.62-7.26). This difference was statistically significant.

Chlamydia trachomatis (CT) positivity rates were similar across the three age bands, with no statistically significant differences between age groups (Table 13).

Table 13. CT results by age bands in clinical and non-clinical settings (Percentage by age band in clinical and non clinical settings)

	Clinical			Non-clinical		
Years	**CT neg** n(%)	**CT pos** n(%)	**Total clinical**	**CT neg** n(%)	**CT pos** n(%)	**Total non-clinical**
18-19	49 (94.2)	3 (5.8)	52 (100)	145 (96.6)	5 (3.4)	150 (100)
20-24	202 (94.4)	12 (5.6)	214 (100)	319 (95.2)	16 (4.8)	335 (100)
25-29	182 (93.8)	12 (6.2)	194 (100)	53 (100)	0	53 (100)
Total	433 (94.1)	27 (5.9)	460 (100)	517 (96.1)	21 (3.9)	538 (100)

Positive male cases were found in both GP and SHU settings (Table 14). Men were not screened at the FPCs.

Table 14. CT results by sex within clinical settings

	GP			SHU			FPC		
	CT neg (%)	**CT pos** (%)	**GP Total** (%)	**CT neg** (%)	**CT pos** (%)	**SHU Total** (%)	**CT neg** (%)	**CT pos** (%)	**FPC Total** (%)
Female	229 (95)	12 (5)	241 (100)	80 (98.8)	1 (1.2)	81 (100)	64 (92.8)	5 (7.2)	69 (100)
Male	30 (85.7)	5 (14.3)	35 (100)	14 (77.8)	4 (22.2)	18 (100)	4 (100)	0	4 (100)
Sex not specified	10 (100)	0	10 (100)	1 (100)	0	1 (100)	1 (100)	0	1 (100)
Total	269 (93.4)	17 (5.9)	288 (100)	95 (95)	5 (5)	100 (100)	69 (9.3)	5 (6.7)	74 (100)

3.4.2 Risk factors

Table 15 shows the risk factors of those screened and among those who tested positive, in clinical settings only. None of the sexual behaviour or symptom risk factors reached statistical significance for CT positivity among those attending clinical settings.

There were no significant differences between males and females in respect to associations of risk factors and test results.

Table 15. Positive test according to sexual behaviour and symptoms in men and women attending clinical settings

Variable	No. of participants	No. of positive cases (%)	Crude OR (95% CI)
Total partners			
1	61	1 (16.4)	1
2-4	132	9 (6.8)	4.4 (0.6, 94.6)
5-9	113	6 (5.3)	3.4 (0.4, 75.9)
10 or more	90	6 (6.7)	4.1 (0.5, 91.8)
New partner in last 3 months			
No	239	13 (5.4)	1
Yes	166	9 (5.4)	1.0 (0.4, 2.6)
Two or more partners in last year			
No	251	9 (3.4)	1
Yes	156	13 (8.3)	2.4 (0.9, 6.6)
Discharge			
No	357	20 (5.6)	1
Yes	53	2 (3.8)	0.7 (0.1, 3.1)
Pain on passing urine			
No	356	18 (5.1)	1
Yes	51	4 (7.8)	1.6 (0.4, 5.3)

The numbers in categories varies due to missing data/non-response.

Of the two risk factors routinely used as risk indicators, only two or more partners in the previous year was a potentially useful discriminator, with a crude odds ratio (OR) of 2.2 (95%CI: 0.9-6.6). The lower CI is very close to 1 and would be worth exploring with a larger sample size. There was the same positivity rate of 5.4% whether or not the case had reported a new partner in the previous three months.

show the risk factors among those persons who tested positive by sex.

Table 16. Risk factors for males in clinical settings by CT result

Risk factors for males in clinical settings	Negative cases n(%)	Positive cases n(%)
Number sex partners		
1	3 (6.2)	0
2-4	9 (18.8)	3 (33.3)
5-9	8 (16.7)	1 (11.1)
10 or more	22 (45.8)	4 (44.4)
Non-response (missing)	6 (12.5)	1 (11.1)
Total	48	9
New partner in past 3 months		
Yes	27 (56.3)	4 (44.4)
No	16 (33.3)	4 (44.4)
Non-response (missing)	5 (10.4)	1 (11.1)
Total	48	9
>2 partners in past 12 months		
Yes	24 (50)	5 (55.6)
No	19 (39.6)	3 (33.3)
Non-response (missing)	5 (10.4)	1 (11.1)
Total	48	9
Pain on passing urine		
Yes	10 (20.8)	3 (33.3)
No	33 (68.8)	5 (55.6)
Non-response	5 (10.4)	1 (11.1)
Total	48	9
Unusual discharge		
Yes	4 (8.3)	0
No	39 (31.2)	8 (88.9)
Non-response	5 (10.4)	1 (11.1)
Total	48	9

Table 17. Risk factors for females in clinical settings by CT result

Risk factors for females in clinical settings	Negative cases n(%)	Positive cases n(%)
Number sex partners		
1	56 (15)	1 (5.6)
2-4	114 (30.6)	6 (33.3)
5-9	99 (26.5)	5 (27.8)
10 or more	61 (16.6)	2 (11.1)
Non-response (missing)	43 (11.5)	4 (22.2)
Total	373	18
New partner in past 3 months		
Yes	129 (34.6)	5 (27.8)
No	208 (55.8)	9 (50)
Non-response (missing)	36 (9.7)	4 (22.2)
Total	373	18
>2 partners in past 12 months		
Yes	118 (31.6)	8 (44.4)
No	221 (59.2)	6 (33.3)
Non-response (missing)	34 (9.1)	4 (22.2)
Total	373	18
Pain on passing urine		
Yes	37 (9.9)	1 (5.6)
No	302 (81)	13 (72.2)
Non-response (missing)	34 (9.1)	4 (22.2)
Total	373	18
Unusual discharge		
Yes	47 (12.6)	2 (11.1)
No	294 (78.8)	12 (66.7)
Non-response (missing)	32 (8.6)	4 (22.2)
Total	373	18

3.4.3 Treatment of positive persons

Forty five (94%) of the 48 CT positive cases were successfully treated. Forty (89%) received a single oral dose of azithromycin 1g, doxycyline and erythromycin were used to treat two additional positive cases, and the treatment type was unknown for three cases where the location of treatment was abroad. Three cases (6.2%) were not contactable and therefore (presumably) not treated for chlamydia.

Table 18. Location of treatment of positive persons summarises those screened in non-clinical settings who attended their GP and /or student heath units for treatment.

Table 18. Location of treatment of positive persons

Setting	Females treated n(%)	Males treated n(%)	Total n(%)
GP	13 (27.0)	5 (10.4)	18 (37.5)
SHU	13 (26.5)	8 (16.6)	21 (43.7)
FPC	4 (8.3)	0	4 (8.3)
GUM	1 (2.0)	0	1 (2.0)
GUM (UK)	1 (2.0)	0	1 (2.0)
Total treated	32 (91.4)	13 (100)	45 (93.8)
Not contactable	3 (6.2)	0	3 (6.2)
Total	35 (72.9)	13 (27.0)	48 (100)

3.4.4 Further STI Testing

Twenty-five (52.1%) positive cases are known to have had further STI testing. Eleven were tested in general practice, where a range of STI tests were performed, while thirteen were tested in GUM clinics. The testing location was unknown for one case. All tested negative for other STIs. Table 19. Outcomes and location of further STI testing/screening on positive cases gives details of these tests.

Four positive cases refused further STI testing. Fifteen did not attend for screening despite some receiving appointment details and all indicating they would attend.

Table 19. Outcomes and location of further STI testing/screening on positive cases

Outcomes	CT pos Female n	CT pos Male n	CT pos Total n(%)
Location of STI testing			
GP	7	4	11 (44)
SHU	0	0	0
FPC	0	0	0
GUM clinics	9	4	13 (52)
Location of further STI testing unknown	1	0	1 (4)
Total tested	**17**	**8**	**25 (100)**

3.4.5 Retests outcomes

All clinical settings offered retest facilities (with urine sampling). Those who did attend for retesting attended their place of original consultation (GP/FPC/ SHU). Table 20 summarises the retest outcomes in clinical and PIP settings.

The RHA contacted by phone 24 positive cases who had been detected in clinical settings and fourteen positive cases detected at the PIP events. The remainder had either not given consent or were not contactable. Nineteen (48.7% of those contacted) were retested and all retest results were negative for chlamydia.

All the PIP positive patients were referred to attend the GUM clinic for their retest (endocervical/urethral swab). Urine testing for the study was no longer available at this time as the urine testing service was provided for a defined period, which had expired. None of the PIP patients attended the GUM clinic for their retest despite five having appointments made for them.

Table 20. Retest outcomes in clinical and non-clinical settings

Clinical settings	n(%)	PIP*	n(%)
Attended & retested	19 (66.6)	Attended	0
Did not attend (after being contacted by RHA)	5 (18.5)	Did not attend (5 appoint. made by RHA)	11 (52.3
Failure to contact∞ (on retest phone call)	2 (7.4)	Failure to contact Not contactable†	3 (14.2) 3 (14.2)
Case not at risk of re-infection	1 (3.7)	No consent to contact	1 (4.7)
		Declined retest	3 (14.2)
Total	27 (100)		21 (100)

*Urine testing was not available to PIP CT positives for retest.

†Non- contactable: no contact number for participant

∞Failure to contact: unable to contact participant after several attempts.

3.4.6 Partner notification

Figure 3 summarises the results of partner notification. Partner notification was not carried out on five of the 48 positive cases:

- One patient did not consent to be referred to the health adviser. The doctor who managed the case conducted initial partner notification discussions with the patient. However, outcomes were not monitored
- One index case refused partner notification with no follow up on partners.

- Three positive cases were non-contactable.

Of the remaining 43 index cases, the RHA discussed and followed up partner notification with 25 (58.1%). A practice nurse from one of the student health units discussed partner notification with 11 cases (25.6%); practice nurses from the family planning clinics took on this role with five cases (11.6%). Partner notification for two cases (4.6%) was done at the local GUM clinic.

The preferred method of notification was patient referral where the index case notified previous and current partners themselves. 83% (46) of notifications were undertaken by the index case (patient referral) and 17% (10) where undertaken by the research heath adviser (provider referral). In addition the RHA did a follow-up call to all consented index cases.

Use of community contact cards

Thirty four contact cards were distributed by the health care providers in primary care and only four cards were returned, which were collected from partners at the following settings: GUM clinic (2), student health unit (1) and general practice (1).

Partner Contact

Overall 68 partners were reported by the 43 index (positive) cases. Fifty six (82.3% of) partners were contacted by either the index cases or health care providers and informed of their potential exposure to chlamydia. Figure 4 summarises the outcomes

Ten partners were not contactable as the index (positive) case had no contact details because these were casual partners. Despite contact details being provided and several attempts being made, two contacts were not contactable.

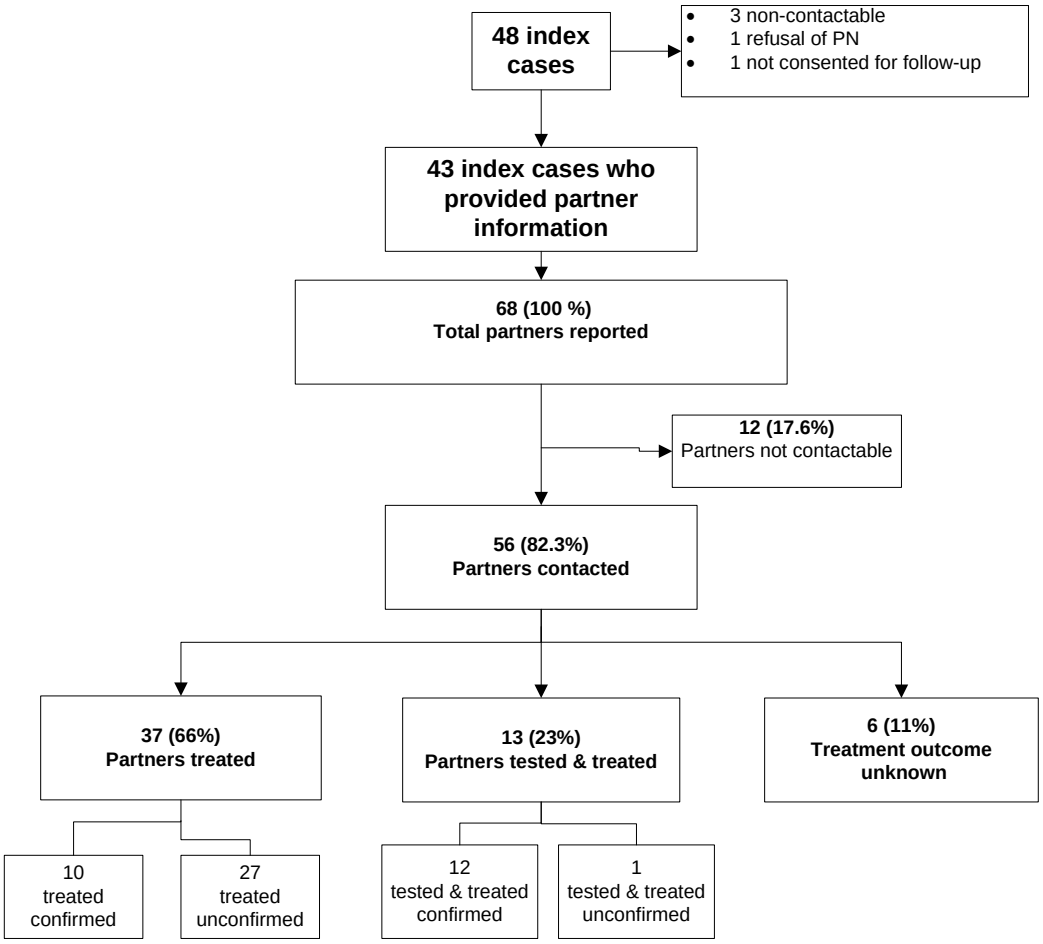


Figure 3. Partner outcomes

Overall 0.3 contacts were screened per contactable index case in the study (clinician confirmed). This and other performance measures for partner management are shown in Table 21. **Performance measures for partner management**.

Table 21. Performance measures for partner management

Published Targets	Pilot Study
NCSP: within 90 days of the first partner notification discussion, at least 0.6 partners are to be verified as treated per index case∞ [9]	0.5
BASSH guidelines and targets: 0.64 contacts are screened per index case for chlamydia (for clinics not in large cities ∞) [7]	0.3
Measures with no targets set†:	
Partners treated per index case (clinician confirmed and non-confirmed)	1.1
Partner contact rate	82.3%

Partner treatment rate	73.5%
Effective partner treatment rate*	89.3%
Effective partner testing rate*	23.2%

∞Except in London or a large city where the standard is 0.4. In this study, the denominator for index cases is 45 (i.e. The number of contactable index cases)
† The NSCP Annual Report 2004-5 described these effectiveness measures of partner notification based on their findings (these are not clinical standards).

* Effective rate uses number of contacted partners (n=56) as denominator.

Note: Unconfirmed indicates reported by the index case.

Treatment outcomes for partners

Treatment outcomes for twenty-eight partners were confirmed by the index cases ('unconfirmed') and for twenty-two partners, treatment was confirmed by a clinician in the settings (doctor or nurse).

Treatment location

Overall, 29 (51.7%) partners were treated in clinical settings with the remaining 27 (48.3%) treated in GUM settings or in other unknown locations. In GUM settings, treatment was confirmed by a health care professional for seven partners with treatment confirmed by the index case in the remaining 7 partners.

The majority of partners within clinical settings (n=22, 40%) were treated in general practice, four (7.2%) were treated in student health units and three (5.4%) were treated in the family planning clinic. Most partner treatments were confirmed by the index cases (see figure 5 for further details). In total, 13 health care providers confirmed partner treatment in primary care.

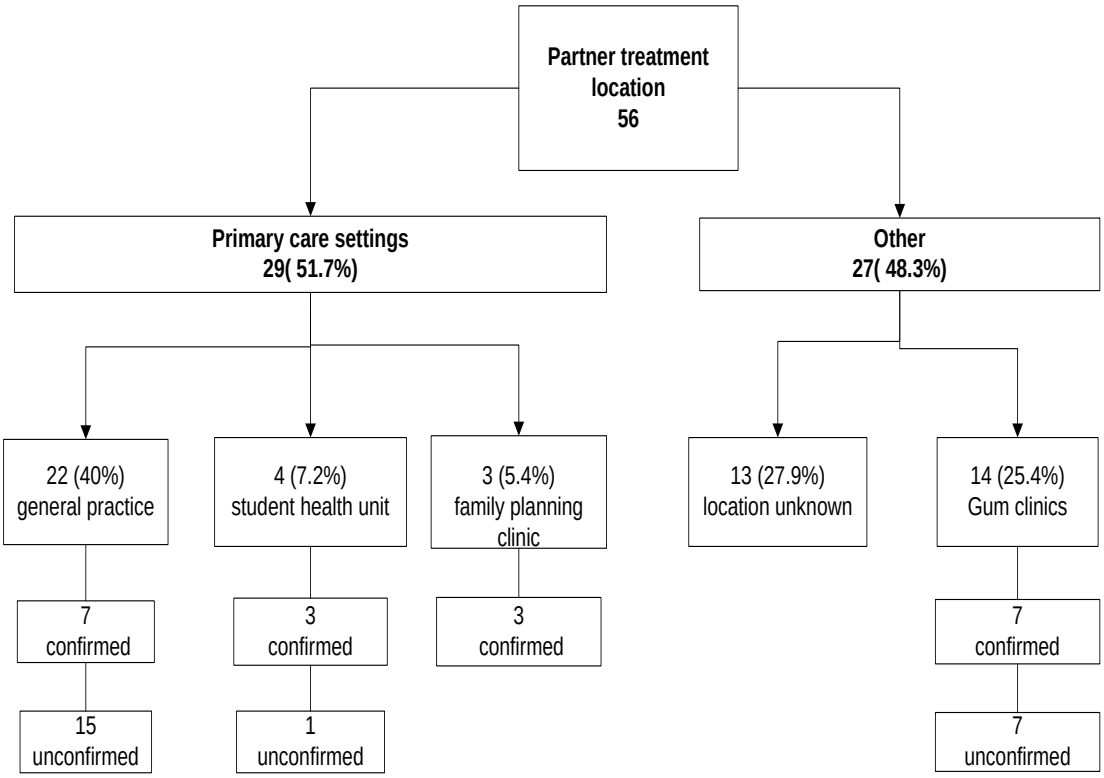


Figure 4. Treatment location of partners

3.5 Interviews with screened participants

This section relates to the thirteen interviews conducted with young adults who had participated in the screening pilot. These consisted of seven interviews with PIP participants and six with clinical setting attendees (FPC, SHU and general practice). The clinical setting attendees included two male students (who attended SHUs) with positive results and four females with positive results: two from general practice settings, one from a family planning clinic and one from a student health unit.

3.5.1 Reasons for accepting the screening offer in clinical settings

For many participants, reasons for accepting the screening offer were multifactorial. These included the following;

1. *'Curiosity'* with some participants detailing no past experience of chlamydia screening and were willing to try it.
2. '*Needed* it'. Some participants knew that they were potentially at risk for an STI due to a personal risk factor e.g. having had unprotected intercourse or change of partner. Thus when the opportunity of the test arose, they were happy to take it '*I reckoned I needed it and when the opportunity came up I took it*'.
3. '*Free so why not?'* In the study the test and treatment was free for participants. During the narratives, several participants reiterated this was a major incentive in accepting the screening offer. Participants felt a maximum cost of €25 would probably be acceptable in a future screening programme. However, felt they were much more likely to get screened if the testing was free.

4. Confidentiality of the screening process. The whole process of screening was regarded as '*confidential'*.
5. '*For a laugh*' - A minority of participants viewed the screening process in a lighted manner and they were happy to participate in the pilot.
6. It was a simple urine test. Participants were pleased with the urine testing as it was perceived as a 'straight forward' process with minimal effort involved.

Some expressed no particular reason for accepting the screening offer.

Knowledge of chlamydia

Most knew about chlamydia but learnt more from the screening experience.

Attitude to STIs

There was generally a negative attitude towards STIs with most describing them as an embarrassing subject with associated stigma and taboo.

History of past STI testing

Very few interviewees reported a previous STI test. Reasons for not having a STI test were discussed and were multi-factorial. A minority of interviewees described feeling 'invincible' and distanced themselves from the likelihood of having an STI. Some described themselves as being 'naïve' and just not perceiving themselves to be at risk.

Several participants were concerned about the perceived painful and invasive nature of STI testing. A common concern for many was being seen in the waiting room of a GUM clinic which was a deterrent for attending the clinic.

Views on charging for screening

While participants mentioned a cost of up to €25 which would probably be acceptable, they were much more likely to get screened if the testing was free.

Views on urine test

All relevant participants were very happy with the urine test, because it was a simple, non-invasive and private test. Other advantage of the urine test for participants was that the urine test was perceived to be 'quick' and participants could do the test themselves.

Prior to screening, participants were anxious that the test could be invasive and this was of particular concern if a health care worker (HCW) of the opposite sex was offering the test. The urine test was considered by participants as a "private" test and thus resolved this issue.

Participant's views on endocervical swab test

Only one interviewee had the swab test. She was having a cervical smear test done so had no problem with the swab;

3.5.2 Participant's views on clinical settings

SHUs

Opinions were very positive regarding this setting for STI testing. It was described as a nice environment with friendly, relaxed staff who explained procedures well.

GP Setting

Positive comments were made regarding the interaction with health care workers in this setting during the study- this included the management of the positive cases. Two interviewees would not have attended their family doctor for screening due to family connection and close proximity in the local community.

FPC Setting

Positive comments were made regarding screening and the aftercare provided by the HCWs here. The FPC was considered an easier setting in which to access STI testing, because the offer of a STI test fits with the context of a sexual health consultation or with a request for contraceptives.

GUM clinic

(Of note since these interviews were recorded, the main GUM clinic involved in this pilot has moved to a new purpose-built building with a larger waiting room).

GUM clinics appear to generate negative connotations for interviewees. One interviewee who had not attended any GUM clinic perceived that attending would make one feel "dirty"; that the clinic is "horrible" and she "would never want to go there".

Some interviewees described being concerned before attending the GUM clinic- their concerns centred on: the physical examinations they might be requested to undergo; the confidentiality of the clinic process and the potential to be seen at the clinic by someone they knew.

One attendee described attending the GUM clinic as the worst part of the screening process as it was a '*public'* experience. Comments were repeatedly expressed by other attendees that attending the GUM clinic was '*unnerving', 'formal' and 'embarrassing'.*

In contrast, one participant was relaxed regarding the GUM clinic and whether or not she was seen by an acquaintance. However this person described herself as being '*different'* to her friends (who would be anxious about attending).

Impressions of the GUM clinic waiting room were generally negative. It was considered not like an ordinary doctor's waiting room; '*awkward'* as very small in size and other attendees were embarrassed and '*hiding behind newspapers'.* This was considered to reflect the '*stigma'* of STIs.

However one respondent (the same one who was relaxed about the GUM clinic) thought the waiting room was fine with a mixture of backgrounds and ages of attendees.

The care provided by health care workers in the GUM clinic was considered professional and to a high standard. It was noted that the doctors appeared under pressure which added to more formal atmosphere. The SHUs were considered by student interviewees more positively as these were more '*relaxed'* settings.

Suggestions on improving GUM clinic:

These included increasing the size of the waiting room; providing more reading materials and making attending more private. This lack of privacy was considered a deterrent to attending.

3.5.3 Perspectives on health care workers characteristics

Sex of health care worker

There was a mixture of opinions on whether a health care worker of same sex was preferred. One male respondent described initial anxiety that the health care worker might be female- this was allayed when he realised that only a urine test was required.

Age of health care workers

A mixture of opinions were again expressed with some preferring a younger health care worker who might relate more to their experiences; while others did not care what age the health care worker was.

Health care worker profession preference

No preference was voiced for nurse or doctor.

Perspectives on role of the research health adviser

Participants who had contact with the research health adviser/nurse were all very positive about this interaction. She fulfilled several functions for the positive cases; these included:

- Normalising the diagnosis and treatment for positive cases
- Explaining and providing information
- Reassuring and providing continued support
- Guiding on partner notification and supporting in this process.

Impact of chlamydia diagnosis on positive cases

Initial impact of diagnosis:

There was an initial negative impact on most cases- describing themselves as being shocked; feeling *'dirty', 'horrible', 'down', 'upset', 'embarrassed', 'disbelief', 'ashamed'* and with lowered self-esteem. Some were annoyed with self or with partner. Worries were expressed regarding future fertility and discomfort was described at not knowing that they were infected –'*That would be the strangest thing, obviously when you have some sort of an infection, disease or whatever it is, and not knowing about it, obviously you're carrying it.., it's off-putting'*. Some were relieved to have the infection picked up and were immediately glad that they had taken the test.

Long term impact of diagnosis- 3-9 months post diagnosis

With time (for some a very short period) their feelings altered and became more positive. They were glad that they did the test; this gave *peace of mind* and *they would do test again.*

Some considered the positive result a *wake-up call* which led to increased sexual health awareness and safer practices.

Retest experience

The re-test experience was valuable to the positive cases- especially the knowledge that they were no longer infected. However they interpreted it as a check to see if the original infection had resolved, while the actual aim was to establish if there had been re-infection.

Testing for further STIs

Among those who went for the further testing; some expressed anxiety while waiting for the results. Once they had completed this testing, they were delighted this was finished and with their negative result.

Some interviewees did not go for further STI testing (though being advised to) because they either did not want it with some considering this health episode finished or they did not consider themselves likely to have another STI; while others did not have a current partner and thus did not consider further testing relevant.

Other interviewees planned to have further STI testing when they had time or when their partner could go with them. Some stated a preference to going to their local GP for further STI testing- due partially to the convenience of the GP setting and partially being familiar with the GP.

Experience of treatment medication

One respondent experienced nausea. The rest had no difficulties- that the medication was provided in the doctor's surgery was appreciated both from a convenience and confidentiality perspective. Attending pharmacies was considered a potential problem as one could meet an acquaintance.

General views on the screening pilot

The overall opinion of the interviewees regarding the screening pilot was very positive. Interviewees were glad that they participated in screening and they considered that the pilot should be continued as the model works well; the process is very quick and easy and that chlamydia screening was important.

Suggestions re improving screening pilot

The following suggestions were repeated by the interviewees.

- Provision of ***increased advertising on chlamydia screening*** especially for males who may not go near a clinical setting routinely.
- Provision of an ***alternative to the GUM clinic for the recommended further STI testing***: "*I think pretty definitely is if you didn't have to go to that STI clinic*".

  One suggestion was for STI testing to be based in the FPCs as "*that would be so much better because you wouldn't feel as paranoid going in there. You wouldn't feel kind of embarrassed going in there because you know it's not just for STD testing*". Others suggested being screened at their local GP surgery.
- Provision of ***more information on chlamydia*** to increase awareness of this infection.
- More ***privacy in the GUM clinic.***

In summary, chlamydia screening, in particular urine testing was very acceptable to interviewees. Interviewees accepted the screening offer for many different reasons such as no charge etc. The use of urine tests removed any potential issue regarding interacting with a HCW of the opposite sex. A positive diagnosis caused an initial negative impact which waned with time. Retesting had a positive impact; however the reason for this second test was not understood. Opinions varied on general

practice as a STI testing setting with support for and against this based on the same proximity factor. Though the service was very professional in the GUM clinic involved with this pilot, these types of settings can generate negative connotations. A solution suggested by some interviewees is to offer further STI screening outside these settings.

3.6 Post-screening interviews with health care providers

At the end of the 9-month pilot screening period, 16 providers who had participated in the pilot were interviewed. These included GPs, practice nurses from general practices and practice nurses and a GP from the family planning clinic and student heath units.

Qualitative interviews were undertaken as a component of the research to explore providers' experience of the screening model. The purpose of the qualitative interviews was to explore the diversity of provider's experiences of chlamydia screening.

3.6.1 Findings

Initial reactions to the pilot were overall quite positive.

> *Well I thought it was a great idea... I was all for it and thought it would be great to offer it.* (Interview 14, rural GP, screened: 2)
>
> *I was interested to do it, I was aware that the incidence was high and that made me interested in doing it.* (Interview 13, rural GP, screened: 5).

Opportunistic screening, while deemed valuable and worthwhile also presented substantial challenges, many of which were not anticipated by providers at the outset of the project. These challenges identified by providers contribute to our understanding of lower than anticipated screening rates. To explore the complexity of the recruitment process as described by interviewees, we crudely divided it into factors which we believe were internal and external to health care providers. These factors played a role in who was (or who was not) invited to participate and indeed those who choose to accept or reject an invitation to test. These factors are discussed below (see Figure 5 for summary?).

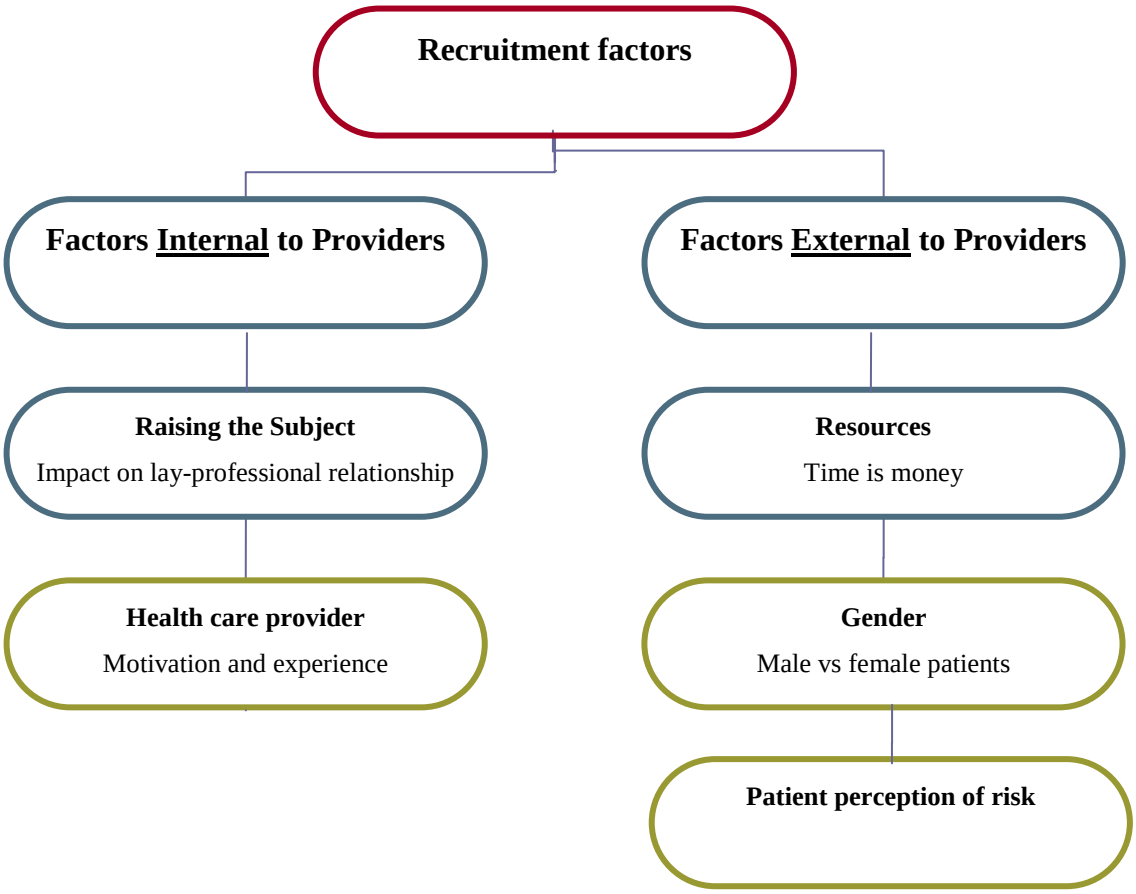


Figure 5. Summary of recruitment factors

3.6.2 Factors Internal to the Recruitment Process

Raising the Subject

The most usual recruitment approach was for health care providers to ask potential participants if they were interested to participate in the screening pilot.

While some interviewees had no problems, many providers voiced some concern, and reported difficulty broaching, the sensitive and potentially stigmatising subject of sexual health in a general consultation. In addition, many lay people were starting from a very low chlamydia knowledge base. Offering the tests to patients, presented a 'risk' for health care providers because of its possible impact on the lay- professional relationship. Some providers felt that the actual process of offering the test created a scenario where they had to somehow ascertain if someone was sexually active which itself was viewed as intrusive.

There are difficulties in general practice… you are not aware

If someone is sexually active… and you are not aware if it

[chlamydia test] needs to be mentioned…It seemed inappropriate to mention it to some people… and some may take offence. (Interview 13, rural GP, screened: 5)

Some providers felt the actual process of inviting someone to test for chlamydia had the effect of not just labelling them as sexually active but also as 'high' risk.

And they might be, just sometimes you would feel are they thinking …that I think… they were high risk, because I'm asking them. (Interview 9, urban GP, screened: 35)

How health providers 'managed' the potential labelling effect of proposing a test varied between providers. One general practitioner reported quite frankly, that she stopped asking and essentially withdrew her practice from any further screening.

after I while I thought, I'm not going to offer because I felt that in case they felt I was you know…, questioning their morality, and I felt that there was an issue… that they felt why should I be screened. (Interview 14, rural GP, screened: 2)

If other health professionals involved felt so strongly, they did not voice it in the interview setting. More usually, providers reported that they attempted to minimise any particular offence that may have been caused by employing techniques such as 'reading' the patient in advance of the invitation to test. In essence, engaging in what might be considered to be selective screening.

But I suppose it was… you kind of get a feel for somebody first and see if they were… you know…willing to talk about it. (Interview 6, practice nurse, urban GP, screened: 60)

Frequently, health providers honed in on the high community prevalence of chlamydia and attempted to use this as a strategy to normalise the testing process.

I would be very particular to say this is just across the board… it's not because we think you have anything… its just, its there, it wont hurt. (Interview 1. practice manager, family planning clinic, screened: 78)

Inviting to test for chlamydia was easier when 'piggy-backed' with other, somewhat related consultations such as the cervical smear programme, or consultations for contraceptive services.

Sometimes, they were coming in for a different reason… it can be difficult then, to change the perspective, like a repeat asthma prescription… that can be trickier… often it is easier to bring up if they are in for something like the pill prescription or contraception. (Interview 13, rural GP, screened: 5)

The timing of the study coincided with the commencement of a national cervical screening programme. This perhaps had positive as well as negative effects on the chlamydia screening pilot. The recent high profile illness and subsequent death of a young female media personality resulted in increased interest in cervical smear testing.

The timing nearly wasn't great as regards all the promotional stuff and then the 'Jade Goody thing'. All everybody was thinking about was cancer and cancer and cancer! (Interview 1. practice nurse, family planning clinic, screened: 78)

Health care provider's motivation and experience

It is perhaps not surprising that providers who expressed the most enthusiasm for the screening pilot were very often those who conducted larger numbers of chlamydia screening tests. Frequently, in many settings a key designated person took the lead in

delivering the pilot and guiding colleagues. For those who had lower rates of screening, lack of motivation was an issue in at least one setting.

> *P: it was quite hard to motivate people to do the screening.*
>
> *I: Do you mean the staff or patients?*
>
> *P: Yes, the staff, to offer the screening because one nurse in particular, she just wasn't comfortable with it, so she didn't offer it.*
>
> *I: Ok, and did she say why or do you know?*
>
> *P: I think that it's that she was a little bit older and that she didn't feel comfortable to discuss those things.*
>
> *I: Ok, would she have had any training in sexual health or the STIF course or anything like that?*
>
> *P: No, there was one nurse who got the training as a result of us doing this and I think that did help with her interest in you know, encouraging, or offering the screen.*

Educational preparation and information support were deemed important by a number of providers.

> *I did the STIF course…which I found really good to be honest… and I have the guidelines there on it.* (Interview 9. urban GP, screened: 35)

Information packs and back up support offered by the research health advisor also contributed to successful screening by many providers

> *P: No, my two favourite bits are probably this*
>
> *[Holds up information leaflet and checklist]*
>
> *I: So the checklist*
>
> *P: Exactly for ourselves just to remind us, and the information leaflet I think is excellent* (Interview 15. GP, student health unit 2, screened: 28)

3.6.3 Factors External to the Recruitment Process

Time

Time constraints were raised by most interviewees as the single most significant barrier to the recruitment process. Many providers stated they simply did not have the time to offer the test to every patient attending in the target group. Several were concerned at the extra time it added on to consultations and felt in particular it was time consuming in the initial consultation. Only three providers were not concerned with the extra time it added on.

> *It took about an extra 3-5 minutes and when you are busy that can delay your other appointments…. had time and if they were in the age bracket, I would ask those I thought might be sexually active.* (Interview 3. rural GP, screened: 18)

A number of providers felt even though initial offering of the screening only took a few minutes, concerns about the accumulative impact on workload were still very relevant if screening was to be offered opportunistically to every patient.

> *Suppose it boils down to trying to make that, I mean, I suppose, it was, I mean, you know, three to four minutes or five minutes in some cases doesn't sound like a lot, but if you are doing it for every fifteen minute consultation, it is a lot*. (Interview 9. urban GP, screened: 35)

Two providers in one student health settings were too busy to offer the screening because of time pressures, one of whom stopped the process due to time pressures

> *The time…Is too difficult on top of our particular practice which is very busy. That's what we found. , so wouldn't be asking everyone do they want it*. (Interview 10. student health unit 2, practice nurse, screened: 28)

The impact of positive results was considered a bigger concern for many

> *I think it's where you get positives that you know things get a little bit more time consuming* (Interview 3. urban GP, screened:18)

Gender

The gender context is also an important recruitment issue. Many interviewees reported that there were recruitment differences between men and women. Firstly some providers found that they asked more females than males.

Explanation for these differences is multifaceted. Some of the issues raised include, less easy access to a male target population in the clinical settings. Many also said it was difficult to offer it opportunistically to men because this group rarely attend general practice 'unless they are worried about something' (unlike women, who more usually attend general practice for contraception and related services). Several providers pointed out that male attendance in the study target age group was generally low. Providers in both student health units remarked if males were attending they are generally quite sick and therefore inappropriate to offer the screen. Also for this reason, in a male consultation other issues came to the fore and a screening test for sexual health was simply not remembered.

> *it probably wouldn't have crossed my mind, because very often if you get males in at that age, they might have been coming in to have sutures removed or something where you are not actually on that train of thought, so it might not have even entered my head to offer.* (Interview 7. rural GP, practice nurse, screened:15)

Secondly, when men were asked, providers reported higher refusal rates with men, compared to their female counterparts and this was particularly commented on in student health settings. One participant estimated two thirds of men refusing the test offer, describing it as a 'closed door'.

> *I. any thoughts on why you think… they refused?*
>
> *P: Well a few could not give a sample at the time. That was their excuse that they gave me….. …. they said, oh I can't actually give you a sample now, I've just been. But why they don't want it, I don't know is it just fear of it or not wanting to know about it, not wanting to deal with it. Or maybe a lack of understanding. But a lot of*

the males that I asked in terms of the ones that refused, a lot of them were male. I would say, out of that ten percent, probably I would say maybe seven out of the ten percent. (Interview 2. urban GP, screened: 64)

Many providers found males more defensive and dismissive than their female counterparts, with some '*just laughing it off'*.

But of the guys, there was sort of a, they were quite dismissive of it and just didn't have any interest in taking part… which is kind of concerning. (Interview 2. urban GP, screened: 64)

Providers felt it was a 'denial thing' in males and a 'lack of understanding' of the asymptomatic nature of chlamydia with men tending not to worry about the long term consequences. Lack of knowledge among men and their perceptions that chlamydia is more associated with women is highlighted in a participant's comment;

Men don't get chlamydia *of course.* (Interview 5. practice nurse, family planning clinic, screened: 78)

The gender of the health care provider was also pertinent. Many female providers felt uncomfortable raising the issue with men and attempts were made to encourage male GPs within the practices to offer it to male patients.

On the other hand, uptake in females was quite high with little refusing the test and also providers reported being more comfortable offering the test to females in related consultations.

Also several providers perceived the long term benefits of screening more relevant to females.

… you tend to maybe go more for the females, I suppose, just because thinking of the consequences, females and younger ones,. (Interview 12, rural GP, screened:10)

with the girls, they are delighted. obviously it's a positive thing for them like if you have a chlamydia *test, if you have it you can treat it, it might help around infertility…….. Whereas with the fellas, if you have* chlamydia *we can treat it to stop you giving it to somebody else. So its, its easier to kind of, I felt, sell it as a good thing for the girls I suppose.* (Interview 12 rural GP, screened:10)

Patient perception of risk

Providers reported that that chlamydia screening did not have much relevance to the lives of some patients. Providers reported that many patients considered that they were not personally 'at risk' and on that basis excluded themselves from screening pilots.

But I think that the most common reason for people refusing is that they don't think they are at risk, that they haven't had multiple partners or they are not aware of their partner you know, having, or where they have used barrier contraception all along. (Interview 3. urban GP, screened:18)

A discrepancy between what lay and professional deemed to be 'risky' was evident in the narratives.

I would usually say if you have ever had unprotected sex, and I think you nearly need to go into it further as what unprotected sex is, because you know, they think they use condoms all the time but when you go in to ask further questions they actually don't. You know, so I think they don't see themselves at risk. (Interview 16. practice nurse, student health unit 1, 81)

Many providers referred to the knowledge deficit which they believe existed about chlamydia and it's symptoms in their patient population.

> *And I think there is still very little knowledge around about* chlamydia *and the lack of symptoms with it, and I suppose it would make it more feasible in general practice if they didn't all look so surprised and you know, blank when you mention something like* chlamydia. (Interview 9. urban GP, 35)

Specimens

Providers indicated high levels of acceptance with the sampling method (specimens) used. Urine samples were offered to all males and urine samples or cervical swab were offered to females. Providers were vociferous in the advantage of urine samples, with ease of method for patients and the implication also for human resources and time within the practices.

Urine testing were 'easy to do' and 'easier to offer' because they were less invasive for patients;

> *Yes, and I found that was, it was much easier to offer. Especially when somebody was in for something unrelated to be able to offer urine than to have to do an invasive test.* (Interview 9. urban GP, screened: 35)

While cervical swabs testing for chlamydia were also deemed useful and convenient when taking a smear.

> *The swabs would have been mainly if I was doing a smear on a female patient at the time, it was as easy to do a swab as to send them off to the toilet which takes a while*. (Interview 9. urban GP, screened: 35)

Providers re-iterated the impact of invasive testing on patients especially for male patients

> *That hugely increased the acceptability, people were willing to consider it, that you know, because last week, we had a gentleman in who wanted it, and but he said to us, there was no way, he couldn't stomach the idea of having the swab, he did the urine test, , so, the fact that the urine test was available would just so much more increase the rates of people who would be using it and availing of it. Yes*. (Interview 8. urban GP, screened: 60*)*

The availability of the urine testing as a method of sampling was welcomed as urine testing for chlamydia was previously unavailable in the region.

> *.., that's the attraction of doing the urine test, I suppose in other places I have worked, urine testing was available for everybody. So I suppose that's a bit unfortunate in X that they are none.* (Interview 11.urban GP, screened:18)

Logistically, urine tests were seen to be quicker to do for providers have an examination room was not required and a consultation may not have been required.

The recommended interval of two hours since last urination was not seen as problematic for most providers with only two providers commented on it.

> *I suppose the peeing in the last two hours, I don't know what it is about people who come into the doctor, they always seem to pee before they come, you know? And doctors are notoriously looking for urine samples, so that probably would have been the worst one.* (Interview 10. student health unit 2, practice nurse, screened:28)

Other logistical issues were also raised in relation to taking and organising samples. A minority of providers reported that submitting specimens to the laboratory within a 24 hour time frame could be difficult. Laboratory restrictions on receiving samples by five pm each evening meant some practices had to limit screening to mornings if delivery only occurred once a day.

> *When we weren't able to get samples over in the afternoon and we probably missed a lot of patients based on that. And we didn't want the patients having access, they weren't allowed to be bringing the samples over so it had to be a member of staff from here and the girl on the front desk couldn't drop everything and go over, so that was a bit inconvenient like, four o clock as a dead line wasn't great…* (Interview 2.urban GP, screened: 64)

Organisation/administrative issues

The overall administration burden generated by the study was referred to by a number of providers. 'Too much paper work' was a common complaint as well as delays in receiving patient results.

> *Probably the length of time it probably took to get back some of the results. Because we were kind of telling them they would get them back in three or four weeks and sometimes it went a little bit longer…* (Interview 5. family planning clinic, practice nurse, screened: 78)

Due to anonymous screening providers were unable to receive results electronically and this caused problems for filing and identifying patients' results. Documents for the screening pilot had to be filed separately in order to identify code and patient details.

One key provider in the practice, usually a GP or a practice nurse generally took responsibility for the organisation and distribution of results which for many helped ensure the system worked efficiently.

Giving patient results

Providers reported in the main that the process of giving patient results was uneventful. Providers' current processes and systems were used where possible to minimise disruption. Providers were given options on how they might like to receive their results[4]. In most cases in the screening study patients were informed of their negative results over the phone. A number of providers stated that they preferred to give a positive chlamydia result face to face, although this was not always practical. Providers also reported that when they were giving out positive chlamydia results, they had to try and manage a multitude of patient reactions, including: shock, surprise and upset.

Partner Notification

Partner notification is the process where people who have exposed to a STI are notified of the exposure and invited to attend clinical services. In the current Chlamydia screening programme and following British Association for Sexual Health guidelines [7] it was recommended that all partners within the previous six months

[4] See Appendix 3 for Screening form used in pilot study

were traced and invited to attend for testing and epidemiological treatment. In the research study, a community based research health advisor was available to conduct partner notification by phone. Providers who had experience in sexual health choose to carry out partner notification themselves while the majority of providers referring to the research health advisor. Providers were advised to distribute the contact cards to patients to assist in tracking the process. The purpose of these cards is to inform contacts that 'may have been exposed to Chlamydia'

A real issue

A number of health care providers identified partner notification as a key concern of patients who are diagnosed with Chlamydia infection.

> *Other than the shock of having it…that's [*partner notification*] a real issue for lots of people.* (Interview 15. student health unit 2. GP, 28)

There was an almost universal acceptance of the importance of notifying partners there were also real world issues that also were raised.

> *So they all understood that a partner should be traced and contacted…and in their own heads… they wanted to try and figure where this came from … or where they got it…* (Interview 8. urban GP, 60)

A difficult issue to discuss

While the benefits of partner notification were raised by some, the difficulties discussing the process were raised by an even larger number of participants. An initial shock factor makes partner notification discussions difficult in the early stages

> *I think they find it hard… it takes, it's like any bad news, you know, it hits you with a wallop in the beginning… and then you mull over it… and then you suck it up... and get on with it, do what has to be done.* (Interview 15. student health unit 2. GP, 28)

Health care providers engaged in a complex process of managing an array of emotions and issues which the partner notification process brought up

> *Either it was… as with the first person… it was a very bad break up… and then with everyone else… I think it was an anger kind of thing first… if they were in a long term relationship… And they just wanted to get it out there themselves with the partner… before they discuss anything with me…*(Interview 6. urban GP, practice nurse, 60)

Nonetheless the complexity of a diagnosis of chlamydia in a presumed monogamous relationship raised issues such as infidelity, which is often reflective in any sexual health work.

> *The blame game, because that's where the biggest problems for people are actually about it, it's the whole relationship, psychological thing, and you know, the blame thing about. Oh well, you know, I have only been with one person, who were you with and you know, I have never been with anyone else, you must have cheated on me and all this kind of stuff.*
>
> *…This comes up in any sexual health, any STI issue* (Interview 10, student health unit 2.practice nurse 28)

Time

The time consuming nature of partner notification work was described by many participants.

> *I think it would be… it does… counselling about contact tracing and getting partners back… that would certainly be…it would be time consuming…* (Interview 1, practice nurse, family planning clinic screened 78)

The potential workload of partner notification was seen as not being 'financially viable' for one practice.

> *I honestly think the only barrier, and I can, the only barrier that I felt was just I didn't have time to go down the road of, I know we only had the one positive, but had we had more. I would have felt that whole workload would have been too much to take on and I think by taking up all the time, I don't think the practice would have been happy. All that time was being taken up with something that wasn't actually being financially viable to the practice if you see what I mean?* (Interview 7, practice nurse, rural GP screened:15)

While a number said that they managed to conduct the process as they did not have large numbers coming through, it would have been a different scenario if they had larger numbers of patients diagnosed with Chlamydia infection.

> *But, I suppose while it was only a small pilot project at the time and we didn't have a massive amount, but if it was a full time thing it would be, like, we wouldn't be able to take on that kind of work really. It would be much easier if there was somebody else to, they had no problem taking in the samples and doing all of that, but then, you know, letting somebody else take over the positive side of it would take a lot of work away.* (Interview 5, practice nurse, family planning clinic, 78)

Many participants used language to suggest that partner notification was something of a chore and they were more than happy for an external person to carry out the process.

> *Most of them were going to talk to you anyway so that got us off the hook a bit* (Interview 1, practice nurse family planning clinic screened: 78)

The referral process

Participants reported discussing partner notification with patients with 'most of them happy enough to do it themselves'.

> *The doctor went through that with them… and then it was left up to the patient to do it…. She went though it with them and then left it up to themselves to do it…* (Interview 6. urban GP, practice nurse, 60)

Contact cards were uniquely devised for the study and were modelled on contact slips used in GUM clinics throughout the UK and Ireland. One provider who conducted extensive partner notification in the practice felt the cards were useful and were used by patients.

> *P: Well I think it's great to have the number on them, the code like for you to link up in the clinic in case they didn't come here, so you know…*
>
> *…and you know, it explains on the front as well, you have been exposed, so I suppose they would phone their partner and they take a card just in case you*

weren't too sure where you were going to go and the clinic details were on the back for the walk in

I: Right, would you feel many would have handed them over to their partners or not?

P: Yes, yes, I feel they did.

I: They did yes.

P: Yes. I guess they were a reminder in the pocket if nothing else.

*(*Interview 16, student health unit 1. practice nurse, 60)

Nobody reported receiving any cards back to their service and in instead received verbal reports from contact attending the service.

Nobody came in holding the card that I recall, people would have come in saying I've been told I've been in contact with Chlamydia… (Interview 15. student health unit 2.GP, 28)

Role of the research health advisor

Providers were happy to refer partner notification to the health advisor with many participants reported that 'she was easily available at the end of the phone'. Communication between the services and the heath advisor was seen to be key.

Several providers expressed concerns about the feasibility of partner notification in primary care within their current systems. The 'labour intensive' and complex nature of partner notification called for additional resources to ensure feasibility in these settings. Although some providers expressed preference to refer to GUM clinics, most were willing to take it on with the necessary supports in place.

Provider overall perspectives on feasibility

Despite significant barriers to offering screening most providers when asked about feasibility favoured a chlamydia screening programme in primary care. Primary care was perceived to be 'an ideal place and ideal time' to offer opportunistic screening

In contrast, one participant explained her reservations about the appropriateness of raising the subject with patients in general practice which she felt was a barrier to feasibility;

I wouldn't be overly confident that it is generally. I think you would need a lot of supports in place And I would have, with the best will in the world hoping to get much higher numbers than I did, and I didn't…can be awkward because they are coming in for something completely different (Interview 9, GP urban, screened: 35)

Feasibility in primary care was dependant on a number of factors. Funding for providers and the availability of urine testing was seen as essential to any future programming. Adequate financial remuneration[5] was a key issue and the need for funding was emphasised by the majority of providers. The meaning of 'adequate'

[5] In the context of the screening study, provider's participation was optionally and largely unremunerated. Provider received €25 for positive case detected

varied between providers. For a minority, a consultation fee to cover the cost of dealing with a positive diagnosis was sufficient and providers were 'just happy to be able to offer the service'. Two such people were practice nurses and perhaps may not have been directly involved in budgetary management for the service. One participant felt that lack of funding should not be a barrier to a screening programme.

While two providers felt the initial offering would require minimal remuneration (twenty-thirty euro), a larger number of providers felt it 'would have to be cost effective for GP's to continue doing it. A normal consultation fee was considered appropriate.

There were varied opinions on the feasibility of chlamydia screening in student settings. While providers acknowledged the appropriateness of offering screening in this setting, time pressures was seen as a major barrier for one student setting.

It was also highlighted in this setting the practice nurse is in a unique position to offer the screen as most students are triaged by the nurse.

> *I think here we have the benefit you know, that most of the students come through the nurse, I think that's a huge thing to be honest because you know, the nurse, the idea of the students seeing the nurse here would be that it cuts down on the doctors time*. (Interview 16, practice nurse, student health unit 1, screened: 81)

Many providers were overwhelming in favour of the benefits and the need for screening in this target group, chlamydia was seen as 'an important disease to screen for'. Prioritising chlamydia screening particularly in the current economic climate was difficult, with providers comparing the long term benefits of screening interventions with interventions such as the HPV vaccination. The majority of providers felt screening should be considered moderately to high as a priority by funding agencies. The long term human and economic costs associated with infertility and pelvic inflammatory disease were considered to be very significant by providers.

Provider's recommendations for screening in primary care

A number of strategies and recommendations to help improve feasibility were identified by providers.

Three providers when asked about future recruitment in general practice suggested systems where patients 'could drop in a sample without seeing a health professional'.

> *… Or a simpler system where you could just leave a sample without seeing the doctor or filling out questionnaires. Not all have to go anonymously… it is not an issue for most people… checking and double checking is laborious… just simply having the testing available for a longer period… people will get used to the idea*. (Interview 13, GP rural, screened: 5)

Having the service available at all time and 'patients requesting a screen themselves' was seen appropriate by some.

In order to address the time issue, some providers suggested more nurse-led screening which could relieve the more expensive GP time.

Write and invite

A call recall system was also raised in three providers.

Like happens in the immunisation programmes or even the cervical smear programme… Yes, something like that would be more beneficial (Interview 13, GP rural, screened 5)

Media

Half of providers felt that the use of the media was also an important aspect in a screening programme. Parallel were drawn with the new national smear campaign, Cervical Check, 'a heavily advertised campaign' would help to increase patient uptake as well as assisting providers offering the test in a general consultation. Patients were more likely to accept if they felt everyone was being asked across the board. A campaign could also be a useful strategy in minimizing any adverse effects of labelling patients when offered a test.

Otherwise I think if there was a media campaign attached to it, it may be much easier to do. ….. there is still very little knowledge around about chlamydia and the lack of symptoms with it, and I suppose it would make it more feasible in general practice if they didn't all look so surprised and you know, blank when you mention something like chlamydia. (Interview 9, GP urban, screened: 35)

Targeting males

While acknowledging difficulties on how best to target men, two providers suggested using the media to target men.

if they think they can go in and get a urine test done, I can't see why men wouldn't go for it an awful lot more… It would be more of an advertisement thing though of course, and the posters would have to show just as many boys as girls like really. Or boy's only posters…. (Interview 5, practice nurse, family planning clinic, screened: 78)

3.7 Interviews with the laboratory team

Increased workload using urine samples: significantly more work was involved in processing urine samples (in comparison to swabs which are routinely processed in the study laboratory). The design and costs of the testing process meant that it was necessary to accumulate a sufficient number of specimens to form a batch for testing, particularly in the early stage of the pilot when recruitment was slow. These specimens had then to be frozen for batch testing. Defrosting these led to increased working time. This impacted significantly on mean turnaround time.

This issue is unlikely to be problematic in the context of a laboratory which is processing urines routinely and is resourced to contribute to an ongoing national screening programme.

Non-clinical PIP screening**:** large numbers of samples were submitted. This combined with other circumstances created pressure on the laboratory performing the testing. This issue would is unlikely to be problematic in the context of a laboratory resourced to contribute to an ongoing national screening programme.

Mislabelling was a problem with some samples. More samples from the non clinical PIP settings had insufficient and/or incorrect details. Resolving these had time implications. Up to 20% of the total sample number would have been discarded if rejection criteria had been followed without efforts to clarify. Sending out results was not a problem for laboratory staff.

4. Discussion

The opportunistic Chlamydia Screening in Ireland Pilot Study that was conducted in the Galway region in 2008-09 built on a body of evidence, which included:

- Qualitative and quantitative interviews on the acceptability of screening, from the perspective of Irish 18-29 year olds in urban and rural settings, and students in two Higher Education Institutions (HEIs) – see *Background Studies: Acceptability and Feasibility of Screening*;
- Qualitative interviews on the views of providers (doctors and nurses in general practice and student health units around the feasibility and design of screening programmes - see *Background Studies: Acceptability and Feasibility of Screening*;
- Lessons learned and materials from an earlier study in HEIs conducted by some of the Galway based-researchers [2] and
- Advice from colleagues of the English National Chlamydia Screening Programme (NCSP), Health Protection Agency, London; and
- Adaptation of materials from the NCSP and the British Association for Sexual Health and HIV (BASHH).

4.1 Study implementation

The results of the background studies, lessons learned from other settings and the participatory approach used by the Research Health Adviser (RHA) meant that the study packs and materials supplied to participating sites (information sheets, forms, questionnaires, and management algorithms) were fit for purpose, both for study implementation and monitoring[6]

The lower than anticipated numbers of young people at the initial nine participating general practices necessitated the recruitment of a further 22 practices. A feature of the implementation, as is commonly found in research pilot studies, was that close support and monitoring as undertaken by the RHA solved early teething problems at participating practices.

The intensity of support reduced over time, as participating practices became more familiar with the protocols. However, the first lesson from the study is the importance of there being a designated trained individual who has overall responsibility for driving and monitoring the implementation of chlamdyia screening and community interventions (including partner notification, retesting and other STI screening), which require different components of the health services to work in a coordinated way.

The post-pilot provider narratives reflected the diversity of participant's experiences and are rich with enthusiasm and interest in exploring the potential of chlamydia

[6] Please see Appendices and website: http://www.hpsc.ie/hpsc/A-Z/HepatitisHIVAIDSandSTIs/SexuallyTransmittedInfections/Chlamydia/Publications/).

screening in Ireland. The challenges, however, that are inherent in offering such a programme resonant strongly throughout the dialogue.

Offer rates

The low offer rates in general practice and in SHUs (less than 0.5 to 9% of those eligible) reflect the time pressures on providers in primary care. Time constraints in busy clinical practices were identified by the providers as a major barrier to effective chlamydia screening and are likely to represent what happens in 'real life'. There was a not unexpected but stark difference between the expectations of much higher rates and the realities in practice. This reality of low coverage is of crucial importance in considering the potential for population health outcomes in terms of reduced transmission and prevalence of *Chlamydia trachomatis* and prevention of PID (*see Economic Evaluation Report*). In common with our pilot, an Australian randomised controlled trial (RCTs) found that the most common barriers to increased chlamydia testing included: lack of time (29/43, 69%) and difficulty remembering to suggest testing to patients (9/43, 21.4%) [10]. The latter finding was also found in our pilot leading to an intervention of computer stickers being used to act as reminders.

The administrative tasks related to our Chlamydia screening pilot were raised by a number of providers. Some of these tasks were related to the research nature of the pilot.

It is likely that financial incentives would have increased offer rates- in our pilot providers only received a payment if they treated a positive case (€25, $AUD33). The need for adequate financial remuneration was a key theme in the provider interviews. In the UK, as part of their chlamydia testing pilot, financial incentives of up to £25 pounds (approximately $AUD50) were offered to practices for the opportunistic chlamydia testing of young women aged 16 to 24 years. General practices had an effective screening rate (ESR) of 46% in the target female population in one of the health authorities [11].

In contrast, with the introduction of the English National Chlamydia Screening Programme (NCSP) in 2003, when financial incentives were discontinued, the ESR initially dropped significantly in general practice to around 10% [12]. However recent NCSP uptake rates (2009/2010) have increased significantly with the proportions tested in 2009/10 were approximately 47% and 25% of sexually active young women and men respectively [13].

In Australia, the aforementioned RCT examined whether offering general practitioners (GP) a small incentive payment per test would increase chlamydia testing in women aged 16 to 24 years, attending general practice [10]. General practice clinics (n = 12) across Victoria, Australia, were cluster randomized to receive either a $AUD5 payment per chlamydia test or no payment for testing 16 to 24 year old women for chlamydia. They found that this small financial incentive alone did not increase chlamydia testing among young women attending general practice. However, two general practitioners dropped out of the non-payment group. The authors considered it possible that small incentive payments in conjunction with reminder and feedback systems may be effective, as may higher financial incentive payments. Our findings indicate more support for the latter suggestion of higher remunerations being necessary.

The interviews with providers indicated that the decision to offer testing was selective rather than random. Tests were more likely to be offered when there was time to give to it (when providers were under less pressure) and when it was considered 'context appropriate'. Offering screening to males was more difficult than to females. Refusal rates were reported to be low (it was not possible to get providers to quantitatively record refusal numbers), which reflects the acceptability of screening. The lower number of screened men, especially in GP settings, may have partly reflected doctors' and nurses' perceived reluctance to offer screening to males. Most providers' perceived male patients would not want an offer of a STI screening during a non sexual health consultation. There may also be a reluctance of men to accept screening.

Males in the target age group were reported to have lower attendance rates however; screening was further hampered by lack of knowledge and fear around invasive testing methods in this group. The use of peer-led screening strategies such as 'pee in the pot' days may prove useful to help tackle the challenge of how best to reach men in this age group for screening. Professional views of patient perception of risk as a barrier to screening recruitment were discussed.

Staff motivation and experience was also an issue during recruitment. Professionals with a background in sexual health appeared better equipped at managing the potential labelling effect and overcoming difficulties in raising the subject in a general consultation.

Screening in clinical and non–clinical settings

In contrast to screening in the clinical settings, where it took nine months to conduct 460 tests across 23 practice settings; the 'pee-in-a-pot' (PIP) events in two non-clinical HEI settings generated 538 samples in 6.5 days in total. Non-clinical PIP screening also yielded 77% (191) of all male specimens in the study. Promoting chlamydia screening to young people in non-clinical settings, where they could discretely and anonymously take a test, was acceptable among male and female students.

The mean number of specimens per practice was higher in urban, group and training practices which is probably a reflection, at least in part, of practice size and patient turnover. In a small number of practices (four), there was highly motivated clinical staff who 'championed' screening with screened numbers greater than twenty. However these sites still had low offer rates.

In general practices, there were more GP screeners (n=19) than practice nurses (n=7) in the pilot. In this type of setting, doctors took the majority of specimens while in FPC and SHUs the majority of specimens were taken by practice nurses. This reflects the nurse-led processes of these sites.

Specimens

Regarding sampling, there was wide acceptance of the non-invasive nature of urine testing with participants and providers expressing support for this method.

The time to take the test varied widely, though with a fairly consistent average time across the three clinical settings: median 5 minutes, range 2-20 minutes. This reflects different clinical consultation styles.

Twenty nine (29.9%) of the cervical swabs processed were taken from participants who were outside the recommended age interval for cervical smears (25- 60 years).

The majority of these were done in general practice. Reasons for having a cervical swab taken may include a request by participants for a cervical smear test or a full STI check-up. While we don't know whether cervical smears were taken in conjunction with these cervical swabs, there may be a training need if cervical smears were taken inappropriately.

Time to results

The time taken to receive results varied in the pilot study with delays experienced by some participants. From interviews with participants this delay in receiving test results caused some anxiety and uncertainty. The delay related to issues specific to the operation of a pilot study that would not apply in a routine service context.

Urine samples were the main specimen type requested during the pilot study, with providers encouraged to take endocervical swabs from women, only where this fitted with the reason for the women's visit (e.g. for a cervical smear test). However, the routine tests for chlamydia in the laboratory used in the pilot study are vaginal, cervical and urethral swabs. Routine clinical specimens are reported within a week of submission in almost all cases. Efficient processing of urine samples within the financial constraints of the study meant that it was necessary to accumulate a sufficient number of urine specimens to form a large enough batch for testing.

The issues in relation to the turnaround time and specimen type for this project are entirely related to the practical difficulties of accommodating the extra work of a once–off research project at the lowest practical cost within a laboratory that was not specifically set up for the purpose and which did not have any spare capacity.

This would not be an issue in the context of an ongoing screening programme with a structured and resourced laboratory service component. In a high throughput national screening programme, economies of scale would allow most specimens to be tested within 2-3 days, which would be more appropriate in terms of clinical management.

4.2 Results of Screening

Sexual Activity Risk factors among screened study population

Risk factor data were only obtained from those screened in clinical settings. Males were significantly more likely than females to have had high numbers of sex partners, a new partner in the last 3 months and more that two partners in the last year. This suggests that while fewer men were screened (12.4% of those screened in clinical settings), those at high risk were screened.

Comparison with the responses to these risk factor questions in the pre-screening survey in primary care settings (see Background Studies*: Acceptability and Feasibility of Screening*) shows that males had a very similar profile: 56.8% (pilot study) versus 55.4% (primary care survey) reporting two or more partners in the previous year. However, the proportion of screened females who reported this risk factor (35.6%) within the screening pilot was somewhat higher than the 25.2% of females in the pre-screening survey. This suggests a slightly higher risk profile for the screened females.

Both sets of clinical setting attendees (male and female primary care survey respondents and screened participants) – were more likely to have 2 or more partner in the previous year (31.9% and 38.4% respectively as a combined sex rate) than the same targeted age group within the Irish Study of Sexual Health and Relationships

(ISSHR) [14] (21.2%) [personal communication with R. Conroy, RCSI]. This suggests that those recruited in clinical settings, whether for a survey of STIs or for a chlamydia screening test, represent a population at somewhat higher risk for STIs than the general population.

This may be because of some degree of pre-selection by health service staff, who may have preferentially selected those they consider more at risk of a STI based on sexual history. It could also be because those who considered themselves more at risk, because of multiple or recent changes of partners, were more likely to accept a screening offer. Other factors could include changing sexual behaviour patterns, compared to approximately six years ago when the ISSHR data were collected.

Positivity rates

This is the first published screening pilot to include primary care settings in Ireland. The overall rate of 4.8% CT positive cases (95% CI 3.5-6.1), 4.8% in females and 5.2% in males, is consistent with, positivity rates in similar screening studies internationally and within Ireland. The positivity rate in the non-clinical PIP setting was lower (3.9%) than in clinical settings (5.9%).

In the English NSCP, overall positivity rates have averaged 7.6% in men and 9.3% in women, based on a total of 370,012 screening tests reported [15]. A systematic review estimated UK prevalence rates of 4-5% for general population women under 20 years and 8-17% in women under 20 attending sexual health services [16]. The authors of the review assumed, in the absence of data, that males had similar rates.

The males attending clinical settings had a statistically significantly higher positivity rate (15.8%), compared to males in non-clinical settings (2.1%). One plausible reason for this finding is that a high proportion of the men screened in the clinical settings recognised themselves to be at risk of an STI with self-selection by service attendees is likely to be plausible. Also, selective screening by providers of males at higher risk may have contributed.

However, these numbers of male positive cases were small (9 from 57 cases in clinical settings, compared to 4 from 191 in non-clinical settings). As the study was not designed as a prevalence study, these chlamydia positivity rates cannot be extrapolated and generalised to any specific population of young men and women in Ireland. What we present are the positivity rates in those who accepted the offer of screening.

With the overall positivity of 4.8%, the positive predictive value of the *Roche Cobas Taqman CT test, v2.0* used in our study is 96%. This is based on a sensitivity of 95.7% and a specificity of 99.8% for urine testing of both sexes: as is reported in the *Roche Cobas Taqman CT test, v2.0 Preparation kit.*

Risk factor associations

Of the two risk factors routinely used as risk indicators, (‘2 or more partners in the last 12 months’ and ‘new sex partner in the last 3 months’) only the former was a potentially useful discriminator between those who tested positive and negative in clinical settings, with a crude odds ratio (OR) of 2.4 (0.9 to 6.6) which is not statistically significant. The English National Chlamydia Screening Programme has reported significant associations with both risk factors in both women and men [15]. Our findings may reflect the lower screening numbers.

Much of the recent literature reviews and randomised controlled trials (RCTs) focus on the importance of high risk groups and the need to target screening and case finding strategies [17;18]. However, there are two important findings which merit further research and discussion on using a risk factor pre-screening approach in Ireland;

1. *many positive cases would be missed*: 23,421 (37% of positive cases) in the English NCSP and 9 of 21 (43%) of positive cases in the Chlamydia Screening in Ireland Pilot Study answered 'no' to the questions 'two or more partners in the previous year'; and 26,206 (41% of) cases in the UK programme and 13 of 21 (57% of) positive cases in this Irish study reported no to 'new sex partner in the past 3 months' [15].
2. *Low acceptability*: the very clear message from young people in the qualitative studies (see *Background Studies: Acceptability and Feasibility of Screening*) was that directly questioning them on their sexual behaviour would deter them from accepting offers of screening.

Only 8% of test positives reported pain passing urine and 4% reported a discharge, suggesting that there is little utility in using symptoms as a predictive indicator of infection. However again these findings are based on low screening numbers and do not reflect the findings of two Irish prevalence studies [2;19]. In one study 9% of the positive cases had suggestive symptoms at the time of the screening, these were not presenting with these, indicating a low level of understanding of potential STI symptoms [2]. While, it is likely that these symptoms were mild and not impacting on the individuals' daily activities this was still worrying as having suggestive symptoms significantly increased the risk of a positive test.

4.3 Management of cases

4.3.1 Treatment

Almost all positive cases received their treatment in primary care settings, suggesting that treatment of chlamydia in primary care is acceptable and feasible for both providers and participants. The treatment protocols and standard operating procedures used during the pilot worked well for providers.

4.3.2 Retesting

Two thirds (66.6 %) of those screened in clinical settings returned for a retest to these settings. This compares well the Netherlands Chlamydia screening programme where 68% of those who were positive did participate when they automatically received a re-screening invitation 6 months later [20]. However none of the PIP participants returned for retests to the GUM clinic. Urine testing was not available in the student health units at the time, thus retesting at the GUM clinic (which involved an invasive test) may have deterred participants for attending.

All those tested had negative results. This is surprising based on recent findings from studies in other countries such as the Netherlands which has reported, a high re-infection rate of 8.2% [20]. However in this Irish pilot only 50% of positive cases were retested.

4.3.3 STI Screening

Just under half of the positive cases (n=25, 52.1%) had further screening for STIs, all known results were negative. Most providers reported not having the resources to offer comprehensive STI services and preferred to refer participants to the GUM clinic. However, providers expressed interest in availing of further training in management of STIs and partner notification. Provider interviews showed varied approaches and practices in the management of STIs in primary care, suggesting the need for standardized practices, supports and guidelines. The full range of laboratory tests for STIs is not uniformly available in Ireland- these should be standardised.

4.3.4 Partner notification

The majority of providers had concerns about partner notification in primary care and viewed this as labour intensive and not feasible. During the pilot most were happy to refer CT positive cases for partner notification and follow-ups to the RHA, and providers reported in post pilot interviews that this approach had worked well.

Based on this pilot study, it would appear that partner notification is not feasible in primary care settings in Ireland, except through the provision of additional resources, such as a community based health adviser.

In 2001/2002 a randomised controlled trial in England compared the effectiveness of, and resources used by, two strategies for managing cases of chlamydia diagnosed in primary care: (i) partner notification by trained practice nurses at the time of diagnosis, with telephone follow up by health advisers; and (ii) referral to a specialist health adviser at a genitourinary medicine clinic [21]. The trial was part of the chlamydia screening studies project (ClaSS), a population based study in which men and women, selected at random from the lists of general practices in parts of England, were invited to provide a home collected urine sample or vulval swab specimen, or both, for testing for *Chlamydia trachomatis*. The research health adviser visited each practice at the start, was available during the trial by telephone or in person, and carried out telephone follow up.

The ClaSS trial found that people diagnosed with chlamydia infection in primary care settings can be managed there by trained staff who are supported by sexual health advisers. These trained practice nurses carried out partner notification that is at least as effective as referral to a specialist health adviser and the practice nurse led strategy costs no more than referral to a specialist health adviser. Their qualitative research showed that patients also preferred this strategy to clinic referral (a third of those referred for specialist partner notification did not attend the genitourinary medicine clinic).

Comparing the ClaSS outcomes to our Irish pilot, show differences, which correspond with the organisation of primary care services in England and Ireland: the practice nurses in the English ClaSS study (with support from the RHA) were successful and participated fully in partner notification [21]. In contrast, the RHA was the main provider of the partner notification in the Irish study, which probably partly reflects the lesser level of practice nurse support in Irish GP practices.

Partner notification by telephone worked well during the pilot with patients satisfied with the service, as reported in the post-pilot qualitative interviews with participants. A confirmed partner treatment rate of 0.5 contacts per index case was recorded. This

compares well with the target set by the NCSP of 0.6 and reflects the success of the partner notification model used in the pilot study.

The use of community contact cards was not successful: the ClaSS study also found that contact slips were not useful for ascertaining contact treatment [21].

4.3.5 Developments in the field of chlamydia screening

Several important papers have been published since the *Research into the Optimal Setting for Chlamydia Screening in Ireland Pilot Study* was commissioned by the Health Protection Surveillance Centre in late 2006. Two reviews of chlamydia screening studies [22;23] have concluded that the evidence is not yet sufficient to justify opportunistic or systematic chlamydia screening approaches. Optimism about the potential of opportunistic chlamydia screening to prevent serious morbidity (chiefly pelvic inflammatory disease [PID] in women) has been tempered. Estimates suggest that only 30% of PID is attributed to chlamydia [22].

The results of the recent randomised control trial (RCT) of screening among students in London showed that most episodes of PID (30 of 38) were in women who tested negative for chlamydia at the start of the 12 month trial [18]. This concluded that "Policy makers might consider focusing on more frequent testing of those at higher risk, such as women with a new sexual partner or a recent history of chlamydial infection".

Mathematical models have estimated that coverage of 26-43% (of the total target population of under 20 years olds or 16-24 year olds, not just of those attending general practices) would be needed to reduce chlamydia prevalence rates by 30% after one year [24;25]. Coverage rates of less than 10% of eligible attendees were estimated for practices in the Chlamydia screening in Ireland pilot study, i.e. those practices that had sufficient interest and enthusiasm to participate.

Similarly low rates (4.9%) of uptake of screening in the target population of 16-24 year olds were initially achieved across three phases of the English National Chlamydia Screening Programme [15] and "in contrast to predicted uptake of 50%, only 2.5% of 16 to 24 year olds were screened" over the course of one year [22]. However as aforementioned uptake has increased significantly as reported in a more recent report (25), with recent NCSP coverage rates (2009/2010) of approximately 47% and 25% of sexually active young women and men respectively [15].

The appropriateness of chlamydia screening in Ireland will need to be reappraised as new evidence becomes available. There are two current trials of both systematic and opportunistic chlamydia screening in the Netherlands [20] and Australia [26]; both involve multiple screening rounds and will provide essential information about the effectiveness of chlamydia screening.

The Netherlands model is a systematic register based chamydia screening programme started in April 2008. Letters are sent annually to all 16 to 29-year-old residents of specific cities and selected municipalities. The letters invite sexually active persons to login to http://www.chlamydiatest.nl with a personal code and to request a test kit. In a lower prevalence area, test kits can only be requested if the internet-based risk assessment exceeds a predefined value. The overall participation rate for the first screening round was 16%.

The Australian Chlamydia Control Effectiveness Pilot (ACCEPt) is a cluster randomised trial with the aim of determining whether annual recall for 16-29 year old women and men attending practices can increase chlamydia screening to levels that are high enough to reduce its prevalence in this population [27].

A useful starting point for Irish policy makers and programme planners when considering the results of the Chlamydia Screening in Ireland Pilot Study is the European Centre for Disease Control's guidance document on Chlamydia control in Europe [28], which has outlined a chlamydia control framework with four levels:

Level A *primary prevention*: health promotion, school programmes and condom distribution

Level B *case management*: surveillance, diagnostic services, clinical services, and patient and partner management services

Level C *opportunistic testing*: offering chlamydia tests to people attending clinical settings for other reasons, so as to identify and treat asymptomatic cases

Level D *screening programme*: "This build on Level C with the addition of the organised provision of regular chlamydia testing to cover a substantial proportion of a defined population, with the aim of reducing chlamydia prevalence in the population".

The report states that decisions on moving from one level of control to the next should be based on "a rigorous appraisal of the evidence for effectiveness, cost-effectiveness and harms".

5. Conclusions

The Chlamydia Screening in Ireland Pilot Study has demonstrated that ***chlamydia screening and provider initiated testing is acceptable to young people when they attend a range of clinical services*** – general practices, family planning clinics and student health services. The study has also demonstrated substantial challenges for primary care providers. ***Feasibility for providers would depend on addressing a number of factors*** as described below.

- Urine testing should be available to all clinical settings.
- Provider training in sexual health is essential.
- Partner notification would be optimally managed by designated health advisers, who could be given a geographical (e.g. a regional) responsibility.
- Well designed incentives (training and supports for partner management are as important as money) are necessary, enabling practices to offer screening.
- Offering a STI test to an asymptomatic (but at-risk) patient involves significant costs. These have to be borne by one or more of the following:
    - *the patient* – those most at risk (16-24 year olds in the international literature) are least able to pay, especially in the economic climate of 2010-11
    - *the provider*– the major costs for diagnosis (laboratory test) and treatment (antibiotics) cannot be covered by the provider
    - *The state* – detection and treatment of chlamydia is a public as well as a private good. Chlamydia notifications are growing rapidly. However the economic analysis illustrates a high cost per QALY (€94,717) which is unlikely to be considered as cost-effective by government decision makers.
- The decision to offer screening is influenced by both the context of the patient's consultation and the provider's perceptions of patient's willingness to accept.

Given the shift back to the importance of identifying and testing those at higher risk of chlamydia infection – but noting the contra-arguments (both epidemiological and sociological) to a risk factor pre-screening approach in Irish settings–there appears to be a strong case for approaches that combine demand-side (patient) with supply-side (provider) interventions. These would focus on:

- ***Demand-side***: health promotion focusing on *primary prevention* (including regular use of condoms) and *secondary prevention* (getting tested after casual unprotected sex or when forming a new sexual partnership).
- ***Supply side***: enabling men and women get tested in a range of primary care settings, where providers have been trained and enabled to maximise acceptability and avoid contributing to stigma effects on young people.

Chlamydia screening is acceptable to young people in non-clinical settings, as part of sexual health awareness activities in Higher Education Institutes (HEIs). It is also

more cost effective than screening in clinical settings (€34,486 per QALY gained). Given the experience of the Chlamydia Screening in Ireland Pilot Study, where large numbers of young people were quickly, easily and unobtrusively screened during such an event, the potential for extending this model of screening into other non-clinical and clinical settings is an area for exploration. However, as noted in the Economic evaluation, 'pee-in-a-pot' screening has lower coverage in the target population than the base-case strategy (primary care settings) and is less effective in identifying infection and reducing overall prevalence levels.

Of interest, the recent analysis of NCSP data by Johnson *et al* found that the greatest proportion of male tests were in university (27%) but this only identified 11% of total male positives [29]. More chlamydia-positive males were diagnosed through healthcare services despite fewer numbers of tests. Johnson *et al*. thus advised the future prioritisation in UK of increasing male testing in healthcare settings.

5.1 Limitations

The major and unavoidable limitation of this study was that only 18-29 year olds were included in the screening pilot. The age restriction, which prevented us screening 16 and 17 year olds, was dictated by legal advice, which precluded research on under 18 year olds without parental permission.

A further limitation is that the study was conducted in urban and rural settings in the Galway region which may not be representative of all parts of Ireland. Positivity rates from various countries including Ireland [30;31] have reported higher chlamydia notification rates in urban working class settings. Of note, these rates included symptomatic and asymptomatic cases and are not prevalence rates. These limitations highlight the need for further prevalence studies in a range of age groups, geographical and socio-economic settings.

Interviews with health care providers and screened participants may have been subject to selection bias, whereby those with more negative views or experiences on testing or on the pilot may not have consented or volunteered to be interviewed.

Vulvo-vaginal swabs were not used in this study because of validation concerns at the time of planning. However this method has equivalent sensitivity to cervical swabs and thus should be considered for acceptability testing in any future screening work.

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Appendices

Appendix A. Patient information leaflet on chlamydia screening

You are invited to take part in a research project on Chlamydia. We are offering both men and women the opportunity to take a free test. The Doctor or Nurse will ask you to provide a urine sample in a pot.
The project is *aimed at men and women aged 18-29 years who have had sex in the last year.*



The purpose of the study is to find out the best settings for Chlamydia screening services for young people.

What is Chlamydia?

Chlamydia is a sexually transmitted infection (STI) caused by bacteria called *Chlamydia trachomatis*. Both men and women can get Chlamydia. The infection is transmitted mainly through unprotected sex, that is, not using a condom. It can be treated with antibiotics.

You may not know you have it!

- Most people do not know they have Chlamydia as often there are no obvious signs or symptoms.
- If there are symptoms they usually show up in 1-3 weeks after someone has contracted Chlamydia.
- Symptoms in men and women can include unusual discharge and abdominal pain.

How serious is it?

Chlamydia, if left untreated can cause long-term health problems. For women, it can cause infertility (not being able to become pregnant), damage to the reproductive organs and problems during pregnancy.

How is Chlamydia diagnosed?

- The test for Chlamydia is a simple urine test.
- It is totally voluntary, you don't have to have one if you don't want to.
- To get tested the Doctor or Nurse will ask you to provide a urine (pee) sample. It is important not to have urinated for 2 hours before taking the test.

Women can also take a swab from their lower vagina themselves. A cotton bud is used to wipe the area. This is not like a smear test. The Doctor or Nurse will give you instructions on how to do it.

Another option is when having a smear test she can also get tested for Chlamydia at the same time. The test will then be sent to the laboratory and the Doctor will receive your results. With your permission, results will be shared with the research team but all information is coded and confidential.

What happens if I have Chlamydia?

- If you test positive for Chlamydia you will be asked to come back and see the Doctor for treatment and follow up.
- Chlamydia is easy to treat with antibiotics prescribed by a Doctor.
- If you think you may be pregnant or if you are on hormonal contraception, it is important to tell the Doctor or Nurse.

Telling your Partner

If you test positive for Chlamydia it is important to tell your previous/current sexual partner(s) as they may have it too.

If you have any further questions, please ask the Nurse or Doctor. You can also arrange to talk to the Research Health Advisor. If you would like to participate and be tested please tell your Doctor or Nurse.

Thank you for your time.

For more information on this research study please contact:
Dee Vaughan
Chlamydia Research Health Advisor

Mobile : 087 7413813
Phone: 091 493490
E-mail: deirdre.vaughan@nuigalway.ie

Appendix B. 3DWLHQW LQIRUPDWLRQ KDQGRXW WR receiving your result¶

A Positive Result for Chlamydia?



You have tested positive for Chlamydia which is a sexually transmitted Infection (STI) caused by bacteria. Chlamydia is easy to treat, you will be given antibiotics by your Doctor. It is important that you take the treatment as soon as possible to prevent further complications.
If you think you could be pregnant, please tell the Doctor or Nurse now.

How serious is it ?

If it is not treated Chlamydia can cause long term health problems in some people, especially women. It can lead to permanent damage that could cause infertility or problems during pregnancy. In both men and women Chlamydia may cause abdominal pain.

How does it occur and why?

Chlamydia is transmitted from one partner to another during sexual intercourse. The risk of catching Chlamydia increases with the number of sexual partners.

Why do I need to tell my sexual partner(s)?

Chlamydia is passed on very easily. If a person is infected, it is highly likely that their sexual partner(s) may become infected. It is very important that all sexual partners in the last 6 months are contacted and encouraged to go for testing.

If you do not tell your partner(s) there could be long term consequences for their health.

If you decide to tell your previous partner(s) yourself, the Doctor or Nurse will give you a referral letter or a contact card for them. Alternatively, it can be arranged that the Doctor or Nurse can contact your partner(s) discreetly with your permission.

Your details will not be mentioned. You can also arrange to talk to the Research Health Advisor.

How can I protect myself in the future?

- Using a condom every time you have sex can prevent Chlamydia and other STIs, including HIV.
- Being on the contraceptive pill does **not** protect you from STIs.
- You should not have sex for at least 7 days after treatment and/or until your current sexual partner(s) is treated.
- It is important to have a check-up for other STI's.
- You should be re-tested for Chlamydia in 3 months time.

Thank you for your time.

For more information on this research study please contact:
Dee Vaughan

Mobile:087 7413813
Phone: 091 493490
E-mail: deirdre.vaughan@nuigalway.ie

Appendix C. Chlamydia Request form

Chlamydia Screen form

Section 1. Staff & Patient to complete ***Clinicans Copy***

Site code/ Pt. ID ☐☐☐☐ / ☐☐☐☐

Surname ☐☐☐☐☐☐☐☐☐☐☐☐ Forename ☐☐☐☐☐☐☐☐☐☐☐☐

Specimen taker: GP ☐ Nurse ☐ Patient☐

Reason for test: Screen ☐ Contact ☐

Specimen type: Urine ☐ cervical swab☐ vulva-vaginal swab☐

Sex: M☐ F☐

Staff: **Please estimate all the time taken to complete the screening test process.** ☐☐ **minutes.**

How would you like to receive your results? Please tick your preference

Negative Result		**Positive Result/ Appointment**	
Phone call	☐	Phone call /appointment	☐
Text message (if available)	☐	Letter/appointment	☐
Call back	☐		

Mobile phone no. ☐☐☐☐☐☐☐☐☐☐ Landline ☐☐☐☐☐☐☐☐☐☐

Address for correspondence with letter ***only*** ☐☐☐☐☐☐☐☐☐☐☐☐

Appendix D. Patient form for risk factors

Patient Card ***Patient to complete***

Instruction

Please answer the questions below.

All information is anonymous.

Site Code/ Pt. ID [/]

Date of Birth ☐☐/☐☐/☐☐☐☐

Country of birth ☐☐☐☐☐☐☐☐☐☐☐☐

Sexual History

How many sexual partners have you had? ☐☐☐

Have you had sex with a new partner in the last 3 months?

Yes ☐ No☐

Have you had sex with 2 or more different partners in the last 12 months?

Yes ☐ No☐

Please tick if you have had any of the following symptoms in the last week?

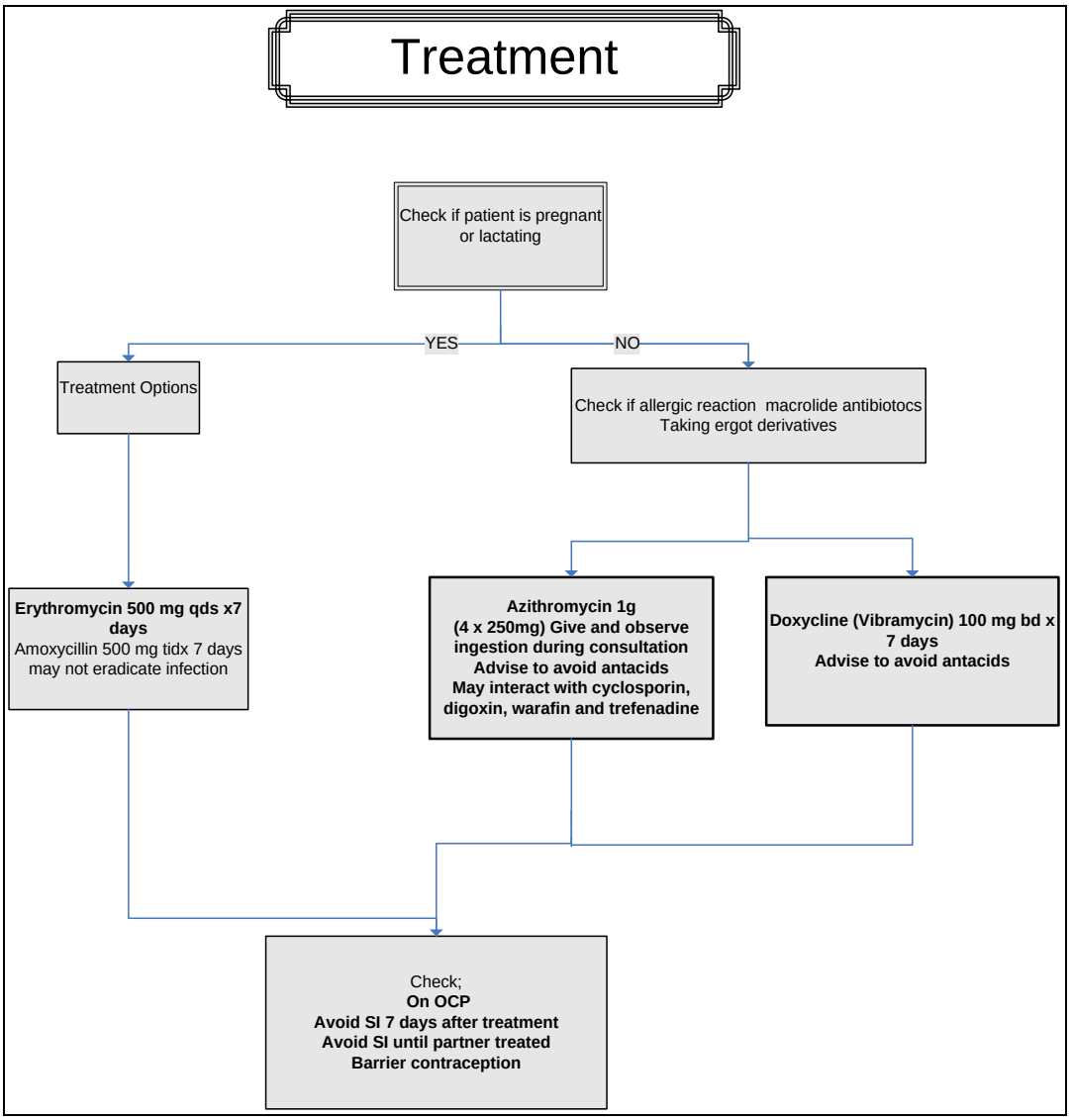
Pain on passing urine ☐

Unusual discharge ☐

Please place in envelope provided

Thank you

Appendix E. Sample of Treatment protocol used



Appendix F. Community Contact card used for study

Back

Dear Staff/GP,

If you have received this card from a patient please call 087 7413813.

This is part of a research study.

Thank you.

Galway STI Clinic 091 525200

Monday 2pm-5pm (appoint. only)

ont of card



Contact Card

CODE:

Contact details:

STI Clinic: 091 525200

Research Healtl
Adviser:087 7413813

Community Contact Card

You may have been exposed to an infection called Chlamydia. This is easily treated with antibiotics. Please seek treatment and bring this card with you.

Appendix G. Protocol for RHA phone calls

Protocol for Retest Phone call

Code: ___ /_____ Date:

1. Establish any new risk factors? ☐
   (unprotected sex with a existing partner or change of partner)

2. Did the patient attend for further STI screening.
   If so, results? ☐

3. Reinforce health education: ☐
   - Barrier protection
   - Risk of PID with repeat infections

4. Enquire about contacts (testing and treatment) ☐

5. Long term advice for retesting ☐

(Yearly checks for male & female /change of partner)

6. Ask about interest in doing an interview ☐

Appendix H. Partner notification Outcome form and guidelines

Partner Notification Form

INDEX CASE Site / Pt. ID: _____ /_____ Contact cards given_____

Phone no._____ Date of positive result:_____

Partner in last 6 months

Regular partner: Yes☐ How long_____ No☐

Last sexual intercourse: When_____

Number of sexual partners in last 6 months_____

Communication & Date:

_____

_____

_____

_____

_____

_____

Partner 1

First name: Phone no. _____

When_____ Condoms: Never ☐ Occasionally ☐ Always ☐

Patient referral ☐ Health Adviser referral ☐ or Provider referral☐

Contacts cards given: ☐☐

Communication & Date:

Outcome:

Tested & treated ☐ Refused treatment ☐ Did not attend ☐

Treated only ☐ Unable to contact ☐ Other, please specify ☐

Partner 2

First name: Phone no. _____

When_____ Condoms: Never ☐ Occasionally ☐ Always ☐

Patient referral ☐ Health Adviser referral ☐ or Provider referral☐

Contacts cards given: ☐☐

Communication & Date:

Outcome:

Tested & treated ☐ Refused treatment ☐ Did not attend ☐

Treated only ☐ Unable to contact ☐ Other, please specify ☐

Standards for good practice in partner notification

- Partner notification (PN) should take place face to face and with the time and privacy necessary to discuss the issue.
- Staff should explain that questions on sexual history are standard questions for every patient to establish who else might be at risk of chlamydia.
- Permission should be sought if being referred to the research health adviser.
- Reasons for non-referral are documented.
- Provider referral is offered to all patients who may have difficulties notifying partners.
- When discussing PN and follow up by phone check that the patient is in a position to have a private conversation, if not find out when it is convenient.

Standard Questions to assess partner risk

The following questions will be used to identify the risk of chlamydia to other sexual partners:

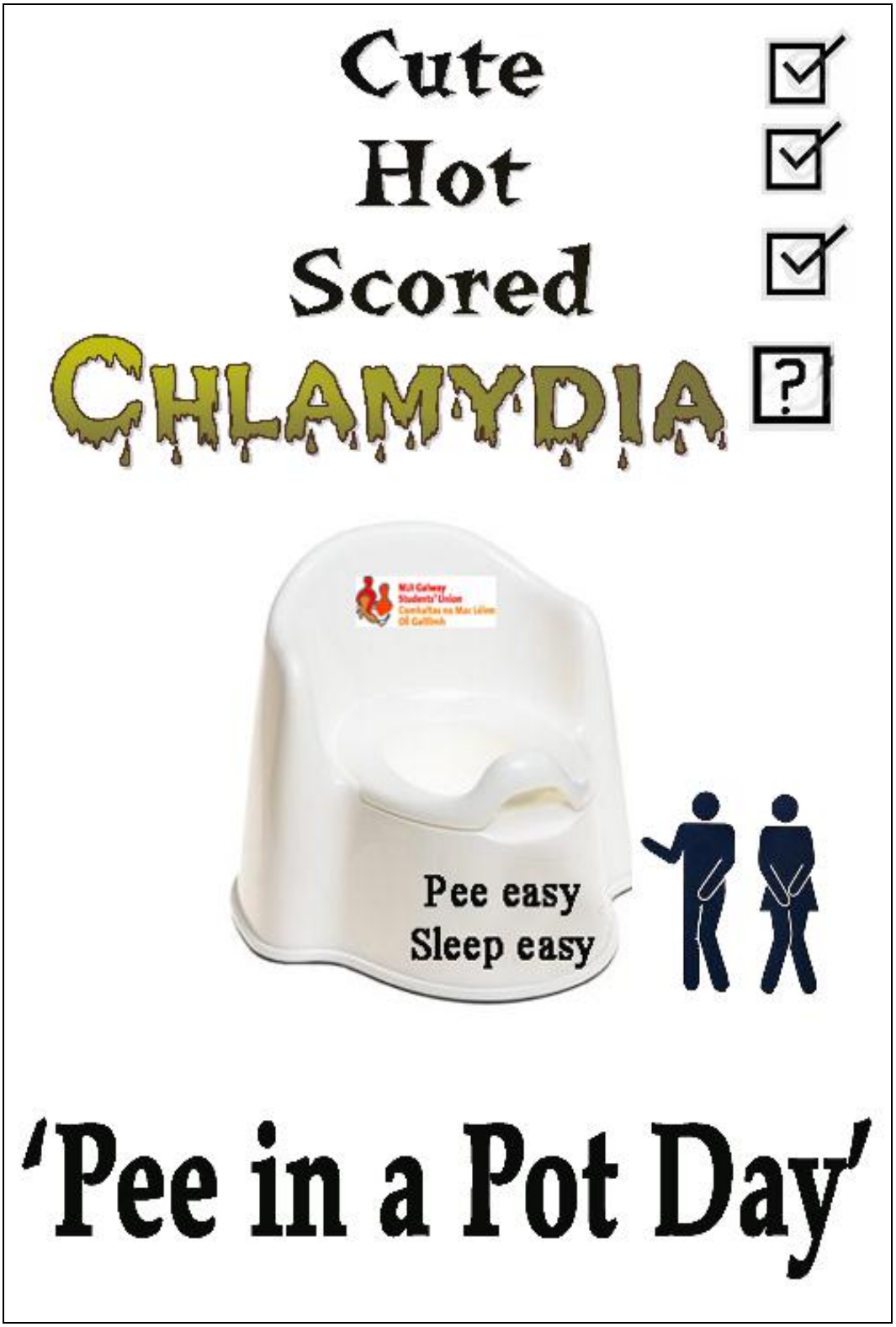
Recent intercourse: When was the last time you had sexual intercourse?

Number of partners: How many partners have you had in the last 6 months

Precaution: Were condoms used? (regularly, never, occasionally)

The outcome of PN should be followed up until partner attendance has been verified, if possible. This may be easier to do by telephone.

Appendix I. Winning poster for SHH -in-a-SRWTcampaign competition



Appendix J. Testing pack for pee in pot days

PEE EASY SLEEP EASY

PEE IN A POT at GMIT 2009



FREE ANNOYMOUS

CONFIDENTIAL TESTING

FOR 18-29YRS.

KEEP THIS CARD

You are invited to take a FREE ANONYMOUS Chlamydia test by simply PEEING IN THE POT!

All you have to do is :
Fill in the sticker on the pot clearly with your

- DATE OF BIRTH
- MOBILE NUMBER
- TICK THE RELEVANT BOX:

For further instruction, please TURN OVER...

CODE: 34/

INSTRUCTIONS:

- Fill in your STICKER ON THE POT.
- Now Pee in the Pot (at least half way) close lid tightly
- Place pot in bag provided and seal bag securely.
- KEEP THIS CARD WITH YOU as you will be asked to quote the code and your D.O.B for your result. Your results will only be discussed with you.
- Drop your pot in designated toilets around campus or at the Student Health.

RESULTS

- If your test is negative you will receive a text message saying "*Your recent test result is negative. Thank you for taking part in this study*".
- If your test is positive you will receive a phone call asking you to make an appointment for treatment.
- Treatment for Chlamydia is a simple course of antibiotics.

For further information on where you can get a free test contact: Dee 0877413813

Appendix K. Image of t-shirts for peer volunteers



Appendix L. Topic guide for interviews with screened persons

Topic guide for positive patient interviews: screening experience

Offering of test

- Can you tell me about your initial response on being offered Chlamydia testing?
- Who asked you if you wanted to take the test?
    - What did you think of how they offered the test?
- How was the test offered? (explore timing, setting, appropriateness/ gender/age)/check covered how test went?
    - Were you given any information about Chlamydia testing, if so, what did you think of this information?
    - Thinking back to when you took the test, what came to mind about Chlamydia?

  If at home probe;
        - For whether they kept the test private.
        - How convenient it was to drop the test back
        - How test was returned/feelings about this method [handing into receptionist].

Decision

- Why did you decide to accept the test (explore feelings/concerns/other factors)?
- Did you consider refusing and why?

Waiting period

- How did you feel waiting for your results? Or can you describe waiting for your result?
    - Did you have any expectation of the result?
- While you were waiting for your results did you tell anyone that you had taken the test [If no: explore why. If yes: explore who was informed]?

Notification

- Could you describe to me the experience of getting the results?
    - (how did you receive your results and by whom?)
    - (how did you feel about that?)

- What was your reaction to receiving a positive result? / explore feelings)
- What was your experience of the treatment/counselling given?
- Do you feel you were prepared for you positive result? (if not, what could have been dine to prepare you more?)
- (Thinking back can you remember what advice you received?)

Partner notification

- Did a HCW talk to you about informing your previous and current partners?(setting or Dee / telephone advice given)
- What did your think of the information (if any) you were given and of the advice?
- Was it helpful to you?
- Were you given contact cards (explain/ did you use them? Do you know if your partners used them?
- Who told your previous /current partner(s)?
- How did you feel about contacting your partners and the reactions of partner(s) (if relevant)
- Did you feel supported? Any suggestions on how else it could be done?

Other STI testing

- Did you get tested for other STI's?
- Where? What was your experience of getting tested? (logistics) What did you like to dislike of he experience
- Did you have any expectation of the STI clinic?

Retesting

- Have you done another test for Chlamydia and can you tell me about this?(logistics, feelings)
- How did you feel about your retest result?

Impact of positive result

- What difference if any, has knowing you have had Chlamydia made?
- Did you tell anyone about your result other than your partner [who/for what reasons?]

- What are your feelings now about deciding to be screened? (explore regret etc.)
- Would you take the test again?

Summary

- On a future screening process, do you have any further advice for us?
- Was there anything you would like to discuss?