



NATIONAL ADVISORY COMMITTEE
ON HEALTH AND DISABILITY

HUNGA KAITIJIRO I TE HAUORA O TE TANGATA

A Consultation Document On Prostate Cancer Screening in New Zealand

September 2003

FOREWORD

Prostate cancer screening is an important and complex health area, and there is considerable interest in prostate cancer screening. The proven impact of prostate cancer screening on men's mortality due to prostate cancer continues to be contentious.

While there are strong differences of opinion about the potential value of Prostate Specific Antigen (PSA) testing of asymptomatic men, there is unanimous agreement that doctors and men should have up-to-date information based on the best available evidence to help them make decisions.

This consultation document presents the conclusions and evidence from an advisory groupⁱ convened by the National Advisory Committee on Health and Disability (National Health Committee, NHC) to specifically examine the issue of population-based screening for prostate cancer and testing of asymptomaticⁱⁱ men in New Zealand.

This is the second time the National Health Committee has examined the issues relating to prostate cancer screening. In 1996/97 the NHC provided advice to the Minister of Health on the use of the PSA test for screening for prostate cancer. At that time, the committee recommended against population screening. However, due to continued high public interest in prostate cancer screening and increasing use of PSA testing, the NHC decided to review its previous advice. In 2001 it convened an advisory group to provide a summary of the evidence on population-based screening for prostate cancer and testing of asymptomatic men in New Zealand, particularly that which has amassed since 1996/97.

It is the purpose of this consultation to gather opinions on the key conclusions and content of the advisory group's background report which are presented in this document.

The information received will inform the NHC's final advice to the Minister of Health on prostate cancer screening in New Zealand.



**Robert Logan
Chair**

ⁱ New Zealand Guidelines Group Prostate Cancer Advisory Group, see page 5 for composition of advisory group.

ⁱⁱ 'Asymptomatic' refers to people who have no symptoms, ie, no symptoms of prostate cancer. Symptomatic means symptoms of the disease are present. There is a blurring of these definitions with prostate cancer, as there is no difference in symptoms resulting from prostate cancer and other causes of enlargement of the prostate gland such as benign prostatic hyperplasia (BPH). Early prostate cancer itself usually will not produce symptoms and lower urinary tract symptoms (LUTS) are usually the result of BPH. BPH is very common amongst older men. See page 15 for more discussion on LUTS and BPH.

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HOW TO HAVE YOUR SAY

The National Health Committee is seeking input from organisations and individuals, including consumer groups interested in men's health. The NHC invites submissions on the content of this consultation document.

Please send your submission to:

Prostate Cancer Screening Submissions
National Health Committee
PO Box 5013
WELLINGTON

Or by email to: Bronwyn_Petrie@nhc.govt.nz

SUBMISSIONS ARE DUE BY: 17 October 2003

This discussion document is available on the NHC website www.nhc.govt.nz. Additional copies can be obtained by calling 04 496 2066.

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.”

The committee has previously undertaken work in the area of screening and provided advice to the Minister of Health on screening for prostate cancer in 1996/97 and colorectal cancer in 1998.

In 2001, the NHC contracted the New Zealand Guidelines Group (NZGG)ⁱⁱⁱ to convene an advisory group (known as the NZGG Prostate Cancer Advisory Group) to provide advice to the NHC about prostate cancer screening in New Zealand. The advisory group was asked to produce evidence-based advice 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^{iv})
- clinicians with the appropriate, accurate and balanced information for making decisions and providing advice on population-based screening for prostate cancer and testing of symptomatic men
- men and their families with appropriate, accurate, balanced information on the risks and benefits of prostate cancer testing of asymptomatic men.

This consultation document contains three pieces of analysis by the NZGG Prostate Cancer Advisory Group:

- summary of the evidence on population-based screening for prostate cancer and testing of asymptomatic men in New Zealand
- assessment of prostate cancer screening using the NHC’s screening assessment criteria
- summary of the benefits, harms and costs of prostate cancer screening.

The advice provided by the NZGG Prostate Cancer Advisory Group built on the National Health Committee’s work on prostate screening, published in 1996/97.

2. Background

In 1996/97 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

ⁱⁱⁱ For more information on the New Zealand Guidelines Group see: <http://www.nzgg.org.nz/>

^{iv} A copy of the review can be seen at:

http://www.nzgg.org.nz/development/documents/Prostate_Cancer_review.pdf

providing advice to men seeking advice on PSA testing and diagnosis and treatment of prostate cancer.

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

1. There was no evidence that screening significantly improved mortality 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 (the PIVOT trial).
4. Treatment options all carry a significant risk of adverse effects on bladder and bowel function, which may reduce overall quality of life.

In 2001, the NHC recognised the need to update and review its 1996/7 advice, as there continues to be high public interest surrounding prostate cancer screening and increasing use of PSA testing.

3. Membership of advisory group

Alistair Woodward (Chair)	National Health Committee member until September 2002, Professor of Public Health, Wellington School of Medicine and Health Sciences, University of Otago
John Childs	Consultant, Radiation Oncology, Auckland
Peter Davidson	Consultant Urological Surgeon, Christchurch
Betsy Marshall	Policy Advisor, Cancer Screening & Cancer Control, Cancer Society of New Zealand, Auckland
Jim Vause	General Practitioner, Blenheim, Representative from the Royal NZ College of General Practice
John McMenamain	General Practitioner, Representative from the Royal NZ College of General Practice
Barry Young	Chair, Prostate Awareness and Support Society, Auckland
Terry Ehau	Ngati Porou Hauora, East Coast
Ann Richardson	Epidemiologist, Christchurch School of Medicine, University of Otago
Brett Delahunt	Professor of Pathology and Molecular Medicine, Wellington School of Medicine and Health Sciences, University of Otago
EX OFFICIO	
Ashley Bloomfield	Public Health Leader, Population Health Screening, National Screening Unit, Ministry of Health
John Durham	General Practitioner/Researcher
Emma Sutich	NZGG Project Manager/Writer (until December 2002)
Catherine Marshall	CEO, NZGG
Stephanie Dixon	Administration Manager, NZGG

4. Key points and summary of evidence on population-based screening for prostate cancer and testing of asymptomatic men in New Zealand

The information presented below is from the NZGG advisory group's report to the National Health Committee.

The NHC is interested in receiving your views on the advisory group's key points and conclusions on population-based screening for prostate cancer and testing of asymptomatic men in New Zealand.

Specifically, the NHC would like your comments on opportunistic^v prostate cancer screening in New Zealand.

KEY POINTS

The NZGG Prostate Cancer 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; about three-quarters 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 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 randomised controlled trials (RCT) 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 agreed 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 were some who support offering the PSA test with full information on the risks and potential benefits of the test.

Others believed 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

^v 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. For more on opportunistic screening see the glossary.

screening he should be given full information about the lack of evidence of benefit and the 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 the individual, with his family or whānau and his doctor with full information of the benefits and harms associated with PSA testing.

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

The following report represents the conclusions of the NZGG Prostate Screening Advisory Group. It is based on a systematic review of population screening for prostate cancer¹. 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 practice² and this is the most likely explanation for the recent rapid increase in the reported incidence of prostate cancer.

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 men³.

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). However, 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 robust³.

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 test⁴.

- 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 countries¹.
 - 1.5. There was an increase in the annual mortality rate for prostate 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 disparity⁵.
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.**
 - 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,¹ 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 seven 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 years¹¹.
 - 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 rates⁶⁻¹⁰.
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.**
 - 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^{12, 13}.
 - 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^{14, 15}.

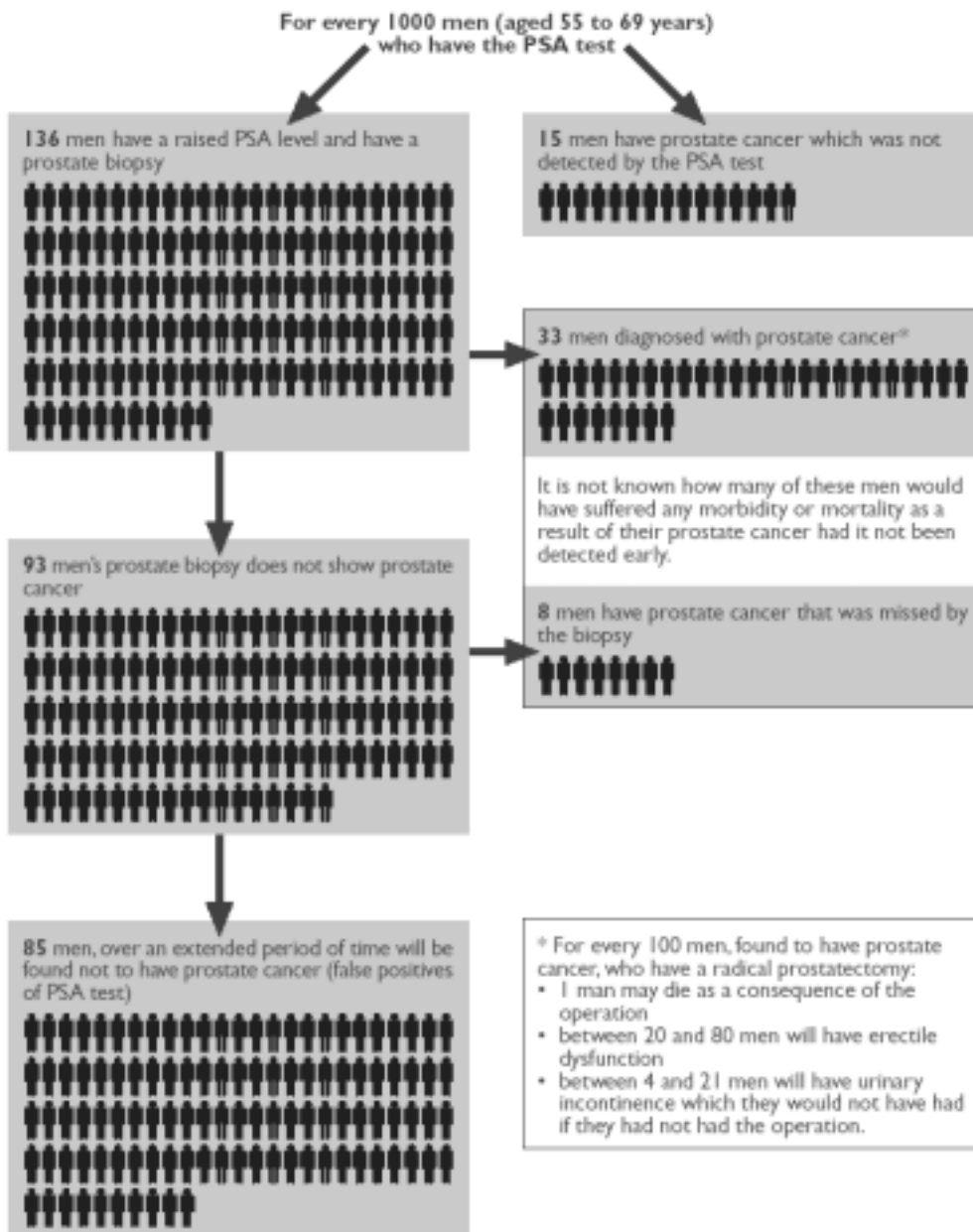
- 3.3. Current indications are that even the lowest estimates for the prevalence of disease detection at post-mortem are greater than the frequency of clinically significant localised prostate cancer, so that there is a potential for detecting many more tumours than will ever present clinically¹.
4. **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 10 years. Between 70 percent and 83 percent of screen-detected cancers are well or moderately well-differentiated tumours.**
 - 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 10 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^{12,13,16,18}.
 - 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^{1, 12, 13}.
 - 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 men¹⁹.
 - 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,¹ 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^{20, 21}.

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.
- 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^{12, 14, 15, 22}.
- 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 prostate 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^{12, 13, 23-26}.
- 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 (see diagram below) :
- 136 men would have a PSA \geq 4.0 ng/ml and would be referred for biopsy
 - 15 men with prostate cancer would have a PSA < 4.0 ng/ml and would be missed
 - 94 of the 136 men with a PSA \geq 4.0 ng/ml would not have prostate 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.

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.



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Adapted from information prepared in 2002 by the Cancer Research UK Primary Care Education Research Group, University of Oxford www.dhpc.ox.ac.uk/crcpccr

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.

5.8. Omitting the DRE and using only the PSA test but with a lower cut-point of ≥ 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 rate²⁷.

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.

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 men²⁸.

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-5 chance of having prostate cancer. If this same man then has the free-to-total PSA measured and the result is negative, this may reduce his chance of having prostate cancer to 1-in-12²⁹.

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 two percent and four percent of the screened population. It is not known what proportion of these cancers would have caused any morbidity or mortality.

7.1. In the initial screening round, in men aged 55 to 69 years, approximately 10 percent (range 7–15%) will have a PSA test of ≥ 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 two percent and four percent³⁰.

7.2. There is no good evidence about the detection rate with repeated screening, but it is likely that this will fall to about one percent or less³¹⁻³⁴.

7.3. Screening using a PSA test ≥ 4.0 ng/ml, as the cut-point for an abnormal result will miss approximately 25 percent of prostate cancers¹.

7.4. The proportion of men who 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 91–92 percent of cancers were well-differentiated or moderately well-differentiated tumours and earlier non-screening studies have found a 90 percent 10-year survival for men with these tumours³⁰.

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 never have caused any symptoms.

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 three percent³⁰.

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 results³⁷.

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). Six 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 biopsy³⁸.

- 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^{39, 40}. 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 one month of surgery of less than one 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 waiting⁴¹. 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 two 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 wellbeing.
- 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.**
- 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 screened⁴². 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 screening⁴³. Reviewers of this topic conclude that there is insufficient evidence to determine whether screening for prostate cancer will have any positive effect¹.

9.3. There are ongoing RCTs and the results of these trials may provide evidence for the benefits of prostate cancer screening in the future³⁰.

9.4 The NZGG Prostate Cancer Screening Advisory Group has reviewed the recently released *Screening to Improve Health in New Zealand: Criteria to assess screening programmes*, issued by the National Health Committee in April 2003. A brief assessment of prostate cancer testing was undertaken using this framework (and is included in this document following this review of evidence). 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 deaths³. 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.

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 2,494 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 cancer⁴⁴. 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 screening⁴. 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 he may face. He should also be informed that on the basis of current evidence it is not known if screening will reduce his 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 Screening⁴⁵ 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 professionals, 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 professionals, men, their families and whānau should be fully evaluated for its effectiveness.

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5. Assessment of prostate cancer screening using the NHC's screening assessment criteria

The NZGG Prostate Cancer Screening Advisory Group was asked to briefly assess population-based screening for prostate cancer and testing of asymptomatic men using the NHC screening assessment criteria¹. The advisory group's assessment is outlined below.

The NHC is interested in receiving your views on the advisory group's assessment of population-based screening for prostate cancer and testing of asymptomatic men using the screening assessment criteria.

1. The condition is a suitable candidate for screening

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 Māori than in non-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.

2. There is a suitable test

The prostate specific antigen (PSA) test has been suggested as a suitable screening test for prostate cancer. 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. 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 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.

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

Treatments for prostate cancer include radical prostatectomy, radiotherapy, and active monitoring. 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. There is no evidence from RCTs that any active treatment of screen-detected prostate cancer, compared with watchful waiting, results in a reduction in overall mortality. Active treatments for prostate cancer have significant side effects, which may include impotence, urinary incontinence, and diarrhoea.

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

There is no current evidence from RCTs to demonstrate that population screening for prostate cancer reduces morbidity or mortality from the disease. Neither do ecological studies of prostate cancer screening provide consistent evidence in support of screening.

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

There is no evidence that the potential benefit from prostate cancer screening would outweigh the potential physical and psychological harm. 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 harmful effects of screening, including increased anxiety levels in men with false positive results and false reassurance for men with false negative results. Also the available treatments for prostate cancer 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 never have caused any symptoms, because screening will detect some cancers that would otherwise never have been detected or caused problems in their lifetime.

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

An increase in awareness and PSA testing for prostate cancer has resulted in a large increase in the incidence of new cases. Increased PSA testing will place increased demand on diagnostic services, including an increase in prostate biopsies. An increase in incidence will be associated with increased demand for treatment services. There are already delays for patients requiring radiotherapy in some regions in New Zealand. 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 screening test, who would need to be referred for biopsy. From these men, between 4,682 and 7,581 men would be identified with prostate cancer. This issue was not otherwise addressed by the working group.

7. There is consideration of social and ethical issues

A population screening programme encourages otherwise healthy, asymptomatic individuals to undergo tests to identify a disease that they do not necessarily perceive that they are at risk from. When a well person is invited to undergo 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. Such evidence is not available for prostate cancer screening.

8. There is consideration of cost-benefit issues

The working group did not consider economic issues. Since PSA screening for prostate cancer does not meet all of the other seven criteria, and does not have proven benefit, it would be premature to consider cost-benefit issues.

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6. Summary of the benefits, harms and costs of prostate cancer screening

The NZGG Prostate Cancer Screening Advisory Group was asked to develop a comprehensive balance sheet that identifies the benefits, costs and harms of prostate cancer screening (outlined below). Please note that the content of the summary below has not yet been peer reviewed.

The National Health Committee's role is to provide the Minister of Health with independent advice on the kinds, and relative priorities, of health and disability services that should, in the committee's opinion, be publicly funded. Therefore, in order for the committee to fulfil this role in relation to prostate cancer screening, it is important to consider the costs (not just in monetary terms) associated with prostate cancer screening.

The NHC is interested in receiving your views on the advisory group's assessment of the benefits, costs and harms associated with prostate cancer screening.

Introduction

It is not possible to provide an accurate balance sheet of the benefits, harms and costs of prostate cancer screening, as the primary benefit of a reduction in mortality has not been demonstrated. There is no good evidence from randomised controlled trials that has shown that prostate cancer screening results in a reduction in mortality¹.

One systematic review of prostate cancer screening estimated that 84 percent of screen-detected cancers would not prove fatal even if untreated and the benefit of prostatectomy for screen-detected cancers was one prostate cancer death averted for every 100 operations². The possible range of outcomes in a sensitivity analysis was none to nine deaths averted per 100 operations with a 0.02 percent probability of achieving the best outcome. In the only randomised controlled trial of the treatment of early prostate cancer comparing watchful waiting with radical prostatectomy, 24 patients would have to be treated by radical prostatectomy to prevent one death from prostate cancer after eight years of follow-up³. In this study only a small proportion of men in both groups had had their prostate cancer detected by screening (5.2%), and nearly 42 percent had been detected because of symptoms, so that this result is unlikely to be representative of the results for men treated as a consequence of having their cancers detected in a population screening programme. A much longer period of follow-up is likely before there is any improvement in mortality between the two groups. The most recent report from the Rotterdam section of the ongoing European Randomised Study of Screening for Prostate Cancer (ERSPC) has estimated that a single screening test at age 55 years results in a lead-time of 12.3 years⁴.

Benefits

The potential benefits from prostate cancer screening are:

1. Prostate cancer deaths avoided because of treatment

2. Reduced morbidity from prostate cancer in men who develop the disease but may or may not die from it.

Although the identification of prostate cancer is sometimes suggested as a benefit of screening, it is only a benefit if there is an effective treatment. It is likely that an unknown, but possibly large, proportion of men who are identified with prostate cancer in a screening programme would have not died from the disease and not suffered any morbidity. For those men who would have developed symptomatic prostate cancer, the above figures suggest that only between 1-in-24 and 1-in-100 men would be prevented from dying from prostate cancer by treatment with a radical prostatectomy.

It is difficult to make any reasonable attempt to estimate the potential reduction in morbidity from prostate cancer without reliable information on the outcome of screening. The recent report from the European RCT suggested an over-detection rate of 48 percent from screening every four years in men aged 55 to 67 years. If this is correct then any likely benefits in morbidity reduction from treating the 52 percent of men who are appropriately identified with prostate cancer would seem to be outweighed by the morbidity experienced by 48 percent of men from their unnecessary treatment.

Harms

Relatively few studies provide detailed information about the risks of screening for and treatment of prostate cancer. Many of the studies that do provide this information originate from tertiary and specialist centres or refer to the development of new techniques, which are unlikely to be representative of the experience of the majority of men subjected to a population screening programme. The complication rates for radical prostatectomy using new "nerve-sparing" techniques may not necessarily be the same as the country-wide results when there is a large increase in the prostatectomy rate in response to mass screening.

Harmful effects of the screening process

There is a potential for both psychological and physiological harmful effects in relation to the screening process. Psychological effects include unnecessary increased anxiety levels in men with false positive results and false reassurance for men with false negative results. Possibly harmful physiological effects include pain, bleeding and infection in relation to the prostate biopsy for men with an initial positive screening test.

The short-term effects of screening on health-related quality of life have been reported for the ERSPC trial of screening in the Netherlands⁵. Health status and anxiety measures showed no significant changes in mean scores for physical, psychological and social functioning during the screening procedure. High levels of anxiety were present throughout the screening process in men with a high initial predisposition to anxiety.

In responses to the specific questions relating to the screening procedures, one percent of men reported pain during the blood sample taken for the PSA test, and 90 percent of men reported pain or physical discomfort with the prostate biopsy procedure. In the week following the prostate biopsy procedure, two percent had

pain for the whole week, four percent had a fever $> 38^{\circ}$ C, three percent had to visit their general practitioner. There was a moderate or greater interference with daily activities for five percent of men, social activities for six percent and sexual activities for four percent.

Another study from the same centre has reported on the complications of transrectal ultrasound-guided systematic sextant biopsies⁶. Major complications in 1,687 biopsies included pain after the procedure in 126 (7.5%), urinary retention in seven (0.4%), and fever $>38.5^{\circ}$ C in 71 (4.2%) of men. In the 71 patients who developed fever, six required hospital admission for parental antibiotic therapy and of these patients, three had positive blood cultures with one man requiring admission to the intensive care unit with sepsis and shock. All men who had a biopsy were given oral antibiotic therapy two hours before and four hours after the procedure. Two men developed allergic reactions to the antibiotic prophylaxis.

Harmful effects of treatment

Men with screen-detected prostate cancer are identified as having cancer and treated earlier than if there had been no screening. For these men, prostate cancer screening results in an increased number of life-years lived with the side effects of treatment. Hopefully, this is balanced by a decrease in prostate cancer mortality so that there is a decrease in the number of men suffering from end-stage disease and dying prematurely.

Several studies have attempted to summarise the harmful effects of treatment⁷⁻⁹. The main long-term physiological complications of treatment are reduced sexual function and urinary and bowel problems. Quality of life measures are difficult to evaluate as they frequently depend on estimates of how men rate the chance of incurring the different side effects compared with the value they place on extra years of life and the impact on their quality of life of the various side effects of treatment¹⁰.

Radical prostatectomy

For the majority of men with screen-detected, localised prostate cancer the treatment of choice is radical prostatectomy. Alternative treatment possibilities are external beam radiation therapy, brachytherapy and androgen deprivation therapy.

Immediate adverse effects

The immediate, significant adverse effects of radical prostatectomy are death and cardiopulmonary complications such as pulmonary embolus. The rate of these complications across a wide range of institutions was reported for a 20 percent national sample of male Medicare beneficiaries aged 65 years and older in 50 American states between 1984 and 1990¹¹. A total of 10,598 prostatectomies were identified for the study, with a wide range in prostatectomy rates from 60 to 130 per 100,000 men for different geographical areas. Mortality within one month of surgery was one percent or less for men aged less than 75 years but was almost two percent for men over 75 years. Between four and five percent of men less than 75 years suffered major cardiopulmonary complications but this increased to nearly eight percent for men older than 75 years.

Sexual dysfunction

There has been one published systematic review and meta-analysis of erectile functioning in¹² men after prostatectomy. This study calculated that the probability of maintaining normal erectile function after surgery was 0.42 (95% CI 0.40-0.43). Subsequent studies have reported a wide variation from approximately 20 percent to 70 percent in the proportion of men who may suffer from impaired sexual function after radical prostatectomy.

One of the difficulties in measuring the incidence of these complications from prostatectomy is that symptoms of erectile dysfunction and urinary incontinence occur in a proportion of men who have prostate cancer and are untreated as well as in men without prostate cancer. A recent study of the quality of life after radical prostatectomy compared men in a randomised controlled trial of radical prostatectomy and watchful waiting¹³. 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.

Urinary incontinence

In the same study comparing the effects of radical prostatectomy with watchful waiting 49 percent of men had symptoms of urinary leakage compared with 21 percent of men who had not had surgery. In the radical prostatectomy group 18 percent of men reported a moderate or severe degree of urinary leakage compared with two 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.

Summary of the harmful effects of treatment

The most recent US Preventive Task Force Report¹⁴ provided the following summary of harms at least one year after treatment:

Treatment	Reduced Sexual Function	Urinary Problems	Bowel Problems
Radical Prostatectomy	20%–70%	15%–50%	
External Beam Radiation Therapy	20%–45%	2%–16%	6%–25%
Brachytherapy	36%	6%–12%	18%

Costs

The following are approximate figures based on current New Zealand laboratory and hospital costs.

Screening

PSA test

The most recently available figures show that there were 234,817 PSA tests for a total cost of \$2,578,247, giving an approximate unit cost of \$11 per test.

It is not known what proportion of the total number of PSA tests in one year have been performed for the purpose of screening. The PSA test is also used in diagnosis of men with symptoms and in monitoring the results of treatment.

In 1998 there were 2,494 new prostate cancer registrations. It is not known how many of these cancers were diagnosed as a result of screening but the great majority (83.4%) of these new registrations were based on a histological diagnosis. Assuming that these histological diagnoses were all from prostate biopsies of patients with positive PSA results and were, therefore, detected as a result of screening, then there were 2,078 (83.4% of 2494) screen-detected cancers in 1998. In fact, the true figure is likely to be lower than this as some of the histologically diagnosed cancers will be in men with symptoms.

If the PSA test has a sensitivity of 74 percent and specificity of 90 percent, the initial prostate biopsy has a false negative rate of 20 percent (ie, misses 1-in-5 cancers) and the prevalence of potentially clinically significant prostate cancer is 5.6 percent, then 33 cancers will be identified for every 1000 PSA tests. Therefore, to identify 2,078 prostate cancers would have required a minimum of 62,970 PSA tests at a cost of \$692,667.

Prostate biopsy

The average price for a hospital-based prostate biopsy is \$1,188 with an average length of hospital stay of 0.9 days.

If all of the 2,078 new registrations of prostate cancer in 1998 based on histological diagnosis, resulted from prostate biopsies and if the approximate yield of prostate cancer is one in every four prostate biopsies then there were 8,312 prostate biopsies at a total cost of \$9,874,656.

Treatment

Radical prostatectomy

In the 2001/02 year there were 1,909 prostatectomies performed at an average hospital cost of \$3,447 with an average hospital stay of 3.6 days. It is not known how many of these prostatectomies were for screen-detected prostate cancer.

In 1998 38 percent of the new registrations for prostate cancer were in men aged 75 years or older. It seems unlikely that a large proportion of these men would have been treated by radical prostatectomy.

It could be assumed that there were approximately 1,283 screen-detected (histological diagnosis) new prostate cancers in men less than 75 years in 1998, and that the majority of these men would have been treated with a radical prostatectomy. If there were 1,283 radical prostatectomies for screen detected prostate cancer in 1998 then the total cost for these operations would have been approximately \$4,422,501.

Overall costs of screening

Based on the above assumptions, then some of the costs for screening for prostate cancer in 1998 were:

PSA tests	\$692,667
Prostate biopsy	\$9,874,656
Radical prostatectomy	\$4,422,501
Total	\$14,989,824

There are many other costs involved in screening for prostate cancer which have not been considered in these approximate calculations.

These costs include the:

1. Direct and indirect costs to individual men involved in screening, such as time lost from work
2. Costs of general practice and specialist consultations involved in PSA testing and advice about the results of PSA tests, prostate biopsies and appropriate treatment
3. Costs of other methods of treatment
4. Costs of the harmful effects of screening and treatment

5. Opportunity costs of this programme of screening and treatment.

The cost of an organised population-screening programme for prostate cancer in New Zealand

The following figures used are based on the New Zealand population in 1998 and assume that the target population for screening is men aged 55 to 69 years. The estimated resident population of New Zealand men aged 50 to 69 years, as at Mean Year Ended 31 December 1998 was 222,990. Only a single screening test is considered. The yield of prostate cancer from repeated screening in an organised programme is likely to fall to less than one percent of the population screened.

In 1998, there were 969 new cases of prostate cancer registered for men aged 55 to 69 years. For men in the same age group there were 91 deaths from prostate cancer and a total of 300 deaths from prostate cancer for men aged 50 to 79 years.

Prevalence of prostate cancer

The best estimates of the prevalence of clinically significant localised prostate cancer was 4.4 percent for men aged 50 to 59 years and 6.4 percent for men aged 60 to 69 years. In New Zealand in 1998 there 87,730 men aged 55 to 59 years and 135,260 men aged 60 to 69 years.

Using these figures the prevalence of localised prostate cancer in New Zealand men aged 55 to 69 years in 1998 would be 5.6 percent or a total of 12,517 men with potentially clinically significant, localised prostate cancer that might be detected on screening.

PSA screening

Using a PSA of ≥ 4.0 ng/ml as the cut-point for an abnormal screening test the Netherlands and Finnish centres of the European RCT have reported detection rates at first screen of 2.1 percent and 3.4 percent. The age-standardised prostate cancer mortality rates in 2000 reported by WHO for the Netherlands (20.0), Finland (19.1) and New Zealand (21.2) are similar, suggesting approximately similar incidence rates for the three countries.

Using these figures, if all men aged 55 to 69 years in New Zealand in 1998 had been screened using the PSA test alone then between 18,954 and 26,758 men would have had a positive PSA screening test and would have been referred for biopsy. From these men, between 4,682 and 7,581 men would have been identified with prostate cancer.

The Finnish protocol for selection of men for screening, randomised men before consent and had a 69 percent attendance rate. This process more closely resembles a true population screening programme. Using these figures and the Finnish prostate cancer detection rate, and applying the same PSA screening test to the New Zealand population in 1998 would have resulted in 153,863 men being screened, 13,078 positive PSA tests and prostate biopsies, and 3,231 prostate cancers identified.

Possible costs include:

153,863 PSA tests	\$1,692,493
13,078 prostate biopsies	\$15,536,664
3,231 prostatectomies	\$11,137,257
Total	\$28,366,414

Over-detection rate

Using the most conservative figures derived from the Finnish arm of the European RCT suggests that an initial screen of the 55 to 69 year male population in New Zealand in 1998 would have identified 3,231 men with prostate cancer. It is not possible to determine how many of these men would have developed symptoms from their prostate cancer. The most recent report from the European RCT⁴ has suggested an over-detection rate of between 27 percent and 50 percent, which would mean that 872 and 1,615 men would be unnecessarily diagnosed as having prostate cancer. The mortality rate from prostate cancer has remained relatively constant in recent years and in 1998 there were 300 deaths from prostate cancer in men aged 50 to 79 years. This would also suggest that a considerable proportion of the men identified by screening would never have been aware of their cancer.

If all of the 3,231 men were treated by radical prostatectomy and the results of the randomised controlled trial of prostatectomy compared with watchful waiting³ are applied to this population, then approximately 135 men would have been prevented from dying from prostate cancer after eight years of follow-up. It is unlikely that the treatment of screen-detected prostate cancer will be this effective and this ignores the potential lead-time of at least 10 years. The potential mortality from the operation is approximately 0.5 percent so that 16 men might have died from the operation and all of the remaining 3,215 men would have been exposed to the possible harmful effects of the operation.

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7. Glossary

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.

Free to total PSA - The majority of the PSA in the blood is bound to antichymotrypsin and there is also a small amount of unbound or "free" PSA. In men with prostate cancer the proportion of "free" PSA in relation to the total concentration of PSA is lower than in other causes of an abnormally raised PSA level. Therefore, in men with abnormally high PSA levels estimation of the free PSA may help to identify those men with prostate cancer and reduce the number of unnecessary biopsies in men who have BPH rather than cancer.

Histological Evidence - Histological evidence pertains to histology – that department of anatomy which deals with the minute structure, composition, and function of the tissues.

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

Metastasis - The process by which malignant disease spreads to distant parts of the body, and also to the secondary tumours resulting from this process.

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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