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## Foreword

Prostate cancer screening is an important, complex and contentious subject in which there is considerable interest. The National Health Committee has used its screening assessment criteria to assess prostate cancer screening in New Zealand.

Prostate cancer is a significant public health issue in New Zealand. It is the most commonly diagnosed cancer in New Zealand men and the third most common cause of male cancer deaths. It accounts for 3.8 percent of all male deaths in New Zealand, with about two-thirds of these occurring in men aged 75 years and older.

There is considerable concern about the disease and increasing demand for the currently available screening test – the Prostate Specific Antigen or PSA test. There are, however, strong differences in opinion about its value. Currently there is no conclusive evidence that having a PSA test will reduce deaths associated with prostate cancer. This test is not completely reliable and can miss some cancers. A positive PSA test may set in train a cascade of interventions that may offer little benefit and have the potential to cause harm.

The National Health Committee has produced this advice so that health care practitioners, men and the wider public can be aware of the issues and the latest evidence concerning prostate cancer screening. Good clinical practice requires health care practitioners to fully inform individuals of the potential risks as well as benefits of any tests or interventions they undergo.

The National Health Committee believes that this advice on prostate cancer screening is comprehensive and should be widely distributed. Health care practitioners, men and the wider public need up-to-date information based on the best available evidence to help them make decisions. However, simply providing written advice – no matter how widely it is circulated – is unlikely to be enough. To develop understanding around this complex issue requires a commitment to a longer-term education campaign.

Further reviews of prostate cancer screening will be needed as a greater understanding of the disease leads to the development of better screening tests and treatment with improved outcomes.



Robert Logan  
Chair

## Members of the National Health Committee

Robert Logan (Chair)  
Geoff Fougere  
Kevin Hague  
Linda Holloway  
Cindy Kiro (until August 2003)  
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National Advisory Committee on Health and Disability

(National Health Committee)

Wellington

April 2004

This report is available on the NHC's website: <http://www.nhc.govt.nz>  
Copies are available by phoning (04) 496 2277 or emailing [moh@wickliffe.co.nz](mailto:moh@wickliffe.co.nz)

This report can be freely quoted, copied and circulated with appropriate acknowledgement.

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## Executive summary

This report to the Minister of Health presents advice on prostate cancer screening in New Zealand. The role of the National Advisory Committee on Health and Disability (the National Health Committee, NHC) is to provide advice on the kinds of health and disability services that should, in the committee's opinion, be publicly funded, and their relative priorities.

Over the last decade there has been a rapid increase in opportunistic testing using the Prostate Specific Antigen (PSA) test, despite limited evidence of its value. Nearly all General Practitioners (GPs) in New Zealand report that they screen some men for prostate cancer.

In 1996 the NHC reviewed the use of the PSA test for screening for prostate cancer and recommended against population screening but advised that the matter should be kept under review. Due to continued high public interest in prostate cancer screening and increasing use of the PSA test, the NHC decided to review that advice.

Using a background report by the New Zealand Guidelines Group Prostate Cancer Screening Advisory Group<sup>1</sup> and the screening assessment criteria<sup>2</sup> developed by the NHC, the committee reassessed prostate cancer screening in New Zealand. This resulting advice to the Minister of Health is in line with the NHC's 1996 advice, but places greater emphasis on providing health care practitioners and men with up-to-date information.

There is still no conclusive evidence to demonstrate that screening using the PSA test or digital rectal examination (DRE) for prostate cancer reduces mortality or morbidity. There is, however, evidence of significant potential for harm. At present there are no tests that can determine accurately which localised prostate cancers are likely to progress and spread outside the prostate and metastasise. Screening may detect slow-growing prostate cancers that may never cause problems nor shorten a man's life. The NHC does not recommend screening men without symptoms for prostate cancer, regardless of age, because the risks associated with screening and subsequent treatment exceed any benefits.

**The National Health Committee does not currently support population-based screening for prostate cancer or opportunistic screening using PSA or DRE for asymptomatic men in New Zealand.**

The NHC recommends that opportunistic screening of asymptomatic men for prostate cancer using either the PSA test or DRE should not be supported until:

- there is a suitable test
- there is quality assurance and monitoring
- the potential for benefit outweighs the harm
- there is a comprehensive framework for collection, storage, retention and access to data.

However, concern over potential harms of screening is not sufficient reason to deny a man the test if he is fully informed and requests it.

Health care practitioners have a responsibility to ensure men are fully informed of the potential risks of prostate cancer screening. Men considering a PSA test should be given detailed information about its limitations, the possible diagnostic and treatment choices and outcomes and that PSA screening is not recommended in New Zealand. They should also be informed that there is still no conclusive evidence that having a PSA test will reduce their chances of dying from prostate cancer.

The committee recognises that appropriate use of the PSA test can only be achieved with increased levels of understanding about the disease by health care practitioners, men and their families/whānau. The Ministry of Health should encourage District Health Boards (DHBs) to inform and educate health care practitioners and the public about prostate cancer screening.

An information brochure for men about prostate cancer screening has been prepared by the New Zealand Guidelines Group. A brochure for health care practitioners and primary health care teams is also available. These will be distributed widely and updated as necessary. Both information brochures can be obtained through local public health services or ordered from Wickliffe on 04 496 2277.

Prostate cancer remains an important public health problem in New Zealand. However, many aspects of the natural history of the disease, the efficiency of the screening tests and the effectiveness of the treatment still require further research. This research may aid in distinguishing between localised prostate cancers and aggressive prostate cancer. While not supporting screening at this time, the NHC does recommend that the benefits and potential for harm from prostate cancer screening should continue to be reviewed as new evidence emerges. To facilitate this the Ministry of Health should monitor the advances in diagnosis and treatment in relation to this disease. The NHC will also maintain an ongoing interest and provide advice accordingly.

## Recommendations

### *The National Health Committee recommends that:*

- Population-based screening for prostate cancer by Prostate Specific Antigen (PSA) and/or Digital Rectal Examination (DRE) is not introduced for asymptomatic men in New Zealand at present.
- Opportunistic screening of asymptomatic men for prostate cancer using PSA and/or DRE is not offered in New Zealand at present.
- Men who request a PSA test and/or DRE be provided with information which clearly explains the possible harms and benefits of screening and subsequent treatment. This is to ensure that men reach a fully informed decision.
- The Ministry of Health encourage District Health Boards (DHBs) to inform and educate health care practitioners and the public about prostate cancer screening.
- The Ministry of Health reviews new evidence on the benefits and harms of prostate cancer screening and treatment and conducts a formal assessment in 2008.

## *Current facts about prostate cancer and screening*

- Prostate cancer is largely a disease of older men and is rare in men below the age of 50.
- Prostate cancers range from slow growing tumours to very aggressive tumours. Slow growing tumours are common and may not cause any symptoms or shorten a man's life.
- The majority of men with prostate cancer will not die from it.
- There is no conclusive evidence that population screening using the PSA test will reduce the chances of men dying from prostate cancer.
- The PSA test does identify many prostate cancers, but is not completely reliable and can miss some cancers.
- At present there are no tests that can accurately predict which localised prostate cancers are likely to progress and spread outside the prostate and metastasise.
- Many men with a positive PSA test who proceed with further investigations and treatment will end up with a poorer quality of life than if they had not had any treatment at all.
- At present there is no good evidence from randomised controlled trials (RCTs) that any active treatment of screen-detected prostate cancer, compared with watchful waiting, results in fewer deaths among men.
- Active treatments for prostate cancer have significant potential for adverse outcomes which may include impotence, urinary incontinence, diarrhoea, and even death. These outcomes could be experienced by men who may never have been aware that they had localised prostate cancer during their lifetime, nor had any symptoms, had they not undergone screening.



**Table One: Summary of prostate cancer screening against the National Health Committee screening assessment criteria**

National Health Committee Screening Assessment Criteria <sup>2</sup>	
<p><b>Criterion 1</b> The condition is a suitable candidate for screening.</p>	<p>✓ At present, the natural history of prostate cancer is not fully understood and it is not possible to determine which tumours are slow-growing and which are aggressive. However, prostate cancer is an important condition and therefore the NHC believes that in principle, prostate cancer is a suitable candidate for screening.</p>
<p><b>Criterion 2</b> There is a suitable test.</p>	<p>✗ At present, the NHC considers that neither the PSA test nor DRE is a suitable screening test for prostate cancer as neither can be considered reliable, accurate, sensitive or specific enough for screening asymptomatic men.</p>
<p><b>Criterion 3</b> There is an effective and accessible treatment or intervention for the condition identified through early detection.</p>	<p>✗ There is no conclusive evidence about the optimum treatment for localised prostate cancer. At present there is no good evidence from randomised control trials (RCTs) that any active treatment of screen-detected prostate cancer, compared with watchful waiting, results in a reduction in overall mortality. Active treatment for prostate cancer has significant potential for adverse outcomes.</p>
<p><b>Criterion 4</b> There is high quality evidence, ideally from randomised controlled trials, that a screening programme is effective in reducing mortality or morbidity.</p>	<p>✗ At present, there is no high quality evidence from RCTs, that population screening for prostate cancer is effective in reducing mortality or morbidity. Some individuals will suffer significant harm and even death as a result of prostate cancer screening. Ongoing RCTs need to be monitored and evaluated for evidence for the benefit of prostate cancer screening in the future.</p>
<p><b>Criterion 5</b> The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment).</p>	<p>✗ There is no conclusive evidence that the potential benefit from prostate cancer screening outweighs the potential physical and psychological harm caused by the test, diagnostic procedures and treatment.</p>
<p><b>Criterion 6</b> The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation.</p>	<p>✗ A population-based screening programme for prostate cancer in asymptomatic men would need considerable funding and associated resources. The NHC believes this is inappropriate considering that the potential benefits may not outweigh the potential harm of screening. Increased PSA testing would place greater demand on both diagnostic and treatment based health services. As yet there is insufficient evidence that such an investment is warranted or available.</p>
<p><b>Criterion 7</b> There is consideration of social and ethical issues.</p>	<p>✗ It is important that health care practitioners and men are provided with the best possible information about prostate cancer screening. Health care practitioners have an obligation to ensure men are fully informed about the potential risks as well as the benefits of their decision to undergo screening.</p>
<p><b>Criterion 8</b> There is consideration of cost-benefit issues.</p>	<p>✗ The opportunity cost of prostate cancer screening is particularly high. The NHC considers that prostate cancer screening is not a good use of limited health resources at this time.</p>

# 1 Introduction

The National Advisory Committee on Health and Disability (the National Health Committee, NHC) 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.

In 2003 the National Health Committee released a report on screening, *Screening to Improve Health in New Zealand: Criteria to assess screening programmes*<sup>2</sup> which recommended the use of eight criteria for assessing current or new screening programmes (Table Two). The NHC used the criteria as a template for considering and framing its advice on prostate cancer screening.

**Table Two**

## 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.

This report presents advice on population-based screening for prostate cancer and testing of asymptomatic men in New Zealand and explains the background to the development of the advice. This report also provides some information about prostate cancer and prostate cancer screening and some of the misconceptions that surround them.

## **1.1 National Health Committee's interest in prostate cancer screening**

This is the second time the National Health Committee has examined the issues relating to prostate cancer screening. In 1996 the NHC reviewed the use of the Prostate Specific Antigen (PSA) test for screening for prostate cancer, in collaboration with the Australian Health Technology Assessment Committee, which conducted the evidence review. The NHC appointed an advisory group comprising health professionals from specialties involved in providing advice to men on PSA testing and diagnosis and treatment of prostate cancer.

At that time the review team's findings, endorsed by the NHC, recommended against population screening on the following grounds:

1. There was no evidence that screening significantly reduced deaths from prostate cancer.
2. There was the potential for significant harms and costs as a result of screening and confirmatory investigations for the 25 percent of men who would have a positive PSA result (three-quarters of whom would not have prostate cancer).
3. There remained controversy about whether active clinical management improved the prognosis over active observation.
4. Treatment options all carry a significant risk of adverse effects on bladder, penile and bowel function, which may reduce overall quality of life.

Due to continued high public interest in prostate cancer screening and increasing use of PSA testing, the NHC decided to review its previous advice.

## **1.2 Process**

In 2001, the NHC contracted the New Zealand Guidelines Group (NZGG) to convene an advisory group (known as the NZGG Prostate Cancer Screening Advisory Group), comprising clinical, epidemiological and consumer representatives. This group was asked to review the evidence relating to prostate cancer screening, particularly that which has amassed since 1996. This background report is attached as Appendix 2. The advisory group was asked to produce an evidence-based report that would provide:

- the NHC with information on the risks and benefits of population screening for prostate cancer and testing of asymptomatic men (the NZGG also commissioned a systematic review of population screening for prostate cancer<sup>i</sup>)
- health care practitioners with appropriate, accurate and balanced information for making decisions and providing advice on population-based screening for prostate cancer and testing of asymptomatic men
- men and their families with appropriate, accurate, balanced information on the risks and benefits of prostate cancer testing of asymptomatic men.

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<sup>i</sup> A copy of the review can be seen at: [http://www.nzgg.org.nz/development/documents/Prostate\\_Cancer\\_review.pdf](http://www.nzgg.org.nz/development/documents/Prostate_Cancer_review.pdf)

The advisory group presented its background report to the NHC in July 2003, and in September 2003 the NHC sent out a consultation paper on prostate cancer screening in New Zealand based upon the background report. Submissions on the consultation paper were analysed.<sup>ii</sup> The final advice represents the committee's considered view of the submissions and the evidence presented in the background report.

The NHC considers the evidence presented in the advisory group's report to be a rigorous and thorough summary of published research on prostate cancer screening at this time. The advisory group's background report is consistent with systematic reviews overseas.

An information brochure for men about prostate cancer has been prepared by the New Zealand Guidelines Group. A brochure for health care practitioners and primary health care teams is also available. These will be distributed widely and updated as necessary. Both information brochures can be obtained through your local public health service or ordered from Wickliffe on 04 496 2277.

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<sup>ii</sup> A summary of submissions is available on the NHC's website – [www.nhc.govt.nz](http://www.nhc.govt.nz)

## **2 Prostate cancer and prostate cancer screening**

### **2.1 What is prostate cancer?**

The prostate is a small gland that sits just below the bladder and surrounds the top part of the urethra. The growth and development of the prostate depends on testosterone. It is common for the prostate gland to get larger as men grow older and this enlargement is called benign prostatic hyperplasia (BPH).

Prostate cancer is a malignant tumour of the prostate gland. Very early prostate cancers are contained within the prostate gland and are called localised cancers. Localised prostate cancer does not usually produce symptoms, may not develop into a serious cancer, and may not require treatment.

However, some prostate cancers grow within the prostate gland and spread to the surrounding tissues. This is called invasive prostate cancer and may spread (metastasise) via the lymphatic system or bloodstream to other parts of the body.

### **2.2 Incidence, mortality rates and trends for prostate cancer**

Prostate cancer is an important cause of morbidity and mortality and accounts for 3.8 percent of all male deaths in New Zealand.<sup>1</sup> It is the most commonly diagnosed cancer in men and the third most common cause of male cancer deaths.<sup>1</sup>

The rapid increase in the reported incidence of prostate cancer in New Zealand since 1991 probably reflects the increased use of PSA testing in asymptomatic men rather than an actual increase in the prevalence of the disease.<sup>3</sup> Nearly all GPs in New Zealand report that they screen some men for prostate cancer.<sup>4</sup> Men who ask their GPs about screening for prostate cancer are very likely to be offered a PSA test.<sup>4</sup>

The majority of new registrations for prostate cancer are in men aged 70 years or older.<sup>1</sup> The registration rate for new prostate cancers in Māori is lower than for non-Māori, however the rate for Māori men is based on relatively small numbers and the estimates for Māori men are less robust due to variable recording of ethnicity data.<sup>1</sup>

The annual mortality rate for prostate cancer for Māori increased by 77 percent between 1996 and 1998. In 1996 the annual mortality rate for Māori was lower than non-Māori and in 1998 it was 55 percent higher. The age-standardised mortality rate in 1998 was 17.6 for non-Māori men compared with 27.2 for Māori men.<sup>1</sup> Changes in population data definition and variable recording of ethnicity may have contributed to some of this disparity.<sup>1</sup> Good ethnicity data collection is important for all ethnic groups and should be made a priority.

Prostate cancer remains an important public health problem in New Zealand. However there are many issues in relation to the natural history of the disease, the efficiency of the screening tests and the effects of the treatment that still require further research.

## 2.3 What is screening?

Screening encourages otherwise healthy, asymptomatic individuals to undergo tests to identify a disease from which they do not necessarily perceive they are at risk.

The National Health Committee defined 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”.<sup>2</sup>

There is a distinction between screening that occurs through organised screening programmes and opportunistic screening.

In screening programmes, all activities along the screening pathway are planned and coordinated. 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. 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.

Opportunistic screening occurs when a person who presents to the health system for a particular reason is asked a question or offered a test in order to detect the presence or confirm the absence of another condition. It may be requested by the patient or offered by the health professional. Opportunistic screening is sometimes confused with case-finding or diagnostic testing, when a person presenting with symptoms that may be related to a condition - but is not asymptomatic - is tested for that condition.

Opportunistic screening may be organised to a greater or lesser degree, but because there are no attendant quality processes, its safety, effectiveness and cost-effectiveness cannot be assessed and guaranteed.

## 2.4 What is prostate cancer screening?

A screening test may give an indication of the likely presence of a disease. Further tests and investigations are usually required to reach a diagnosis.

Digital rectal examination (DRE) of the prostate is used by doctors to assess the size, shape and texture of the prostate.

A blood test may be carried out to measure the levels of Prostate Specific Antigen (PSA), a raised level of which is at present the best indicator of the presence of localised prostate cancer. However, because the PSA test is organ rather than tumour specific it may also

be raised in association with other urological conditions such as benign prostatic hyperplasia (BPH) and urinary tract infections.

A biopsy of the prostate is frequently undertaken in response to a raised PSA result. This involves the insertion of a needle into the prostate, guided by an ultrasound probe in the rectum (this is called transrectal ultrasound or TRUS). Prostate tissue is withdrawn from different parts of the gland and sent for examination under a microscope.

If malignant cells are found after the biopsy, they are assessed or graded for their aggressiveness. The most common way of grading prostate histologically is to give the tumour a score (known as a Gleason Score) of its potential malignancy.

Treatment options vary depending on the age of the man and the grade and the stage of the cancer. Options include: watchful waiting; surgery; radiation therapy; hormone therapy; or a combination. The choice will depend on the informed preferences of the man.

## **2.5 *Misconceptions around prostate cancer screening***

There are many misconceptions and a lack of knowledge about screening and about prostate cancer screening in particular.

Screening may reduce the risk of disease or its complications through early detection and treatment, but it is not a guarantee of prevention, or diagnosis and cure.<sup>2</sup> In some cases screening and the subsequent treatment has the potential to prevent the development of disease and to prevent premature death and disability. However, screening also has attendant costs to both the individual and wider society and the potential to cause harm.<sup>2</sup>

Screening should bring benefit to the population as a whole; however, screening may offer only a small benefit to each individual, while some may suffer adverse effects. It is generally believed that early diagnosis of disease is beneficial and therefore screening will invariably be effective. However, it cannot be assumed that each individual who is screened or diagnosed within a screening programme will benefit from participation, or that outcomes will be improved by the early detection of the disease.

Successful outcomes for individuals cannot be extrapolated to population screening. Such experiences, particularly when promoted by the media, lead to unrealistic expectations that tests for early detection are 100 percent reliable and always ensure a cure. The public is generally unaware of the potential for harm associated with testing, subsequent investigations and treatment.

It is not often realised that prostate cancer usually develops slowly and that the majority of men with prostate cancer die with it, not from it. The result is that for the vast majority of men with a positive PSA test the side-effects of the treatment will result in a poorer quality of life than if they had not had any treatment at all.



It is a commonly held belief that a prostate cancer screening programme should be introduced and/or asymptomatic men should be proactively offered PSA testing. However, in the absence of proven effectiveness this may reflect differing personal philosophies and levels of knowledge about the potential risks and benefits of prostate cancer screening. Opinions on prostate cancer screening by experts, community groups and individuals are often divided and contradictory and result in the general public receiving mixed messages about its value.

There has been a rapid increase in PSA testing despite a lack of conclusive evidence that screening is effective in reducing deaths associated with prostate cancer. It is not known exactly why this increase has occurred but it is likely to be associated with growing public concern around health issues generally and a greater demand for the PSA test by men worried about the disease.

Despite this lack of proven effectiveness in reducing prostate cancer deaths, prostate cancer screening using PSA is often perceived as a win:win situation for patient and health care practitioner, based on an erroneous belief in the predictive powers of the PSA test. The patient may be reassured by a negative test or, on the other hand, be grateful for the opportunity of a cure following early detection of prostate cancer when it is positive. Where a negative test turns out to be false both can feel that they did the best they could. Adverse outcomes such as impotence and incontinence after surgery may be accepted as a price worth paying for what is perceived as a cure.

It is important to address misconceptions about prostate cancer screening and screening in general and to improve understanding around these. The NHC hopes that this report goes some way to achieving this, but recognises that it will be an ongoing process.



### 3 Examination of prostate cancer screening using the NHC screening assessment criteria

This section assesses prostate cancer screening using the eight screening assessment criteria developed by the National Health Committee.<sup>2</sup> Table One on page 6 provides a summary of this section.

The criteria were not intended to be absolute, as no existing or potential screening programme fulfils every criterion entirely. Policy implications and research questions should be identified, whether or not a screening programme is recommended.

#### **Criterion 1:**

##### **The condition is a suitable candidate for screening.**

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

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

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

Prostate cancer is an important cause of morbidity and mortality in New Zealand. It is the most commonly diagnosed cancer in men, and the third most common cause of male cancer deaths. Prostate cancer incidence and mortality rates are slightly lower in non-Māori than in Māori men, but the rates in Māori men are based on relatively small numbers, and there has been variable recording of ethnicity data, so the estimates for Māori men are less robust.

Post-mortem studies show that histological evidence of prostate cancer is very common and increases with age.<sup>1</sup> Prevalence rates from any form of prostate cancer greatly overstate the prevalence of localised prostate cancer that has the potential to progress to overt disease.<sup>1</sup>

The majority of cases of prostate cancers are very slow-growing and not life-threatening, only a small minority of cases progress rapidly with invasion of surrounding tissues and distant metastases.<sup>4</sup> Unfortunately, it is not possible to accurately determine which tumours are slow-growing and which are aggressive.

Age has no significant prognostic effect on the rate of progression of prostate cancer. In particular, aggressive tumours are not more common in younger men compared with older men.<sup>1</sup>

The natural history of prostate cancer is not fully understood. There are no known risk factors or clinical indicators of malignancy to facilitate targeting of high-risk groups or individuals.

On balance, the NHC feels that prostate cancer screening only just meets this suitability criterion because it attempts to address an important health condition. However, the natural history of the disease is not adequately understood.

At present, the natural history of prostate cancer is not fully understood and it is not possible to determine which tumours are slow-growing and which are aggressive. However, prostate cancer is an important condition and therefore the NHC believes that in principle, prostate cancer is a suitable candidate for screening.

## **Criterion 2:**

### **There is a suitable test.**

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

- Safe:** harm is kept to a minimum.
- Simple:** a test should be easy to perform, to interpret, and capable of use by paramedical and other personnel where possible.
- Reliable:** the test should give consistent results.
- Accurate/valid:** a test must give a true measurement of the condition or symptom under investigation.
- Highly sensitive:** high probability of giving a positive finding when the person being screened has the condition being sought. Sensitivity should be sufficient to lead to a substantial impact on the disease from a population perspective.
- Highly specific:** high probability of giving a negative finding when the person being screened does not have the condition being sought. Specificity should be sufficiently high that a positive test is reasonably predictive of the target condition. This is important because of harms that result from false positive screening tests.

### **Pre-implementation issues**

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

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

It is not possible to derive exact estimates of sensitivity<sup>iii</sup> and specificity<sup>iv</sup> for PSA and DRE. However the best estimates for sensitivity and specificity of the PSA test are 74–84 percent sensitivity and 90–94 percent specificity, with the lower values for each most likely to be the true values.<sup>1</sup>

Assuming a prevalence of prostate cancer of 5.6 percent, PSA sensitivity of 74 percent and specificity of 90 percent, then PSA testing in 1,000 men would result in 136 men having a PSA  $\geq$  4.0 ng/ml<sup>v</sup> and being referred for biopsy. Fifteen men with prostate cancer would have a 'normal' PSA test and would be missed. From the 136 men referred for biopsy, 41 would have prostate cancer, but there is a false negative rate of up to 20 percent for prostate biopsy so that up to eight of these cancers would also be missed by the initial biopsy. This gives an overall result of 33 out of a possible 56 cancers detected for each 1000 men screened, and in some of these men the cancer would not otherwise have become clinically evident in their lifetime.<sup>1</sup> (See diagram opposite page).

Even the lowest estimates for the prevalence of disease detection at post-mortem are greater than the frequency of clinically significant localised prostate cancer, so there is a real potential for detecting many more tumours than will present clinically.<sup>4</sup>

Screening for prostate cancer with the PSA test will detect clinically localised cancers at a stage when curative treatment may be possible. The detection rate varies with different populations and screening protocols, but on average detection rate is of the order of three percent.<sup>2</sup> The proportion of men that will be found by screening to have prostate cancer, but who will not die from their prostate cancer, is not known.<sup>1</sup>

Screening that uses both DRE and PSA, and requires either a positive PSA test or a positive DRE as an indication for biopsy, will result in a small increase in the detection rate of prostate cancer but a larger increase in the false positive rate (more unnecessary biopsies). Using both tests together in this way, it is estimated that for every 1000 men screened, approximately one less cancer would be missed and 40 additional men would be wrongly identified as having cancer.<sup>1</sup>

At present, the NHC considers that neither the PSA test nor DRE is a suitable screening test for prostate cancer as neither can be considered reliable, accurate, sensitive or specific enough for screening asymptomatic men.

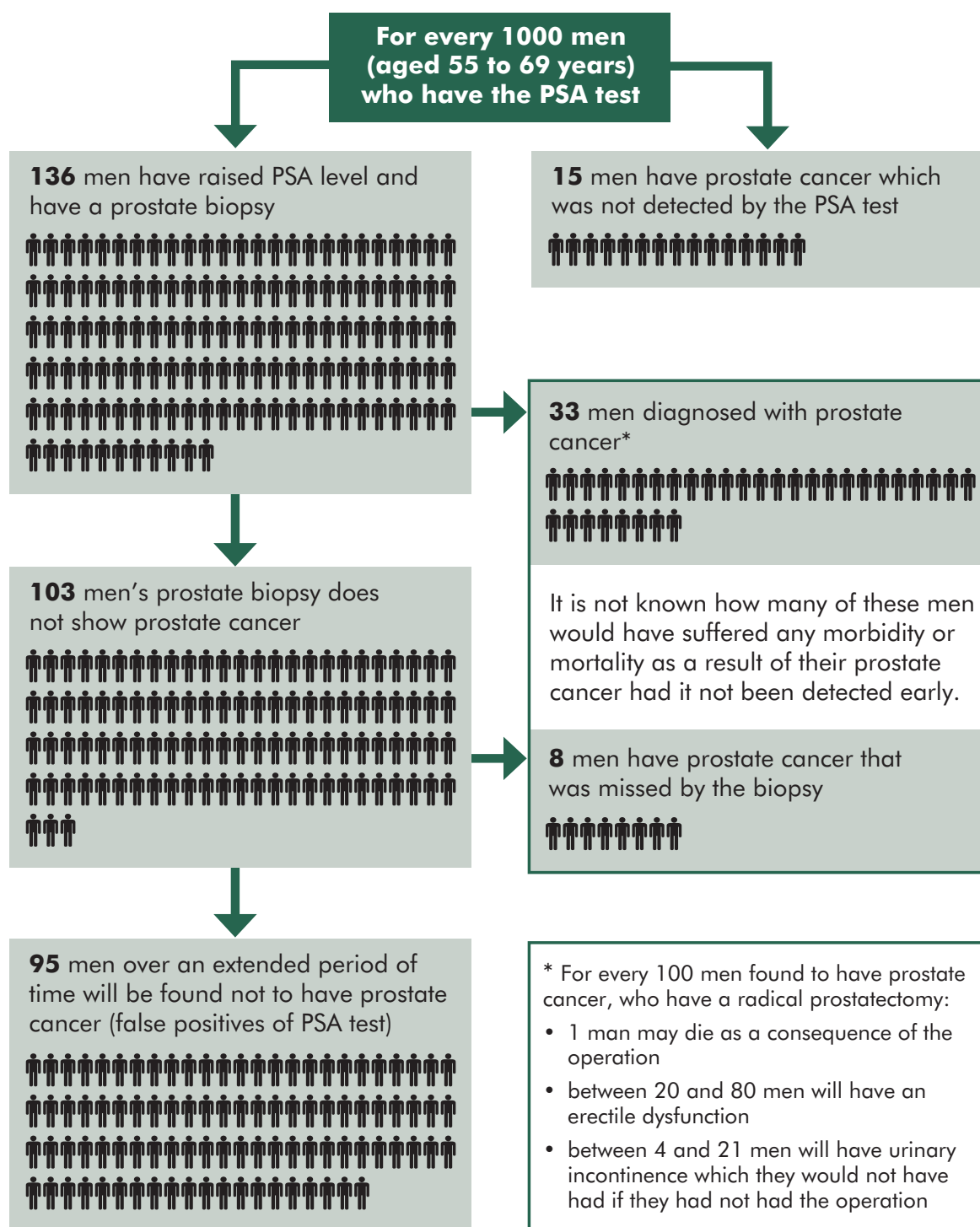
<sup>iii</sup> The proportion of people in the screened population who have the condition in question and who are correctly identified (by the screening test) as having the disease.

<sup>iv</sup> The proportion of people in the screened population who do not have the condition in question and who are correctly identified as not having the condition.

<sup>v</sup> 4.0 ng/ml is the serum concentration of prostate specific antigen that is most commonly used as the cut off point, above which further investigation is indicated.

## Outcome of PSA testing in 1000 men

The figure below is a simplified representation of what would happen to 1000 men who had a PSA test. The numbers are approximate and would be influenced by age and many other factors. The figure needs to be considered within the context of information provided earlier on the key issues surrounding the PSA test.



Adapted from information prepared in 2002 by the Cancer Research UK Primary Care Education Research Group, University of Oxford, [www.dphpc.ox.ac.uk/crcpcerg](http://www.dphpc.ox.ac.uk/crcpcerg)

### **Criterion 3:**

#### **There is an effective and accessible treatment or intervention for the condition identified 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.

Treatments for prostate cancer include radical prostatectomy and radiotherapy. Active monitoring is another option. There is no strong evidence about the optimum treatment for localised prostate cancer, and there is continuing debate regarding the appropriate selection of patients for the different treatment options.

At present there is no good evidence from randomised controlled trials (RCTs) that any active treatment of screen-detected prostate cancer, compared with watchful waiting, results in a reduction in overall mortality (although there will obviously be individual cases where the mortality is reduced). Active treatments for prostate cancer have significant potential for adverse outcomes, which may include impotence, urinary incontinence, diarrhoea and even death.<sup>1</sup>

It is likely that curative treatment (eg, radical prostatectomy or radiotherapy) for localised prostate cancer will prevent progression of the disease and death from prostate cancer in some men.<sup>1</sup> However, many men will suffer from the harmful effects of treatment for a condition that they would never have been aware of and which would not have affected their lives if they had not undergone the screening process.<sup>1</sup>

There is no conclusive evidence about the optimum treatment for localised prostate cancer. At present there is no good evidence from RCTs that any active treatment of screen-detected prostate cancer, compared with watchful waiting, results in a reduction in overall mortality. Active treatment for prostate cancer has significant potential for adverse outcomes.

#### **Criterion 4:**

#### **There is high quality evidence, ideally from RCTs, that a screening programme is effective in reducing mortality or morbidity.**

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

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

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

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

Currently, there is insufficient evidence from RCTs to demonstrate that population screening for prostate cancer reduces morbidity or mortality from the disease.<sup>4</sup> Ecological studies of prostate cancer screening also do not provide consistent evidence in support of screening.

There is an ethical requirement that the potential benefits of screening should clearly outweigh any potential risks or harmful effects. When well men are offered screening there should be conclusive evidence that it can significantly alter the natural history of the disease in a significant proportion of those screened.<sup>3</sup> In screening for prostate cancer some individuals will suffer significant harm and even death as a result of screening.<sup>1</sup>

However, there are ongoing RCTs and the results of these trials may provide evidence for the benefits of prostate cancer screening in the future.<sup>7</sup> Advice on the benefits and harms of prostate cancer screening tests should be reviewed as new evidence emerges.

At present, there is no high quality evidence from RCTs, that population screening for prostate cancer is effective in reducing mortality or morbidity. Some individuals will suffer significant harm and even death as a result of prostate cancer screening. Ongoing RCTs need to be monitored and evaluated for evidence for the benefit of prostate cancer screening in the future.

### **Criterion 5:**

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

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

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

There is insufficient conclusive evidence that the potential benefit from prostate cancer screening would outweigh the potential psychological and physical harm (of the test and future investigations to the population as a whole). There is no evidence that screening will reduce prostate cancer morbidity and mortality, however screening will cause harm in some men. There are potentially both psychological and physical effects of screening, including increased anxiety levels in men with false positive results and false reassurance for men with false negative results.<sup>9</sup>

The reported complication rates for prostate biopsy vary widely.<sup>1</sup> The main complications are pain, bleeding and infection which may become chronic with a small proportion of men experiencing life threatening infections.

The available treatments for prostate cancer cause significant harm in a proportion of men.<sup>1</sup> These harmful effects include impotence, urinary incontinence, diarrhoea, and death.<sup>1</sup> It is likely that some men will suffer these consequences as a result of treatment for a prostate cancer that would never have caused any symptoms, because screening will detect some cancers that would never have caused problems in their lifetime.<sup>1</sup>

There is no conclusive evidence that the potential benefit from prostate cancer screening outweighs the potential physical and psychological harm caused by the test, diagnostic procedures and treatment.



### **Criterion 6:**

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

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

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

#### **Pre-implementation issues**

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

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

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

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

It is estimated that a single PSA screen for all New Zealand men aged 55 to 69 years would result in between 18,954 and 26,758 men with a positive PSA test, who would need to be referred for biopsy. Of these men, between 4,682 and 7,581 men would be identified with histologically diagnosed prostate cancer, although as already mentioned, for the vast majority of these men this cancer would not have become symptomatic during their lifetime.

An increase in PSA testing may be in direct competition with the diagnosis and treatment services of other cancers or other common health problems for men such as benign prostatic hyperplasia. An increase in incidence in prostate cancer will be associated with increased demand for treatment services used for all other cancers. There are already delays for patients requiring radiotherapy for many cancers in some regions in New Zealand.



An increase in PSA testing would place a considerable demand on a small workforce, for example pathologists. This work is time intensive, requires a high level of expertise and is not an efficient use of limited resources.

A population-based screening programme for prostate cancer in asymptomatic men would need considerable funding and associated resources. The NHC believes this is inappropriate considering that the potential benefits may not outweigh the potential harm of screening. Increased PSA testing would place greater demand on both diagnostic and treatment based health services. As yet there is insufficient evidence that such an investment is warranted or available.

### **Criterion 7:**

#### **There is 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 care practitioners 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).

Screening encourages otherwise healthy, asymptomatic individuals to undergo tests to identify a disease from which they do not necessarily perceive they are at risk. When a well person is invited to undergo a screening test, there should be conclusive evidence that the screening test and subsequent treatment can alter the natural history of the disease in a significant proportion of those screened. Such evidence is not available for prostate cancer screening at present.

There is significant public expectation for GPs to screen for prostate cancer, which can be difficult for GPs to manage despite the body of evidence against prostate cancer screening. In the absence of clear evidence that shows whether screening can improve survival and quality of life, it is important that health care practitioners and men are provided with the best possible information about the potential benefits and risks of detecting and treating asymptomatic prostate cancer.<sup>4</sup>

Currently, the NHC believes, men in New Zealand are often being offered PSA testing without being fully informed. Men considering a PSA test should be given detailed information about the limitations of the screening tests and the possible diagnostic and treatment choices they may face. They should also be informed that on the basis of the current evidence it is not known if screening will reduce their chances of dying from prostate cancer.<sup>1</sup> Health care practitioners have a responsibility and obligation to ensure men are fully informed.

The simple provision of information to patients alone will be insufficient to change practice. Education is essential to reduce pressure on health care practitioners to test for the disease. A well-devised, planned and audited educational programme is necessary.

Any educational material about screening for prostate cancer that is made available to health care practitioners, men and their families/whānau should be fully evaluated for its effectiveness in assisting them to arrive at an informed decision. Information for men about prostate cancer screening must meet the needs of Māori men and their whānau. Given Māori men's poorer health status, it is vital to ensure that they are well informed. Information should also meet the needs of other ethnic groups, for example Pacific people.

Assessment of the current screening, diagnosis and management of prostate cancer in New Zealand is constrained by the lack of information about the frequency of PSA testing, the frequency of the different treatments for prostate cancer and the outcomes of these treatments.<sup>1</sup> There is a need for better information regarding Māori mortality rates and further research is needed to examine the impacts of prostate cancer screening for Māori men. The importance of prostate cancer and the existing and potential costs to the New Zealand health care system suggest that collection of this information should be addressed.

It is important that health care practitioners and men are provided with the best possible information about prostate cancer screening. Health care practitioners have an obligation to ensure men are fully informed about the potential risks as well as the benefits of their decision to undergo screening.

### **Criterion 8:**

#### **There is 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.

A comprehensive assessment of the cost-benefit issues has not been completed. However, the NHC considers that at this time, the opportunity cost of prostate cancer screening is particularly high, given that health resources are limited. In other words it may be more cost-effective to invest limited resources in programmes of more proven benefit and in developing or finding a more sensitive and specific PSA test that can determine which prostate cancers become aggressive invasive cancers.

The NHC considers it unacceptable to divert limited health resources to screening for prostate cancer at the expense of the many men who require screening and treatment for other conditions.

The NHC's role is to provide advice on the kinds of health and disability services that should, in the committee's opinion, be publicly funded. The NHC considers that prostate cancer screening is not a good use of limited health resources.

The opportunity cost of prostate cancer screening is particularly high. The NHC considers that prostate cancer screening is not a good use of limited health resources at this time.

## Glossary

**Asymptomatic/symptomatic** – “asymptomatic” refers to people who have no symptoms, that is, no symptoms of prostate cancer. “Symptomatic” means symptoms of the disease are present. Early prostate cancer usually will not produce any symptoms – though benign prostatic hyperplasia (BPH), which is more common, will do so.

**Ecological study** – the main objective of an ecological study is to detect associations between risk and exposure levels and then suggest, or preferably confirm explanatory hypotheses. It is the group rather than the individual that constitutes the basic statistical unit.

**Histological evidence** – the examination of cells and tissues by use of the microscope.

**Incidence** – the incidence of a disease is the number of new cases arising in a given period in a specified population.

**Metastasis** – a secondary tumour that has spread from a primary source.

**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 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.

**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.

**Prevalence** – the prevalence of a disease is the number of cases in a defined population at a specified point in time.

**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.

**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 disease.

**Specificity** – the proportion of people in the screened population who do not have the condition in question and who are correctly identified as not having the condition.

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**Population-based  
Screening for  
*Prostate Cancer*  
and Testing of  
Asymptomatic Men in  
New Zealand**

Final Report to the  
National Health Committee





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# KEY POINTS

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The New Zealand Guidelines Group Prostate Cancer Screening Advisory Group offers the following conclusions to the National Health Committee about prostate cancer screening in New Zealand.

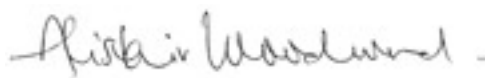
- Prostate cancer accounts for 3.8 percent of all male deaths in New Zealand; approximately two-thirds of these deaths occur amongst men aged 75 years and older. It is not known whether the incidence of prostate cancer for Māori men is more or less than for New Zealanders of European origin. The recent rise in the reported incidence of prostate cancer is largely due to widespread Prostate Specific Antigen (PSA) testing in general practice.
- Many men, their families and whānau, are concerned about prostate cancer and ask about prostate screening.
- Currently there is no evidence from RCTs that demonstrates whether or not population screening for prostate cancer has a positive effect on the mortality and morbidity from this disease.
- Advice on the benefits and harms of prostate cancer screening tests should be reviewed as new evidence emerges.
- Because of the lack of proven benefit and the potential for harm, screening for prostate cancer is not supported.

All members of the group agree that there is no evidence at this time to support an organised, publicly funded, screening programme. However, there was a spectrum of views within the advisory group on the issue of opportunistic screening. There are some who support offering the PSA test with full information on the risks and potential benefits of the test.

Others believe that because of the lack of evidence of benefit and potential for harm, men should not be offered PSA screening. If a man asks about PSA screening he should be given full information about the lack of evidence of benefit and potential for harm, and should be informed that PSA screening is not recommended in New Zealand.

All members of the group agreed that if a PSA test is being discussed, the decision to use a screening test should be made by an individual, with his family, whānau and his doctor with full information of the benefits and harms associated with PSA testing.

The NZGG Prostate Cancer Screening Advisory Group believes that a range of stakeholders should be invited to comment on the evidence in this report and the issues concerned with opportunistic screening.



Alistair Woodward  
Chairman  
NZGG Prostate Cancer Screening Advisory Group

# SUMMARY

## OF THE EVIDENCE ON POPULATION-BASED SCREENING FOR PROSTATE CANCER AND TESTING OF ASYMPTOMATIC MEN IN NEW ZEALAND

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The following report represents the conclusions of the NZGG Prostate Cancer Screening Advisory Group. It is based on a systematic review of population screening for prostate cancer<sup>1</sup> and each heading is referenced to the relevant section of this review. In addition, references to the original source documents are provided for the supporting statements and other references are given for any statements that are not part of the systematic review.

- 1 Prostate cancer is an important cause of morbidity and mortality in New Zealand. It is the most commonly diagnosed cancer in men and the third most common cause of male cancer deaths. It is largely a disease of older men. Incidence, mortality rates, and trends are similar to those in other western countries. There is widespread opportunistic screening for prostate cancer in New Zealand general practice<sup>2</sup> and this is the most likely explanation for the recent rapid increase in the reported incidence of prostate cancer.**

(Population screening for prostate cancer. A systematic review. Pages 24-31)

- 1.1 Since 1991, there has been a rapid increase in the reported incidence of prostate cancer in New Zealand. The increase in the registration of new cancers reached a peak in 1995 and has fallen slightly since then. The most likely explanation for the increased incidence is the increased use of PSA testing in asymptomatic men.<sup>3</sup>
- 1.2 The majority (60%) of new registrations for prostate cancer are in men aged 70 years or older. In 1998, 65.3 percent of all deaths from prostate cancer were in men aged 75 years or older and 2.1 percent of prostate cancer deaths were in men aged less than 60 years. The registration rate for new prostate cancers in Māori is lower than for non-Māori (71.3 per 100,000 population compared with 96.2 per 100,000 population), but the rates in Māori men are based on relatively small numbers, and there has been variable recording of ethnicity data, so the estimates for Māori men are less robust.<sup>3</sup>
- 1.3 Nearly all general practitioners in New Zealand claim to be screening for prostate cancer in some men. For the majority of general practitioners this is by PSA testing with or without digital rectal examination (DRE). Men who ask their general practitioner about screening for prostate cancer are very likely to be offered a PSA test.<sup>4</sup>

- 1.4 The age-standardised mortality rate for prostate cancer in New Zealand in 1998 was 18.0 per 100,000 for the total male population. This rate had increased steadily until 1989 but between 1989 and 1998 there was a 5.3 percent decrease in the rate. These changes are consistent with similar trends of increased incidence and falling mortality rates in other developed countries.<sup>1</sup>
- 1.5 There was an increase in the annual mortality rate for Māori of 77 percent between 1996 and 1998. In 1996 the Māori rate was lower than the non-Māori rate and in 1998 it was 55 percent higher. The age-standardised mortality rate in 1998 was 17.6 for the non-Māori population compared with 27.2 for the Māori population. It is likely that the changes in population data definitions and variable recording of ethnicity data have contributed to some of this disparity.<sup>5</sup>

## **2 Ecological studies of prostate cancer screening do not provide evidence that the decrease in prostate cancer mortality in New Zealand is likely to be due to prostate cancer screening.**

(Population screening for prostate cancer. A systematic review. Pages 31-33)

- 2.1 The 5.3 percent decrease in prostate cancer mortality in New Zealand from 1989 to 1998 cannot be due to the increase in PSA screening,<sup>1</sup> as the timing is wrong. If screening for prostate cancer is effective in reducing mortality, it is likely that any reduction in the mortality rate due to screening will occur at least 7 years and possibly as much as 15 years after the start of screening. The true lead-time between diagnosis at screening and the presentation of symptomatic prostate cancer is uncertain and could be more or less than the suggested five to seven years.<sup>11</sup>
- 2.2 Ecological studies in other countries have not provided consistent evidence that either supports or refutes an association between increased PSA screening and falling mortality rates.<sup>6-10</sup>

## **3 Estimates of the prevalence of prostate cancer greatly over-estimate the number of clinically significant prostate cancers. Screening for prostate cancer is likely to detect many prostate cancers that would never have caused any morbidity or mortality.**

(Population screening for prostate cancer. A systematic review. Pages 36-37)

- 3.1 Post-mortem studies show that histological evidence of prostate cancer is very common and increases with age. Generally accepted figures for the prevalence rate of any form of prostate cancer are 15-24 percent for men aged 50 to 59 years, increasing to 39-44 percent for men aged 70 to 79 years, but these data may include some histological changes, which would not now be recognised as cancer.<sup>12, 13</sup>
- 3.2 These figures greatly overstate the prevalence of localised prostate cancer that has the potential to progress to overt disease. The best estimates for the prevalence rate of clinically significant cancers is 4.4 percent in men aged 50 to 59 years, increasing to 11.4 percent in men aged 70 to 79 years.<sup>14, 15</sup>

- 3.3 Current indications are that even the lowest estimates for the prevalence of disease detection at post-mortem are greater than the frequency of clinically significant localised prostate cancer, so that there is a potential for detecting many more tumours than will ever present clinically.<sup>1</sup>
- 4 The disease specific survival rates for men with well – and moderately well – differentiated tumours, who are not given curative treatment, are approximately 90 percent at ten years. Between 70 percent and 83 percent of screen-detected, organ confined cancers are well – or moderately well – differentiated tumours.**  
(Population screening for prostate cancer. A systematic review. Pages 12-14 and pages 41-42)
- 4.1 The best predictor of tumour progression and metastasis and, therefore, of survival rate is the histological grade of the tumour. Most studies reporting long-term survival rates for the different histological grades of prostate cancer use the Gleason scoring system. The degree of histological differentiation of the cancer cells is given a score between two and ten and these scores are usually grouped into well – differentiated (score 2-4), moderately – differentiated (score 5-7) and poorly – differentiated tumours (score 8-10). There are no long-term studies of survival which use more accurate methods of identifying the tumours that are most likely to progress.<sup>12,13,16-18</sup>
- 4.2 The best estimates for disease specific survival suggest an 87-92 percent 10-year survival for well – differentiated and moderately – differentiated tumours. The 10-year survival rate for poorly – differentiated tumours is in the region of 44 percent. One study estimated the case fatality rate for untreated prostate cancer as 22 percent up to the age of 85 years.<sup>1, 12, 13</sup>
- 4.3 Age has no significant prognostic effect on the rate of progression of prostate cancer and aggressive tumours are not more common in younger men compared with older men.<sup>19</sup>
- 4.4 None of the studies of survival rates are for screen-detected cancers. The cancers for the majority of men in these studies were detected because of clinical symptoms. Survival rates for prostate cancer detected at screening are likely to be better than these estimates because of the lead time between cancer detected by screening and prostate cancer presenting with clinical symptoms,<sup>1</sup> and the tendency for screen-detected tumours to be slower growing.
- 4.5 The results of the first screening round in 15,502 men, in the European Randomised Control Trial in Finland and the Netherlands, found that between 77 percent and 92 percent of cancers were organ confined and of these between 88 percent and 92 percent were well – or moderately – differentiated tumours.<sup>20, 21</sup>

**5 It is not possible to calculate exact values for the efficiency of screening tests for prostate cancer (DRE and PSA). The best estimates for the sensitivity and specificity of the PSA test are 74-84 percent and 90-94 percent respectively. Screening will give rise to a significant number of false-positive and false-negative results.**

(Population screening for prostate cancer. A systematic review. Pages 48-51)

- 5.1 It is not possible to derive exact estimates of sensitivity and specificity for the DRE and PSA test because there is no available reference (gold) standard that can be applied to all individuals.
- 5.2 The positive predictive value of these tests varies with the prevalence of prostate cancer in the population and is, therefore, specific to each population studied.
- 5.3 The best estimates for the DRE are a sensitivity of 55-69 percent and a specificity of 89-97 percent. It is likely that the true values for this test are at the lower end of these ranges.<sup>12, 14, 15, 22</sup>
- 5.4 Assuming that the true prevalence rate of clinically significant localised prostate cancer is 5.6 percent in men aged 55 to 69 years in New Zealand, then a sensitivity of 55 percent and a specificity of 89 percent would produce the following results for every 1000 men screened by DRE:
  - 135 men would have a positive DRE and would be referred for biopsy
  - 25 men with prostate cancer would be missed
  - 104 of the 135 men with a positive DRE would not have cancer and would have an unnecessary biopsy
  - 31 men with a positive DRE would have prostate cancer. In some of these men the cancer would not otherwise have become clinically evident in their lifetime.
- 5.5 The best estimates for the PSA are a sensitivity of 74-84 percent and a specificity of 90-94 percent. It is likely that the true values for this test are at the lower end of these ranges.<sup>12, 13, 23-26</sup>
- 5.6 Assuming that the true prevalence rate of clinically significant localised prostate cancer in New Zealand is 5.6 percent in men aged 55 to 69 years, then a sensitivity of 74 percent and a specificity of 90 percent would produce the following results for every 1000 men screened (by PSA):
  - 136 men would have a PSA  $\geq$  4.0 ng/ml and would be referred for biopsy
  - 15 men with cancer would have a PSA  $<$  4.0 ng/ml and would be missed
  - 95 of the 136 men with a PSA  $\geq$  4.0 ng/ml would not have cancer and would have an unnecessary biopsy
  - 41 men with a PSA  $\geq$  4.0 ng/ml would have prostate cancer. In some of these men the cancer would not otherwise have become clinically evident in their lifetime.

5.7 Screening that uses both DRE and PSA, and requires either a positive PSA test or a positive DRE as an indication for biopsy will result in a small increase in the detection rate of prostate cancer but a larger increase in the false-positive rate (more unnecessary biopsies). It is not possible to calculate accurate figures for using both tests together in this way, but for every 1000 men screened approximately one less cancer would be missed and 40 additional men would be wrongly identified as having cancer. Omitting the DRE and using only the PSA test but with a lower cut-point of  $\geq 3.0$  ng/ml (instead of 4.0 ng/ml) reduces the number of unnecessary biopsies but with only a small decrease in the detection rate.<sup>27</sup>

**6 Refinements of the PSA test do not add significantly to the efficiency of the test in a screening setting. Free-to-total PSA for PSA values between 4.0 ng/ml and 10.0 ng/ml will reduce the proportion of false-positive results but it is doubtful whether this will be sufficient to persuade many men not to have a prostate biopsy.**

(Population screening for prostate cancer. A systematic review. Pages 51-52)

6.1 PSA density, PSA velocity and age-adjusted PSA cut-points do not make a useful contribution to improving the sensitivity and specificity of the PSA test. Age-adjusted cut-points increase sensitivity and reduce specificity in younger men and have the reverse effect of reducing sensitivity and increasing specificity in older men.<sup>28</sup>

6.2 Free-to-total PSA measurements for PSA values between 4.0 and 10.0 ng/ml improves the sensitivity of the test and reduces the number of false negative results. A man with a PSA result between 4.0 and 10.0 ng/ml has an approximately 1-in-4 chance of having prostate cancer. If this same man then has the free-to-total PSA measured and the result is negative then this may reduce his chance of having prostate cancer to 1-in-12.<sup>29</sup>

**7 Screening for prostate cancer will detect clinically localised cancers at a stage when curative treatment may be possible. The likely detection rate for all cancers is between 2 percent and 4 percent of the screened population. It is not known what proportion of these cancers would have caused any morbidity or mortality.**

(Population screening for prostate cancer. A systematic review. Pages 49-51)

7.1 In the initial screening round, in men aged 55 to 69 years, approximately 10 percent (range 7-15 percent) will have a PSA test of  $\geq 4.0$  ng/ml and one out of every four prostate biopsies at the first screening round will detect prostate cancer. This will give an approximate initial detection rate of between 2 percent and 4 percent.<sup>30</sup>

7.2 There is no good evidence about the detection rate with repeated screening, but it is likely that this will fall to about 1 percent or less.<sup>31-34</sup>

7.3 Screening using a PSA test  $\geq 4.0$  ng/ml, as the cut-point for an abnormal result will miss approximately 25 percent of prostate cancers.<sup>1</sup>



7.4 The proportion of men that will be found by a screening programme to have prostate cancer, but who will not die from their prostate cancer, is not known. In the published results of the European RCT 91 percent-92 percent of cancers were well - differentiated or moderately well - differentiated tumours and earlier non-screening studies have found a 90 percent ten-year survival for men with these tumours.<sup>30</sup>

**8 Screening has the potential to cure some men of their prostate cancer before it causes any problem, but there is no good evidence of any improved mortality or benefit from screening for prostate cancer. The available treatments cause significant harm in a proportion of men. These harmful effects include impotence, urinary incontinence, diarrhoea, and death. It is likely that some men will suffer these consequences as a result of treatment for a prostate cancer that would have never caused any symptoms.**

(Population screening for prostate cancer. A systematic review. Pages 60-61)

8.1 Screening for prostate cancer with the PSA test will identify many of the potentially curable and clinically significant cancers. The detection rate varies with different populations and screening protocols, but an average detection rate is of the order of 3 percent.<sup>30</sup>

8.2 It is likely that curative treatment (eg, radical prostatectomy or radiotherapy) for men identified with localised prostate cancer will prevent progression of the disease and death from prostate cancer in some men.

8.3 Some men will suffer from the harmful effects of treatment for a condition that they would never have been aware of if they had not undergone the screening process.

8.4 There are potentially both psychological and physical harmful effects from the screening process. The psychological effects include increased anxiety levels in men with false-positive results and false reassurance for men with false-negative results.<sup>37</sup>

8.5 The main physical harmful effects are pain, bleeding and infection in relation to the prostate biopsy. A very small proportion of men will have life-threatening infections as a result of their prostate biopsy. The reported complication rates vary widely. One screening study of 1,687 transrectal ultrasound-guided systematic sextant biopsies identified:

- haematuria or haemospermia in the three months following the biopsy in approximately one-third of men
- pain after the procedure in 7.5 percent (126 men)
- urinary retention in 0.4 percent (7 men)
- fever >38.5°C in 4.2 percent (71 men). 6 men required hospital admission with one man requiring admission to the intensive care unit with sepsis and shock
- two men developed allergic reactions to the antibiotic prophylaxis given routinely to all men before the biopsy.<sup>38</sup>

- 8.6 The harmful effects of screening include the complications and side effects of treatment in men found to have prostate cancer. These are both the immediate mortality and morbidity of the treatment, and the possible long-term complications such as sexual dysfunction, urinary incontinence, and bowel dysfunction. An inevitable consequence of screening is that some men will experience the complications of treatment for a condition that would never have caused them any problem.
- 8.7 There is a wide variation in the reported complication rates<sup>39, 40</sup>. Studies use different definitions of the complications and different methods of assessment, and many reports are from tertiary and specialist centres, which are unlikely to be representative of the experience of the majority of men in a population-screening programme. The best estimates of the complications rates are:
- a mortality rate within 1 month of surgery of less than 1 percent for men aged less than 75 years
  - after radical prostatectomy 20-70 percent of men have reduced sexual function and 15-50 percent have urinary problems
  - after radiation therapy 20-45 percent of men have reduced sexual function, 2-16 percent have urinary problems and 6-25 percent have bowel problems.
- 8.8 A recent RCT of quality of life after radical prostatectomy compared men following radical prostatectomy and watchful waiting<sup>41</sup>. Erectile dysfunction occurred in 80 percent of men after surgery compared with 45 percent of men in the watchful waiting group. After prostatectomy 56 percent of men were moderately or greatly distressed from compromised sexuality compared with 40 percent of men in the watchful waiting group. In the same study 49 percent of men had symptoms of urinary leakage compared with 21 percent of men who had not had surgery, and 18 percent of men reported a moderate or severe degree of urinary leakage compared with 2 percent of men in the watchful waiting group. In contrast, obstructive urinary problems were more common in the men who had not had surgery but these symptoms caused less distress. Twenty-seven percent of men were moderately or greatly distressed by urinary problems at least 12 months after prostatectomy compared with 18 percent of men in the watchful waiting group. Both the men in the radical prostatectomy group and the watchful waiting group reported similar outcomes on measures of quality of life, and psychological and physical well-being.

**9 Currently there is no evidence from RCTs that demonstrates whether or not population screening for prostate cancer has a positive effect on the mortality and morbidity from this disease.**

(Population screening for prostate cancer. A systematic review. Pages 60-61)

9.1 There is an ethical requirement that the potential benefits of screening should clearly outweigh any potential risks or harmful effects. Screening encourages otherwise healthy, asymptomatic individuals to undergo tests to identify a disease that they do not necessarily perceive that they are at risk from. This is different from a doctor trying the best available treatment, despite defects in medical knowledge, to help a patient with a disease. When a well person is offered a screening test there should be conclusive evidence that screening can alter the natural history of the disease in a significant proportion of those screened<sup>42</sup>.

In screening for prostate cancer some individuals will suffer significant harm and even death as a result of screening.

9.2 As the results of screening are not predictable, the results of well-organised RCTs must be assessed before deciding to offer screening<sup>43</sup>. Reviewers of this topic conclude that there is insufficient evidence to determine whether screening for prostate cancer will have any positive effect.<sup>1</sup>

9.3 There are ongoing RCTs and the results of these trials may provide evidence for the benefits of prostate cancer screening in the future.<sup>30</sup>

9.4 The NZGG Prostate Cancer Screening Advisory Group has reviewed the recently released Screening to Improve Health in New Zealand, issued by the National Health Committee. A brief assessment of prostate cancer testing has been undertaken using this framework, and will be forwarded separately to the NHC. PSA screening for prostate cancer does not satisfy the criteria, as it does not have proven benefit, and has the potential for harm.

**10 Prostate cancer accounts for 3.8 percent of all male deaths.<sup>3</sup> The recent rise in the reported incidence of prostate cancer is largely due to widespread PSA screening in general practice. There is no evidence that the 5.3 percent decrease in prostate cancer mortality is due to screening. Many men and their families and whānau are concerned about prostate cancer and ask about prostate screening. The decision to be screened should be made with full information by the man, his family, whānau and his doctor. Men considering a PSA test should be given detailed information about the limitations of the screening tests and the possible diagnostic and treatment choices they may face. They should also be informed that on the basis of the current evidence it is not known if screening will reduce their chances of dying from cancer.**

(Population screening for prostate cancer. A systematic review. Pages 15, 24-28)

10.1 Since 1991 there has been a rapid increase in the reported incidence of prostate cancer in New Zealand. In 1998 there were 524 deaths from prostate cancer and 2494 new cases. This is 13 percent of all male cancer deaths and 27 percent of all new male cancers registered in 1998. Although evidence does not yet support screening for prostate cancer, there is growing public concern and a considerable demand for the PSA test by men worried about the disease. The recent rapid increase in prostate cancer incidence is largely due to widespread PSA testing in New Zealand general practice.

10.2 Localised prostate cancer does not usually produce symptoms. The lower urinary tract symptoms (LUTS) of frequency, urgency, hesitancy, and terminal dribbling are usually the result of benign prostatic hyperplasia (BPH). LUTS are also the most common presenting symptoms of prostate cancer and result from involvement of the urinary tract and bladder neck by the enlarged prostate gland. This is usually at a stage when curative treatment is no longer possible. There is no evidence to suggest that men with LUTS or BPH have an increased risk of prostate cancer<sup>44</sup>. The absence of any good evidence supporting an association between LUTS or BPH and prostate cancer means that the decision, whether or not to test for prostate cancer, should be the same as the decision, whether or not to screen an asymptomatic man, with the same requirement to fully counsel the man on the implications of the test.

10.3 An increasing number of men and their whānau are sufficiently anxious about prostate cancer to seek help, principally by asking for a PSA test. At the moment some men are being offered a PSA test but in an unstructured and sometimes ill-informed way, whilst others are currently dissuaded from having a PSA test because of the policy on population screening<sup>4</sup>. Any man considering a PSA test should be given detailed information about the performance of the test, and the possible further diagnostic and treatment choices with which he may be faced. They should also be informed that on the basis of current evidence it is not known if screening will reduce their chances of dying from prostate cancer and that screening is not currently recommended by the National Health Committee.

10.4 A recent study published in the Journal of Medical Screening<sup>45</sup> shows that Australian men who received an evidence-based booklet designed to promote informed decision-making for men considering PSA screening had significantly improved decision-making and lower levels of decisional conflict, even amongst passive decision makers. The advisory group has reviewed examples of evidence-based advice published in Australia and the United Kingdom for health care practitioners, and information for men, their families and whānau. It is suggested that this material could be used to assist in drafting further information for New Zealand men.

## **11 Assessment of the current screening, diagnosis and management of prostate cancer in New Zealand is seriously handicapped by the lack of information about the frequency of PSA testing, the frequency of the different treatments for prostate cancer and the outcomes of these treatments.**

11.1 The importance of prostate cancer and the existing and potential costs to the New Zealand health care system suggest that collection of this information should be made a priority. For the same reason, any educational material about screening for prostate cancer that is made available to health care practitioners, men, their families and whānau should be fully evaluated for its effectiveness.

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# COMPOSITION OF THE ADVISORY GROUP

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