



NATIONAL ADVISORY COMMITTEE
ON HEALTH AND DISABILITY
HEALTH SERVICES OF THE ECONOMY OF THE GOVERNMENT

Incorporating the Public Health Advisory Committee
Te Rōpū Tokutoha i Te Hauora Tūmatanui

January 2004

Summary of submissions in response to National Health Committee consultation paper on prostate cancer screening in New Zealand

Introduction

This summary summarises the results of the National Health Committee's (NHC) consultation with organisations and individuals, including consumer groups interested in prostate cancer screening. The consultation process was based on a consultation paper on prostate cancer in New Zealand distributed in September 2003. The consultation document invited submissions from the various stakeholders in the health and disability sectors.

The structure of this summary follows the headings in the consultation paper.

A total of 25 written submissions were received.

General comments on the consultation document

Some respondents expressed negative views about the consultation document suggesting that:

- it presented an unbalanced view of the disease
- it overemphasised the negative effects of screening
- the references were less than exhaustive and very selective
- the data quoted was predominantly from historical and overseas populations and did not reflect clinical practice today.

Others suggested that the consultation document presented a good overview of the literature with logical conclusions and with the benefits and harms of screening for prostate cancer clearly presented.

Views about prostate cancer screening

The majority of respondents felt that because of the lack of proven benefit and the potential for harm, screening for prostate cancer should not be supported and that currently there is no good justification for instituting a population-based screening programme in New Zealand or for testing asymptomatic men opportunistically, using the prostate specific antigen (PSA) test or digital rectal examination (DRE). A few respondents stated strongly that it is unethical to invite a man to have a PSA test to screen for prostate cancer because there is no conclusive evidence that having such a screening test would benefit him.

In the absence of conclusive evidence of benefit for a population-screening programme, some people felt that it would be unethical to carry out opportunistic screening for prostate cancer, as there is:

- less quality assurance and monitoring
- greater potential for harm
- no provision for follow-up diagnostic and treatment services
- limited transparency in decision-making processes when offering the screening test
- limited comprehensive data collection, storage, retention and access framework
- increased risk of increasing health inequalities.

It was felt by a number of respondents that 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. One respondent suggested that if, having received full information about PSA screening, a man still wishes to have a PSA test, he should pay for the test himself.

A few respondents suggested that because PSA testing is of uncertain benefit it should not be publicly funded given that health resources are scarce. A few suggested that PSA testing should be available to specialist practitioners only, or to primary care practitioners who can show that the PSA test is being used for a purpose other than screening.

It was felt by some that if PSA screening for prostate cancer turns out to have no benefit, then inviting men to have a PSA test, either as part of an organised screening programme or opportunistically, could result in harm to hundreds of men. It was felt that it is not good enough to offer PSA screening in the hope that it will be found to be beneficial and men should not be subjected to the inconvenience and potential hazards of screening unless there is conclusive evidence that they could benefit.

A couple of people felt that patients who are healthy enough to benefit from a possible cure from prostate cancer (ie, those with a life expectancy of more than 10–15 years) and who are old enough to have a reasonable chance of having prostate cancer (ie, older than 50 years without a family history) should be informed about the PSA test and DRE and be given a chance to make up their own minds about whether they wish to be screened.

Prostate cancer screening is a complex and personal issue. One respondent who had just been diagnosed with cancer, commented on the biopsy: “yes, it hurt, yes I am worried, yes it is my decision”, but found the pain and uncertainty associated with the biopsy “acceptable and reasonable”.

A minority of respondents felt that PSA testing has already advantaged many men in New Zealand and should continue but in an “informed way”. It was also felt that to deny patients the right to make up their own mind after being informed of the potential benefits and risks of prostate cancer screening is “overly paternalistic”.

Two people felt that it would be unethical to not offer opportunistic screening as it is “possible that early detection reduces the mortality from prostate cancer” and that a consequence of not carrying out PSA testing is that men with aggressive lesions will not be diagnosed while cure is possible.

Specific comments on the consultation document

Section 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.

It was recognised that prostate cancer is an important health issue which is reflected by the significant resources that are invested in providing screening and treatment.

It was felt by some respondents that nearly all New Zealand general practitioners test for prostate cancer (using a PSA test) with or without DRE and that this has become the "standard of care" in New Zealand.

Section 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.

Submissions said that regional studies do not reflect national use of the PSA test because of the regional variations in PSA test prevalence.

Some respondents agreed that ecological studies of prostate cancer mortality do not provide appropriate evidence for the effectiveness or efficacy of prostate cancer screening and that the observed decreases in prostate cancer mortality in New Zealand are not due to prostate cancer screening. However, it was suggested that it is impossible to truly judge what has led to improved survival as there are so many factors involved and it is simplistic to isolate one factor and conclude that it has or has not contributed.

Section 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.

Some respondents felt that overdiagnosis is likely to be a major problem in prostate cancer screening. Some of the men who suffer the side effects from treatment

would never have known they had prostate cancer in the absence of screening, so they may have been directly harmed as a consequence of being screened.

One respondent disagreed that screening for prostate cancer is likely to detect many prostate cancers that would never have caused any morbidity or mortality.

Section 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.

A few respondents disagreed with focussing on overall survival and stated that it is also important to look at the morbidity of advanced prostate cancer. It was felt that of much greater relevance than natural life expectancy of 10 years would be 15, 20 or even 25-year data where the difference in disease specific survival becomes marked.

One respondent suggested that there are many studies of survival and other parameters for PSA-detected cancers in treated series and to assume that improved survival will be due to lead-time and not curative treatment is not supportable.

One respondent felt that the prognostic effects of tumour size, and extravascular and perineural spread needs to be mentioned.

Section 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.

Some respondents agreed that the true values of sensitivity for PSA are likely to be at the lower end of these ranges and due to the considerable detection of clinically irrelevant disease by PSA testing. However, two respondents felt that the figures quoted for DRE and PSA screening may be “worst case” compared to standard clinical practice and that specificity has improved significantly in the way it is currently being used. It was suggested that the performances of PSA and DRE as screening tests need to be discussed in combination as this is the way they are currently used.

One respondent felt that the quoted mortality from radical prostatectomy is incorrect and that most contemporary series show mortality from this procedure of between 0.1 and 0.5 percent (in an appropriately aged population, ie, under 75 years), not 1 in 100 as quoted.

One person suggested that the figures for sensitivity and specificity of DRE testing appear much higher than usually clinically achievable and sensitivities of 25–30 percent, and specificities of 40–50 percent would be more generally accepted.

It was suggested by one respondent that that clinicians working in this area are aware of the limitations of PSA testing, and endeavour to improve its performance for their patients by treating other causes of elevation, eg, infection, where suspected, or by simply repeating the test and waiting for a trend before investigation.

One respondent felt that the screening efficiency of PSA against other accepted screening tests for example mammography or cervical smears should be considered.

Section 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.

There were no specific comments on section six.

Section 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.

One respondent suggested that while there is a clear discrepancy between the post-mortem prevalence of prostate cancer and that of clinically significant prostate cancer, there may not be as obvious a difference between the prevalence of PSA-detected prostate cancer and clinically significant prostate cancer.

It was also stated that the current life expectancy of a 75-year-old male in New Zealand is just under 15 years and in the group most likely to benefit from early detection (under 65), life expectancy is over 20 years. Not only is the benefit in years saved greater in younger patients but the surgery related risks are also lower.

Section 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.

It was felt that the harmful effects of prostate biopsy do not reflect current practice and that most modern series have lower rates of sepsis and with modern peri-prostatic local anaesthesia the procedure is much less uncomfortable than previously. It was felt by one respondent that the section on pain, bleeding and side effects of biopsy and treatment was 'overplayed'.

One submission suggested that impotence following radical prostatectomy remains a major problem and so, to a lesser extent, does incontinence but that techniques and results have continued to improve.

One submission highlighted the Steineck study quoted in section 8.8 which showed that men who had had prostatectomy had more problems with impotence and incontinence and also found that there was no difference in quality of life and psychological and physical well-being between the watchful waiting and radical prostatectomy groups and suggested that anti-screening advocates overplay the harms of screening (psychological trauma and effects on the patient's quality of life).

One respondent felt that there are no risks with having a PSA test and in reality the anxiety associated with PSA screening is nothing compared to the anguish and anger men have when they find they have untreatable cancer when early detection might have saved their lives or at least given them the option of treatment.

Section 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.

A few respondents agreed that there was mixed evidence but suggested it is possible that early detection of prostate cancer can help in reducing overall mortality. Studies were highlighted that demonstrate that population screening has an effect on mortality and morbidity, although these studies have been heavily criticised for their design and result analysis (recruitment rate of only 23.1% of the men invited to join the screening programme; considerable crossover between the two groups and analysis on a treated, rather than an intent-to-treat basis).

It was suggested that the NHC should address policy and other changes that could be implemented to improve the ethical use of PSA tests in medicine and to clearly describe some analysis of how PSA screening could be reduced. In addition, it was suggested that there is a need for a discussion about the beneficial effects on the health of men that making the PSA test a specialist-only request may have (unless a man has had a previous diagnosis of prostate cancer or prostatitis).

One respondent stressed that there is no evidence that screening for prostate cancer is effective and therefore there is an ethical duty to make policy that will severely discourage the practice as there is clearly physical harm from the practice.

Section 10

Prostate cancer accounts for 3.8 percent of all male deaths. 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.

It was stated that this section emphasises that the risk of prostate cancer is no greater in men with LUTS (lower urinary tract symptoms) and suggests that the same decision making process of whether or not to look for prostate cancer in these men should be undertaken.

It was felt that it must be made clear to men and the public in general that symptoms of LUTS do not increase their risk of prostate cancer. There should also be a clear definition LUTS.

Informed consent and information

A study by Arrol et al concluded that men in New Zealand are being offered PSA testing without being fully informed and this is important as the provision of adequate information about the PSA test can change men's views.ⁱ The survey of current prostate cancer screening practice revealed a major difference between what GPs are currently doing in terms of screening for prostate cancer, and what they believe that they should be doing. Thus, a concerted effort will be needed to close the gap between current and 'optimal' practice, and this will require a range of initiatives.

One respondent felt that men should be informed that there is uncertainty over the benefits of radical treatment and that the side-effects of prostate cancer screening and treatment should be emphasised to men to help their decision-making. One submission stressed that if PSA testing is to be offered it is important that men understand fully the implications of their choice.

One respondent suggested a major problem with offering or inviting men to have a PSA test is that men are likely to assume that the PSA test is beneficial because men assume that their doctors would not offer them unproven and possibly harmful tests.

One submission acknowledged that there is evidence of benefit, but it is of low level and conflicting and that patients should be made aware that the results of randomised studies comparing screened and non-screened populations are not yet available. It has been noted in a number of different situations that increased

ⁱ Arrol B, Pandit S, Buetow S. 2003. Prostate cancer screening: knowledge, experiences and attitudes of men aged 40-79 years. *NZMJ* 116; 1176.

detection of prostate cancer is followed by a reduction in age-adjusted mortality. Men must be informed of the uncertainty over this data.

Another respondent felt that providing men with all the necessary information was a weak response that will have minimal effectiveness long term. It is stated that the medical profession needs to actively support discouragement of PSA screening and this requires leadership from the medical profession. It is suggested that education particularly of men is essential for the reduction of the disease and a well devised, planned and audited educational programme is necessary.

One submission made the comment that no matter what the outcome of PSA testing, both the man and his doctor will be positively reinforced and quoted that, as “a physician is positively reinforced for recommending screening, regardless of the test result, because a negative result makes the patient grateful for reassurance and a positive result makes a patient grateful for early detection. A patient who is impotent and incontinent after a decision for curative treatment may attribute his survival to surgery and be grateful for have his cancer cured”.ⁱⁱ

A number of submissions stressed the need for timely and up-to-date information for health professionals and the public so that informed decisions can be made.

Section 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.

The majority of submissions stressed that advice on the benefits and harms of prostate cancer screening tests should be reviewed as new evidence emerges.

It was stated that there is a need for better information into about Māori mortality rates and further research is needed to examine the impacts of prostate cancer screening for Māori men.

Comments on definitions

One respondent stated that the term “screening” is not appropriate in this context, rather what is been described in the questionnaire case vignettes is early diagnosis after informed consent in a consultation setting, and actively sanctioned by virtually all relevant peer groups.

Some respondents stressed that some words and phrases used in the consultation document have the potential to lead to confusion or misinterpretation and need to be clarified these include: ‘opportunistic screening’, ‘population-based screening’ and ‘evidence’.

One respondent felt that the public should be aware that population-based screening is different to case-finding in individual patients.

ⁱⁱ Ransohoff DF, Collins MM, Fowler FJ. 2002. Why is prostate screening so common when the evidence is so uncertain? A system without negative feedback. *AMJ*; 113: 663-7.

Comments about the criteria

A number of submissions agreed that there is not sufficient evidence to support the development of an organised, publicly funded, prostate cancer screening programme at this time because of the lack of evidence of benefit and potential for harm.

It is stated in the consultation document that there is no evidence that active treatment of screen detected prostate cancer, compared with watchful waiting, results in reductions in overall mortality. One respondent suggested that this is at odds with the paper in the Lancet in 1997, which is quoted in the consultation document, which compared the survival of 60,000 patients treated by radical prostatectomy, radiotherapy, or watchful waiting. This study showed a comparative benefit of increased survival in certain groups of patients. The study shown that those with Gleason score of 2–4 were unlikely to benefit; those with Gleason scores of 5–7 were most likely to benefit from radical treatment, with a bias in favour of radical surgery (this group being the target). There was a less marked benefit in patients with a score greater or equal to 8, an enhanced but marginal benefit of surgery remained high in this group however.

One submission suggested that radical prostatectomy clearly has an impact on the development of prostatic metastases and death from prostate cancer. It is suggested that patients who would or would not benefit from treatment can be identified from a Gleason score and PSA.

It was felt by one respondent that ethical (and social) issues have been presented for population screening but not for opportunistic screening and this needs to be addressed, for example the legal issues around a public health system that funds a test for which there is (as yet) no proven evidence of benefit and with a potential for harm.

One respondent questioned whether cervical and breast cancer programmes also meet the screening assessment criteria.

Benefits, costs and harms associated with prostate cancer screening

A number of respondents suggested that the PSA tests to screen for prostate cancer should no longer publicly funded.

One submission stressed the potential benefits that freeing up \$30 million in health care would have for men, women and children in New Zealand and that this should be discussed in more detail. It was stated that \$30 million a year in health expenditure on PSA testing cannot be justified. One respondent felt that the considerable resources saved from not publicly funding PSA screening could be directed to evidence-based health interventions to improve the health of all New Zealanders.

One respondent felt that there was limited analysis of resourcing issues and that this needed further development. It was suggested that information regarding the demand for resources (under assessment of screening criteria) and the costs needed to be incorporated into the findings and recommendations. It was felt that it was vital to consider the cost-benefit issues.

One submission supported the analysis on the benefits, costs and harms associated with prostate cancer screening.

Two submissions stated that the costings of prostate cancer screening were poorly constructed, inaccurate and were based on a number of assumptions, many of which they felt were incorrect. They gave the following views:

- the dollar figure applied to a prostate biopsy is \$1,188 with an average length of hospital stay of 0.9 days, grossly overestimates the cost of a biopsy process
- the assumption that one in four biopsies would be positive is misleading
- the number of prostatectomies performed in the 2001 and 2002 was over estimated
- an assumption is made that the majority of patients with a localised cancer would be treated with a radical prostatectomy, whereas the true figure is probably considerably less
- many of the cancers detected will not be amenable to local treatment.

It was suggested in one submission that any attempt to work out a meaningful cost benefit for prostate cancer screening must include the cost of looking after preventable advanced disease and also the various direct and indirect costs for individual men involved such as time lost from work not only in diagnosis and treatment of cancer, but also in the terminal stages of the malignancy.

One respondent stated that PSA testing would increase the cancer service workload by more than a third and the radiotherapy workload even more. This respondent stated that the workforce is currently severely stretched and could not cope, and is probably currently not coping, with the demands forced upon it by ineffective public policy on prostate cancer screening.

Summary

From the number of submissions received on this issue, it is clear that there is high interest in the area. It is also clear that there is a range of views on the consultation document on prostate cancer screening produced by the National Health Committee. This reflects the diversity of opinions and perspectives about prostate cancer screening more generally.

This summary of submissions will help to inform the NHC's advice on the issue.