

Prostate Cancer Active Surveillance Guidance

1. About this guidance

This guidance is for urologists and other health practitioners involved in the management of men with localised prostate cancer. It clarifies the roles of all health practitioners in active surveillance and aims to standardise care nationally so all New Zealand men experience the same quality of prostate cancer care. Greater consistency in the use of active surveillance can improve men's prostate cancer health outcomes.

The guidance recommends an evidence-based, best practice clinical pathway to support discussion and decision making between a man with localised prostate cancer and his doctor about when and how to use active surveillance as a management option.

The guidance has been developed by the specialist sub-group of the Prostate Cancer Working Group. This includes input from members of other sub-groups such as general practitioners and pathologists. The specialist sub-group includes urologists, radiation oncologists and nurse practitioners. The Working Group is overseeing the implementation of the Ministry of Health's *Prostate Cancer Awareness and Quality Improvement Programme*¹. The programme aims to raise awareness of prostate cancer, improve the quality of care, and improve outcomes through improved survival and reduced morbidity from advanced disease while also reducing the harms caused by over treatment.

2. Integrating this guidance into care pathways and practice

It is envisaged that care pathways will include this active surveillance document. Integrating the guidance into care systems and pathways will be managed by district health boards (DHBs) and primary health organisation (PHO) partnerships reflecting the needs of their patients and communities.

3. What is active surveillance?

Deferring the treatment of low risk, low volume prostate cancer in men with more than 10 years life expectancy, due to the low risk of disease progression and morbidity of treatment.

Sometimes referred to as active monitoring, active surveillance involves monitoring localised prostate cancer with regular prostate specific antigen (PSA) tests, examinations and biopsies with the intention of offering curative treatment if the cancer progresses.² It provides men and their doctor with an option to monitor and delay or avoid invasive treatment and the potential for treatment related harms. If the cancer progresses or the man changes his mind about remaining on active surveillance, he can proceed to treatment such as surgery or radiation therapy. Every man on active surveillance should have an agreed plan of care.

Active surveillance and watchful waiting are different. Watchful waiting is an alternative option for men with prostate cancer where there is no intention to cure, but subsequent symptoms may be treated. This is often used in older men with more medical co-morbidity.

4. Providing active surveillance – roles and responsibilities

It is recommended that active surveillance of men with prostate cancer is led by a urologist. In certain circumstances sharing aspects of patient care and monitoring with other health practitioners (such as doctors working in general practice and advanced practice nurses) may be required. This is particularly for men living in isolated or remote environments. This should be discussed and agreed on a case by case basis and be clearly defined in the man's active surveillance care plan. Where an aspect of care has been devolved to another health professional, regular contact with the lead urologist is required. The regular review of active surveillance plans by a urologist is a core requirement of active surveillance.

5. The rationale for active surveillance

PSA based prostate cancer screening results in the diagnosis of prostate cancer in many men who will have no progression of the disease during their lifetime.^{3,4,5,6} The use of curative treatments (radical prostatectomy, radiation therapy) therefore carries a risk of “overtreatment”. Traditionally, older men with limited life expectancy, asymptomatic men with advanced disease and those with low grade, small volume disease were regarded as appropriate for watchful waiting. This was essentially expectant management with intervention triggered by evidence of biochemical progression (based on serum PSA) or the development of metastatic disease.⁷ Active surveillance is different to watchful waiting and provides men and their doctor with an option to more closely monitor men with prostate cancer and delay or avoid invasive treatment. It is a recognised management option for men with localised, low risk, low volume prostate cancer and involves intense monitoring. This includes the requirement for repeat prostate biopsies in order to detect any increase in tumour grade. Higher grade tumours confer a higher likelihood of clinical progression and therefore provide the trigger for exiting active surveillance in favour of either radical prostatectomy or radiation therapy.^{8,9}

Globally, 20-30% of men diagnosed with the cancer will choose active surveillance as a management option rather than radical prostatectomy or radiation therapy.¹⁰ If New Zealand follows a similar trend then this means approximately 600-900 New Zealand men will annually choose active surveillance as the preferred primary treatment option.

It is essential that every man on active surveillance should have an agreed plan of care. If the prostate cancer progresses or the man changes his mind about remaining on active surveillance, he can proceed to either radical prostatectomy or radiotherapy.

6. The assignment of risk

Establishing the risk of prostate cancer progression is an essential part of determining which men are likely to benefit from active surveillance. This requires measurement of the serum PSA, accurate staging of the disease, and determination of Gleason grade. The role of the pathologist in distinguishing Gleason pattern 3 from Gleason pattern 4 is a critical part of the assessment and important consensus has now been reached on the histopathologic criteria to be used for reporting of biopsy specimens.¹¹ Men must be assigned a category of low, intermediate or high risk of disease progression according to the following criteria.

6.1 Prostate cancer is low risk when all of the following criteria are met:

- PSA < 10 ng/mL
- Gleason grade 3+3=6
- Tumour Stage ≤ T2

When low risk cancer is suspected from the PSA and Gleason grade, staging using a combination of clinical examination (digital rectal exam, DRE) and prostate MRI using T2 and diffusion-weighted imaging is appropriate. Technetium Tc99 bone scans or NaF/PET scanning are rarely indicated in the absence of clinical symptoms and should not be routinely employed.

6.2 Prostate cancer is intermediate risk when any of the following criteria are met:

- PSA 10-20 ng/mL
- Gleason grade 3+4 or 4+3
- Tumour stage ≥ T2

6.3 Prostate cancer is high risk when any of the following criteria are met:

- PSA ≥ 20
- Gleason grade 4+4 or higher
- Tumour stage ≥ T3

When intermediate/high risk cancer is suspected from the PSA and Gleason grade, staging using a combination of clinical examination (DRE) and pelvic MRI is appropriate. The MRI protocol should include T2 and diffusion-weighted imaging, nodal staging with an overview of the abdomen, spine and pelvis. Diffusion contrast enhancement (DCE) is optional. MR spectroscopy (MRS) is not required. Isotope bone scans or NaF/PET scanning is required. In very high risk men a CT scan of the chest and upper abdomen should be performed to assess for soft tissue disease, for example in the lung or liver.

7. Active Surveillance Guidance

7.1 Informed consent

It is essential that health practitioners obtain informed consent before a man enters into an active surveillance programme. Treatment and care should take into account individual needs and preferences.

All health practitioners have a duty, under the Code of Health and Disability Services Consumers' Rights Regulations 1996, to provide patients who enter an active surveillance programme with good, balanced information on prostate cancer and the possible benefits and harms of testing and treatment. When considering the options, men should be offered the opportunity to discuss radiation options with a Radiation Oncologist.

Best practice involves presenting the extent of the harms and benefits in a way that men and whānau can understand.

7.2 Entry Criteria

- The man makes an informed choice and has consented to active surveillance
- Histologic diagnosis Gleason 3+3
- low volume disease
- PSA < 10 ng/mL
- Clinical stage ≤ T2

All of the entry criteria must be matched for a man to be suitable for active surveillance. The clinical criteria for low volume disease vary, but can include ≤ 3 cores involved, ≤ 50 percent one core involved or ≤ 4 mm length positive histology in one core.

Cases outside these criteria should be discussed within a multi-disciplinary team environment before proceeding with an active surveillance plan. Active surveillance may be considered for select men with favourable, localised intermediate risk prostate cancer. Active surveillance should not be offered to men with high risk prostate cancer

7.3 Active Surveillance protocol

Timing	Requirements
Year 1	Measure PSA every 3 months DRE every 6 months Prostate biopsy at 12 months
Years 2 and every subsequent year	Measure PSA every 3–12 months +/- DRE Prostate biopsy every 2–4 years
Notes: PSA monitoring may be undertaken in primary care as part of a shared care management plan. Multi-parametric MRI should be considered prior to entry to active surveillance and before repeat prostate biopsy.	

7.4 Active Surveillance exit criteria

- Where life expectancy ≤ 10 years management should be changed to watchful waiting
- When criteria for entry to active surveillance are no longer met:
 - Repeat biopsy shows Gleason grade $> 3+3$
 - higher volume disease
 - PSA > 10 ng/ml
 - Clinical stage $> T2$

The clinical criteria for higher volume disease vary, but can include > 3 cores involved, > 50 percent one core involved or > 4 mm length positive histology in one core. It is anticipated 30 percent of men undergoing active surveillance plan will exit the surveillance plan and undergo treatment with curative intent. A man can decide to exit from their active surveillance plan, having decided it is no longer a preferred option. This typically occurs in the first two years of a plan commencing.¹²

8. Further information

Further information about prostate cancer, including the Ministry of Health Awareness and Quality Improvement Programme and information for men, their families and their whanau can be found on the Ministry's website www.health.govt.nz.

9. References

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