Screening to Improve Health in New Zealand

Criteria to assess screening programmes

April 2003

Incorporating the Public Health Advisory Committee
Te Ropū Tohutohu I Te Hauora Tōmatawai
The cover illustrates the “Screening Pathway”
(identification, invitation, information,
testing, treatment, monitoring/evaluation).

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\(^1\) Ashley Bloomfield was the Manager of the National Health Committee until September 2002.
Foreword from the National Health Committee

The possibility of screening people before they develop a condition or at an early disease stage is an appealing prospect that became popular in the 1960s. Health care systems worldwide now incorporate a range of screening activities across the lifecourse, from routine screening as part of antenatal care to screening older people for a range of conditions.

Screening has the potential to prevent the development of disease, prevent premature death and disability and to improve quality of life. However, it also has attendant costs and the potential to cause harm.

Screening is a complex process that requires careful consideration of clinical, social, ethical and economic issues. Screening programmes should be based on good quality evidence that they do more good than harm, at reasonable cost, and they should be delivered within the context of an effective quality assurance programme.

New Zealand needs agreed assessment criteria to inform decisions about prospective new screening programmes and to reassess or alter existing programmes. Some screening currently being offered in New Zealand is not supported by good evidence that it is beneficial. Over time, such screening needs to be formally evaluated and essential elements put in place to ensure it is effective and safe.

The National Health Committee believes that the screening assessment criteria in this report should guide future decisions about existing and potential new screening in New Zealand. Ideally, there should also be a specific body that is charged with making such decisions and overseeing screening in New Zealand.

Robert Logan
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Executive Summary

This report presents criteria for assessing screening programmes in New Zealand.

Screening

Screening is a complex process that is not generally well understood by professionals and the public for a range of reasons. This report seeks to help improve this understanding.

The National Health Committee 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.”

Screening occurs in two ways – as part of screening programmes and opportunistically. In screening programmes (as defined by the NHC) all activities along the screening pathway are planned, co-ordinated, monitored and evaluated. Most screening in New Zealand currently occurs outside of formal programmes.

In contrast to screening programmes, opportunistic screening lacks formal quality processes. Opportunistic screening is undertaken for a wide range of conditions and risk factors, usually when a test for an unsuspected disorder is offered at a time that an individual comes into contact with the health system for another reason. Such screening occurs with varying degrees of organisation, but there is no formal co-ordination, monitoring and evaluation.

Screening has the potential for benefit, but also the potential for harm. Once the invitation to be screened is issued, there is an ethical obligation to ensure that the screening programme can deliver the potential benefits and minimise the potential harms. Therefore, before a screening programme is initiated, both the benefits and harms must be carefully assessed.

Screening programme participants should have access to the information they need to make an informed decision about whether or not to participate. In practice, it is not easy to achieve individual informed consent for screening. The provision of information and the necessary discussion and reflection on it requires considerable effort, time and skill, and consumes health care resources. These factors must be considered when implementing a screening programme.

In the context of screening, equity of access to quality services is important. Those within the target population should have a fair opportunity to participate in the screening programme. Ideally, there should be a specific mechanism to identify all eligible individuals, for example a population register.

Screening programmes must not exacerbate health inequalities by being less accessible to groups with poorer health status, or by depriving those groups of resources for other services that would improve their health. Screening programmes need to operate from a cultural context that makes sense to participants.
Assessment of screening programmes in New Zealand to date

In New Zealand, some screening programmes were established following a formal assessment of the evidence, pilot programmes and consideration of implementation issues. Other screening has evolved with no such formal assessment.

To date, no single body has been responsible for making decisions on whether screening programmes should be established in New Zealand. Various approaches have been applied to assessing potential screening programmes.

Principles of screening and screening assessment criteria

In 1968, the World Health Organization proposed principles of screening, which continue to inform screening policy decisions today. These screening assessment principles have been adapted over time, to respond to contemporary screening issues and general health care developments.

In proposing criteria for New Zealand, the NHC considered a number of screening principles and assessment criteria used worldwide. In particular the Committee drew on the criteria established by the United Kingdom National Screening Committee and those developed for the Canadian Strategy for Cancer Control.

The Committee recommends that the following eight criteria be used to assess screening programmes in New Zealand. These criteria will provide decision-makers with the necessary information to ensure that an informed decision is made about establishing a new screening programme or maintaining an existing one. The criteria are intended to inform judgement and are not absolute, as no existing or potential screening programme fulfils every criterion entirely.

Criteria for assessing screening programmes

1. The condition is a suitable candidate for screening.
2. There is a suitable test.
3. There is an effective and accessible treatment or intervention for the condition identified through early detection.
4. There is high quality evidence, ideally from randomised controlled trials, that a screening programme is effective in reducing mortality or morbidity.
5. The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment).
6. The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation.
7. There is consideration of social and ethical issues.
8. There is consideration of cost-benefit issues.
1. Introduction

The National Health Committee (the NHC, the Committee) provides the Minister of Health with independent advice on “the kinds, and relative priorities, of public health services, personal health services, and disability support services that should, in the Committee’s opinion, be publicly funded.” The Committee has previously undertaken work in the area of screening and has provided advice to the Minister of Health on screening for colorectal cancer and prostate cancer.

1.1 Purpose and structure of this report

This report presents the recommended criteria for assessing screening programmes in New Zealand and provides the background to their development. These criteria will be essential for the Committee’s current work on antenatal HIV screening and can also be used by other organisations to assist with making decisions about whether a screening programme should be established or an existing programme altered.

The criteria cover the key issues that need to be considered to ensure that a screening programme is, or will be, safe and effective. The criteria are not intended to be absolute – no existing or potential screening programme fulfils every criterion perfectly. Ultimately the decision is one of considered judgement and the NHC criteria will help ensure that this judgement is as well informed as possible.

This report begins by defining screening and screening programmes, explaining the benefits and limitations of screening and identifying key ethical and social issues associated with screening (Chapter Two). New Zealand’s experience assessing screening for selected conditions is briefly outlined in Chapter Three. Chapter Four summarises the original principles of screening formulated by Wilson and Jungner and summarises modifications made since to reflect contemporary screening issues. Finally, recommended screening appraisal criteria for New Zealand are presented in Chapter Five.

1.2 Process

This process was initiated by a Ministry of Health request for the NHC to identify appropriate screening programme assessment criteria for New Zealand. The Committee examined screening programme assessment criteria used in different countries, and examined screening issues generally.

A draft report was peer reviewed and feedback was incorporated, with further refinement of the screening programme assessment criteria. A draft report was then sent out widely as a discussion document. Feedback on the discussion document was integrated into this final report.

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[a] New Zealand Public Health and Disability Act 2000, Section 13 (1a).
2. **Background**

Screening is a complex process that spans education, invitation, disease detection, diagnosis and management, as well as long-term follow-up to determine outcomes. Early detection of disease through screening can result in benefits to both individuals and wider society by reducing the number of people suffering or dying from diseases and sometimes reducing the costs associated with their care.

This section defines screening and clarifies important terminology. It describes two types of screening – screening programmes and opportunistic screening – and discusses particular ethical considerations in screening.

2.1 **What is screening?**

While there are many definitions of screening, the NHC has adopted the following definition, based closely on that of the United Kingdom National Screening Committee (UKNSC).²

“Screening is 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.”

Screening is not just the initial test but also the sequence of events that comprise the screening **pathway**. The above definition distinguishes between two types of screening:

- screening for disease risk, which is an assessment of the probability that an individual will develop a disease in the future, for example screening for cardiovascular disease risk factors
- screening for a disease precursor or an early asymptomatic stage of a disease that is amenable to treatment, for example cervical screening and breast screening respectively.

The principles outlined in this paper apply to both these types of screening.

Screening reduces the risk of disease or its complications through early detection and treatment but is not a guarantee of prevention, or diagnosis and cure. Thus, for example:

- the breast screening programme reduces the risk of dying from breast cancer
- the cervical screening programme reduces the risk of developing and dying from cervical cancer
- retinal screening in people with diabetes reduces the risk of visual impairment.
2.2 Why is screening important?

Screening has become a common health care activity and there are several reasons why it is being paid increasing attention:

✦ its potential to improve public health
✦ the (usually) fine balance between benefits and harms
✦ the need to demonstrate cost-effectiveness and fair access
✦ the increasing focus on an informed decision by participants.

When conducted appropriately, screening has the potential to improve public health and, potentially, reduce health inequalities. As life expectancy and the quality of life improves in developed countries, the focus of health care is shifting away from just the diagnosis and treatment of illness and its complications towards prevention, early detection and modification of risk factors, and the detection and management of disease precursors or early disease. Here, screening plays a central role.

Technological developments and the experience that early detection of some diseases is beneficial create pressure for new screening programmes. Screening for a range of conditions is increasing, often despite acknowledged risks and a lack of proven effectiveness, for example screening for prostate cancer. Advocacy by health professionals can be a driver of this, for example in the cases of breast screening for women under 50 and prostate screening. Consumer expectations as a result of media publicity, especially about the personal experience of high-profile individuals, also play a role. The coding of the human genome creates further potential for screening entire populations or specific subgroups for genetic susceptibility to disease.

Even when screening is shown to be effective however, there is often a fine balance between the expected benefits and potential harms of screening. All steps in the screening pathway must be undertaken to a high standard to guarantee that the benefits outweigh the harms. As in other countries, high profile quality problems with New Zealand’s organised screening programmes have generated considerable publicity. The quality problems and subsequent publicity have highlighted the need for improved understanding of the complexities of screening programmes, including the underlying ethical issues, the balance of harms and benefits, and the resource implications of ensuring that organised screening is effective and safe.

Capped overall expenditure on health care demands adequate scrutiny of the opportunity costs of screening. Inequalities in health outcomes and in access to health care services in New Zealand create a strong imperative to ensure that screening is not exacerbating these inequalities, either through being less accessible to groups with poorer health or by diverting resources from services that may be of greater benefit to those groups.

Screening was developed as a public health service designed to improve the health of populations. In general, many individuals benefited while some people suffered adverse effects, but in population terms there was a net gain. The main focus of screening was to deliver a service to populations and seek to ‘recruit’ as high a percentage of the population
as possible. This traditional approach to screening, which emphasised the benefits and aimed to achieve high levels of coverage, now needs to be balanced with the need to provide individual participants with sufficient information to enable an informed decision to participate or not.²

2.3 Ways that screening is undertaken

Screening occurs in two ways – through screening programmes and opportunistically. The assessment criteria discussed in this paper have been developed for application to screening programmes. They are also applicable to opportunistic screening, which should only be undertaken after careful consideration (and discussion) of the balance between benefits, harms and costs.

2.3.1 Screening programmes

In screening programmes, all activities along the screening pathway are planned and co-ordinated. Thus, screening programmes have resources committed to the development, implementation, monitoring and evaluation of all aspects of the programme, from the identification of the population at risk, to the diagnosis of the disease or its precursor in certain individuals, to the treatment of those individuals.⁸

Population screening programmes involve screening entire populations or a large and easily identifiable group within the population. The target population group for screening may be defined geographically or by some other characteristics such as gender, age or ethnicity. The New Zealand cervical and breast screening programmes are examples of population screening programmes.

A population-based screening programme is one in which screening is systematically offered by invitation to a defined, identifiable population: this requires a means of identifying and inviting the target population, for example through a population register.

2.3.2 Opportunistic screening

The key feature that distinguishes opportunistic screening from screening programmes is the lack of a quality process, including routine monitoring and evaluation. Opportunistic screening usually occurs when a person who is presenting to the health system for another reason is asked a question or offered a test in order to detect the presence or confirm the absence of a specific condition. Opportunistic screening may be organised to a greater or lesser degree. However, because there are no attendant quality processes, its safety, effectiveness and cost-effectiveness cannot be assessed and guaranteed.

Opportunistic screening occurs for a wide range of conditions and risk factors (Table 1).iii Sometimes people are recruited ‘opportunistically’ to participate in an organised screening programme, for instance a GP notes that a woman is almost due for her regular cervical smear when she consults for another matter and decides to offer the smear there and then.

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³ii A related but distinct process is case-finding. This involves identifying people who are asymptomatic but who are at risk of a disease because they are related to a symptomatic individual, e.g. contacting relatives of a person who has had bowel cancer at a young age and has been diagnosed as having hereditary adenomatous polyposis. These individuals may have a regular screening test as part of ongoing surveillance.
Table 1  *Organised and opportunistic screening in New Zealand*

<table>
<thead>
<tr>
<th>TYPE OF SCREENING</th>
<th>CURRENT EXAMPLES</th>
</tr>
</thead>
</table>
| Screening programmes       | ✦ Breast cancer screening (BreastScreen Aotearoa/BSA)  
✦ Cervical screening (National Cervical Screening Programme/NCSP)  
✦ Newborn baby metabolic screening for phenylketonuria, maple syrup urine disease, galactosaemia, biotinidase deficiency, congenital adrenal hyperplasia, congenital hypothyroidism, cystic fibrosis  
✦ Adult Hepatitis B screening |
| Opportunistic screening    | ✦ Screening for hearing impairment at school entry  
✦ Antenatal screening:  
✧ anaemia  
✧ rhesus incompatibility (to avoid newborn haemolytic disease)  
✧ gestational diabetes  
✧ serology for syphilis, rubella, hepatitis B  
✧ ultrasound screening for anatomical abnormalities eg, neural tube defects  
✧ risk factors for HIV  
✧ chromosomal abnormalities eg, Down syndrome (nuchal translucency +/- maternal serum screening)  
✦ Newborn physical examination to screen for congenital hip dislocation, undescended testes, cardiac abnormalities, etc  
✦ Well Child screening for developmental delays  
✦ Screening for complications of diabetes (retinal, foot and kidney)  
✦ Screening for breast cancer with clinical breast examination  
✦ Mammographic breast screening outside of BSA  
✦ Diabetes screening  
✦ Colorectal cancer screening  
✦ Prostate cancer screening  
✦ Cardiovascular disease risk factor screening (smoking, serum cholesterol, hypertension)  
✦ Screening for alcohol and drug misuse among adolescents and adults  
✦ Osteoporosis risk factor screening (which may include bone mineral density scanning)  
✦ Screening for congenital hearing impairment |

Some screening policies, such as screening for complications of diabetes, are clearly stated but are not delivered consistently or comprehensively. On the other hand, screening tests may be applied consistently or comprehensively to specific populations, for example most antenatal screening, but the essential quality assurance, monitoring and evaluation activities do not occur and there is no formalised programme oversight.

It is difficult to have adequate quality processes outside of organised screening programmes. However, the quality of much opportunistic screening could be improved by having appropriate professional audit and collecting and analysing appropriate monitoring data.

### 2.4 Screening activities in New Zealand

Existing screening activities in New Zealand have developed over time in a range of ways, and this is reflected in their current degree of organisation. Some screening was established following a process of systematic appraisal of evidence, the establishment and evaluation of
pilot programmes, and the development of formal quality assurance and oversight mechanisms as part of implementation, for example breast screening as part of the national breast screening programme.

Other screening has ‘evolved’ over time in response to emerging evidence but with no formal assessment using screening programme criteria. This applies to screening with both a high degree of organisation, for example screening for hearing impairment at school entry, and less organised screening, for example screening for diabetes.

Opportunistic screening is undertaken with varying evidence to support it, including:

✦ **conclusive** evidence from randomised controlled trials (RCTs) for overall benefit from screening, but practical reasons for not establishing an organised population screening programme, for example colorectal cancer screening;¹⁰

✦ **some** evidence from RCTs for benefit from screening, insufficient to support an organised screening programme but sufficient in the view of individual clinicians to offer screening opportunistically with full information, for example breast screening in women between the age of 40 and 49;¹¹

✦ **no** RCT evidence for benefit, for example breast screening under age 40 and prostate cancer screening.

As can be seen in Table 1, most existing screening in New Zealand occurs outside of formal programmes with their attendant quality assurance and monitoring processes. Over time, existing opportunistic screening needs to be properly evaluated and, if it is to continue, appropriate quality processes established.

### 2.5 Social and ethical issues in screening

Screening raises important ethical issues.¹² Individuals who considered themselves to be healthy may, after screening, be identified as potentially ill – some wrongly so. These ethical issues must be specifically considered when making decisions about screening programmes.

An effective screening programme for Māori needs to be delivered within a responsive framework, which attends to Treaty of Waitangi, workforce, and ownership of information issues. These are discussed in Section 5.2.

#### 2.5.1 Balancing benefits and harms

Screening has the potential to prevent the development of disease (eg, cervical cancer), prevent premature death and disability (eg, breast screening) and to improve quality of life. Screening also has attendant costs to both individuals and wider society and the potential to cause harm.¹ Some people who participate in a screening programme may not personally benefit from it.

Poor screening programme quality, or a decline in screening programme quality can tip the balance between benefits and harms the wrong way. Once the invitation to be screened is issued, there is an ethical obligation to ensure that the programme can deliver the potential benefits through appropriate quality management.¹² It often requires significant investment.
to achieve and maintain the level of quality necessary to ensure the expected benefits occur. Thus, before a screening programme is introduced, both the benefits and disadvantages need to be assessed (Table 2), and efficiency and feasibility evaluated.\(^{15}\)

Screening can lead to widespread detection and over-treatment of inconsequential disease,\(^{14}\) where there is microscopic evidence of disease but the changes are low grade and unlikely to progress to invasive, symptomatic disease in many individuals. The extent of inconsequential disease that will be generated by a screening programme should be estimated and carefully considered before widespread introduction of screening.\(^{14}\)

In the case of communicable diseases, in addition to the benefits and harms for the individual screened, there may be ‘public good’ benefits to society from reduced transmission. Similarly, for some non-communicable diseases, for example phenylketonuria, screening may save money for society and extend the benefits beyond the individual screened.\(^{15}\) When considering and evaluating a prospective screening programme, it is important to consider the direct benefit to participants and any public good benefits that may result.

**Table 2 Benefits and disadvantages of screening**

<table>
<thead>
<tr>
<th>BENEFITS</th>
<th>DISADVANTAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved prognosis for some cases detected by screening</td>
<td>Longer morbidity for cases whose prognosis is unaltered</td>
</tr>
<tr>
<td>Earlier treatment (cheaper, less radical, cures some early cases with improved quality of life)</td>
<td>Over-treatment of questionable abnormalities</td>
</tr>
<tr>
<td>Potential resource savings</td>
<td>Resource costs</td>
</tr>
<tr>
<td>Reassurance for those with true negative test results</td>
<td>False reassurance for those with false-negative results and possibility of later treatment with worse prognosis</td>
</tr>
<tr>
<td>Wider ‘public good’ benefits in the case of infectious diseases, due to reduced transmission</td>
<td>Anxiety, lingering doubts and sometimes morbidity for those with false-positive results</td>
</tr>
<tr>
<td>Knowledge of their situation for people with true positive test results</td>
<td>Screening procedures are often accompanied by some discomfort, anxiety, and inconvenience for symptomless individuals</td>
</tr>
<tr>
<td>Opportunity for counselling on lifestyle</td>
<td>Anxiety and risks associated with further investigations, which may be unnecessary for those with false-positive results</td>
</tr>
<tr>
<td></td>
<td>Exacerbation of inequalities if there is unequal access to screening</td>
</tr>
<tr>
<td></td>
<td>Costs and inconvenience incurred during investigations and treatment</td>
</tr>
<tr>
<td></td>
<td>Hazard of screening test, eg, radiation</td>
</tr>
</tbody>
</table>

Adapted from Chamberlain (1984),\(^{16}\) Cuckle and Wald (1984),\(^{17}\) Shickle and Chadwick (1994),\(^{18}\) Calem and Downie (1997).\(^{19}\)
2.5.2 Informed consent

Information is valued by consumers and the provision of information increases levels of satisfaction. Consumers generally want more information about screening than they receive, especially on harms and false results. Harm to screening programme participants can lead to anger, loss of confidence in health services, and occasionally litigation. These are compounded if participants are not fully informed. Individuals’ stories may be interpreted as ‘scandals’ if there is poor public understanding of the nature of screening, meaning that every public criticism of screening has to be countered with ever more positive assertions in order that public confidence is not shaken. Thus, potential programme participants should have access to the information they need to make an informed decision about whether or not to participate, as identified by the United Kingdom National Screening Committee (UKNSC):

“There is a responsibility to ensure that those who accept an invitation (to screening) do so on the basis of informed choice, and appreciate that in accepting an invitation or participating in a programme to reduce their risk of a disease, there is a risk of an adverse outcome.”

Thinking on informed consent for screening is changing rapidly and requires urgent research and debate. The overall benefits of screening programmes depend on a high level of participation by the target population. In the past, information about screening has tended to omit the ‘negative’ aspects so as not to raise anxiety and potentially reduce participation.

There is now an increasing emphasis being placed on informed choice by individuals. Eligible individuals have the right to receive an invitation to participate in screening, along with full information, and make a personal decision about whether or not to participate. Consequent to this, there is debate about the extent to which screening programmes should be judged by their participation rate or by their capacity to provide for an informed decision to participate or not.

One concern about providing full information about the benefits and harms of screening is that this might result in reduced participation, in particular by disadvantaged groups. However, participation by individuals in disadvantaged groups should be addressed by improving service accessibility, including acceptability, rather than by selective use of information.

New Zealand health care consumers have a legal right to appropriate information in order to give informed consent, which applies to consent for both screening as part of organised programmes and opportunistic screening. In the case of screening, individuals are not just consenting to a screening test but to the full screening pathway.

The widely cited United Kingdom General Medical Council consent guidelines describe the information that should be provided when seeking informed consent for screening (Appendix 1). The advice from the Medical Council of New Zealand about consent for screening draws on that of the United Kingdom General Medical Council.

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20 Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996. Two rights of the Code are of particular importance when considering screening and screening programmes – Right 6 (the right to be fully informed) and Right 7 (the right to make an informed choice and give informed consent).
“Doctors have a special duty of care when enrolling an apparently healthy asymptomatic person in screening programmes, to make him or her aware of the limitations of screening and the uncertainties, in particular the chance of false positive and false negative results. Before obtaining consent the doctor should explain, or give information to the patient that explains:

✦ the purpose of the screening,
✦ the uncertainties,
✦ any significant medical, social or financial implications of the condition for which the screening is done and,
✦ follow up plans, including availability of counselling and support services.”

In practice, it is not always easy to achieve individual informed consent for screening. Good information is needed to support health promotion programmes and individual health professionals to communicate effectively with people eligible for screening. The provision of information and the necessary discussion and reflection on it require considerable effort, time and skill, and consumes health care resources. These factors must be considered when implementing and evaluating a screening programme.

There may be special ethical considerations in screening children where, as for other medical procedures, consent is obtained from the parent or guardian. A parent may decline screening despite evidence that screening potentially has profound benefits and carries minimal risks, for example most newborn baby metabolic screening. Some observers have argued that this could be infringing the rights of the child. This issue needs further debate in New Zealand.

The monitoring and evaluation of screening programmes may involve the analysis of identifiable individual data to help ensure that the screening programme is of high quality and is providing the best possible outcomes for the target population. It is important that participants are aware of this when they consent to being part of the screening programme, to avoid any compromise of their individual autonomy. There is a requirement under the Health Information Privacy Code that participants be made aware of what the information collected about them will be used for, and the basis on which it can be accessed and by whom.

2.5.3 Equity

In the context of screening, equity requires that all people within the target population have a fair opportunity to participate in the programme. Equity of access to quality services is important. A specific mechanism, for example a population register, is required to identify and invite all eligible individuals, and to assess equity of access by determining whether low coverage is due to individuals declining to take part or is instead due to failure to invite eligible individuals. Screening providers have a responsibly to ensure that all barriers to screening are minimised for participants.
As screening programmes are usually expensive, they carry significant opportunity costs. It is important that screening programmes are not exacerbating health inequalities by being less accessible to groups with poorer health status while at the same time depriving those groups of resources for other services that would improve their health.

In practice, a service can be judged to be equitable ‘when people are treated in as fair a manner as possible by ignoring irrelevant differences between them, but taking into account relevant differences.’\(^{24}\) In New Zealand there is a diverse range of cultural groups, and cultural factors can be relevant differences. Thus, a screening programme needs to operate from a cultural context that makes sense to participants.\(^{25}\)

### 2.6 Conclusion

Screening is a complex process that requires careful consideration of clinical, social, ethical and economic issues. Screening occurs in two ways – through screening programmes and opportunistically. In a screening programme all activities along the screening pathway are planned, co-ordinated, monitored and evaluated. Opportunistic screening occurs in the absence of formal co-ordination, monitoring and evaluation, usually when a person presents to the health system for another reason.

Screening programmes should be based on good quality evidence that they do more good than harm, at reasonable cost, and they should be delivered within the context of an effective quality assurance and improvement programme. New Zealand has a wide range of screening activities (Table 1). However, some screening currently being offered to people is not supported by good evidence for benefit. Furthermore, only a small proportion of screening is undertaken within the context of a quality assurance system and appropriate monitoring that would allow quality failures to be anticipated, identified and addressed.

Thus, there is a strong case for New Zealand having agreed assessment criteria to inform decisions about prospective new screening programmes and to reassess or alter existing programmes. While some opportunistic screening may be beneficial, it is not possible to confirm its safety, effectiveness and cost-effectiveness. Over time, existing opportunistic screening needs to be properly evaluated and appropriate quality processes put in place. In some cases, this may require an organised screening programme, while in others appropriate professional audit and monitoring and oversight may be sufficient.
3. The assessment of selected New Zealand screening programmes

This section briefly describes New Zealand’s experience with assessing potential and established screening programmes. The processes are not described in detail: the intention is to provide some insight into the complexities of making decisions about screening programmes.

To date, no single body has had responsibility for making decisions on screening programmes in New Zealand and there are no formal criteria for assessing whether a screening programme should be established. Various approaches have been applied to assessing screening programmes. The processes and criteria that have been used to assess cervical, breast cancer, hepatitis B, prostate cancer, and colorectal cancer screening in New Zealand are outlined below.

3.1 Cervical screening

In 1985, in response to concern about the rising incidence of cervical cancer in young women, a working group on cervical screening was established at the invitation of the Cancer Society and the Department of Health. The group recommended that all women who had had sexual intercourse should be offered screening at least three-yearly, up to age 65. In developing its recommendations, the working group assessed a number of aspects of cervical screening, including the epidemiology of cervical cancer, the value of screening, current cervical screening practices in New Zealand, the benefits and disadvantages of screening, and international policy.

In addition to the recommendations of the working group, the push for a national population-based cervical screening programme came from a report in 1988 concerning the allegations into the treatment of cervical cancer at National Women’s Hospital (The Cartwright Report).

In 1991 the Department of Health and the Cancer Society invited a working group to review the 1985 recommendations on cervical screening. The working group made minor modifications to the earlier recommendations. The modifications were that screening should be recommended three yearly (rather than at least three yearly) and that the age range for screening be shifted to 20 up to 70 years.

In 1990 an Expert Group presented a report to the Minister of Health on the national policy and resource allocation for a National Screening Cervical Programme (NSCP). The NSCP was the first organised cancer screening programme in New Zealand. The NSCP became operational in 1990/1 with the aim of reducing the incidence of and mortality from squamous cell cancer of the cervix. The programme aims to screen all women aged 20–69 years who have ever been sexually active, every three years.
3.2 Breast screening

In 1987, on the basis of emerging international evidence, the Cancer Society and the Department of Health invited a working group to make recommendations on breast screening using mammography as the screening test. The working group assessed a number of factors associated with mammography screening (Appendix 2).31

The report concluded that New Zealand had a shortage of professionals skilled in the specialised techniques required for the screening of asymptomatic women and recommended that decisions about routine screening be delayed until pilot programmes were established, with assessment of their effectiveness, economic efficiency and social acceptability.31 In 1991, as a result of the report, the Government agreed to fund two pilot mammography screening programmes (Waikato and Otago/Southland).

In 1995, the Minister of Health announced the establishment of a national breast screening programme for women aged 50 to 64 (inclusive). Following this announcement, the Minister of Health appointed a Breast Cancer Screening Policy Advisory Group (BCSPAG) to provide policy advice on the development of the programme.32

BreastScreen Aotearoa, a national breast screening programme, was launched nationally in December 1998 with services offered progressively throughout the country. Subsequent to the launch of the screening programme, quality assurance processes were further developed and consolidated and several mobile screening units established to improve access.

3.3 Hepatitis B screening

In 1994, a Ministry of Health working party on hepatitis B reviewed the literature on chronic hepatitis B infection. The working party concluded that insufficient evidence existed to recommend screening for hepatitis B carriers and recommended that individuals who have been identified as carriers be provided with education, counselling and clinical follow-up.33

The 1994 working party used a number of principles to assess whether a screening programme should be introduced. The working party relied on the criteria used to assess mammography screening in the United Kingdom in 1986 (Appendix 6).34

In 1996, a further working party was established to develop an economic model to determine the feasibility and cost-effectiveness of screening for (detection) and screening of (surveillance) hepatitis B carriers in high-risk groups in a single geographic area. The working group referred to the requirements for an effective screening programme formulated by Wilson and Jungner in 1968,35 and the principles developed at Hui Whakamaarama in 1992.25

In 1997, the Health Funding Authority set about implementing a pilot programme for hepatitis B screening, but this was abandoned as the government opted to establish a more extensive ‘one-off’ screening programme.36 The latter programme was set up in 1999 aiming to screen 70 percent of Māori, Pacific and Asian people aged between 15 and 45 years for hepatitis B, to immunise non-immune individuals, and to provide follow-up surveillance for identified carriers.37 Two providers currently deliver the programme: the Northern Regional Hepatitis Consortium for Auckland and Northland, and the Hepatitis Foundation for the remainder of the North Island.37
3.4 Prostate cancer screening

In 1996, the NHC established a Prostate Cancer Screening Working Party to assess the potential risks and benefits of screening. The working party report to the NHC concluded that the significant potential risks associated with confirmatory tests and treatment for prostate cancer outweighed the as yet unproven benefits of earlier intervention that would be achieved by screening asymptomatic men for prostate cancer.

The NHC advised the Minister of Health that there was no strong evidence to suggest that men should be screened for prostate cancer if they are well.

The NHC has commissioned the New Zealand Guidelines Group to review recent evidence on prostate cancer screening and advise whether there should be a change in the current policy. The NHC will provide advice on this mid-2003.

3.5 Colorectal cancer screening

In 1997, the NHC convened an expert working party to make recommendations on the advisability of introducing a publicly funded population-screening programme using faecal occult blood test (FOBT) screening to detect colorectal cancer.

The working party reviewed the evidence and considered the feasibility of population screening for colorectal cancer in light of the Wilson and Jungner (1968) principles for population screening, and the World Health Organization’s account of the characteristics of an acceptable population screening programme.

Taking into account the modest potential benefit, the considerable commitment of health resources required and the real potential for harm, the working group did not recommend population screening for colorectal cancer in New Zealand. The working party also explicitly stated that it did not recommend the FOBT as a screening test for colorectal cancer in average-risk individual cases outside a screening programme, i.e., opportunistically.

A sub-group of the working party has since developed guidelines for the surveillance of people at high risk of colorectal cancer, and these will be published in mid-2003.
4. Review of screening principles and assessment criteria

In a landmark World Health Organization report in 1968, Wilson and Jungner proposed basic principles of screening (Table 3). The principles continue to inform screening policy decisions worldwide.

Table 3  World Health Organization screening criteria

<table>
<thead>
<tr>
<th>PRINCIPLES OF EARLY DISEASE DETECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Condition</strong></td>
</tr>
<tr>
<td>✦ The condition should be an important health problem</td>
</tr>
<tr>
<td>✦ There should be a recognisable latent or early symptomatic stage</td>
</tr>
<tr>
<td>✦ The natural history of the disease, from latent phase to declared disease, should be adequately understood</td>
</tr>
<tr>
<td><strong>Test</strong></td>
</tr>
<tr>
<td>✦ There should be a suitable test or examination</td>
</tr>
<tr>
<td>✦ The test should be acceptable to the population</td>
</tr>
<tr>
<td><strong>Treatment</strong></td>
</tr>
<tr>
<td>✦ There should be an accepted treatment for patients with recognised disease</td>
</tr>
<tr>
<td><strong>Screening Programme</strong></td>
</tr>
<tr>
<td>✦ Facilities for diagnosis and treatment should be available</td>
</tr>
<tr>
<td>✦ There should be an agreed policy on whom to treat as patients</td>
</tr>
<tr>
<td>✦ The cost of casefinding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole</td>
</tr>
<tr>
<td>✦ Casefinding should be a continuing process and not a ‘once for all’ activity</td>
</tr>
</tbody>
</table>


Since 1968, modifications of the original principles have been proposed in response to contemporary screening issues and general health care developments.

In 1971, Cochrane and Holland proposed that the decision as to which conditions justify screening should be based on an evaluation of the test used to detect them. They built on the Wilson and Jungner criterion relating to suitability of the test and suggested seven criteria for the validation of any screening test (Appendix 3).13

Eight requirements for worthwhile screening programmes were summarised by Cuckle and Wald in 1984.17 The first three requirements relate to the disorder, its prevalence and its natural history. The next four ensure that certain financial and ethical prerequisites will be satisfied. The last requirement is that the distributions of test values in affected and unaffected individuals are known in order to determine the detection rates and false-positive rates, which together with data on prevalence, permit the estimation of the risk of being affected (Appendix 4).17 In addition, Lunt (1984) outlined key organisational requirements for a successful screening programme (Appendix 5).40
The United Kingdom Department of Health and Social Security commissioned a working group in 1986, chaired by Professor Sir Patrick Forrest, to examine breast screening in the United Kingdom.34 The working group used principles based on the 1968 Wilson and Jungner criteria and considered the extent to which breast screening met these criteria (Appendix 6). New criteria added to the original criteria for the purpose of that review were:

✦ for diseases of insidious onset, screening should be repeated at intervals determined by the natural history of the disease

✦ the chance of physical or psychological harm to those screened should be less than the chance of benefit

✦ the cost of screening should be balanced against the benefit it provides.

In 1994, the Committee of the Health Council of The Netherlands formulated criteria for the introduction of genetic screening programmes,41 based on the criteria of Wilson and Jungner. This Committee divided these criteria into 11 absolute criteria, which have to be satisfied before the introduction of a screening programme. The criteria are also weighted on the basis of information that has to be provided to the review body so that it can make an informed consideration of the advantages and disadvantages of screening (Appendix 7).

Gray (1997) suggested that with the increasing demand for health care, the development of new technology, rising patient expectations and increasing pressure on decision-makers, there is a need to add to the criteria of Wilson and Jungner.42 He formulated a list of additional criteria that can be added to the Wilson and Jungner criteria to ensure that they are relevant to appraising screening (Table 4).

Table 4  Gray’s additional screening appraisal criteria

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there evidence from a good-quality RCT, analysed on an intention-to-treat basis, that the proposed screening programme is effective in reducing mortality? If the answer is ‘no’, there is no case for implementation. If ‘yes’, the following questions should be addressed.</td>
</tr>
<tr>
<td>✦ How many people have to be screened to find one case or prevent one death (the number needed to treat: NNT)?</td>
</tr>
<tr>
<td>✦ How many people would be adversely affected by screening: per thousand; per life saved?</td>
</tr>
<tr>
<td>✦ How broad are the confidence intervals around the estimated size of the beneficial effect, and what are, at each end of the confidence intervals, the NNT; numbers adversely affected?</td>
</tr>
<tr>
<td>✦ What are the financial costs of the screening programme, and what health benefit would be obtained by using those resources allocated to screening on:</td>
</tr>
<tr>
<td>1. other ways of managing the health problem that the screening programme has been designed to tackle, for example, improving the treatment of breast cancer;</td>
</tr>
<tr>
<td>2. other services for that population the screening programme is designed to benefit; any other service for any other population group;</td>
</tr>
<tr>
<td>3. any other service for any other population group?</td>
</tr>
</tbody>
</table>

Source: Gray (1997).42
Fowler and Austoker (1997) outlined a number of essential elements for a planned screening programme (Appendix 8). They considered these to be an extension of standard screening assessment criteria, specifically focused on the ‘screening programme’.

In 1998, the United Kingdom National Screening Committee (UKNSC) developed national criteria for appraising the viability, effectiveness and appropriateness of a screening programme (Table 5). The criteria are based on the classic Wilson and Jungner criteria but take into account both the more rigorous standards of evidence required to improve effectiveness and the greater concern about the adverse effects of health care. These criteria include many of the modifications proposed since the original Wilson and Jungner criteria in 1968. The UKNSC assesses proposed new screening programmes against these criteria covering the condition, the test, the treatment options, and the effectiveness and acceptability of the screening programme, all of which should be met before screening is initiated.

**Table 5 United Kingdom National Screening Committee’s criteria for appraising the viability, effectiveness and appropriateness of a screening programme**

| The condition | ✦ The condition should be an important health problem.  
✦ The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood and there should be a detectable risk factor, or disease marker and a latent period or early symptomatic stage.  
✦ All the cost-effective primary prevention interventions should have been implemented as far as practicable. |
| The test | ✦ There should be a simple, safe, precise and validated screening test.  
✦ The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.  
✦ The test should be acceptable to the population.  
✦ There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals. |
| The treatment | ✦ There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes than late treatment.  
✦ There should be agreed evidence-based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.  
✦ Clinical management of the condition and patient outcomes should be optimised by all health care providers prior to participation in a screening programme. |

*Table 5 continued over ...*
Table 5 *United Kingdom National Screening Committee’s criteria for appraising the viability, effectiveness and appropriateness of a screening programme – continued*

| The screening programme | ✦ There must be evidence from high quality randomised controlled trials that the screening programme is effective in reducing mortality or morbidity. Where screening is aimed solely at providing information to allow the person being screened to make an ‘informed choice’ (eg, Down syndrome, cystic fibrosis carrier screening), there must be evidence from high quality trials that the test accurately measures risk. The information that is provided about the test and its outcome must be of value and readily understood by the individual being screened. ✦ There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is clinically, socially and ethically acceptable to health professionals and the public. ✦ The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment). ✦ The opportunity cost of the screening programme (including testing, diagnosis, treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (ie, value for money). ✦ There must be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards. ✦ Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be made available prior to the commencement of the screening programme. ✦ All other options for managing the condition should have been considered (eg, improving treatment, providing other services), to ensure that no more cost effective intervention could be introduced or current interventions increased within the resources available. ✦ Evidence-based information, explaining the consequences of testing, investigation and treatment, should be made available to potential participants to assist them in making an informed choice. ✦ Public pressure for widening the eligibility criteria, for reducing the screening interval, and for increasing the sensitivity of the testing process, should be anticipated. Decisions about these parameters should be scientifically justifiable to the public. |

Source: United Kingdom National Screening Committee (1998).5

In 2002, the Canadian Strategy for Cancer Control, produced by a screening working group, outlined a conceptual framework for considering new and evaluating existing cancer screening programmes and guidelines (Table 6).44 The framework is strongly based on the original screening criteria by Wilson and Jungner.35
### Table 6  Operating principles of the Canadian National Cancer Screening Committee

<table>
<thead>
<tr>
<th>CRITERIA FOR CANCER SCREENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>✦ The target cancer should be appropriate for screening.</td>
</tr>
<tr>
<td>✦ The objectives of screening must be clearly identified.</td>
</tr>
<tr>
<td>✦ There should be an appropriate screening test.</td>
</tr>
<tr>
<td>✦ There should be agreement on the appropriate management of people with positive results on the screening test.</td>
</tr>
<tr>
<td>✦ There must be sound evidence that screening impacts favourably on its intended objectives. This evidence must deal effectively with critical potential biases, including length, lead-time, over-diagnosis and selection bias. Randomised control trial (RCT) evidence should be the required standard, wherever possible, for new screening strategies.</td>
</tr>
<tr>
<td>✦ Screening should do more good than harm.</td>
</tr>
<tr>
<td>✦ The health care system should be capable of supporting all necessary elements of screening, including diagnosis and treatment.</td>
</tr>
<tr>
<td>✦ Screening should be endorsed only if it is provided in a continuous manner in conjunction with the necessary quality assurance and programmatic elements.</td>
</tr>
</tbody>
</table>

Source: Canadian Strategy for Cancer Control: Screening Working Group (2002).44
5. New Zealand screening programme assessment criteria

In determining screening criteria for New Zealand, the NHC referred to its work in the 1990s, which outlined a number of key principles that the Committee considered important in deciding on health services in New Zealand. The four principles are encapsulated in these questions:

✦ is it beneficial? (effectiveness)
✦ is it value for money? (efficiency)
✦ is it fair? (equity)
✦ is it what people want? (acceptability).

More recently, the Committee has expanded on these principles and, through the Committee’s work on quality improvement in New Zealand, it has developed five components of quality (Table 7). These can be used as a platform for considering what factors are important for determining screening assessment criteria.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Safety</td>
<td>the extent to which harm from a service is kept to a minimum.</td>
</tr>
<tr>
<td>Consumer focus</td>
<td>the extent to which a service meets the needs of consumers, incorporates community values, and allows opportunities for participation and input into decision-making.</td>
</tr>
<tr>
<td>Access</td>
<td>the extent to which people are able to receive a service on the basis of need and irrespective of factors such as ethnicity, age, location, impairment or gender.</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>the extent to which a service achieves an expected and measurable benefit.</td>
</tr>
<tr>
<td>Efficiency</td>
<td>the extent to which the service obtains the greatest possible benefit from available funding – that it is the best value for money.</td>
</tr>
</tbody>
</table>

In addition to published screening assessment criteria, the Committee identified criteria used in other countries (Appendix 9). The Committee has drawn most strongly on United Kingdom National Screening Committee criteria and the conceptual framework developed for the Canadian Strategy for Cancer Control. It is important to note that although the NHC has drawn on international work, recommendations about screening programmes in this country must be relevant to the New Zealand context. When considering the New Zealand context of screening and screening programmes, it is important to recognise the impact of the Cartwright Inquiry and the subsequent report about the treatment of cervical cancer at National Women’s Hospital. The report made recommendations for new structures and processes to reform medical ethics and protect patients’ rights. The recommendations emphasised the importance of informed consent between health care professionals and participants, and also the need to enhance public scrutiny of medical practice.
5.1 **Recommended New Zealand screening assessment criteria**

Assessing a potential or existing screening programme will require balancing these criteria in the context of the overall programme. Their consideration will provide the necessary information to ensure an informed decision is made about whether to introduce, maintain or modify a screening programme. The criteria are not intended to be absolute, as no existing or potential screening programme fulfils every criterion entirely.

As the criteria are examined, it is important to consider other options for reducing morbidity and mortality and improving quality of care for the condition in question. Policy implications and research questions should be identified, whether or not a screening programme is recommended.

<table>
<thead>
<tr>
<th>Criteria for assessing screening programmes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The condition is a suitable candidate for screening.</td>
</tr>
<tr>
<td>2. There is a suitable test.</td>
</tr>
<tr>
<td>3. There is an effective and accessible treatment or intervention for the condition identified through early detection.</td>
</tr>
<tr>
<td>4. There is high quality evidence, ideally from randomised controlled trials, that a screening programme is effective in reducing mortality or morbidity.</td>
</tr>
<tr>
<td>5. The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment).</td>
</tr>
<tr>
<td>6. The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation.</td>
</tr>
<tr>
<td>7. There is consideration of social and ethical issues.</td>
</tr>
<tr>
<td>8. There is consideration of cost-benefit issues.</td>
</tr>
</tbody>
</table>
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.

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.

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**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.
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.

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 a 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.

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.
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.

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).

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.

5.2 **Incorporating Māori views**

In establishing screening assessment criteria for New Zealand, the NHC wanted to ensure that the criteria were comprehensive, clear and fitted a New Zealand context.

Screening programmes need to specifically consider and respond to Māori, if they are to ensure participation by Māori. Māori participation in screening programmes is crucial to reducing inequalities in morbidity and mortality for Māori in New Zealand.

The NHC considered Māori views on screening and integrated the themes from Hui Whakamaarama, a hui held in 1992 to discuss screening criteria. There was discussion at Hui Whakamaarama about criteria for evaluating whether or not a screening programme is a suitable intervention to prevent, identify and treat a particular disease or illness in the community. The criteria formulated by Wilson and Jungner in 1968 were examined at this hui, but it was felt that additional criteria are required to ensure effective screening programmes for Māori.

At Hui Whakamaarama it was emphasised that treatments must be effective and accessible for Māori. This is reflected in screening assessment criterion three: “there is an effective, acceptable and accessible treatment or intervention identified through early detection.”

Treatments also need to be acceptable. The acceptability of screening is essential for all ethnic groups in New Zealand, including Māori. This is reflected in criterion seven, which
incorporates a requirement that “there should be evidence that the complete screening programme is clinically, socially and ethically understood and acceptable to health professionals and the wider public.”

At Hui Whakamaarama, it was mentioned that screening programmes that operate in isolation are limited in what they can achieve. The screening assessment criteria emphasise the importance of Māori participation, by stating under criterion six that screening programmes should be integrated with existing health services as far as practicable, with specific goals for Māori participation.

Hui Whakamaarama participants agreed that even when the Wilson and Jungner criteria are rigorously applied, screening programmes commonly achieve lower coverage of Māori, despite the often increased risk within Māori populations. Criterion six requires that “any screening programme reaches those who need it the most, which may require specific initiatives to reach particular population groups.”

The NHC agreed that screening programmes should enable the participation of Māori in the planning, delivery and promotion, monitoring and evaluation of the programme. This is reflected in the criterion seven requirement that the “screening programme is planned, monitored, delivered and evaluated in partnership with the population group offered screening.”

The Committee also agreed that the screening programme should be delivered within a framework that is responsive to Māori, which is reflected in criterion seven. Three particular issues are the Treaty of Waitangi, workforce, and ownership of information issues.

1. Treaty of Waitangi

As the founding document of New Zealand, the Treaty of Waitangi should be acknowledged and its principles incorporated in all aspects of health service provision for all New Zealanders, in particular for Māori. As a Treaty partner, the Government recognises the relationship between iwi and the Crown, and appreciates that the principles of the Treaty – partnership, participation, and protection – must underpin all health service provision.

2. Workforce

Māori health workforce development will bring about health gains and assist in addressing the health disparities between Māori and non-Māori. Equity of participation at all levels and improvement of Māori health outcomes is essential. It is important to ensure that the mainstream health workforce is culturally competent. The issue of choice of service provider is very important to Māori, for example, for Māori women having cervical smears.

3. Ownership of information

As health information is considered a taonga, it must be treated with the utmost respect. In 1993, Te Puni Kokiri made a number of recommendations on Māori issues that concerned the Code of Practice for Health Information and reflected concerns about information needs, collection of information, informed consent and the protection of information. These are highly relevant to screening programmes.
Glossary

Coverage
The proportion of the potential target population who participate in the screening programme.

False negative
A negative screening test in a person who does have the condition being screened for.

False positive
A positive screening test in a person who does not have the condition being screened for.

Opportunity cost
The opportunity forgone by allocating resources to a particular option.

Opportunistic screening
The key feature that distinguishes opportunistic screening from screening programmes is the lack of a quality process, including routine monitoring and evaluation. Opportunistic screening usually occurs when a person who is presenting to the health system for another reason is asked a question or offered a test in order to detect the presence or confirm the absence of a specific condition. Opportunistic screening may be organised to a greater or lesser degree. However, because there are no attendant quality processes, its safety, effectiveness and cost-effectiveness cannot be assessed and guaranteed.

Population-based screening programme
A population-based screening programme is one in which screening is systematically offered by invitation to a defined, identifiable population: this requires a means of identifying and inviting the target population, for example through a population register.

Population screening programmes
Population screening programmes involve screening entire populations or a large and easily identifiable group within the population. The target population group for screening may be defined geographically or by some other characteristics such as gender, age or ethnicity. The New Zealand cervical and breast screening programmes are examples of population screening programmes.

Screening
Screening is 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.
Screening pathway
This is the screening process from a participant’s perspective. It includes:

✦ an invitation to be screened
✦ being given information about the purpose of the screening, the likelihood and possibility of false positive/negative results, the uncertainties and risks attached to the screening process, any significant medical, social or financial implications of screening for the particular condition or predisposition, follow up plans, including availability of counselling and support services
✦ being questioned or offered a test
✦ having the test
✦ receiving of test results
✦ assessment and diagnosis if the test is positive
✦ possible treatment
✦ understanding that there are activities to monitor and evaluate all these stages.

Surveillance
The monitoring of people known to have a disease or to be at increased risk of a disease.

Predictive value of a negative test (negative predictive value)
The negative predictive value is the proportion of those who are healthy among those with a negative test.

Predictive value of a positive test (positive predictive value)
The positive predictive value is the proportion of those with the pre-clinical condition among those with a positive result.

Sensitivity
The proportion of people in the screened population who have the condition in question and who are correctly identified (by the screening test) as having the condition.

Specificity
The proportion of people in the screened population who do not have the condition in question and who are correctly identified (by the screening test) as not having the condition.

Quality Assessment
Performance measurement against standards, and investment in selection and training of professionals.

Quality Assurance
Detection of problems through external or internal inspection, and their correction through systematic activity.

Quality Improvement
Prevention of problems and control of unintended variations in process through total quality management.
Appendix 1 – United Kingdom General Medical Council advice on seeking informed consent for screening

“Screening (which may involve testing) healthy or asymptomatic people to detect genetic predispositions or early signs of debilitating or life threatening conditions can be an important tool in providing effective care. But the uncertainties involved in screening may be great, for example the risk of false positive or false negative results. Some findings may potentially have serious medical, social or financial consequences not only for the individuals, but also for their relatives. In some cases the fact of having been screened may itself have serious implications.

You must ensure that anyone considering whether to consent to screening can make a properly informed decision. As far as possible, you should ensure that screening would not be contrary to the individual’s interest. You must pay particular attention to ensuring that the information the person wants or ought to have is identified and provided. You should be careful to explain clearly:

✦ the purpose of the screening;
✦ the likelihood of positive/negative findings and possibility of false positive/negative results;
✦ the uncertainties and risks attached to the screening process;
✦ any significant medical, social or financial implications of screening for the particular condition or predisposition;
✦ follow up plans, including availability of counselling and support services.

If you are considering the possibility of screening children, or adults who are not able to decide for themselves, you should refer to the guidance at paragraphs 19–25. In appropriate cases, you should take account of the guidance issued by bodies such as the Advisory Committee on Genetic Testing.”
## Appendix 2 – New Zealand’s experience with screening for selected conditions

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>DECISION CRITERIA</th>
<th>TIMEFRAME TO MOVE FROM DECISION TO OPERATING POLICY TO IMPLEMENTATION</th>
<th>CURRENT STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cervical Screening</strong></td>
<td>A working group was formed in 1985 to review recommendations on cervical screening.</td>
<td>✦ In determining the recommendations the working group assessed:</td>
<td>✦ The National Cervical Screening Programme for all women aged between 20 and 70 years. It aims to reduce the incidence and mortality from cervical cancer.</td>
</tr>
<tr>
<td></td>
<td>✦ the epidemiology of cervical cancer</td>
<td>✦ 1985 – working group formed and recommendations made</td>
<td>✦</td>
</tr>
<tr>
<td></td>
<td>✦ the value of screening</td>
<td>✦ 1988 – The Cartwright Report</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ current practice in New Zealand</td>
<td>✦ Pilot programmes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ the benefits and disadvantages of routine screening</td>
<td>✦ 1990 – Establishment of National Cervical Screening Programme</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ international policies.</td>
<td>✦ 1991 – review of the 1985 recommendations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ 1987 – working group established</td>
<td>✦ 1990 – Establishment of National Cervical Screening Programme</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ 1995 – nationwide breast screening programme announced</td>
<td>✦ 1996–1998 – development of national targets and indicators, a national monitoring and evaluation system and an information system to support the programme</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ 1998 – Breast Screen Aotearoa established.</td>
<td>✦ 1998 – Breast Screen Aotearoa established.</td>
<td></td>
</tr>
<tr>
<td><strong>Breast Screening</strong></td>
<td>A working group established in 1987 to make recommendations on breast screening by mammography.</td>
<td>✦ The working party assessed:</td>
<td>✦ An organised breast screening programme. BreastScreen Aotearoa (BSA) has been running since 1998. Screening mammography is free for women in New Zealand aged 50 to 64 years who have no symptoms. It aims to reduce the number of women who die from breast cancer.</td>
</tr>
<tr>
<td></td>
<td>✦ the benefits and risks of mammography</td>
<td>✦ 1987 – working group established</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ an economic assessment of mammographic screening</td>
<td>✦ 1991 – two pilot programmes established</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ screening cancer practice in other countries</td>
<td>✦ 1995 – nationwide breast screening programme announced</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ current breast screening in New Zealand.</td>
<td>✦ 1995 – Breast Cancer Screening Policy Advisory Group (BCSPAG) established</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>✦ 1996–1998 – development of national targets and indicators, a national monitoring and evaluation system and an information system to support the programme</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>✦ 1998 – Breast Screen Aotearoa established.</td>
<td></td>
</tr>
<tr>
<td><strong>Hepatitis B Screening</strong></td>
<td>In 1994 a working party reviewed literature related to chronic hepatitis B.</td>
<td>✦ The Working Group assessed:</td>
<td>✦ Chronic hepatitis B virus carrier screening programme set up in 1999 to screen 70 percent of Māori, Pacific and Asian people aged 15 to 45 years, to immunise non-immune individuals, and provide follow-up surveillance for carriers.</td>
</tr>
<tr>
<td></td>
<td>✦ Whether it is an important health problem?</td>
<td>✦ 1994 – first working party report</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ Whether the natural history of the disease is well understood?</td>
<td>✦ 1996 – a working party established to determine the feasibility and cost effectiveness of screening for and screening of hepatitis B in high-risk groups in a single geographic area</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ Whether the available test is acceptable to the general population, knowing that it must be applied not once, but at defined intervals?</td>
<td>✦ 1999 – Chronic hepatitis B virus carrier screening programme set up to screen 70 percent of Māori, Pacific and Asian people aged 15 to 45 years, to immunise non-immune individuals and to provide follow-up surveillance for carriers.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ How the treatment of the disease during its pre-clinical phase, compare to treatment when it is symptomatic, does the treatment prolong life and/or enhance the quality of life?</td>
<td>✦</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ Whether there are adequate facilities provided for the diagnosis and treatment of the condition detected in those who are test-positive?</td>
<td>✦</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ Whether the cost in terms of expenditure of resources justify the benefit provided?</td>
<td>✦</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✦ Whether the potential physical, social and psychological harm justify the benefit provided?</td>
<td>✦</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix 2 – New Zealand’s experience with screening for selected conditions – continued

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
<th>Decision Criteria</th>
<th>Timeframe to Move from Decision to Implementation</th>
<th>Current Status</th>
</tr>
</thead>
</table>
| Prostate Cancer    | In 1996 an Independent Prostate Cancer Screening Working Party, sponsored by the National Health Committee, reviewed the evidence on prostate cancer screening. | The working group considered the published evidence on the benefits, harms and costs of screening for prostate cancer.                                                                                                                                                                                                                                                                                                                                 |✦ 1996 – working party convened  
✦ 12 August 1996 – NHC recommends “a systematic prostate cancer screening programme for men without symptoms should not be introduced. The matter should be kept under review.”  
✦ 2001 – working party reconvenes to re-examine recent evidence, updated advice to be published mid-2003 |✦ There is currently no organised prostate cancer screening programme in New Zealand. Opportunistic screening is widespread.                                                                                       |
| Colorectal Cancer  | In 1997 the National Health Committee convened a working party to make recommendations on the advisability of introducing a publicly funded population-screening programme using faecal occult blood tests as the screening test. | The working group considered the:  
✦ health implications of colorectal cancer  
✦ all possible screening methods  
✦ the likely impact on publicly funded follow-up and diagnosis and treatment services  
✦ characteristics of an acceptable population screening programme developed by the World Health Organisation  
✦ principles for population screening formulated by Wilson and Jungner in 1968.  
The working group reviewed evidence relating to:  
✦ the epidemiology of colorectal cancer  
✦ the natural history and treatment of colorectal polyps and cancer  
✦ primary prevention strategies  
✦ screening test options  
✦ participation in colorectal screening  
✦ public concerns about screening  
✦ cultural implications for screening for Māori  
✦ ethical and legal considerations for Māori  
✦ the costs of a screening programme  
✦ groups of people at increased risk of developing colorectal cancer. |✦ 1997 – working party convened  
✦ 1998 – recommendation made that population-based screening for colorectal cancer with faecal occult blood tests is not suited for New Zealand. |✦ There is currently no organised colorectal screening programme in New Zealand. Guidelines for surveillance of individuals at high-risk for colorectal cancer to be published mid-2003. |
### Appendix 3 – Validation of screening test methods

<table>
<thead>
<tr>
<th>VALIDATION OF SCREENING TEST METHODS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Simplicity</strong></td>
</tr>
<tr>
<td><strong>Acceptability</strong></td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
</tr>
<tr>
<td><strong>Cost</strong></td>
</tr>
<tr>
<td><strong>Precision or repeatability</strong></td>
</tr>
<tr>
<td><strong>Sensitivity</strong></td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
</tr>
</tbody>
</table>

Source: Cochrane and Holland (1971).[^13]
**Appendix 4 – Requirements for a worthwhile screening programme proposed by Cuckle and Wald**

<table>
<thead>
<tr>
<th>ASPECT</th>
<th>REQUIREMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Disorder</td>
<td>Well defined</td>
</tr>
<tr>
<td>2. Prevalence</td>
<td>Known</td>
</tr>
<tr>
<td>3. Natural history</td>
<td>Medically important disorder for which there is an effective remedy available</td>
</tr>
<tr>
<td>4. Financial</td>
<td>Cost-effective</td>
</tr>
<tr>
<td>5. Facilities</td>
<td>Available and easily installed</td>
</tr>
<tr>
<td>6. Ethical</td>
<td>Procedures following a positive result are generally agreed and acceptable both to the screening authorities and to patients</td>
</tr>
<tr>
<td>7. Test</td>
<td>Simple and safe</td>
</tr>
<tr>
<td>8. Test performance</td>
<td>Distributions of test values in affected and unaffected individuals known, extent overlap sufficiently small, and suitable cut-off level defined</td>
</tr>
</tbody>
</table>

Source: Cuckle and Wald (1984).17
Appendix 5 – Organisational requirements identified by the World Health Organisation for a successful cervical screening programme

<table>
<thead>
<tr>
<th>KEY ORGANISATIONAL REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>✦ A central office or individual responsible for planning, co-ordinating and evaluating the programme</td>
</tr>
<tr>
<td>✦ An agreed policy and set objectives for the programme, against which to measure the programme</td>
</tr>
<tr>
<td>✦ Computer-based information systems</td>
</tr>
<tr>
<td>✦ Extensive coverage of the eligible population</td>
</tr>
<tr>
<td>✦ Quality control of both smear-taking and smear reading</td>
</tr>
<tr>
<td>✦ Measures to ensure that women with abnormal smears are followed up and treated</td>
</tr>
</tbody>
</table>

## Appendix 6 – Principles of screening and their application to breast screening in the UK

<table>
<thead>
<tr>
<th>PRINCIPLES OF SCREENING AND THEIR APPLICATION TO BREAST CANCER</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The condition sought should pose an important health problem</td>
</tr>
<tr>
<td>2. The natural history of the disease should be well understood</td>
</tr>
<tr>
<td>3. There should be a recognised early stage</td>
</tr>
<tr>
<td>4. Treatment of the disease at an early stage should be of more benefit than treatment started at a later stage</td>
</tr>
<tr>
<td>5. There should be a suitable test</td>
</tr>
<tr>
<td>6. The test should be acceptable to the population</td>
</tr>
<tr>
<td>7. There should be adequate facilities for the diagnosis and treatment of abnormalities</td>
</tr>
<tr>
<td>8. For diseases of insidious onset, screening should be repeated at intervals determined by the natural history of the disease</td>
</tr>
<tr>
<td>9. The chance of physical or psychological harm to those screened should be less than the chance of benefit</td>
</tr>
<tr>
<td>10. The cost of a screening programme should be balanced against the benefit it provides</td>
</tr>
</tbody>
</table>

Source: Department of Health and Social Security (1986).34
### Appendix 7 – Introduction of genetic screening programmes: criteria used in the Netherlands

#### INTRODUCTION OF GENETIC SCREENING PROGRAMMES: CRITERIA

| Absolute criteria | ✦ The programme concerns a health problem or condition that can lead to a health problem  
| | ✦ The target population is clearly defined  
| | ✦ The programme enables participants to become aware of the disease or carrier status  
| | ✦ Practical courses of action are open to the participants  
| | ✦ Participation is voluntary and consent is based on good information  
| | ✦ The target group is supplied with accurate and comprehensive information  
| | ✦ A suitable test method is available  
| | ✦ There are sufficient facilities for every step in screening and diagnosis  
| | ✦ The personal privacy of the participants is protected  
| | ✦ If scientific research is carried out, participants are properly informed about this  
| | ✦ There is continuous quality assurance regarding tests, follow-up and participant information  
| Weighting criteria. There should be information about: | ✦ The prevalence of the disease or disorder  
| | ✦ The natural course of the disorder  
| | ✦ All possible target groups and the considerations which led to the selection of the target group and the time in life for testing  
| | ✦ The performance of the screening test, including the burden which testing imposes on participants  
| | ✦ The available courses of action after a positive test result  
| | ✦ The time allowed for consideration and possible implementation of the courses of action  
| | ✦ The possible psychological, social and other repercussions of the offer, participation and non-participation to participants and other people  
| | ✦ The possibility and consequences of erroneous results  
| | ✦ The guarantees to prevent participants experiencing unjustified impediments from obtaining employment or private insurance cover as a result of (non-)participation in the screening and follow-up testing  
| | ✦ The costs which are linked to the screening and to the attainment of the requisite infrastructure  

Source: Health Council of The Netherlands (1994).\(^1\)
Appendix 8 – Key elements for organising a screening programme proposed by Fowler and Austoker (1997)

<table>
<thead>
<tr>
<th>KEY ELEMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>✦ Identify the target population</td>
</tr>
<tr>
<td>✦ Ensure adequate facilities for screening and the interpretation of the screened material</td>
</tr>
<tr>
<td>✦ Ensure adequate quality control both within and between centres for the screening procedure and its interpretation</td>
</tr>
<tr>
<td>✦ Establish an agreed referral system</td>
</tr>
<tr>
<td>✦ Ensure a reliable fail-safe procedure to ensure that action is taken on all positive results</td>
</tr>
<tr>
<td>✦ Ensure adequate facilities for the diagnosis and appropriate treatment of screening detected disease, and for the follow-up of treated individuals</td>
</tr>
<tr>
<td>✦ Ensure systematic evaluation and monitoring of the whole programme</td>
</tr>
<tr>
<td>✦ Ensure adequate training for all key personal</td>
</tr>
</tbody>
</table>

Source: Fowler and Austoker (1997).43
Appendix 9 – Screening criteria used in other jurisdictions

Australia

In Australia the Wilson and Jungner 1968 principles for health screening programmes are used for appraising screening programmes (A Koukari, personal communication, July 2002).

Canada

In Canada the appraisal of screening interventions is part of the assessment of wider preventive initiatives. The Canadian Task Force on Preventive Health Care (Task Force) published The Canadian Guide to Clinical Preventive Health Care (1994), which is designed as a practical guide to aid clinicians, health professionals, professional associations and health care planners in determining the inclusion or exclusion, content and frequency of a wide variety of preventive health interventions including screening.

The methodology employed in Canada to evaluate the effectiveness of preventive health care interventions and for developing clinical practice guidelines is based on the premise of forming recommendations of graded-strength based on the quality of published medical evidence. The greatest weight is placed on features of study design and analysis that tend to eliminate or minimise biased results. There are grading systems for both the quality of evidence and the strength of recommendations.

The analytical process utilised by the Task Force involves four major aspects. Defining criteria for effectiveness is the first of these and is most relevant to screening criteria. In defining criteria for effectiveness the Task Force examines whether performing the proposed manoeuvre is likely to result in more good than harm. The Task Force stipulates that the strongest evidence that a preventive service is beneficial comes from well-designed studies with adequate follow-up that demonstrates that people who receive the clinical action experience a significantly better overall clinical outcome than those who do not.

In determining the criteria for effectiveness the Task Force also examines the “causal pathway” to illustrate the sequence of events that must occur for a given manoeuvre to influence a target condition. The causal pathway for screening tests clarifies the need to evaluate two causal links to infer effectiveness:

1. the ability of the early detection procedure to identify the target condition
2. the ability of a treatment intervention to achieve a favourable outcome.

The Task Force’s first requirement to prove the value of screening is to verify the ability of a test to detect early-stage disease. This requires an examination of sensitivity (the proportion of persons with the condition who are correctly identified by the screening test), and specificity (the proportion of persons without the condition who correctly test negative). It is also important to determine the positive predictive value and negative predictive values of the test in the population to be screened.

The second requirement to prove the value of screening is to demonstrate the added value of early detection. This is essentially to prove that asymptomatic persons with early-stage disease have a significantly better response to treatment than those who first present with symptoms.
The Task Force recognises other factors which are important for establishing criteria for effectiveness. Firstly, the Task Force understands that even if all the available evidence from studies suggests that a preventive service will achieve a favourable outcome the procedure may fail to achieve the same beneficial effects under the less controlled conditions of clinical practice. The Task Force also acknowledges that beyond discomfort some tests may also result in physical complications and that the results of screening tests can influence clinical decisions to perform interventions that are themselves associated with a certain level of risk. Finally, the Task Force acknowledges the psychological effects of labelling.48

In Canada, the Canadian Strategy for Cancer Control: Screening Working Group has produced a conceptual framework for considering new and evaluating existing cancer screening programmes and guidelines. It is strongly based on the original screening criteria by Wilson and Jungner, but has been applied specifically to cancer.

The Netherlands

In the Netherlands, the Dutch Population Screening Act requires that central government approve certain screening programmes before they are implemented. In 1994 a Committee of the Health Council of The Netherlands formulated criteria for the introduction of genetic screening programmes, based on the criteria of Wilson and Jungner35 (Appendix 7).

United Kingdom

The United Kingdom National Screening Committee (UKNSC) has developed criteria for appraising the viability, effectiveness and appropriateness of a screening programme (Table 5).2 The criteria are based on the principles of early disease detection developed by Wilson and Jungner35, but take into account both the more rigorous standards of evidence required to improve effectiveness and the greater concern about the adverse effects of healthcare. The UKNSC has outlined specific criteria that should be met before screening for a condition is initiated. The criteria cover four main areas: the condition; the test; the treatment; the screening programme.

United States

As for Canada, the appraisal of screening interventions in the US is part of the assessment of wider preventive initiatives. The United States Preventive Service Task Force (USPSTF) has published a Guide to Clinical Preventive Services49 which provides recommendations for clinical practice on preventive interventions – screening tests, counselling interventions, immunisations and chemoprophylaxis regimes – for the prevention of more than 80 target conditions. The criteria for determining effectiveness of screening tests are outlined in the report. It stipulates that screening must satisfy two major requirements to be considered effective: the accuracy of the test and the effectiveness of early detection.

The recommendations reflect a standardised review of current scientific evidence and include a summary of published clinical research regarding the clinical effectiveness of each preventive service.
The ‘accuracy of the test’ is used to describe accuracy and reliability. Accuracy is measured in terms of sensitivity and specificity. Reliability is measured in the test’s ability to obtain the same results when repeated. The test must be able to detect the target condition earlier than without screening and with sufficient accuracy to avoid producing large numbers of false-positives and false-negatives.

The second requirement for a screening test to be considered effective is the ‘effectiveness of early detection.’ Screening and treating persons with early disease should improve the likelihood of favourable health outcomes compared to treating patients when they present with signs or symptoms of the disease.

The recommendations to perform or not to perform a preventive service can be influenced by a number of factors. The recommendations in the USPSTF report are influenced largely by only one factor – scientific evidence.

There are grading systems for both the quality of evidence and the strength of recommendations, similar to the grading systems utilised by the Canadian Task Force.
### Appendix 10 – Individuals and organisations that commented on the discussion document

<table>
<thead>
<tr>
<th>NAME</th>
<th>ORGANISATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allison Carding</td>
<td>Services Coordinator, Cystic Fibrosis Association of New Zealand</td>
</tr>
<tr>
<td>Ann Richardson</td>
<td>Senior Lecturer in Epidemiology, Christchurch School of Medicine, University of Otago</td>
</tr>
<tr>
<td>Barbara Robson</td>
<td>Co-convenor, Federation of Women’s Health Councils of Aotearoa New Zealand</td>
</tr>
<tr>
<td>Betsy Marshall</td>
<td>Policy Advisor, Cancer Screening and Cancer Control, Cancer Society of New Zealand</td>
</tr>
<tr>
<td>Bill McDonald</td>
<td>Chief Operating Officer, Canterbury District Health Board</td>
</tr>
<tr>
<td>Bruce Arroll</td>
<td>Associate Professor, Department of General Practice and Primary Health Care, University of Auckland</td>
</tr>
<tr>
<td>Charlotte Paul</td>
<td>Associate Professor Department of Preventive and Social Medicine, University of Otago</td>
</tr>
<tr>
<td>Dianne Webster</td>
<td>Director, National Testing Centre, Auckland District Health Board</td>
</tr>
<tr>
<td>Gill Greer</td>
<td>Executive Director, Family Planning Association</td>
</tr>
<tr>
<td>Hazel Lewis</td>
<td>Clinical Leader, National Cervical Screening Programme, National Screening Unit</td>
</tr>
<tr>
<td>Jane McEntee</td>
<td>Manager, National Cervical Screening Programme, National Screening Unit</td>
</tr>
<tr>
<td>Jill McIlraith</td>
<td>Clinical Director, Healthcare Otago</td>
</tr>
<tr>
<td>Judi Strid</td>
<td>Trustee, Women’s Health Action</td>
</tr>
<tr>
<td>Julia Peters</td>
<td>Public Health Physician, Waitemata District Health Board</td>
</tr>
<tr>
<td>Karen Guilliland</td>
<td>Chief Executive Officer, New Zealand College of Midwives</td>
</tr>
<tr>
<td>Lindsey Bates</td>
<td>Group Manager, MidCentral Health</td>
</tr>
<tr>
<td>Lucille Wilkinson</td>
<td>Obstetric Physician, National Women’s Hospital</td>
</tr>
<tr>
<td>Lynda Sutherland</td>
<td>Executive Officer, National Council of Women of New Zealand</td>
</tr>
<tr>
<td>Lynda Williams</td>
<td>Chair, Auckland Women’s Health Council</td>
</tr>
<tr>
<td>Lynda Williams</td>
<td>Co-ordinator, Maternity Services Consumer Council</td>
</tr>
<tr>
<td>Lynn Saul</td>
<td>Project Development Officer, Royal New Zealand College of General Practitioners</td>
</tr>
<tr>
<td>Mark Thomas</td>
<td>Infectious Diseases Physician, Auckland Hospital</td>
</tr>
<tr>
<td>Melvin Brieseman</td>
<td>Medical Officer of Health, Crown Public Health</td>
</tr>
<tr>
<td>Nigel Dickson</td>
<td>Senior Lecturer, Department of Preventive and Social Medicine, University of Otago</td>
</tr>
<tr>
<td>Peter Leslie</td>
<td>Chair, Council of Medical Colleges in New Zealand</td>
</tr>
<tr>
<td>Peter Stone</td>
<td>Professor and Head of Division Obstetrics &amp; Gynaecology Clinical Director Maternal Fetal Medicine, National Women’s Hospital</td>
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<td>Health and Disability Commissioner, Office of the Health and Disability Commissioner</td>
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<tr>
<td>Sandra Coney</td>
<td>CEO and Trustee, Women’s Health Action</td>
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<tr>
<td>Simon Baker</td>
<td>Public Health Physician, National Screening Unit</td>
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<td>Stephen Cornelissen</td>
<td>Director Clinical Services, Timaru Hospital and Community Services</td>
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<tr>
<td>Steve Chambers</td>
<td>Associate Professor of Pathology, Christchurch School of Medicine</td>
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References


