

**Chlamydia Screening
in New Zealand: Report
for the National
Screening Unit
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1 Executive summary

1.1 Background

The bacterial sexually transmissible infection (STI) *Chlamydia trachomatis* (chlamydia) is regarded as a serious public health problem due to its relatively infectious nature and the long-term effects which can result from untreated chlamydial infection. Chlamydia is reported to be the most common, treatable STI diagnosed in young adults in New Zealand (NZ). Although there are significant gaps in the information available on the epidemiology of chlamydia in NZ, the data suggest the incidence is increasing and this represents a considerable burden of disease.

Sexual health physicians, other health care providers and researchers in NZ have voiced alarm at the increased diagnoses of a chlamydial infection in recent years and have called for a screening programme for chlamydia.

1.2 Aim and objectives

The aim of this report is to provide information for the National Screening Unit (NSU) to assess and develop policy advice on a chlamydia screening programme.

The objectives of the report are:

- To examine and summarise the evidence available on the need for a chlamydia screening programme in NZ, using the National Health Committee's (NHCs) screening assessment criteria as framework.
- To review policies and practices for chlamydia screening in other Organisation for Economic Cooperation and Development (OECD) countries as a comparison for chlamydia screening in NZ.
- To provide information from specific research and projects in NZ relevant to chlamydia screening.
- To review current policy, practice and stakeholder opinions on chlamydia screening in NZ.

1.3 Methods

1. Literature review.
2. Review of recent projects and research from NZ relevant to chlamydia screening.
3. Examination of the evidence for a chlamydia screening programme in NZ using the NHC framework.
4. Review of current policies and practices in other OECD countries.
5. Review of relevant government policy documents in NZ.
6. Consultation with key stakeholders.
7. Formulation of recommendations.

1.4 Results

1.4.1 Assessment using NHC framework

Assessment of *Chlamydia trachomatis* infection as a suitable candidate for screening using the NHC framework is summarised in the following table.

Criterion	Conclusion
The condition is a suitable candidate for screening	Chlamydial infection can cause serious long-term health problems. Although the surveillance data in NZ is limited, chlamydia is the most common curable STI diagnosed and reported and prevalence appears to be high in specific groups, representing a considerable burden of disease.
There is a suitable test	There is a safe, simple and reliable test but this test is not yet standard at all NZ laboratories. Standardised laboratory procedures and protocols for equivocal tests and confirmation of positive tests need to be discussed and developed.
There is an effective and accessible treatment or intervention identified for the condition through early detection	Chlamydial infection is easily treated with antibiotics. The antibiotics required for uncomplicated infection are now available on the Medical Practitioner Supply Order (MPSO).
There is high-quality evidence, ideally from randomised controlled trials, that the screening programme is effective in reducing mortality or morbidity	There is good evidence that early detection and treatment reduces the chances for an individual to progress to serious sequelae but more limited evidence (one Randomised Controlled Trial (RCT) and some observational studies) that screening will reduce prevalence and incidence of serious sequelae in the general population.
The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment)	Ad hoc opportunistic screening already occurs and is likely to increase in NZ. There is evidence that targeting of screening to high-risk populations and improving access for hard to reach high-risk groups will reduce the potential harm from screening.
The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation	Not all elements are in place to ensure quality issues for a chlamydia screening programme would be met: there is evidence that high-risk groups are not likely to be accessed and screened; Nucleic Acid Amplification Techniques (NAATs) testing is not available in all laboratories; confirmatory tests for all positive and equivocal tests are not performed in all laboratories; there is limited contact tracing carried out and there is inadequate surveillance to support robust evaluation and monitoring of screening.

Criterion	Conclusion
There should be consideration of social and ethical issues	Screening appears to be clinically and socially understood and acceptable. There is evidence that there are ethnic and gender inequalities in the current provision of ad hoc screening and that these inequalities may increase unless there is selective and targeted screening and the use of innovative approaches to improve access to services by specific high-risk groups.
There should be consideration of cost-benefit issues	Screening for chlamydia in pregnant or young women is shown to be the most cost-effective option when the outcome measured is sequelae averted. However, experience in other OECD countries suggests that inclusion of men may be required to reduce prevalence of this preventable infection in the population. A reduction in prevalence is required if we hope to be able to reduce the need for widespread screening in the future.

1.4.2 Chlamydia screening in other OECD countries

Chlamydia screening in OECD countries is generally on an ad hoc opportunistic basis with targeting of groups shown, or thought to be, high risk. Many countries are undertaking studies to inform changes in screening practices, including whether to introduce screening programmes.

Sweden introduced a programme in 1988 which observational studies indicate has reduced the rate of pelvic inflammatory disease (Kamwendo et al 1996). Early studies also indicated that prevalence had decreased but this has not been sustained (Gotz H et al 2002). It has been postulated that the resurgence in prevalence is due to the low rates of screening and the failure to include men comprehensively in the screening programme.

England introduced a screening programme in 2003 which is being progressively rolled out across the country. The RCT cited to support the introduction of the national chlamydia screening programme used a population register for recruitment of patients for screening, though England has opted to use opportunistic recruitment as the invitation to screen in its programme. It has been questioned by experts as to whether the same improvement in population outcomes can be expected with this difference.

The Australian Government launched a national STI strategy in July 2005 in which it is noted that STI prevention and control requires a range of behavioural and clinical tools. The launch coincided with the announcement that the Government would provide AU\$12.5 million over four years for increased awareness, improved surveillance and a pilot testing programme for chlamydia. The aim of the chlamydia pilot testing programme is to determine if testing for chlamydia in Australia is sufficiently feasible, acceptable and cost effective to warrant the introduction of a national chlamydia testing programme. Evaluation of the pilot programme is expected to be completed by 2009.

1.4.3 New Zealand projects

The results of the Family Planning Association of New Zealand (FPA) project on chlamydia screening in their Wellington clinics indicate that it is practical and acceptable to offer screening to clients and that a reasonable uptake of the offer will occur. The test positivity rate of 8% cannot be extrapolated to the general under 25 year old age group but does support other studies which suggest that NZ has a significant burden of chlamydial infection in this age group and that this burden may be higher in Māori and Pacific peoples. The fact that testing rates returned to levels similar to those prior to the project suggests that an organised approach is more likely to result in the offer of screening being made.

The recently established Whangarei Chlamydia Trachomatis (CT) Screening Project will not be completed until late 2007, but is expected to give valuable information on screening in the general population across all health care settings with associated ethnicity data. Information will also be gained on the feasibility and effect of outreach activities on rates of screening of groups thought to be high risk but who are perceived to have low access of existing services.

The NSU has contributed some funding to both these NZ projects.

1.4.4 Review of New Zealand policies and practices

Concern over STI incidence and prevalence, and prevention and control strategies for STIs, have clearly been identified as a priority in government policy since in the 1990s. Targeted testing of asymptomatic people has been recommended as one strategy for chlamydia control since 2003, along with development of guidelines for STI management.

1.4.5 Review of current practices in New Zealand

It is difficult to estimate the amount of chlamydia screening and testing which currently occurs as this information is not currently collected by the STI surveillance system. Predicting future screening and testing volumes, regardless of whether there is a formal screening programme, is important as these costs will be incurred no matter whether a screening programme is implemented or not. There is evidence that testing rates for chlamydia have increased, at least in some District Health Boards (DHBs), in recent years. There is also good evidence that there is increasing interest and planning for prevention and control of STIs at the DHB and Primary Health Organisation (PHO) level. These plans generally provide for free sexual health visits for young people and encourage chlamydia screening. It is therefore likely that testing rates will increase further as a result of these strategies. Current surveillance does not allow either a breakdown of testing patterns to see if testing is appropriately targeted or the use of test positivity as a guide to prevalence in specific age or ethnic groups.

1.4.6 Stakeholder opinions

Discussions were held with a range of stakeholders as to their perception of the need for chlamydia screening in NZ, and whether this screening organised as a formal programme. There was widespread concern about the apparent high and increasing rates of chlamydial infection and the need for screening as a control measure. There is a general feeling that a 'programme' is needed because this will ensure commitment of

the resources by the Ministry of Health that are considered necessary to provide needed research (including pilots of screening strategies), improved surveillance, national guidelines for STI management, funding of adequate personnel for all aspects of prevention and control activities and monitoring/evaluation of outcomes.

1.5 Recommendations

While some stakeholders have called for a national screening programme for chlamydia, real health gains could be made within existing structures, to enhance current surveillance and improve prevention and early intervention through primary care settings. To address the public health problem of chlamydia in NZ, the following recommendations are presented:

1. The surveillance of chlamydial infection in NZ should be extended to include data from all laboratories as a matter of urgency. This would be facilitated by the enactment of either the Law Reform (Epidemic Preparedness) Bill or the new Public Health Bill.
2. Laboratory data collected for surveillance purposes should include basic demographics on all chlamydia tests requested, specifically age, gender, ethnicity, domicile and requestor type.
3. Parameters for adherence to the existing recommendations for chlamydia control, including screening, should be added as a Primary Health Organisation Indicator in DHB contracts.
4. National guidelines for management of STIs, including interim guidelines for opportunistic screening and contact tracing should be developed and provided to all DHBs.
5. An advisory group should be established to evaluate prevention and control options for chlamydia, including screening strategies and assess their sustainability and appropriateness for NZs social and health care settings.
6. The advisory group should identify additional research, surveillance data, modelling or pilot studies that are required to inform these decisions.

2 Introduction

The bacterial sexually transmissible infection (STI) *Chlamydia trachomatis* (chlamydia) is regarded as a serious public health problem due to its relatively infectious nature and the long-term effects which may result from untreated chlamydial infection (UNAIDS/WHO 1999). At least 70% of acute infections in women, and 50% in men, are asymptomatic, but the infection is easily diagnosed and treated at this stage (Chin 2000, Nelson et al 2001, Say 2002). Prevention and control of STIs is a complex challenge but it has been recognised that for those STIs caused by bacteria, such as chlamydia, the resulting human and economic costs are almost completely preventable (Patrick 1997). The National Screening Unit (NSU) commenced work to assess and develop a policy position on chlamydia screening in 2005.

2.1 Aim of report

To provide information to assess and develop policy advice on chlamydia screening for New Zealand (NZ).

2.2 Objectives

1. To examine and summarise the evidence available on the need for a chlamydia screening programme in NZ, using the screening assessment criteria developed by the National Health Committee (NHC) as the framework.
2. To review policies and practices for chlamydia screening in other Organisation for Economic Cooperation and Development (OECD) countries as a comparison for chlamydia screening in NZ.
3. To provide information from specific research and projects in NZ relevant to chlamydia screening.
4. To review current policy, practice and stakeholder opinions on chlamydia screening in NZ.

2.3 Methods and structure of the report

A literature review was carried out using Medline, the Cochrane database and Index NZ database 1993–2005. Data was obtained from the Institute of Environmental and Scientific Research Ltd (ESR) annual STI reports, District Health Board (DHB) reports as well as from personal communications from specific Medical Officers of Health (MOsH) and sexual health physicians. This information, along with the findings of the economic evaluation of a chlamydia screening programme commissioned by the NSU from Auckland Uniservices Ltd in 2005, is used to examine the evidence supporting a chlamydia screening programme using the NHC framework, and is presented in Section 4.

Information on current policies and practices in other OECD countries was obtained from relevant websites and government publications and is presented in Section 5.

The findings of recent projects and research from NZ relevant to chlamydia screening are reviewed in Section 6.

Key points of relevant government policy documents in NZ are reviewed and combined with the results of consultation with stakeholders to provide information in Section 7 on current practice, policies and opinions in NZ.

The findings are then discussed and recommendations formulated in Section 8.

3 Background

Worldwide chlamydia is the commonest bacterial STI (Chin 2000) and it is reported to be the most common, treatable STI diagnosed in young adults in NZ (ESR 2006). There are significant gaps in the information available on the epidemiology of chlamydia in NZ but the data suggest there is a high incidence and prevalence of bacterial STIs in the general population relative to other industrialised countries (ESR 2006). From the limited information available, these rates appear to be increasing and represent a considerable burden of disease in NZ. Various studies have reported prevalence in NZ of between 2 and 12%.

Sexual health physicians, other health care providers and researchers across NZ have voiced alarm at the increased diagnoses of a chlamydial infection in recent years and have called for a screening programme (Lawton et al 2004, McIlraith 2003, *New Zealand Herald* 2004, Perkins 2004). The Family Planning Association of New Zealand (FPA) undertook a 6 month project on chlamydia screening during 2004–2005 at its Wellington and Hutt Valley Clinics which suggested a prevalence rate of 8%. FPA has concluded that it is feasible and acceptable to offer screening for chlamydia at its clinics (FPA 2006). Another chlamydia screening project has commenced in Whangarei (personal communication Mary Carthew, Manaia Health).

The 2001 Sexual and Reproductive Health Strategy Phase One, stated that the data available indicated that “New Zealand faces a chlamydia epidemic” and proposed the development of action plans to address this and other concerns identified (Minister of Health 2001a). A specific action plan was then developed for HIV/AIDs with other recommendations contained in the 2003 Ministry of Health document *Sexual and Reproductive Health: A resource book for New Zealand health care organisations* (Minister of Health 2003a). This document recommends that young people should be encouraged to have sexual health check-ups and states the following.

To reduce the transmission of asymptomatic infections like chlamydia, opportunistic testing for chlamydia is recommended for:

- *sexually active people under the age of 25 years*
- *women presenting for pregnancy testing*
- *women attending antenatal clinics*
- *women seeking termination of pregnancy.*

Although the term ‘testing’, rather than ‘screening’ is used, the reference to health check-ups and asymptomatic infections indicates this policy aims to encourage targeted opportunistic screening.

Surveillance data and anecdotal evidence indicate there have been increases in ad hoc opportunistic testing for chlamydia over recent years (ESR 2005). The questions that have arisen are whether there should be a publicly funded ‘programme’ for chlamydia screening and whether the recommendations in the ‘Resource Book’ as to who should be targeted should be revised.

The NHC defines screening as:

... a health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by, a disease or its complications, are asked a question or offered a test to identify those individuals who are more likely to be helped than harmed by further tests or treatments to reduce the risk of disease or its complications.

They also state that in screening programmes: 'all activities along the screening pathway are planned, co-ordinated, monitored and evaluated' whereas, in contrast, 'opportunistic screening lacks [these] formal quality processes' (NHC 2003).

The potential for harm as well as benefit should be assessed before initiating a screening programme, as well as the capability of ensuring equitable access to the service and the likelihood of exacerbating health inequalities. The lack of routine monitoring and evaluation in opportunistic screening that occurs outside a formal programme, means that safety, effectiveness and cost-effectiveness cannot be guaranteed and are difficult to assess (NHC 2003). It should be noted that the invitation to be screened in a programme may be offered 'opportunistically', rather than by a systematic offer of an invitation. The latter generally involves a means of identifying the target population such as by use of a population register. To avoid confusion, screening which occurs outside a formal programme is often referred to as 'ad hoc' opportunistic screening.

4 Examination of chlamydia screening using the NHC screening assessment criteria

This section assesses chlamydia screening using the eight screening assessment criteria developed by the NHC. It should be noted that these criteria are not absolute, as no existing or potential screening programme fulfils every criterion entirely.

4.1 Criterion 1: The condition is a suitable candidate for screening

The condition should be an important health problem. This criterion is best viewed as a combination of disease incidence and prognosis, and should be considered from both an individual and a community perspective.

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 pre-symptomatic stage.

The burden of the condition on all sectors of our community should be considered, including specifically for Māori.

4.1.1 Pathophysiology and natural history of infection

Chlamydiae are intracellular obligate bacteria, with several species causing human disease. *C. trachomatis* serotypes D–K are implicated in urogenital chlamydial infection with the reservoir being humans and the mode of transmission sexual intercourse. Worldwide *C. trachomatis* is the commonest bacterial STI of the genital tract causing cervicitis, urethritis, proctitis and vaginitis (the latter in prepubertal females only). Ascending infection may lead to endometritis, salpingitis, pelvic inflammatory disease (PID) or epididymitis. Transmission of infection from mother to neonate may occur during birth, causing conjunctivitis that develops by the sixth post-partum day, or pneumonia that develops from six weeks to six months (Chin 2000, Monif Gilles and Baker 2004, Say 2002).

There is limited evidence for spontaneous resolution of infection, although one study showed resolution in almost 50% of untreated, pregnant women who had an earlier positive nucleic acid amplification test (NAAT) (Sheffield et al 2005).

4.1.2 Prognosis

It is thought that approximately 30% of untreated infections in women will lead to PID (Nelson et al 2001), but there is now some debate about the accuracy of this figure, particularly with the advent of more sensitive diagnostic tests (Low and Eggerb 2002, van Valkengoed et al 2004). The PID caused by chlamydia is less likely to be symptomatic than that caused by gonorrhoeal infection, with the consequence that there is a lower chance of early treatment, resulting in an increased risk of further destructive sequelae (Monif Gilles and Baker 2004).

After two attacks of chlamydial PID there is a 30–50% incidence of infertility due to tubal factors, a 15% incidence of ectopic pregnancy and a 25% incidence of chronic pelvic pain and adhesions (Chin 2000, Monif Gilles and Baker 2004, Say 2002).

Reiter's syndrome and male infertility are also important potential sequelae (Chin 2000, Say 2002).

Neonatal transmission results in conjunctivitis in 50%, and pneumonia in 8%, of neonates of untreated, infected mothers (Canadian STD Guidelines 1998, Say 2002).

4.1.3 Latent/pre-symptomatic phase for screening

The initial infection is asymptomatic in 70–90% of infected women and various studies have shown 30–40% of infected males are also asymptomatic. The incubation period is not well understood but is thought to be 14 days or longer (Chin 2000, Monif Gilles and Baker 2004, Say 2002). The period of communicability is also unknown, but it is clear that males and females with asymptomatic infections are an important reservoir for ongoing transmission, that they may remain infective for years and that re-infection may occur (Chin 2000, Monif Gilles and Baker 2004, Nelson et al 2001, Say 2002).

4.1.4 Incidence/prevalence in New Zealand

Information on incidence and prevalence in NZ is available from STI surveillance data collected by ESR and prevalence studies carried out for research purposes.

The ESR data come from most of the Sexual Health Clinics (SHCs), Family Planning Clinics (FPCs) and Student and Youth Health Clinics (SYHCs) throughout the country, and from laboratories in several geographical regions. Rates are calculated for the clinic data by using the total number of client visits for the time period in question as the denominator, whereas rates calculated for the laboratory data are population based (ESR 2006).

The total number of confirmed and probable chlamydia cases increased by 38.9% in SHCs, and almost doubled in FPCs and SYHCs from 2000 to 2005. Whether this increase is a reflection of increasing prevalence and incidence or reflects increased screening/testing and the more sensitive testing methods now used by some laboratories is unknown (ESR 2006).

Over 75% of chlamydial infections reported from these clinics in 2005 were in patients aged <25 years, with higher rates reported in Māori and Pacific peoples. Higher rates are also reported for males at SHCs and FPCs. It is suggested the higher rates reported from the clinics for these groups may be partly explained by choice of health care providers by certain age groups and ethnic groups, health access behaviour in symptomatic males, and males presenting as a result of contact tracing (ESR 2006).

Laboratory data from Waikato, Bay of Plenty and Auckland for 2005 showed a general population rate of 744 per 100,000, which is a 51.6% increase over the 2001 rate of 491 per 100,000. This trend is reported to be significant and only partly explained by increasing test volumes and the introduction of more sensitive tests. Higher rates were reported in females than males, with the highest rates in 15–19 year old females and 20–24 year old males. Test positivity rates for each of these regions are 10.1%, 10.3% and 6.7% respectively (ESR 2006). Ethnicity is not part of the laboratory-based data collected. Lack of provision of even basic demographic data to ESR for all laboratory tests performed (ie, data on those with negative as well as positive results) means that positivity rates by age band and gender are not able to be calculated from the information currently available (ESR 2005). This means that testing patterns and

positivity rates cannot be analysed and used to help interpret population rates. The importance of this is illustrated by the following example.

It has been commonly stated that NZ has a chlamydia infection rate six times higher than in Australia, but the difference in surveillance systems and testing rates between countries makes true comparisons difficult. For instance, the Waikato and Bay of Plenty regions (population 500,000) and New South Wales (population >6 million) tested a similar number of chlamydia specimens in the years compared, which is likely to explain much of the higher population rate reported in NZ.

Table 1: Comparison of Australian and New Zealand chlamydia statistics

	Bay of Plenty & Waikato (2003)	NSW (2001)
Laboratory reports/notifications: Number of cases	4,371	4,418
Approximate population	0.5 million	6.6 million
Chlamydia infection rates reported: Cases/100,000	739	<90
Chlamydia tests	42,916	52,790
Approximate chlamydia testing rates: Tests/100,000	8583	800
Yield of positive tests	10.1%	8.5%

All data in table derived from: STIs in New Zealand, Annual Surveillance Report 2004.

Chlamydial infections in infants are included in the laboratory-based surveillance so data is only available from areas where there is laboratory-based reporting. There were 113 cases reported in 2005, up from 71 cases in 2004 (ESR 2005, ESR 2006). This increase may reflect the higher number of laboratories now reporting to ESR rather than indicate an increase in population incidence.

Prevalence of chlamydial infection has been assessed in different populations over the past 10 years, and results range from 2.0% in secondary school students in Christchurch, to 18.6 percent in Pacific women attending a termination of pregnancy (TOP) clinic (Corwin et al 2002, Rose et al 2005). Lack of representativeness in the different studies limits their usefulness to estimate prevalence in the wider community. A table summarising these studies is in Appendix One, where it can be seen that the rates of testing in the eligible populations vary widely, which may account for some of the apparent difference in prevalence between different age and ethnic groups. However, the data from the TOP clinic audit, where all patients were tested, does show significantly higher rates of infection in those aged under 25 years and those with self-reported ethnicity of Māori or Pacific (Rose et al 2005).

4.1.5 Discussion of epidemiology

Since ESR extended surveillance to include data from almost all laboratories in the Bay of Plenty, Waikato and Auckland, it has become apparent that a high percentage of chlamydial infections are diagnosed outside of SHCs, FPCs, and SYHCs. For instance,

in 2000, 65.5% of laboratory-reported chlamydia was diagnosed in primary care (ESR 2004) and a similar percentage, 66.6%, was reported for 2005 (ESR 2006).

Other sources also confirm that more chlamydial infections are diagnosed in primary care, outside of the SHCs, FPCs and SYHCs. Data from 2003 provided by the community laboratories in Dunedin to local sexual health physicians show that two-thirds of the positive chlamydia tests were ordered by general practitioners (GPs) (McIlraith 2003). There appears to be a similar pattern in the community laboratory, Wellington Medlab, data for the Wellington region (personal communication, Dr B Lawton 2005, Wellington School of Medicine and Health Sciences). In Hawke's Bay it is reported that seven times more people are identified with chlamydial infections than the case numbers reported by the SHCs, suggesting that the majority of infections are diagnosed in primary care (HBDHB 2006).

4.1.6 Burden of disease for Māori

It is often reported in the NZ media that Māori have a higher rate of chlamydial infection. This statement is based on either the higher clinic rates, where the denominator used for the 'rate' is client visits, or on higher prevalence in studies which have been done on specific populations.

The higher clinic rates reported for Māori may merely reflect variations in accessibility and health care provision to different ethnic groups, or could be a combination of several factors, including a true higher prevalence for Māori.

The rates in the prevalence studies may reflect the different testing patterns for different ethnic groups apparent in some of these studies. However, this is not the case in the TOP audit study where all women were tested, which indicates there is a true increased prevalence for Māori when compared with non-Māori, non-Pacific peoples in this particular study population (Rose et al 2005). Whether this difference in prevalence in the TOP clinic attendees can be extrapolated to the general population is unknown.

Data is not currently collected that enables calculation of a population-based incidence or prevalence rate for chlamydial infection in Māori.

4.1.7 Conclusion

Chlamydial infection can cause serious long-term health problems. Although the surveillance data is limited chlamydia is the most common curable STI diagnosed and reported in NZ and prevalence appears to be high in specific groups, representing a considerable burden of disease.

4.2 Criterion 2: There is a suitable test

There should be a suitable screening test. Specific consideration needs to be given to the following test characteristics.

Safe – harm is kept to a minimum.

Simple – a test should be easy to perform, to interpret, and capable of use by paramedical and other personnel where possible.

Reliable – the test should give consistent results.

Accurate/valid – a test must give a true measurement of the condition or symptom under investigation.

Highly sensitive – high probability of giving a positive finding when the person being screened has the condition being sought. Sensitivity should be sufficient to lead to a substantial impact on the disease from a population perspective.

Highly specific – high probability of giving a negative finding when the person being screened does not have the condition being sought. Specificity should be sufficiently high that a positive test is reasonably predictive of the target condition. This is important because of harms that result from false positive screening tests.

Pre-implementation issues

The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed. The cut-off level determines whether someone is classified as having a positive or negative screening test.

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.

Diagnosis was traditionally by tissue culture, but the use of antigen detection tests in the 1980s and, more recently, nucleic acid amplification tests (NAATs) in OECD countries has resulted in much easier diagnosis (Chin 2000, Say 2002). NAATs may be performed on urine, endocervical, vaginal or urethral swabs.

NAATs are generally regarded as highly sensitive, with sensitivities of 85 to 90% reported (Gaydos et al May 1998, Johnson et al 2000, Marrazzo et al 2005). However, a recent study of adolescent women found lower sensitivities than previously reported, with a range of 44 to 63% for specimens taken from a single anatomic source. The authors noted that clinicians need to consider the limitations of a single test site and that further research is needed to assess the efficacy of screening strategies which alternate collection of specimens from different anatomic sites (Shrier et al 2004). The updated Centers for Disease Control and Prevention (CDC) guidelines for chlamydia testing (CDC 2002c) note that there is probable bias in many studies, with the result that NAAT sensitivities are likely somewhat lower than often quoted.

NAATs are highly specific, with most studies showing >99% specificity (Gaydos et al May 1998, Johnson et al 2000, Marrazzo et al 2005, Shrier et al 2004).

The positive predictive value is lower if the prevalence is low, and the CDC recommends an additional test for verification of all positive or equivocal tests where prevalence is <5% (CDC 2002c).

Strict quality control procedures are important for NAATs as false-positive results may occur due to contamination and false-negative results due to inhibitors in the specimens (CDC 2002c).

Other non-culture tests are still used at some laboratories in NZ. These are generally enzyme immunoassay (EIA) tests which have lower sensitivities and specificities than reported for NAATs (Newhall et al 1999). They are, however, cheaper and laboratory quality control issues are less important (CDC 2002c).

4.2.1 Conclusion

There is a safe, simple and reliable test but this test is not yet standard at all laboratories in NZ. Standardised laboratory protocols for testing procedures, equivocal tests, and confirmation of positive tests need to be discussed and developed.

4.3 Criterion 3: There is an effective and accessible treatment or intervention identified for the condition through early detection

There should be evidence that early treatment leads to better outcomes than late treatment.

Pre-implementation issues

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

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

Acquired immunity has not been demonstrated but the infection is sensitive to antibiotics, with lower tract infection responding to a stat dose of the macrolide antibiotic, azithromycin (Nelson et al 2001, Say 2002).

Longer courses of treatment may be required in ascending or chronic infection and in pregnancy (Canadian STD Guidelines 1998).

4.3.1 Conclusion

Chlamydial infection is easily treated with antibiotics. The antibiotics required for uncomplicated infection are now available on the Medical Practitioner Supply Order (MPSO).

4.4 Criterion 4: There is high-quality evidence, ideally from randomised controlled trials, that the screening programme is effective in reducing mortality or morbidity

A high standard of evidence is essential because screening is actively promoted to healthy populations and has potential for causing harm. The best level of evidence comes from randomised control trials (RCTs). Well controlled RCTs deal effectively with critical potential biases, including length, lead-time, over-diagnosis and selection bias.

It is important that RCTs of screening meet general quality criteria, that is, there should be allocation concealment, blind assessment of outcomes, small losses to follow-up, and analysis by intention to treat.

If an RCT is in progress, then formal assessment of a proposed programme should be deferred until that evidence is available. If RCT evidence is not available and is not likely to become available, then a programme should only be endorsed with caution, and only if this endorsement is based on very strong evidence from other sources.

Where screening is aimed solely at providing information to allow the person being screened to make an 'informed choice' (eg, Down syndrome, cystic fibrosis carrier screening), there must be evidence from high-quality trials that the test accurately predicts the probability of having the condition.

There is limited evidence from randomised controlled trials (RCTs) as few have been reported. An RCT using female enrollees of a health maintenance organisation in the United States, who were aged 18 to 34 years, reported a significant reduction in PID among the screened group at the end of the follow-up period of one year (Scholes et al 1996).

There is also evidence from an observational study in Sweden of a reduction in the incidence of PID over 25 years which parallels a reduction in the incidence of urogenital chlamydial (Kamwendo et al 1996).

Most evidence supporting the effectiveness of chlamydia screening is based on observational studies where the endpoint is a reduction in prevalence, as estimated by test positivity. These studies show that where the screening rate is high, as is seen in the United States, there is a reduction in prevalence of up to 50% (CDC 2002b, Mertz et al 1997). Where the screening rate is not high, as is seen in the Scandinavian countries, some early reduction in prevalence (where prevalence is estimated by test positivity) has been seen, followed by an increase in prevalence (Gotz H et al 2002).

4.4.1 Conclusion

There is good evidence that early detection and treatment reduces the chances for an individual to progress to serious sequelae, but more limited evidence (one RCT and some observational studies) that screening will reduce prevalence and incidence of serious sequelae in the general population.

4.5 Criterion 5: The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment)

The screening programme should ensure that the benefit is maximised and the harm minimised.

If a clear benefit of screening is demonstrable in RCTs, the physical and psychological harms of screening need to be weighed against the benefit and an assessment made of whether there is both a net benefit to the population, and that individual participants can reasonably expect more benefit than harm from screening.

There is no physical harm likely to result from testing or treatment. Unlike many other health conditions, the screening test is also the diagnostic test. Testing may be performed on urine samples (men and women), urethral swabs (men – may be self-collected), vulvo-vaginal swab (women – may be self-collected), or endocervical swabs and cervical samples collected for liquid-based cytology (women). There are no major side-effects from the antibiotics apart from allergy, which is rare.

Although the specificity of NAATs is high, there are potential social issues resulting from false positives. These are more likely to occur where prevalence is low, which supports targeting screening to higher-risk populations and standardised laboratory protocols for verification of positive and equivocal tests.

Concern has been expressed about the 'message' being promoted if only women are targeted in a screening programme, as it could infer that only women are susceptible and need to be screened (Duncan and Hart 1999, O'Connell 2003).

The continuation of the current opportunistic ad hoc screening in NZ may further emphasise and contribute to ethnic and gender inequalities, as there is evidence that there are differences in patterns of access of existing services.

4.5.1 Conclusion

Ad hoc opportunistic screening already occurs and is likely to increase in NZ. There is evidence that targeting of screening to high-risk populations and improving access for hard to reach high-risk groups will reduce the potential harm from screening.

4.6 Criterion 6: The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation

To use RCT evidence of efficacy to justify a screening programme, essential programme elements must be in place to ensure screening in practice will match the quality standards of the RCT. The programme elements will include population recruitment, systematic recall, linkage to follow-up assessment, dedicated assessment centres and continuous monitoring and evaluation.

The screening programme should be integrated with existing health services, as far as practicable, with specific goals for Māori participation.

Pre-implementation issues

There must be a plan for managing, monitoring and systematically evaluating the screening programme, a nationally agreed information system for collating data, and an agreed set of quality assurance standards. A quality assurance/quality improvement framework needs to be established from the beginning.

Adequate training for all key personnel, adequate staffing and facilities for testing, delivery of results, diagnosis, treatment and programme management should be made available prior to the commencement of the screening programme.

Pressure for widening the eligibility criteria, for reducing the screening interval, and for increasing the sensitivity of the testing process should be anticipated. Reasons for the decisions about the parameters should be publicly justifiable.

The screening programme needs to reach all those likely to benefit from it, which may require specific initiatives to reach particular population groups. There is a special imperative to ensure that this is so for Māori.

The current situation is ad hoc opportunistic screening in a variety of clinical settings including SHCs, FPAs, SYHCs, antenatal clinics, TOP clinics, gynaecological settings and primary care settings.

4.6.1 Population recruitment

There is currently no formal population recruitment for screening. From the surveillance data reported by ESR, and the information provided by various Medical Officers of Health and sexual health physicians who have collected laboratory data for their regions, it is apparent that there is wide variability in testing and screening patterns, by gender, geography and ethnicity. Recommendations to target and test asymptomatic high-risk people, with the categories listed, were published by the Ministry of Health in 2003 (Minister of Health 2003a).

The cost of attending a primary care health practitioner may be a barrier to access care but many DHBs have initiated, or are planning, strategies to address this concern for those under 25 years of age. These are discussed further in Section 6.

4.6.2 Laboratory capacity and standards

There is currently variability in the type of test offered, as well as the standard of testing when there are equivocal test results (see 4.2).

4.6.3 Treatment and follow-up

Azithromycin has recently been added to the MPSO, thus removing cost as a barrier to access treatment.

There is limited contact tracing, and this varies in different locations throughout the country. Evidence from other OECD countries suggests that vigorous contact tracing and treatment is necessary for a sustained reduction in prevalence (Gotz H et al 2002, Westh and Kolmos 2003).

4.6.4 Evaluation and monitoring

Evaluation and monitoring of current screening activities and development of evidence-based strategies for chlamydia (and other STIs) control is hampered by the lack of robust STI surveillance in NZ. Although the gold standard to assess trends in prevalence would be regularly repeated, standardised prevalence surveys these are expensive, difficult to maintain in a standardised format and, given the diverse nature of NZ society, difficult to plan to be representative of the whole population (personal communication Dr Graham MacBride-Stewart, ESR, 2005). A systematic review of chlamydia prevalence studies in the United Kingdom noted a large degree of heterogeneity in the sampling and testing methods in the studies and that there were few studies reporting on male data and the general population (Adams et al 2004a).

For these reasons, most OECD countries rely on test positivity as an estimate of prevalence for planning and evaluation purposes (Adams et al 2004a, Dicker et al 1998, Gotz H et al 2002, Westh and Kolmos 2003). This requires surveillance on all of the chlamydia tests requested by practitioners, not just those with a positive result. This allows test positivity to be calculated for different age bands, ethnicities, gender and any other parameters and risk factors for which information is available. Collection and analysis of data on all tests ordered can also be used to provide valuable insights into the screening behaviour of health practitioners as well as patients (Staff et al 2004).

4.6.5 Conclusion

Not all elements are in place to ensure quality issues for a chlamydia screening programme would be met: there is evidence that high-risk groups are less likely to be accessed and screened; NAATs testing is not available in all laboratories; confirmatory tests for positive and equivocal tests are not performed in all laboratories; there is limited contact tracing carried out; and there is inadequate surveillance to support robust evaluation and monitoring of screening.

4.7 Criterion 7: There should be consideration of social and ethical issues

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

Potential participants in the screening programme should be given information that allows them to weigh up the probable benefit and harms, using their own values and preferences.

Culturally appropriate, evidence-based information should be available for people offered screening to assist them in making an informed decision. This information should also explain the consequences of testing, the possibility and importance of false-negatives and false-positives, investigation and treatment.

Pre-implementation issues

The screening programme should be planned, monitored, delivered and evaluated in partnership with the population group offered screening.

The screening programme should continue to reduce inequalities, in particular, the programme should address Māori health as a priority.

The screening programme should be delivered within a framework that is responsive to Māori (attending to Treaty of Waitangi, workforce and information ownership issues).

There is information from the FPA Wellington project and the Whangarei chlamydia screening project that screening is acceptable to health professionals and the public (see Section 6).

The limited data available suggest there is a higher prevalence of chlamydial infection in youth and young adults, and that these rates are higher in Māori and Pacific youth and young adults. There is insufficient data to ascertain if these groups currently access testing/screening at appropriate rates for the prevalence of infection in these groups (see 4.1.4–4.1.6).

These apparent inequalities may increase with a screening programme. A more robust data collection system is required to evaluate and monitor the baseline situation as well as the results of any intervention, whether this is a screening programme or ongoing increases in ad hoc opportunistic screening.

4.7.1 Conclusion

Screening appears to be clinically and socially understood and acceptable, but there is evidence that there are inequalities in the current provision of ad hoc screening and that these may increase unless there is selective and targeted screening.

4.8 Criterion 8: There should be consideration of cost-benefit issues

As for other health care interventions, there needs to be scrutiny of the cost benefit of screening programmes, as they are resource intensive. Careful cost-benefit (including cost-effectiveness) analysis is important so that the screening programme can be compared with other health care interventions.

Cost-benefit analysis should consider the opportunity cost of the screening programme compared with other health care interventions. Other options for minimising the morbidity and mortality of the condition should be considered to ensure screening is the most cost-effective way of obtaining health gains.

Primary prevention interventions, which may be more cost-effective than the proposed screening programme, should have been implemented as far as practicable.

4.8.1 Overseas published studies

A major review of published studies on the cost-effectiveness of screening for *C. trachomatis* in asymptomatic sexually active women aged under 30 years of age was published in 2002. The outcomes in the studies assessed are cases detected, PID prevented and associated costs. All of these studies are modelled scenarios and are too heterogeneous to allow for a quantitative analysis. All of the studies show screening to be cost effective at the prevalence expected in the target populations (>3%) when age is used as a selection factor and NAATs are performed on urine samples. However, the review also notes that many of the assumptions used in the models are difficult to confirm, and there is a need for more data, especially on the risk of complications (Honey et al 2002).

More recent studies, also modelled scenarios, have been reported from Scotland, England and the United States (Adams et al 2004b, Hu et al 2004, Norman et al 2004). These studies all note similar limitations due to the estimates required for various clinical events, uptake rates and prevalence of infection.

The Scottish study does not show screening to be cost saving in the clinic settings used for the study, but indicates that selective age-based screening is more cost effective than universal screening (Norman et al 2004).

The United States study analysed several different scenarios (no screening, annual screening for all women, annual screening for all women with one repeat test three to six months after a positive test, annual screening followed by selective semi-annual screening for those with a history of infection) and targeted these strategies to specific age groups (15–19 years, 15–24 years and 15–29 years). The study reported the most effective and cost-effective strategy is annual screening for women 15–29 years of age, followed by semi-annual screening for those with a history of infection (Hu et al 2004). The annual incidence used in the model for women aged 15–19 years was 6% and this

was reduced for the older age groups. This rate is similar to laboratory-based population rates in NZ in 2005, which range from 4–11% for 15–19 year old women (ESR 2006).

4.8.2 New Zealand cost-effectiveness modelling

The NSU commissioned an evaluation of the cost-effectiveness of a chlamydia screening programme in NZ, targeting young people aged 16–24 years old. The uncertainty of much of the NZ-specific data on the prevalence and incidence of, and testing rates for, chlamydia, along with the uncertainty over the natural history of the infection and complication rates, limits the strength of the conclusions able to be drawn from this report (Ashton and Ashraf 2006).

The end point looked at was ‘case of sequelae averted’. It is recognised this does not ascribe value to either treating the infection in an individual, or the potential for reducing prevalence (with subsequent reduction in risk of transmission) within the population.

Several different screening scenarios were compared with the current situation. This required that probabilities for sexual activity, attendance at primary care, screening uptake, prevalence, test sensitivity and specificity, treatment rates, compliance and effectiveness, complication rates and rates for treatment of complications, and costs had to be estimated for the current situation (termed ‘no screening’) and several hypothetical situations of ‘screening’. There were wide ranges estimated for some of these parameters due to lack of robust surveillance data in NZ and uncertainty about the natural history of chlamydial infection. This meant that estimates for the total cost for each of these programme options was very uncertain with wide confidence intervals.

The parameters, which were found to be key cost drivers or subject to a high degree of uncertainty, were subjected to sensitivity analyses to assess their impact on the results. These parameters are:

- prevalence of chlamydia
- uptake rates
- sensitivity and cost of laboratory test
- progression to PID and cost of PID treatment
- cost of screening programme.

Under the base case assumptions, screening in ‘women only’ would prevent a further 1774 cases of PID and other sequelae, including 21 cases of infant pneumonia and 41 cases of neonatal conjunctivitis, at a cost of \$371 per case averted, when compared with the current situation. Screening women would also cure an additional 4125 cases of chlamydia. The modelling suggests that net savings may occur if the prevalence of chlamydia was higher than 8% in the eligible population, if the risk of progression of untreated chlamydia to PID is greater than 50% or if the costs of treating PID are approximately 25% higher than that used for the base case.

Screening both men and women would be less cost effective, at a cost of \$1,654 per case of sequelae averted but would avert a total of 2125 cases of sequelae, cure an additional 6918 cases of infection, and avoid the transfer of 4497 infections to partners compared with the current situation. This cost may drop to \$904 per case averted if prevalence is higher than 7% in men and 8% in women in the eligible population. The

incremental cost of this strategy, compared with screening women only, would cost an additional \$1,827 per case of sequelae averted, using the base case probabilities.

Screening all pregnant women would have a net cost of \$184 per case of sequelae averted and may result in net savings if the prevalence is higher than 11.2%, or if the cost of screening is slightly lower than has been used for the base case. This strategy would avert 1527 cases of sequelae, cure an additional 2106 cases and avoid the transfer of 1368 infections to male partners.

4.8.3 Discussion

The results of this economic evaluation are broadly in line with those reported from evaluations in other countries. The most cost-effective scenario tested in this model is that of screening all pregnant women. However, there are important limitations in this study as noted below.

As with studies in other countries, the main weakness of the study is the large number of unknowns and uncertainties around the natural history of chlamydial infection, as well as the likely uptake of screening. The lack of robust data on prevalence of chlamydia, and current testing/screening rates for chlamydia, in NZ add to the difficulty in interpretation of the outcomes from the modelling in this study.

The summary measure of outcome is numbers of cases of sequelae averted and places equal value on these various sequelae in terms of their health impact. This is clearly not the case.

Potential benefits of screening, such as reduction in prevalence from curing more cases and reducing transmission of infection, is not accounted for.

Other costs, such as indirect costs from loss of productivity or psychological costs, have not been measured.

The discount rate of 8% is an arbitrary choice. Use of a lower rate would increase the cost-effectiveness of all three options.

Policy makers do have control over two of the variables shown to be key cost drivers – uptake rate and programme cost. Experience from the United Kingdom indicates that increased uptake rate can be achieved but this may require increased programme costs for health promotion/social marketing.

This study shows that including young men in screening is less cost effective, when the summary measure of outcome is 'sequelae averted'. The potential effect that screening men would have on reducing prevalence was not measured in this or other studies but is now considered likely to be important in achieving the goal of reducing prevalence (Chen and Donovan 2003, Low and Eggerb 2002).

An important limitation of the modelling is that the 'status quo' of ad hoc opportunistic screening is assumed to be a static situation with static costs. The increased costs for the screening programme scenarios presented are shown to be largely dependent on assumed increases in testing rates and costs for a social marketing/health promotion campaign which would occur if a screening programme was implemented. The model does not allow for increasing costs due to increases in testing rates or provision of

social marketing/health promotion campaigns as part of continuation of the status quo. Evidence presented in Section 5 suggests that these scenarios are likely to occur.

4.8.4 Conclusion

Cost-effectiveness modelling, both overseas and in NZ, is limited by the need for numerous estimates and assumptions and is sensitive to changes in the values of several underlying parameters. The lack of information on current screening practices and prevalence of infection are particular problems in interpreting the results of the NZ modelling.

Screening for chlamydia in pregnant or young women is shown to be the most cost-effective option when the outcome measured is sequelae averted. However, it appears that inclusion of men is likely to be required to reduce prevalence of this preventable infection in the population. Such a reduction is needed if we hope to be able to reduce the need for widespread screening in the future.

5 Chlamydia screening policies and programmes in other OECD countries

5.1 Chlamydia screening programme in England

An expert advisory group on *C. trachomatis*, convened in 1996 by the Chief Medical Officer, concluded that there was evidence for the effectiveness of chlamydia screening and that the government should take steps to establish a national programme. The summary and conclusions of this report are available at <http://www.dh.gov.uk/assetRoot/04/06/22/64/04062264.pdf>.

Pilot studies were conducted at two sites from 1999–2000 to determine the feasibility and acceptability of a programme targeting sexually active young women aged 16–24 years. Opportunistic testing was offered to all sexually active young women attending a range of health care settings, regardless of whether they had symptoms. Acceptance and uptake were found to be more than 75%, and greater than 50% of the eligible population was tested in an 11-month period. Prevalence (estimated) at the two sites was found to 9.8% and 11.2% (Department of Health 2004).

A national chlamydia screening programme is now being phased in across England. It targets all sexually active men and women aged under 25 years in a variety of health care settings. Programme activities are overseen and coordinated by the National Chlamydia Screening Steering Group, but organisation, delivery and monitoring of the programme is at the local level (Department of Health 2004). An overview of the programme is summarised below.

5.1.1 Local core requirements

Each local area is to develop, implement and monitor a plan to cover the following elements.

- Patient selection – all sexually active men and women under the age of 25 years who would not normally be offered a test for chlamydia, and all partners of those found positive on screening, regardless of age.
- Range of screening locations – these include, but are not limited to, contraception clinics, youth services, gynaecology departments, antenatal services, colposcopy services, TOP services, general practices and non-traditional sites such as schools, prisons, military bases and special outreach events.
- Patient consent and recruitment – resources to assist patients to make an informed choice about participation and to understand what monitoring will occur.
- Frequency of screening.
- Specimen collection – it is recommended that that any one of urine (men and women), self-taken vulvo-vaginal swabs or cervical swabs (if cervical examination is being undertaken for another reason) can be used.
- Laboratory testing – recommendations include that NAATs be used, that there are appropriately trained staff, that laboratory assurance systems are in place, that positive tests are repeated on the same specimen to exclude false positives and that specimens may be pooled.

- Patient management procedures – protocols for reporting and management of results, negative and positive, to be developed as well as management of non-responders.
- Treatment – standardised and free (azithromycin).
- Partner notification – considered a key element.
- Test of cure – not recommended unless treated with erythromycin.

5.1.2 Data collection and reporting

The key data items are listed as those necessary to monitor and evaluate the national programme and the epidemiology of chlamydial infection. These have been agreed on after wide consultation at a national level and consist of core (required) and enhanced (optional) items. The data are returned from local areas electronically on a quarterly basis. Each data file submitted must be encrypted for security reasons and to ensure patient confidentiality.

Outcomes, such as patient treatment and partner notification, assessment and treatment, are monitored locally but aggregate summary information is submitted nationally at the end of each financial year for inclusion in the annual report of the Department of Health.

5.1.3 Programme monitoring and evaluation

Data collection and analysis is decided on at the national level. At a minimum, evaluation of the programme is to review:

- implementation
- screening coverage
- uptake, service delivery and screening volume
- prevalence reductions – estimates using test positivity (expect to see measurable reductions in certain settings after three years of high-volume screening)
- costs.

Surveillance analyses are designed to inform the epidemiology of infection in the screened population and the impact of the screening activities on the population served and will include the elements that follow.

- Prevalence – estimates to be made but these were not reported in either the 2003/04 or 2004/05 annual reports.
- Positivity rate – used in 2003/04 and 2004/05 annual reports to monitor trends. (The Programme Overview, 2004, stated they are to be compared with estimated prevalence rates to see if positivity rates can be used as a proxy measure for prevalence – it would appear this is what is already happening, at least as an interim measure.)
- Risk factors.
- Re-infection rates.
- Trends.

Analysis of public health interventions is done locally at the level where patient and partner management responsibilities lie.

5.1.4 Quality assurance

Much of this work will be done locally, but members of the technical subcommittee of the National Chlamydia Screening Steering Group undertake quality assurance visits to local programme areas. The Steering Group and professional organisations provide guidance on relevant standards and targets for laboratories and staff working in the National Chlamydia Screening Programme.

5.1.5 Discussion

The randomised control trial cited as high-level evidence to support the introduction of the national chlamydia screening programme in England used a population register for recruitment of patients for screening (as NZ does for the National Cervical Screening Programme), but England has opted to use opportunistic recruitment as the invitation to screen in its programme (as NZ does for BreastScreen Aotearoa). It has been questioned by experts as to whether the same improvement in population outcomes can be expected with this difference (Low and Eggerb 2002).

5.2 Chlamydia screening in other European countries

Screening practices for STIs, including chlamydia, vary widely between different European countries and even within countries. It ranges from testing in some STI clinics only, to screening of pregnant women, to screening at primary care sites, including general practice. In general, the screening that does occur is on an ad hoc opportunistic basis (Lowndes and Fenton 2004). It has been noted that there are increasing rates of chlamydia reported in European countries (Low 2004).

Sweden has had a legal requirement since 1988 to provide free testing, treatment and contact tracing for any patient with suspected chlamydia, and to report diagnosed infections. This has resulted in screening targeted at sexually active women aged 15–29 years presenting for contraception or abortion, and men found through contact tracing or who present with symptoms. Although this is referred to as a ‘programme’, there is no national coordination of this screening or mechanisms to ensure compliance by clinicians. Local organisation of screening has led to variations in the intensity of screening in different geographical regions.

Observational studies indicate there has been a reduction in the rate of pelvic inflammatory disease since introduction of this legal requirement to screen (Kamwendo et al 1996). Early studies also indicated that prevalence had decreased but this was not been sustained, with an increase in prevalence noted from 1997–2003 (Gotz H et al 2002). Data from 2003 indicate that 13% of the population aged 15–39 years was tested for chlamydia and that only 25% of these were men (Low 2004). It has been postulated that the resurgence in prevalence is due to the failure to include men comprehensively in the screening programme (Low and Eggerb 2002).

Two studies in the Netherlands did not support universal systematic screening, but rather a targeted approach (Gotz et al 2005, van Bergen et al 2005). Studies are also underway in Ireland and Denmark to inform future screening (Lowndes and Fenton 2004).

5.3 Chlamydia screening programme in Australia

In June 2005 the Australian Government launched the *National Sexually Transmissible Infections Strategy 2005–2008*, which it noted is the first of its kind in Australia. The strategy recognises that STI prevention and control requires a range of behavioural and clinical tools. It recommends a comprehensive approach that includes health promotion and education, access to clinical care, screening and testing, partner notification, treatment, surveillance and vaccines (Minister of Health and Ageing 2005).

The launch coincided with the announcement that the Government would provide AU\$12.5 million over four years for increased awareness, improved surveillance and a pilot testing programme for chlamydia. In October 2005, the Chlamydia Program Implementation Committee (CPIC) was established to provide advice on development and implementation of the pilot programme as well as assist in overseeing the evaluation of the various stages of the programme.

5.3.1 Overview of pilot programme

The aim of the chlamydia pilot testing programme is to determine if testing for chlamydia in Australia is sufficiently feasible, acceptable and cost effective to warrant the introduction of a national chlamydia testing programme. The chlamydia testing pilot programme will consist of three stages, as described below.

Stage 1 Chlamydia testing – Targeted Grants Program

Stage 2 Chlamydia pilot testing sites in general practice settings

Stage 3 Monitoring, evaluation and recommendation.

Stage 1 is designed in acknowledgement of the fact that many people at high risk of chlamydia infection either choose not to access health care in a general practice setting or are unable to do so. It will help inform the selection of pilot sites under Stage 2, and guide the approach taken to testing in the pilot sites. Evaluation of both stages is to be concurrent with the programmes, with the overall, final evaluation commencing in 2008 and completed by 2009. Further details of the proposed timeline are detailed in Appendix 2.

5.3.2 Stage 1

Projects under Stage 1 will target high-risk groups such as young people aged 16-25 years, Aboriginal and Torres Strait Islander people, homosexually active men and pregnant women. The projects will be conducted in urban, rural and remote Australia, in a variety of health care and community settings. Different aspects of screening such as testing methods, approaches to communication and education, contact tracing, culturally and linguistically diverse support systems, health care utilisation of target groups and testing effectiveness will be examined by a variety of projects over the next two years. Successful projects were announced in August 2006, see <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediare-yr2006-ta-abb115.htm>.

5.3.3 Stage 2

It is planned to establish three to four pilot testing sites in general practice settings with a phased in approach to testing at each of the sites. Specific target groups will have been identified and the sites will be required to meet specific selection criteria.

5.3.4 Stage 3

The evaluation and monitoring of stages one and two will take place concurrently. External evaluation of the whole pilot testing programme will be undertaken and this will be completed by June 2009.

5.4 Chlamydia screening in the United States

Screening recommendations are contained in national treatment guidelines developed by the Centres for Disease Control (CDC) after consultation with professionals with expertise in the field of STIs in 2000 (CDC 2002b).

The CDC recommends annual chlamydia screening for all sexually active women aged 25 years and under as well as older women with risk factors such as a new sex partner or multiple sex partners. CDC further recommends that an appropriate sexual risk assessment should always be conducted and that this may indicate more frequent screening for some women. It also recommends that health care providers consider advising all women with a positive test to be re-screened (for re-infection, not for as a test-of-cure) three to four months after completion of treatment (CDC 2002a).

It is recommended that all pregnant women should be tested for chlamydia at their first antenatal visit. It is further recommended that those aged under 25 years or with other risk factors for infection should also be tested in the third trimester (CDC 2002a).

5.5 Chlamydia screening in Canada

Chlamydia screening occurs on an ad hoc opportunistic basis in Canada.

Guidelines for screening were updated by the Canadian Task Force on the Periodic Health Examination in 1996 (Davies and Wang 1996). The update advised that there is fair evidence to support screening of pregnant women during the first trimester, as well as annual screening of selected high-risk groups. These groups are defined as sexually active women aged less than 25 years, men and women with new or multiple sex partners during the preceding year and women who use non-barrier methods of birth control.

5.6 Conclusions

Chlamydia screening in OECD countries is generally on an ad hoc opportunistic basis, with targeting of groups shown, or thought to be, high risk. Many countries are undertaking studies to inform changes in screening practices or are piloting programmes.

The RCT cited to support the introduction of the national chlamydia screening programme in England used a population register for recruitment of patients for screening (Scholes et al 1996). However, England is using opportunistic recruitment as the invitation to screen in its programme.

6 Review of New Zealand-based research and specific projects on chlamydia screening

6.1 Chlamydia Screening in Wellington FPA Clinics

This demonstration project was initiated and carried out by Wellington FPA over a six-month period from November 2004 to May 2005. The NSU provided partial funding with the expectation that the project would demonstrate the acceptability, effectiveness and practicality of screening for *Chlamydia trachomatis* for the people attending FPA clinics in the Wellington region. The final report was published in May 2006 (FPA 2006).

6.1.1 Outline of the pilot

The components of service in the contract with NSU were the following:

- Development of health education material, including consent forms, information sheets for clients, client questionnaire covering risk factors, staff questionnaires and information posters.
- Invitation to all male and female Wellington FPA clients under 25 years of age to participate in the study.
- Recall, counselling and treatment of clients found to have a positive result and request to these clients to notify their partner for treatment, as is usual practice.
- Administration of the screening test and appropriate follow-up of individuals with positive results.
- Assessment of the practicality and acceptability of the pilot by semi-structured interviews with reception and clinical staff, analysis of clinic records and the self-administered questionnaires, and follow-up phone calls to clients who test positive in order to assess recall and treatment rates, partner notification rates and perceptions of the service.
- Collection of accurate ethnicity data to allow comparative analyses between different ethnic groups.

6.1.2 Outcomes

The final FPA report was published, and provided to NSU, in May 2006. Results are summarised below.

Eligibility is defined as:

- clients under 25 years of age
- had not passed urine in last hour, preferably two hours
- had not taken antibiotics in past two weeks
- had engaged in sex on at least one occasion.

Clients were requested to not pass urine within two hours of their clinic appointment when booking appointments.

The survey population is 4674 of which 2559 (55%) are said to be 'eligible' and 2115 (45%) 'excluded'. Fifty-four percent of the total surveyed provided a valid urine sample.

Reasons listed for 'exclusion' include 'already screened' (27%) and 'did not want to participate' (11%) as well as not meeting the eligibility criteria listed. This appears to have resulted in eligible clients being included in the 'excluded' group and some eligible clients being counted in both groups as a result of more than one visit.

The survey population is of client visits, not individuals. The report noted increasing numbers in the 'already screened' category towards the end of the study.

The uptake rate of screening among the under 25 years of age, sexually active population attending these clinics, is difficult to calculate without knowing how many were repeat clients and how many of these repeat clients had repeat screens.

Qualitative analysis of the questionnaires to clients, reception staff and clinicians indicates the pilot was well accepted by clients and staff.

The test positivity rate for the females tested was 8% and for males 15%. The higher rate for males reflected that the reason given for attending the clinic was for an STI check in 94% of cases, whereas the most common reason for females was for hormonal contraception.

The test positivity did not differ significantly across the three age bands analysed (10–14, 15–19, 20–24 years).

Māori and Pacific peoples had test positivity rates of 14% and 16% respectively, compared with 7% for European, 6% for Asian and 6% for Other.

The clinicians' assessments record that 70% of urine tests were taken for the screening study, 60% of partners of those with a positive test were successfully notified and 68% of these were known to be treated.

Laboratory data provided by Wellington Medlab for a four-month block of the study period are compared with similar time blocks in previous years and a later time block in 2005. This shows an increase in testing rates during the study to a level similar to another block in 2003 but that this testing level returns to pre-pilot levels in the latter half of 2005 (FPA 2006).

6.1.3 Conclusions

The FPA chlamydia pilot results indicate that it is practical and acceptable to offer screening to clients at its clinics and that a reasonable uptake of the offer will occur. The test positivity rate of 8% cannot be extrapolated to the general under 25 year old age group but does support other studies which suggest that NZ has a significant burden of chlamydial infection in this age group and that this burden may be higher in Māori and Pacific peoples. It is of concern that testing rates dropped off after the pilot was completed. This suggests that an organised approach by health care providers is more likely to result in the offer of screening being made to those eligible.

6.2 Whangarei Chlamydia Trachomatis Screening Project

The Whangarei Chlamydia Trachomatis (CT) Screening Project commenced in 2005 with the aim of reducing the asymptomatic pool of chlamydial infections in the under 25 year old age group who live in the Whangarei district. The project developed out of concerns expressed after four 'Chlamydia Road Shows' held throughout Northland in 2004 by the local Medical Officer of Health, Dr Jonathan Jarman. Cross-sectoral collaboration among stakeholders and a consultation process resulted in evidence being gathered to support a screening project in the Whangarei area and shaped the form of the project (Manaia Health 2005).

The NSU is providing part funding for the project and has directed this to costs for the initial set-up phase and evaluation of the project.

6.2.1 Background information for project

Important evidence presented is summarised below.

- Laboratory-based surveillance for chlamydial infection commenced in Whangarei in late 2003 and shows higher population rates of infection in the general and youth populations in Whangarei city than for Auckland, Bay of Plenty or Waikato.
- The laboratory figures indicate that 3000–4000 chlamydia tests were performed in 2003 in Whangarei and that 2000 of these were FPA clients. Of all FPA clients (n=2165) only 6% were male and only 25% of these males seen were Māori.
- Anecdotal reports to the MOH suggest that there are low chlamydia testing rates in Māori and males, especially Māori males.
- There is evidence from the Youth 2000 national survey that there is high youth sexual activity in the region.
- Ectopic pregnancy rates are significantly higher in Māori in the region than the national rates for Māori.
- Whangarei demographics from the 2001 census show that 32.4% of the 15–24 year age group are Māori.

6.2.2 Components of the screening project

- To provide outreach opportunistic screening, treatment and follow up in youth-focused settings, prioritising asymptomatic, sexually active Māori males aged less than 25 years.
- To develop a social marketing campaign, in conjunction with a sexual health promotion campaign, to promote prevention and raise awareness about the importance of chlamydia screening.
- To work with existing health services to enhance current opportunistic screening to ensure services and treatments offered are consistent, accessible, appropriate and free to people aged less than 25 years, and that partner follow up and treatment is provided.
- To collect ethnicity data as part of the laboratory dataset on all chlamydia tests performed.

6.2.3 Timeline

The set-up phase was completed in March 2006 with major milestones as follows:

- Registered nurse employed by project and has developed and implemented the plan to enhance and coordinate existing services.
- Health promoter employed by project and has developed targeted outreach services for the priority groups and social marketing campaign plans.
- Both of these positions are based with one of the iwi providers in Whangarei.
- Method for including ethnicity as part of the data set collected by laboratory on tests from all sites has been developed.
- All IT systems have been set up, trialled and tested ready for implementation of targeted screening and collection of data.
- The implementation stage of the CT project was commenced in June 2006.
- A trial sample group screening was run prior to the implementation phase starting.
- FPA, practice nurses, school health teams, iwi providers, Whitecross and 123 sexual health service are all committed to the project and have commenced screening.
- Screening has now commenced in both the outreach and general practice settings and will commence in targeted secondary schools in the next school term.
- There is high local media interest in the project. TV 3 has asked to do a documentary on the project once it is further down the track.

6.2.4 Conclusions

This project will not be completed until late 2007. However, it should give valuable information on screening in the general population across all health care settings along with associated ethnicity data. Information will also be gained on the feasibility and effect of outreach activities on the rates of screening for groups thought to be high risk but which historically have low rates of access of existing services.

6.3 Health Research Council Proposal: Tackling the chlamydia epidemic in New Zealand youth: an RCT in primary care

This proposal, by Dr Beverley Lawton, Wellington School of Medicine, is for a randomised control trial on chlamydia screening in the Wellington area. A decision on funding from the Health Research Council (HRC) is pending.

The RCT aims to evaluate a new primary-care-based intervention designed to increase testing in under 25 year old males and females. Those attending general practice, and their social networks, will be targeted for confidential, easy-access testing and treatment with self-testing as an option. Rates of chlamydia testing and detection for practices delivering the intervention will be compared with those of practices offering 'usual care', over a 24-month period.

The NSU supported the application for funding to the HRC and expects the research would:

- improve the evidence available on the feasibility and social acceptability of specific screening strategies across primary care

- examine innovative approaches to broadening the group being tested to include those who are unlikely to routinely see a health care provider
- evaluate specific implementation strategies, their sustainability and appropriateness for NZs social and health care settings.

6.4 Health Research Council Proposal: Feasibility study for a national *Chlamydia trachomatis* prevalence survey

This proposal, headed by Dr Edward Coughlan, Christchurch Sexual Health, is for a feasibility study for a national *Chlamydia trachomatis* prevalence survey. The aims of the feasibility study are:

- to examine the participation rates for two different methods of undertaking a survey of *C. trachomatis* prevalence
- to pilot the survey methods, including the questionnaire, sample collection and laboratory testing, and analysis and reporting of results.

The NSU supported the application for funding to HRC on the following grounds:

- The lack of robust prevalence data for chlamydial infection in NZ has been identified as a limiting factor in the development of evidence-based policies for control of this disease, particularly when evaluating the economic effects of a potential screening programme and in determining whether a targeted approach would be more effective.
- Ongoing monitoring of prevalence is commonly used as a measure of the effectiveness of STI prevention and control activities in other OECD countries. Prevalence may be determined by specific prevalence surveys or may be estimated by calculating the proportion of routinely ordered tests that are positive (test positivity). Test positivity is generally not able to be measured in NZ due to the unavailability of national population-based laboratory data to ESR.
- Specific surveys give a more accurate determination of prevalence than test positivity but this is dependent on uptake of the test by the surveyed population. The cost of such surveys may limit the feasibility of serial surveys to monitor programmes.
- Results of this feasibility study would provide evidence on the feasibility, practicality and cost of undertaking a national prevalence survey. This evidence could be used to inform decisions on the methodology for determining prevalence for use in the planning and monitoring of a chlamydia screening programme.

6.5 Current Ministry of Health work relevant to chlamydia screening

6.5.1 DHB Sexual and Reproductive Health Questionnaire

This questionnaire was sent to all DHBs in January 2006, and responses were received from all 21 DHBs. The aim was to quantify the type and level of sexual and reproductive health services being delivered across the country, to identify any issues that may exist, and to assist with policy and service development for sexual health. The information is to be used to inform decisions regarding the Ministry-funded sexual and reproductive health services and to highlight any service coverage issues that require attention from

within available funding. Results have been collated and summarised, lead by the Communicable Diseases team.

Increasing rates of STIs is one of five main issues identified by DHBs. Specific concerns noted in this area are poor surveillance of STIs, growing demand for services, lack of quality data available for planning purposes and the need for better integration of services.

6.5.2 Sexually Transmitted Infections Notification Group

This group was convened to examine and give advice on the current surveillance, including revisiting whether STIs (with a particular focus on the bacterial STIs) should be notifiable. This was to include the laboratory implications for improving surveillance and notification. The group met in early April 2006 and discussions from the meeting will be used as the basis for further targeted consultation with the sector before final decisions are made. This process is being lead by the Communicable Disease and Immunisation Team in the Public Health Directorate.

6.5.3 Public health legislation review

The Public Health Bill has been under review for many years. Following public and government consultation, a draft Bill is at present being prepared to be considered by Cabinet towards mid 2006. There are two main implications in the current proposals that are relevant to chlamydia screening. Under the current legislation, there is no provision for laboratories to be the entity required to notify a disease or health condition, and there is no provision for notification of anonymised data. The proposed legislation will have provision for a legal basis requiring laboratories to report certain conditions and that reporting of certain specified conditions will be by use of anonymised data.

The Law Reform (Epidemic Preparedness) Bill is now before Parliament. This Bill includes provision for a legal basis for laboratory reporting of notifiable conditions. Passage of this Bill is likely to occur before the new Public Health Bill and may provide a platform for mandated reporting of anonymised data on chlamydia testing by laboratories.

7 Review of current policies and practices for chlamydia screening in New Zealand

7.1 Policies

Concern about STIs, and recognition of the need for enhanced prevention and control activities, is a common theme found in many New Zealand Ministry of Health and government documents.

7.1.1 Sexual and Reproductive Health Strategy, May 1996

One of the overall aims of this strategy was to reduce the incidence of STIs and HIV/AIDS. The objectives included reducing the spread and prevention of STIs, the piloting of programmes to improve delivery of sexual and reproductive health care services, particularly to Pacific peoples, and the provision of information about sexual and reproductive health challenges for rangatahi to aid them to develop evidence-based policy (Minister of Health 1996).

7.1.2 New Zealand Health Strategy 2000

The New Zealand Health Strategy was released by the Government in December 2000 with the comment that it would 'set the platform for the Government's action on health'. The strategy presented underlying principles from which broad goals and associated objectives were developed. Among the 10 goals, healthy lifestyles, has the improvement of sexual and reproductive health listed as one objective. However, only 13 of the 61 objectives were chosen for implementation in the short to medium term and improvement of sexual and reproductive health was not one of the 13 priority objectives (Minister of Health 2000).

7.1.3 Sexual and Reproductive Health Strategy Phase One, 2001

This strategy notes that Government's concern is focused on two key areas, one being the increasing burden of STIs, especially HIV, chlamydia and gonorrhoea. Four strategic directions provide the framework to plan future work in this area, which was said to include detailed action plans (Phase 2) in the areas of STIs and unintended/unwanted pregnancies, sexual and reproductive issues for Māori, a plan for Pacific peoples and an HIV/AIDS plan. The HIV/AIDS action plan was released in 2003. Instead of the other three proposed action plans, the following resource book was released, also in 2003 (Minister of Health 2001a).

7.1.4 Sexual and Reproductive Health: A resource book for New Zealand health care organisations 2003

The introduction states that 'the Ministry of Health has developed this resource book to support the Minister of Health's Sexual and Reproductive Health Strategy' and that it is intended as a 'guide', primarily for DHBs and PHOs (Minister of Health 2003a).

The section titled 'Designing Services' notes that there is growing evidence to support the effectiveness of particular approaches to improving sexual health and lists 'approaches that work'. These include 'sexual warrants of fitness' being offered by some practices as a way of offering chlamydia screening to younger clients who may be harder to reach by more traditional approaches.

Section Three provides 'Strategies for Action' and, under the subsection 'Personal knowledge and skills', suggests that young people should be encouraged to incorporate sexual health checkups as a part of their general health checks, stating that:

To reduce the transmission of asymptomatic infections like chlamydia, opportunistic testing for chlamydia is recommended for:

- *sexually active people under the age of 25 years*
- *women presenting for pregnancy testing*
- *women attending antenatal clinics*
- *women seeking termination of pregnancy.*

The term 'testing' is usually reserved for when a laboratory test is used for diagnosis in the presence of symptoms and/or signs. However it is reasonable to think that in this context the term refers to 'screening'. It is used in the same sentence where it has already been stated that chlamydia is an 'asymptomatic infection', indicating that any tests ordered would not be on the basis of symptoms. It is also combined with the word 'opportunistic', which also implies these recommendations are referring to screening.

Suggestions are made as to ways to progress the strategies listed in this section and include 'more frequent and more effective use of nurses to deliver sexual and reproductive health advice and screening'. It is also recommended that 'each region should look at developing guidelines to make sure health care professionals work together to establish effective local protocols for testing, managing and following up STI/HIV-positive cases that are identified through screening'. The recommendation for opportunistic testing of these same groups is repeated in the section on 'Strategies for Māori'.

7.1.5 Integrated Approach to Infectious Disease: Priorities for Action 2002–2006

This document sets out the key priorities for action for prevention and control of infectious diseases at national and local levels. All infectious diseases are categorised to reflect modes of transmission, affected populations and control measures and these groups are prioritised into need for action. The STI group is one of six groups given highest priority, and has objectives, targets, key strategies and agreed actions outlined. One of these key strategies is to evaluate the cost-effectiveness of chlamydia screening in defined populations and, if appropriate, pilot such screening (Minister of Health 2001b).

7.1.6 HIV/AIDS Action Plan Sexual and Reproductive Health Strategy

This strategy notes that early and effective treatment of other STIs is considered as an important component of HIV prevention in the United Nations AIDS Report on the Global HIV/AIDS Epidemic 2002 (Minister of Health 2003b).

7.1.7 Conclusions

Concern over STI incidence and prevalence, and the need for prevention and control strategies for STIs, has clearly been identified as a priority in government policy since the 1990s. Targeted testing of asymptomatic people has been recommended as one strategy for chlamydia control since 2003, along with the development of guidelines for STI management.

7.2 Current practice

It is difficult to estimate the amount of chlamydia screening and testing which currently occurs as this information is not currently collected by the STI surveillance system. Predicting future screening and testing volumes, regardless of whether there is a formal screening programme, is important as these costs will be incurred no matter whether a screening programme is implemented or not. The following information was obtained from an informal email request for information from MOsH and the review of responses to the 2006 DHB Sexual and Reproductive Health Questionnaire sent out by the Communicable Diseases Team, Ministry of Health.

7.2.1 Northland

Information is available from the Whangarei CT screening project. The total resident population for Whangarei aged 15–24 years in the 2001 census was 7561. Laboratory data for 2003–2004 indicated that 3000–4000 chlamydia tests were performed annually. The implementation of the CT screening project in June 2006 would suggest that the number of chlamydia tests will increase in this age range. It would seem likely that the social marketing campaign may also cause an increase in testing among high-risk people in older age groups.

7.2.2 Counties Manukau

Counties Manukau DHB has an 'Under 22' strategy for provision of free sexual health services for both males and females aged 22 years or less. Currently, this is noted to be reaching a large number of females for contraceptive services. Planning is underway to increase access for males, and the 15–19 year age group; to improve training for primary health care providers; to provide evidence-based guidelines for treatment decisions in sexual health; to improve contact tracing and to increase awareness in the general population of the importance of good sexual health. It is likely that this strategy will result in increases in chlamydia screening.

7.2.3 Waikato

Waikato DHB has been funding free sexual health services for under 25 year olds since the beginning of 2004 in most general practices and primary healthcare providers in the region. The response to the Ministry of Health's 2006 DHB Sexual and Reproductive Health Questionnaire, records interest in a national chlamydia screening programme and the need for development of national treatment guidelines for sexual health.

7.2.4 Hawke's Bay

The draft Hawke's Bay DHB Strategy 2006–2011, *Let's Talk About Sex*, proposes to provide free STI services in primary care (HBDHB 2006).

The background paper for this draft strategy recommended screening for chlamydia in those aged under 29 years who also had one of the following: new sexual partner in past 12 months; more than two sexual partners in past 60 days; symptomatic sexual partner; sexual partner who has had other sexual contacts; previous STI in past 12 months or no stable partner and not using condoms.

The background paper also noted that analysis of clinic and laboratory data from the area indicates that seven times more people are diagnosed with chlamydia infections than the case numbers reported by the clinics alone. Test volumes per capita for

chlamydia testing were shown to have increased by a factor of approximately 50% from 2000/2001 to 2003/2004.

7.2.5 Capital and Coast

Capital and Coast DHB funds all sexual health consultations for those aged under 25 years who are enrolled with a PHO or who attend as 'casual' patients for this service. The DHB published a draft report on primary sexual health services for young people in March 2006 which reviews the sexual and reproductive health of young people in the DHB region, the services available to them and recommends future service provision (CCDHB 2006).

The report notes that 'STIs, especially Chlamydia, are at unacceptably high levels' and identifies improved access to screening for chlamydia and other STIs as an important goal. Recommendations listed in the Executive Summary include that 'opportunistic screening for Chlamydia and other STIs should be offered to all sexually active males and females at risk'.

7.2.6 Nelson Marlborough

The Nelson Marlborough DHB has collected and analysed laboratory data for chlamydial infections from 2000–2004. This was initiated by a working group reviewing the provision of sexual health services in the area. Positive chlamydia tests show a general increase over this time period, with the greatest increase in the 15–24 year age group. More positive tests are recorded as being requested by health care providers than by either FPCs or SHCs. Overall test positivity has increased from 7.7% to 11.6% over this time period. This suggests that prevalence may be increasing but may also reflect more targeted testing and/or improved tracing and testing of contacts. The data is unable to provide information on testing patterns as total tests requested is not available by age band or requestor type. However, it is of interest to note that the total number of tests requested has increased from approximately 5000 per annum in 2000 to over 6000 in 2003 and 2004 (personal communication 2005, Dr Ed Kiddle, Nelson Public Health Unit).

7.2.7 Canterbury DHB

Community Public Health (CPH) reports that several PHOs and the Youth Health services in Christchurch aim to offer chlamydia screening to all clients aged 16–25 years annually (personal communication 2005, Dr Alistair Humphrey, CPH).

7.2.8 Otago

The Dunedin PHO (79,000 patients in 32 practices) commenced an 'Under 25' sexual health programme in January 2005 which provides free sexual health services for all enrolled patients aged under 25 years. This is reported to have been well accepted by the GPs (personal communication 2005, Dr Jill McIlraith, Public Health South). Data has been collected from the two main laboratories used by GPs in Dunedin and show that, in 2004, 88% of positive chlamydia tests were requested by community health care providers (GPs, after hours services, SYHCs, FPCs) with the remainder coming from SHCs and other hospital departments. Between 2002 and 2004 there has been a 32% increase in the number of chlamydia tests ordered and a 69% increase in the number of positive tests.

Other local initiatives include education for GPs and other health care providers on chlamydia, including when and how to screen; a project reviewing use and acceptability of self-administered vaginal swabs for screening; and raising community and media awareness about sexual health and chlamydia screening.

7.2.9 Conclusions

There is evidence that testing rates for chlamydia have increased in recent years. There is also good evidence that there is increasing interest and planning for prevention and control of STIs at the DHB and PHO level. These plans generally provide for free sexual health visits for young people and encourage chlamydia screening. It is likely that testing rates will increase further as a result of these strategies. Current surveillance does not allow a breakdown of testing patterns to see if testing is appropriately targeted or to use test positivity for particular age groups as a guide to prevalence.

7.3 Stakeholder opinions

Discussions were held with a range of stakeholders as to their perception of the need for chlamydia screening, and whether this screening should be part of an organised programme, as listed below.

- Ria Earp, Deputy Director-General, Māori Health Directorate
- Dr Beverley Lawton, Women's Health Research Centre, Wellington School of Medicine
- Dr Jane Morgan, Sexual Health Physician, Waikato DHB
- Dr Edward Coughlan, Sexual Health Physician, Christchurch Sexual Health
- Dr Margaret Sparrow, FPA, Wellington
- Dr Jonathan Jarman, MOH, Northland DHB
- Dr Jim Vause, President, New Zealand College of General Practice (now past-president)
- Dr Graham MacBride-Stewart, ESR, Porirua

More informal discussions were held with other sexual health physicians and Ministry of Health Officials.

The general themes identified are listed below.

- Population rates for chlamydial infection and prevalence in specific populations indicate that NZ has high levels of disease.
- Chlamydial infection is under-diagnosed in NZ and we are likely to have a high level of preventable sequelae as a result.
- There is good evidence from overseas studies that screening for chlamydia reduces the incidence of sequelae in the population and may reduce prevalence.
- Screening for chlamydia should be offered to selected high-risk groups.
- The limited surveillance of STIs in NZ means that we lack the evidence base to inform selection of groups for screening and to adequately evaluate outcomes.
- The surveillance and research available indicates that the burden of acute infection and sequelae may be spread unequally across ethnic groups.

- There is a lack of awareness of the current recommendations in the 2003 Resource Book for targeted testing for chlamydia, especially amongst clinicians and primary health care providers.
- There is a need for national guidelines for testing, treatment and contact tracing for all STIs.
- The invitation to screening should be on an 'opportunistic basis', but this should not be limited to traditional health care settings – outreach strategies are needed to target certain groups.

7.3.1 Conclusion

There is general support for chlamydia screening for selected high-risk groups and general agreement that further research and better surveillance are needed to determine these exact groups. There appears to be a feeling that a 'programme' is needed because this will ensure commitment of the resources by the Ministry of Health that are considered necessary to provide needed research (including pilots of screening strategies), improved surveillance, national guidelines for STI management, funding of adequate personnel for all aspects of prevention and control activities and monitoring/evaluation of outcomes.

8 Discussion and recommendations

8.1 Discussion

8.1.1 Findings

Chlamydia is now the most common, treatable, sexually transmitted infection (STI) diagnosed in young adults in NZ. There is evidence that Māori and Pacific peoples have an increased prevalence of infection but may be less likely to be tested or screened.

Prevention and control of STIs requires a range of strategies that may include screening, and there have been increasing calls for a chlamydia screening programme to be instituted in NZ. The disadvantages of ad hoc opportunistic screening, as currently occurs for chlamydia screening in NZ, compared with a screening programme, are that safety, effectiveness and cost-effectiveness cannot be guaranteed and are difficult to assess.

Examination of the evidence using the NHC framework shows that chlamydial infection does meet many of the criteria for screening. This is summarised in Table 2. In addition to the conclusions presented in the summary, there are some important concerns that should be addressed before a screening programme is considered.

There is a lack of robust surveillance data to inform which groups have highest prevalence of infection and are therefore most likely to benefit from screening for infection. This is particularly evident when assessing age-based risk for those aged over 24 years and risk for different ethnic groups.

The evidence for a reduction in long-term morbidity across populations is limited but this will be informed by the outcomes of ongoing evaluation of the NCSP in England, the pilot studies in Australia and other studies underway in Europe.

The necessary elements to ensure quality assurance throughout the screening pathway in NZ are not in place. Standardisation of laboratory protocols and testing procedures, improvements in contact tracing and management and improvements in surveillance are all required to achieve this.

There is also evidence there are inequalities in disease burden for Māori and Pacific peoples and that these may be accentuated unless innovative strategies are used in future screening, whether such screening occurs in an ad hoc opportunistic fashion or as part of a screening programme.

Table 2: Assessment of chlamydia screening using the NHC framework

Criterion	Conclusion
The condition is a suitable candidate for screening	Chlamydial infection can cause serious long-term health problems. Although surveillance data is limited, chlamydia is the most common curable STI diagnosed and reported in NZ and prevalence appears to be high in specific groups, representing a considerable burden of disease.
There is a suitable test	There is a safe, simple and reliable test, but this test is not yet standard at all laboratories in NZ. Standardised laboratory procedures and protocols for equivocal tests and confirmation of positive tests need to be discussed and developed.
There is an effective and accessible treatment or intervention identified for the condition through early detection	Chlamydial infection is easily treated with antibiotics. The antibiotics required for uncomplicated infection are now available on the MPSO.
There is high-quality evidence, ideally from randomised controlled trials, that the screening programme is effective in reducing mortality or morbidity	There is good evidence that early detection and treatment reduces the chances for an individual to progress to serious sequelae, but more limited evidence (one RCT and some observational studies) that screening will reduce prevalence and incidence of serious sequelae in the general population.
The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment)	Ad hoc opportunistic screening already occurs and is likely to increase in NZ. There is evidence that targeting of screening to high-risk populations and improving access for hard to reach high-risk groups will reduce the potential harm from screening.
The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation	Not all elements are in place to ensure quality issues for chlamydia screening would be met: there is evidence that high-risk groups are not likely to access screening, NAATs testing is not available in all laboratories; confirmatory tests for all positive and equivocal tests are not performed in all laboratories; there is limited contact tracing and there is inadequate surveillance to support robust evaluation and monitoring of screening.
There should be consideration of social and ethical issues	Screening appears to be clinically and socially understood and acceptable. There is evidence that there are ethnic and gender inequalities in the current provision of ad hoc screening and that these inequalities may increase unless there is selective and targeted screening and the use of innovative approaches to improve access to services
There should be consideration of cost-benefit issues	Screening for chlamydia in pregnant or young women is shown to be the most cost-effective option when the outcome measured is sequelae averted. However, experience in other OECD countries suggests that inclusion of men may be required to reduce prevalence of this preventable infection in the population. A reduction in prevalence is required if the aim is to reduce the need for widespread screening in the future.

Chlamydia screening in OECD countries is generally on an ad hoc opportunistic basis with targeting of groups shown, or thought to be, high risk. Many countries are undertaking studies to inform changes to screening practices. The RCT cited to support the introduction of the national chlamydia screening programme in England used a population register for recruitment of patients for screening but England is, instead, using opportunistic recruitment as the invitation to screen in its programme (see 5.1).

Overseas experience suggests that success in controlling chlamydia is likely to depend on achieving consistent and high levels of uptake of testing and partner notification amongst both men and women across a range of settings, including primary care and outreach settings. The Australian STI strategy notes that 'control of chlamydia and its complications is feasible through the primary healthcare system but it will require a coordinated national approach' (Minister of Health and Ageing 2005). Recognition of the variables which may affect the cost-effectiveness of a chlamydia screening programme is the basis for the Australian plan to assess these variables before implementing a chlamydia screening programme (see 5.2).

The FPA chlamydia pilot results indicate that it is practical and acceptable to offer screening to clients at its clinics and that a reasonable uptake of the offer will occur. The test positivity rate from the FPA pilot of 8% cannot be extrapolated to the general under 25 year old age group, but does support other studies that suggest that NZ has a significant burden of chlamydial infection in this age group. The results of the pilot indicate that this burden may be higher in Māori and Pacific peoples. It is of interest that the laboratory data indicate that testing rates dropped off to 'pre pilot' levels after the study was completed (see 6.1).

The Whangarei chlamydia screening project is expected to give valuable information on screening in the general population across all health care settings, but will not be completed until late 2007. The pilot will collect ethnicity data from all settings which will allow for calculation of population rates and test positivity by ethnicity. Information will also be gained on the feasibility and effect of outreach activities on rates of screening in groups thought to be high risk but with perceived low access of existing services (see 6.2).

Other proposed research would improve the evidence available on the feasibility and social acceptability of specific screening strategies across primary care and examine innovative approaches to broadening the group being tested to include those who are unlikely to routinely see a health care provider (see 6.3).

Several current Ministry initiatives have the potential to support chlamydia screening by improving surveillance and providing the legal framework for mandatory laboratory reporting of anonymised data suitable for planning and evaluation purposes to inform chlamydia prevention and control strategies (see 6.5)

Concern over STI incidence and prevalence, and prevention and control strategies for STIs, have clearly been identified as a priority in government policy since in the 1990s. Targeted testing of asymptomatic people has been recommended as one strategy for chlamydia control since 2003, along with development of guidelines for STI management. The data suggests that implementation of these recommendations has been uneven across the country. There is evidence of inequalities (ethnic, gender, age,

geographic) in both disease burden and access to services, and that increases in ad hoc opportunistic screening may further increase inequalities (see 7.1).

It is difficult to estimate the amount of chlamydia screening and testing which currently occurs as this information is not currently collected by the STI surveillance system. Predicting future screening and testing volumes, regardless of whether there is a formal screening programme is important as these costs will be incurred no matter whether a screening programme is implemented or not. There is evidence that testing rates for chlamydia have increased in recent years. There is also good evidence that there is increasing interest and planning for prevention and control of STIs at the DHB and PHO level. These plans generally provide for free sexual health visits for young people and encourage chlamydia screening. Current surveillance does not allow a breakdown of testing patterns to see if testing is appropriately targeted or to use test positivity as a guide to prevalence in specific age and ethnic groups (see 7.2).

There is a general feeling from stakeholders that a 'programme' is needed for chlamydia screening. This is despite some of the stakeholders not being aware that government policy since 2003 is to recommend testing of asymptomatic people in selected high-risk groups. Stakeholders appeared to support a programme because it is thought that this will ensure commitment of the resources by the Ministry of Health that are considered necessary to provide needed research (including pilots of screening strategies), improved surveillance, national guidelines for STI management, funding of adequate personnel for all aspects of prevention and control activities and monitoring/evaluation of outcomes (see 7.3).

8.1.2 Implications

The findings show that screening for chlamydial infection already occurs in NZ and that it is likely that testing rates will increase further as a result of increasing public and individual health care provider awareness as well as specific programmes set up by various DHBs and PHOs.

The lack of robust surveillance data hampers evidence-based decisions as to selection of high-risk groups for targeting and evaluation of screening activities.

There is evidence that inequalities exist (ethnic, gender, age, geographic) in both disease burden and access to services and that increases in screening may further increase these inequalities. This must be considered in ad hoc screening as well as if a programme is implemented.

Evidence from overseas research and experience indicates that standardisation of laboratory protocols and testing procedures, rigorous attention to contact tracing and management, and high uptake rates of the screening offer are all necessary to achieve a reduction in both the population rate of sequelae of infection and prevalence of infection.

Assessment of the variables shown to affect the cost-effectiveness of screening would assist in determining future recommendations for screening. For instance, there is currently a lack of evidence that screening is acceptable and feasible in general practice or in outreach settings in NZ at the rates required to achieve improved population outcomes.

While there appears to be widespread support for a chlamydia screening programme amongst many stakeholders, including the public and clinicians, their perception of the likely outcomes may not be realistic, given the research findings and results from more intensive screening activities in Sweden and the United States (Fairley 2005). The benefit to individuals of treating their infection is clear from overseas studies, but the population benefit is less certain.

These conclusions, along with the resource constraints, suggest that implementation of a chlamydia screening programme by the NSU should not be a high priority at this time. However, the evidence presented indicates that important benefits and risk mitigation could be gained by improvements within existing health system structures.

8.1.3 Limitations

The lack of certainty in several important parameters used in the economic evaluation used to inform this report limits the conclusions that can be drawn about the cost-effectiveness of chlamydia screening.

The lack of population-based data ethnicity data (for prevalence of infection and access to testing) limits the ability to accurately assess current, or predict future, disparities.

This report does not attempt to prioritise a chlamydia screening programme against other screening programmes, other strategies for chlamydia control or other health care strategies.

8.1.4 Further work

Specific research and surveillance activities directed to improving our knowledge of prevalence and incidence of chlamydial infection are required.

Pilot studies to assess the feasibility and acceptability of screening across a range of primary care settings, including outreach situations and innovative strategies to target those who do not traditionally access health services, should be funded and evaluated.

The National Screening Advisory Committee, the Communicable Diseases Team and DHB Funding and Planning should provide detailed opinions on an STI prevention and control strategy, the priority a chlamydia screening programme should have within this strategy and the risk of continuing with the current situation of ad hoc screening.

8.2 Recommendations

While some stakeholders have called for a national screening programme for chlamydia, real health gains could be made within existing structures, to enhance current surveillance and improve prevention and early intervention through primary care settings. To address the public health problem of chlamydia in NZ, the following recommendations are presented:

1. The surveillance of chlamydial infection in NZ should be extended to include data from all laboratories as a matter of urgency. This would be facilitated by the enactment of either the Law Reform (Epidemic Preparedness) Bill or the new Public Health Bill.

2. Laboratory data collected for surveillance purposes should include basic demographics on all chlamydia tests requested, specifically age, gender, ethnicity, domicile and requestor type.
3. Parameters for adherence to the existing recommendations for chlamydia control, including screening, should be added as a Primary Health Organisation Indicator in DHB contracts.
4. National guidelines for management of STIs, including interim guidelines for opportunistic screening and contact tracing should be developed and provided to all DHBs.
5. An advisory group should be established to evaluate prevention and control options for chlamydia, including screening strategies and assess their sustainability and appropriateness for NZs social and health care settings.
6. The advisory group should identify additional research, surveillance data, modelling or pilot studies that are required to inform these decisions.

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Appendix 1 Summary of New Zealand chlamydia studies

Table 3: Summary of New Zealand chlamydia prevalence studies

Study population	Year	Test	Eligible population	% Participation	% eligible population tested	% study population tested	Test positivity %	Reference
Study on pregnant women	1999–2003	PCR						(Lawton et al 2004)
n=7913			6614	84	37.5	31.4	4.8	
< 25 yrs			985		61.7		12.2	
≥ 25 yrs			5629		33.3		2.3	
NZ European			4015		32.5		2.0	
Māori			505		54.9		15.2	
Pacific			581		59.0		12.5	
Asian			495		40.8		0.5	
Neonatal eye swabs			3 years data:n=5, 10 and 47				20.0; 20.0; 4.25	
Christchurch high school students 16–18 yrs on school roll	2001	PCR	Those who attended assembly/classroom on a particular day	48	72		2.0	(Corwin et al 2002)
Audit in TOP* clinic patients	2003	PCR		Assumed 100	Assumed 100			(Rose et al 2005)
All women			1001			7.7		
< 25 yrs			535			11.2		
≥ 25 yrs			466			3.6		

Study population	Year	Test	Eligible population	% Participation	% eligible population tested	% study population tested	Test positivity %	Reference
NZ European			385			4.4		
Māori			170			12.9		
Pacific			70			18.6		
Asian			343			7.3		
Female university students 18–25 yrs	2003	PCR						(Baker et al 2005)
All					59.9	2.7		
Māori			49		68.0	4.1		
Pacific			26		61.5	13.3		

* Termination of pregnancy.

Appendix 2: Chlamydia Pilot Program Timeline (Australia)

