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

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CHLAMYDIA SCREENING IN IRELAND

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

SUMMARY INTEGRATED REPORT

REPORT PREPARED BY CHLAMYDIA SCREENING STEERING GROUP

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

Integrated Report and Website

This integrated report summarises the Chlamydia Screening in Ireland Pilot Study conducted between 2007 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. Background Studies: Acceptability and Feasibility of Screening

Chlamydia Screening in Ireland Pilot Study. Screening Report

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 Glossary

BASHH	British Association for Sexual Health and HIV
CI	confidence interval: the likely range of the true value
CT	*Chlamydia trachomatis*
FPC	family planning clinic
GP	general practice/practitioner
GUM	genito-urinary medicine
HIV	human immunodeficiency virus
HPSC	Health Protection Surveillance Centre
HRB	Health Research Board
HSE	Health Service Executive
ICER	incremental cost-effectiveness ratio
MOA	major outcomes averted
NCSP	National Chlamydia Screening Programme
NUI Galway	National University of Ireland Galway
PID	pelvic inflammatory disease
PIP	'Pee-in-a-pot'
PCR	polymerase chain reaction
QALY	quality adjusted life year
RCSI	Royal College of Surgeons in Ireland
RHA	Research Health Adviser
SHU	student health unit
STI	sexually transmitted infection

Index case: The first documented case of a disease in a group or population

Odds ratio: The comparison of the chance of an event occurring in one group to the chance of it occurring in another group. The odds ratio is a measure of effect size.

Sensitivity analysis: The effects of model uncertainty and parameter uncertainty on the outcome of the economic evaluation are systematically evaluated using sensitivity analyses. *One-way sensitivity analysis* is conducted by specifying a range of plausible values for key model assumptions, and re-estimating the cost-effectiveness results for each plausible value. *Probabilistic sensitivity analysis* is used to assess uncertainty surrounding input parameters used in a model. Each input parameter is specified a probability distribution. A Monte Carlo simulation process simultaneously generates a random value for each parameter from its probability distribution, and the cost-effectiveness results are re-estimated. This process is repeated many times to generate an empirical distribution of the cost-effectiveness results. These data can be used to plot cost-effectiveness acceptability curves which estimate the probability that a treatment option is cost effective relative to some comparator.

Executive Summary

Findings

1. 18–29-year-old women and men in Ireland expressed strong preferences for:
   (a) the availability of a range of clinical settings where health-care providers (doctors and nurses) would offer and provide tests for detecting sexually transmitted infections (STIs)
   (b) settings and providers that would not stigmatise them if they accepted an STI test
   (c) the normalisation of STI services so that STI consultations are seen to be like any other health check up and 'a good thing to do'
   (d) discretion and confidentiality
   (e) STI services that are affordable and preferably free.
2. Opportunistic screening using urine testing to detect chlamydia in clinical settings (general practice, student health units and family planning clinics) and non-clinical settings ('pee-in-a-pot' screening in higher education institutions) is acceptable to 18–29 year old men and women.
3. Opportunistic screening in clinical settings would be acceptable to doctors and nurses if appropriately resourced:
   (a) Enabling factors in this study were the availability of urine tests and the support of the Research Health Adviser, especially for partner notification.
   (b) Significant obstacles for providers included the lack of payment, time pressures and difficulties raising the issue of STIs, especially with young men, if unrelated to the presenting complaint.
4. The numbers screened in clinical settings were low, reflecting low screening offer rates. Refusal rates were also low.
5. The chlamydia positivity rate was 4.8% (48 cases detected in 998 persons screened). This is similar to rates reported in international and other Irish studies. As the study was not designed as a prevalence study, these chlamydia positivity rates are not prevalence rates that can be extrapolated and generalised to any specific population of young people in Ireland.
6. In this study population sexual behavioural risk factors (recent or multiple partners) were not useful indicators or predictors of chlamydia infection. Targeted screening based on risk factors has been used in other settings. Our findings, while not out-ruling, do not support this approach.
7. Pee-in-the-pot (PIP) screening in non-clinical settings in two higher education institutions (HEIs) was popular and readily used by young people due to the combination of private, anonymous and accessible testing.
8. Urine specimens were tested in batches at the regional hospital microbiology laboratory to manage workload and contain costs. This delayed the turnaround time for results, which would not be expected to occur in a scaled-up programme.
9. Management of chlamydia positive cases was successful:

(a) Most chlamydia positive cases identified were treated in the screening settings rather than in a genito-urinary medicine (GUM) specialist clinic setting. Half of these cases had further STI screening tests, all of which were negative.

(b) Partner notification was successfully achieved in 82% of reported partners of test positive cases. This was principally led by an experienced health adviser, who was also the screening research coordinator. The verified screening rate for partners was 0.3 per index case and the verified treatment rate was 0.5 per index case, which are comparable with international rates.

(c) Most of the cases detected in the clinical settings were retested for chlamydia three to six months later: all were negative.

10. Opportunistic screening for chlamydia, based on the results of this pilot study, is unlikely to be considered to be cost effective where proposed Irish cut-off thresholds or norms for cost effectiveness are used:

(a) Chlamydia screening costs were €26 per chlamydia test offer, €66 per negative case, €152 per positive case detected and treated, and €74 per partner notified and treated. The cost-effectiveness analysis estimated an incremental cost per quality adjusted life year (QALY) gained of €94,717 for the clinical settings combined (general practice where both a doctor and nurse were offering screening, student health units and family planning clinic). While no single cost-effectiveness threshold value has been agreed for health technology assessment in Ireland, it is highly unlikely that such screening would be considered cost effective.

(b) Nurse-led screening within general practice was less costly than doctor-led (general practitioner) screening. However, neither strategy is likely to be considered cost effective at €62,603 and €113,523 per QALY, respectively.

(c) Sensitivity analyses and estimates for other settings were conducted. A lower offer rate of 5% reduced the cost per QALY gained to €69,991. Nurse-led screening outside general practice settings was more cost effective: €46,618 in student health units, €39,185 in family planning clinics and €34,486 per QALY in the student PIP setting. Screening in these settings, however, is less effective in identifying infection and reducing overall prevalence levels.

Implications for chlamydia screening policy and practice

1. There is not sufficient justification, at this time and given current evidence, for an Irish national opportunistic screening programme for chlamydia targeting all 18–29 year olds because:

(a) Recent large-scale trials from other national settings and international reviews have cast serious doubt on the potential of such programmes to (i) prevent pelvic inflammatory disease or (ii) achieve sufficient coverage in the target population to reduce population chlamydia prevalence, which is a key component of cost-effectiveness models.

(b) The Chlamydia Screening in Ireland Pilot Study achieved low coverage levels in clinical settings (general practice, family planning clinic, student health unit), and would have limited feasibility in these settings without significant investment. This investment would need to include financial incentives and training for general practice staff and support via a community sexual health adviser.

2. Opportunistic screening in GP settings is not cost effective, based on the cost effectiveness and sensitivity analyses conducted in this pilot screening study. Opportunistic screening in other clinical and in non-clinical settings could be judged cost effective, if policy makers considered a cost-effectiveness threshold of €45,000 per QALY or higher to be appropriate. However, this is unlikely to be the case in the current economic climate.
3. Laboratory requirements for chlamydia testing include:
   (a) resources (including trained staff and adequate automated equipment) and a high level of organisation.
   (b) strict labelling requirements with a policy of rejection for inadequately labelled specimens.
   (c) a high throughput service based on a limited number of (possibly regional) laboratories using an automated and uniform testing methodology, each dealing with a high volume of specimens. The ideal system would process samples on the day that they arrive (thus avoiding time lags with freezing and defrosting). The cost per test might be lower with such arrangements, but only if there is high volume testing.

Implications for sexual health policy and practice

1. A national action plan to promote sexual health and safer sexual practices is required. This was described in the Health Strategy of 2001 *Quality and Fairness. A Health System for You* (Department of Health and Children). This action plan should include actions for the control of chlamydia and other STIs. In line with the recent European Centre for Disease Prevention and Control (ECDC) guidance document on chlamydia control in Europe [1], a step-by-step or 'building blocks' approach to STI control in Ireland should focus on:
   (a) *Primary prevention* (Level A): health promotion, school programmes and condom distribution.
   (b) *Case management* (Level B) '*supply side*' interventions: surveillance, diagnostic services, clinical STI treatment and follow-up, and partner notification services.
   (c) *Case management* (Level B) '*demand-side*' interventions: to emphasise to young women and men that chlamydia can be detected by a simple screening test of a person's urine. A demand-side intervention, which could increase health seeking for STI testing, needs to be preceded by and matched with the establishment and easy accessibility of STI case management services.
2. The findings on opportunistic chlamydia screening do not point to a clear set of programmatic recommendations for scaling-up chlamydia screening. However, the Chlamydia Screening in Ireland Pilot Study has demonstrated both a need and demand from 18–29 year old Irish women and men for acceptable and accessible sexual health services, which include STI testing services.
3. Three components of the screening model were particularly popular among providers and young people and would be key to increasing the population coverage of STI case management and prevention:
   (a) easy access for providers to free urine-based testing for chlamydia
   (b) free STI treatment

(c) a health adviser to support primary care providers in following up cases and partners and ensuring that all STI control programme objectives are achieved.

4. Measures to strengthen case management services include:

   (a) Support existing primary care providers – GP, family planning, student health and other clinical services for young people – some of which are already providing comprehensive sexual health and family planning services for women and men.

   (b) Primary care providers should be funded to undertake training in the delivery of sexual and reproductive health services, including how to respond to young people's concerns about their sexual health and how to conduct partner notification.

   (c) Identify geographical areas and other target population gaps, for example rural settings, where there may be limited access to comprehensive sexual health services to young women and men and consider steps for meeting this need.

5. Control of chlamydia and other STIs is a public as well as a private good. The prevention of transmission benefits the entire population:

   (a) Testing, treatment and partner notification of STIs should be free at the point of delivery in general practice and other primary care settings, as is currently the case in Health Service Executive-funded GUM clinics.

   (b) Health advisers are required, to be available on a population basis, to support primary care providers in providing free STI services.

Further evidence needed

1. Before future decisions are made on opportunistic screening, further evidence is needed from research studies in Irish settings and from findings in comparable non-Irish settings, including:

   (a) chlamydia prevalence and risk factor studies in males and females in the age group 16–29 years, where the highest prevalences have been reported internationally. Clarification is needed on the legality of doing such studies in 16 and 17 year olds without parental permission. This requires joined-up government responses (including the Department of Justice and Equality and the Department of Health and Children) and policy guidance so that this highly vulnerable, high priority group is not neglected.

   (b) prevalence and acceptability studies in settings where PIP-type targeted screening could be feasible; investigations are needed of the feasibility of screening 'hard to reach' groups such as young people not in education and socially excluded groups.

   (c) Economic analyses should be conducted as part of these studies.

   (d) Further evidence is required to address the uncertainties that pervade the existing models of chlamydia infection and transmission, especially the risks of incident (new) infections following screening, which may be due to reinfection due to failure to implement effective contact tracing and treatment, or because of other behavioural and transmission factors.

   (e) Further evidence is required on economic impacts and health-care utilisation associated with the complications of chlamydia in Ireland and internationally.

1. Introduction

Genital *Chlamydia trachomatis* (CT) infection is the most common curable, bacterial sexually transmitted infection (STI) worldwide [1, 2]. The number of cases notified in Ireland increased from 3,353 in 2005 to 5,781 in 2009 [3]. Notifications have increased since 2004 when legislation requiring laboratory notification came into effect. Chlamydia is usually a 'silent' asymptomatic infection, spread without the knowledge of those transmitting and contracting it: most cases remain undetected and thus untreated. It is a major public health problem because it causes pelvic inflammatory disease (PID) in up to 30% of infected women who are not treated, which can lead to ectopic pregnancy and tubal factor infertility, and it also facilitates the transmission of HIV in both women and men [1, 4].

Prevalence studies in Ireland have detected chlamydia in 4–11% of young people [5, 6, 7], with positivity rates of over 10% in some settings [8]. Similar rates have been found in large studies in the United Kingdom (UK) [9], elsewhere in Europe [10] and North America [11]. A 2004 review estimated UK rates of 4–5% for women under 20 years in the general population, and 8–17% in women under 20 years attending sexual health services [9]. The authors of the review assumed, in the absence of data, that males had similar rates. Age under 25 years is considered a risk factor for infection in England [12]. In the English National Chlamydia Screening Programme (NCSP) overall chlamydia positivity rates have averaged 7.6% in men and 9.3% in women, based on a total of 370,012 screening tests reported [13].

Chlamydia screening has become more feasible due to the development of urine-based laboratory tests, which can be used in clinical and non-clinical settings, instead of more invasive and uncomfortable methods such as endocervical and urethral swabs. Urine testing is now the norm for screening men for chlamydia. For these reasons and because most cases are asymptomatic and undetected, especially in women, several countries have introduced chlamydia screening interventions [1].

A 2005 report prepared by the Health Protection Surveillance Centre (HPSC) [14] concluded that an investigation of the feasibility, acceptability and likely uptake of chlamydia screening in various settings in Ireland should be prioritised. It also concluded that agreement on best practice for the management of identified infections and partner notification was urgently needed. Following a competitive tendering process in late 2006, the HPSC, supported by the Health Research Board (HRB), contracted a team of population health and other specialists from the Royal College of Surgeons in Ireland (RCSI), the National University of Ireland Galway (NUIG) and the Health Service Executive (HSE) to conduct a pilot study of chlamydia screening. The study ran from 2007 to 2009.

Since 2009, several articles and reports have been published internationally, including reviews and the results of screening studies, which question the case for chlamydia screening in the general population. A systematic review of screening programmes concluded that the available evidence did not justify the establishment of opportunistic chlamydia screening programmes in under-25 year olds in the general population, given methodological weaknesses in the trials cited as justification for screening [4].

A review of the three phases of the English National Chlamydia Screening Programme (NCSP) reported screening coverage levels in the target population of only 4.8% in 2007–2008 [13]; although by 2009–2010, 47% of sexually active young women and 25% of men had been tested [15]. A review by the English National Audit

Office [16] concluded that the NCSP had not demonstrated value for money, citing lack of efficiencies in purchasing and logistics. Also, models had shown that annual testing rates of young people of between 26% and 43% would be needed in order to significantly reduce the prevalence of chlamydia [17]. The recent higher coverage levels achieved by the NCSP in reaching these recommended levels is a cause for optimism, and valuable lessons will be learned from the English national programme.

However, the potential of opportunistic chlamydia screening to prevent serious morbidity (chiefly pelvic inflammatory disease in women) has been challenged by the results of an important randomised control trial of screening among young female students in London [18]. The trial found that most episodes of PID (30 of 38) would not have been prevented by annual screening as they occurred in women who had tested negative for chlamydia at the start of the 12 months.

2. Study Aims

The primary aim of the Chlamydia Screening in Ireland Pilot Study was to investigate the acceptability, feasibility and cost effectiveness of opportunistic screening in settings other than specialist genito-urinary medicine (GUM) clinics.

We proposed to identify barriers and enablers to screening and to use this evidence to design screening models. This approach was about planning and investigating feasibility in a number of contexts, based on information from potential users and service providers, so as to maximise screening uptake. This study was not designed to measure chlamydia prevalence rates in different populations.

Background Studies: Background research was conducted in 2007–2008 to inform the design of the pilot study (see *Background Studies: Acceptability and Feasibility of Screening* on the HPSC website).[2] Using qualitative and then quantitative methods, enablers and barriers to screening were identified, explored and measured from the perspective of 18–29-year-old men and women who would be the target of screening, and from the perspectives of health-care providers in settings where screening programmes might be established.

Issues and questions to be explored in the Year 1 studies covered acceptability (to young people) and feasibility (to providers), including:

- identifying and exploring potential barriers to uptake of screening, including inconvenience, cost, stigma, embarrassment, consequences of a positive test for one's relationships and denial of risk
- young people's preferences for or against health service and non-health service settings for accessing services
- the design of suitable educational materials for the potential participants that include sex education messages
- identifying and addressing the training needs of health-care providers
- design of standard operating procedures for screening in different settings
- preferences for partner notification models
- identifying the most suitable and most acceptable sample type from participants' and providers' perspectives.

The Screening Intervention: The findings from the Background Studies were used to design screening models and test-positive follow-up models. These were piloted in the Screening Intervention in 2008–2009 in a range of clinical settings other than specialist GUM clinics. Settings in Galway city and county included GPs, student health units (SHUs) and a family planning clinic (FPC). Exploratory studies of screening in non-clinical settings were undertaken. 'Pee-in-a-pot' (PIP) non-clinical screening took place on campuses of two higher education institutions (HEIs).

The pilot programme targeted 18–29 year olds. This age group includes the age group with the highest chlamydia notification rates in Ireland (20–29 year olds). Extension of the age group to under-18s was precluded following legal advice.

Screening numbers were recorded in these settings including:

- numbers of chlamydia tests done and the characteristics of those accepting a test

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

- percentage testing positive and any risk factors or markers so as to assess the potential of more selective screening approaches in these settings
- assessment of rates of follow up (retests, testing for other STIs, partner notification and partner treatment) strategies.

Additional funding was provided for an economic evaluation to measure the cost effectiveness of opportunistic chlamydia screening, utilising data from the pilot study. Further details on the objectives, methods and findings of the sub-studies are in the accompanying reports:

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

Chlamydia Screening in Ireland Pilot Study. Screening Intervention

Chlamydia Screening in Ireland Pilot Study. Economic Evaluation

3. Methods

3.1 Background research studies

Qualitative and quantitative studies were conducted in Dublin and Galway by researchers from the RCSI, HSE and NUI Galway. These studies aimed to explore and measure young people's attitudes and views on the acceptability of screening. Topics included the suitability of different settings, preferred providers, and preferences on how to receive test results and on how to notify or inform sexual partners if the tested person had an STI. Further details are in the Background Studies document on the HPSC website.[3]

Semi-structured interviews were conducted with 18–29 year olds, including 35 women who had never attended for an STI test, and 21 women and 9 men who had previously had an STI test. Interviews were conducted with 18 health-care providers (8 doctors and 10 practice nurses), based in the three types of clinical settings – GP, FPC and SHU – to elicit their views on the feasibility and optimal approaches for implementing screening in their primary care settings.

Drawing on the qualitative findings, **structured questionnaires** were designed, which were completed by 400 young people (76% female) attending the range of clinical settings where screening programmes might be established: urban and rural general practices, an SHU setting and also a GUM clinic. A similar but shorter intranet survey with the same core set of questions was completed by 5,685 HEI students (60% female) in five HEIs in the Republic of Ireland.

Three exploratory focus group discussions were conducted with students (two with females and one with males) in two HEIs to identify what would be the most acceptable ways of screening students in non-clinical settings and to design screening promotion and educational materials for students in these settings. A range of organisations working with 'harder to reach' groups such as homeless people, asylum seekers, prisoners and construction workers were consulted about possible ways to deliver screening in other non-clinical settings. However, it was not feasible to investigate these groups further.

3.2 Pilot screening intervention

A Research Health Adviser (RHA) was recruited who coordinated the design and implementation of the screening interventions. Materials included standard operating procedures and toolkits, laboratory request forms, patient information leaflets, care management pathways and information materials, adapting materials used in other screening studies. A detailed outline of the pilot methods and findings is on the HPSC website.[3]

Models were initially designed for the delivery of **screening in primary care clinical settings** routinely used by young people, where the screening would be undertaken by GPs, and by practice and clinic nurses. Screening was offered opportunistically by health-care providers to women and men aged 18–29 who were attending these clinical settings. They included urban and rural general practices, two student health units and a family planning clinic in the West of Ireland.

Screening commenced in July 2008. Twenty-three general practices participated: 18 were group practices, 16 had a practice nurse, and 13 were urban and 10 rural.

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

Demographic and risk factor data were collected from participants in clinical settings using a short self-administered anonymous questionnaire.

Screening programmes were later designed and rolled out in non-clinical settings in two HEIs. This '**pee-in-a-pot**' (**PIP**) **screening** was organised to coincide with sexual health awareness weeks for students. Materials including urine containers, patient information leaflets, pens and instruction cards were made available to students in toilets and other accessible areas in the two HEIs. Pee-in-the-pot screening was publicised by student (peer) volunteers who were recruited to distribute testing packs and information leaflets to potential participants around the campuses.

In clinical or non-clinical settings, urine specimens were the main specimens collected. In clinical settings an endocervical swab was taken if appropriate (e.g. if a woman was attending for a cervical smear test).

Specimens were transported to and processed at a regional university hospital microbiology laboratory where they were frozen and tested later in batches using polymerase chain reaction (PCR) testing technology. Test results were communicated to the clinical settings where the individual had been screened, where the clinician took responsibility for case management as per routine practice.

In clinical settings participants were informed of their results by the clinic staff using the patient's preferred communication method (text message or phone call), as had been recorded on the laboratory form. Positive results in non-clinical PIP settings were communicated to the student health unit doctors who phoned these persons directly to organise treatment. People who tested negative received a standard text message from the RHA.

Most providers did not wish to carry out partner notification and referred chlamydia positive cases to the RHA, who conducted partner notification by phone. In addition, she followed up on all index cases to establish partner outcomes; organise or advise on STI testing, chlamydia retesting and treatment; and provide health education and counselling. Further STI testing of all positive cases was recommended in accordance with standard international practice, and cases were also offered repeat chlamydia testing three to six months after the initial screen.

After the screening pilot, semi-structured interviews were conducted to explore participant and provider experiences around acceptability, feasibility, the utility of standard operating procedures used, and to ascertain their views and recommendations on the design and roll out of a chlamydia screening programme. These interviews were done with 13 screened participants and 18 health-care providers including two staff members of the Microbiology Department who had participated in the pilot.

Systems for managing and analysing data were designed using Access, SPSS, Epi-Info and N-Vivo.

3.3 Economic evaluation

The process of economic evaluation involved a comparative analysis of alternative courses of action in terms of both their costs and consequences [19]. The evaluation process consisted of three phases of analysis, which are described in detail in the Economic Evaluation report on the HPSC website.[4]

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

In brief, a dynamic transmission model was combined with an economic model to evaluate the pilot opportunistic screening programmes over a time horizon of 10 years.

In the base-case analyses, screening was modelled to represent both screening approaches tested in the pilot study: clinical setting screening and non-clinical PIP screening. In both cases, screening was compared to a control strategy of no organised screening (existing care in Ireland).

A health-care system or provider perspective was adopted with respect to costs. The analysis considered the cost of screening to the health service, and the costs of infections and complications. Unit costs were obtained from national data sources and were transformed to euros (€) in 2008 prices using an appropriate inflation rate index.

The effectiveness of screening was evaluated in terms of the major chlamydia outcomes that would be averted, and the resulting impacts in terms of quality adjusted life expectancy.

An incremental analysis was undertaken to explore the cost effectiveness of both opportunistic screening strategies relative to a control of no organised screening, i.e. current practice in Ireland. This involved comparing the alternative strategies in terms of both their cost and effectiveness, and applying a set of decision rules that define one treatment option as cost effective relative to a comparator. These include if it is:

1. Less costly and more effective;
2. More costly and more effective, but its additional cost per additional unit of effect is considered worth paying by decision makers;
3. Less costly and less effective, but the additional cost per additional unit of effect generated by the comparator is not considered worth paying by decision makers.

In scenario (1) the outcome is straightforward, i.e. the less costly and more effective option is dominant. In scenarios (2) and (3) a key factor in the determination of cost effectiveness is the threshold value, which is interpreted as the decision maker's maximum willingness to pay for an additional unit of health gain. In such cases, the results from economic evaluation are presented in terms of an incremental cost-effectiveness ratio or ICER (*difference in mean cost/difference in mean effect*), which is compared directly to the appropriate threshold value.

In Ireland, there is no fixed and generally agreed cost effectiveness threshold below which health care technologies would be considered by policy makers to be cost effective [2]. It is possible, however, to infer a broad range for this parameter based on decisions previously taken regarding what technologies should be funded. In the current economic climate, we suggest that, in the majority of cases, only those interventions with an incremental cost effectiveness ratio of €20,000 per QALY gained or less will have any likelihood of being considered cost effective. Uncertainty relating to the appropriate threshold value and the underlying assumptions of the modelling approaches adopted for the base-case analyses were explicitly explored using probabilistic and one-way sensitivity analysis.

4. Results of Background Studies

4.1 Acceptability of screening for 18–29 year olds

4.1.1 Qualitative findings (interviews, focus groups)

The most important barrier reported by young women who had never gone for STI testing was the stigma they associated with chlamydia and other STIs, which was most strongly reported by younger women and those recruited in rural and working-class urban health-care settings.

These women had generally conservative opinions about the settings where they wanted opportunistic screening services to be offered, preferring traditional medical settings (e.g. GP practices). They had clear preferences about who should offer them a screening test – trained health professionals, preferably non-judgemental female doctors or nurses.

Women in rural settings or from rural backgrounds (and students) expressed concerns about possible breeches in confidentiality if they were offered STI screening at their local general practice. Women in urban working-class settings were worried that their peers would observe and stigmatise them if they were observed attending a setting or clinic associated with STI testing, such as a GUM or special (sexual health) clinic.

Factors that would encourage them to accept screening included provision of free screening, normalising screening (not asking about risk factors such as number of sexual partners), and being offered screening by younger non-judgemental female health-care professionals. Some stressed the importance of staff highlighting that acceptance of screening is a positive, healthy and responsible practice.

Factors conducive to screening in respondents who had previously had an STI test included viewing testing as a responsible practice, being protective towards partners, fear of future infertility, perceptions around whether or not sexual partners might be infected and anxiety around the silent nature of the infection. All respondents said that they would feel guilty if they transmitted an STI to another person.

Focus group discussions with students raised similar issues and concerns to those raised in the one-on-one interviews – the importance of framing STI screening as normal, the staff's communication style, and the importance of privacy and confidentiality. Students stressed the importance of not being questioned about or being singled out because of their sexual behaviour or possible risk factors. Anonymous testing, where students did not have to volunteer their names and addresses, was preferable (this approach was used later in the PIP pilot).

Lack of information about chlamydia and testing methods was a big barrier to taking a test, especially for young men who were self-conscious about reading educational material in public areas such as a GP's waiting room. Participants reported that the way the media portrayed STIs was 'not educated' and was often 'blown out of proportion'.

Most respondents said they would prefer to notify current partners themselves if they tested positive for chlamydia. However, respondents, especially men, were less likely to inform previous partners, which highlighted the need for contact tracing in a screening programme. Female respondents were most positive about notification when it was framed as a way of avoiding contributing to infertility in other women, which suggested an approach that could be built upon to promote partner notification.

4.1.2 Quantitative findings (questionnaires, internet survey)

The responses of these two groups of 18–29 year olds, health service attendees and students were similar, and reflected the views expressed in the qualitative research. The great majority (94–96%) said they would find it acceptable to be offered chlamydia screening, and most (75% of students and 91% of patients) would accept if offered a test.

The most common factors that might deter them were cost (24% of respondents), embarrassment (22%), having to tell their current partner (17%) or tell a previous partner (12%), inconvenience (14%) and worry (12%). Primary care attendees were generally more positive about paying for a chlamydia test: 65% said they would and only 17% said they would not, whereas only 44% of students would pay for a test.

Respondents were asked about specific settings (including in their own homes) where testing might take place. About half said they would find home testing acceptable, around 40% felt the same about primary care settings such as the GP, but very few (3%) reported that non-clinical settings such as chemist shops would be acceptable. Genito-urinary medicine clinics were generally acceptable to the students (56%), though less so to respondents recruited in primary care settings (20%).

Most (70–80%) had a preference for a health professional (doctor or nurse) to offer them screening and 95% would not be comfortable if a receptionist made the offer. Two-thirds of female respondents preferred a female health professional to offer them the screening test, whereas men did not have a strong preference around the sex of the provider. Privacy and confidentiality were the priorities for young people.

A range of test result notification mechanisms were suggested to respondents. A call to their mobile phone was the most popular mechanism for receipt of a negative result (34%) and also if the test was positive (over 50% preferred this option). Most (80%) would be willing to have their current partner informed if they themselves were diagnosed with chlamydia; and most would prefer themselves to tell their current partner (87%) and a previous partner (57%) about the result.

4.2 Views of health professionals on the feasibility of screening

Providers (doctors and nurses) reported that young people were particularly vulnerable to STI infection due to being ‘very sexually active’, combined with high alcohol consumption and low levels of safe sexual practice. Approaching the topic of STI screening sensitively to ensure acceptability to young people was seen as crucial to avoid causing offence to patients. Most providers felt that chlamydia screening should be integrated into general consultations.

There was consensus among health-care providers that the main feasibility obstacles were lack of time, lack of staff (especially for partner notification) and lack of training. Lack of time and trained staff would impact especially on effective and comprehensive partner notification, and on counselling patients and explaining the consequences of a positive result. Young men, who were seen as low attendees, might be more difficult to reach.

However, all the GPs and practice nurses interviewed were enthusiastic about the pilot study and were optimistic that they would achieve high take-up rates in the region of 20–50 tests per month if a screening pilot was implemented. All believed that the testing setting (i.e. their practices) was the correct setting for managing test

positive cases, but most said they would need the support of a trained health adviser to undertake partner notification and contract tracing.

5. Results of the Pilot Screening Study

The screening models were based on the Background Studies' findings and were modified and adapted during implementation, based on feedback and advice from participating providers, screened individuals, the Steering and Advisory Committees.

5.1 Participation in screening

Over one thousand (1,112) participants were screened, of whom 998 were eligible for analysis; 114 were excluded because they were outside the eligible age range or because of mislabelling or insufficient identifying information.

Accurate information on offer rates and refusal rates in clinical settings was not obtained as it was not possible for providers to systematically record such data because of time constraints. Based on a review of computerised patient databases in a selection of general practices, we estimated that in clinical settings, among eligible attendees, in the range of 2–9% of eligible females and 1–3% of eligible males were offered screening. Refusal rates settings varied – it was estimated by providers to be 33% in one SHU, 20% in the FPC and less than 10% in general practices.

5.2 Study population

The study population consisted of 460 recruited from clinical settings (286 from GPs, 100 from SHUs and 74 from FPCs) and 538 from non-clinical PIP settings. Figure 1 summarises the demographic characteristics of the population screened (percentages are out of a total *n* of 998).

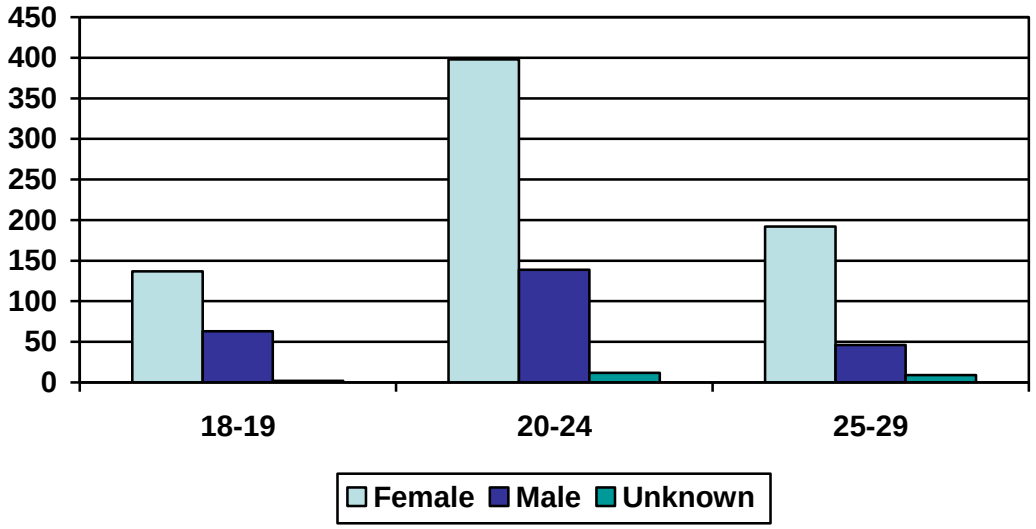

Figure 1 Description of eligible people screened during the pilot.

5.3 Screening process

Of the eligible specimens 91% (878) were urines and 9.7% (97) were cervical swabs (representing 13% of all female screening tests). In GP settings, doctors took the majority (71%) of specimens. In SHUs and the FPCs, nurses took over 90% of the specimens.

The median time for both doctors and nurses to obtain a urine test was five minutes. The median time to take a cervical swab was five minutes for a practice nurse, and

seven minutes for a doctor. The overall range in time reported for taking tests was two to 20 minutes.

The time intervals from the date the test was taken to the date the sample was processed in the laboratory varied, with a mean interval of 4.97 weeks (median = 5). For a small proportion of tests (7.4%), the interval was longer than eight weeks. In the pilot study, testing was done in batches to contain costs. These times would not reflect processing times in a large-scale screening programme with a high throughput.

5.4 Screening in clinical settings

Overall, 286 eligible persons (240 females, 35 males and 11 sex not specified) were screened in 23 general practices. In the two SHUs 100 persons (81 females, 18 males and 1 sex not specified) were screened and in one FPC 74 persons (70 female and 4 males) were screened.

The mean number of specimens (urine and cervical swab) per general practice was 12.4 (range 1–61, median 6). The four practices that screened more than 20 people were urban group practices with a female clinician who provided sexual and reproductive health services. However all sites had a low offer rate when the size of the practice population was taken into account.

5.5 Risk factors in clinical settings

Risk factor data were collected from individuals screened in clinical settings only and not from those tested in the PIP events. The mean number of lifetime sex partners was 6.7 (range 0–60, median: 5). Males were significantly more likely than females to have had more than 14 lifetime sex partners (30% versus 7.2%), a new partner in the last three months and more than two partners in the last year.

Most participants (88%) did not report symptoms such as a history of genital discharge or pain passing urine. However, males in this population were significantly more likely than females to report pain on passing urine.

5.6 Screening in non-clinical 'pee-in-a-pot' settings

Between the two HEIs a total of 6.5 days of PIP activities were conducted with 48% of the test kits distributed returned. During the PIP periods, 538 eligible urine tests were collected (mean 90 per full day of screening): 191 (35%) were from men (compared to 12% in the clinical settings). Of the participants, 485 (90%) were under 25 years of age and 336 (62.4%) were female.

5.7 Test results

Of the total of 998 eligible people screened, 48 (4.8%, 95% CI 3.5–6.1) tested positive: 35 females (4.8%, 95% CI 3.3 –6.3) and 13 males (5.2%, 95% CI 2.5–8.0).

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. Table 1 shows details of positivity by sex.

The positivity rates in clinical settings for females (4.6%) were not statistically significantly different from females in non-clinical settings (5%), whereas for males in clinical settings the positivity rate (15.8%) was significantly higher than in males in non-clinical PIP settings (2.1%), odds ratio = 8.77 (95% CI 2.33–35.5). However, this was based on small numbers (9 of 57 males tested positive in clinical settings). Males

attending clinical settings were also statistically significantly more likely to be CT positive than females attending clinical settings, relative risk = 3.43 (95% CI 1.62–7.26).

Table 1. *Chlamydia trachomatis* (CT) 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)	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)

None of the associations of sexual behaviour or symptom risk factors with CT positivity were statistically significant (these data were only collected from those tested in clinical settings).

5.8 Management of test positive cases

Forty-five (94%) of the 48 chlamydia positive people were treated successfully, the majority with a single dose of Azithromycin, and three cases (6%) were not contactable and therefore not treated for chlamydia. Of those treated, most received this at the SHUs (21, 46.7%), by GPs (18, 40%) and at FPCs (4, 8.8%), with only two cases (4.4%) treated at GUM clinics.

Over half (25, 52%) of the chlamydia cases were known to have had further STI testing. Eleven were tested in general practice and 13 were tested in GUM clinics. The testing site for one was unknown. **All tests for other STIs were negative**.

Those who attended for chlamydia retesting attended their place of original diagnosis (GP, FPC or SHU). Nineteen (42% of those contactable) were retested. All retest results were negative. None of the PIP positive patients attended for a retest. They were all referred to attend the GUM clinic for their retest as urine testing was no longer available at this time. The option of retesting in a GUM clinic involved an invasive swab test that may have been a deterrent.

5.9 Partner notification

Forty-three of the chlamydia positive cases gave consent for follow-up. Partner notification was discussed and followed up by the RHA with 25 (58.1%) index cases. This was conducted by a practice nurse from one of the SHUs with 11 (25.6%) and by practice nurses from the FPC with 5 (11.6%). Partner notification for 2 cases (4.6%) was carried out at the local GUM clinic. **Thirty-four contact cards were given to positive persons but only four were reported as returned**.

Overall 68 partners were reported by the 43 positive cases who gave consent for follow up. Of these 68, 56 (82.3%) were contacted and informed of their potential exposure to chlamydia. Of these, 46 were contacted by the index cases themselves (patient referral) and 10 by the RHA (provider referral).

Of the 56 partners contacted, 13 (23%) were tested and treated, 37 (66%) were treated only (of which 10 were confirmed as treated). The outcome was unknown in 6 (11%) cases. Partner treatment took place in GP, SHU and FPC settings (29 cases) and in GUM clinics (14) or other unknown settings (13). **Overall, 0.5 contacts per index case were verified as treated in the study**.

5.10 Screened participants' views

Acceptability of being screened: Semi-structured interviews were conducted with seven young adults who had participated in the PIP screening and with six who had been screened in clinical settings. Reasons given for accepting a test included a fear or realisation that they might have exposed themselves to infection. Urine testing made chlamydia screening highly acceptable, and free testing was an enabling factor. Waiting for test results caused anxiety in some of those screened. The screening experiences in the clinical (GP, SHU or FP) and non-clinical (PIP) settings were reported very positively. Factors enhancing student participation in PIP sessions included anonymity, convenience, accessibility of testing and the informal approach to testing outside a health-care setting.

Reactions to test positive results: The initial reaction of young people who had tested positive was shock, anger and disbelief, using terms such as: feeling 'dirty', 'horrible', 'upset and embarrassed', 'ashamed' and 'low self-esteem'. Their initial anxieties developed into relief following treatment and follow-up, describing a positive result as a 'wake-up call'.

Those who had attended a GUM clinic for further STI testing reported that, while the care provided was felt to be professional and of a high standard, the experience was perceived as 'embarrassing' and 'public'.

Overall views of the screening programme were very positive, and respondents were glad that they had participated and wished to see the pilot continue as the models worked well. The screening process was quick and easy, and they now knew more about chlamydia and believed screening was important.

5.11 Service providers' views

At the end of the nine-month screening pilot, 16 health-care professionals were interviewed. Most were positive about the pilot screening programme, describing enabling factors such as the availability of urine-based testing for chlamydia (which was only available in this geographical area during the study), and the patient follow-up and partner notification service provided by the RHA. However, they highlighted several significant challenges:

- The time involved for the provider/practice staff was seen as a major deterrent.
- Raising the sensitive and potentially stigmatising subject of STIs during a general consultation was seen as a 'risk' to the provider's relationship with his/her patient. Opportunities to link or piggyback chlamydia screening onto a context-appropriate service (cervical smear tests or contraceptive consultation) were enabling factors, though limited to women.
- Many providers reported that it was easier to offer screening to women. They partially attributed this to denial and dismissiveness among young men, their lack of knowledge and the greater difficulty in persuading men of the importance of

screening for an infection whose primary complication was experienced by women.

- Despite the challenges raised, most providers were supportive of screening being introduced. However, adequate resources and remuneration were seen as essential.

5.12 Interviews with laboratory team

Two staff members of the Microbiology Department were also interviewed. The pilot study had significant impacts on laboratory systems relating to:

- The increased workload associated with processing and testing urine samples. This involved significantly more work 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), which had to be frozen. Defrosting also increased working time, which impacted significantly on mean test result turnaround time.
- During the non-clinical PIP screening, large numbers of samples were submitted in a short period of time. This combined with other circumstances, created surges and pressure on the laboratory performing the testing.

The above issues would not be expected to occur in the context of a laboratory that is routinely processing large volumes of specimens and is resourced to contribute to an ongoing national programme.

- Mislabelling of some samples was also a difficulty. More samples from the non-clinical PIP settings had insufficient and/or incorrect details. Resolving these problems took time and had implications for workloads. Between 10–20% more of the total sample number would have been discarded if rejection criteria had been followed without efforts to clarify.

6. Results of Economic Evaluation

6.1 Cost analysis

The costs of screening were estimated prospectively alongside the pilot study and were calculated individually for each screening programme and for each stage of the screening process. The results for clinical-setting screening and PIP screening are presented in Table 2 as follows: the *cost per offer*, the *cost per negative case*, the *cost per positive case* and the *cost per partner notified and treated*. In the clinical base-case analysis, it was assumed that GPs and practice nurses equally shared the work of offering screening in general practice. In the sensitivity analysis, alternative clinical strategies were modelled whereby it was assumed that screening offers were made solely by GPs or practice nurses. A divergence in the costing process for clinical-setting screening and PIP screening derived from how screening was offered in each case. Whereas screening was offered by a clinician in the former, this was not the case in the latter.

Table 2. Cost analysis results.

Screening programme	Clinical base case (€)	Clinical GP only (€)	Clinical PN only (€)	Non-clinical PIP (€)
Cost per offer (no screening uptake)	26	38	15	n/a
Cost per negative case	66	91	42	39
Cost per positive case treated	152	177	128	125
Cost per partner notified and treated	74	74	74	74

Euro (€) in 2008 prices. GP = general practitioner; PN = practice nurse.

6.2 Cost-effectiveness analysis

The results from the model-based analysis indicated that clinical setting screening and PIP screening both led to improved health outcomes but required additional health care resources, even when programme outlays were set against projected savings from avoided infections and complications.

Within the modelled population of 20,000 males and females aged 16 to 45 years, the results revealed that screening of 18–29-year-old males and females in clinical settings was associated with 699 fewer major outcomes and 45 QALYs gained at an additional cost of €4,258,868 over 10 years, when compared to the control strategy. Discounting future costs and effects to the base year, this translated into an incremental cost per major outcome averted (MOA) of €6,093, and an incremental cost per QALY gained of €94,717.

The results from the probabilistic sensitivity analysis were used to plot cost effectiveness acceptability curves which indicated that the probability of screening being cost effective was less than 1% for a range of potential threshold values of up to and including €45,000 per QALY gained. This would suggest that clinical setting screening, as modelled in the analysis, is unlikely to be considered cost effective.

A series of one-way sensitivity analyses were undertaken to explore the impact of varying the assumptions of the base-case analysis for screening in clinical settings. The results were broadly similar to those observed in the base-case analysis in that

screening was predicted to result in fewer major outcomes, fewer QALYs lost and higher health-care costs than the control strategy.

The modelled rate of progression from chlamydia to pelvic inflammatory disease (PID) was shown to be a significant parameter in the cost-effectiveness analysis. Increasing the rate from 10% to 30% had the effect of reducing the incremental cost per QALY gained to €39,126. However, recent evidence calls into question the likelihood of chlamydia progression to PID being as high as 30% [18]. Conversely, reducing the PID progression rate to 1% increased the ICER to €700,144 per QALY gained, i.e. making it less cost effective.

Nurse-led screening (one in which only the nurse offered testing to eligible individuals) was shown to be a less costly strategy than GP-led screening. However, neither strategy is likely to be considered cost effective, yielding incremental cost per QALY ratios of €62,603 and €113,523, respectively.

Screening offered in student health and family planning clinics yielded ICERs of €46,618 and €39,185 per QALY gained, respectively. These findings are subject to caveats. Firstly, data on screening coverage for both family planning and student health settings were only obtained for the limited number of these clinics which participated in the pilot study. Evidence from a larger range and number of settings would be required to test the robustness of these results.

Secondly, screening in these settings had lower coverage in the target population than the base-case strategy and were less effective in identifying infection and reducing overall prevalence levels. This had direct implications for the cost-effectiveness analysis as the total cost of implementing screening was less for programmes with low coverage than for programmes with high coverage.

In addition, the cost of identifying a positive case in the years after screening implementation was less in a low-coverage programme. This is because the impact of screening in reducing chlamydia prevalence was less in a low-coverage programme, which means that there were more residual cases in the target population that could be detected at a lower cost per case than would be the case if the programme had high coverage.

Consideration must be also given to equity concerns arising from offering screening in a manner that potentially excludes members of the target population who do not attend student health or family planning clinics.

In the base-case analysis, we assume that once an individual is screened they are ineligible for an opportunistic screening offer for one year. An alternative approach is to assume that individuals are eligible for a screening offer each time they attend the clinical setting. Eliminating the assumption of a minimum gap between screens has the result of increasing the ICER to €129,303.

Reducing the health-care provider offer rate from the 70% adopted in the base-case analysis to 5%, 20% and 40%, to reflect the rates observed in the pilot study, did have the impact of reducing the ICER to €69,991, €74,045 and €87,132, respectively, thereby increasing the cost effectiveness. However, assumptions around the longer-term objective of reducing the population prevalence of chlamydia would no longer hold true with low-screening coverage rates in the target population.

If the estimate of 1–3% of males and 2–9% of females offered screening in a subset of clinical screening sites is generalised and combined with male GP attendance rates of 53% and females of 82% in one year, then coverage rates would be even lower than

observed here, especially in men, where they could fall to a range of 0.5% to 1.5% [20]. Higher coverage rates (16%) achieved in some Primary Care Trusts in England after three full years of the NCSP would be difficult to replicate in Irish general practices [13, 15].

Alternatively, increasing the offer rate to 100% had the impact of increasing the ICER to €97,733. This can be attributed to the positive relationship between the offer rate and the coverage rate of the screening programme, and the resulting impacts on the total cost of screening implementation.

As was the case in the clinical setting, PIP screening was estimated to bring health benefits in terms of MOAs and QALYs gained and would require additional health-care resources compared to the control strategy.

Within the modelled population, the incremental results indicated that PIP screening of 18–29-year-old males and females was associated with 44 MOAs averted and 3 QALYs gained at an additional cost of €100,513 over 10 years. Discounting future costs and effects to the base year, this translated into an incremental cost per MOA of €2,294 and an incremental cost per QALY gained of €34,486.

The results from the probabilistic sensitivity analysis, using cost-effectiveness acceptability curves, indicated that for the potential cost-effectiveness threshold values of €15,000, €30,000 and €45,000, the probability of the screening being cost effective is 14%, 41% and 94%, respectively.

The results from the 'Pee-in-a-pot' strategy, as modelled, may be considered cost effective if decision makers are willing to pay a threshold in the region of €45,000 per QALY gained. However, whereas this might have merited serious consideration when the pilot study was first commissioned in late 2006, this option would be subject to much more stringent consideration given current economic conditions in Ireland. Indeed, we suggest that, in the current economic climate, only those interventions with an incremental cost effectiveness ratio of €20,000 per QALY gained or less will have any likelihood of being considered cost effective. Furthermore, it is evident that 'Pee-in-a-pot' screening would have a low level of coverage in the target population and, as a result, a minimal effect in terms of reducing overall prevalence levels and improving population health.

Thus chlamydia screening in either the clinical settings or in the PIP model is unlikely to be considered cost effective.

7. Discussion

7.1 Acceptability and feasibility

The Background Studies and the Screening Intervention showed that chlamydia screening is acceptable to young people and to health-care providers, and more so when urine-based tests are available. However, despite this acceptability and contrary to provider expectations of high testing rates, the chlamydia screening offer rates in clinical settings were low – considerably lower than participating GPs had predicted – and the anticipated numbers of screening participants were not recruited in the clinical settings.

Interviews with **providers** highlighted important enablers and obstacles to screening, which have wider implications for the provision of STI diagnostic and case management services. Well-designed incentives (training, support for partner management and financial remuneration) would be necessary to enable practices to offer screening.

Interviews with **young people** conducted after the end of the screening programme reported some short-lived negative psychosocial impacts of screening on test positive participants and on those waiting for their results, which had resolved over time. Overall, participants reported that they were happy to have been screened and they particularly appreciated the role of the RHA. In the Background Studies, some respondents had reported travelling from other areas to visit GP practices that provided 'youth friendly' sexual health services.

The feasibility issues encountered by the **laboratory service**, which were with respect to the need for batch testing to maintain efficiencies, and the difficulties in anticipating and dealing with surges in demand, are not likely to occur in large scale and adequately resourced chlamydia screening programmes.

7.2 Epidemiology

The chlamydia positivity rate of 4.8%, while based on small numbers (48 positives out of 998 screenings), is similar to national and international prevalences and positivity rates in opportunistic screening studies [1, 5, 6, 7, 9, 10]. There was some heterogeneity, for example higher positivity in males screened in clinical settings (16%). However, these rates were based on very small numbers (9 of 57 tested), with wide confidence intervals.

We emphasise that the chlamydia positivity rates based on a screening intervention do not equate with prevalence rates in any identifiable population. Only a minority of eligible young people were offered, and a smaller number accepted, a chlamydia screening test. In clinical settings, selection of 'likely candidates' by providers, and 'self-selection' by young people appear to take place and may well have contributed to the high positivity rates in males in clinical settings – 9 of 57 (15.8%) tested – as does self-selection when screening is made available and publicised in non-clinical settings and at events such as HEI sexual health awareness weeks.

Data were collected from those screened in the clinical settings on the two risk indicators that are used in the English NCSP: 'two or more partners in previous year' and 'a new partner in previous three months' [13]. The association of these risk factors with chlamydia positivity in this study was not statistically significant, which may reflect the low screening sample size or a true weakness of the association.

Based on the findings of the Irish study, the recommendation is for providers and screening programmes not to directly ask young people about their sexual history. The consequences of using a risk-factor pre-screening approach, where only those who report risk factors are screened, would include:

- **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%) positive cases in this Irish study reported no to 'new sex partner in the past three months' [13].
- **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.

However, these findings do not rule out a risk factor screening approach as part of sexual health promotion strategies or within the screening setting. Advertising screening criteria such as a change of partner could alert those at higher risk of chlamydia infection. No direct questioning of a patient re his/her personal risk needs to take place in the screening / clinical setting. Such risk factor data and demographic data could be collected anonymously via self-administered short questionnaires (as in our pilot questionnaire and intranet survey, and in the English NCSP).

In our studies between 75 and 77% answered the questions on these risk factors, which suggests that it would be acceptable to those being screened in clinical settings. The acceptability of anonymised questions on risk factors should to be assessed in non-clinical settings. The current screening study in the Netherlands involves obtaining risk-factor data from participants via online questionnaires [22]: individuals in a lower prevalence area are only able to request a test kit if their internet risk assessment exceeds a predefined value.

7.3 Targeted chlamydia screening events

Although in the Background Studies preferences were expressed for a health-care professional to offer chlamydia screening, during the non-clinical PIP screening, higher numbers of participants (538) were recruited over a total of 6.5 days than were screened in 26 clinical settings over nine months (460).

The success of the PIP reflected its design, which was done in collaboration with students and the Student Unions. It involved an anonymous, private, accessible, well-publicised and youth-friendly screening process. This supports the findings of the Background Studies for screening to be offered in a discrete and confidential manner, which avoids the potential stigma of requesting or being seen (by ones' peers or by a GP who is known by one's parents) to be accepting an STI test. The settings (HEIs) and events (sexual health awareness and guidance weeks) were particularly suitable, and these successes might not be easily replicated in other settings. An added advantage is that the participant is not dependent on a screening offer being made to them by a health care provider. As was seen in this pilot the screening offer rates by providers were very low.

7.4 Management of chlamydia cases and contacts

The high rate of contacting and treating contacts of index cases testifies to the effectiveness of a community-based, primary care delivered approach. Partner notification worked well, largely due to the diligence of the RHA. The recommended target of the English NCSP is 0.6 partners to be verified as treated per index case [23]. In this Irish pilot study, 0.5 partners per index case were verified as treated.

The use of contact cards to track partner outcomes was ineffective, necessitating reliance on the RHA for contact tracing. Exploration of alternative methods of making contact with partners through the use of email and text messaging [24] could be future options, as these options were explored for the communication of test results in the Background Studies questionnaire surveys (see Appendix A).

Based on emerging evidence that reinfection rates are likely to be highest among women who previously tested positive (as recommended by the Centers for Disease Control and Treatment (CDC) Guidelines 2006 [11]), retesting was offered at three to six months after the original test. All contactable positive cases were offered retesting and all of those tested had negative results (nineteen, 42%).

7.5 Cost effectiveness of chlamydia screening

The modelled scenario for screening offered in the form of a short duration mass PIP testing campaign in higher education institutions relative to no screening had a lower cost per QALY (€34,486) than screening in clinical settings (€94,717). Nurse-led screening outside GP settings was more cost effective: €46,618 per QALY gained in student health units, €39,185 in the family planning clinic and €34,486 in the student PIP.

The results of the economic evaluation, as modelled in the cost-effectiveness analysis, do not support the adoption of opportunistic chlamydia screening programmes in clinical settings. The modelled scenario for screening in clinical settings could reduce overall chlamydia prevalence rates if high screening offer and uptake rates were achieved. However, low offer and coverage rates were achieved in this study (at the lower end of a range of 0.5 to 8%), falling short of coverage rates proposed in models as necessary to reduce population chlamydia prevalence [17].

The economic model included the cost of the screening programme – provider time input, testing materials, laboratory analysis, treatment, follow-up and overheads, including those of the RHA. Excluded were costs that might attend a programme such as screening incentives paid to participating GPs or those that might be borne by the individual participant such as travel. These will further increase costs, reduce cost effectiveness and introduce further resource implications.

7.6 Limitations of the pilot screening study

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.

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. Studies in various countries including Ireland [8] 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, and 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.

7.7 Recent evidence

There are now serious doubts about some of the assumptions that were accepted as 'given' in 2007 when the Chlamydia Screening in Ireland Pilot Study started, which undermine the case for widespread or systematic opportunistic chlamydia screening in the general population of under-25 year olds:

- Early screening uptake levels in the English NCSP were unlikely to be sufficient to reduce the population prevalence of chlamydia [13, 4,], implying that young people will continue to be at risk of chlamydia. However uptake rates in 2009–2010 have reached 47% of sexually active young women and 25% of men, which would be sufficient to reduce chlamydia prevalence (at least in women) [15].
- Annual screening may be considerably less effective at preventing PID than was hitherto believed to be the case [17]; and value for money has not been demonstrated in the NCSP in England [16]. While that conclusion appears to be based on an analysis of spending patterns, rather than cost-effectiveness analyses as were conducted for the Irish study, these inefficiencies could easily be replicated in an Irish national screening programme.

7.8 Recommendations for a sexual health action plan

Ireland's national health strategy – *Quality and Fairness: A Health System for You* – proposed the adoption of a national action plan to promote sexual health and safer sexual practices [25]. This should include actions for the control of chlamydia and other STIs.

The recent 2009 ECDC Guidance on chlamydia *case management* [1] suggests a step-by-step approach to ensure that primary prevention activities (Level A) and adequate STI case management infrastructure, management guidelines and quality controls (Level B) are in place before other community-based interventions such as opportunistic testing (Level C) and population screening (Level D) are introduced.

Based on the findings of these studies, we recommend that Level A and B chlamydia control steps, as outlined in the ECDC Guidance, should be addressed and essential components put in place.

This also conforms with internationally recognised criteria for a screening programme, as proposed by the World Health Organisation [26] and the UK National Screening Committee [27], which include: 'all cost-effective primary prevention interventions should be implemented' and 'there should be evidence from high quality Randomised Controlled Trials that the screening programme is effective in reducing morbidity'.

Taking into account the specific national opportunities and limitations, the model for chlamydia suggested for Ireland should be part of a national action plan for sexual health that includes:

1. Ensuring population coverage and quality of primary prevention activities (Level A). These could include education for young people commencing before sexual debut, including young people in and out of school, on:

   (a) the nature of chlamydia (a silent infection that cannot be detected by the appearance of partners and the potential for reproductive consequences such as infertility)

   (b) the importance of always using condoms outside long-term monogamous relationships

   (c) information on other STIs.

2. Ensuring population coverage and quality of STI case management systems (Level B) including:

   (a) Standardised national guidelines for STI diagnosis, treatment, follow-up and re-testing.

   (b) Partner notification support structures (community sexual health advisers) that can be accessed and used by primary care providers.

   (c) Urine chlamydia testing should be readily available to primary care providers at a regional level. Laboratories should receive sufficiently high numbers of urine specimens and should be adequately resourced for an efficient throughput of specimens and timely feedback of results to clinicians.

   (d) Training for primary care staff (doctors and nurses) on the technical, interpersonal and communication components of a sexual health and chlamydia testing service, including a 'youth friendly' approach.

   (e) Free testing and treatment in primary care settings for the treatment of chlamydia. Even in a resource-challenged and constrained health service, the case for this is strong as STI control is a 'mixed public–private good', meaning that interventions that prevent the transmission of STIs benefit the wider community and population, and not just the individual.

3. Studies to determine prevalence and risk factors in different settings or target groups where targeted screening of young people could be tested.

   If the PIP approach were to be assessed in other settings, preliminary studies would need to include:

   (a) Identifying suitable settings. Students in our qualitative studies advised against the 'easy option' of leisure events, such as concerts, where a focus on STIs would be considered intrusive and counter-productive. Similar concerns have been expressed regarding sporting events, which are often family events.

   (b) Chlamydia prevalence studies in suitable settings/target groups to identify the greatest need and 'best buys' for investing in chlamydia screening.

Case management (Level B) 'demand-side' interventions should be considered, once diagnostic, case management and partner notification services are in place and prepared for managing demand. These should include awareness raising media and other campaigns directed at young people to encourage them to go for a simple urine

test for chlamydia. Careful attention is needed in the design of these messages to achieving the appropriate balance between stimulating demand in those at real risk of being infected, in whom positivity rates will exceed the average prevalence for the age group, versus inducing demand by the 'worried well' [22]. Such a programme would require careful monitoring and evaluation because of the silent nature of chlamydia and the limited evidence of the low predictive value of risk-factor and symptom-based approaches to detection.

The issue of how to intervene using primary and secondary prevention measures in under-18 year olds, and more so with under-16 years olds, is fraught with difficulty due to uncertainty around the legal implications of recognising and dealing with what may be illegal acts. Joined-up government responses (Department of Justice and Equality and the Department of Health and Children) and policy guidance is needed so that this highly vulnerable, high-priority group is not neglected.

The appropriateness of chlamydia screening in Ireland will need to be reappraised as new evidence becomes available, such as the findings of two trials of both systematic and opportunistic chlamydia screening currently under way in the Netherlands and Australia [22, 28]. These will involve multiple screening rounds and provide essential information about the effectiveness of chlamydia screening [29].

POLICY RECOMMENDATIONS

- **We recommend prioritising primary prevention activities such as sexual health education and condom promotion.**
- **Support should be provided to primary care clinical staff for optimal sexually transmitted infection (STI) case detection, management and follow-up.**
- **The appointment of dedicated regional health advisers would provide support to primary care healthcare providers who are willing to provide STI testing services, and in coordinating partner notification, testing and treatment.**

Our findings do not support the establishment of an opportunistic screening programme for chlamydia in Ireland.

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Appendix A: Published Articles of the Chlamydia Screening in Ireland Pilot Study

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