Diagnosis and Management of Prostate Cancer in New Zealand Men

Recommendations from the Prostate Cancer Taskforce

Citation: Prostate Cancer Taskforce. 2012. *Diagnosis and Management of Prostate Cancer in New Zealand Men: Recommendations from the Prostate Cancer Taskforce*. Wellington: Ministry of Health.

Published in May 2013 by the
Ministry of Health
PO Box 5013, Wellington 6145, New Zealand

ISBN 978-0-478-40264-3 (online)
HP 5647

This document is available at www.health.govt.nz

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Executive summary

Prostate cancer is a significant burden to men's health. It is now one of the most important problems facing New Zealand men.

Prostate cancer has a slow rate of growth and most tumours remain organ confined for longer than other malignancies. Because of these features, clinicians have been working to find a reliable way of detecting it early so that potentially life-saving treatments can be implemented promptly. To date, prostate specific antigen (PSA) testing has provided a relatively simple means of population screening for prostate cancer. Unfortunately, however, PSA does not diagnose prostate cancer with certainty and not all men with prostate cancer will have high PSA levels. In addition, where prostate cancer is detected early, clinically indolent cancers may be overdiagnosed resulting in overtreatment, although this consequence is reducing as active surveillance is increasingly being adopted as a first-line management strategy.

These conundrums have led to the current disagreement among clinicians and public health workers regarding which patients should be offered screening for prostate cancer. Furthermore, there is now a great deal of confusion among men, their families and whānau and their general practitioners as to the value of PSA testing and the benefit or otherwise of treating newly diagnosed prostate cancer.

In light of the issues surrounding screening for prostate cancer and the benefits or otherwise of early diagnosis, the Health Committee conducted an inquiry into the early detection and management of prostate cancer in New Zealand. The Health Committee considered that before organised national screening could be advocated in New Zealand, there would have to be clear evidence that the benefits of screening outweigh the harms. Currently this has not been established.

While not recommending a national prostate screening programme on current evidence, the Health Committee did recommend establishing an equity-focused Quality Improvement Programme. This programme would ensure that men receive evidence-based information about prostate cancer testing and treatment, which they could use to make informed decisions, and that they have timely access to high-quality care along the entire treatment pathway.

It was therefore determined that the Ministry of Health would develop a framework for the Quality Improvement Programme, as recommended by the Health Committee, within existing resources.

The Prostate Cancer Taskforce (the Taskforce) has developed the clinical content and key recommendations to inform the Quality Improvement Programme. The Ministry of Health will produce a costed Quality Improvement Programme based on the Taskforce's information and recommendations.

After considering all components of the clinical pathway, the Taskforce has developed its list of recommendations. At the start of the pathway it recommends providing men and their families and whānau with information about the prostate, prostate cancer and symptoms through the public domain. This information must be relevant, unambiguous and culturally appropriate. Next the Taskforce emphasises the central role of the general practitioner in screening and assessing men for prostate cancer. General practitioners and their practices must support men who are entering a prostate cancer pathway of care after the initial diagnosis and through subsequent treatment. Their role may include monitoring men under watchful waiting or active surveillance and the management of metastatic disease and palliative care.

The Taskforce has reviewed indications for referral for specialist management. Specialist management includes further clinical assessment, which may lead to men undergoing prostate biopsy and relies on accurate prostate cancer grading by the pathologist. Treatment options include active surveillance and curative treatment using surgery or radiation therapy. Other considerations that the Taskforce has addressed are palliative care and access to health services.

Recommendations

The Taskforce presents the following recommendations.

1. A National Prostate Cancer Working Group is established to oversee the implementation of the recommendations made by the Prostate Cancer Taskforce. This must include a high level of Māori health expertise.

Equity

2. The National Prostate Cancer Working Group works with key stakeholders to develop and implement strategies to support Māori health professional workforce development along the prostate cancer care pathway.

3. The National Prostate Cancer Working Group oversees the development and implementation of an equity-focused Quality Improvement Plan for the prostate cancer care pathway for men and their families and whānau. This should include:
   - development and implementation of a change management programme to raise awareness among health providers of the need to focus on and achieve equity along the prostate cancer care pathway
   - working collaboratively with prostate cancer researchers to promote an equity focus, enhance outcomes, promote dissemination of information and support ongoing research, such as research on the impact of prostate cancer on the socioeconomic position of men and their families and whānau, and ways to mitigate those impacts)

4. The National Prostate Cancer Working Group develops and promotes the use of measures to prevent or lessen the social and economic impact of prostate cancer on men and their families and whānau. This should include measures based on areas of impact along the prostate cancer care pathway, as identified through research.

5. A quality monitoring framework is developed to promote and monitor change toward equity-focused quality improvement. This should include:
   - indicators based on areas of inequity along the pathway identified through appropriate research
   - a minimum national data set
   - professional and organisational standards
   - data collection and management frameworks.

   Indicators should be reported by ethnicity so that inequities can be identified and addressed, and progress toward achieving equity can be monitored and reported.

Independent Māori monitoring and reporting should be established following methods similar to those used for BreastScreen Aotearoa.

Public domain

6. Through public information, men and their families and whānau are provided with concise material that will allow them to develop a basic level of knowledge about the prostate gland and prostate cancer. This material should include a description of:
   - the prostate gland, including where it is and what it does
   - cancer in general and how it develops and spreads
   - the natural history of prostate cancer, including its ability to progress over time and spread to other organs. Prostate cancers may be fast or slow growing. Slow-growing prostate cancers are common and may not cause symptoms or shorten life. Others may develop into a serious cancer, growing within the prostate gland and later spreading to surrounding areas or to elsewhere in the body.
7. Through public information, men and their families and whānau are advised that there is no proven prevention for prostate cancer. There is some evidence that lowered intake of animal fat may be of small benefit.
8. Through public information, men and their families and whānau are advised that men with a first-degree relative with prostate cancer are at much greater risk of developing prostate cancer themselves.
9. Through public information, men and their families and whānau are advised that Māori men have a lower chance of surviving prostate cancer than non-Māori men and that the Ministry of Health is working with health professionals and Māori leaders to improve the quality of the prostate cancer care pathway in order to address this inequity.
10. The Cancer Registry provides sufficient detail on prostate cancer incidence and survival to allow research on the differences between Māori, non-Māori and Pacific men.
11. Through public information, men and their families and whānau are advised that men with urinary symptoms should request assessment by their general practitioner. This assessment is likely to include a PSA blood test and digital rectal examination (DRE). The general practitioner may suggest referral to a specialist depending on the severity of the symptoms or if there is a suspicion that there may be underlying prostate cancer.
12. Through public information, men and their families and whānau are advised of the procedure of prostate biopsy and its associated risks. Men also need to be advised that a negative biopsy does not rule out the presence of underlying prostate cancer and that, if the biopsy is negative, ongoing observation will probably be recommended.
13. Through public information, men and their families and whānau are advised of the consequences of prostate biopsy with respect to the likely requirement of staging investigations. They should also be presented with a general guide to the currently available treatment options. This should include a commentary on the place of 'non-mainstream' curative treatments and the current developments with chemotherapy and immune therapies. The guide should also consider the potential benefits and harms of treatment.

14. Information needs to be available at a level of understanding relevant to the patient and should take into account different patient perspectives, such as age, co-morbidity and family history.
    - Information should be in a variety of formats, such as written text, diagrams, video and internet, and take account of issues such as sight or hearing problems.
    - Information should reflect best evidence.
    - Information should be culturally appropriate.
    - Information resources must be developed in consultation with Māori.
    - Information should be available in the languages of major ethnic groups within New Zealand (Māori, Chinese languages, Pacific languages).

Prostate cancer in primary care

15. Primary health care should provide high-quality, culturally appropriate information on prostate cancer and PSA testing to men aged 50 to 70 years. All men who are concerned about prostate cancer or are requesting a PSA test must be presented with high-quality, culturally appropriate information.

16. Systems must be introduced to general practices to facilitate the informed consent process.

17. Screening for prostate cancer must be by both PSA and DRE testing. PSA testing alone is acceptable only where DRE is considered a barrier to testing.

18. All men presenting with lower urinary tract symptoms, and men with systemic features of malignancy, must have an appropriate examination and assessment, which includes checking for prostate cancer. This check will include a serum PSA and creatinine, other appropriate blood tests, urinalysis and a clinical examination, including digital rectal examination.

19. In the presence of a normal DRE, PSA values of <4.0 ng/mL do not generally merit specialist referral. A significant PSA rise in a man whose PSA has previously been low may warrant referral.

20. General practitioners should refer patients to a urologist according to the following criteria:
    - men aged 50–70 years – when the PSA is elevated to ≥4.0 ng/mL
    - men aged 71–75 years – when the PSA is elevated to ≥10.0 ng/mL
    - men aged ≥76 years – when the PSA is elevated to ≥20 ng/mL
    - men with a palpable abnormality in the prostate on DRE
    - a significant PSA rise in a man whose PSA has previously been low may warrant referral.

21. The primary health organisation or clinical network in which the patients are enrolled must support general practices in meeting some of the requirements of a Quality Improvement Programme. The Ministry of Health must lead a national process to define a prostate care pathway with provision of appropriate resources.

22. A national telephone information service should be available. This would be staffed by experienced, educationally prepared prostate cancer nurses. The nurses would have access to good-quality, written patient information to mail out to callers in response to enquiries and to support phone discussions. The nurses would work under strict guidelines and would not offer direct treatment decision advice.

Diagnostic guidelines

23. The PSA modifications should be restricted in their use to those men in whom the decision on whether or not to biopsy is difficult, based on the grounds of either age or co-morbidity.

24. Men meeting the following criteria should be considered for prostate biopsy after taking into account clinical considerations, elimination of benign causes of high PSA, age, co-morbidity and patient choice:
    - suspicion of malignancy on digital rectal examination
    - men up to the age of 70 years with a PSA ≥4 ng/mL
    - men between 71–75 years with a PSA ≥10 ng/mL
    - men aged ≥76 years with a PSA ≥20 ng/mL
    - a significant PSA rise in a man with previously low PSA values.

Pathology reporting of prostate cancer biopsies

25. Cores of tissue from each biopsy site are submitted in a separate specimen container and a record is made of the location from which the biopsy is taken.

26. Findings are in a structured (synoptic) format according to each biopsy site, with the minimum data set being the presence or absence of tumour, the tumour type, extent of involvement of the core by tumour, the presence or absence of extraprostatic extension and the grade of the tumour.

27. A web-based tutorial programme is made available for routine use by pathologists.

28. In order to improve consistency and reduce interobserver variation, an expert panel of pathologists should be convened in order to provide regular review of a proportion of tumours reported over a defined timeframe by all pathologists involved in the diagnostic reporting of prostate cancer specimens.

Active surveillance

29. The most suitable patients for active surveillance are those with low volume T1a or T1c, Gleason score =6 and PSA ≤10. T1b and T2a tumours may be considered for active surveillance with caution. Careful monitoring of men in an active surveillance programme is essential.
    - All men diagnosed with localised prostate cancer and considering active surveillance should be offered the chance to discuss their options with both a urologist and a radiation oncologist, and most should consult with both specialists.

- Monitoring during active surveillance must be meticulous and include regular PSA monitoring, DRE and an early repeat biopsy within 12 months of initial biopsy and further repeat biopsies as clinically indicated.
- All patients diagnosed with localised prostate cancer should be appropriately informed about active surveillance as a treatment option.
- Men entering an active surveillance programme as a cancer treatment option need to be tracked in the general practice IT system. This should reflect a care plan agreed between the specialist, patient and general practitioner.

Curative treatments

30. Men at significant risk of metastases and those with locally advanced disease should be considered for appropriate staging investigations.

31. All men diagnosed with localised prostate cancer should be assigned a 'risk category' to help assess appropriate management options.

32. All men diagnosed with localised prostate cancer should be offered the opportunity to discuss their options with both a urologist and a radiation oncologist, and most should consult with both specialists.

33. The option of radical prostatectomy should be considered for localised prostate cancer in men who are fit and have a good life expectancy.
    - Radical prostatectomy is most suitable for men with low and intermediate risk tumours but can be considered in selected high-risk patients
    - Men considering radical prostatectomy should be informed about the options of open incisional, laparoscopic or robotic-assisted laparoscopic techniques.
    - Men considering radical prostatectomy should be informed about active surveillance and radiation therapy alternatives and have the opportunity to consult appropriate specialists.

34. Radiation treatment should be with contemporary techniques of intensity modulated radiotherapy (IMRT) with daily image guidance (image guided radiotherapy, IGRT).

35. All the appropriate radiation treatments, including external beam, low dose rate and high dose rate brachytherapy, should be discussed with men considering curative treatment.

Metastatic prostate cancer

36. New Zealand Clinical Practice Guidelines are developed for metastatic prostate cancer.

37. Research is undertaken to determine the burden of disease and reduce inequities in Māori men with metastatic prostate cancer.

Access to health services

38. Data must be collected on wait times for all men undergoing assessment for possible prostate cancer and those undergoing prostate cancer treatment through all stages of the cancer care pathway. These data must be analysed and reported according to ethnicity.

39. A regional and national stocktake and review of data collected on prostate cancer diagnosis and management, including wait times, should be undertaken. This should include district health boards and private and public sector providers.

40. A national core prostate cancer data set should be developed and implemented to permit monitoring of a national quality plan. Quality indicators, which should include monitoring treatment pathway times, must be developed and implemented.

1 Introduction

Prostate cancer is a significant burden to men's health. It is now one of the most important problems facing New Zealand men. Prostate cancer is the most common non-cutaneous malignancy diagnosed in New Zealand and is the third most common cause of cancer death in men after lung cancer and bowel cancer.[1] In 2008 approximately 900,000 men were diagnosed with prostate cancer worldwide, with the highest rates primarily in developed countries of Europe, North and South America, and Oceania.[2] These data include 2939 New Zealand men diagnosed with prostate cancer.[3] Prostate cancer most commonly occurs in men over 65 years of age and is rare in men under 50 years (61 cases and 2 deaths in 2008). In 2008 a total of 670 men died from the disease. Of these, 316 deaths (53%) were of men younger than 78.4 years, which is the life expectancy of New Zealand men.[4]

In spite of its high incidence and prevalence, prostate cancer has a relatively slow rate of growth, meaning that it also takes longer than other malignancies to progress from early to advanced disease.[5] Because of these conditions, clinicians have been working to find a reliable way of detecting it early so that potentially life-saving treatments can be implemented promptly.[6] Such treatment has the dual aim of reducing prostate-related mortality and reducing the significant morbidity associated with advanced disease.

To date, prostate specific antigen (PSA) testing has provided a relatively simple means of population screening for prostate cancer. Unfortunately, however, PSA does not diagnose prostate cancer with certainty as its serum value can be elevated in both benign and malignant conditions of the prostate and not all men with prostate cancer will have high PSA levels. In addition, where prostate cancer is detected early, clinically indolent cancers may be overdiagnosed, resulting in overtreatment, and men may experience side effects from untoward treatment that reduce their quality of life. There may also be unnecessary costs and burdens to our health care system. However, as active surveillance is increasingly being adopted as a first-line treatment for men with 'very low' and 'low' risk disease, the risks of overtreatment have been substantially reduced; some studies report up to 40 percent of newly diagnosed men enter this treatment pathway.[7]

These conundrums have led to the current disagreement among clinicians and public health workers regarding which patients should be offered screening for prostate cancer. Furthermore, there is now a great deal of confusion among men, their families and whānau and their general practitioners as to the value of PSA testing and the benefit or otherwise of treating newly diagnosed prostate cancer.

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1 Age-specific rates per 100,000 for the five most common causes of cancer death 2008. In Ministry of Health. 2011. *Cancer: New registrations and deaths 2008*. Wellington: Ministry of Health.

2 Center M, Siegel R, Ahmedin J. 2011. *Global Cancer Facts and Figures.* 2nd edition. Atlanta: American Cancer Society.

3 Ministry of Health. 2011. *Cancer: New registrations and deaths 2008*. Wellington: Ministry of Health.

4 Ministry of Social Development. 2010. *Social Report 2010*. Wellington: Ministry of Social Development.

5 Galper SL, Chen MH, Catalona WJ, et al. 2006. Evidence to support a continued stage migration and decrease in prostate cancer specific mortality. *Journal of Urology* 175(3): 907–12.

6 Lamb DS, Slaney D, Smart R, et al. 2007. Prostate cancer: the new evidence base for diagnosis and treatment. *Pathology* 39(6): 1–8.

7 Hugosson J, Carlsson S, Aus G, et al. 2010. Mortality results from the Göteborg randomized population based prostate cancer screening trial. *Lancet Oncology* 11(8): 725–32.

Results on prostate screening from the European Randomised Screening for Prostate Cancer (ERSPC), the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial, and Göteborg Swedish trials are controversial. The ERSPC and Göteborg trials showed a reduction in prostate cancer mortality and the PLCO trial showed no benefit.[8, 9, 10] The United States Preventative Health Service Task Force (USPSTF) states that evidence is insufficient to assess the risks and benefits of prostate cancer screening in men younger than 75 years.[11] A common theme from all groups is that an informed decision with patients is strongly recommended and that screening does increase the number of men diagnosed with non-metastatic, early disease. These benefits must be weighed against the potential downsides of overdiagnosis and overtreatment of clinically insignificant cancers.

In light of the issues surrounding screening for prostate cancer and the benefits or otherwise of early diagnosis, the Health Committee conducted an inquiry into the early detection and management of prostate cancer in New Zealand. Its report *Inquiry into Early Detection and Treatment of Prostate Cancer*, which was presented to the House in July 2011, contained 17 recommendations.[12]

The Health Committee considers that before any organised national screening programme could be established there would have to be clear evidence that any harm it might cause from overdiagnosis and overtreatment would be outweighed by a reduction in mortality and morbidity. Currently the evidence is inconclusive on this point. While a national prostate screening programme is not recommended at this time, the Health Committee does recommend establishing an equity-focused Quality Improvement Programme. This programme would ensure that men receive evidence-based information about prostate cancer testing and treatment, which they could use to make informed decisions, and that they have timely access to high-quality care along the entire treatment pathway.

The Ministry of Health has noted that there are inconsistencies in the quality and equity of services for the early detection and treatment of prostate cancer in New Zealand. In addition, not all men currently receive evidence-based information to help them make informed decisions.

It was therefore determined that the Ministry of Health would develop a framework for the Quality Improvement Programme within existing resources. It is expected that the Minister of Health will report back to Cabinet by March 2013 on the associated costs and benefits of implementing this plan.

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8 Schröder FH, Hugosson J, Roobol MJ, et al. 2009. Screening and prostate-cancer mortality in a randomized European study. *New England Journal of Medicine* 360: 1320–8.

9 Andriole GL, Crawford ED, Grubb RL 3rd, et al. 2009. Mortality results from a randomized prostate-cancer screening trial. *New England Journal of Medicine* 360: 1310–19.

10 Hugosson J, Carlsson S, Aus G, et al. 2010. Mortality results from the Göteborg randomized population based prostate cancer screening trial. *Lancet Oncology* 11(8): 725–32.

11 US Preventive Services Task Force. 2008. Screening for prostate cancer. US Preventive Services Task Force recommendation statement. *Annals of Internal Medicine* 149(3): 185–91.

12 Health Committee. 2011. *Inquiry into Early Detection and Treatment of Prostate Cancer*. Report of the Health Committee. 49th parliament, Dr Paul Hutchison, Chairperson.

1.1 Prostate Cancer Quality Improvement Programme

The Ministry of Health will produce a costed implementation plan for the Quality Improvement Programme for the early detection and treatment of prostate cancer – a programme that is equity-focused and covers all aspects of the early detection and treatment pathway. This plan will address inequities in access to and in quality of prostate cancer care and screening. It will also provide guidelines and frameworks for monitoring the programme and ensuring standards are met.

Another aspect of the Quality Improvement Programme is to develop information resources for health professionals and men in the general population. A prompt decision support tool for the Patient Management System used in primary care settings will also be developed and costed.

As a result of these initiatives, it is expected that men and their families and whānau will have access to consistent, high-quality information on prostate cancer and prostate cancer screening, and that men who wish to undergo testing for prostate cancer can do so.

1.2 Role of the Prostate Cancer Taskforce

The Prostate Cancer Taskforce (the Taskforce) will develop the clinical content and provide key recommendations to inform the Quality Improvement Programme. The Ministry of Health will produce the costed implementation plan for the Quality Improvement Programme based on the Taskforce's information and recommendations. This Taskforce document will be submitted to Cabinet in conjunction with the costed implementation plan.

1.3 Achieving equity

The advisors' report to the Health Committee shows that inequities in prostate cancer are significant and of great concern. Although they are not yet well understood, these inequities appear to be due to differences in access to and quality of diagnosis and treatment. Prostate cancer has the second largest inequity in cancer survival between Māori and non-Māori. Although Māori men are about 25% less likely to be diagnosed with prostate cancer than non-Māori men, they are almost 50% more likely to die from the disease.[13]

To improve health outcomes for Māori and achieve equity in prostate cancer survival between Māori and non-Māori, the Taskforce has focused on identifying areas of inequity along the prostate cancer care and screening pathway. This project has ensured Māori participation on the Taskforce.

1.4 Project governance and reporting

The Cancer Programme Steering Group provides governance for the Cancer Programme. This national programme covers the activity of the Ministry of Health, district health boards and regional cancer networks that relates to implementing the New Zealand Cancer Control Strategy. The Taskforce is a time-limited subgroup of the Cancer Treatment Advisory Group, which provides clinical advice on cancer treatment to the Cancer Programme Steering Group.

[13] Prostate cancer registrations and deaths 2008 from Ministry of Health. 2011. *Cancer: New registrations and deaths 2008*. Wellington: Ministry of Health.

1.5 Taskforce membership

The Taskforce comprises members who collectively have knowledge and experience to contribute to the development of an equity-focused Quality Improvement Programme for the early detection and treatment of prostate cancer. The Ministry appointed the Taskforce members following discussions with relevant stakeholders including providers, consumer groups and professional groups. This membership is listed in ‘Appendix: Prostate Cancer Taskforce membership’.

1.6 Process

The Taskforce had face-to-face meetings in February, April, July and December 2012. To make it easier to assimilate the very large amount of information on the topic of prostate cancer, Taskforce members were assigned to workgroups responsible for the specific threads of equity, information in the public domain, primary care, diagnosis, pathology reporting, active surveillance, curative treatments, advanced disease and palliative care. Each workgroup reported to the full Taskforce. After the wider group discussed and considered each report, it developed the list of recommendations.

2 Equity

The Prostate Cancer Taskforce recognises that inequities are preventable, unfair and fixable and that responsibility for identifying and eliminating prostate cancer inequities lies within all levels of the health system. Achieving equity in prostate cancer outcomes between Māori and non-Māori will require quality improvements along the entire prostate cancer care pathway, but with extra focus on access to and quality of treatment for Māori.

Prostate cancer inequities are significant in New Zealand but not yet well understood.[14] Most notably there are inequities in survival and death rates between Māori and non-Māori. Compared with non-Māori men, Māori men are 76% more likely to die of prostate cancer once diagnosed (taking age and stage into account). Death rates from prostate cancer are 59% higher for Māori men than for non-Māori men.[15]

Rates of prostate cancer diagnosis are more a measure of screening activity than of true incidence of prostate cancer. Māori men are about 10% less likely to be diagnosed with prostate cancer than non-Māori men. Prostate cancer survival and mortality inequities between Māori and non-Māori fit the inequity profile of most other cancers in that they can be explained only partially, if at all, by a greater risk of getting cancer. As with almost all other cancers, the reasons for survival inequities between Māori and non-Māori prostate cancer patients are unclear.

Although research on prostate cancer specifically is needed to provide answers, research into bowel cancer has provided some clues. If these prostate cancer survival inequities have similar causes to those for bowel cancer, then some of the causes are that Māori men with prostate cancer are diagnosed at a later stage, have higher rates of co-morbidity, and have poorer access to and lower quality of health care compared with non-Māori men.[16, 17, 18] These assumptions have some support from research findings suggesting that, compared with non-Māori men, Māori men are more than two times less likely to be offered screening for prostate cancer,[19] 354% more likely to be diagnosed late and, as noted above, 76% more likely to die once diagnosed (taking stage at diagnosis and age into account).

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[14] Lamb DS, Bupha-Intr O, Bethwaite P, et al. 2008. Prostate cancer – are ethnic minorities disadvantaged? *Anticancer Research* 28: 3891–6.

[15] Robson B, Purdie G, Cormack, D. 2010. *Unequal Impact II: Māori and Non-Māori cancer statistics by deprivation and rural–urban status, 2002–2006*. Wellington: Ministry of Health.

[16] Hill S, Sarfati D, Blakely T, et al. 2010. Ethnicity and management of colon cancer in New Zealand: do indigenous patients get a worse deal? *Cancer* 116(13): 3205–14.

[17] Hill C, Hill S, Sarfati D, et al. 2010. Survival disparities in Indigenous and non-Indigenous New Zealanders with colon cancer: the role of patient comorbidity, treatment and health service factors. *Journal of Epidemiology and Community Health* 64: 117–23.

[18] Sarfati D, Hill S, Blakely T, et al. 2009. The effect of comorbidity on the use of adjuvant chemotherapy and survival from colon cancer: a retrospective cohort study. *BMC Cancer* 9: 116.

[19] Lawrenson R. 2012. Midland Prostate Cancer Study.

There are likely to be regional differences in access to and quality of treatment for men with prostate cancer. However, such differences are unlikely to be as large as differences between Māori and non-Māori men.[20] This idea is supported by preliminary results from a study on regional differences in prostate cancer survival. Some differences in access and quality are also likely to relate to socioeconomic position, as mortality rates for prostate cancer increase and survival rates decrease with increasing levels of socioeconomic deprivation. Again, these differences are smaller than the survival and mortality gaps between Māori and non-Māori.

It is unclear whether, or to what extent, Māori and non-Māori men differ in their views on the acceptability of screening or testing for prostate cancer. Even if such differences did exist, it is uncertain whether they would contribute to differences in death rates. Because survival inequities take into account late stage of diagnosis, theoretical differences in acceptability of screening and/or testing would not contribute to the survival inequity between Māori and non-Māori.

A number of barriers that prevent Māori men from seeking prostate health care have been described. Most of these have arisen because the health system has not dealt appropriately with cultural issues. Other barriers are a lack of prostate knowledge, because appropriate information was not available, and social pressure related to being male.[21]

Four trends characterise the Māori population: the rate of growth is relatively high (compared with the total New Zealand population); the median age is relatively young (22 years); the population is ageing; and the population is mobile (both nationally and internationally). Therefore, despite the youthfulness of the Māori population, the proportion of older family members is growing. An increase in Māori life expectancy (to 70.4 years for males and 75.1 years for females) has resulted in more adults over the age of 65 years.[22]

Inevitably the goal must be to achieve equity in access to care and quality of diagnosis and treatment for prostate cancer between Māori and non-Māori. The Taskforce considers that achieving this goal will require two areas of focus – health services, and impact – which recognises that a diagnosis of prostate cancer could have a devastating effect on the financial and social resources of the man and his family and whānau.

2.1 Health services

There are three objectives for health services. [23]

1. Raise awareness of prostate cancer inequities and recognise the role of health services in achieving equity.
2. Promote equity-focused quality improvement along the prostate cancer care pathway among health and disability service providers.
3. Support the development of the Māori workforce along the prostate cancer care pathway.

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[20] Gray MA, Crampton P, Weinstein P, Nacey JN. 2004. Differences in prostate disease symptoms and visits to the general practitioner among three ethnic groups in New Zealand. *BJU International* 94(1): 96–100.

[21] Williams P, Gray MA, Ka'ai T, et al. 2003. Maori men's perceptions and experiences of health seeking for prostate health problems in New Zealand. *Pacific Health Dialogue* 10(2): 71–8.

[22] Taskforce on Whānau-centred Initiatives. 2010. *Whānau Ora: 2010 report of the Taskforce on whānau-centred Initiatives*. Wellington: Ministry of Social Development.

[23] Kotter JP. 1995. Leading change: why transformation efforts fail. *Harvard Business Review* 73(2): 59–68.

2.1.1 Raise awareness and recognise the role of health services in achieving equity

Health services have a pivotal role in decreasing inequities in prostate cancer mortality.[22] It is important to raise awareness among health and disability service providers of the need to focus on and achieve equity along the prostate cancer care pathway and of their role in achieving this goal. Ways of raising their awareness and involving them in working towards the goal are to:

- establish a sense of urgency – identifying key messages and developing a communications plan
- communicate a goal, principles and key messages, which should include exemplars and success stories – for example, 'Get access to and quality of prostate care right for Māori and we get it right for all. It doesn't work the other way around'
- identify and remove barriers to achieving the goal – using research and planning
- plan for and create short-term wins then communicate them extensively.

2.1.2 Promote equity-focused quality improvement along the prostate cancer care pathway among health and disability service providers

It is possible to use communications and clinical governance frameworks to gain the voluntary engagement of health providers in achieving equity along the prostate cancer pathway. Clinical governance approaches are based on the premise that changes in provider behaviour will increase quality of care. Using a long-term, supportive approach will help to make achieving equity in prostate cancer care the easy choice for providers.[24, 25, 26]

Change can be promoted and monitored using a monitoring framework. This would require the development of indicators (based on areas of inequity along the pathway identified through research), a minimum national data set, and professional and organisational standards. Data collection and management issues would need to be addressed. The framework would include independent Māori monitoring (as with BreastScreen Aotearoa)[27] and reporting as part of a communications plan.

Tools for achieving equity-focused quality improvement along the prostate cancer pathway would need to be developed and include whānau-centred initiatives. For example, a prostate cancer decision aid could be developed to include information on cancer screening, treatment and inequities. The aid would be developed and implemented to ensure that Māori men:

- are no less likely to take part in screening as a result of the decision aid
- have the same or improved levels of confidence and knowledge around prostate cancer screening and treatment compared with non-Māori.

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[24] Campbell S, Sheaff R, Sibbald B, et al. 2002. Implementing clinical governance in English primary care groups/trusts: reconciling quality improvement and quality assurance. *Quality and Safety in Health Care* 11: 9–14.

[25] Braithwaite J, Travaglia F. 2008. An overview of clinical governance, policies, practices and initiatives. *Australian Health Review* 32: 10–22.

[26] Campbell S, Sheaff R, Sibbald B, et al. 2002. Implementing clinical governance in English primary care groups/trusts: reconciling quality improvement and quality assurance. *Quality and Safety in Health Care* 11: 9–14.

[27] Simmonds S, Robson B, Stanley J. 2010. *Draft Independent Māori Monitoring Report 2, Breast Screen Aotearoa January 2006 to December 2007.* Wellington: Te Rōpū Rangahau Hauora a Eru Pomare, University of Otago Wellington.

2.1.3 Support the development of the Māori workforce along the prostate cancer care pathway

Strategies would need to be developed and implemented to develop the Māori health professional workforce along the prostate cancer care pathway. Areas of focus would include primary care, urology, radiation oncology and medical oncology, palliative care and public health screening and quality expertise.

2.2 Impact

A diagnosis of prostate cancer could have a devastating effect on the financial and social resources of a man and his family and whānau, particularly if they are not well off to start with. As with inequities in mortality and survival, there are gaps in socioeconomic position between rural and urban locations, regions and ethnic groups, but the largest gap is between Māori and non-Māori.

In working to achieve equity, some of the key messages could focus on:

- health literacy, which is low for Māori
- poverty – half of Māori men who die from prostate cancer are among the poorest 20% of people in New Zealand.

Health providers must take measures to prevent or lessen the social and economic impact of prostate cancer on men and their families and whānau. Supporting them to take such initiatives would involve: raising awareness; promoting methods to decrease the impact of prostate cancer on socioeconomic position and to reduce health inequities for individuals and their families and whānau along the pathway; and developing a monitoring framework and communications plan. These forms of support would need to be based on areas of impact along the prostate cancer care pathway, as identified through research. One tool could be a socioeconomic needs assessment for men with prostate cancer. Key messages for care providers could include information on the socioeconomic positions of Māori men with prostate cancer. Areas of research could include the impact of prostate cancer on the socioeconomic position of men and their families and whānau, and ways to mitigate that impact.

Recommendation 1

A National Prostate Cancer Working Group is established to oversee the implementation of the recommendations made by the Prostate Cancer Taskforce. This must include a high level of Māori health expertise.

Recommendation 2

The National Prostate Cancer Working Group works with key stakeholders to develop and implement strategies to support Māori health professional workforce development along the prostate cancer care pathway.

Recommendation 3

The National Prostate Cancer Working Group oversees the development and implementation of an equity-focused Quality Improvement Plan for the prostate cancer care pathway for men and their families and whānau. This should include:

- development and implementation of a change management programme to raise awareness among health providers of the need to focus on and achieve equity along the prostate cancer care pathway
- working collaboratively with prostate cancer researchers to promote an equity focus, enhance outcomes, promote dissemination of information and support ongoing research, such as research on the impact of prostate cancer on the socioeconomic position of men and their families and whānau, and ways to mitigate those impacts.

Recommendation 4

The National Prostate Cancer Working Group develops and promotes the use of measures to prevent or lessen the social and economic impact of prostate cancer on men and their families and whānau. This should include measures based on areas of impact along the prostate cancer care pathway, as identified through research.

Recommendation 5

A quality monitoring framework is developed to promote and monitor change toward equity-focused quality improvement. This should include:

- indicators based on areas of inequity along the pathway identified through appropriate research
- a minimum national data set
- professional and organisational standards
- data collection and management frameworks.

Indicators should be reported by ethnicity so that inequities can be identified and addressed, and progress toward achieving equity can be monitored and reported.

Independent Māori monitoring and reporting should be established following methods similar to those used for BreastScreen Aotearoa.

3 Public domain

Prostate cancer differs from most other cancers in that it lacks symptoms in its early stages, and has a particularly variable clinical course and many possible ways of managing it.

As early, low-grade prostate cancer causes no symptoms, screening is the only way of detecting it early and therefore of identifying cancer that is potentially curable. Conversely the same screening may unknowingly detect indolent cancer, resulting in unnecessary treatment.

Once diagnosed, localised prostate cancer may be treated by many different methods. These include not only the 'mainstream' treatments of radical prostatectomy, external beam radiation therapy and radioactive seed implantation (brachytherapy) but also the less common treatments of cryosurgery, hi-intensity focused ultrasound (HIFU) and photodynamic therapy. Another approach gaining increasing attention is active surveillance – now a key management strategy for some men with small-volume, low-grade tumours. The efficacy of any one of these treatments may differ widely from patient to patient and from one specialist clinician to another. Such differences may reflect differences in specialist skill level and experience.

Added to all of these circumstances is the perceived lack of consensus among experts regarding the value of early diagnosis of prostate cancer. It is not surprising, therefore, that men are confused about the need for prostate cancer screening, and bewildered by the range of options available should a diagnosis of prostate cancer be made. Unfortunately, and again not surprisingly, this confusion extends to general practitioners and prostate cancer specialists.

It is a matter of urgency to provide appropriate information on the diagnosis and management of prostate cancer for men and their families and whānau. This information must be available in the public domain and provide not just factual material about prostate cancer, but also guidance as to how to use this information and the steps men and their families and whānau need to take to get medical assistance and enter the pathway of care. The information must cover the benefits and risks of screening, the option of active surveillance and the various curative treatments available.

3.1 Prostate cancer

As expected, men and their families and whānau differ widely in their levels of knowledge about prostate cancer, and the amount of information available on the topic is potentially vast. They are often uncertain about whether they should undergo screening, and uncertain and concerned about the implications of this disease if diagnosed. If men are to increase their awareness and understanding of prostate cancer along the health care pathway, then they must have access to high-quality factual information about cancer in general and some detail about basic prostate anatomy and pathology of prostate cancer.

Recommendation 6

Through public information, men and their families and whānau are provided with concise material that will allow them to develop a basic level of knowledge about the prostate gland and prostate cancer. This material should include a description of:

- the prostate gland, including where it is and what it does
- cancer in general and how it develops and spreads
- the natural history of prostate cancer, including its ability to progress over time and spread to other organs. Prostate cancers may be fast or slow growing. Slow-growing prostate cancers are common and may not cause symptoms or shorten life. Others may develop into a serious cancer, growing within the prostate gland and later spreading to surrounding areas or to elsewhere in the body.

3.2 Prevention of prostate cancer

Prostate cancer currently cannot be prevented although certain factors have been discussed as being important to its development. These factors include food consumption, pattern of sexual behaviour, alcohol consumption, exposure to ultraviolet radiation, chronic inflammation and occupational exposure.[28]

Dietary and nutritional factors that may influence disease development include total energy intake (as reflected by body mass index), dietary fat, cooked meat, micronutrients and vitamins (carotenoids, retinoids, vitamins C, D and E), fruit and vegetable intake, minerals (calcium, selenium), and phyto-oestrogens (isoflavonoids, flavonoids, lignans), or statins and/or cholesterol intake. Because most studies reported to date are case-control analyses, there remain more questions than evidence-based data available to answer them. Several ongoing, large, randomised trials are trying to clarify the role of such risk factors and the potential for successfully preventing prostate cancer.[29]

The key question is whether there is enough evidence to recommend lifestyle changes (lowered intake of animal fat and increased intake of fruit, cereals and vegetables) in order to decrease the risk. There is some evidence to support such a recommendation and this information can be given to male relatives of prostate cancer patients who ask about the impact of diet.[30]

Recommendation 7

Through public information, men and their families and whānau are advised that there is no proven prevention for prostate cancer. There is some evidence that lowered intake of animal fat may be of small benefit.

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[28] Kolonel LN, Altshuler D, Henderson BE. 2004. The multiethnic cohort study: exploring genes, lifestyle and cancer risk. *Nature Reviews Cancer* 4(7): 519–27.

[29] Schmid H-P, Engeler DS, Pummer K, et al. 2007. Prevention of prostate cancer: more questions than data. *Recent Results in Cancer Research* 174: 101–7.

[30] Schulman CC, Zlotta AR, Denis L, et al. 2000. Prevention of prostate cancer. *Scandinavian Journal of Urology and Nephrology* (205): 50–61.

3.3 Relatives with prostate cancer

If a man has one first-order relative (father or brother) with prostate cancer, then his risk of developing prostate cancer is at least doubled. If two or more first-order relatives are affected, the risk increases by 5–11 times.[31, 32] A small subpopulation of men with prostate cancer (about 9%) has the true hereditary form of the disease. This is defined as three or more affected relatives, or at least two relatives who have developed early onset disease (before the age of 55 years).[33] Patients with hereditary prostate cancer usually have an onset six to seven years earlier than spontaneous cases, but do not differ in other ways.[34] The risk is higher if more than one close relative is affected and is also higher if a close relative is diagnosed at a younger age (under 65 years).

Recommendation 8

Through public information, men and their families and whānau are advised that men with a first-degree relative with prostate cancer are at much greater risk of developing prostate cancer themselves.

3.4 Prostate cancer in Māori and Pacific men

For Pacific men, the rates of prostate cancer incidence (98.5 per 100,000) and mortality (23.2 per 100,000) are similar to the rates for all men. For Māori men, while their prostate cancer incidence rate is lower than for all men (74.9 per 100,000), their mortality rate due to prostate cancer is higher (32.9 per 100,000). It is not known whether the higher prostate cancer mortality observed in Māori men in spite of lower incidence reflects later diagnosis or differences in treatment.[35]

Preliminary research suggests that general practitioners are less likely to screen Māori men for prostate cancer than non-Māori men. Māori men are also less likely to be diagnosed with prostate cancer than non-Māori men. When they are diagnosed, they are more likely to be diagnosed when the prostate cancer is at a more advanced stage and therefore less likely to be cured. There is no evidence that Māori men are less likely than non-Māori men to accept an offer of screening or testing for prostate cancer. Once diagnosed with prostate cancer, and taking account of age and stage of prostate cancer at diagnosis, Māori men are 60% more likely to die of their prostate cancer than non-Māori.

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31 Steinberg GD, Carter BS, Beaty TH, et al. 1990. Family history and the risk of prostate cancer. *Prostate* 17(4): 337–47.

32 Gronberg H, Damber L, Damber JE. 1996. Familial prostate cancer in Sweden: a nationwide register cohort study. *Cancer* 77(1): 138–43.

33 Carter BS, Beaty TH, Steinberg GD, et al. 1992. Mendelian inheritance of familial prostate cancer. *Proceedings of the National Academy of Sciences of the United States of America* 89(8): 3367–71.

34 Bratt O. 2002. Hereditary prostate cancer: clinical aspects. *Journal of Urology* 168(3): 906–13.

35 Gray MA, Borman B, Crampton P, et al. 2005. Elevated serum prostate-specific antigen levels and public health issues in three New Zealand ethnic groups: European, Maori and Pacific Islands men. *New Zealand Medical Journal* 118: 1209.

Recommendation 9

Through public information, men and their families and whānau are advised that Māori men have a lower chance of surviving prostate cancer than non-Māori men and that the Ministry of Health is working with health professionals and Māori leaders to improve the quality of the prostate cancer care pathway in order to address this inequity.

Recommendation 10

The Cancer Registry provides sufficient detail on prostate cancer incidence and survival to allow research on the differences between Māori, non-Māori and Pacific men.

3.5 Diagnosis of prostate cancer

3.5.1 Signs and symptoms

Early, low-grade prostate cancer causes no symptoms. It is often not until the cancer is locally advanced that men will develop urinary problems. Symptoms of prostate cancer are similar to those of benign (non-cancerous) prostate conditions. These include decreased force of the urine stream, passing urine more frequently, sometimes with delay in starting (hesitancy) and dribbling at the end of the urine flow. Occasionally prostate cancer can cause blood in the urine.

Men with advanced prostate cancer, where the cancer has spread beyond the prostate gland to other parts of the body, may present with weight loss, fatigue and bone pain.

3.5.2 Prostate specific antigen

PSA is produced almost exclusively by the epithelial cells of the prostate. For practical purposes it is organ-specific but not cancer-specific. Therefore, serum levels may be elevated in the presence of benign prostatic hypertrophy (BPH), prostatitis and other non-malignant conditions. The level of PSA as an independent variable is a better predictor of cancer than suspicious findings on digital rectal examination (DRE) or transrectal ultrasound (TRUS).[36]

The level of PSA is a continuous parameter: the higher the value, the more likely it is that prostate cancer exists. Many men may have prostate cancer despite low levels of serum PSA.[37]

[36] Stamey TA, Yang N, Hay AR, et al. 1987. Prostate-specific antigen as a serum marker for adenocarcinoma of the prostate. *New England Journal of Medicine* 317(15): 909–16.

[37] Thompson IM, Pauler DK, Goodman PJ, et al. 2004. Prevalence of prostate cancer among men with a prostate-specific antigen level < or =4.0 ng per milliliter. *New England Journal of Medicine* 350(22): 2239–46.

3.5.3 Digital rectal examination

Most prostate cancers are located in the peripheral zone of the prostate and some may be detected by DRE. Prostate cancer may present as a hard discrete nodule or with asymmetry of the gland. In about 18% of all patients, prostate cancer is detected by a suspect DRE alone, irrespective of the PSA level.[38] A suspect DRE in patients with a PSA level of up to 2 ng/mL has a positive predictive value of 5–30%.[39] A suspect DRE is a strong indication for prostate biopsy as it is predictive for more aggressive prostate cancer.[40, 41]

Recommendation 11

Through public information, men and their families and whānau are advised that men with urinary symptoms should request assessment by their general practitioner. This assessment is likely to include a PSA blood test and DRE. The general practitioner may suggest referral to a specialist depending on the severity of the symptoms or if there is a suspicion that there may be underlying prostate cancer.

3.5.4 Referral to a specialist

If the specialist confirms the general practitioner's provisional diagnosis of prostate cancer, then it is likely that prostate biopsy will be required.

Recommendation 12

Through public information, men and their families and whānau are advised of the procedure of prostate biopsy and its associated risks. Men also need to be advised that a negative biopsy does not rule out the presence of underlying prostate cancer and that, if the biopsy is negative, ongoing observation will probably be recommended.

[38] Richie JP, Catalona WJ, Ahmann FR, et al. 1993. Effect of patient age on early detection of prostate cancer with serum prostate-specific antigen and digital rectal examination. *Urology* 42(4): 365–74.

[39] Carvalhal GF, Smith DS, Mager DE, et al. 1999. Digital rectal examination for detecting prostate cancer at prostate specific antigen levels of 4 ng/ml or less. *Journal of Urology* 161: 835–9.

[40] Katie OT, Roehl KA, Han M, et al. 2007. Characteristics of prostate cancer detected by digital rectal examination only. *Urology* 70(6): 1117–20.

[41] Gosselaar C, Roobol MJ, Roemeling S, et al. 2008. The role of the digital rectal examination in subsequent screening visits in the European randomized study of screening for prostate cancer (ERSPC), Rotterdam. *European Urology* 54(3): 581–8.

3.6 Management of prostate cancer

Following the diagnosis of prostate cancer, a man and his family and whānau will be continuing along a pathway of care that is likely to include further investigations. A treatment plan will need to be chosen, which differs for each individual and will be influenced by the man's age, general health, grade and stage of the cancer, symptoms, lifestyle and personal choice. The treatment options may include watchful waiting, active surveillance, curative treatment or (in the case of metastatic disease) androgen deprivation therapy. Men and their families and whānau will differ greatly in their level of knowledge about these options, but usually this knowledge is minimal and often confused. Some men may be aware of the less common curative treatments of cryosurgery, hi-intensity focused ultrasound and photodynamic therapy and may have information about the current third-line treatments of chemotherapy using docetaxel and immune therapy using sipuleucel.

Recommendation 13

Through public information, men and their families and whānau are advised of the consequences of prostate biopsy with respect to the likely requirement of staging investigations. They should also be presented with a general guide to the currently available treatment options. This should include a commentary on the place of 'non-mainstream' curative treatments and the current developments with chemotherapy and immune therapies. The guide should also consider the potential benefits and harms of treatment.

3.7 Presentation of information

To make informed decisions about the need for prostate cancer screening, and the options available to them if further investigation or treatment is required, men must be presented with relevant, high-quality information. This information needs to be at a level of understanding that takes into account differences in age, ethnicity, co-morbidity and family history.

Recommendation 14

Information needs to be available at a level of understanding relevant to the patient and should take into account different patient perspectives, such as age, co-morbidity and family history.

- Information should be in a variety of formats, such as written text, diagrams, video and internet, and take account of issues such as sight or hearing problems.
- Information should reflect best evidence.
- Information should be culturally appropriate.
- Information resources must be developed in consultation with Māori.
- Information should be available in the languages of major ethnic groups within New Zealand (Māori, Chinese languages, Pacific languages).

4 Prostate cancer in primary care

General practitioners have the central role in screening and assessing men for prostate cancer. They and their practices must also support men entering a prostate cancer pathway of care following the initial diagnosis and through subsequent treatment. This support may include monitoring men under watchful waiting or active surveillance, and managing metastatic disease and palliative care. It is likely that general practitioners will also be closely involved in managing men with the complications and adverse effects of treatment. These effects are common, and range from the potential complications of incontinence, erectile dysfunction and bowel symptoms from the curative treatments, to the wide range of symptoms related to androgen deprivation therapy and chemotherapy.

One of the issues that general practitioners face when they are considering prostate cancer screening and diagnosis is the widespread use of opportunistic screening without agreed pathways of management for positive tests. In addition, many older men are tested with less likelihood of gain, and the role of age bands for prostate cancer screening is not clear.

Many men will see their general practitioners and have little or no knowledge about prostate cancer. However, an increasing proportion will come well informed and initiate discussions themselves. This informed response is likely to be more common after appropriate information about prostate cancer is introduced into the public domain. General practitioners therefore need to be equally well informed about this disease process. They must be able to provide clear guidance to men who request prostate cancer screening, and appropriately investigate men who present with signs and symptoms that may be the result of early or advanced disease. General practitioners must be ready and able to answer in helpful and informative ways the questions that patients and their families and whānau may ask.

4.1 Clinical presentations to general practice

4.1.1 Asymptomatic men requesting prostate cancer information or testing

Population screening for asymptomatic men with PSA testing is currently not recommended. However, men or their partners may present to a general practitioner with a request for prostate cancer screening (usually involving a PSA test), for information on prostate cancer or for a general practitioner's opinion on prostate cancer screening.

Under these circumstances, Rule 6 of the Health and Disability Commissioner's code is applied to all clinicians.[42] Namely the information that is provided to men is sufficient for them to make an informed decision. In addition, the Medical Council of New Zealand states that patients must be given all the information they want or need to know including any expected risks and benefits.[43] The National Screening Advisory Committee and National Health Committee advise that the complete screening pathway should be explained.

[42] The Patient Code of Rights. Health and Disability Commissioner Act 1994.

[43] Medical Council of New Zealand. 2008. *Good Medical Practice: A guide for doctors*. Wellington: Medical Council of New Zealand.

The information provided must use high-quality data that reflect best evidence on the harms and benefits of prostate screening. It must be presented in a manner that is easy to understand and minimises clinician bias. The evidence needs to be specific to the man's age and culture. Qualitative descriptions are insufficient; numeric data must be used, in particular on absolute rather than relative harm and benefit. These numeric data should be presented visually (paling charts and bar graphs) in order to make it easier to interpret the figures. Presentation methodologies must take into account language and cultural issues.

Recommendation 15

Primary health care should provide high-quality, culturally appropriate information on prostate cancer and PSA testing to men aged 50 to 70 years.

All men who are concerned about prostate cancer or are requesting a PSA test must be presented with high-quality, culturally appropriate information.

If the clinician (general practitioner or nurse) is to meet the requirement of achieving informed consent with the man presenting for screening, they need appropriate support tools for this process within the practice setting. These tools should ideally be written, visual and interactive.

Recommendation 16

Systems must be introduced to general practices to facilitate the informed consent process.

4.1.2 Screening for prostate cancer as part of a well man's check

Where well men are having a health check, recommendation 15 and the related rules described in section 4.1.1 above apply. These men are essentially asymptomatic and are therefore being screened.

4.1.3 Screening for prostate cancer as part of a public health campaign

Practices or practitioners providing information to the wider public must be aware of the requirements of the Health and Disability Commissioner's code and their professional obligation toward their colleagues, in particular a man's own general practitioner.

4.1.4 Screening investigation

If a man has chosen to enter the screening pathway after appropriate discussion with the general practitioner, the most appropriate screening test is measurement of the serum PSA. The PSA test remains the best single modality for detecting a risk of prostate cancer. In the ERSPC study, the positive predictive value of a DRE in men with a PSA of <3 ng/mL was only 4–11%, prompting calls to exclude the DRE from prostate screening. Nevertheless, the combination of PSA and DRE remains the most sensitive investigation for prostate cancers, particularly for higher-grade cancers. The risk of missing a significant cancer by omitting the

DRE has been estimated to be as high as 17%.[44, 45, 46] PSA testing alone is acceptable only where DRE is considered a barrier to testing.[47]

Recommendation 17

Screening for prostate cancer must be by both PSA and DRE testing. PSA testing alone is acceptable only where DRE is considered a barrier to testing.

4.1.5 Men with symptoms

Lower urinary tract symptoms become more prevalent in men with increasing age. These symptoms include decreased force of the urine stream, passing urine more frequently, sometimes with delay in starting (hesitancy) and dribbling at the end of the urine flow. The most common cause of these symptoms is benign prostatic hyperplasia (BPH) but a wide range of non-prostatic causes such as diabetes, spinal nerve problems and bladder abnormalities can present in a similar manner. For this reason all men presenting with urinary symptoms require a full history and appropriate clinical examination. Men with lower urinary tract symptoms do not have a higher risk of prostate cancer than other men of their age but if the symptoms are caused by prostate cancer then this is likely to be more advanced than if the cancer been detected while asymptomatic. Men with symptoms need investigation to determine the likely cause, with age being the most useful risk factor for consideration in a diagnosis of cancer.

Men may also present with systemic features of malignancy related to prostate cancer. These may include lethargy, anaemia, weight loss (especially in the elderly), anorexia and lymphadenopathy. Bone pain, especially in the pelvis and lower spine, is sometimes seen in advanced disease.

Men presenting with these signs or symptoms where there is no apparent cause should have an appropriate examination and assessment, which includes checking for prostate cancer. This check will include a serum PSA, complete blood count, assessment of renal and liver function, urinalysis with direct microscopy and culture, and full clinical examination including a digital rectal examination.

Recommendation 18

All men presenting with lower urinary tract symptoms, and men with systemic features of malignancy, must have an appropriate examination and assessment, which includes checking for prostate cancer. This check will include a serum PSA and creatinine, other appropriate blood tests, urinalysis and a clinical examination, including digital rectal examination.

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[44] Bretton PR. 1994. Prostate-specific antigen and digital rectal examination in screening for prostate cancer: a community-based study. *Southern Medical Journal* 87: 720.

[45] Muschenheim F, Omarbasha B, Kardjian PM, et al. 1991. Screening for carcinoma of the prostate with prostate specific antigen. *Annals of Clinical and Laboratory Science* 21: 371.

[46] Richie JP, Catalona WJ, Ahmann FR, et al. 1993. Effect of patient age on early detection of prostate cancer with serum prostate-specific antigen and digital rectal examination. *Urology* 42: 365.

[47] Nagler HM, Gerber EW, Homel P, et al. 2005. Digital rectal examination is barrier to population-based prostate cancer screening. *Urology* 65: 1137.

4.2 Use and interpretation of the serum PSA test

4.2.1 When should the PSA be measured?

Serum PSA should **not** be measured within three days of ejaculation as this can result in an elevated PSA. A digital rectal examination can also result in an elevated PSA, so blood should be collected before this examination. Prostate biopsies can lead to either upward or downward movement in the PSA, which may persist for months after the procedure.

4.2.2 What is a normal PSA?

The normal reference ranges for total PSA increase with age, and the upper limit of normal with decreasing age is much lower than the 4.0 ng/mL cut-off point attached to the first commercial PSA test in 1986. However, although lowering the upper limit of normal to a more technically 'correct' 2.5 ng/mL results increases the number of cases of prostate cancer that are diagnosed, it also leads to more overdiagnosis and overtreatment of cancers that are not clinically significant.[48]

> ***Recommendation 19***
>
> In the presence of a normal DRE, PSA values of <4.0 ng/mL do not generally merit specialist referral. A significant PSA rise in a man whose PSA has previously been low may warrant referral.

4.2.3 What does an elevated total PSA mean?

The higher the PSA level, the more likely it is that a cancer is present. If the value is between 4.0 and 10.0 ng/mL there is an approximately 40% chance of cancer being detected on prostate biopsy.[49] The incidence of cancer may actually be slightly higher than this, because low-volume cancers can be 'missed' even when systematic zonal biopsies are taken. Other explanations for a small elevation in PSA are BPH and prostatitis.

A PSA >10.0 ng/mL indicates a 67% chance that a cancer is present. Values this high are rarely the result of BPH, but prostatitis can cause a significant and rapid rise in PSA.

A PSA >20.0 ng/mL means a cancer is highly likely to be present, and metastases can sometimes already be demonstrated on bone or CT scan. Prostatitis is the most common alternative cause of this level of PSA elevation.

An elevated PSA may be transient. Therefore (in the absence of an abnormal DRE) the PSA should always be repeated after an interval of 6 to 12 weeks.

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[48] Thompson IM, Pauler DK, Goodman PJ, et al. 2004. Prevalence of prostate cancer among men with a prostate-specific antigen level < or =4.0 ng per milliliter. *New England Journal of Medicine* 350(22): 2239–46.

[49] Leinert AR, Davidson PJ, Wells JE. 2009. The outcomes of transrectal ultrasound guided biopsy of the prostate in a New Zealand population. *New Zealand Medical Journal* 122 (1288): 39–49.

4.3 Use and interpretation of the digital rectal examination

The normal prostate feels small, has two lobes, and is smooth surfaced and symmetrical. With age, it is common to have BPH which enlarges the gland but preserves the symmetry and smoothness. The best predictive sign for prostate cancer is the presence of a nodule in the prostate. This is a hard lump or irregularity of the prostate surface and is often a sign of a more advanced cancer. Other features such as lack of a central sulcus offer less predictive value.

Drawbacks to digital rectal examination are that it is unlikely to detect tumours in the anterior aspect of the prostate and is of limited value in detecting early, low-volume cancer.

A small percentage of men with prostate cancer (10–15%) have a palpable tumour (usually stage T2A) but the PSA remains <4 ng/mL.

4.4 Management of the screening and diagnostic pathway in a general practice

Irrespective of the manner in which a man enters a diagnostic or screening pathway, his general practitioner is responsible for adequate tracking and follow-up. This responsibility ends only when care is transferred to another clinician such as a urologist.

The general practice in which the general practitioner works must have appropriate processes to ensure the tracking and follow-up occur. To this end, the practice needs to:

- have a clinical policy and protocol for delivering a prostate information service
- track PSA and other investigations
- track referrals to secondary care, ideally through an eReferrals process
- have practice-level clinical governance to oversee that the tracking is functioning correctly, such as through audit and data review.

4.5 When to refer

The trigger for referral to a urologist is age dependent because the benefits of early diagnosis reduce with increasing age. At 70 years of age a man diagnosed with prostate cancer as a result of an elevated PSA has an approximately 50% chance that the cancer will become symptomatic in his lifetime. By 75 years this risk has reduced to just 33%.[50]

Prostate cancer is also a disease that becomes more common in men as they get older. This means that there is the potential for referring many elderly men for biopsy. If this high volume of referrals eventuates, the biopsy service will be overwhelmed, and the diagnosis of clinically significant prostate cancers in younger men will then be delayed.

Most urologists and radiation oncologists would consider that men over the age of 75 years are rarely suitable for radical prostatectomy.

[50] Lamb DS, Slaney D, Smart R, et al. 2007. Prostate cancer: the new evidence base for diagnosis and treatment. *Pathology* 39(6): 537–44.

Recommendation 20

General practitioners should refer patients to a urologist according to the following criteria:

- men aged 50–70 years – when the PSA is elevated to ≥4.0 ng/mL
- men aged 71–75 years – when the PSA is elevated to ≥10.0 ng/mL
- men aged ≥76 years – when the PSA is elevated to ≥20 ng/mL
- men with a palpable abnormality in the prostate on DRE
- a significant PSA rise in a man whose PSA has previously been low may warrant referral.

4.6 Network support

The primary health organisation or clinical network in which patients are enrolled should support general practices in meeting some of the requirements of a Quality Improvement Programme. Part of this support is to integrate with the regional district health board through appropriate information technology (IT) services. Other aspects of this support should include:

- IT services for eReferrals and eDischarges meeting the national standards, of both the Health Information Standards Organisation (HISO) and the National Information Clinical Leadership Group (NICLG), including tracking and responses
- a defined local prostate care pathway and appropriate resources
- data on and audit of referrals, investigations and surveillance
- access to the decision tools (electronic or otherwise) used by secondary care to ensure the same information is being discussed in primary and secondary care
- inclusion of a cancer care navigator for those men undergoing treatment
- patient access to the shared care record including those on active surveillance.

Recommendation 21

The primary health organisation or clinical network in which patients are enrolled must support general practices in meeting some of the requirements of a Quality Improvement Programme.

The Ministry of Health must lead a national process to define a prostate care pathway with provision of appropriate resources.

4.7 Active surveillance

Men entering an active surveillance programme for cancer management need to be tracked in the general practice's IT system. This programme must reflect a care plan agreed between the specialist, patient and general practitioner. The minimum requirements for active surveillance are:

- a clear identification with the practice medical records of the patient's status of active surveillance
- a failsafe system of recall/reminder at the practice to ensure the patient does receive the appropriate surveillance
- appropriate transfer of care protocols to ensure ongoing surveillance if the man transfers out of the area in which the initial diagnosis and the decision to undertake active surveillance were made.

4.8 Follow-up after successful care for prostate cancer

Men who have had successful prostate cancer treatment will remain at risk of cancer recurrence. They will also be at risk of developing other clinical conditions that may result from the cancer treatment, such as irritable bowel symptoms from radiation. These men will need active follow-up.

4.9 Palliative care

Appropriate provision of palliative care services is essential in general practice. The practice may provide these services alone or in association with hospice or other palliative care services. In working with other services, the practice or general practitioner must take active steps to remain fully aware of the patient's status in the palliative care pathway. Where it is working alone, the practice must meet the standards of 'Aiming for Excellence' on the provision of palliative care services.

4.10 The role of advanced practice nurses

Nurses have opportunities to enhance the care of men and their families and whānau at the time of diagnosis with prostate cancer, before, during and after treatment and throughout the follow-up period. They may enhance care primarily, although not exclusively, through patient education, decision support, care coordination and advocacy. Decision support is particularly relevant given most men with prostate cancer prefer to be actively involved in decision-making about their treatment.[51, 52, 53, 54]

[51] Davison BJ, Goldenburg SL, Wiens KP, et al. 2007. Comparing a generic and individualised information decision support intervention for men newly diagnosed with localised prostate cancer. *Cancer Nursing* 30(5): E7–15.

[52] Flynn D, van Schaik P, van Wersch A, et al. 2004. The utility of a multimedia education program for prostate cancer patients: a formative evaluation. *British Journal of Cancer* 91(5): 855–60.

[53] Steginga SK, Occhipinti S, Gardiner RA, et al. 2004. Prospective study of men's psychological and decision-related adjustment after treatment for localised prostate cancer. *Urology* 63(4): 751–6.

[54] Wong F, Stewart DE, Dancey J, et al. 2000. Men with prostate cancer: influence of psychological factors on informational needs and decision making. *Journal of Psychosomatic Research* 49(1): 13–19.

In the care of women with breast cancer, specialist breast care nurses are advanced practice nurses whose skills include coordinating care; counselling; providing information and support; clarifying and reinforcing information; providing continuity of care; and facilitating specialist referral. Research shows they have been effective and beneficial in the ongoing care of the patient. In a project conducted by the National Breast Care Centre (Australia) among women with breast cancer, 80% of respondents believed specialist breast care nurses made a significant contribution to their care and 99% reported they would recommend seeking treatment at a centre that provides a breast care nurse.[55, 56]

Prostate cancer nurse roles are emerging in Australia and New Zealand but are less well-established than specialist breast care nurses. Specialist prostate cancer nurses are uniquely positioned to provide support and practical assistance to patients throughout various stages of their treatment. Emerging evidence suggests that prostate care nurses are seen as very acceptable sources of information and support for men with prostate cancer.

There is inequity of access to specialist prostate cancer nurses across the regions, with few New Zealand district health boards employing nurses in these roles. Emerging evidence shows that men with prostate cancer report that they rely strongly on their clinician for information and support in making treatment choices. It is possible that men who do not have access to specialised prostate cancer nurses have fewer opportunities to have information enhanced or clarified in a timely manner when they have received that information from their specialist or general practitioner, or from the internet. They may also receive less support as they navigate both the health system and their options.

A variety of models for providing cancer services to rural communities has been reported, including shared care or outreach programmes and tele-oncology. Studies suggest that such initiatives make specialist care more accessible. Studies have also demonstrated that where specialist cancer nurses provide education and support for patients in rural areas, there are benefits such as improved knowledge and psychosocial support.[57]

In response to the inequity of access to specialist nurses, a national telephone information service should be established. This service would be staffed by experienced prostate cancer nurses who have had appropriate educational preparation. It could operate in a similar way to the Prostate Cancer Charity (UK), where nurses take phone calls and respond to emails for a few hours in the middle of each day and also for two evenings per week. This service could be linked to the Prostate Cancer Foundation or the Cancer Society. Alternatively it could be one of the services available through the Ministry of Health's Healthline phone service. The nurses would need to have access to good-quality, written patient information to mail out to callers in response to enquiries and to support phone discussions. They would also work under strict guidelines and would not offer direct advice on treatment decisions.[58, 59]

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55 National Breast Cancer Centre. 2003. *Clinical Practice Guidelines for the Psychosocial Care of Adults with Cancer*. Camperdown, NSW: National Breast Cancer Centre and National Cancer Control Initiative.

56 Boxhall S, Dougherty M. 2001. The role of the prostate care nurse in an outpatient setting. Australian Prostate Cancer Collaboration Annual Meeting, Education Workshop, Sydney.

57 Lepore SJ, Helgeson VS. 1999. Psychosocial support group enhances quality of life after prostate cancer. *Cancer Research Therapy & Control* 8(1): 81–91.

58 Hack TF, Pickles T, Bultz BD, et al. 1999. Feasibility of an audiotape intervention for patients with cancer: a multicentre, randomised, controlled pilot study. *Journal of Psychosocial Oncology* 17(2): 1–15.

59 Mishel MH, Belyea M, Germino B, et al. 2002. Helping patients with localised prostate carcinoma manage uncertainty and treatment side effects: nurse-delivered psychoeducational intervention over the telephone. *Cancer* 96(6): 1854–66.

The Cancer Society employs liaison nurses who accept referrals in urban centres and visit patients and their families and whānau in their homes to offer education and support. These highly skilled nurses generally have a broad oncology preparation, but may not be well versed in the specifics of prostate cancer. These nurses, along with general practitioners, practice nurses and Prostate Cancer Foundation peer support volunteers, could direct patients to the prostate cancer nurses' helpline for expertise on prostate cancer.

Recommendation 22

A national telephone information service should be available. This would be staffed by experienced, educationally prepared prostate cancer nurses. The nurses would have access to good-quality, written patient information to mail out to callers in response to enquiries and to support phone discussions. The nurses would work under strict guidelines and would not offer direct treatment decision advice.

5 Diagnostic guidelines

Prostate cancer is diagnosed following histological examination of tissue specimens. This process may involve needle biopsy of the prostate performed specifically because clinical findings have indicated a likelihood of underlying prostate cancer; curettings following transurethral or open prostatectomy; and less commonly lymph node, bone or other tissue biopsy at the site of metastatic disease.

This discussion is restricted to core prostate biopsies obtained by either transrectal or transperineal sampling under ultrasound guidance (TRUS). The cancer detection rates of perineal prostate biopsies are comparable with those obtained for transrectal biopsies.[60, 61]

The decision on whether to proceed with prostate biopsy is made after considering patient preference, patient age, life expectancy, co-morbidity, abnormality on rectal examination, suspicion of malignancy on diagnostic imaging and abnormality of serum PSA. Occasionally PSA modifications may be taken into account as part of the decision-making process.

To help men decide whether to have a prostate biopsy, health care professionals should discuss with them their PSA level, DRE findings (including an estimate of prostate size) and co-morbidities. They should also discuss any risk factors, which include age and family history of prostate cancer. A man and his partner, family and whānau or carer should be given information, support and adequate time to decide whether or not he wishes to undergo prostate biopsy. The information should include an explanation of the risks (including the increased chance of having to live with the diagnosis of clinically insignificant prostate cancer) and benefits of prostate biopsy.

If the clinical suspicion of prostate cancer is high, because of a high PSA value and evidence of bone metastases (identified by a positive isotope bone scan or sclerotic metastases on plain radiographs), prostate biopsy for histological confirmation may not need to be performed.

5.1 PSA modifications

A number of modifications of the PSA test may influence the decision on whether to proceed with biopsy.

5.1.1 Free : total PSA ratio

PSA made by prostate cancer binds more easily to plasma proteins than PSA made by ‘normal’ prostates does. As a result, prostate cancer is more likely when the ratio is low (<0.25). The ratio is particularly useful when the PSA is in the 4.0–10.0 ng/mL range and there are other possible explanations such as BPH for the PSA elevation. Nevertheless, the concept must be used with caution as several pre-analytical and clinical factors may influence the ratio, such as instability of free PSA, variable assay characteristics and very large prostate size.[62]

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60 Hara R, Jo Y, Fujii T, et al. 2008. Optimal approach for prostate cancer detection as initial biopsy: prospective randomized study comparing transperineal versus transrectal systematic 12-core biopsy. *Urology* 71(2): 191–5.

61 Takenaka A, Hara R, Ishimura T, et al. 2008. A prospective randomized comparison of diagnostic efficiency between transperineal and transrectal 12-core prostate biopsy. *Prostate Cancer and Prostatic Diseases* 11: 134–8.

62 Stephan C, Lein M, Jung K, et al. 1997. The influence of prostate volume on the ratio of free to total prostate specific antigen in serum of patients with prostate carcinoma and benign prostate hyperplasia. *Cancer* 79(1): 104–9.

Furthermore, the ratio is of no clinical use in total serum PSA values >10 ng/mL or during follow-up of patients with known prostate cancer.

5.1.2 PSA velocity

PSA velocity is the change in PSA concentration over time. More rapid change makes prostate cancer more likely, and very rapid change means it is likely that the man has an aggressive form of cancer. This concept may have a prognostic role in patients with treated prostate cancer,[63] but can be of limited use in the diagnosis of prostate cancer because of background noise (total volume of prostate, BPH), the variations in interval between PSA determinations, and acceleration/deceleration of PSA velocity over time. While some prospective studies have shown that these measurements do not provide information additional to that provided by PSA alone,[64, 65, 66] the judicious use of PSA velocity can be of value in prostate cancer diagnosis.

5.1.3 PSA doubling time

PSA doubling time is the same as the PSA velocity, but puts a numerical value in months on the rate of change.

5.1.4 PSA density

PSA density compares the PSA concentration and the volume of the prostate (as measured by ultrasound).

5.1.5 Age adjusted reference ranges

Men with larger prostates tend to produce more PSA, and the upper limit of PSA 'normality' may need to be adjusted upwards in these men.

These modifications all increase the specificity of PSA testing (fewer biopsies performed) but also decrease the sensitivity (more cancers missed). There remains no consensus on optimal strategies for the use of these different modifications of PSA testing.

> ***Recommendation 23***
>
> The PSA modifications should be restricted in their use to those men in whom the decision on whether or not to biopsy is difficult, based on the grounds of either age or co-morbidity.

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63 Arlen PM, Bianco F, Dahut WL, et al. 2008. Prostate Specific Antigen Working Group guidelines on prostate specific antigen doubling time. *Journal of Urology* 179(6): 2181–5; discussion 2185–6.

64 Heidenreich A. 2008. Identification of high-risk prostate cancer: role of prostate-specific antigen, PSA doubling time, and PSA velocity. *European Urology* 54(5): 976–7; discussion 978–9.

65 Ramirez ML, Nelson EC, Devere White RW, et al. 2008. Current applications for prostate-specific antigen doubling time. *European Urology* 54(2): 291–300.

66 O'Brien MF, Cronin AM, Fearn PA, et al. 2009. Pretreatment prostate-specific antigen (PSA) velocity and doubling time are associated with outcome but neither improves prediction of outcome beyond pretreatment PSA alone in patients treated with radical prostatectomy. *Journal of Clinical Oncology* 27(22): 3591–7.

5.2 The decision to proceed with prostate biopsy

Men with an abnormal rectal examination, or a PSA of >4 ng/mL (≤70 years of age), or a PSA of ≥10 ng/mL (70–75 years) or a PSA of >20 ng/mL (76 years of age or older) should be considered for biopsy. The urologist's decision to biopsy will be modified on grounds of age and co-morbidity.[67] The decision to biopsy may be influenced further by use of other PSA modifications.

Recommendation 24

Men meeting the following criteria should be considered for prostate biopsy after taking into account clinical considerations, elimination of benign causes of high PSA, age, co-morbidity and patient choice:

- suspicion of malignancy on digital rectal examination
- men up to the age of 70 years with a PSA ≥4 ng/mL
- men between 71–75 years with a PSA ≥10 ng/mL
- men aged ≥76 years with a PSA ≥20 ng/mL
- a significant PSA rise in a man with previously low PSA values.

5.3 Biopsy technique

Prostate biopsy is usually performed under intravenous sedation, local anaesthetic or light general anaesthetic. Most commonly urologists use ultrasound guided transrectal biopsies, but occasionally the transperineal route is used. Prostate biopsies carry a risk of bleeding, which may be manifest as local extravasation, haematuria, haemospermia or (rarely) troublesome rectal bleeding. Aspirin does not need to be stopped prior to biopsy. Cessation of other agents should be judged based on harms and benefits of cessation for the man concerned. Any decision should be made in conjunction with the clinician responsible for the anticoagulation/ antiplatelet therapy. Prostate biopsies also carry a risk of infection, which may progress to systemic infection and rarely septicaemia with shock. It is therefore important that urologists employ appropriate measures to minimise these risks.[68, 69]

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[67] Roobol MJ, Steyerberg EW, Kranse R, et al. 2010. A risk-based strategy improves prostate-specific antigen driven detection of prostate cancer. *European Urology* 57(1): 79–85.

[68] Cuevas O, Oteo J, Lázaro E, et al. 2011. Significant ecological impact on the progression of fluoroquinolone resistance in Escherichia coli with increased community use of moxifloxacin, levofloxacin and amoxicillin/clavulanic acid. *Journal of Antimicrobial Chemotherapy* 66(3): 664–9.

[69] Loeb S, Carter HB, Berndt SI, et al. 2011. Complications after prostate biopsy: data from SEER-medicare. *Journal of Urology* 186(5): 1830–4.

On baseline prostate biopsies, the sample sites should be as far posterior and lateral as possible in the periphery of the gland. Additional cores should be obtained from suspect areas by DRE/TRUS. These should be chosen on an individual basis. 'Sextant' biopsy is no longer considered adequate. At a prostate gland volume of 30–40 mL, at least eight cores should be sampled. The British Prostate Testing for Cancer and Treatment Study has recommended 10 core biopsies.[70] More than 12 cores are not significantly more conclusive.[71]

[70] Donovan J, Hamdy F, Neal D, et al. 2003. Prostate Testing for Cancer and Treatment (ProtecT) feasibility study. *Health Technology Assessment* 7(14): 1–88.

[71] Eichler K, Hempel S, Wilby J, et al. 2006. Diagnostic value of systematic biopsy methods in the investigation of prostate cancer: a systematic review. *Journal of Urology* 175(5): 1605–12.

6 Pathology reporting of prostate cancer biopsies

The pathology reporting of thin core biopsies of prostate is key to the diagnosis and outcome prediction of prostate cancer. In addition, information contained in the pathology report will be used in the treatment and follow-up of patients.

For prostate cancer, the ultimate diagnosis depends on detection of cancer in one or more thin core biopsies; however, the report should also contain data that will guide the urologist or oncologist in determining the appropriate treatment for individual patients. For this reason, it is imperative that reporting is uniform between different pathologists. To promote this uniformity, a variety of professional groups, including the College of American Pathologists and the Royal College of Pathologists (UK), has produced recommendations for specimen handling and reporting guidelines. Recently an international consortium was formed to produce international guidelines that incorporate published recommendations, which will also help to advance uniform reporting.

In New Zealand, reporting of the thin core biopsies is based on the Structured Reporting Protocol of the Royal College of Pathologists of Australasia developed in 2011.[72] This protocol defines compulsory reporting standards and also includes guidelines for the recording of additional details that are of potential prognostic importance.

Clinical standards include information relating to patient identification and the site(s) from which the biopsy or biopsies have been taken. These latter data are necessary for the accurate assessment of tumour spread, which permits formal staging of the tumour. Tumour stage is a measure of the extent of spread of the tumour and itself influences treatment, as it is a major marker of prognosis or tumour-related outcome. To facilitate this assessment, tissue from each site must be submitted in a separate container and the location from which the biopsy is taken must be recorded.[731]

Recommendation 25

Cores of tissue from each biopsy site are submitted in a separate specimen container and a record is made of the location from which the biopsy is taken.

For each thin core biopsy specimen, the findings must be recorded individually. The minimum data set is the presence or absence of tumour and, if present, the tumour type, extent of involvement of the core by tumour, the presence or absence of extraprostatic extension and the grade of the tumour. The extent of the tumour involvement of the core is measured as percentage of the total core length, while extraprostatic extension is identified by infiltration of the fat, which is usually present at the tip of the core beyond the outer contour of the prostatic tissue.

[72] Kench J, Clouston D, Delahunt B, et al. 2011. *Prostate Cancer (Core Biopsy) Structured Reporting Protocol.* 1st edition. Sydney: Royal College of Pathologists of Australasia.

[73] Eichler K, Hempel S, Wilby J, et al. 2006. Diagnostic value of systematic biopsy methods in the investigation of prostate cancer: a systematic review. *Journal of Urology* 175(5): 1605–12.

Recommendation 26

Findings are in structured (synoptic) format according to each biopsy site, with the minimum data set being the presence or absence of tumour, the tumour type, extent of involvement of the core by tumour, the presence or absence of extraprostatic extension and the grade of the tumour.

The grading of prostate cancer is based on a system developed by Donald Gleason in 1966.[74] Over the years this grading system has been revised and in 2005 a major modification was developed by consensus and accepted for international implementation by the International Society of Urological Pathology.[75] In this modified system, tumours are graded from 1 to 5 on the basis of increasing architectural disorganisation. It is acknowledged that grades 1 and 2 should not be reported in thin core biopsies and thus grade 3 tumours represent the lowest grade of tumour, which is considered to be well differentiated. Given that many prostate cancers contain more than one grading pattern, a Gleason score for each core is reported. A Gleason score is the sum of the most common grade (primary pattern) and the second most common grade (secondary pattern). As a consequence, Gleason scores range from 6 (tumours containing pattern 3 only, ie, 3+3=6) to 10 (tumours containing pattern 5 only, ie, 5+5=10).

Although the criteria for each of the grades in the modified grading system are well described in the literature, there are currently issues relating to interpretation of grading by individual pathologists. In particular, several studies have demonstrated that interobserver reproducibility varies considerably in the reporting of tumour grade. For general pathologists, reproducibility has been shown to range from weak[76] to moderate,[77] while for specialist urological pathologists it is either substantial[78] or good to excellent.[79] These findings imply that to achieve uniformity of grading among the pathology community, additional grading guidelines should be made available. This recommendation is supported by the observation that the provision of web-based images promotes uniformity of reporting and reduces interobserver variability between participating pathologists.[80]

Recommendation 27

A web-based tutorial programme is made available for routine use by pathologists.

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74 Gleason DF. 1966. Classification of prostatic carcinomas. *Cancer Chemotherapy Reports* 50: 125–8.

75 Epstein JI, Alhbrook WCJ, Amin MB, et al. 2005. The 2005 International Society of Urological Pathology (ISUP) consensus conference on Gleason grading of prostatic carcinoma. *American Journal of Surgical Pathology* 29: 1228–42.

76 Veloso SG, Lima MF, Smalles PG, et al. 2007. Interobserver agreement of Gleason score and modified Gleason score in needle and in surgical specimens of prostate cancer. *International Brazilian Journal of Urology* 33: 639–46.

77 Allsbrook WC Jr, Mangold KA, Johnson MH, et al. 2001. Interobserver reproducibility of Gleason grading of prostatic carcinoma: general pathologist. *Human Pathology* 32: 81–8.

78 Allsbrook WC Jr, Mangold KA, Johnson MH, et al. 2001. Interobserver reproducibility of Gleason grading of prostatic carcinomas: urologic pathologists. *Human Pathology* 32: 74–80.

79 Rodriguez-Urrego PA, Cronin AM, Al-Ahmadie HA, et al. 2011. Interobserver and intraobserver reproducibility in digital and routine microscopic assessment of prostate needle biopsies. *Human Pathology* 42: 68–74.

80 Egevad L. 2001. Reproducibility of Gleason grading of prostate cancer can be improved by the use of reference images. *Urology* 57: 291–5.

Another way to enhance uniformity of grading would be for an expert panel to regularly review a proportion of tumours reported over a defined timeframe. This panel should provide a regular report of its findings, which would include strategies to promote uniformity if significant variances in grading are detected.

Recommendation 28

In order to improve consistency and reduce interobserver variation, an expert panel of pathologists should be convened in order to provide regular review of a proportion of tumours reported over a defined timeframe by all pathologists involved in the diagnostic reporting of prostate cancer specimens.

7 Active surveillance

The introduction of PSA screening has increased the rate of diagnosis of small, localised, well-differentiated prostate cancer. There is a great difference between the incidence of prostate cancer, and cancer deaths from prostate cancer.[81] In Western Europe and the United States, prostate cancer is diagnosed in 15–20% of men during their lifetime, with a 3% lifetime risk of death.[82, 83] In New Zealand, where there is less PSA-based screening, prostate cancer is diagnosed in about 12% of men, with a 3% lifetime risk of death. This disparity between the incidence of prostate cancer and the death rate from prostate cancer suggests that many men with localised prostate cancer would not actually benefit from curative treatment.

Active surveillance is considered as a means of avoiding overtreatment in the subgroup of lower-risk prostate cancer patients, while leaving open the opportunity for cure if treatment becomes necessary. This method involves identifying those men who are at low risk of having life-threatening prostate cancer. Monitoring involves repeated clinical evaluation, PSA measurements and prostate biopsy. Curative therapy is recommended to those men in whom there is evidence of cancer progression indicating that the cancer may be a more significant threat to life than initially assessed.

[81] Boyle P, Ferlay J. 2005. Cancer incidence and mortality in Europe 2004. *Annals of Oncology* 16(3): 481–8.

[82] Jemal A, Siegel R, Ward E, et al. 2008. Cancer statistics, 2008. *CA: A Cancer Journal for Clinicians* 8(2): 71–96.

[83] Quinn M, Babb P. 2002. Patterns and trends in prostate cancer incidence, survival, prevalence and mortality. Part I: international comparisons. *BJU International* 90(2): 162–73.

Table 1: Clinical trials of active surveillance for organ-confined prostate cancer: inclusion criteria, EAU guidelines 2012[84]

Trial	N	Median age	Criteria
Dall'Era[85]	376	62	Gleason <3+3, PSAd <0,15 ng/dL, T <T2,<33% biopsies+, <50% cores
Van den Berg[86]	616	66	Gleason <3+3, PSA <10 ng/mL, PSAd <0,2 ng/dL, T<T2, <2 biopsies +
Van As[87]	326	67	Gleason <3+4, PSA <15 ng/mL, T <T2a,<50% biopsies +
Soloway[88]	230	64	Gleason =6, PSA <10 ng/dL, T <T2, <2 biopsies+, <20% cores +
Klotz[89]	453	70	Gleason =6, PSA <10 ng/dL (up to 1999: Gleason <3+4, PSA <15 ng/mL) <3 biopsies +, <50% each core
Tosoain[90]	633	66	Gleason <3+3, PSAd <0,15 ng/dL, T1, <2 biopsies+, <50% cores
Adamy[91]	238	64	Gleason <3+3, PSA <10 ng/mL, T <T2a, <3 biopsies+, <50% length

The most mature trial is that published by Klotz and co-workers. A total of 450 patients with localised prostate cancer (clinical stage T1c or T2a, PSA <10ng/mL, Gleason score ≤6) were enrolled. Patients aged >70 years may have had a Gleason score ≤7 (3+4). Initially 6 biopsies were performed, followed by the usual extended 12-core protocol during the study. At a median follow-up of 6.8 years, the 10-year overall survival was 68%. At 10 years, the disease-specific survival was 97.2%, with 62% of men still alive on active surveillance. Subsequently 30% of patients underwent radical treatment for the following reasons: 48% for a PSA doubling time of <3 years; 27% for Gleason score progression on repeat biopsies; and 10% because of patient preference.

All other similar studies have confirmed that in well-selected patients with low risk disease there was a very low rate of cancer progression and cancer-specific death. Generally one-third of men entering into active surveillance have subsequently required curative treatment.

The Göteborg study of prostate cancer screening showed a survival benefit to screening for prostate cancer even when 40% of the patients were initially managed by active surveillance. At the time that the results were analysed, 28% were still on active surveillance.

Randomised trials of active surveillance versus immediate curative treatment, such as the Surveillance Therapy Against Radical Treatment (START) trial, are in progress. Currently, however, they have a follow-up of less than 10 years.

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84 Heidenreich A, Bastian PJ, Bellmunt J, et al. 2012. *Guidelines on Prostate Cancer*. European Association of Urology.

85 Dall'Era MA, Konety BR, Cowan JE, et al. 2008. Active surveillance for the management of prostate cancer in a contemporary cohort. *Cancer* 112(12): 2664–70.

86 Van den Bergh RC, Roemeling S, Roobol MJ, et al. 2009. Outcomes of men with screen-detected prostate cancer eligible for active surveillance who were managed expectantly. *European Urology* 55(1): 1–8.

87 Van As NJ, Norman AR, Thomas K, et al. 2008. Predicting the probability of deferred radical treatment for localised prostate cancer managed by active surveillance. *European Urology* 54(6): 1297–305.

88 Soloway MS, Soloway CT, Eldefrawy A, et al. 2010. Careful selection and close monitoring of low-risk prostate cancer patients on active surveillance minimizes the need for treatment. *European Urology* 58(6): 831–5.

89 Klotz L, Zhang L, Lam A, et al. 2010. Clinical results of long-term follow-up of a large, active surveillance cohort with localized prostate cancer. *Journal of Clinical Oncology* 28 (1): 126–31.

90 Tosoian JJ, Trock BJ, Landis P, et al. 2011. Active surveillance program for prostate cancer: an update of the Johns Hopkins experience. *Journal of Clinical Oncology* 29(16): 2185–90.

91 Adamy A, Yee DS, Matsushita K, et al. 2011. Role of prostate specific antigen and immediate confirmatory biopsy in predicting progression during active surveillance for low risk prostate cancer. *Journal of Urology* 185(2): 477–82.

7.1 Eligibility

All men with newly diagnosed localised prostate cancer should be assigned a risk category reflecting the risk of disease recurrence and chance of prostate cancer death. This is based on the PSA level, clinical stage (assessed by digital rectal examination) and biopsy result (Gleason score). The categories are:

- very low risk: PSA <10 ng/mL and <3 biopsy cores +ve, <50% cancer in any core and PSA density <0.15 ng/mL/gm, Stages T1a, T1c, Gleason score =6
- low risk: PSA <10 ng/mL and Gleason score =6 and clinical stage T1–T2a
- intermediate risk: PSA 10–20 ng/mL or Gleason 7 or T2b–T2c
- high risk: PSA >20 ng/mL or Gleason score 8–10 or T3–T4.

Active surveillance is most suitable for the group of men with small-volume prostate cancer that is categorised as very low risk or low risk. Different studies have used different eligibility criteria for enrolment (see Table 1 above). Typically these patients have clinically confined prostate cancer (stage T1–T2), a Gleason score of 3+3, limited tumour volume (defined by a low number of involved cores and a low tumour length on each involved core) and PSA density less than 0.10–0.15 ng/mL. Epstein's criteria are commonly used, which include the above factors and where the core length involvement is restricted to less than 50% of the most involved core.

Where a patient is diagnosed with prostate cancer based on the results of prostate tissue obtained from a transurethral resection, a subsequent TRUS biopsy should be considered. The results would allow more accurate assessment of tumour volume and thus of the patient's eligibility for active surveillance.

Because of the need for care in selecting patients for active surveillance, some urologists prefer to carry out initial imaging, usually with MRI scan of the prostate, to endeavour to back up clinical staging, which is otherwise dependent on subjective rectal examination findings. Such imaging may provide a useful baseline for future reference. However, there is no evidence to date that including this step improves outcomes.

Conducting a second TRUS biopsy within 12 months, usually 3–6 months, after initial diagnosis is an important part of the selection process to increase the reliability of the histological findings.[85, 91, 92]

Age should not be a contraindication for active surveillance. Younger men with prostate cancer have much to gain from the method, especially in terms of sexual function and fertility, compared with alternatives. In addition, the recent wide acceptance of active surveillance in the medical and general communities helps to make PSA and rectal examination testing more acceptable to men and general practitioners because they know low risk disease will be appropriately managed.

[92] Al Otaibi M, Ross P, Fahmy N, et al. 2008. Role of repeated biopsy of the prostate in predicting disease progression in patients with prostate cancer on active surveillance. *Cancer* 113(2): 286–92.

7.2 Clinical monitoring methods

All the elements in an ideal regimen for active surveillance have not been defined but they should include periodic physical examination, regular PSA testing and rectal examination. An early repeated biopsy (within 12 months of the initial biopsy) is an important part of the surveillance process because of the risk of under-detection of Gleason grade 4 disease. Usually prostate biopsies are repeated when there is suspicion of progression based on changes observed from PSA and rectal examinations. Some protocols advocate regular biopsies, from annually to once every three years.

Typically PSA and rectal examinations are carried out six monthly, but three-monthly intervals may be required where there is concern about the disease progressing more rapidly. If baseline imaging such as MRI was performed then follow-up studies may be useful, although evidence for that is currently lacking.

Monitoring during active surveillance must be meticulous. It is especially important in younger men with a long life expectancy where there is a greater opportunity for cancer progression than there is for older men with short life expectancy.

7.3 Indications for treatment

Trigger points for intervention are based on PSA change, repeat prostate biopsy results, clinical findings and patient request. Treatment should be recommended in men who demonstrate a Gleason grade of 4 or 5 on repeat biopsy, or cancer in a greater number of prostate biopsies or greater extent of prostate biopsies. Usually these histological changes are the reason for giving clinical advice to consider treatment.

PSA doubling times of less than two to four years have been used as an indication to intervene. The use of PSA doubling time has more recently been questioned because of a weak link between PSA doubling time and grade progression on repeated biopsy.[93] In addition, there is concern about the recent report from Klotz and his co-workers of a 50% failure to cure rate based on PSA results in their group of men requiring curative treatment after going on to active surveillance.[89] The researchers use a PSA doubling time of less than three years as an indicator for treatment, tolerating greater PSA doubling times. A more conservative view is to regard any significant rise in PSA as suspicious and an indication for repeat biopsy, rather than tolerate an increase based on a doubling time calculation, which is difficult and arguably inconsistent.

The decision to proceed to curative therapy needs to be made in light of the man's personal preferences, co-morbidities and life expectancy.[94]

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[93] Ross AE, Loeb S, Landis P, et al. 2010. Prostate-specific antigen kinetics during follow-up are an unreliable trigger for intervention in a prostate cancer surveillance program. *Journal of Clinical Oncology* 28(17): 2810–6.

[94] Steineck G, Helgesen F, Adolfsson J, et al. 2002. Scandinavian Prostatic Cancer Group Study Number 4. Quality of life after radical prostatectomy or watchful waiting. *New England Journal of Medicine* 347(11): 790–6.

Recommendation 29

The most suitable patients for active surveillance are those with low volume T1a or T1c, Gleason score =6 and PSA≤10. T1b and T2a tumours may be considered for active surveillance with caution. Careful monitoring of men in an active surveillance programme is essential.

- All men diagnosed with localised prostate cancer and considering active surveillance should be offered the chance to discuss their options with both a urologist and a radiation oncologist, and most should consult with both specialists.
- Monitoring during active surveillance must be meticulous and include regular PSA monitoring, DRE and an early repeat biopsy within 12 months of initial biopsy and further repeat biopsies as clinically indicated.
- All patients diagnosed with localised prostate cancer should be appropriately informed about active surveillance as a treatment option.
- Men entering an active surveillance programme as a cancer treatment option need to be tracked in the general practice IT system. This should reflect a care plan agreed between the specialist, patient and general practitioner.

For men younger than 60 years, a more conservative approach may be warranted by using the more restrictive Epstein criteria of involvement: less than one-third of cores, and no more than 50% involvement of individual cores.

Ultimately a recommendation for active surveillance must be based on careful, individualised weighing of a number of factors: life expectancy, disease characteristics, general health condition, potential side effects of treatment, and patient preference.

8 Watchful waiting

Men who choose not to undergo immediate therapy may opt for continued follow-up under a programme of watchful waiting rather than active surveillance.

Watchful waiting is based on the premise that some patients will not benefit from definitive treatment of the primary prostate cancer. The decision is made at the outset to forgo definitive treatment and to instead provide palliative treatment for local or metastatic progression if and when it occurs.

This option is most suitable for older men, and men with significant co-morbidities and life expectancy of less than 10 years.

Options for local palliation could include transurethral resection of the prostate or other procedures for the management of urinary tract obstruction, and hormonal therapy or radiotherapy for palliation of metastatic lesions.

9 Curative treatments

Prostate cancer has a wide range of clinical presentations. The tumour varies in its extent and aggressiveness, and the patients vary from the very young and fit to the elderly and those with significant co-morbidities and limited life expectancy.

Management options include active surveillance, and radical treatment with curative intent. The radical options are surgery and several different types of radiation therapy. Androgen deprivation therapy may also be used in conjunction with these treatments in patients at higher risk of recurrence. Other treatment methods include hi-intensity focused ultrasound (HIFU) and cryotherapy (freezing) but these are early in development, still investigational and not widely used. Patients with significant co-morbidities or wanting only a very conservative, non-curative approach to their localised cancer can be managed with wait and watch or androgen suppression.

The principal aim of treatment is to achieve cure by removing or destroying the prostate cancer before it spreads. A further aim in those with occult metastatic disease is to achieve better local control and prevent symptoms related to bladder outflow obstruction, ureteric obstruction, bleeding and local advancement into the pelvis including the rectum and bony pelvis.

Usually these radical and potentially curative treatments are only used where there is good evidence that the cancer is still localised to the prostate gland and there is no evidence of metastases. Information to support the diagnosis of localised disease comes from various tests. These include the specialists' clinical examinations, particularly the rectal examination; the transrectal ultrasound scan biopsy findings; and information gained from imaging which may include CT or MRI and/or isotope bone scanning. Exceptions include some high-dose radiation therapy methods which can offer a chance of cure when there is some nearby early local spread, and some situations where men have known distant spread to other parts of the body but there is concern that the local cancer in the prostate poses a significant threat to quality of life. In this setting, radiation therapy is the usual mode of treatment. There are some highly selected situations carrying a significant risk of metastases where surgery may be considered, usually in the context of multi-modal treatment.

All men diagnosed with prostate cancer and at significant risk of metastatic disease should have timely access to appropriate staging investigations, as outlined in Table 2.

Table 2: Investigation of metastatic disease

Type of investigation	Indications
Bone scan for skeletal metastases	Stage T1 and PSA >20 ng/mL or Stage T2 and PSA >10 ng/mL or Gleason >8 or Stage T3, T4 or Symptomatic with bone pain
Pelvic CT or MRI for nodal metastases	Stage T3, T4 or Stage T1, T2 if probability of nadal involvement is >10–20%

Local staging with MRI (preferably multi-parametric) should be considered where site and extent of prostatic disease and the presence or absence of extracapsular spread and seminal vesicle involvement would modify treatment. For example, they might affect radiation therapy treatment volumes and an assessment of the patient's suitability for brachytherapy.

Recommendation 30

Men at significant risk of metastases and those with locally advanced disease should be considered for appropriate staging investigations.

After diagnosis and staging tests, if appropriate, it is possible to determine the likelihood of recurrence after treatment and to assign the patient to a 'risk group' on this basis. The recognised risk groups for recurrence range from very low risk to very high risk. These groups are helpful in determining the likely suitable management approaches and likely outcome. Within each risk group a number of treatment options may be reasonable depending on a man's particular situation including urinary, bowel and sexual function as well as any significant medical co-morbidities. The intermediate risk group includes tumours with a wide range of tumour bulk and significant difference in outcome. It can be subdivided into 'favourable' and 'unfavourable' intermediate risk. This gives a useful guide as to those men that may be suitable for LDR I-125 seed brachytherapy ('favourable') and those that may benefit from neo-adjuvant hormone treatment and/or dose escalation with combined external beam and HDR brachytherapy ('unfavourable'). These risk groups and options are listed in Table 3, as adapted from the National Comprehensive Cancer Network (2012) Guidelines Version 3.

In general, there is no clearly established cancer survival benefit for any of the options listed in the various risk groups. Therefore, once suitable treatment options have been established a man should choose his treatment based on his preference for type of treatment. His options may include surgical versus non-surgical or minimally invasive treatment, and the decision will take into account his view of the acceptability of any side effects that may be associated with a particular treatment.

Recommendation 31

All men diagnosed with localised prostate cancer should be assigned a 'risk category' to help assess appropriate management options.

Table 3: Risk of recurrence groups and treatment options[95]

	Risk of recurrence group	Criteria	Recommended management options
1.	Very low risk	Stages T1a, T1c, Gleason =6, PSA <10 ng/mL **and** <3 biopsy cores +ve, <50% cancer in any core **and** PSA density <0.15 ng/mL/gm	Generally active surveillance Consider radical treatment if young or wanting active approach Consider watch and wait if significant co-morbidity or >75 years or wanting conservative approach
2.	Low risk	Stage T1a, T1c, T2a, Gleason =6, PSA <10 ng/mL	**Either** radical treatment **or** active surveillance depending on age and desire for active or conservative approach
3a.	Favourable intermediate risk	Stage T1b, T1c – T2a, PSA <10 **and** Gleason 3+4=7, <50% cores involved **or** Stage T1b, T1c–T2a, Gleason =6 **and** PSA 10–15, <50% cores involved	Generally radical treatment Consider watch and wait if significant co-morbidity or >75 years and wanting conservative approach
3b.	Unfavourable intermediate risk	T2b–T2c Gleason =6 **or** Gleason 4+3 =7 **or** Gleason 3+4 =7 >50% cores involved **and** PSA 10–15, <50% cores involved	Generally radical treatment Consider watch and wait or androgen suppression if significant co-morbidity or >75 years and wanting conservative approach
4.	High risk	**Either** Stage T3a or Gleason 8–10 or PSA >20 ng/mL **or** two or more of risk factors: Stage T2b–T2c, Gleason 7, PSA 10–20	**Either** radical treatment **or** androgen suppression if significant co-morbidity or >75 years or wanting conservative approach
5.	Very high risk at diagnosis	Stage cT3b–T4, or cN1, M0	**Either** radical treatment if younger, fitter and keen for active approach **or** androgen suppression if significant co-morbidity or >75 years or wanting conservative approach
6.	Very high risk after radical prostatectomy ± pelvic node dissection	Stage pT3–T4, or pN1	**Either** radical treatment with external beam radiation treatment if younger, fitter and keen for active approach **or** androgen suppression if significant co-morbidity or wanting conservative approach

Radical treatment such as surgery or radiation treatment should only be applied after adequate consideration and discussion between the man, involved specialists and, where appropriate, the general practitioner. Discussion should include the method of treatment, its advantages, disadvantages and potential complications, and other practical alternatives. The discussion should especially include the option of active surveillance for suitable very low and low risk cancers. Generally the curative treatments are only used for cancers that are potentially threatening and not suitable for active surveillance. However, it is acknowledged that some men with very low and low risk cancers prefer to undergo curative treatment after adequate discussion of what is involved in active surveillance.

[95] Adapted from National Comprehensive Cancer Network. 2012. *Guidelines Version 3.*

All men diagnosed with localised prostate cancer should have the opportunity to discuss the options of management with both a urologist and a radiation oncologist, and most men should consult with both specialists. Such wide consultation ensures that men considering active surveillance have a good understanding of all the radical options before making a decision and are fully informed about their treatment options if they choose active surveillance and subsequently their cancer progresses and they need treatment.

> ***Recommendation 32***
>
> All men diagnosed with localised prostate cancer should be offered the opportunity to discuss their options with both a urologist and a radiation oncologist, and most should consult with both specialists.

9.1 Active surveillance

Active surveillance requires careful monitoring with PSA, DRE and repeat biopsies so men can proceed to treatment if the prostate cancer is becoming clinically significant and threatening. Active surveillance should be considered for very low risk and low risk cancers.

9.2 Radical prostatectomy

The surgical treatment of prostate cancer consists of radical prostatectomy, which involves removal of the entire prostate gland along with sufficient surrounding tissue to obtain a negative margin. This tissue may include the seminal vesicles. In men with localised prostate cancer and a life expectancy of more than 10 years, the goal of radical prostatectomy by any approach must be to eradicate disease while preserving continence and, whenever possible, potency. Options include open, laparoscopic and robotic-assisted laparoscopic radical prostatectomy.

Bilateral nerve-sparing should be considered in low risk and favourable patients but unilateral or non-nerve-sparing procedures are generally required for patients with locally advanced and high risk disease. Nerve-sparing techniques endeavouring to preserve erectile function should be considered when it appears cancer clearance will not be compromised.

These techniques appear to have similar cancer and functional outcomes. No evidence from long-term follow-up studies on these various options is currently available. Minimally invasive techniques may reduce blood loss, as well as the length of hospitalisation and convalescence. Theatre time is significantly longer and the cost is higher.

Important outcomes, especially urinary continence, erectile function and cancer clearance, are significantly better if radical prostatectomy is carried out by an experienced urologist who frequently performs this procedure. Men considering radical prostatectomy should be advised of this advantage.

Radical prostatectomy is most suitable for medically fit, younger patients. However, there is no age threshold and a patient should not be denied this procedure on the grounds of age alone.[96] Increasing co-morbidity greatly increases the risk of dying from causes that are not related to prostate cancer[97] and an estimation of life expectancy is paramount in counselling a patient about surgery.[98] In practice, it is uncommon for radical prostatectomy to be carried out for men older than 75 years.

Radical prostatectomy is most suitable for men with T1 or T2 prostate cancer and no evidence for metastases, who are fit for surgery, usually younger than 75 years and with more than 10 years of apparent life expectancy. Most will be low or intermediate risk.

It may be considered for men with T3 high risk prostate cancer, provided that they understand there is a substantial chance that supplementary radiation therapy will be required to increase the likelihood of cure.

Surgery should be considered for patients with significant obstructive symptoms as the surgery manages both the cancer and the obstruction. In patients with intermediate and particularly high risk disease, there is a significant risk of requiring adjuvant or salvage external beam radiation therapy. These patients should be aware of the potential need for that therapy in conjunction with the surgery. Patients with a significant risk of nodal disease (15–30% or higher) should be considered for extended pelvic lymph node dissection.

Recommendation 33

The option of radical prostatectomy should be considered for localised prostate cancer in men who are fit and have a good life expectancy.

- Radical prostatectomy is most suitable for men with low and intermediate risk tumours but can be considered in selected high-risk patients.
- Men considering radical prostatectomy should be informed about the options of open incisional, laparoscopic or robotic-assisted laparoscopic techniques.
- Men considering radical prostatectomy should be informed about active surveillance and radiation therapy alternatives and have the opportunity to consult appropriate specialists.

[96] Droz JP, Balducci L, Bolla M, et al. 2010. Background for the proposal of SIOG guidelines for the management of prostate cancer in senior adults. *Critical Reviews in Oncology/Hematology* 73(1): 68–91.

[97] Albertsen PC, Moore DF, Shih W, et al. 2011. Impact of comorbidity on survival among men with localized prostate cancer. *Journal of Clinical Oncology* 29(10): 1335–41.

[98] Walz J, Gallina A, Saad F, et al. 2007. A nomogram predicting 10-year life expectancy in candidates for radical prostatectomy or radiotherapy for prostate cancer. *Journal of Clinical Oncology* 25(24): 3576–81.

9.3 Radiation therapy

9.3.1 General

There are no randomised studies comparing radical prostatectomy with either external beam radiation therapy (EBRT) or brachytherapy for localised prostate cancer. However, the National Institutes of Health consensus in 1988[99] remains valid: external irradiation offers the same long-term survival results as surgery; moreover, EBRT provides a quality of life at least as good as that provided by surgery.[100]

Intensity modulated radiotherapy (IMRT) with image guided radiotherapy (IGRT) is the gold standard. All centres unable to offer this form of therapy should have a plan to introduce it as a routine for the definitive treatment of prostate cancer.

In addition to external irradiation, transperineal low-dose or high-dose rate brachytherapy is widely used. In localised and locally advanced prostate cancer, several randomised phase III trials have established the indications for the combination of external irradiation and androgen deprivation treatment (ADT). These trials have been conducted by radiation therapy scientific societies such as the Radiation Therapy Oncology Group, the European Organisation for Research and Treatment of Cancer, and the Trans Tasman Radiation Oncology Group.

Whatever the technique used, the choice of treatment (after the appropriate assessment of tumour extension) must be based on a multidisciplinary approach. In addition, it should consider:

- 2009 TNM classification
- Gleason score defined on a sufficient number of core biopsies (at least 12)
- baseline PSA
- age of the patient
- patient's co-morbidity, life expectancy and quality of life
- International Prostate Symptom Score (IPSS) and uroflowmetry recordings
- National Comprehensive Cancer Network (NCCN) and prognostic class in D'Amico's prognostic factor classification.

It is essential to obtain a patient's informed consent after providing him with full information regarding diagnosis, therapeutic modalities and morbidity.

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[99] National Institutes of Health Consensus Development Panel. 1988. Consensus statement: the management of clinically localized prostate cancer. *JNCI Monographs* (7): 3–6.

[100] Fowler FJ, Barry MJ, Lu-Yao G, et al. 1996. Outcomes of external beam radiation therapy for prostate cancer: a study of Medicare beneficiaries in three surveillance epidemiology and end results areas. *Journal of Clinical Oncology* 14(8): 2258–65.

9.3.2 External beam radiation therapy

Consensus guidelines for definitive external beam were published by the Australian and New Zealand Faculty of Radiation Oncology Genito-Urinary Group in 2010.[101] This document covers the role of image guidance, prescribed dose and reporting, treatment planning, target delineation, treatment margins and critical structure delineation and dose constraints.

Patients should have moderately good urinary function; those with significant obstructive urinary symptoms despite treatment with alpha-blockers should be considered for transurethral prostatectomy prior to treatment. Treatment should be IMRT (including intensity modulated arc therapy) with daily image guidance (IGRT) with gold seed fiducial markers or other methods such as cone beam CT, ultrasound based systems and implantable transponders. The recommended dose is ≥74 Gy for those in the low risk group. Dose escalation in intermediate and high risk groups improves relapse-free survival and >74 Gy and preferably 78 Gy is recommended in these patients, particularly if they are not receiving neo-adjuvant androgen deprivation.

Patients with bulky, high-volume and locally advanced (Stage ≥T2b) cancers are recommended to have six months of neo-adjuvant androgen deprivation therapy which improves local control and reduces the chance of future metastatic recurrence. Patients at high risk of occult metastatic disease should consider ongoing adjuvant androgen deprivation for up to three years depending on risk and tolerance. Those with significant risk of nodal involvement (>15%) can be considered for pelvic irradiation. This should preferably be with 3D-CRT with IMRT or VMAT.

> ***Recommendation 34***
>
> Radiation treatment should be with contemporary techniques of IMRT with daily image guidance (IGRT).

Patients with known pelvic node involvement or at high risk of this (>15%) can be considered for inclusion of the pelvic nodes along with the prostate and in conjunction with long-term androgen deprivation.

External beam radiation therapy is not a suitable option for patients with inflammatory bowel disease such as ulcerative colitis and Crohn's disease because of the high risk of serious, ongoing bowel problems. Anticoagulants (other than aspirin) are a relative contraindication because of the potential problems with excessive bleeding from radiation proctitis or cystitis.

[101] Hayden A, Martin J, Kneebone A, et al. 2010. Australian & New Zealand Faculty of Radiation Oncology Genito-Urinary Group: 2010 consensus guidelines for definitive external beam radiotherapy for prostate carcinoma. *Journal of Medical Imaging and Radiation Oncology* 54: 513–25.

9.3.3 Transperineal brachytherapy – low dose rate

Transperineal permanent brachytherapy is a safe and effective technique. It is highly convenient for men and their families and whānau because it can be performed as a day case or 24-hour hospital stay procedure.

Low dose rate (LDR) brachytherapy (seed implantation) is most suitable for patients with good urinary function, a prostate size of less than 50–60 cm^3 and low risk cancer. Patients with obstructive urinary symptoms may become suitable after limited transurethral prostatectomy or bladder neck incision but may have an increased risk of long-term urinary side effects. Patients with large prostates may be suitable for implantation after a three-month period of androgen deprivation if this has reduced prostate size sufficiently.

In the intermediate risk group the most suitable patients for low dose rate brachytherapy are those with <30–50% positive biopsies, no perineural invasion and Gleason 3+4 =7 disease.

Anticoagulation is not a contraindication to treatment (although it should be temporarily stopped prior to implant). Men with inflammatory bowel disease may undergo treatment as the risk of proctitis is less than with external beam radiation therapy.

9.3.4 External beam and temporary high dose rate brachytherapy

External beam and temporary high dose rate (HDR) brachytherapy is a combined treatment that delivers higher dose than external beam radiation therapy alone. It is most suitable for 'unfavourable' intermediate risk patients with >50% positive biopsies, Gleason 3+4=7, extensive perineural invasion and locally advanced bulky cancers.

The treatment is most suitable for patients with good urinary function and with prostate size less than 50 cm^3. Patients with large glands may become suitable after three months of androgen deprivation treatment if this has reduced prostate size sufficiently.

Being on anticoagulation is a contraindication because of the potential problems with excessive bleeding at time of implantation as the brachytherapy needles extend into the bladder. Patients with locally advanced disease and high risk disease should consider neo-adjuvant and adjuvant androgen deprivation, as for external beam radiation therapy (see section 9.3.2).

The benefits of neo-adjuvant treatment have not been as clearly established as for external beam alone. They may be less important given the high doses delivered with the combined external beam and temporary brachytherapy. This may make the combined treatment a suitable option for men without high risk of metastatic disease who wish to avoid androgen deprivation.

Patients with known pelvic node involvement or who are at high risk of this (>15%) can be considered for inclusion of the pelvic nodes along with the external beam treatment of the prostate and in conjunction with long-term androgen deprivation.

9.3.5 Guidelines summary for definitive radiation therapy

1. In localised prostate cancer (T1c–T2c N0 M0), external beam radiation therapy is a suitable option, including for young patients who decline or are not suitable for surgical intervention. Treatment should be image guided with IMRT. Dose should be ≥74 Gy at 2 Gy /fraction.

2. In patients with low risk disease (T1c, 2a, Gleason <6, and PSA <10 ng/mL) and favourable* intermediate risk disease, permanent transperineal low dose rate brachytherapy should also be considered as an alternative to EBRT. This treatment option is most suitable for patients with good urinary function, no previous transurethral prostatectomy and prostate size <60 cc and with no pubic arch interference. (* Men with Gleason 3+4=7 or Gleason 3+3=6 and PSA 10–20 ng/mL with preferably <50% of the biopsy cores positive.)

3. In bulky, unfavourable, intermediate risk and locally advanced prostate cancer (T3–4 N0 M0), neoadjuvant and concomitant androgen derivation treatment in conjunction with external beam radiation therapy improves overall survival. EBRT should start five months after commencing ADT. Optimal duration for ADT is uncertain but in those at high risk of occult metastatic disease, a longer duration may add further benefit and can be considered for up to a total of two to three years, especially if well tolerated.

4. In high risk patients (PSA >20, or Gl >8, or T >3 or 2: PSA 10–20 or T2b, or Gl 7), long-term ADT prior to, during and after EBRT is recommended as it increases overall survival. EBRT should start five months after beginning ADT. Optimal duration for ADT is uncertain but can be considered for up to three years if tolerated well.

5. In locally advanced and high risk prostate cancer, dose escalation >74 Gy and up to 78 Gy in 2 Gy/fraction is preferred and improves local control and biochemical relapse-free survival whether or not neo-adjuvant ADT is used. Combined short course EBRT (45–50 Gy at 1.8 to 2 Gy/fraction) and brachytherapy (eg, temporary high dose rate prostate implant) is a well-established alternative option for dose escalation. In contrast to EBRT alone, the role of neo-adjuvant ADT is not well-established with combined external beam radiation and brachytherapy treatment combined external radiation, and brachytherapy without ADT can be considered in men who want to avoid ADT. Temporary transperineal HDR brachytherapy is most suitable in men with good urinary function who do not have a large prostate.

6. In very high risk prostate cancer (c-pN1M0) and with no severe co-morbidity, it is recommended that pelvic irradiation including the pelvic nodes and immediate long-term ADT (>1 year) be considered as it may improve biochemical control, metastatic failure, disease specific and overall survival.

7. In patients with pathological tumour stage T3 N0 M0 and/or positive surgical margins, immediate post-operative adjuvant radiation therapy after radical prostatectomy improves long-term biochemical, clinical disease-free and overall survival.

8. In patients with pathological tumour stage T 2–3 N0 M0 and/or positive surgical margins with persisting or rising PSA >0.2 ng/mL, salvage radiation therapy improves relapse-free survival. Outcomes are better when treated before PSA level rises above 0.5 ng/mL.

Recommendation 35

All the appropriate radiation treatments, including external beam, low dose rate and high dose rate brachytherapy, should be discussed with men considering curative treatment.

9.4 Quality of life of patients with localised prostate cancer

The increase in life expectancy of patients with localised prostate cancer has made the quality of life after treatment a key issue for prostate cancer survivors. The term 'health-related quality of life' (HRQoL) is typically used.[102, 103, 104, 105] HRQoL is a patient-centred outcome which is rated by the patient himself, particularly as physicians often underestimate the impact of disease and treatment on their patients' lives.[106]

In prostate cancer, HRQoL is usually divided into prostate cancer-specific and prostate cancer-general issues. Prostate cancer-specific HRQoL refers to the disease-specific outcome of prostate cancer, including urinary, bowel and sexual functioning. Prostate cancer-general HRQoL refers to generic issues of wellbeing, including physical, social, emotional and cognitive functioning, vitality/fatigue, pain, general health status, global quality of life and life satisfaction.[107] HRQoL is measured using standardised questionnaires, which collect patient-centric data and provide an objective assessment and perception of both generic and disease-specific domains. Several comprehensive HRQoL questionnaires have been validated and used to measure early stage prostate cancer outcomes.

Various forms of therapy have different impacts on HRQoL. A comparison of the most common contemporary therapies for localised prostate cancer (radical prostatectomy, brachytherapy, external beam radiation therapy and active surveillance) is necessary to inform patients about treatment options and to address individual patient preferences for the various possible outcomes. There are still very few objective data about HRQoL for prostate cancer treatment, mainly because of a lack of prospective trials.

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102 Leplège A, Hunt S. 1997. The problem of quality of life in medicine. *Journal of the American Medical Association* 278(1): 47–50.

103 Osoba D. 1993. Self-rating symptom checklists: a simple method for recording and evaluating symptom control in oncology. *Cancer Treatment Reviews* 19 Suppl A: 43–51.

104 Patrick DL, Erickson P. 1993. Assessing health-related quality of life for clinical decision-making. In: SR Walker, RM Rosser (eds) *Quality of Life Assessment: Key issues in the 1990s*. Boston: Dordrecht Kluwer.

105 Schumacher M, Olschewski M, Schulgen G. 1991. Assessment of quality of life in clinical trials. *Statistics in Medicine* 10(12): 1915–30.

106 Litwin M, Lubeck D, Henning J, et al. 1998. Differences in urologist and patient assessments of health related quality of life in men with prostate cancer: results of the CaPSURE database. *Journal of Urology* 159(6): 1988–92.

107 Eton DT, Lepore SJ. 2002. Prostate cancer and health-related quality of life: a review of the literature. *Psychooncology* 11(4): 307–26.

9.4.1 Active surveillance

Although active surveillance avoids treatment-related side effects, it carries an increased risk of psychological distress, which can have significant effects on the patient's HRQoL. There are certain risk factors for patients who may not do well on active surveillance. These factors include the patient's perception that the physician is making most of the decisions, a poor physical health score, a high neuroticism (anxiety) score and a high PSA value. All these factors were found to have significant positive associations with lower HRQoL scores in multivariate analysis.[108] Anxiety and distress did not increase and remained low during the first nine months of surveillance in men enrolled in the active surveillance PRIAS study.[109, 110]

9.4.2 Radical prostatectomy

Several trials have shown that radical prostatectomy has a significant negative effect on multiple QoL domains. Side effects identified include a lower sexual function score, lower urinary function and incontinence scores, and a lower physical HRQoL.[111, 112]

Certain advances, such as nerve-sparing radical prostatectomy or robotic-assisted radical prostatectomy, have helped diminish these side effects. However, their impact on HRQoL remains controversial.

9.4.3 External-beam radiation therapy and low dose rate brachytherapy

Patients undergoing EBRT and I125 LDR brachytherapy may have urinary, sexual and bowel dysfunction after treatment. Both methods can result in irritative voiding symptoms, such as urgency, frequency and urge incontinence, that negatively affect overall urinary function and HRQoL. The most predominant severe acute toxicity after LDR brachytherapy is urinary retention requiring catheterisation.[113]

It has been shown that both EBRT and LDR brachytherapy had a significant impact on the bowel and rectal HRQoL domains. Bowel/rectal problems appeared to have an overall impact close to that of the urinary domain.[114] The onset of symptoms occurred during or early after treatment, and sometimes persisted longer into follow-up.

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[108] Van den Bergh RC, Essink-Bot ML, Roobol MJ, et al. 2009. Anxiety and distress during active surveillance for early prostate cancer. *Cancer* 115(17): 3868–78.

[109] Van den Bergh RC, Essink-Bot ML, Roobol MJ, et al. 2010. Do anxiety and distress increase during active surveillance for low risk prostate cancer? *Journal of Urology* 183(5): 1786–91.

[110] Sanda MG, Dunn RL, Michalski J, et al. 2008. Quality of life and satisfaction with outcome among prostate cancer survivors. *New England Journal of Medicine* 358(12): 1250–61.

[111] Bellizzi KM, Latini DM, Cowan JE, et al. 2008. Fear of recurrence, symptom burden, and health-related quality of life in men with prostate cancer. *Urology* 72(6): 1269–73.

[112] Potosky AL, Legler J, Albertsen PC, et al. 2000. Health outcomes after prostatectomy or radiotherapy for prostate cancer: results from the Prostate Cancer Outcomes Study. *Journal of the National Cancer Institute* 92(19): 1582–92.

[113] Roeloffzen EM, Hinnen KA, Battermann JJ, et al. 2010. The impact of acute urinary retention after iodine-125 prostate brachytherapy on health-related quality of life. *International Journal of Radiation Oncology Biology Physics* 77(5): 1322–8.

[114] Madalinska JB, Essink-Bot ML, de Koning HJ, et al. 2001. Health-related quality-of-life effects of radical prostatectomy and primary radiotherapy for screen-detected or clinically diagnosed localized prostate cancer. *Journal of Clinical Oncology* 19(6): 1619–28.

Roeloffzen reported a statistically significant deterioration in HRQoL in patients treated with I125 LDR brachytherapy at six years for urinary symptoms, bowel symptoms, pain, physical functioning and sexual activity.[115] However, most of these changes were not clinically relevant.

9.4.4 Comparison of HRQoL between treatment modalities

The limitations of all published studies assessing QoL include the lack of randomisation to treatment and therefore the presence of selection bias, which may influence outcomes. Thus, information regarding comparative outcome relies largely on results from non-randomised observational cohorts. Treatment comparison requires a long follow-up, as measures of quality of life may change with time. There are very few trials investigating a direct comparison of different treatment modalities.

Most early studies addressing general HRQoL issues (general physical function, role function, social function, emotional wellbeing, body pain, general health, or vitality/energy) have found few differences across treatments for clinically localised disease.[116, 117] In more recent longitudinal studies, both surgery- and radiotherapy-treated men have reported some declines in role function and vitality/energy shortly after treatment, with surgically treated men reporting more dysfunction.[118, 119] However, most men recovered function by one year after treatment.

The presence of co-morbid psychiatric conditions (ie, prior psychiatric history, alcohol abuse, drug abuse) and the experience of pain after treatment were considered to be certain risk factors for poor general HRQoL in men after treatment for localised prostate cancer.[120]

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115 Roeloffzen EM, Lips IM, van Gellekom MP, et al. 2010. Health-related quality of life up to six years after (125) brachytherapy for early-stage prostate cancer. *International Journal of Radiation Oncology Biology Physics* 76(4): 1054–60.

116 Eton DT, Lepore SJ. 2002. Prostate cancer and health-related quality of life: a review of the literature. *Psychooncology* 11(4): 307–26.

117 Litwin MS, Hays RD, Fink A, et al. 1995. Quality-of-life outcomes in men treated for localized prostate cancer. *Journal of the American Medical Association* 273(2): 129–35.

118 Lubeck DP, Litwin MS, Henning JM, et al. 1999. Changes in health-related quality of life in the first year after treatment for prostate cancer: results from CaPSURE. *Urology* 53(1): 180–6.

119 Beard CJ, Propert KJ, Rieker PP, et al. 1997. Complications after treatment with external-beam irradiation in early-stage prostate cancer patients: a prospective multiinstitutional outcomes study. *Journal of Clinical Oncology* 15(1): 223–9.

120 Borghede G, Karlsson J, Sullivan M. 1997. Quality of life in patients with prostatic cancer: results from a Swedish population study. *Journal of Urology* 158(4): 1477–85; discussion 1486.

10 Metastatic prostate cancer

Prostate cancer is usually responsive to androgen deprivation therapy. ADT may involve bilateral orchiectomy (castration) or pharmacologic therapy using anti-androgens and (LHRH) analogues. These treatments can be used sequentially and in combination, and can often control metastatic prostate cancer for years. There is limited evidence on the optimal sequencing and combination of these treatments. In addition, new anti-androgens are being trialled in studies and are likely to be other useful treatments.

Chemotherapy, in particular docetaxel, also has an established role in castrate resistant symptomatic patients. Other drugs that are being developed are also likely to be available for use in the foreseeable future. Immunotherapy, with sipuleucel, is emerging as another valid option but is currently only available in the United States of America.

Bone metastasis is the most common site of systemic spread and generally occurs first. Palliative radiation treatment of symptomatic metastatic sites therefore has a major role in the management of these patients when progressing after systemic treatment.

Other bone treatments such as bisphosphonates and radioactive isotopes may help to prevent, delay or treat symptomatic bone metastases in some patients. However, the optimal way to integrate these various treatments remains to be clarified in ongoing and future studies.

Pelvic and abdominal node metastasis is the next most common site of metastatic involvement. Palliative radiation treatment may be helpful in preventing or relieving symptoms from these metastases. Other sites of metastases are much less common and often occur very late if at all in the disease.

Patients with metastatic prostate cancer often have a long time course of 5 to 10 years or more and there is the potential for prolonged suffering if symptom control is not addressed adequately. Bone pain is the most frequent symptom but unfortunately pain management can be difficult and is suboptimal for many patients.

Palliative, supportive and hospice cares are a very important part of the management of patients with metastatic prostate cancer and need to be integrated into the patient's care, especially when the patient is symptomatic and castrate resistant. In 2010 the Australian National Health and Medical Research Council issued *Clinical Practice Guidelines for the Management of Metastatic Prostate Cancer*.[121] Similar guidelines, applicable to clinical practice in New Zealand, could be developed and would assist general practitioners, oncologists, urologists and others in clinical decision-making and help optimise care for men with metastatic disease.

Recommendation 36

New Zealand Clinical Practice Guidelines are developed for metastatic prostate cancer.

[121] NHMRC. 2010. *Clinical Practice Guidelines for the Management of Metastatic Prostate Cancer*. Canberra: National Health and Medical Research Council.

The management of a man with metastatic prostate cancer is clearly a multidisciplinary task, involving the medical and nursing care from a number of different specialties such as general practice, urology, radiation and medical oncology, palliative care and hospice. An individual will receive the best care when these specialties work together as a cooperative, integrated team.

A guideline for the management of systemic disease is therefore different to the guidelines for management of early detection and management of localised disease that the current Taskforce is developing.

There are large inequities in the management of men with advanced and metastatic prostate cancer, including in access to systemic treatment as well as to palliative and hospice cares. These inequities need to be specifically addressed. Current research into Māori palliative care is essential to determine the burden of disease and the steps that need to be taken to address the inequities.

Recommendation 37

Research is undertaken to determine the burden of disease and reduce inequities in Māori men with metastatic prostate cancer.

Men with metastatic prostate cancer should have a comprehensive handout or reference to help them understand the natural history and treatment guidelines. It should also provide information on likely side effects and ways of minimising them, based on the clinical practice guidelines produced for New Zealand men. The Australia Cancer Network and Australia Prostate Cancer Collaboration produced a booklet, *Advanced Prostate Cancer: A guide for men and their families*, in 2009, which would provide an excellent basis for a similar New Zealand booklet. The New Zealand version would take into account any differences in practice and drugs and include Māori perspectives and issues specific to Māori.

11 Access to health services

It is essential that all men requiring assessment for possible prostate cancer and all men requiring investigation and treatment of a confirmed diagnosis of prostate cancer have timely access to high-quality health care. Achieving this level of access includes: having an acceptable wait time following general practice referral to prostate biopsy under specialist care; timely reporting on specimens by pathologists; informing men and their families and whānau of the diagnosis in a timely manner; and having acceptable wait times for treatment. These conditions apply to all of the treatment options, including active surveillance, surgery, radiation therapy and palliative care.

At present the Ministry of Health collects data on wait times for radiation treatment from first radiation oncology specialist assessment. Through the faster cancer treatment project, data will be collected on other wait times for those with a high suspicion of cancer but this may not be all patients with prostate cancer.

No national information on wait times for referral from general practice to urology is available. There are also no national data about wait times for referral between specialities such as from urologist to radiation oncologist.

Recommendation 38

Data must be collected on wait times for all men undergoing assessment for possible prostate cancer and those undergoing prostate cancer treatment through all stages of the cancer care pathway. These data must be analysed and reported according to ethnicity.

Apart from appropriate and timely access to primary and specialist health care, it is essential that men have access to the best-quality treatment. Measures to assist this access include providing hardware that meets international standards of care and includes equipment such as linear accelerators, and providing HDR brachytherapy and LDR brachytherapy.

Recommendation 39

A regional and national stocktake and review of data collected on prostate cancer diagnosis and management, including wait times, should be undertaken. This should include district health boards and private and public sector providers.

Recommendation 40

A national core prostate cancer data set should be developed and implemented to permit monitoring of a national quality plan. Quality indicators, which should include monitoring treatment pathway times, must be developed and implemented.

Appendix: Prostate Cancer Taskforce membership

Professor John Nacey (Chair) MB, ChB, MBA, MD, FRACS
Department of Surgery & Anaesthesia
University of Otago, Wellington

Associate Professor Chris Atkinson BSc, MB, ChB, Dip Ob, FRANZCR, FAChPM
St George's Cancer Care Centre
Christchurch

Keith Beck DipBusStud PGDipSci, TIPENZ, REA
Chief Executive Officer, Prostate Cancer Foundation
Dunedin

Ms Sue Osborne RCp N, BHSc, MN (Hons), NP
Department of Urology
Waitemata District Health Board
Auckland

Dr Nina Scott, Ngāti Whātua, Waikato
MB, ChB, DCCH, DCH, MPH, FNZCPHM
Te Puna Oranga, Māori Strategy Unit
Waikato District Health Board
Hamilton

Dr John McMenamin MB, ChB, MD FRNZCGP
Wicksteed Medical Centre
Wanganui

Dalton Kelly QSM
Chief Executive
Cancer Society of New Zealand
Wellington

Professor Brett Delahunt ONZM, KStJ, BSc (Hons), BMedSc, MB, ChB, MD, Dist FRCPA, FFSc (RCPA), FRCPath, AFNZIM, FRSNZ
Department of Pathology and Molecular Medicine
University of Otago
Wellington

Dr John H L Mathews MB, ChB, FRANZCR, FAChPM
Department of Radiation Oncology
Auckland Regional Cancer and Blood Service
Auckland

Professor David Lamb ONZM, MB, BS, FRCR, FRANZCR
Department of Pathology and Molecular Medicine
University of Otago
Wellington

Dr Rod Studd MB, ChB, FRACS
Department of Urology
Capital Coast Health
Wellington

Professor Ross Lawrenson MD, FRCGP, DRCOG, FFPH, FAFPHM
Head of Waikato Clinical School and Professor of Primary Care
The University of Auckland

Dr Jim Vause, MB, ChB, Dip GP, Dist FRNZGP
General Practitioner
Blenheim

Dr John Childs MB, ChB, FRACP, FRANZCR
Clinical Advisor Cancer Programme
Ministry of Health
Wellington

Dr Peter Davidson MB, ChB, FRACS
Department of Urology
Canterbury District Health Board
Christchurch

Dr Robin Smart MB, ChB, FRCS, FRCSEd, FRACS, FNZMA
Urologist
Auckland

Dr Ian Beer BSc, MB, ChB, FRCPA
Pathologist
Pathlab Waikato
Hamilton

Wi Keelan RPN, PG Dip Nursing
Chief Advisor Māori Health
Sector Capability & Innovation Directorate

Ministry of Health staff

Mhairi Porteous
Manager, Bowel Cancer Programme
Personal Health Service Improvement Group

Gill Slaughter BSocSc, GDipT
Advisor, Cancer, Personal Health Service Improvement Group

Emily Barrett
Senior Advisor, Communications
Personal Health Service Improvement Group

Lynette Drew
Senior Advisor Quality, Bowel Cancer Programme
Personal Health Service Improvement Group

Glossary of terms and abbreviations

active surveillance	active surveillance is a management option for prostate cancer which aims to avoid or delay treatment in men with low risk prostate cancer. Monitoring involves regular repeated clinical evaluation, PSA measurements and, if required, further prostate biopsies. Curative therapy is recommended to those men where there is evidence of cancer progression that may present a more significant threat than initially assessed
ADT	androgen derivation treatment (therapies that reduce or block action of testosterone on prostate cancer cells)
biopsy	removal of small pieces of tissue for examination under a microscope to determine the diagnosis and, if shown to be malignant (cancerous), to determine the tumour grade (degree of aggression)
BPH	benign prostatic hypertrophy (a non-cancerous enlargement of the prostate gland)
co-morbidity	two or more coexisting medical conditions or disease processes that are additional to an initial diagnosis
DRE	digital rectal examination
EBRT	external beam radiation therapy
equity/inequity	inequity has a moral and ethical dimension, resulting from avoidable and unjust differentials in health status. Equity is concerned with creating equal opportunities for health and with bringing health differentials down to the lowest possible level
ERSPC	European Randomised Screening for Prostate Cancer
evidence-based information	information that comes from the body of clinical studies from which the benefits and harms of diagnostic tests and treatments can be evaluated. The quality of evidence from those clinical studies can be evaluated according to the type of study as well as other factors including statistical validity, clinical relevance, currency and peer-review acceptance
Gleason score	a system of grading prostate cancer based on microscopic characteristics. Gleason scores range from 2 to 10 and indicate how likely it is that a tumour will spread. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumour is less likely to spread; a high Gleason score means the cancer tissue is very different from normal and the tumour is more likely to spread
HRQoL	health-related quality of life
IGRT	image guided radiotherapy
IMRT	intensity modulated radiotherapy
LDR	low dose rate
metastasis	the spread of cancer away from the place where it began

morbidity	disease, disorder, illness; incidence of ill health
mortality	a fatal outcome, death
prostate cancer care pathway	clinical/care pathways – also known as critical pathways, care paths, integrated care pathways, case management plans, clinical care pathways or care maps – are used to systematically plan and follow up a patient-focused care programme. A prostate cancer care pathway is a standardised algorithm of the best way to manage prostate cancer
PSA	prostate specific antigen. The higher the PSA level, the more likely it is that a cancer is present
TRUS	transrectal ultrasound
uroflowmetry	uroflowmetry is a test that measures the volume of urine released from the body, the speed with which it is released, and how long the release takes
watchful waiting	an option for cancer management that is based on the premise that some patients will not benefit from definitive, curative treatment of the primary prostate cancer. The decision is made at the outset to delay curative treatment and to instead provide treatment for progressive local or metastatic cancer. This treatment is less likely to be curative and will usually be palliative
whānau	a collective of people connected through a common ancestor (whakapapa) or as the result of a common purpose (kaupapa)
whānau ora	an inclusive interagency approach to providing health and social services to build the capacity of all New Zealand families in need. It empowers whānau as a whole rather than focusing separately on individual family members and their problems