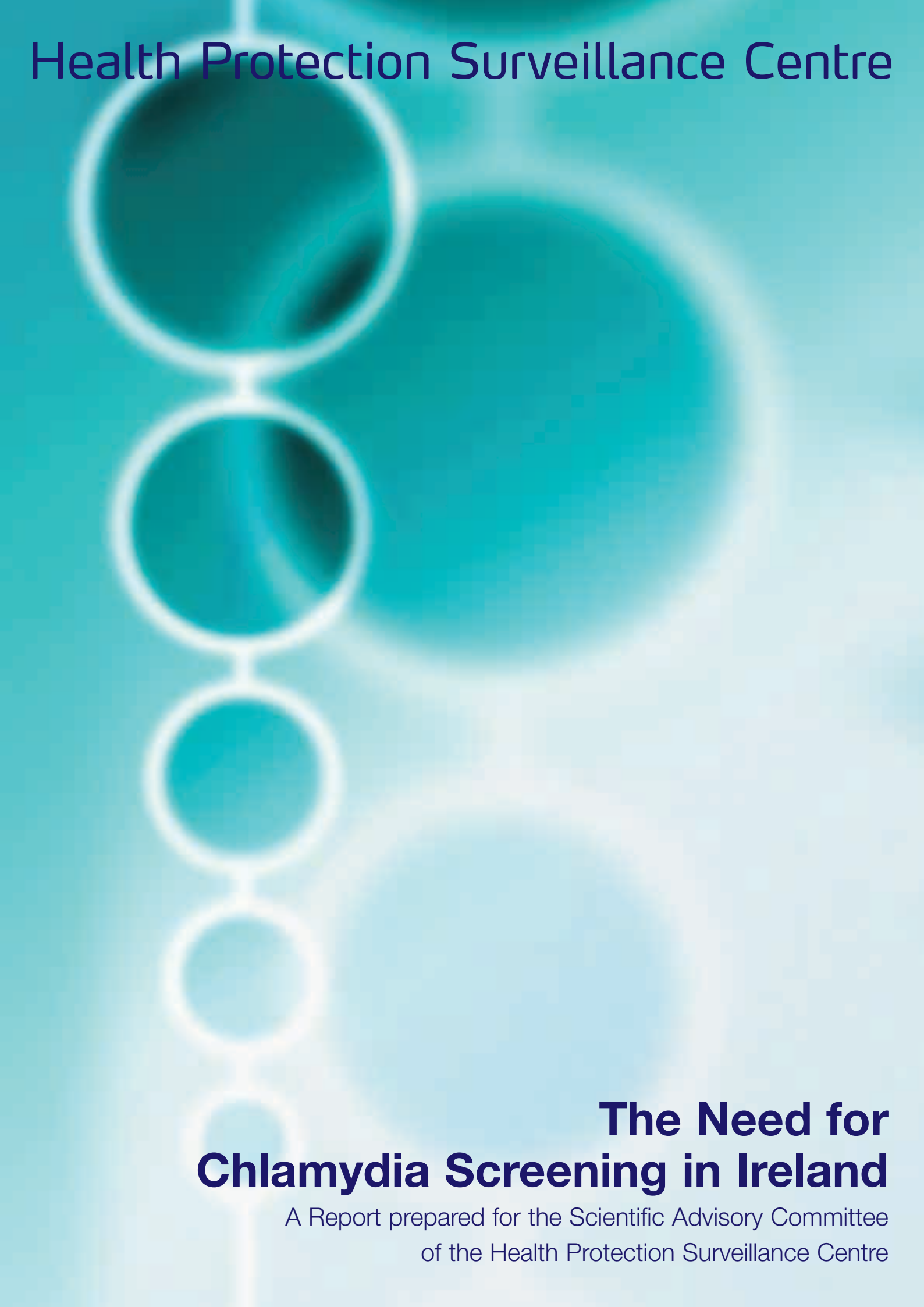
Health Protection Surveillance Centre



The Need for Chlamydia Screening in Ireland

A Report prepared for the Scientific Advisory Committee of the Health Protection Surveillance Centre

The Need for Chlamydia Screening in Ireland

A Report prepared for the Scientific Advisory Committee of the Health Protection Surveillance Centre

October 2005

ISBN: O-9540177-9-X

TABLE OF CONTENTS

Foreword

Genital *Chlamydia trachomatis* is the most common bacterial sexually transmitted infection (STIs) worldwide with an estimated 89 million new cases each year. The infection can be cured with antibiotics and transmission prevented by treating sexual partners. It is a transmissible cause of severe reproductive morbidity, including Pelvic Inflammatory Disease (PID), tubal factor infertility and ectopic pregnancy in women. The economic and human costs of managing the complications of genital *Chlamydia trachomatis* infection are considerable.

The number of reported cases in Ireland increased ten-fold between 1995 and 2004. The number of cases reported represents only a fraction of the true incidence of infection, as most infections are asymptomatic. Screening or case finding is an essential component of control programmes. Chlamydia screening programmes are in place in Sweden, the United States (US), Canada and a programme is currently being rolled out in the England. In addition, various models for screening are currently being examined in other European Union (EU) countries.

This report contains a comprehensive review of the international literature in relation to screening for chlamydia infection. It brings together the limited Irish data available on the subject and identifies the gaps in the information available. The committee concluded that priority should be given to obtaining data from Irish research to establish the prevalence of genital *Chlamydia trachomatis* infection in different subpopulations in Ireland in order to inform policy on the need for screening in Ireland. Studies to establish the feasibility, acceptability and likely uptake of screening in various settings in Ireland and best practice for management of identified infections and partner notification are also *urgently* required. The report identifies options whereby the necessary research could be carried out. The report also highlights the additional clinical and laboratory services needed in the context of the introduction of a screening programme in Ireland.

I would like to take this opportunity to thank the members of the committee for their contributions to the report. I would also like to acknowledge in particular Dr Kate O'Donnell for her work and commitment in producing the report and Dr Patricia McDonnell who conducted an extensive review of the literature on the topic.

Mary C. Cronin
Chairperson of the Sexually Transmitted Infections Subcommittee
September 2005

Summary

- The 2001 Health Strategy contains a recommendation that 'an Action Plan for Sexual Health' should be prepared. In this context the National AIDS Strategy Committee (NASC) has recommended that the conclusions of the subcommittee, which is considering the need for chlamydia screening in Ireland, should be considered *as a matter of priority*.

- Genital *C. trachomatis* is:

    - the most common bacterial STI worldwide.

    - a transmissible cause of severe reproductive morbidity, including PID, tubal factor infertility and ectopic pregnancy in women

    - easily treatable and curable.

- The economic and human costs of managing the complications of genital *C. trachomatis* infection are considerable. Most infections are asymptomatic and therefore screening or case finding is an essential component of control programmes.

- The increase in the numbers of reported diagnoses reflect a true underlying increase in the incidence of genital chlamydia infection but also reflect increased screening for and recognition of asymptomatic infection and the increasing use of highly sensitive and specific DNA amplification techniques or nucleic acid amplification tests (NAATs) for diagnosis of *C. trachomatis*. These tests can be used on non-invasively collected specimens, such as urine and self-collected vulvo-vaginal swabs. They are the diagnostic tests of choice for laboratory diagnosis of *C. trachomatis* infection and are now routinely used.

- Young age and recent change in sexual partner are the most commonly reported risk factors for infection in other countries. There are very limited data available on prevalence of *C. trachomatis* in Irish settings. The data available from STI clinics, FPCs, student and antenatal settings in Ireland suggest similar trends to those seen in the UK and other parts of Europe.

- While further evidence from ongoing research in relation to aspects of screening intervals, natural history of NAATS detected infections and relapse/re-infection rates, which will allow more accurate cost effectiveness analysis, is awaited, there is evidence that case finding for genital chlamydia infection, based on screening for infection among sections of the sexually active population, can reduce the prevalence of genital tract infections and PID in women.

- Chlamydia screening programmes are in place in Sweden, the US and Canada. Various models for screening are also currently being examined in other EU countries.

- A National Chlamydia Screening Programme (NCSP) is also being 'rolled out' in England, targeting young men and women under the age of 25 who are attending healthcare facilities not traditionally associated with providing specialist sexual health services including contraceptive clinics, general practices, young people's services, antenatal services, colposcopy and infertility units. Screening is also encouraged through innovative outreach strategies, such as "pee in a pot" days at military bases, university campuses, prisons and other non-traditional settings.

- Countries with screening programmes such as Sweden and the US and those without screening programmes, have shown similar recent increases in the prevalence of genital *C. trachomatis* which may be explained by failure to include men in screening programmes, resulting in a circulating pool of untreated asymptomatic genital chlamydia infection, or by increased risk-taking behaviour. Recent commentators have concluded that screening programmes must employ innovative strategies to maximize screening opportunities beyond traditional settings and must also target men in screening programmes.

- The committee considered that data from Irish research is *urgently* required to establish the prevalence of genital *C. trachomatis* infection in different subpopulations in Ireland in order to inform policy on the need for screening in Ireland and that studies to establish the feasibility, acceptability and likely uptake of screening in various settings in Ireland. Best practice for management of identified infections and partner notification are also *urgently* required.

- Two options were considered by the committee in order to progress the research required:

    - The Health Protection Surveillance Centre (HPSC), supported by the Health Services Executive (HSE), would commission the research required.

    - A researcher would be employed by HPSC to develop a proposal and identify sources of funding for research. This person would subsequently take the lead role in co-ordinating the research and would report to a steering committee set up to oversee the research. The person would have a clinical background and possess the requisite epidemiological and leadership skills in order to be able to manage the process satisfactorily.

- In the context of a screening programme, current STI clinic capacity should be enhanced in order to meet anticipated increased demand for services.

- In the context of any new screening programme, there is a need for support for General Practice in terms of education, training and additional resources in order to develop its role.

- Pending the outcome of research and the possible introduction of a screening programme, there is a need for the development of guidelines in relation to treatment, management and follow up (including contact tracing/partner notification) of genital *C. trachomatis* infections which are currently being identified in general practice.

- The following will need consideration from a diagnostic laboratory perspective:

    - development of suitable testing protocols both from a practical and a cost perspective, including details of specimen requirements and NAATS to be used

    - development of Standard Operating Procedures (SOPs) for collection and processing of specimens, including the need for refrigeration of specimens following collection and transportation of specimens to the laboratory

1. Introduction

In 2001, the Scientific Advisory Committee (SAC) of the HPSC, known formerly as the National Disease Surveillance Centre (NDSC), established an STI subcommittee.

The terms of reference of the subcommittee were as follows:

1. To review the current system of notification of STIs and make recommendations regarding:

   - the diseases under surveillance and the data items required for effective surveillance;

   - the process of notification and systems/structures required to facilitate easy communication of information between notifiers and public health;

   - ensuring patient confidentiality;

   - the use of surveillance information to inform policy and prevention strategies for sexual health.

2. To identify the need for primary and reference laboratory facilities and to make appropriate recommendations.

3. To investigate the need for screening for chlamydia in Ireland

Membership of the STI subcommittee was as follows:

Dr Anthony Breslin	Regional AIDS coordinator HSE - North Western area (Replaced Dr Wilson in June 2004)
Dr Mary Cronin (Chair)	Specialist in Public Health Medicine Health Protection Surveillance Centre
Professor Mary Cafferkey	Consultant Clinical Microbiologist Rotunda Hospital, Dublin 1
Dr Lisa Domegan	Surveillance Scientist Health Protection Surveillance Centre (Leave from Sept 2004 to May 2005)
Dr Margaret Fitzgerald	Specialist in Public Health Medicine HSE - Eastern region
Dr Cliodhna Foley-Nolan	Specialist in Public Health Medicine HSE - Southern area (Resigned September 2004)
Dr Derek Freedman	GenitoUrinary Medicine Physician Irish College of General Practitioners
Ms Eleanor Kehoe	Infection Control Nurse Specialist St James's Hospital Dublin 8 (Resigned from the committee in Nov 2004)

Dr Anne Moloney	Consultant Clinical Microbiologist HSE - South Eastern area
Dr Fiona Mulcahy	Consultant in GenitoUrinary Medicine St James's Hospital, Dublin 8
Dr Maire O'Connor	Specialist in Public Health Medicine HSE - South Eastern area (Resigned from the committee in 2003)
Dr Nuala O'Connor	General Practitioner Irish College of General Practitioners
Dr Kate O'Donnell	Surveillance Scientist Health Protection Surveillance Centre (Replaced Dr Domegan in Sept 2004)
Dr Mary O'Mahony	Specialist in Public Health Medicine HSE - Southern area (Resigned from the committee in 2003)
Dr Lelia Thornton	Specialist in Public Health Medicine Health Protection Surveillance Centre (Replaced Dr Foley-Nolan in Sept 2004)
Dr Therese Wilson	Regional AIDS coordinator HSE - South Eastern area (Retired in June 2004)

In order to deal with the 3rd term of reference, *"To investigate the need for screening for chlamydia in Ireland",* a subgroup was formed with additional membership of people with interest and expertise in the particular area.

Membership of the Chlamydia Screening subgroup was as follows:

Dr Mary Cronin, SPHM, HPSC **(Chair)**
Prof. Mary Cafferkey, Consultant Clinical Microbiologist, Rotunda Hospital, Dublin
Dr Suzie Coughlan, Senior Scientist, National Virus Reference Laboratory
Dr Lisa Domegan, Surveillance Scientist, HPSC (Leave from Sept 2004 to May 2005)
Dr Margaret Fitzgerald, SPHM, HSE - Eastern Region
Dr Cliodhna Foley-Nolan, SPHM, HSE - Southern Area (Resigned in Sept 04)
Dr Sheila Jones, Medical Director, Irish Family Planning Association
Dr Fiona Lyons, SpR in GUM, St James's Hospital
Dr Fiona Mulcahy, Consultant in GUM, St James's Hospital
Dr Kate O'Donnell, Surveillance Scientist, HPSC (Replaced Dr Domegan)
Dr Fiona Thompson, Student Health Service, University College Dublin
Dr Sandra Tighe, Medical Director, Student Health Services, UCD

The Scientific Advisory Committee of the HPSC, having considered the chapter '*The Need for Chlamydia Screening in Ireland',* decided that, because of the importance of the issue, this chapter of the report should be put out for consultation and subsequently published as a 'stand alone' document at the earliest possible opportunity.

2. Epidemiology of genital *C. trachomatis* infection

2.1Genital C. trachomatis infection

Genital *C. trachomatis* infection is the most common, curable, bacterial STI in the world with an estimated 89 million new cases each year.[1,2] The infection can be cured with antibiotics and transmission prevented by treating sexual partners. Genital chlamydia is a transmissible cause of severe reproductive morbidity, including PID, tubal factor infertility and ectopic pregnancy in women.[3] A review by the Centers for Disease Control and Prevention (CDC) in the US concluded that approximately 40% of women with untreated *C. trachomatis* infection experience PID and of those with PID, 20% will become infertile, 18% will experience chronic pelvic pain and 9% will have a life-threatening tubal pregnancy.[4] In addition, there is evidence that genital chlamydia infection increases the risk of HIV transmission[5] and that infection is an independent risk factor for invasive cervical squamous cell carcinoma.[6] Complications among men with untreated infection include urethritis, epididymitis and Reiter's syndrome.[7] Recent evidence has also suggested that infection can cause male infertility.[8] Complications may not become manifest until many years or decades after the initial infection and therefore the impact of today's infection rate may not be seen for many years. Treating complications of genital *C. trachomatis* infection is estimated to cost £100 million per year in the United Kingdom (UK).[9]

Most infections are asymptomatic or cause only mild non-specific symptoms and so may remain undiagnosed. Up to 70% of women and 75% of infected men are asymptomatic[10] and therefore screening or case finding of those at risk in order to detect asymptomatic infection is an essential component of *C. trachomatis* control programmes.

Key points:

- **Genital *C. trachomatis* is:**
  - **the most common bacterial sexually transmitted infection worldwide.**
  - **a transmissible cause of severe reproductive morbidity, including PID, tubal factor infertility and ectopic pregnancy in women.**
  - **easily treatable and curable.**
- **The economic and human costs of managing the complications of genital *C. trachomatis* infection are considerable.**
- **Most infections are asymptomatic and therefore screening or case finding is an essential component of control programmes.**

2.2 Notification data from Ireland

C. trachomatis became notifiable in Ireland under S.I. No 268/1985 Infectious Diseases (Amendment) Regulations 1985. Routinely available data for Ireland on diagnoses of genital *C. trachomatis* infections are based on aggregate data collected quarterly on the number of notified infections from Departments of Public Health in the HSE regions. The data are collated and published by the HPSC. STI data are mainly clinic based, although some notifications also come from primary care. The data underestimates the total burden of STIs, particularly those presenting to GPs, FPCs, student health services and hospital specialities, other than STI clinics. In order in assist in planning and evaluating any screening programme, the quality of the surveillance data currently being collected from STI clinics and general practice needs to be improved.

Between 1995 and 2004, notified cases of genital *C. trachomatis* infection increased more than ten-fold (Figure 1). Between 1989 and 1994, the number of notified cases of *C. trachomatis* generally remained stable fluctuating around a mean of 205 reported cases per year.

Between 1989 and 1999, *C. trachomatis* was the fourth most frequently notified STI each year (candidiasis, non-specific urethritis and ano-genital warts were the most frequently notified STIs). During 2000, *C. trachomatis* was the third most frequently notified STI. *C. trachomatis* notifications increased substantially during 2001, 2002 and 2003 representing 17%, 18% and 20.2% of the total number of STI notifications, respectively. (Figure 2). On 1st January 2004, Infectious Diseases Amendment S.I. No. 707 of 2003 established a revised list of STIs in which candidiasis, molluscum contagiosum

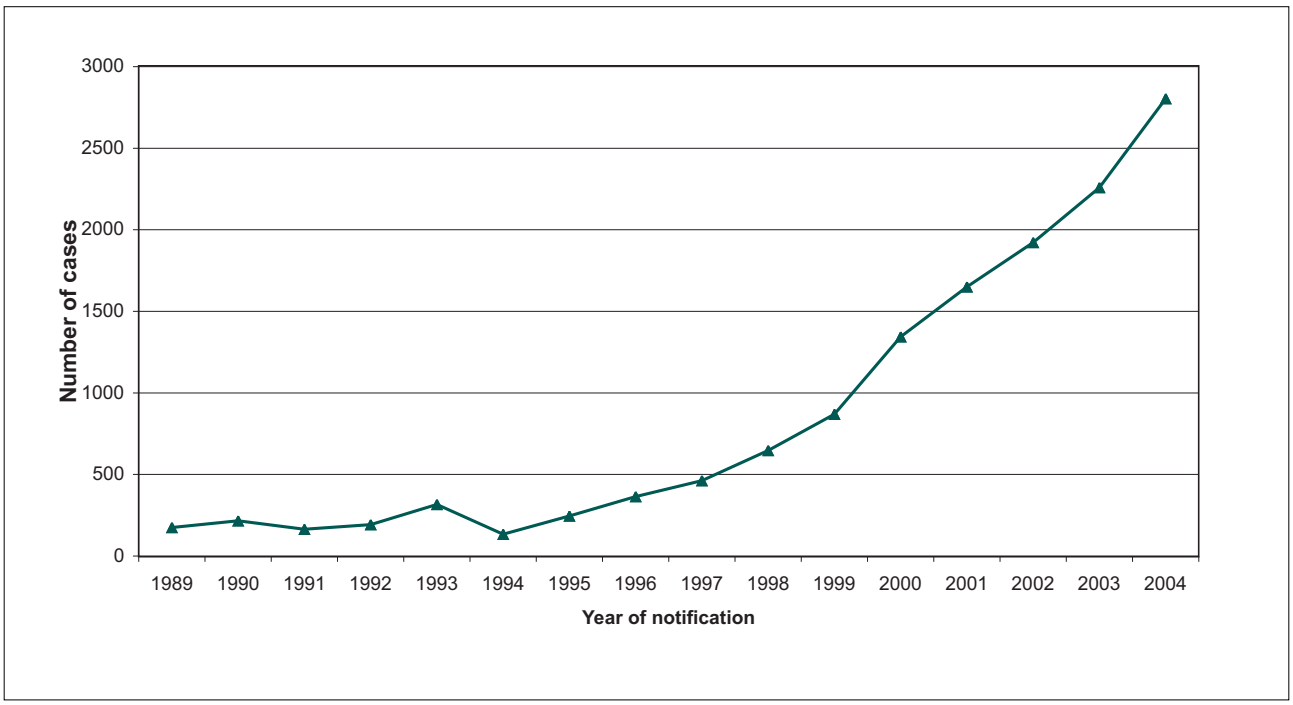


Figure 1: Number of notifications of *C. trachomatis* by year of notification, 1989 to 2004[1].

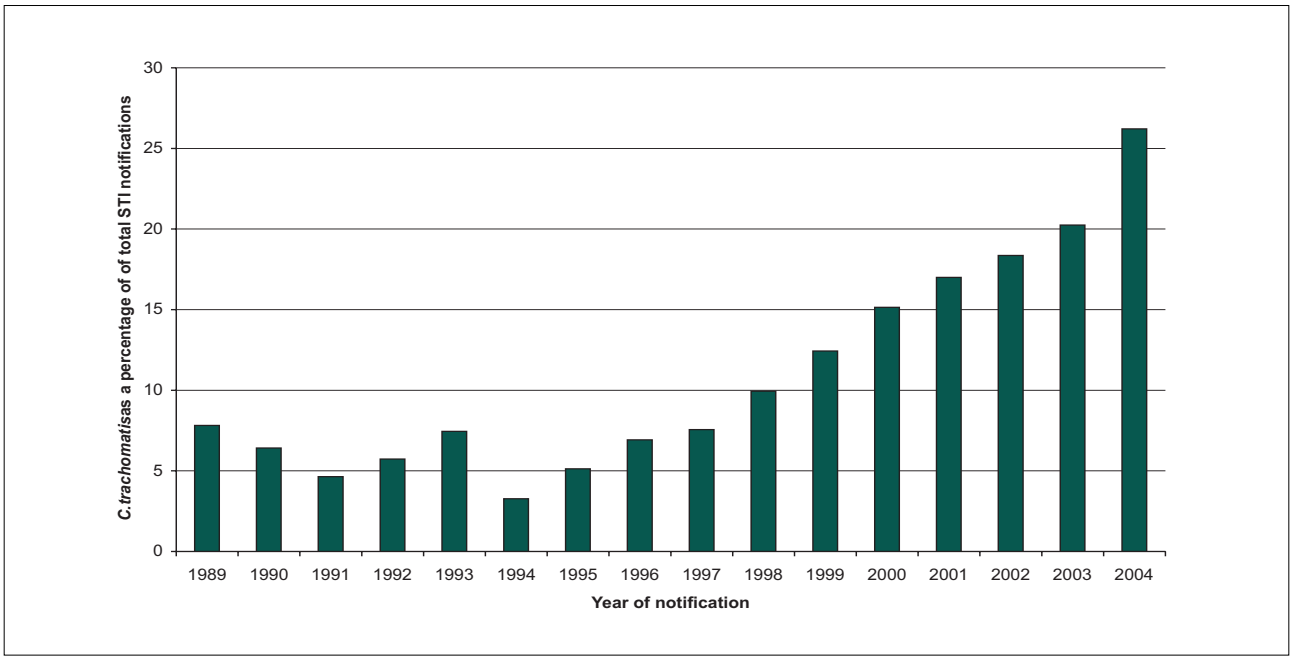


Figure 2: Number of *C. trachomatis* notifications, as a percentage of the total number of STI notifications, by year of notification, between 1989 and 2004.*

*On 1st January 2004, Infectious Diseases Amendment S.I. No. 707 of 2003 established a revised list of STIs in which candidiasis, molluscum contagiosum and pediculosis pubis are no longer notifiable.

and pediculosis pubis are no longer notifiable. In that same year 10,695 STIs were notified in total and *C. trachomatis* are now the second most commonly notified STI in Ireland after ano-genital warts.

Since 1995, age group and gender data for notified STIs are available. Age-group data should be interpreted with caution, as the age group for 62.4% of cases notified between 1995 and 2002 was unknown. However, in 2003, age group was provided for 98% of cases notified but in 2004 this percentage dropped to 65.8% but this was largely attributable to ano-genital warts notifications. In 2004, age group was provided for almost 99% of *C. trachomatis* cases notified. Between 1995 and 2003, the mean percentage of male and female *C. trachomatis* cases notified each year was 45.1% and 53.2%, respectively (Figure 3). Between 2003 and 2004, the majority (average=69.5%) of all *C. trachomatis* notifications were among 20-29 year olds (Figure 4).

[1]Sources of data: 1989 to June 2000, Department of Health and Children (DOHC); from July 2000, HPSC.

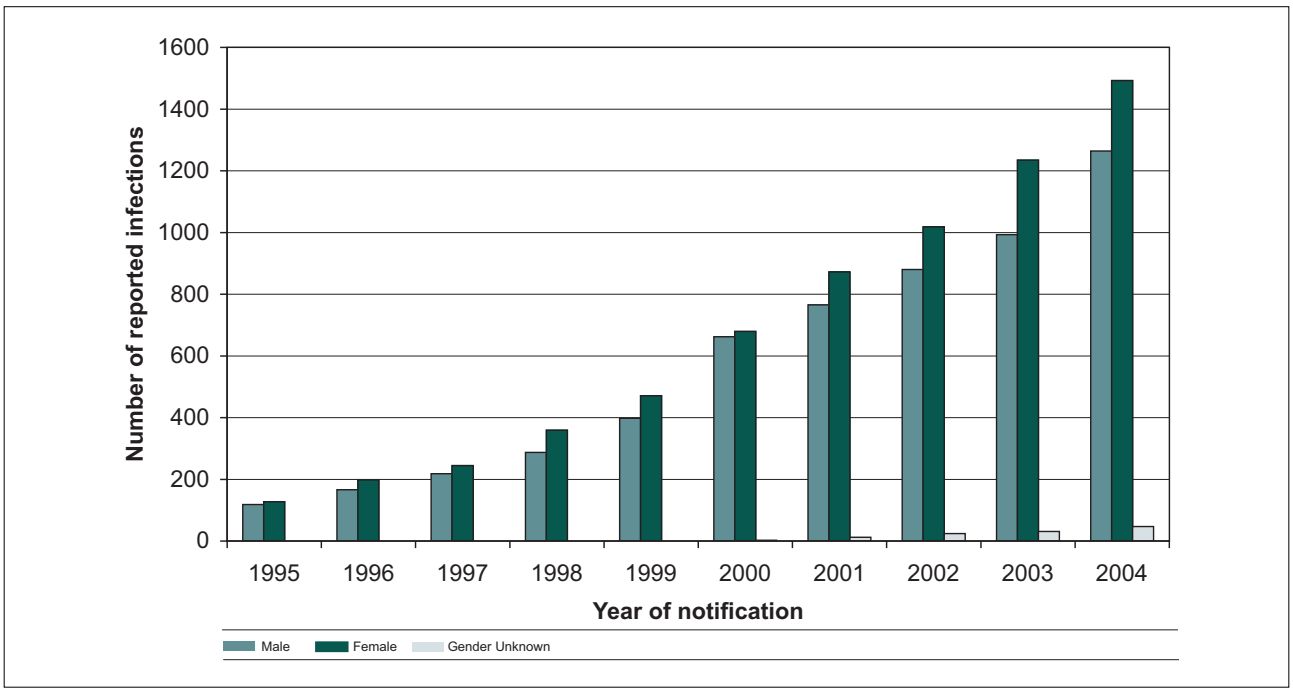


Figure 3: Number of notifications of *C. trachomatis* by gender and year of notification between 1995 and 2004.

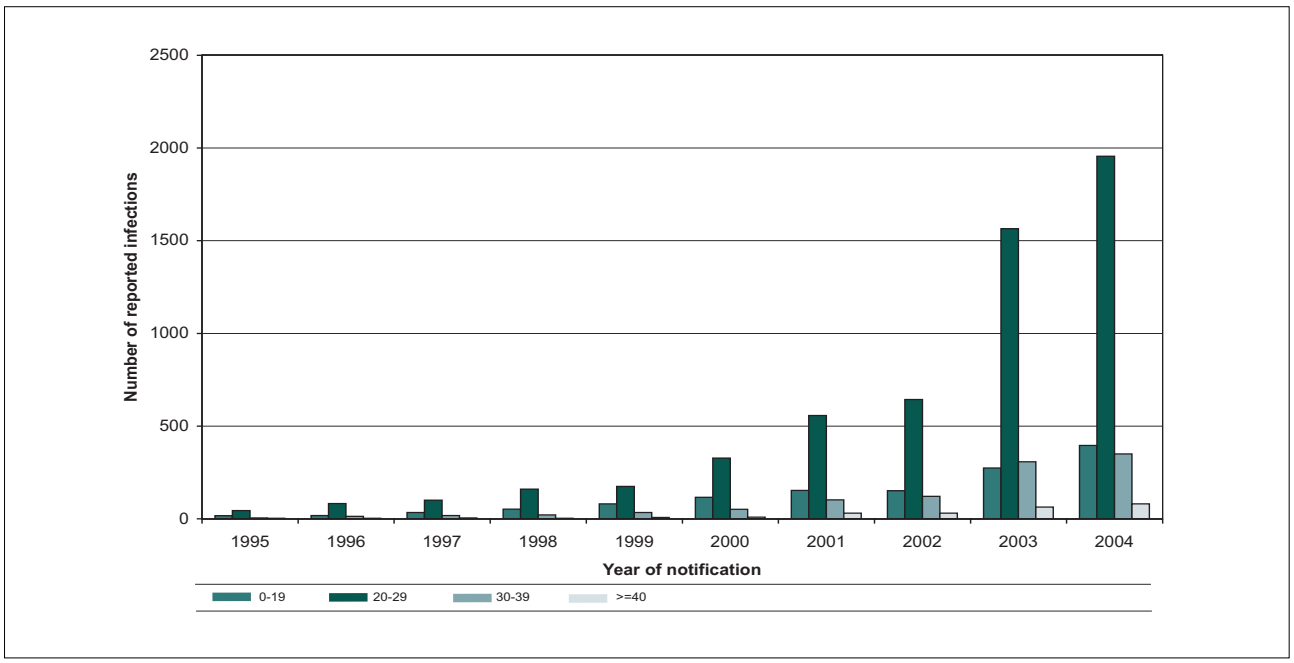


Figure 4: Number of notifications of *C. trachomatis* by age group (in years) and year of notification between 1995 and 2004 (Data for age group unknown not included).

These figures are likely to reflect a real increase in the rate of genital *C. trachomatis* infection but also reflect increased screening for and recognition of asymptomatic infection. Improved reporting capacity, the increasing use of highly sensitive and specific DNA amplification techniques for diagnosis of *C. trachomatis* which can be used on non-invasively collected specimens, particularly urine, have also probably contributed to the increase.

2.3 Outcome data

In addition to data on genital *C. trachomatis* infection, outcome data in relation to some of the long-term sequelae of genital chlamydia infection are available from the Hospital Inpatient Enquiry (HIPE) system.[11] The HIPE System is a computer-based health information system designed to collect clinical and administrative data regarding discharges and deaths from acute hospitals in Ireland.

Historical HIPE data have limitations, as data from Maternity Hospitals were not required until 1999, although some data have been submitted since 1994. In addition, each HIPE discharge record represents one episode of care and patients may have been admitted to hospital(s) more than once with the same or different diagnoses. The records facilitate analyses of hospital activity rather than "incidence" of disease.

Table 1 illustrates the number of patient discharges, with diagnoses of PID, tubal (Ectopic) pregnancy or tubal factor infertility per 100,000 total hospital discharges for the years 1999 to 2003.
During the five years, 1999 to 2003, there was a 28% increase in the proportion of discharges with a diagnosis of tubal (ectopic) pregnancy per 100,000 total hospital discharges and a 3.2% % increase in the proportion of discharges with a diagnosis of PID per 100,000 total hospital discharges. Over the same time period, the proportion of discharges with a diagnosis of tubal factor infertility decreased from 33.7 per 100,000 total discharges in 1999 to 21.5 per 100,000 total discharges in 2003. There is a strong association between *C. trachomatis* infection, tubal factor infertility and ectopic pregnancy in women with or without a history of PID.[12] However, this data relates to hospital inpatient episodes and not incidence of these conditions, therefore one cannot conclude that complication rates from *C. trachomatis* infection are on the increase. There are other factors, which may have had an impact on the HIPE data, such as a change in the practice of admitting patients to hospital for investigation of infertility or for symptoms of PID. However, systematic collection of hospital discharge data on a prospective basis will be valuable in terms of evaluation of any screening programme for genital *C. trachomatis* infection.

Table 1: Rate of patient discharges, with diagnosis of PID, tubal (Ectopic) pregnancy or tubal factor infertility 1999-2003.

Year	Rate per 100,000 discharges		
	Tubal Pregnancy	PID	Tubal factor infertility
1999	43.3	157.8	33.7
2000	50.5	158.1	35.8
2001	44.2	151.8	31.4
2002	51.7	154.5	29
2003	55.1	162.8	21.5

2.4 Epidemiology in other European Union (EU) countries and the United States (US)
In a review of recent trends in the epidemiology of STIs in the EU, Fenton and Lowndes note that 'available surveillance data confirms the disproportionate disease burden occurring in young women aged less than 20 years'.[13] They also note that 'because of frequently asymptomatic nature of infections, our understanding of chlamydial epidemiology in Europe is also greatly enhanced by data from *ad hoc* prevalence studies'. They quote from a systematic review, published in 2002 by Wilson *et al*, looking at the prevalence of genital *C. trachomatis* infection in unscreened asymptomatic women in Europe, which found rates ranging from 1.7% to 17% depending on setting, context and country.[14] The mode was 6% for women seeking contraception and 4% for women having cervical smears.

In the UK, the prevalence of genital chlamydial infection varies from 1% to 29%.[15] Since 1995, reported diagnoses of genital chlamydial infection seen in genitourinary medicine (GUM) clinics in the UK have been rising steadily.[15] However, it is estimated that less than 10% of prevalent infections are diagnosed in GUM clinics in the UK.[16] A recent study in the UK concluded that the prevalence of genital *C. trachomatis* infection outside specialist GUM clinics is substantial.[16] In the study, prevalence was higher in younger women aged 16-20 than in those aged 21-24 years and was highly variable in different healthcare settings (range 3.4%-17.6%). The study concluded that prevalence in general practice in the UK was approximately 9%. A recently published systematic review and analysis of prevalence studies in the UK [17] also indicated clear trends of high prevalence in younger age groups with decreases with increasing age across settings and also prevalence differences by setting. For example, for females <20 years the prevalence ranged from 17.3% at GUM clinics, to 8.1% in GP surgery, to 4.8% in the general population, with the corresponding figures for females >30 years 3.2%, 1.4% and 0.8% respectively.

A cross sectional study conducted in the US, of more than 14,000 young adults between 18 and 26 years, found a prevalence of chlamydial infection of 4% in both men and women.[18]

Key Points:

- Between 1995 and 2003, numbers of chlamydia infections reported in Ireland increased over 9-fold.
- The numbers of cases reported reflect true underlying increases in rates of chlamydial infection and also increased screening for and recognition of asymptomatic infection and increasing use of highly sensitive and specific DNA amplification techniques (NAATS) for diagnosis of *C. trachomatis* which can be used on non-invasively collected specimens such as urine and self collected vaginal swabs.
- Notwithstanding that the data available relates to hospital inpatient episodes and not incidence of these conditions, between 1999 and 2003, there was a 28% increase in the proportion of discharges with a diagnosis of tubal (ectopic) pregnancy and a 3.2% increase in the proportion of discharges with a diagnosis of PID.
- Since 1995, reported diagnoses of genital chlamydial infection seen in GUM clinics in the UK have been rising steadily and it is estimated that less than 10% of prevalent infections are diagnosed in GUM clinics in the UK. There is a clear trend of higher prevalence in younger age-groups in the UK.
- A systematic review, published in 2002 looking at the prevalence of genital *C. trachomatis* infection in unscreened asymptomatic women in Europe, found rates ranging from 1.7% to 17% depending on setting, context and country.

3. Literature Review

3.1 Is screening for genital C. trachomatis an effective intervention strategy?

The Second Report of the UK National Screening Committee[19] set out a number of criteria for appraising the viability, effectiveness and appropriateness of a screening programme (see Appendix 1), based on the set of classic criteria for screening first promulgated by Wilson and Jungner in a WHO Report in 1966.[20] Genital chlamydia infection fulfils these criteria in terms of the condition, the test and the treatment with perhaps some reservations in relation to the natural history of 'screen detected infection'. The criteria also state that 'adequate staffing and facilities for testing, diagnosis, treatment and programme management should be made available prior to the commencement of the screening programme.'

3.2 The screening test

The positive predictive value (PPV) of a screening test estimates the probability that, given a positive result, the individual in question actually has the condition.

Calculation of PPV of a screening test and the impact of prevalence

The following is a worked example of the impact of the prevalence of a disease or condition on the target population and the sensitivity and specificity of a screening test on the PPV of a screening test.

1. Population true positives and negatives:

Pop A: Prevalence 2% Population of 1000	True positives= 20	True negatives= 980
Pop B: Prevalence 10% Population of 1000	True positives= 100	True negatives= 900

2. Test pick up of positives:

Pop A: Prevalence 2% Sensitivity of 90%	Test positives= 18	False negatives = 2
Pop B: Prevalence 10% Sensitivity of 90%	Test positives= 90	False negatives =10

3. Test pick up of negatives:

Pop A: Prevalence 2% Specificity of 98%	Test negatives= 960	False positives = 20
Pop B: Prevalence 10% Specificity of 98%	Test negatives=882	False positives = 8

4. PPV

A. Population A with 2% prevalence:

The test found 18 positives in point 2 and 20 positives in point 3 above = total of 38 positives.
Only 18 are true positives: 18/38 = 47% Positive Predictive Value

Result:

Prevalence = 2%	Sensitivity=90%	Specificity=98%	PPV= 47%

B. Population B with 10% prevalence:

The test identified 90 positives in point 2 above and 8 positives in point 3 = total of 98 positives.
Only 90 of these are true positives: 90/98 = 92% PPV

The higher the prevalence of the disease in the population being screened and the higher the sensitivity and specificity of the test, the better the positive predictive value.

DNA amplification tests now provide highly sensitive and specific diagnostic techniques that are more acceptable to patients than previously available tests because they can be performed on non-invasively collected specimens, such as urine and self-collected vulvo-vaginal swabs. In a recently published comparison of three nucleic acid amplification tests (NAATs) for *C. trachomatis,* detection sensitivities of between 96% and 100%, and specificities of between 99% to 100% were demonstrated.[21] NAATs are now the test of choice for diagnosis of genital chlamydia infection and are routinely used. The availability of these tests has resulted in increasing interest and debate in relation to the introduction of screening programmes for genital chlamydia infection.

3.3 Randomised Controlled Trial

International evidence from several case studies[22,23] and one widely quoted randomised controlled trial (RCT)[24] suggest that screening reduces the prevalence of genital tract infections and PID in women. The RCT was conducted in Seattle, Washington State, USA, between 1990 and 1992. Women who were at high risk for disease were identified by means of a questionnaire mailed to all women enrolees in a health maintenance organization between 18 to 34 years of age. Eligible respondents were randomly assigned to undergo testing for *C. trachomatis* or to receive usual care; both groups were followed for one year. Possible cases of PID were identified through a variety of databases and were confirmed by review of the women's medical records. A strategy of identifying, testing, and treating women at increased risk for cervical chlamydial infection was associated with a reduced incidence of PID. There were a number of limitations to the RCT which related to: the difficulties involved in identifying the population at risk for chlamydia infection (only 57% of women returned questionnaires), getting a high response to an invitation for screening (only 64% of invitees attended for screening) and the emphasis on following up non-responding women in the intervention group rather than the usual care group, suggesting the possibility of selection bias. Only a small proportion of the women randomised at the start of the study were included in the final analysis. Women younger than eighteen years of age were not included in the study. Overall numbers of cases were small and the follow-up period was only twelve months. Long-term outcomes such as ectopic pregnancy, infertility, chronic pelvic pain or recurrence were therefore not addressed in the study. In addition, women who attended for screening may have changed their life style risk factors following the attendance at the clinic and thus health promotion rather than antibiotic treatment may have been responsible for the reduction in PID. The RCT evaluated a population-based approach to screening but this trial has also been cited as evidence in support of opportunistic screening of people using existing health services. Commenting on this trial, Low and Egger state that 'it is unclear to what extent the results of population based screening can be extrapolated to opportunistic strategies[1].

3.4 Case Studies

A national programme of active case finding, or screening, for genital *C. trachomatis* infection in Sweden was initially associated with dramatic reductions in the incidence of infection and its sequelae.[25] However, as cited by Low[26] in a recent article summarising the current status of screening for genital *C. trachomatis* in Europe, national clinical notifications of infections in Sweden, show that *C. trachomatis* rates increased in all counties in Sweden between 1997 and 2003.

Although the prevalence of chlamydial infection in women attending FPCs in the northwestern USA declined dramatically after the implementation of screening, the decline has not been sustained, nor replicated in other regions of the US.[27] A recent commentary in the Lancet suggests that the current screening policy in the US, to offer screening to all sexually active women aged 25 years and younger appears to be unable to bring about and sustain a reduction in the risk of acquiring chlamydia.[27]

3.5 Recent increases in prevalence

Low and Egger[1] suggest that a possible explanation for the resurgence in numbers of reported cases could be the failure to include men comprehensively in the screening programme. They argue that the assumption that the prevalence of *C. trachomatis* is lower in men than in women is not necessarily correct and therefore opportunistic screening in health care settings, which tends to miss a large proportion of men at risk, together with partner notification, may not be sufficient to produce a sustained reduction in prevalence of *C. trachomatis* infection, resulting in a circulating pool of untreated asymptomatic infection. They argue that these findings suggest that the opportunistic screening approach to control may have reached its limit.

In Finland[28] incidence rates have been increasing since 1995, despite no major changes in the public sexually transmitted disease services or screening practices in that country. These trends, which have been highest among young women and men less than 20 years, may be explained by increased risk-taking behaviour. [28]

In the recent Lancet commentary, Miller concludes that the current targeted opportunistic screening programmes in England and the US are 'important steps toward limiting the complications of chlamydial infection. However, these programmes will likely have more individual than public-health benefit.' He says that 'long-term reduction in the prevalence of chlamydial infection seems improbable with the current programmes, unless men are targeted, clinic-based screening is maximised and innovative strategies are developed to encourage young people to be screened'.[27]

Key points:

- **Highly sensitive and specific NAATs on non-invasive specimens (urine, self collected vulvo-vaginal swabs) or endocervical swabs are the diagnostic tests of choice for laboratory diagnosis of *C. trachomatis* infection and are now routinely used.**
- **There is evidence that case finding for genital chlamydia infection, based on screening for infection among sections of the sexually active population, can reduce the prevalence of genital tract infections and PID in women.**
- **Countries with and without screening programmes have shown similar recent increases in the prevalence of genital *C. trachomatis*, which may be explained by failure to include men in screening programmes, resulting in a circulating pool of untreated asymptomatic genital chlamydia infection, or by increased risk-taking behaviour.**
- **Recent commentators have concluded that screening programmes must employ innovative strategies to maximize screening opportunities beyond traditional settings and must also target men in screening programmes.**

3.6 Cost effectiveness of screening

The positive predictive value of a screening test, that is the proportion of true positive tests among all positive tests, depends on the specificity and sensitivity of the test and most importantly on the prevalence of the disease in the tested population as illustrated in section 3.2. If the prevalence of the disease is low, even a highly valid test in terms of sensitivity and specificity, will yield a low positive predictive value. Honey *et al* carried out a review of published studies in relation to the cost effectiveness of screening for *C. trachomatis* and concluded that, in general, universal screening (in which all individuals within a target population are screened) is cost effective and saves resources if the prevalence is above 3.1%.[29] However, if the prevalence is less than 3.1%, selective screening on the basis of predefined risk factor criteria is considered to be more cost effective. Nelson *et al* say that opportunistic screening will detect relatively small numbers of infections but will optimise cost effectiveness and offer the opportunity to limit the possible adverse effects of screening by carefully selecting and counselling eligible candidates.[30]

The Chief Medical Officer's (CMO) advisory group in the UK recommended opportunistic screening for case finding, rather than a call-recall system based on age or sex.[9] The group concluded that an age-based, call-recall system could be very inefficient because resources are wasted in inappropriately contacting people who are not sexually active. [31]

3.7 Who should be targeted?

The most difficult aspect of any type of screening is deciding who to screen and how often to do so. Several international studies have identified various demographic or behavioural risk factors associated with genital *C. trachomatis* infection, including younger age (particularly under 25 years), multiple partners, recent change of partner, single marital status, minority ethnic groups, low school leaving age, genital symptoms, or the presence of another STI. [4] Young age and recent change of sexual partner are the most commonly reported risk factors for infection.

The CMO's expert advisory group in the UK[9] concluded that, in addition to testing all symptomatic patients and those at higher risk of infection e.g. people attending GUM clinics, the evidence supported opportunistic screening of the general population and concluded that screening should be offered to sexually active women under 25 and also to those over 25 with a new sexual partner or who have had two or more partners in the past year. The group advocated the use of general practice and FPCs for screening and also stressed the importance of partner notification, which it recommended should be undertaken in collaboration with GUM clinics. The National Chlamydia Screening Programme (NCSP) in England offers screening to sexually active young men and women aged under 25 attending a variety of specialist and general healthcare settings.[32]

The CDC in the US recommends screening sexually active women < 20 years for chlamydial infection during routine annual examinations and annual screening of women aged >20 years on the basis of inconsistent use of barrier contraception and partner change[33].

In an ethnically and socioeconomically homogeneous population with a low prevalence of genital chlamydia infection attending two FPCs in Finland, Paukku *et al*[34] demonstrated that screening women 25 years or younger would have identified 28% of all chlamydial infections, while screening women aged 30 years or younger would have identified 83% of infections. They concluded that because of its feasibility, age appears to be the best screening criterion and they suggest that extension of the screening age to include women up to 34 years of age should be considered.

The model for screening in a general practice setting which was developed in Belgium by Verhoeven[31] *et al* was based not on age but on the number of partners in the past year as the primary determinant for screening. They proposed screening all women under 35 with >1 partner in the past year and screening all women with two of the following characteristics: age 18–27 years, frequent postcoital bleeding, no contraception or a partner with urinary complaints. In this model 37.5% of the population is screened and 92.3% of infections are detected.

Key points:

- **In a low prevalence population, selective screening on the basis of risk factors is considered to be more cost effective than universal screening.**
- **Young age and recent change in sexual partner are the most commonly reported risk factors for infection.**
- **In the UK, the NCSP policy is that, in addition to all symptomatic patients and GUM clinic attenders, screening should be offered to sexually active men and women under 25 and also to those over 25 with a new sexual partner or who have had two or more partners in the previous year.**

3.8 How often should screening be carried out?

The Sexually Transmitted Diseases Guidelines from the CDC[35] state that, a high prevalence of *C. trachomatis* infection is found in women who have had chlamydial infection in the preceding several months. Most post-treatment infections result from reinfection, often occurring because the patient's sex partners were not treated or because the patient resumed sex among a network of persons with a high prevalence of infection. Repeat infection confers an increased risk of PID and other complications, when compared with initial infection. The CDC guidelines state that 'recently infected women are a high priority for repeat testing for *C. trachomatis* and recommend that "clinicians and health-care agencies should consider advising all women with chlamydial infection to be rescreened 3-4 months after initial treatment. Some specialists believe rescreening is an especially high priority for adolescents. Providers are strongly encouraged to rescreen all women treated for chlamydial infection whenever they next present for care within the following 12 months, regardless of whether the patient believes that her sex partners were treated". [33]

3.9 In which settings should screening be carried out?

i. Primary Care

Women use health services more often and so are a more accessible population than men. Verhoeven[31] *et al* state that the general practice setting offers unique opportunities, not only to estimate STI risk, but also to discuss sexual health in a broader context. They suggest that a 'pill check' or routine gynaecological examination is an ideal opportunity to establish whether any symptoms suggestive of genital *C. trachomatis* infection are present which might often be too mild to be mentioned spontaneously. Discussing their proposed model for screening in a general practice setting, which would be based not on age but on the number of partners in the past year as the primary determinant for screening, they say that implementation of this strategy would demand sustained efforts from healthcare providers. They point out that it is easier for a physician to assess his/her female patient's age or education level, than to specifically and actively ask some questions related to her sexual activities. The latter, they say, is labour intensive and requires considerable communication skills especially since STI issues have to be raised with asymptomatic patients. They conclude that, for primary care based chlamydia control programmes to succeed, educating physicians is a preliminary condition.

In England, chlamydia screening is being rolled out nationally through GPs and FPCs. Catchpole *et al*[36] in an editorial piece on chlamydia screening in the UK say that 'mainstreaming' of chlamydia screening in primary care in the UK, 'which mainly practises reactive care', is a major challenge which should not be underestimated. They say that achieving this, at a cost which will ensure that the programme is cost effective, is likely to be one of the first significant tests of the feasibility of implementing opportunistic chlamydia screening in the UK.

ii. Feasibility and acceptability of screening in various settings in the UK

Published results of a pilot study of opportunistic screening, using first void urine (FVU) samples tested by ligase chain

reaction (LCR), of sexually active young women attending a range of healthcare settings including general practice, family planning, genitourinary medicine, adolescent sexual health, termination of pregnancy clinics and women's services in hospitals (antenatal, colposcopy, gynaecology and infertility clinics) in the UK, demonstrated that this method of screening is feasible and acceptable, achieving high levels of population coverage.[16]

iii. Screening during routine cervical smear testing
A systematic review of the prevalence of *C. trachomatis* infection in unscreened asymptomatic women in Europe, found prevalence rates from 1.7 to 17% depending upon the setting, context and country[14] The mode was ~6% for women seeking contraception and 4% for women undergoing cervical smears. A study in the UK documented lower than expected prevalence in cervical smear seekers with higher rates in those with known risk factors, especially young age and multiple partners[37] The authors concluded that screening asymptomatic women for chlamydia during routine cervical smear testing might yield fewer positive results than screening women with symptoms or in STI clinics.

iv. Chlamydia screening of pregnant women
A US review looked at prevalence studies in pregnant women and found rates of chlamydia infection ranging from 2% to 31%[38]. Risk factors for chlamydia infection in pregnant women were similar to those for non-pregnant women with the addition of late onset of prenatal care. The U.S. Preventive Services Task Force (USPSTF)[39] concluded that there is fair evidence that screening and treatment of women at risk for chlamydial infection improves pregnancy outcomes and that the benefits of screening outweigh potential harms and recommends that clinicians routinely screen all asymptomatic pregnant women aged 25 years and younger and others at increased risk for infection for chlamydial infection. However, the optimal timing of screening in pregnancy is uncertain. Screening early in pregnancy provides greater opportunities to improve pregnancy outcomes, including low birth weight and premature delivery; however, screening in the third trimester may be more effective at preventing transmission of chlamydial infection to the infant during birth.

v. Screening in non-traditional, non-clinic-based settings
Screening in non-clinic based settings is advocated by some authors who say that opportunities may be missed particularly in non-STD settings. A randomised controlled trial, comparing the effect of two population-based outreach screening strategies (a home sampling kit mailed directly to a centrally registered home address or a reply card mailed to a home address with which a home sampling kit could be ordered) were compared with usual care practices for *C. trachomatis* infection in a population of 30,439 persons 21-23 years old in Aarhus County, Denmark. Both screening strategies were highly effective, but men benefited the most from having the home sampling kit provided directly.[40]

A study recently published in the BMJ which invited 19,773 men and women aged 16-39, randomly selected from 27 general practices in the West Midlands and Avon to collect their own specimens (urine in men, urine and vulvovaginal swab in women) and return them by post together with a questionnaire on risk factors demonstrated the feasibility of postal chlamydia screening.[41] Coverage was incomplete and uptake was modest. There was lower coverage in areas with more non-white residents, along with poorer uptake in more deprived areas and among women at higher risk of infection. However, the authors did feel that postal screening could have a role as an adjunct to opportunistic screening as a proportion of individuals who had not visited their GP practice in the past year were reached.

In contrast, pharmacy-based testing does not seem promising as an approach to substantially increasing screening opportunities among young people. Free pharmacy-based testing was recently assessed in Amsterdam, the Netherlands. Women aged 15–29 years who were collecting contraceptives were actively offered a chlamydia test by a pharmacist. Only 13% of the eligible population was tested over a 2-year period, distribution declined over time, and the intervention was not cost-effective. It seems reasonable to assume that, without active encouragement, uptake would be even lower. Further, pharmacy testing is unlikely to increase screening coverage among men, who probably have less reason to attend pharmacies.[42]

Some studies have shown that screening for curable STIs in some schools in the US is feasible, although participation in testing programmes is complicated by the issue of a minor's ability to legally consent to STI testing.[43] Summarising the literature on testing for chlamydial and gonorrhoeal infections outside of clinic settings, Ford *et al*[43] conclude that 'challenges include defining and reaching target populations, overcoming logistic issues, developing communication and counselling strategies, and determining whether alternative testing strategies are effectively reducing infection rates'.

3.10 Gaps in the evidence
From the international literature there are gaps in the evidence, which limit support for large-scale routine screening. These gaps include: optimum screening intervals, issues in relation to relapse and re-infection, the issue of whether screening should be offered to men and the natural history of NAAT-detected infections.[44]

Case finding for genital chlamydia has expanded as a result of the introduction of NAATs. However, it is not known whether the natural history of NAAT-detected infections is the same as culture detected infections. For example, it is unknown whether NAAT positive/culture negative infections are as likely to progress to PID. Citing results by Scholes *et al*,[24] Honey *et al*[29] urge the conduct of further clinical trials to improve the accuracy and strength of evidence of the morbidity assumptions involved in cost effectiveness analysis (CEA) of chlamydia screening. In an editorial published in Sexually Transmitted Infections, Mehta *et al*, also conclude that 'studies are needed to improve accuracy and morbidity assumptions in relation to screening of any chlamydia screening cost effectiveness analysis'.[44]
In an editorial on chlamydia screening in the UK,[36] Catchpole refers to ongoing studies in the UK which are looking at incidence and re-infection rates for genital chlamydia infections. He says that the outcome of these studies will assist in informing the recommendations for screening and will be of interest internationally.

Mcleod *et al* in a recent letter to the Lancet state that 'opportunistic screening in primary care with home based screening of infrequent attenders might be the most rational approach' to chlamydia screening and that 'any approach to screening needs to be rigorously assessed and properly resourced'.[45]

Key points:

- **Macleod et al in a recent letter to the Lancet, state that 'opportunistic screening in primary care with home based screening of infrequent attenders might be the most rational approach' to chlamydia screening and that 'any approach to screening needs to be rigorously assessed and properly resourced'.**
- **Further evidence in relation to aspects of screening intervals, relapse/re-infection rates and the natural history of NAATs-detected infections which will allow more accurate cost effectiveness analysis, is awaited.**

3.11 Screening in other countries
Screening programmes for *C. trachomatis* are in place in several western countries including Sweden, the US, the UK and Canada. In a recent article which reviewed the current status of chlamydia screening in Europe, Low writes that, 'despite the apparent success in Sweden, the availability of NAATs to facilitate screening and the fact that chlamydia rates are increasing across the western hemisphere, European countries have been slow to implement chlamydia screening'.[26] A Chlamydia screening programme is currently being 'rolled out' in England, targeting young men and women under the age of 25 who are attending healthcare facilities not traditionally associated with providing specialist sexual health services, including contraceptive clinics, general practices, young people's services, antenatal services, colposcopy and infertility units. Screening is also encouraged through innovative outreach strategies, such as "pee in a pot" days at military bases, university campuses, prisons and other non traditional settings.[46] In Sweden, opportunistic chlamydia screening of young women in a variety of healthcare settings was introduced in the early 1980s and was associated with dramatic reductions in the incidence of infection and its sequelae, although between 1997 and 2003 rates of infection rose. Factors to explain this resurgence could be the failure to include men comprehensively in the screening programme and an increase in risk taking behaviours.[47] Since 1988, the law has made it compulsory across the country to provide free testing, treatment and contact tracing to any patient with suspected chlamydia infection and to report diagnosed infections. Screening in Sweden is targeted at sexually active women aged 15-29 years seeking contraception or abortion. Men are screened when found through contact tracing or if symptomatic.[48]

Postal screening, where the person takes a sample at home and sends it to the laboratory without consulting a doctor, has been shown to be cost effective in Denmark even with modest uptake of screening.[49] Patients with a positive test result contact their doctor for follow up and identification of sexual partners. A commission has been set up to examine the issue of a screening programme for *C. trachomatis* in Denmark.

In March 2004, the Gezondheidsraad (Health Council of the Netherlands) published a report stating that there was insufficient evidence to support a national screening programme for the Netherlands.[50] However, while the outcome of further research is awaited they recommended 'a more active prevention policy, as a matter of urgency'. This includes: 'more active case-finding, notably in those with mild or non-specific symptoms; raising awareness in schools, primary care, and through information campaigns; and screening in abortion and fertility clinics'.

Key points:

- Screening programmes for *C. trachomatis* are in place in several western countries including Sweden, the US and Canada.
- Various models for screening are currently being examined in other EU countries.
- A national chlamydia screening programme, principally targeting sexually active women aged between 16 and 24 and attending selected healthcare settings, is now expanding in England.

4. Irish Research

4.1 Prevalence data from Ireland

Due to the asymptomatic and persistent nature of *C. trachomatis* infection, prevalence data are more useful than reported diagnoses of infection. However, only two small prevalence studies in Irish settings have been published in peer reviewed journals.[51,52]

1. Over a twelve month period in 1991, of 32 teenage girls who attended the STI Clinic at the Mater Misericordiae University Hospital in Dublin for the first time, 2 (6.2%) were positive for *C. trachomatis* infection.

2. Two groups of men: (a) fracture and injury patients, attending an orthopaedic outpatients department (OPD) in the Mid-Western Health Board and (b) students and paying customers at a third level sports complex at the University of Limerick, were recruited to a chlamydia prevalence study. A FVU sample was collected and tested by LCR. All recruits to the study were sexually active men aged 17-35. Chlamydia prevalence was 13/207 (6.3%) at the OPD and 10/186 (5.4%) at the University.

The following data were also available to the committee:

i. A study carried out in 1997 at three Well Woman clinics in Dublin where urine samples were screened (using LCR) for *C. trachomatis* is described in a report on Review of Services for STIs in the Eastern Regional Health Authority (ERHA).[53] A prevalence rate of 3.5% (95% C.I. 1.9% to 5.1%) for *C. trachomatis* was observed. The authors of the report felt that this figure might be an underestimation of prevalence in the community as women in low income groups, teenagers and the less well educated were under-represented in the study population compared to the general population. The screening method used was found to be very acceptable to the study population.

ii. Attendees at STI clinics in Ireland are generally tested for *C. trachomatis* regardless of symptoms. In 1999 the prevalence rate of *C. trachomatis* infection at the GUIDE clinic, St. James's Hospital was 9.5% (Personal communication, Dr Fiona Lyons). This rate compares with a reported median prevalence rate of 16.4% among GUM clinic attendees in the UK.[54]

iii. Clients of the Irish Family Planning Association are tested on the basis of 'risk', for example they are tested if they are symptomatic. Testing (endocervical swab) of clients, 100 in each of two clinics in Dublin in 2002, showed 13% and 9% positivity for *C. trachomatis*, respectively (Personal communication, Dr Sheila Jones, Irish Family Planning Association).

iv. There have been almost 1000 women screened antenatally at the Rotunda Hospital. A midwife has been recruited on a sessional basis (3 sessions per week) to recruit women attending antenatal clinics at the Rotunda and to provide counselling in relation to providing a FVU specimen for testing for *C. trachomatis*. Data are available in relation to 695 of which 5% were chlamydia positive on PCR. (Personal communication, Professor Mary Cafferkey, Rotunda Hospital).

v. A rate of up to 17% was reported from the National Maternity Hospital, Dublin in an asymptomatic antenatal population (Personal communication, Dr Mary Wingfield, National Maternity Hospital).

vi. Among the student population in UCD between 2000 and 2002, 8.5% of symptomatic women and 10.0% of symptomatic males who were opportunistically screened for *C. trachomatis,* were positive. In the same population, 4% of asymptomatic patients were positive. A gender breakdown for asymptomatic patients is not available, but they were thought to be primarily female as the specimens were mostly endocervical specimens obtained in conjunction with cervical smear testing in women over the age of 20 (Personal communication, Dr Fiona Thompson, Student Health Service, University College Dublin).

vii. Endocervical swabs for *C. trachomatis* at routine cervical smear testing at the Student Health Centre, TCD, provided the following data: (Personal Communication, Dr David Thomas, Student Health Service, Trinity College Dublin).

C. trachomatis infections detected at routine cervical smear testing Student Health Services Trinity College Dublin		
Period	**Positive tests/Number tested**	**% Positive**
Oct '99 - Sept 2000	5/84	5.9%
Oct 2000- Sept 2001	2/154	1.3%
Oct 2001-Sept 2002	13/300	4.3%
Oct 2002-Sept 2003	13/336	3.9%
Oct 2003-Sept 2004	16/423	3.8%

4.2 Research undertaken on behalf of the STI Subcommittee

Two research projects, one looking at the diagnosis, management and notification of STIs, including *C. trachomatis,* in Irish general practice and the other, a survey looking at the diagnostic and reporting practices of clinical microbiology laboratories in Ireland in relation to STIs, were undertaken under the auspices of the STI Subcommittee of the HPSC Scientific Advisory Committee. Both projects provide some information in relation to current *C. trachomatis* testing in Ireland:

i. *' STIs in Irish General Practice' Research Project*

The general practice setting offers unique opportunities, not only to estimate STI risk, but also to discuss sexual health in a broader context. The availability of non-invasive diagnostic tests for *C. trachomatis* using a FVU specimen or an endocervical swab for women at insertion of an intrauterine contraceptive device (IUD) or on routine cervical smear testing, has greatly increased the number of diagnostic tests for *C. trachomatis* infection performed by GPs.

Research, carried out by the HPSC in conjunction with the Irish College of General Practitioners (ICGP) in 2003, comprised work with focus groups of GPs together with a questionnaire survey of 656 Irish GPs, found that most GPs (87%) were in favour of targeted chlamydia screening in young women.

ii. Survey of STI Diagnostic Laboratories in Ireland

In 2003, HPSC, in conjunction with the Irish Society of Clinical Microbiologists (ICSM), Imperial College London and the European Surveillance of Sexually Transmitted Infections (ESSTI) collaborative group, carried out a survey, which looked at the diagnostic and reporting practices of clinical diagnostic microbiology laboratories in Ireland in relation to STIs. The survey demonstrated that significant numbers of specimens for *C. trachomatis* testing originate from outside STI clinics.

4.3 Further Irish Research Required

Data to establish the prevalence of genital *C. trachomatis* infection in different subpopulations in Ireland, such as general practice attenders (in different age groups and socio-economic groups), attenders at FPCs, student health services and antenatal clinics is *urgently* required in order to inform the deliberations of the committee in relation to the need for screening in Ireland. Such data, in conjunction with good quality surveillance data, will help determine where screening initiatives are most needed and will provide a baseline for evaluation of control measures.

Feasibility, acceptability and effectiveness of screening in an Irish context

Studies to establish the feasibility, acceptability and effectiveness of screening for *C. trachomatis* in an Irish context are also required. The uptake of screening, the feasibility and the acceptability of screening in different primary care settings such as general practice, student health services and FPCs must be established. In addition, the various management options (referral to an STI service for management of infection and partner notification, management of the infection in the setting where diagnosis was made with referral to an STI clinic for partner notification or, management and partner notification in the diagnostic setting) in terms of, number of partners identified, re-infection rates and costs will need to be evaluated.

In this regard, it may be useful to revisit a research proposal developed in 2001, which did not progress at that time. The study which was proposed at that time, sought to establish the prevalence of *C. trachomatis* in a cohort of sexually active Irish women aged between 16 and 30 years and to determine best practice for the management of identified infections in an Irish setting.

4.4 Proposals to develop the research agenda

The committee agreed that there is an urgent need for research to be conducted in order to:

i. Establish the prevalence of genital *C. trachomatis* infection in various settings in Ireland (general practice, FPCs, student health services)

ii. Establish the feasibility and acceptability of screening for genital Chlamydia infection, including the likely uptake of screening, among patients in various settings in an Irish context

iii. Identify and appraise the options for management and follow up of identified infections and partner notification

The committee considered two options in order to address these questions:

1. The HPSC, supported by the HSE, would put out a call for proposals to address the issues as outlined above and subsequently commission the research required.

2. A researcher would be employed by the HPSC to develop a detailed research proposal and identify possible sources of funding for the research. This person would subsequently take the lead role in co-ordinating the research. The appointed person would have a good knowledge of the STI clinical services and possess the requisite epidemiological and leadership skills to be able to manage the process satisfactorily. It is envisaged that the person would be appointed for two years initially and would report to a steering committee set up to oversee the research. The steering committee would have representatives from the HSE, STI clinic consultants, the ICGP, Department of Health and Children (DOHC) and the HPSC.

Key points:

- **There are limited data available on prevalence of *C. trachomatis* in Irish settings.**
- **The limited data available from STI clinics, FPCs, student and antenatal settings suggest similar trends to those seen in the UK and other parts of Europe.**
- **Research is needed to**
  - **establish the prevalence of genital *C. trachomatis* in various settings in Ireland,**
  - **look at the feasibility and acceptability and likely uptake of screening in Ireland**
  - **appraise the options for management and follow up of identified infections**

5. Services

The Second Report of the UK National Screening Committee[19] set out a number of criteria for appraising the viability, effectiveness and appropriateness of a screening programme, based on the set of classic criteria for screening first promulgated by Wilson and Jungner in a WHO Report in 1966.[20] One of these criteria stated that '*adequate staffing and facilities for testing, diagnosis, treatment and programme management should be made available prior to the commencement of the screening programme*'.

5.1 STI clinic capacity

There will be a need to enhance current STI clinic capacity and to provide staff education and training to meet the anticipated increased demand. A survey of Departments of Public Health carried out in July/August 2004, concluded that there are no nationally agreed protocols/ guidelines or co-ordinated practice in place for public health follow up of notified STIs in Ireland. The only provision for contact tracing/partner notification in Ireland is through STI clinics. Many STI clinics are currently under pressure, as evidenced by long waiting lists in many clinics. Therefore, the issue of capacity in STI clinics and in general practice to treat patients and carry out partner notification will need to be addressed in the context of developing a screening programme for *C. trachomatis*. Evidence for the effectiveness of partner notification strategies, in whichever settings this is carried out, will also need to be established. Cognisance should be taken of the recommendations of a report by the Care and Management subcommittee of the NASC. This report made recommendations in relation to the development of clinical and support services for STI and HIV, both within and outside the HSE, Eastern Region and set out a timetable for the development of services.[55]

5.2 Services in primary care

In the course of the deliberations of the committee, it became apparent that, due to an increased awareness about genital chlamydia infection and the availability of highly sensitive and specific NAATs, which can be performed on urine as well as endocervical specimens, there is a significant increase in the numbers of tests being carried out for genital chlamydia infection in general practice in Ireland which is also evidenced by the increasing numbers of specimens being received in diagnostic laboratories from sources other than STI clinics. There are currently no national guidelines in relation to testing, diagnosis and management of genital chlamydia infection in primary care. Testing may be offered where there is a clinical suspicion, where a patient feels they have put themselves at risk, in response to a patient request, at a 'pill check' or at fitting of an IUD. Diagnosis and management of genital chlamydia infection in general practice is usually carried out in the context of a holistic approach to sexual health, encompassing issues such as unplanned pregnancy, in addition to prevention and treatment of other STIs and HIV, which may be part of the same patient consultation process.

The committee considered that there is a need to distinguish between case finding/diagnostic testing of patients presenting in general practice who may be symptomatic or who may be concerned that they have contracted an STI and a national screening programme based on criteria such as gender, age-group and numbers of sexual partners. The committee considered that prior to any decision in relation to the introduction of a systematic screening programme, it is vital that the research, as set out in Sections 4.3 and 4.4 of this report be carried out. This research will aim to determine the prevalence of genital *C. trachomatis* infection in various settings in Ireland (general practice, FPCs, student health services), to establish the feasibility, acceptability and the likely uptake of screening among patients in various settings in an Irish context and to evaluate the options for management and follow up. The issue of the age of consent for testing will also need to be addressed in the context of a screening programme. In Ireland, the age below which parental consent is necessary for a medical procedure is 16 years. However, there is no case law in Ireland to support the use of 16 years as the age of general consent. Seventeen years is the age of consent in Ireland for sexual activity. Careful consideration will need to be given to the minimum age for testing for *C. trachomatis* without parental consent and it may be prudent to set this age at 18 years in the context of any guidelines for screening. The committee considered that, in context of any new screening programme, general practice will need to be supported in terms of education, training and provision of additional resources to develop its role.

The committee acknowledged that, pending the outcome of further research and the possible introduction of a screening programme, there is a need for the development of guidelines in relation to treatment, management and follow up (including contact tracing/partner notification) of genital *C. trachomatis* infections which are currently being identified in general practice.

Key points:

- **In the context of any screening programme, there will be a need to enhance current STI clinic capacity and to provide staff education and training to meet the anticipated increased demand for services.**
- **In the context of any new screening programme, general practice will need to be supported in terms of education, training and provision of additional resources in order to develop its role.**
- **The committee acknowledges that, pending the introduction of a screening programme, there is a need for the development of guidelines in relation to treatment, management and follow up (including contact tracing/partner notification) of genital *C. trachomatis* infections which are currently being identified in general practice.**

5.3 Laboratory Issues

5.3.1 Laboratory testing methods

Laboratory tests for *C. trachomatis* include culture based tests, enzyme immunoassays (EIA), NAATs, and nucleic acid hybridisation tests. Until 2004 the Abbott LcX assay was the most commonly used test system, however this kit has been withdrawn from the market. In terms of current diagnostic practices, NAATs are replacing other methods for a number of reasons including; 1) increased specificity: tests are designed to specifically amplify DNA from the *C. trachomatis* organism, 2) increased sensitivity: tests have the ability to produce a positive signal from a single copy of target DNA, 3) unlike culture tests do not require viable organisms, 4) tests can be carried out on a variety of sample types including urine from males and females. A recently published comparison of three commercially available NAATs demonstrated sensitivities of between 96 – 100% and specificities of between 99 –100% when FVU samples were analysed.[21]

Clinical samples for testing for *C. trachomatis* include: endocervical swabs and vulvo-vaginal swabs from females, urethral swabs from males and urines from both males and females. Correct specimen collection and handling techniques are critical for all methods as accurate test results are compromised if samples are inappropriately processed. With NAATs, non-invasive sampling is feasible for a screening programme.

There are a number of commercially available NAATs, which have been approved by the Food and Drug Administration (FDA) and have received European CE certification to detect *C. trachomatis* DNA from clinical samples. Appropriate certification of NAATs is required by the EU IVD Directive 98/79/EC in order to use a test to generate a diagnostic result. As NAATs can be susceptible to amplification inhibitors it is recommended that an internal amplification control be processed with each specimen. Additionally, laboratories processing clinical diagnostic specimens for *C. trachomatis* should participate in external quality assessment programmes.

5.3.2 Clinical Diagnostic Laboratory Services

The National Virus Reference Laboratory (NVRL) and a number of local hospital laboratories currently provide the diagnostic service for *C. trachomatis* in Ireland. A survey of clinical diagnostic laboratories in Ireland in 2003 demonstrated that a significant numbers of specimens received in laboratories for *C. trachomatis* testing come from sources other than STI clinics. This highlights the importance of notification data from laboratories in monitoring the epidemiology of *C. trachomatis* infection in Ireland.

A summary of the results of the 2003 survey in relation to chlamydia testing is presented in Appendix 2. Although most laboratories currently use NAATs, there is diversity in the commercial test used, highlighting the need for standard operating procedures (SOPs) both in terms of laboratory testing algorithms and interpretation of results and collection and processing of specimens. Laboratory capacity and resources will need to be increased to meet the anticipated demand for laboratory diagnostic services as a consequence of increasing awareness among professionals and the public about genital chlamydia infection. A screening programme for chlamydia will need to factor in additional resources to fund laboratory diagnostic services in terms of capacity, availability of expertise and additional costs for the programme. Laboratories participating in any screening programme must satisfy the requirement of physical space for separation of work areas for NAATs (e.g. separation of sample processing and amplification) and must have adequate quality control systems in place.

Key points:

- Due to increased sensitivity and specificity, NAATs is currently the methodology of choice for screening of *C. trachomatis*. NAATs are in use in most clinical diagnostic laboratory settings in Ireland.

- The following issues will need consideration both from a practical and economic perspective:
  - a suitable testing algorithm, including details of specimen requirements and procedures for interpretation of results.

  - the increased laboratory capacity and resources which will be required to meet the anticipated demand for laboratory diagnostic services as a consequence of increasing awareness among professionals and the public about genital chlamydia infection.

6. Development of policy

6.1 Health Strategy 2001

The National Health Strategy 2001[56] states that "measures will be taken to promote sexual health and safer sexual practices" and provides a commitment to the preparation of an 'Action Plan' for sexual health and to the full implementation of the recommendations of the 'AIDS Strategy 2000'. The committee fully endorses the commitment to the preparation of 'an Action Plan for Sexual Health' and urges that work begin *as a matter of priority* on the development of such an action plan within which the recommendations of the subcommittee can be prioritised, funded and bought forward.

6.2 National AIDS Strategy Committee (NASC)

The committee noted that a recent report from the Care and Management Subcommittee of NASC, states that the recommendations of this committee in relation to the need for a screening programme in Ireland for genital *C. trachomatis* will be considered by NASC *as a matter of priority*.[55]

Key Points:

- **The committee fully endorses the commitment to the preparation of 'an Action Plan for Sexual Health' in the 2001 Health Strategy within which the recommendations of the subcommittee can be prioritised, funded and brought forward.**
- **The committee notes that the recommendations of this committee in relation to the need for a screening programme in Ireland for genital *C. trachomatis*, as set out in the Report of the NASC Care and Management Committee will be considered by NASC *as a matter of priority*.**

7. Recommendations

General

1. An 'Action Plan for Sexual Health', as recommended by the Health Strategy 2001, should be developed *as a matter of priority*, within which the recommendations of the subcommittee can be prioritised, funded and bought forward.

2. It is noted that the recommendations of this committee in relation to the need for a screening programme in Ireland for genital *C. trachomatis* will be considered by NASC *as a matter of priority*.

Research

3. The committee strongly recommends that prevalence studies in STI clinics, general practice, FPCs, student health services and antenatal clinics in Ireland, among different age-groups, gender and socioeconomic groups should be carried out as a matter of *urgency*.

4. In addition, the committee *strongly recommends* that the feasibility, acceptability, likely uptake and effectiveness of screening in various settings in Ireland should be examined *as a matter of priority*, including the issue of best practice for partner notification and follow up.

5. In order to progress the research required, the committee that recommends that depending on the availability of funding, two options should be considered, as follows:
   - The HPSC, supported by the HSE, should put out a call for proposals to address the issues as outlined above and subsequently commission the research required.

   - A researcher should be employed by HPSC to develop a proposal and identify sources of funding for research. This person should subsequently take the lead role in co-ordinating the research and should report to a steering committee set up to oversee the research. The person should have a clinical background and possess the requisite epidemiological and leadership skills in order to be able to manage the process satisfactorily. The appointment should be for a period of at least two years initially. The committee recommends that this person should report to a steering committee which would be set up to oversee the research. The committee should have representatives from the HSE, STI clinic consultants, ICGP, DOHC and HPSC.

Primary care

6. The committee recommends that any screening programme in general practice should address the following areas:
   - Target group for testing
   - Patient confidentiality
   - The age of consent for testing
   - Standard operating procedures to be agreed with laboratories for the collection and processing of specimens.
   - Need for re-screening
   - Treatment guidelines
   - Contact tracing/partner notification and follow up.

7. Pending the outcome of research and the possible introduction of a screening programme, guidelines in relation to treatment, management and follow up (including contact tracing/partner notification) of genital *C. trachomatis* infections which are currently being identified in general practice should be developed.

Gaps in the evidence

8. Cognisance should taken of the research which is ongoing in the UK in relation to the natural history of chlamydial infection and of NAATs-detected chlamydial infection, including the determination of the optimal testing intervals for screening.

Surveillance

9. In order in assist in the planning and evaluation of any screening programme, the quality of the surveillance data currently being collected from STI clinics and general practice should be improved.

10. There should be systematic collection of outcome data in relation to long term sequelae of chlamydia infection (ectopic pregnancy, PID and tubal factor infertility) in order to measure effectiveness of any screening programme in the medium to long term.

Education and training

11. Awareness raising and education of health professionals and the public about STIs and particularly genital chlamydia infection, should be promoted in collaboration with the Education and Prevention Subcommittee of the NASC and the proposed 'Action Plan for Sexual Health'.

Services

12. In conjunction with raising awareness among the public and professionals, with the introduction of any screening programme for genital chlamydia, the capacity of STI clinics and GP services should be increased with 'ring fenced' adequate funding for this purpose being made available for clinical services. In this regard cognisance should be taken of the 'Report by the Care and Management Subcommittee of the NASC on HIV/STI Services in Ireland'. This report makes recommendations in relation to the development of clinical and support services for STI and HIV, both within and outside the HSE-Eastern Region, and sets out a timetable for the development of services in Ireland.

Laboratory issues

13. Laboratory capacity and resources should be increased to meet the anticipated increased demand for laboratory diagnostic services as a consequence of increasing awareness among professionals and the public in relation to genital *C. trachomatis* infection.
14. Development of suitable testing protocols, including details of specimen requirements and NAAT to be used, should be considered both from a practical and cost perspective.
15. Standard operating procedures for collecting and processing specimens, to include collection of specimens, the need for refrigeration of specimens following collection, and transport to laboratory should be agreed.

8. References

1. Low N. and Egger M. What should we do about screening for genital chlamydia? *Int.J.Epidemiol.* 2002;**31**:891-893

2. Clinical Effectiveness Group (AGUM and MSSVD). Clinical effectiveness guidelines for the management of *Chlamydia trachomatis* genital tract infection 2004

3. Cates W Jr, Rolfs RT Jr, and Aral SO. Sexually transmitted diseases, pelvic inflammatory disease, and infertility: an epidemiologic update. *Epidemiol.Rev.* 1990;**12**:199-220

4. Johnson RE, Newhall WJ, Papp JR, Knapp JS, Blac CM, Gift TL, Steece R, Markowitz LE, Devine OJ, Walsh CM, Wang S, Gunter DC, Irwin KL, DeLisle S, and Berman SM. Screening tests to detect *Chlamydia trachomatis* and Neisseria gonorrhoeae infections. *MMWR Recomm.Rep.* 18-10-2002;**51**:1-38

5. Anderson RM. Transmission dynamics of sexually transmitted infections 1999;3rd edition: 25-38

6. Koskela P, Anttila T, Bjorge T, Brunsvig A, Dillner J, Hakama M, Hakulinen T, Jellum E, Lehtinen M, Lenner P, Luostarinen T, Pukkala E, Saikku P, Thoresen S, Youngman L, and Paavonen J. *Chlamydia trachomatis* infection as a risk factor for invasive cervical cancer. *Int.J.Cancer* 1-1-2000;**85**:35-39

7. Stamm WEW. *Chlamydia trachomatis* infections of the adult 2004: 407-422

8. Idahl A. Demonstration of *Chlamydia trachomatis* IgG antibodies in the male partner of the infertile couple is correlated with a reduced likelihood of achieving pregnancy. *Human Reproduction* 2004;**19**(5): 1121-1126

9. Chief Medical Officers Expert Advisory Group, Department of Health United Kingdom. Main report of the CMO's expert advisory group on *Chlamydia trachomatis*. Department of Health United Kingdom. 1998.

10. Hollblad-Fadiman K Goldman SM. American College of Preventive Medicine Practice Policy Statement. American *Journal of Preventive Medicine* 2004;**24**(3): 287-292

11. Activity in Acute Public Hospitals1990-1999. Economic and Social Research Institute. Ireland. 2004

12. Paavonen, J. Immunopathogenesis of pelvic inflammatory disease and infertility-what do we know and what shall we do? *J Br Fer Soc* 1996;**1**:42-45

13. K A Fenton. Recent trends in the epidemiology of sexually transmitted infections in the European Union. *Sex Transm Infect* 2004;**80**): 255-263

14. Wilson JS, Honey E, Templeton A, Paavonen J, Mardh PA, and Stray-Pedersen B. A systematic review of the prevalence of *Chlamydia trachomatis* among European women, H*um.Reprod.Update.* 2002;**8**:385-394

15. Pimenta J and Fenton KA. Recent trends in *Chlamydia trachomatis* in the United Kingdom and the potential for national screening, *Euro.Surveill* 2001;**6**:81-84

16. Pimenta JM, Catchpole M, Rogers PA, Hopwood J, Randall S, Mallinson H, Perkins E, Jackson N, Carlisle C, Hewitt G, Underhill G, Gleave T, McLean L, Ghosh A, Tobin J, and Harindra V. Opportunistic screening for genital chlamydial infection. II: prevalence among healthcare attenders, outcome, and evaluation of positive cases *Sex Transm.Infect.* 2003;**79**:22-27

17. Adams EJ. *Chlamydia trachomatis* in the United Kingdom: a systematic review and analysis of prevalance studies. *Sex Transm Infect* 2004;**80**): 354-362

18. Miller WC, Ford CA, Morris M, Handcock MS, Schmitz JL, Hobbs MM, Cohen MS, Harris KM, and Udry R. Prevalence of chlamydial and gonococcal infections among young adults in the United States. *JAMA* 2004;**291**:2229-2236

19. Second Report of the UK National Screening Committee.Department of Health United Kingdom. 2000

20. Wilson JM. Principles and practice of screening for disease. Public Health Paper 2004;No 34

21. Gaydos CA. Comparison of three nucleic acid amplification tests for detection of chlamydia trachomatis in urine specimens. *J Clin Microbiol* 2004;42(7): 3041-3045

22. Addiss DG, Vaughan ML, Ludka, Pfister, and Davis. Decreased prevalence of *Chlamydia trachomatis* infection associated with a selective screening program in family planning clinics in *Wisconsin. Sex Transm Dis* 1993;**20**:28-35

23. Herrmann BF, Johansson AB, and Mardh PA. A retrospective study of efforts to diagnose infections by *Chlamydia trachomatis* in a Swedish county. *Sex Transm. Dis.* 1991;**18**:233-237

24. Scholes D, Stergachis A, Heidrich FE, Andrilla H, Holmes KK, and Stamm WE. Prevention of pelvic inflammatory disease by screening for cervical chlamydial infection. *N.Engl.J.Med.* 23-5-1996;**334:**1362-1366

25. Kamwendo F, Forslin L, Bodin L, and Danielson D. Programmes to reduce pelvic inflammatory disease - the Swedish experience. *Lancet* 1998;**351**:25-28

26. Low N. Current Status of Chlamydia Screening in Europe. *Eurosurveillance Weekly* 2004;**8**:41

27. Miller WC. Screening for chlamydial infection: are we doing enough? *Lancet* 2005;**365**:456-458

28. Hiltunen-Back E, Haikala O, Kautiainen H, Ruutu P, Paavonen J, and Reunala T. Nationwide increase of *Chlamydia trachomatis* infection in Finland: highest rise among adolescent women and men. *Sex Transm.Dis.* 2003;**30**:737-741

29. Honey E, Augood C, Templeton A, Russell I, Paavonen J, Mardh PA, Stary A, and Stray-Pedersen B. Cost effectiveness of screening for *Chlamydia trachomatis*: a review of published studies. *Sex Transm.Infect.* 2002;**78**:406-412

30. Nelson HD and Helfand M. Screening for chlamydial infection. *Am.J.Prev.Med.* 2001;**20**:95-107

31. Verhoeven V, Avonts D, Meheus A, Goossens H, Leven M, Chapelle S, Lammens C, and Van Royen P . Chlamydial infection: an accurate model for opportunistic screening in general practice. *Sex Transm.Infect.* 2003;**79**:313-317

32. LaMontagne DS, Fenton KA, Randall S, Anderson S, and Carter P. Establishing the national chlamydia screening programme in England: results from the first full year of screening. *Sex Trans Infect* 2004;**80**:335-341

33. Sexually Transmitted Diseases Treatment Guidelines 2002. Centers for Disease Control and Prevention *MMWR Recomm.Rep.* 10-5-2002;**51**:1-78

34. Paukku M, Kilpikari R, Puolakkainen M, Oksanen H, Apter D, and Paavonen J. Criteria for selective screening for *Chlamydia trachomatis*. Sex Transm.Dis. 2003;30:120-123

35. Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2002 Supplement, *Chlamydia Prevalence Monitoring Project*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. 2001.

36. Catchpole M, Robinson A, and Temple A. Chlamydia screening in the United Kingdom. S*ex Transm Infect* 2003;**79**:3-4

37. Oakeshott P, Kerry S, Hay S, and Hay P. Opportunistic screening for chlamydial infection at time of cervical smear testing in general practice: prevalence study. *BMJ* 31-1-1998;**316**:351-352

38. Kohl KS, Markowitz LE, and Koumans EH. Developments in the screening for *Chlamydia trachomatis*: a review. *Obstet.Gynecol.Clin.North Am.* 2003;**30**:637-658

39. Agency for Healthcare Research and Quality. Screening for Chlamydial Infection: Recommendations and Rationale. *Am J Prev Med* 2004;**20**:90-94

40. Anderson B, Olsen F, Moller JK, and Ostergaard L. Population-based strategies for outreach screening of urogenital *C.trachomatis* infections: a randomised, controlled trial. *J.Infect.Dis.* 2002;**185**:252-258

41. Macleod, John, Salisbury, Chris, Low, Nicola, McCarthy, Anne, Sterne, Jonathan A. C., Holloway, Aisha, Patel, Rita, Sanford, Emma, Morcom, Andrea, Horner, Paddy, Davey Smith, George, Skidmore, Susan, Herring, Alan, Caul, Owen, Hobbs, F. D. R., and Egger, Matthias. Coverage and uptake of systematic postal screening for genital Chlamydia trachomatis and prevalence of infection in the United Kingdom general population: cross sectional study. *BMJ* 23-4-2005;**330**:940-

42. van Bergen JE, Postma MJ, Peerbooms PG, Spangenberg AC, Tjen-A-Tak J, and Bindels PJ. Effectiveness and cost-effectiveness of a pharmacy-cased screening programme for Chlamydia trachomatis in a high-risk health centre population in Amsterdam using mailed home-collected urine samples. *Int J STD AIDS* 2004;**15**:797-802

43. Ford CA, Viadro CI, and Miller WC. Testing for chlamydial and gonorrheal infections outside of clinic settings: a summary of the literature. *Sex Transm.Dis.* 2004;**31**:38-51

44. Mehta SD, Shahmanesh M, and Zenilman JM. Spending money to save money. *Sex Transm.Infect.* 2003;**79**:4-6

45. McLeod J, Salisbury C, and Low N. Screening for Chlamydia. *Lancet* 2005;**365**:1539-1540

46. Scott LaMontagne. Chlamydia incidence in young people in England:results from a widespread screening programme. *Eurosurveillance Weekly* 2004;**8**:43

47. Kamwendo F, Forslin L, Bodin L, and Danielsson D. Programmes to reduce pelvic inflammatory disease—the Swedish experience. *Lancet* 1998;351 Suppl **3**:25-28

48. Herrmann B. Genital *Chlamydia trachomatis* infections in Uppsala County, Sweden, 1985-1993: declining rates for how much longer? *Sex Transm Dis* 2004;**22**: 253-260

49. Ostergaard L. *Screening for klamydia med hjemmetest - en medicinsk teknologivurdering*. 2004;**4**(2): 1-151

50. Health Council of the Netherlands. Screening for Chlamydia. [Executive summary] 2004(Publication no. 2004/07).

51. Fitzpatrick C, McKenna P, and Hone R. Teenage girls attending a Dublin sexually transmitted disease clinic: a socio-sexual and diagnostic profile. *Ir.J.Med.Sci.* 1992;**161**:460-462

52. Powell J. *Chlamydia trachomatis*. Prevalence in Men in the Mid-West of Ireland. *Sex Trans Infect* 2004;**80**: 349-353

53. Review of Services for Sexually Transmitted Infections in Eastern Regional Health Authority. Department of Public Health,Eastern Regional Health Authority 2000

54. Hughes G., Simms I., Rogers PA, Swan AV, and Catchpole M. New cases seen at genitourinary medicine clinics: England 1997. Commun.Dis.Rep.*CDR Suppl* 1998;**8**:S1-11

55. Report by the Care and Management Sub-Committee of the National AIDS Strategy Committee on HIV/STI Services in Ireland. 2005. http://www.dohc.ie/publications/pdf/care_and_management_sub_committee.pdf.

56. Department of Health and Children. Quality and Fairness: a Health System for You. Health Strategy 2001

9. Appendix 1

The NSC Criteria for appraising the viability, effectiveness and appropriateness of a screening programme

The criteria, which are set out below, are based on the classic criteria first promulgated in a WHO Report in 1966 but take into account both the more rigorous standards of evidence required to improve effectiveness and the greater concern about the adverse effects of healthcare; regrettably some people who undergo screening will suffer adverse effects without receiving benefit from the programme.

These criteria have been prepared taking into account international work on the appraisal of screening programmes, particularly that in Canada (2) and the United States (3). It is recognised that not all of the Criteria and questions raised in the Format will be applicable to every proposed programme, but as many as possible should be answered since this will assist the NSC to make quicker and better evidence based decisions.

All of the following criteria should be met before screening for a condition is initiated:

The condition

1.1. The condition should be an important health problem.

1.2. The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood and there should be a detectable risk factor, or disease marker and a latent period or early symptomatic stage.

1.3. All the cost-effective primary prevention interventions should have been implemented as far as practicable.

The test

1.4. There should be a simple, safe, precise and validated screening test.

1.5. The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.

1.6. The test should be acceptable to the population.

1.7. There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.

The treatment

1.8. There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes than late treatment.

1.9. There should be agreed evidence based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.

1.10. Clinical management of the condition and patient outcomes should be optimised by all health care providers prior to participation in a screening programme.

The screening programme

1.11. There must be evidence from high quality Randomised Controlled Trials that the screening programme is effective in reducing mortality or morbidity. Where screening is aimed solely at providing information to allow the person being screened to make an "informed choice" (e.g. Down's syndrome, cystic fibrosis carrier screening), there must be evidence from high quality trials that the test accurately measures risk. The information that is provided about the test and its outcome must be of value and readily understood by the individual being screened.

1.12. There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is clinically, socially and ethically acceptable to health professionals and the public.

1.13. The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).

1.14. The opportunity cost of the screening programme (including testing, diagnosis, treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (i.e. value for money).

1.15. There must be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.

1.16. Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be made available prior to the commencement of the screening programme.

1.17. All other options for managing the condition should have been considered (e.g. improving treatment, providing other services), to ensure that no more cost effective intervention could be introduced or current interventions increased within the resources available.

1.18. Evidence-based information, explaining the consequences of testing, investigation and treatment, should be made available to potential participants to assist them in making an informed choice.

1.19. Public pressure for widening the eligibility criteria for reducing the screening interval, and for increasing the sensitivity of the testing process, should be anticipated. Decisions about these parameters should be scientifically justifiable to the public.

References:

Department of Health. *Screening of pregnant women for hepatitis B and immunisation of babies at risk*. London: Department of Health, 1998. (Health Service Circular: HSC 1998/127)

Wilson JMG, Jungner G. Principles and practice of screening for disease. Public Health Paper Number 34. Geneva: WHO, 1968.

Cochrane AL. Holland WW. Validation of screening procedures. Br Med Bull. 1971, 27, 3.

Sackett DL, Holland WW. Controversy in the detection of disease. Lancet 1975; 2:357-9.

Wald NJ (Editor). Antenatal and Neonatal screening. Oxford University Press, 1984.

Holland WW, Stewart S. Screening in Healthcare. The Nuffield Provincial Hospitals Trust, 1990.

Gray JAM. Dimensions and definitions of screening. Milton Keynes: NHS Executive Anglia and Oxford, Research and Development Directorate, 1996.

9. Appendix 2

Response from laboratories, by health board region[1], to survey of clinical laboratory STI diagnostic services carried out in 2003 by the National Disease Surveillance Centre.

	No laboratories cited[2] per region	Diagnostic technology in use in 2003	Test(s) in use (most recent data)	Approximate numbers tested in 2002	Approximate numbers tested in 2003	Approximate numbers tested in 2004
Eastern Regional Health Authority	5	NAAT	BD ProbeTec™ ET Roche Amplicor®	21,033	26,427	
Midland Health Board	1	NAAT	Mullingar Lab testing since 2004 Roche Amplicor®	N/A	N/A	1,000 (Approx for full year)
Mid Western Health Board	1	NAAT	RealArt™C.trachomatis	4,927	5,460	6,255
North Eastern Health Board	1	EIA	Currently using Clearview EIA Proposal submitted to change to NAAT	430	774	928
North Western Health Board	1	EIA	DAKO	-	-	
South Eastern Health Board	1	Abbott LcX to June 2003 EIA to Jan 2005	RealArt™C.trachomatis From 2005	3,772	3,869	5,206
Southern Health Board	1	NAAT	Roche Amplicor®	8,000	8,760	12,806
Western Health Board	2	NAAT	Roche Amplicor®	3,644	4118	5190

[1]Until end 2004 there were 10 health boards (the Eastern Regional Health Authority (ERHA) encompassed 3 Area Health Boards) in Ireland

[2] Laboratories providing a testing service for *C. trachomatis* (per HPSC Laboratory Survey 2003)

10. Abbreviations

Term	Explanation
CDC	Centre for Disease Control and Prevention
CEA	Cost Effectiveness Analysis
CMO	Chief Medical Officer
DoHC	Department of Health and Children
EIA	Enzyme Immunoassay
ERHA	Eastern Regional Health Authority
ESSTI	European Surveillance of Sexually Transmitted Infections
EU	European Union
FPC	Family Planning Clinic
FDA	Food and Drug Administration
FVU	First Void Urine
GP	General Practitioner
GUM	Genito-Urinary Medicine
HIPE	Hospital In-Patient Enquiry
HPSC	Health Protection Surveillance Centre
HSE	Health Service Executive
ICGP	Irish College of General Practitioners
ISCM	Irish Society for Clinical Microbiologists
IUD	Intrauterine Contraceptive Device
LCR	Ligase Chain Reaction
NAATs	Nucleic Acid Amplification Tests
NASC	National AIDS Strategy Committee
NCSP	National Chlamydia Screening Programme
NDSC	National Disease Surveillance Centre
NVRL	National Virus Reference Laboratory
OPD	Out Patients Department
PID	Pelvic Inflammatory Disease
PPV	Positive Predictive Value
RCT	Randomised Controlled Trial
SAC	Scientific Advisory Committee
SOPs	Standard Operating Procedures
STI	Sexually Transmitted Infection
UCD	University College Dublin
UK	United Kingdom
US	United States
WHO	World Health Organisation