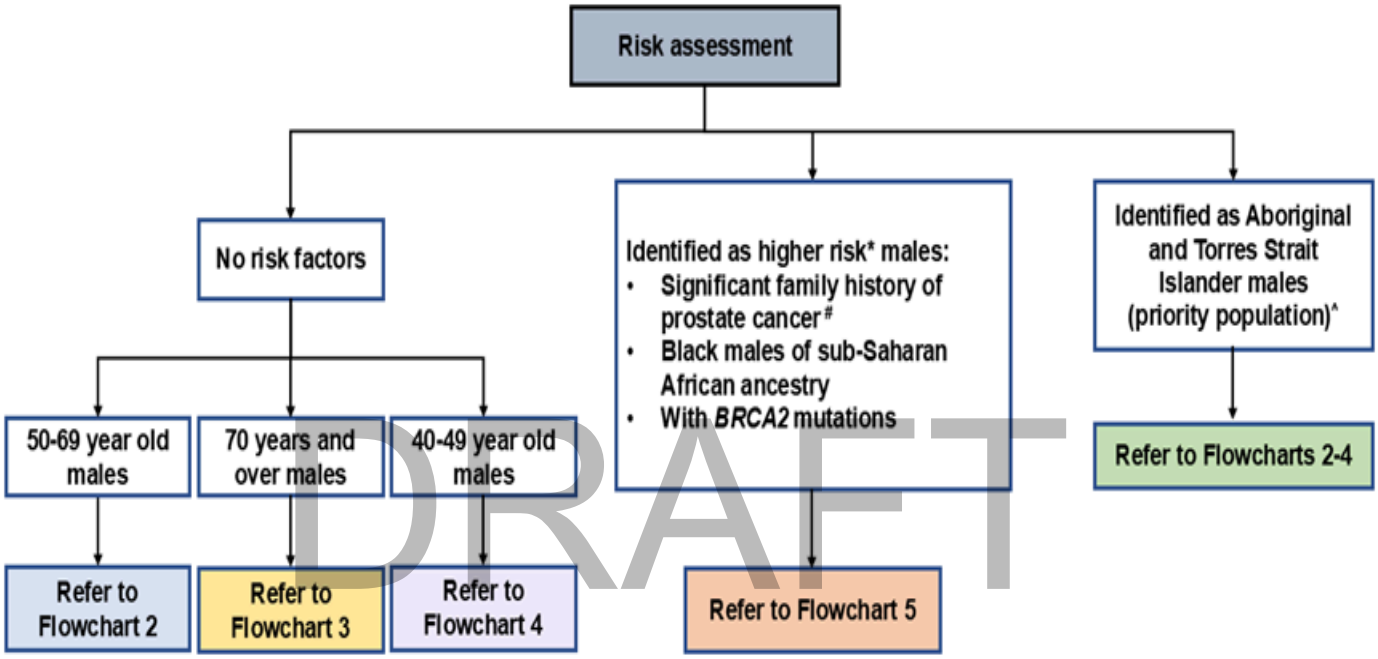
Summary of recommendations

Section A: Risk assessment

Risk assessment flowchart

Flowcharts reflecting the PSA testing recommendations have been developed to aid clinical decision making. Flowchart 1 describes risk assessment for the early detection of prostate cancer in Australia.

Flowchart 1: Risk assessment for the early detection of prostate cancer in Australia



* Higher risk includes but is not restricted to, males with a brother or father diagnosed with prostate cancer, or two second degree relatives diagnosed with prostate cancer, Black males of sub-Saharan African ancestry, and/or confirmed BRCA2 gene mutations (refer 1.1 Family history of prostate cancer). Familial syndromes such as hereditary breast and ovarian cancer and Lynch syndrome are also associated with increased risk of clinically significant prostate cancer compared to the general population.

Significant family history of prostate cancer = a brother diagnosed with prostate cancer, their father diagnosed with prostate cancer before the age of 65, or two or more second degree relatives who died of prostate cancer (refer 1.1 Family history of prostate cancer).

^ PSA testing recommendations for Aboriginal and Torres Strait Islander males are the same as for the general population (refer Section C: Priority populations)

Flowcharts 2-5 can be found in Primary health care setting - PSA testing, describing PSA testing in the primary care setting for:

- 50-69 year old males (Flowchart 2)
- Males 70 years and over (Flowchart 3)
- 40-49 year old males (Flowchart 4)
- Males at higher risk (Flowchart 5)

1.1 Family history of prostate cancer

Strong recommendation

1.1.1 We recommend that males are considered as being at higher risk of prostate cancer mortality for the purposes of PSA testing in the primary care setting if they have significant family history:

- A brother diagnosed with prostate cancer
- A father diagnosed with prostate cancer before the age of 65
- Two or more second degree relatives who died of prostate cancer.

In this population the risk of dying from prostate cancer is at least double that of non-higher risk males.

Review by 2030, subject to emerging evidence

Conditional recommendation

1.1.2 We suggest that males should be considered at higher risk of prostate cancer mortality for the purposes of PSA testing if their father was diagnosed with prostate cancer at any age.

In this population the risk of dying from prostate cancer is likely to be more than double that of non-higher risk males.

Review by 2030, subject to emerging evidence

Consensus recommendation

1.1.3 We propose that males should be considered at higher risk of prostate cancer mortality for the purposes of PSA testing if two or more second degree relatives (uncle, grandfather, etc.) were diagnosed with prostate cancer.

In this population the risk of dying from prostate cancer is likely to be more than double that of non-higher risk males.

Review by 2030, subject to emerging evidence

1.2 Black males of sub-Saharan African ancestry living in Australia

Consensus recommendation

1.2.1 We propose that Black males of sub-Saharan African ancestry be considered at higher risk of clinically significant prostate cancer.

Review by 2030, subject to emerging evidence

Key message

1.2.2 To best support Black males of sub-Saharan African ancestry, development and implementation of targeted, culturally appropriate health promotion/education campaigns are needed to increase awareness of prostate cancer and risk.

Review by 2030, subject to emerging evidence

1.3 Germline mutations

Good practice statement

1.3.1 Consider males with a *BRCA2* mutation as higher risk.

Review by 2030, subject to emerging evidence

1.4 Other risk factors

Good practice statement

1.4.1 Familial syndromes such as hereditary breast and ovarian cancer and Lynch Syndrome are also associated with increased risk of clinically significant prostate cancer compared to the general population.

Review by 2030, subject to emerging evidence

Section B: Decision support

2. Decision support

Good practice statement

2.1 Offer decision support in accordance with current best practice. Approaches to decision support should take into account personal preferences and circumstances.

Decision support is more likely to be required in circumstances where there are alternative management options.

Decision support approaches can include:

- Informal discussions phrased in terms of options and potentially a recommendation
- In-depth discussions explaining benefits, potential harms and timelines of testing
- Provision of general written information, and/or provision of decision support tools
- Referral to digital resources such as websites or apps from reputable organisations.

Review by 2030, subject to emerging evidence

Section C: Priority populations

3.1 Aboriginal and Torres Strait Islander males

Key messages

3.1.1

PSA testing should be embedded into the Aboriginal and Torres Strait Islander annual health assessment program.

3.1.2

Through programs such as the Medical Specialist Outreach Assistance Program (MSOAP), existing telehealth infrastructure, and point of care testing for PSA in Aboriginal Community Controlled Health Organisations, Aboriginal and Torres Strait Islander males, particularly in rural and remote communities, have facilitated access to specialist diagnostic and management services once they are identified as at-risk. These existing infrastructures can be utilised to support males undergoing PSA testing who require further testing/care.

3.1.3

To further support Aboriginal and Torres Strait Islander males, development and implementation of targeted, culturally appropriate health promotion/education campaigns are needed to reduce stigma around testing and increase awareness of prostate cancer. These programs should commence early and run in parallel with the Aboriginal and Torres Strait Islander annual health assessment program.

Review by 2030, subject to emerging evidence

3.2 Other priority populations

Section D: Early detection

4. Digital Rectal Examination (DRE)

Conditional recommendation against

4.1 We suggest that digital rectal examination not be offered in the primary care setting as a routine addition to PSA testing and risk assessment.

Review by 2030, subject to emerging evidence

Good practice statement

4.2 Although DRE is not recommended as a routine test for men who, after advice, wish to be tested for the presence of prostate cancer, it will still be an important part of the man's assessment on referral to a urologist or other specialist for further assessment prior to consideration for biopsy.

Review by 2030, subject to emerging evidence

5. Primary health care setting - PSA testing

Good practice statement

5.1 For males aged 50 years and over, initiate a discussion regarding the benefits and possible harms of testing for the early detection of prostate cancer.

For males aged 40 to 49 years, assess whether they are at higher risk* of prostate cancer than the general population.

For males aged 40 to 49 years who are assessed as not at higher risk but who enquire about their prostate health, it is reasonable to discuss the benefits and possible harms of the early detection of prostate cancer.

To be read in conjunction with recommendations 5.3, 5.4 and 5.5.

Refer Section B: Decision support for approaches to decision support.

*Males are considered to be at higher risk if they have a risk of clinically significant prostate cancer or prostate cancer death that is at least double that of the overall risk for the Australian male population. Higher risk includes, but is not restricted to, males with certain patterns of family history, Black males of sub-Saharan African ancestry and/or males with confirmed *BRCA2* gene mutations. For further details, refer to Section A: Risk assessment.

Review by 2030, subject to emerging evidence

Good practice statement

5.2 The early detection of clinically significant prostate cancer requires an individualised, risk-adapted, harm-minimisation approach which may include decision support, PSA testing and multiparametric magnetic resonance imaging (mpMRI) in conjunction with:

- Digital rectal examination (refer Digital rectal examination).
- Harm-minimisation strategies including prostate biopsy techniques (refer 6. Specialist setting- Multiparametric magnetic resonance imaging and 7. Specialist setting - Prostate biopsy).
- Management strategies including active surveillance (refer 8. Active surveillance).

This co-ordinated approach is consistent with a harm minimisation imperative and leads to a reduction in over-treatment.

Refer 5.1 Good practice statement

Refer 5.3 Strong recommendation

Review by 2030, subject to emerging evidence

Strong recommendation

5.3 We recommend offering males aged 50 to 69 years PSA testing every two years.
If total PSA is 3.0 µg/L or greater repeat the test within 1-3 months, and, if confirmed, offer referral for further investigation.

Refer 5.1 Good practice statement

Refer 5.2 Good practice statement.

Review by 2030, subject to emerging evidence

Strong recommendation

5.4 We recommend offering PSA testing to males who are at higher risk* and refer readers to 5.5 Consensus recommendation for testing regimen.

* Males are considered to be at higher risk if they have a risk of clinically significant prostate cancer or prostate cancer death that is at least double that of the overall risk for the Australian male population. Higher risk includes, but is not restricted to, males with certain patterns of family history, Black males of sub-Saharan African ancestry and/or males with confirmed *BRCA2* gene mutations.

For further details, refer to Section A: Risk assessment

Review by 2030, subject to emerging evidence

Consensus recommendation

5.5 In view of Strong recommendation 5.4 above, we propose offering males who are at higher risk PSA testing every two years from age 40 years.

- For males aged 40 to 49 years if total PSA is 1.0 µg/L or greater repeat the test within 1-3 months, and, if confirmed, consider referral and further investigation.
- For males aged 50 to 69 years if total PSA is 2.0 µg/L or greater repeat the test within 1-3 months, and, if confirmed, consider referral and further investigation.

Refer Section A: Risk assessment.

Review by 2030, subject to emerging evidence

Consensus recommendation

5.6 Note that PSA testing recommendations for Aboriginal and Torres Strait Islander males are the same as for the general population.

- We propose offering Aboriginal and Torres Strait Islander males PSA testing every two years from age 50 to 69 years. If total PSA is 3.0 µg/L or greater repeat the test within 1-3 months, and, if confirmed, consider referral and further investigation.
- We propose offering Aboriginal and Torres Strait Islander males who are not at a higher risk and who are interested in their prostate health an initial PSA test from age 40 years. If total PSA is 1.0 µg/L or greater repeat the test within 1-3 months, and, if confirmed, consider referral and further investigation. If total PSA is less than 1.0 µg/L, no further PSA testing is recommended until age 50 years.
- We propose offering Aboriginal and Torres Strait Islander males aged 70 years and over a PSA test every two years subject to clinical assessment, which may include consideration of life expectancy, comorbidities, and patient values and preferences. If total PSA is 5.5 µg/L or greater repeat the test within 1-3 months, and, if confirmed, consider referral and further investigation.
- We propose for Aboriginal and Torres Strait Islander males aged 70 years or over, if their PSA is less than 5.5 µg/L, continued testing be subject to clinical assessment, which may include consideration of life expectancy, comorbidities, and patient values and preferences.

For further details, refer to Section C: Priority populations

Review by 2030, subject to emerging evidence

Conditional recommendation

5.7 We suggest offering PSA testing only to males whose life expectancy is greater than seven years.

Review by 2030, subject to emerging evidence

Consensus recommendation

5.8 We propose offering males who are not at a higher risk and who are interested in their prostate health an initial PSA test from age 40 years.

- In males aged 40 to 49 years, if total PSA is 1.0 µg/L or greater repeat the test within 1-3 months, and, if confirmed, consider referral and further investigation.

If total PSA is less than 1.0 µg/L, no further PSA testing is recommended until age 50 years.

For further details, refer to Section A: Risk assessment.

Review by 2030, subject to emerging evidence

Consensus recommendation

5.9 We propose offering males aged 70 years and over a PSA test every two years subject to clinical assessment, which may include consideration of life expectancy, comorbidities, and patient values and preferences. If total PSA is 5.5 µg/L or greater repeat the test within 1-3 months, and, if confirmed, consider referral and further investigation.

Review by 2030, subject to emerging evidence

Consensus recommendation

5.10 We propose for males aged 70 years or over, if their PSA is less than 5.5 µg/L, continued testing be subject to clinical assessment, which may include consideration of life expectancy, comorbidities, and patient values and preferences.

Review by 2030, subject to emerging evidence

Key message

5.11 To support awareness of prostate cancer risk factors for males aged 40 years and above, a national public education campaign focused on the importance of understanding risk factors and the early detection of prostate cancer is essential.

Review by 2030, subject to emerging evidence

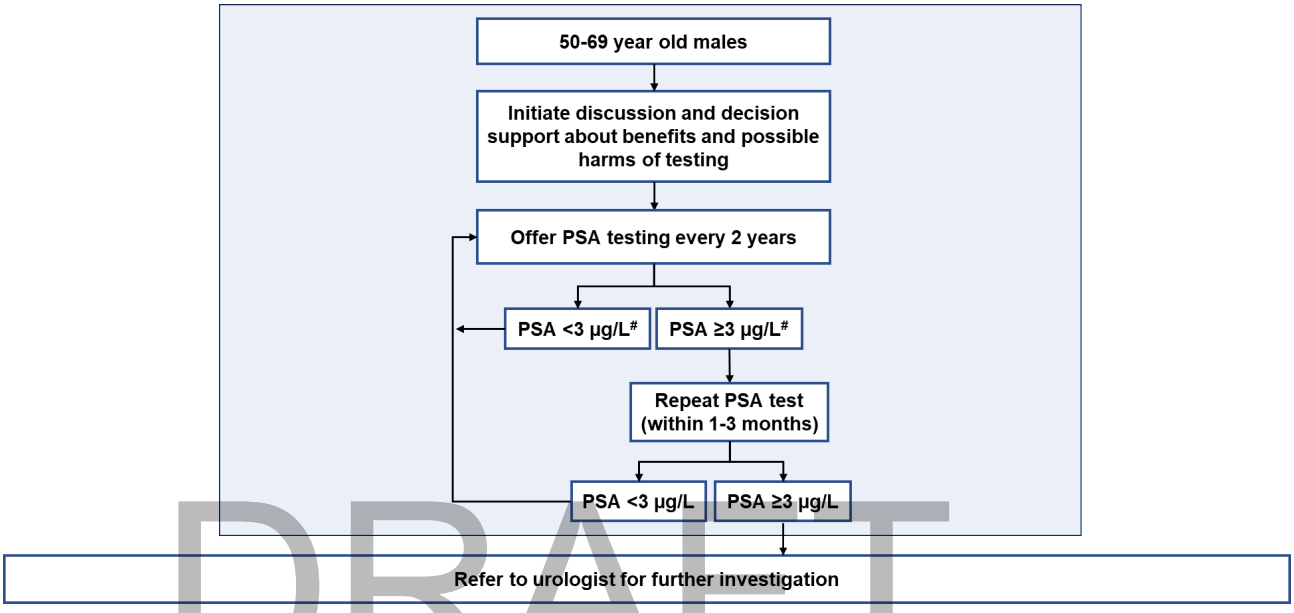
Flowcharts for PSA testing

Flowcharts reflecting the PSA testing recommendations have been developed to aid clinical decision making. Flowchart 1 in Section A: Risk assessment describes risk assessment for the early detection of prostate cancer in Australia.

The following flow charts describe PSA testing in the primary care setting for:

- 50 to 69 year old males (flowchart 2)
- Males 70 years and over (flowchart 3)
- 40to 49 year old males (flowchart 4)
- Males at higher risk (flowchart 5)

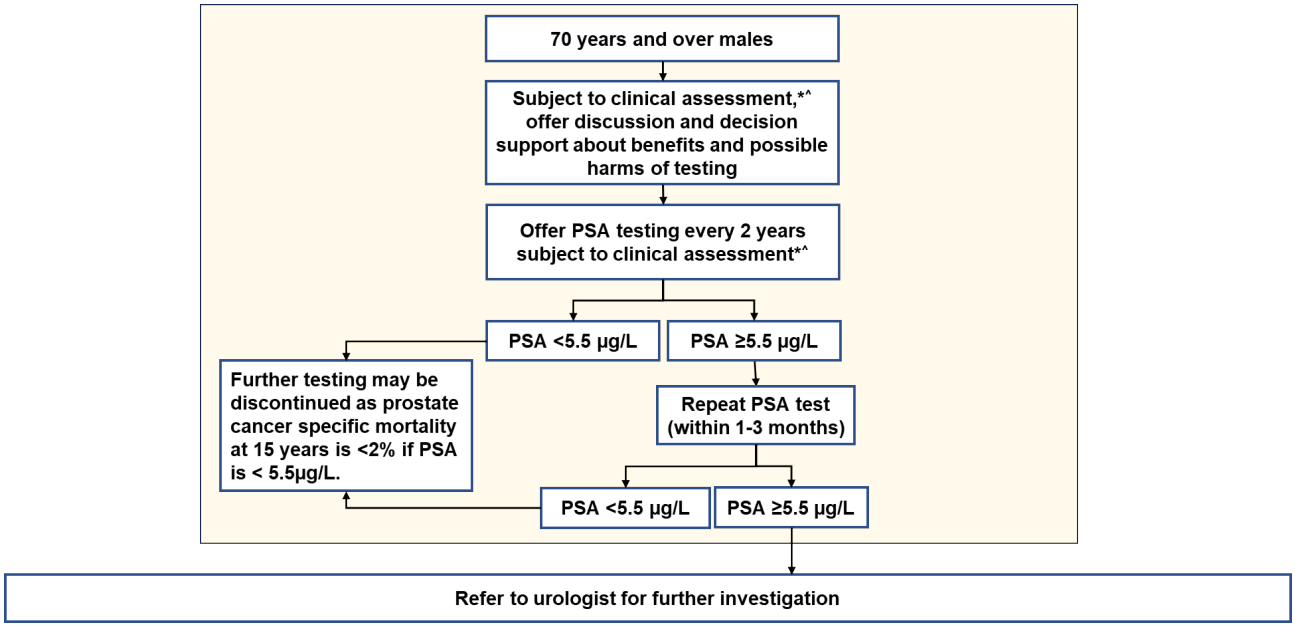
Flowchart 2: PSA testing of 50 to 69 year old males in the primary care setting



PSA ≥2 µg/L if significant family history of prostate cancer. Significant family history of prostate cancer = a brother diagnosed with prostate cancer, their father diagnosed with prostate cancer before the age of 65, or two or more second degree relatives who died of prostate cancer (refer Section A Risk assessment).

Higher risk includes, but is not restricted to, males with a brother or father diagnosed with prostate cancer, or two second degree relatives diagnosed with prostate cancer, Black males of sub-Saharan African ancestry and/or confirmed *BRCA2* gene mutations. Familial syndromes such as hereditary breast and ovarian cancer and Lynch syndrome are also associated with increased risk of clinically significant prostate cancer compared to the general population. (refer Section A Risk assessment).

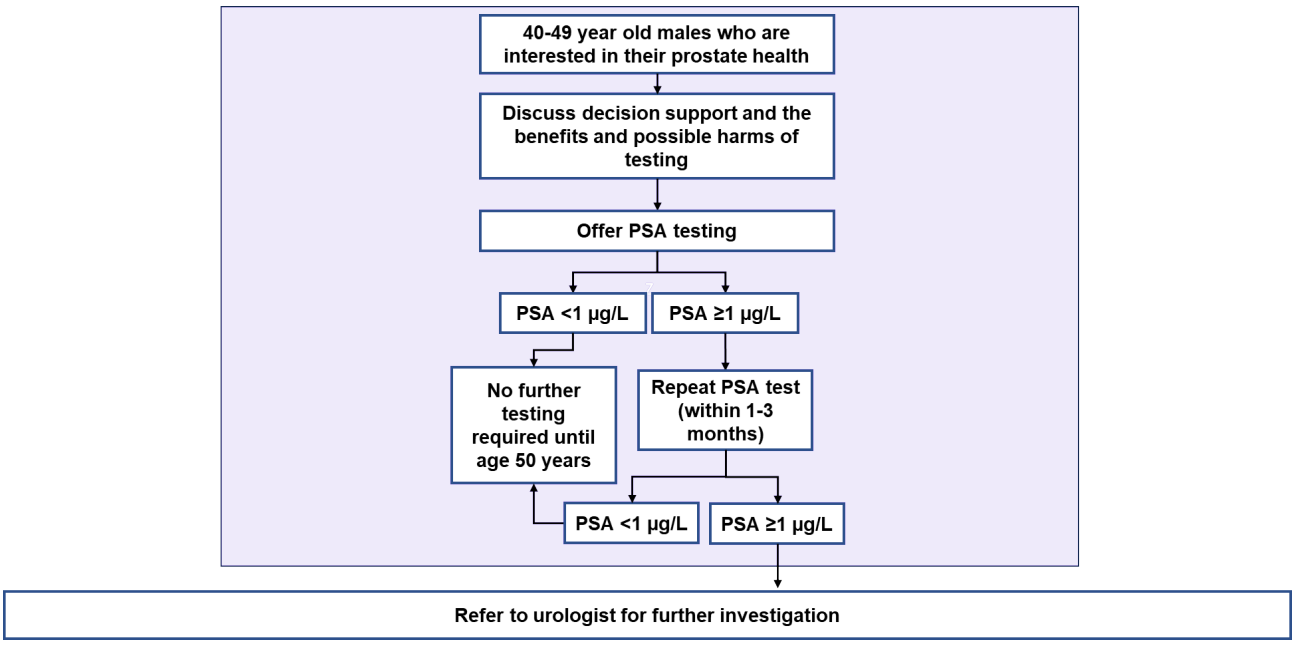
Flowchart 3: PSA testing of males 70 years and over in the primary care setting.



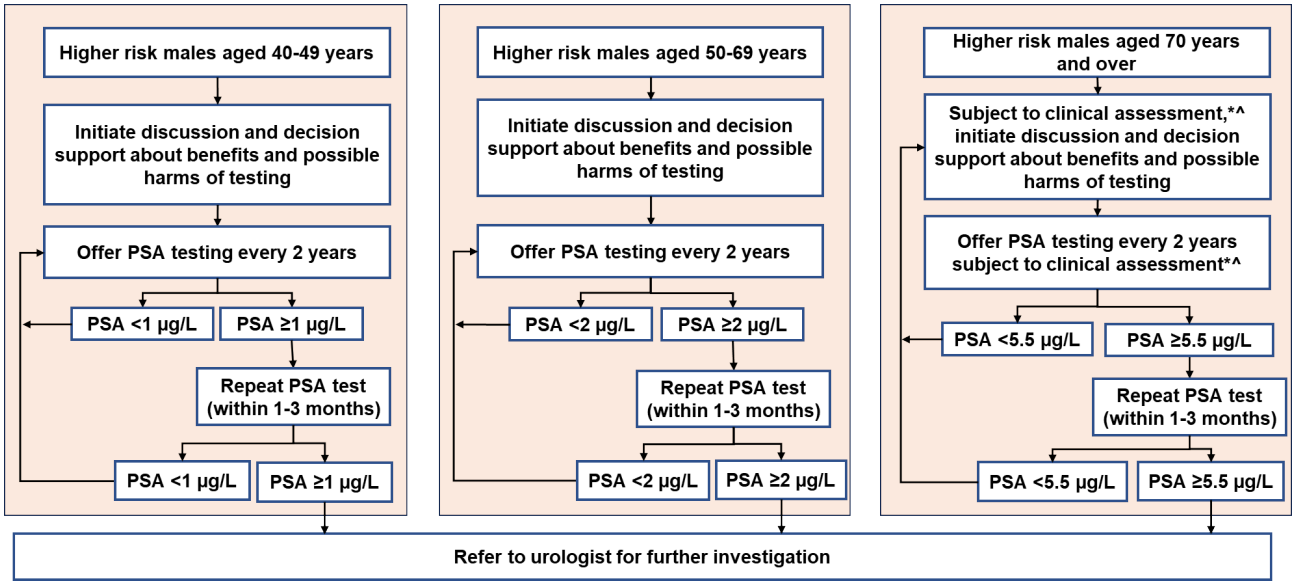
* Only offer testing if life expectancy is greater than 7 years.

^ Clinical assessment may include consideration of life expectancy, comorbidities, and patient values and preferences.

Flowchart 4: PSA testing of 40 to 49 year old males in the primary care setting



Flowchart 5: PSA testing of males at higher risk in the primary care setting



Higher risk includes, but is not restricted to, males with a brother or father diagnosed with prostate cancer, or two second degree relatives diagnosed with prostate cancer, Black males of sub-Saharan African ancestry and/or confirmed *BRCA2* gene mutations (refer Section 1.1). Familial syndromes such as hereditary breast and ovarian cancer and Lynch syndrome are also associated with increased risk of clinically significant prostate cancer compared to the general population.

* Only offer testing if life expectancy is greater than 7 years.

^ Clinical assessment may include consideration of life expectancy, comorbidities, and patient values and preferences.

6. Specialist setting - Multiparametric magnetic resonance imaging

Good practice statement

6.1 For males requiring further investigation on the basis of their PSA, an mpMRI is recommended as their next diagnostic test to determine if a biopsy is indicated.

Review by 2030, subject to emerging evidence

Conditional recommendation

6.2 We suggest offering prostate biopsy to males with an mpMRI suspicious of prostate cancer (Prostate Imaging Reporting and Data System [PI-RADS] 4-5).

We suggest offering prostate biopsy to males with an equivocal PI-RADS 3 mpMRI and PSA density (PSAD) ≥ 0.15 µg/L/mL.

Review by 2030, subject to emerging evidence

Conditional recommendation

6.3 We suggest that males with an equivocal PI-RADS 3 mpMRI and PSAD < 0.15 µg/L/mL may not require prostate biopsy subject to clinical assessment.

We suggest that males with an mpMRI not suspicious of prostate cancer (PI-RADS 1-2) may not require prostate biopsy subject to clinical assessment.

*For males who do not require biopsy, refer 6.4 Consensus recommendation.

Review by 2030, subject to emerging evidence

Consensus recomendation

6.4 We propose that for males with elevated PSA who do not require biopsy based on the 6.3 Conditional recommendation subsequent management will vary according to their degree of clinical risk. This should include discussion of individual preferences.

A repeat PSA and specialist review should guide subsequent management. For males with additional risk factors for cancer and those more concerned about missing a diagnosis, further management options may include a repeat PSA within 6 months, a prostate specific membrane antigen positron emission tomography with computer tomography (PSMA PET/CT) scan, or undergoing a transperineal systematic biopsy.

Refer 7.3 Good practice statement

Review by 2030, subject to emerging evidence

Good practice statement

6.5 Males who cannot access or have an mpMRI may be offered a systematic transperineal biopsy or PSMA PET/CT.

mpMRI acquisition should include T2-weighted, diffusion-weighted and dynamic contrast-enhanced series.

mpMRI reports should include the PI-RADS score for each suspicious lesion, the prostate volume, and the PSAD calculation.

The PSAD calculation should be based on the most recent PSA result prior to the mpMRI.

Review by 2030, subject to emerging evidence

7. Specialist setting - Prostate biopsy

Conditional recommendation

7.1 We suggest that for patients with a Prostate Imaging Reporting and Data System (PI-RADS) 4-5 lesion, multiparametric magnetic resonance imaging (mpMRI) targeted plus systematic biopsies should be undertaken.

Review by 2030, subject to emerging evidence

Conditional recommendation

7.2 We suggest that for patients with a PI-RADS 3 lesion who require biopsy, mpMRI-targeted biopsies plus systematic biopsies should be undertaken.

Review by 2030, subject to emerging evidence

Good practice statement

7.3 If the mpMRI is not suspicious of prostate cancer (PI-RADS 1 or 2), we propose systematic biopsies may still be performed if there is clinical concern, such as a digital rectal examination suspicious of prostate cancer, or a high risk of clinically significant prostate cancer.

Review by 2030, subject to emerging evidence

Good practice statement

7.4 When performing prostate biopsy for the early detection of prostate cancer, an ultrasound-guided transperineal approach is preferred as there is less risk of post-biopsy infection. In addition, the ultrasound images are in the axial plane as are the MRI images which facilitates more accurate target biopsies.

Review by 2030, subject to emerging evidence

Good practice statement

7.5 In most circumstances, prior to considering prostate biopsy for the early detection of prostate cancer, patients should have had a urological consultation which may include a history, discussion of benefits and possible harms of diagnosis, clinical examination, PSA testing and mpMRI.

Review by 2030, subject to emerging evidence

Good practice statement

7.6 The optimal number of cores for targeted biopsy should be at least 3-4.

As the number of systematic biopsy cores increases, the rate of diagnosis of clinically significant and insignificant prostate cancers rises. In addition, increased number of systematic cores may also increase the risk of complications arising such as bleeding, urinary retention, erectile dysfunction, and/or urinary infection.

Review by 2030, subject to emerging evidence

Good practice statement

7.7 In patients whose biopsies are benign, subsequent management will vary according to their risk profile. A discussion of their individual preferences is advised.

Options for ongoing management may include resumption of their previous PSA testing protocol, repeat imaging or repeat biopsy at varying intervals depending on their risk profile.

Review by 2030, subject to emerging evidence

Section E: Management

8. Active surveillance

8.1 Criteria for choosing active surveillance

Good practice statement

8.1.1 The definition of active surveillance is a monitoring strategy for patients with clinically localised prostate cancer.

The intention of active surveillance is to minimise treatment-related toxicity without compromising survival by achieving correct timing for curative treatment for those who may eventually require it.

Review by 2030, subject to emerging evidence

Consensus recommendation

8.1.2 We propose that active surveillance be offered to patients with low-risk prostate cancer and may be offered to some patients with intermediate risk prostate cancer as below.

In patients diagnosed with prostate cancer, if all the following criteria are met*:

- PSA < 10 µg/L
- Clinical stage T1-T2a
- Multiparametric magnetic resonance imaging (mpMRI) Prostate Imaging Reporting and Data System (PI-RADS) 3 or less
- PSA density (PSAD) 0.15 µg/L/mL or less.

Then,

1. Offer active surveillance to patients with International Society of Urological Pathology (ISUP) Grade Group 1
2. Consider offering active surveillance to patients with ISUP Grade Group 2 with less than or equal to 10% of Gleason pattern 4.

*Note that in selected cases, subject to a patient's individual circumstances, active surveillance may still be offered if PSA is >10 µg/L, or clinical stage is T2b or T2c, or mpMRI PI-RADS >3, or PSAD >0.15 µg/L/mL.

Review by 2030, subject to emerging evidence

Good practice statement

8.1.3 When considering active surveillance, take into account other factors that may be associated with the risk of future pathological progression such as total cancer length or percentage core involvement at biopsy and tumour volume.

Active surveillance is not advised in patients with:

- Variant histology, including sarcomatoid, small cell, cribriform

- Histologic features, including intraduct, extra-prostatic extension, lymphovascular invasion and perineural invasion.

Review by 2030, subject to emerging evidence

Good practice statement

8.1.4 Perform mpMRI if no MRI has been performed before the initial biopsy.

Review by 2030, subject to emerging evidence

8.2 Monitoring protocols for active surveillance

Consensus recommendation

8.2.1 We propose for patients with prostate cancer who are being managed by active surveillance offer:

- Initial three to six-monthly PSA measurements
- Digital rectal examination periodically
- Repeat multiparametric magnetic resonance imaging (mpMRI) may be offered after 12 to 24 months and again at three years, or earlier, if clinically indicated
- Repeat the prostate biopsy in the first 12 months at clinician's discretion e.g., where there is uncertainty regarding initial diagnostic biopsy, changes in PSA, digital rectal examination or mpMRI.

Subsequent repeat prostate biopsies are usually not required in less than three years unless there are changes in PSA, digital rectal examination or mpMRI.

Review by 2030, subject to emerging evidence

Consensus recommendation

8.2.2 We propose that for patients being managed by active surveillance, offer definitive treatment if:

- Pathological progression is detected on biopsy
- Patient preference.

Note: Progression on mpMRI is not an indication for definitive treatment but will likely prompt the need for repeat biopsies.

Review by 2030, subject to emerging evidence

Good practice statement

8.2.3 Avoid a change in treatment on an increase in PSA alone.

Perform repeat mpMRI preferably before repeat biopsy if PSA is increasing (PSA doubling time < 3 years).

Repeat biopsy may still have value even with an unchanged mpMRI.

Review by 2030, subject to emerging evidence

Good practice statement

8.2.4 Males with ultralow volume, low risk prostate cancer may be excused from more rigorous surveillance protocols.

Review by 2030, subject to emerging evidence

9. Watchful waiting

Good practice statement

9.1 The practice of watchful waiting is a patient-centred conservative strategy for managing prostate cancer when cure is not the goal. The aim is to maximise the patient's quality of life in alignment with their initial and evolving stated goals of care.

A comprehensive approach to managing prostate cancer involves the following general principles of monitoring and management options:

- Identify the patient's goals of care
- Tailor plans to the patient's wishes and needs
- Plan should include continuing clinical review, even if no investigations are to be done
- Ensure clear ongoing communication with the patient and their carers/families
- Allow for the possibility that the patient might want to change goals of care and approach to care.

Multidisciplinary management is recommended, involving the patient, primary health care and specialist settings, and other relevant health professionals.

Review by 2030, subject to emerging evidence