# PSA TESTING AND EARLY MANAGEMENT OF TEST-DETECTED PROSTATE CANCER
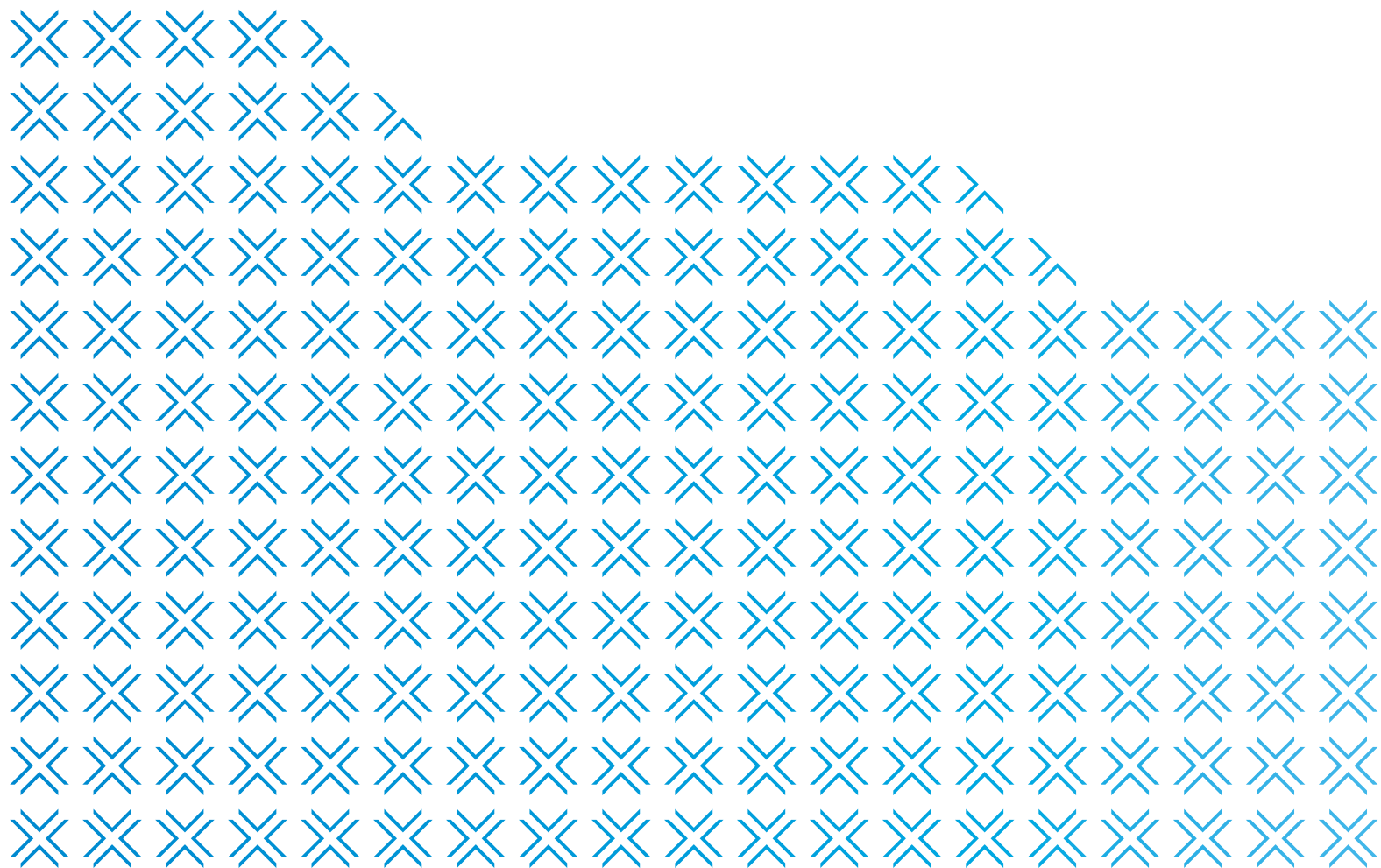
SHORT FORM SUMMARY

A guideline for health professionals

**Prostate Cancer Foundation of Australia**

**Cancer Council Australia**

## Disclaimer

The guidelines document is a general guide to appropriate practice, to be followed subject to the clinician's judgment and the patient's preference in each individual case.

The guidelines are designed to provide information to assist in decision-making. The guidelines are not meant to be prescriptive.

## Conflict of interest

The development of these clinical practice guidelines has been undertaken by a non-remunerated Expert Advisory Panel of Prostate Cancer Foundation of Australia and Cancer Council Australia.

Some members of the Expert Advisory Panel have received sponsorship to attend scientific meetings, been supported in the conducting of clinical trials, or have been involved in an advisory capacity by pharmaceutical and biochemical companies. (Refer to Appendix 6)

## Periodic updates

Prostate Cancer Foundation of Australia and Cancer Council Australia plan to review the guidelines as a whole every three years. Readers should check for any reviews or updates of these guidelines.

New information arising in areas considered to be of importance will be posted periodically on Cancer Council Australia's website at www.cancer.org.au. This information will be included as appropriate in future editions of the document.

## Suggested citation

The complete guidelines and associated documentation (i.e. Administrative and Technical Reports) can be accessed and downloaded at:

wiki.cancer.org.au/psaguidelines

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**Publication Approval**

**Australian Government**
**National Health and Medical Research Council**

The guidelines (recommendations) on pages 7-13 were approved by the Chief Executive Officer of the National Health and Medical Research Council (NHMRC) on 2 November 2015 under section 14A of the N*ational Health and Medical Research Council Act 1992*. In approving the guidelines (recommendations), NHMRC considers that they meet the NHMRC standard for clinical practice guidelines. This approval is valid for a period of five years.

NHMRC is satisfied that the guidelines (recommendations) are systematically derived, based on the identification and synthesis of the best available scientific evidence, and developed for health professionals practising in an Australian health care setting.

This publication reflects the views of the authors and not necessarily the views of the Australian Government.

# PSA TESTING AND EARLY MANAGEMENT OF TEST-DETECTED PROSTATE CANCER

**This short form summary provides an overview of the clinical questions and recommendations in the _Draft Clinical Practice Guidelines for PSA Testing and Early Management of Test-detected Prostate Cancer._**

The guideline does not recommend a population screening program for prostate cancer (a program that offers testing to all men in a certain age group who do not have prostate cancer or symptoms that suggest prostate cancer). Current evidence does not support such a program. The guideline is intended for use in the context of interactions between men and their doctors when men are considering having a PSA test or, having or who decide to have a test after they have been informed of the benefits and harms of testing. This is outlined in more detail in the introductory sections of the complete guidelines.
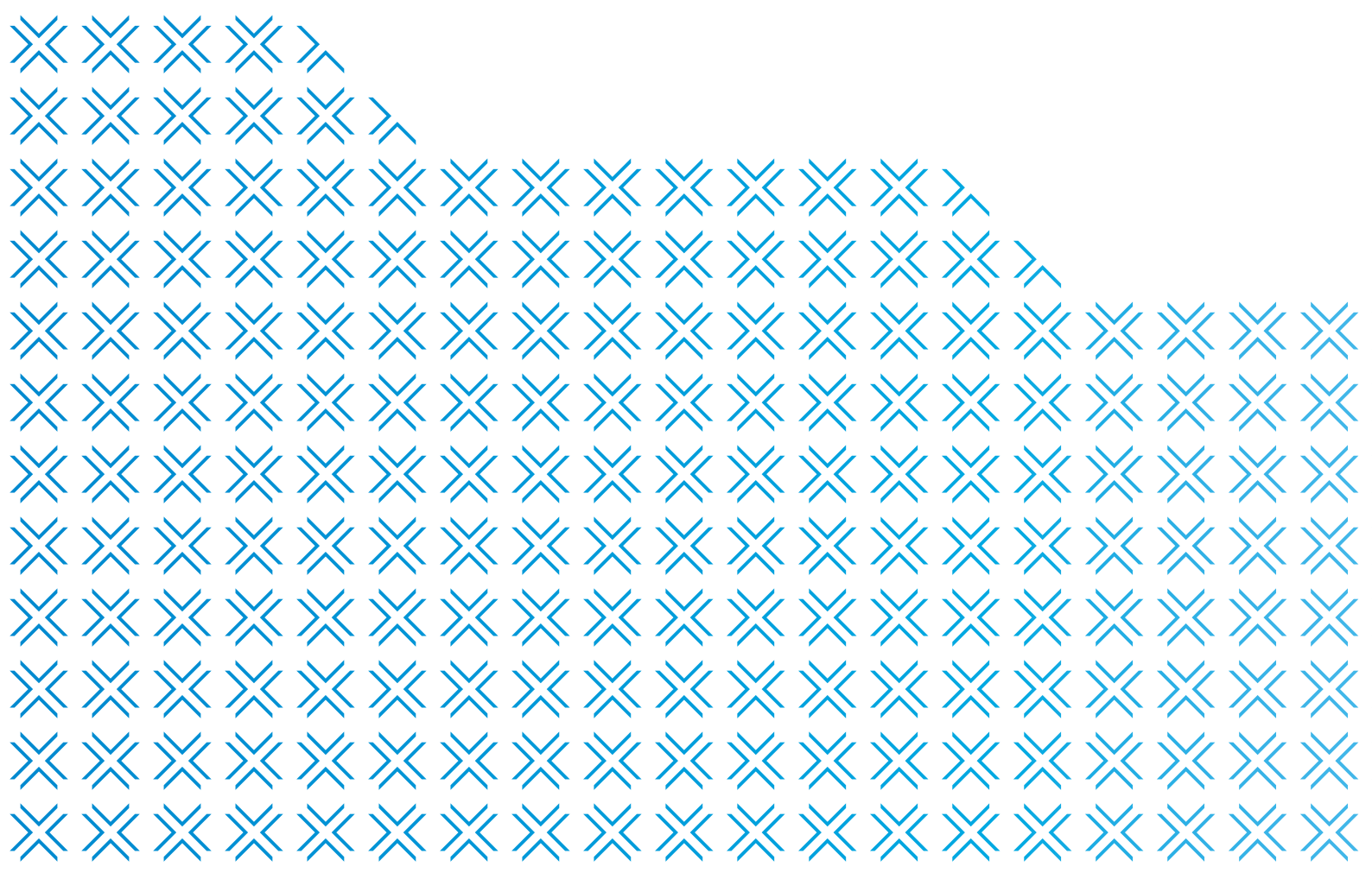
# CLINICAL
# QUESTIONS
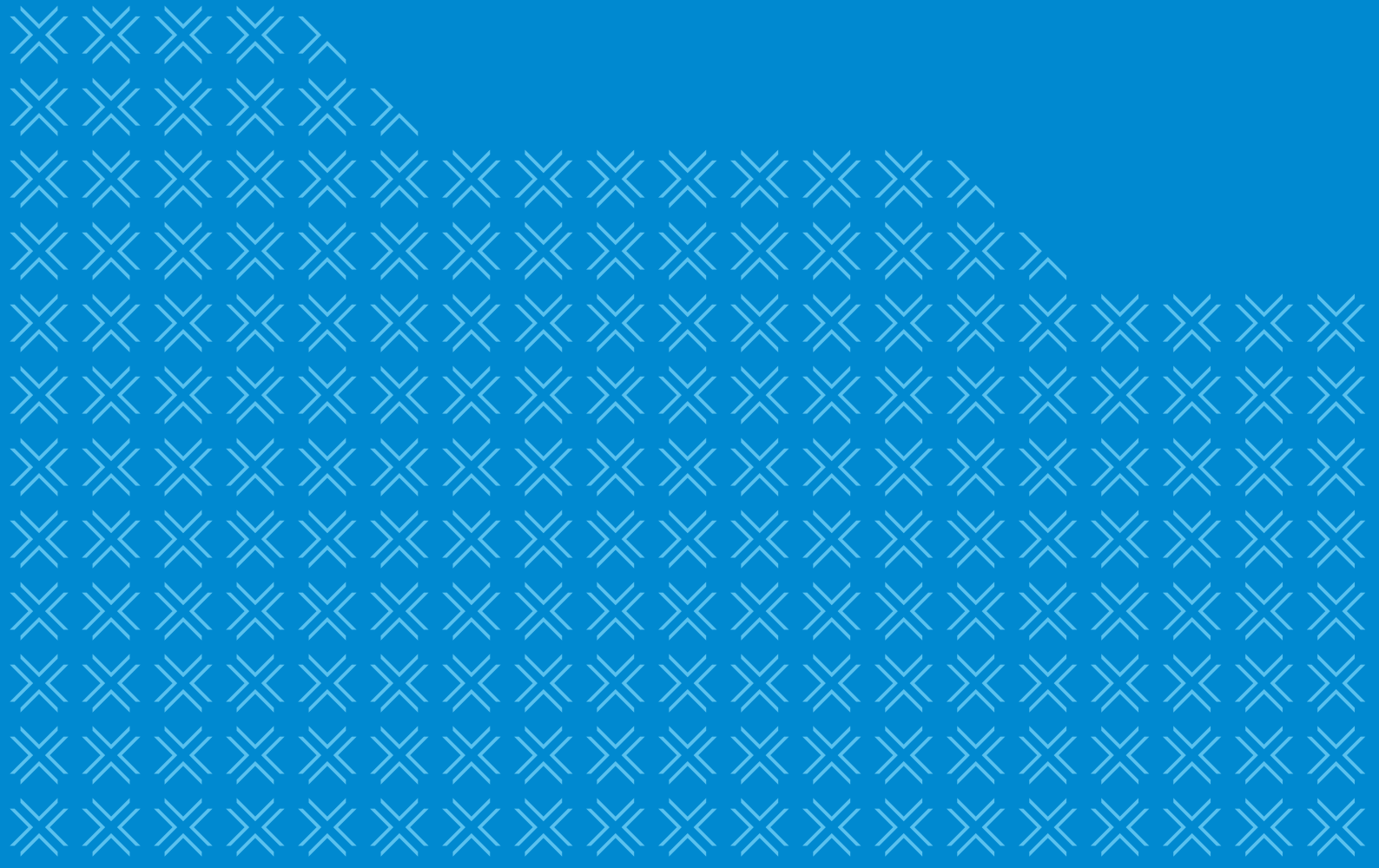
# CLINICAL QUESTIONS

The table below provides a comprehensive register of the clinical questions and corresponding PICO question(s) addressed.

**Table i. List of clinical questions**

| Question No. | Clinical Questions | Corresponding PICO Question(s) |
|---|---|---|
| **RISK** | | |
| **1** | What risk factors can identify Australian men who are at high risk of prostate cancer or death from prostate cancer?<br>Suggested risk factors include:<br>– Family history | **1:** For Australian men, has a family history of prostate cancer been shown to be reliably associated with a 2.0-fold or greater increase in risk of occurrence of or death from prostate cancer when compared to men who do not have a family history of prostate cancer? |
| **TESTING** | | |
| **2** | What methods of decision support for men about PSA testing increase men's capacity to make an informed decision for or against testing? | **2:** In men without evidence of prostate cancer does a decision support intervention or decision aid compared with usual care improve knowledge, decisional satisfaction, decision-related distress and decisional uncertainty about PSA testing for early detection of prostate cancer? |
| **3** | In men without a prior history of prostate cancer or symptoms that might indicate prostate cancer, what should be the PSA testing strategies (age to start, level at which to declare a test abnormal and frequency of subsequent testing if the PSA level is normal) for men at average risk of prostate cancer and how should they be modified, if at all, for men at high risk of prostate cancer? | **3.1:** For men without a prostate cancer diagnosis or symptoms that might indicate prostate cancer what PSA testing strategies (with or without DRE), compared with no PSA testing or other PSA testing strategies, reduce prostate cancer specific mortality or the incidence of metastases at diagnosis and offer the best balance of benefits to harms of testing?<br><br>**3.2:** For men without a prostate cancer diagnosis or symptoms that might indicate prostate cancer what PSA testing strategies with or without DRE perform best in detecting any prostate cancer or high grade prostate cancer diagnosed in biopsy tissue?<br><br>**3.3:** For men without a prostate cancer diagnosis or symptoms that might indicate prostate cancer does a PSA level measured at a particular age in men assist with determining the recommended interval to the next PSA test? |
| **4** | How best can DRE be used, if at all, in association with PSA testing? | **4:** For men without a prostate cancer diagnosis or symptoms that might indicate prostate cancer what is the incremental value of performing a digital rectal examination (DRE) in addition to PSA testing in detecting any prostate cancer? |
| **5** | What age or health status criteria should be used to identify men who would be unlikely to live long enough to benefit from PSA testing and who, in consequence, would not be offered PSA testing? | **5:** For men without a prostate cancer diagnosis or symptoms that might indicate prostate cancer, how many years after the start of PSA testing is the benefit of PSA testing apparent? |

| Question No. | Clinical Questions | Corresponding PICO Question(s) |
|---|---|---|
| 6 | In men without a prior history of prostate cancer or symptoms that might indicate prostate cancer, what tests for prostate cancer should be offered in addition to a PSA test?<br><br>Candidate tests include:<br>— free-to total PSA %<br>— PSA velocity<br>— Prostate health index<br>— Repeated total PSA | **Free-to-total PSA %**<br>**6.1 a:** For asymptomatic men with an initial total PSA below or equal to 3.0 ng/mL does measuring free-to-total PSA percentage improve the detection of prostate cancer or high-grade prostate cancer without resulting in unacceptable numbers of unnecessary biopsies, when compared with a single total PSA result above 3.0 ng/mL?<br><br>**6.1 b:** For asymptomatic men with an initial total PSA above 3.0 ng/mL, does measuring free-to-total PSA percentage improve relative specificity without compromising prostate cancer or high-grade prostate cancer detection, when compared with a single total PSA result above 3.0 ng/mL?<br><br>**PSA velocity**<br>**6.2 a:** For asymptomatic men with an initial total PSA below or equal to 3.0 ng/mL does measuring PSA velocity improve the detection of prostate cancer or high-grade prostate cancer without resulting in unacceptable numbers of unnecessary biopsies, when compared with a single elevated total PSA result above 3.0 ng/mL?<br><br>**6.2 b:** For asymptomatic men with an initial total PSA above 3.0 ng/mL, does measuring PSA velocity improve relative specificity without compromising prostate cancer or high-grade prostate cancer detection, when compared with a single total PSA result above 3.0 ng/mL?<br><br>**Prostate Health Index (PHI)**<br>**6.3 a:** For asymptomatic men with an initial total PSA below or equal to 3.0 ng/mL does measuring the Prostate Health Index (PHI) improve the detection of prostate cancer or high-grade prostate cancer without resulting in unacceptable numbers of unnecessary biopsies, when compared with a single elevated total PSA result above 3.0 ng/mL?<br><br>**6.3 b:** For asymptomatic men with an initial total PSA above 3.0 ng/mL, does measuring the Prostate Health Index (PHI) improve relative specificity without compromising prostate cancer or high-grade prostate cancer detection, when compared with a single elevated total PSA result above 3.0 ng/mL?<br><br>**Repeated total PSA**<br>**6.4:** For asymptomatic men with initial total PSA above 3.0 ng/mL, does repeating the total PSA test and using an initial and repeat total PSA above 3.0 ng/mL as the indication for biopsy, improve relative specificity without compromising prostate cancer or high-grade prostate cancer detection, when compared with a single total PSA result above 3.0 ng/mL as the indication for biopsy? |

# CLINICAL QUESTIONS

| Question No. | Clinical Questions | Corresponding PICO Question(s) |
|---|---|---|
| **PROSTATE BIOPSY AND MULTIPARAMETRIC MRI** | | |
| 7 | What constitutes an adequate prostate biopsy? | **7:** For men undergoing an initial prostate biopsy how many biopsy cores, which pattern of biopsy sampling sites and which approach constitute an adequate prostate biopsy |
| 8 | If prostate cancer is not found in an adequate biopsy what if any additional steps should be taken and what recommendations should be made regarding the strategy for subsequent PSA testing? | **8.1:** In men who have been referred with suspected prostate cancer, what are the prognostic factors that determine the need for further investigation following a prior negative biopsy? **8.2:** In men with suspected prostate cancer whose initial TRUS biopsy is negative, what should be the next investigation(s)? |
| **ACTIVE SURVEILLANCE** | | |
| 9 | What should be the criteria for choosing active surveillance in preference to definitive treatment to offer as primary management to men who have a positive prostate biopsy? | **9:** For men with biopsy-diagnosed prostate cancer, for which patients (based on diagnostic, clinical and other criteria) does active surveillance achieve equivalent or better outcomes in terms of length and quality of life than definitive treatment? |
| 10 | What is the best monitoring protocol for active surveillance and what should be the criteria for intervention? | **10:** For men with biopsy-diagnosed prostate cancer following an active surveillance protocol, which combination of monitoring tests, testing frequency and clinical or other criteria for intervention achieve the best outcomes in terms of length and quality of life? |
| **WATCHFUL WAITING** | | |
| 11 | What should be the criteria for choosing watchful waiting in preference to definitive treatment to offer as primary management to men who have a positive prostate biopsy? | **11:** For men with biopsy-diagnosed prostate cancer, for which patients (based on diagnostic, clinical and other criteria) does watchful waiting achieve equivalent or better outcomes in terms of length and quality of life than definitive treatment? |
| 12 | What is the best monitoring protocol for watchful waiting and what should be the criteria for intervention? | **12:** For men with biopsy-diagnosed prostate cancer following a watchful waiting protocol, which combination of monitoring tests, testing frequency and clinical or other criteria for intervention achieve the best outcomes in terms of length and quality of life? |

# SUMMARY OF CLINICAL PRACTICE RECOMMENDATIONS
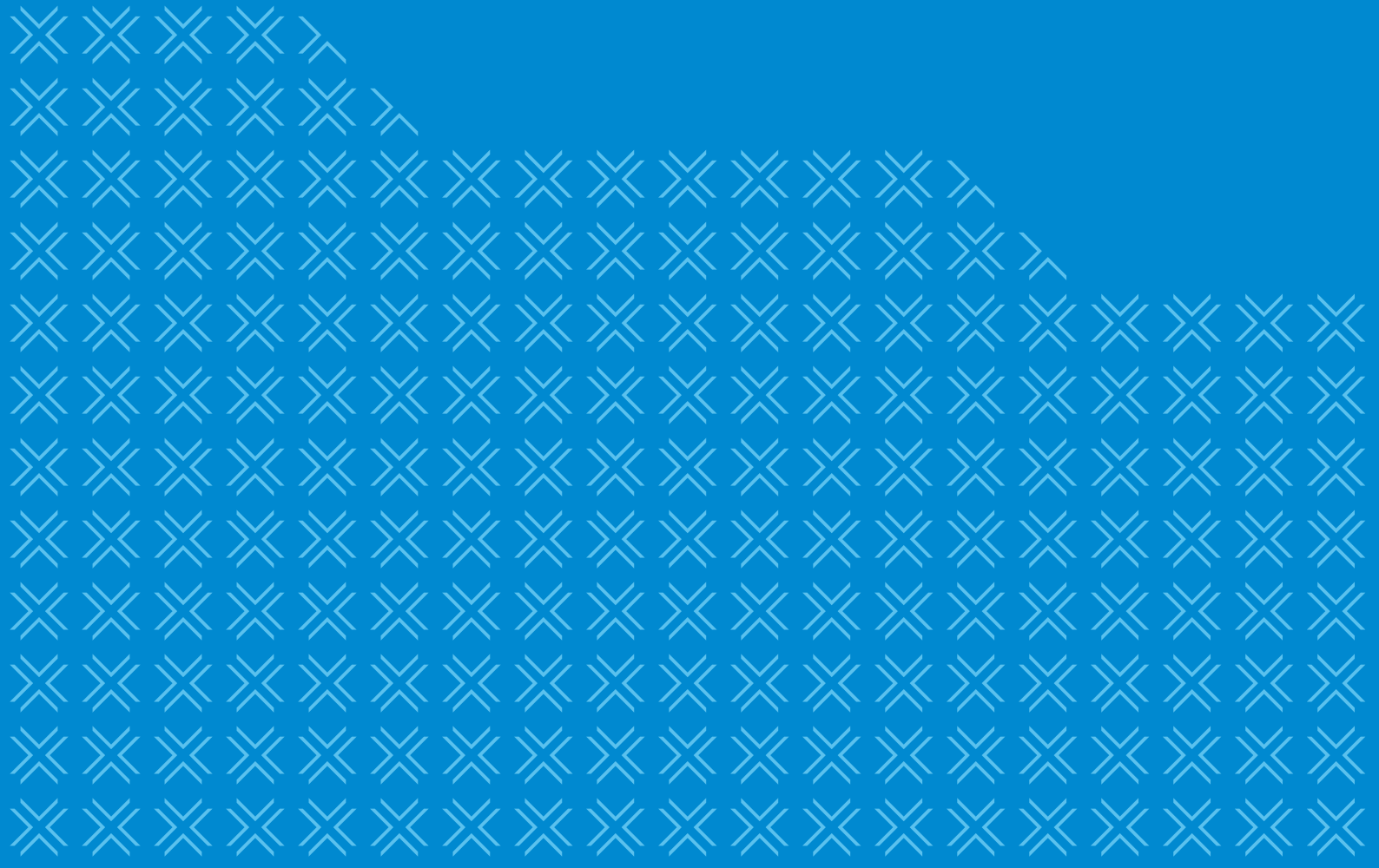
# SUMMARY OF CLINICAL PRACTICE RECOMMENDATIONS

*Table iv* below provides a summary of the evidence-based recommendations (EBR), consensus-based recommendations (CBR) and practice points (PP) in the *Draft Clinical Practice Guidelines for PSA Testing and Early Management of Test-detected Prostate Cancer.* See *Table ii* for a definition of the types of recommendations.

Recommendations and practice points were developed by working party members and subcommittee members using a consensus-finding process. Each EBR was assigned a grade by the expert working group, taking into account the volume, consistency, generalisability, applicability and clinical impact of the body of evidence supporting each recommendation (*Table iii*).

The evidence tables in each chapter contain information about the level of evidence of the studies on which recommendations were based.

## Table ii. Definition of types of recommendations

| Abbreviation | Type of recommendation |
|---|---|
| EBR | Evidence-based recommendation: a recommendation based on the best available evidence identified by a systematic review of evidence. |
| CBR | Consensus-based recommendation: a recommendation based on clinical expertise, expert opinion and available evidence, and formulated using a consensus process, after a systematic review of the evidence found insufficient evidence on which to base a recommendation. |
| PP | Practice point: a point of guidance to support the evidence-based recommendations, based on expert opinion and formulated by a consensus process, on a subject outside the scope of the systematic reviews. |

## Table iii. Definition of grades for evidence-based recommendations

| Grade of recommendation | Description |
|---|---|
| A | Body of evidence can be trusted to guide practice |
| B | Body of evidence can be trusted to guide practice in most situations |
| C | Body of evidence provides some support for recommendation(s) but care should be taken in its application |
| D | Body of evidence is weak and recommendation must be applied with caution |

**Table iv. Summary of recommendations and practice points**

| Recommendation | Type (and grade, if applicable) | Section | PICO question # |
|---|---|---|---|
| **Chapter 1: Risk** | | | |
| Non-applicable [The question does not lead to a recommendation.] | Non-applicable | 1 | 1 |
| **Chapter 2: PSA Testing Strategies** | | | |
| Offer evidence-based decisional support to men considering whether or not to have a PSA test, including the opportunity to discuss the benefits and harms of PSA testing before making the decision. | EBR (C) | 2.1 | 2 |
| Familiarity with the NHMRC fact sheet *PSA testing for prostate cancer in asymptomatic men. Information for health practitioners,* which summarises evidence on the benefits and harms of PSA testing, should help health practitioners to accurately inform men about PSA testing.[i] | PP | 2.1 | 2 |
| For men at average risk of prostate cancer who have been informed of the benefits and harms of testing and who decide to undergo regular testing for prostate cancer, offer PSA testing every 2 years from age 50 to age 69, and offer further investigation if total PSA is greater than 3.0 ng/mL. | EBR (C) | 2.2 | 3.1, 3.2 |
| If the necessary data become available and the required processes put in place to ensure effective implementation, consider replacing > 3.0 ng/mL with > 95th percentile for age as the criterion for further investigation. | CBR | 2.2 | 3.1 |
| Do not offer PSA testing at age 40 years to predict risk of prostate cancer death. | CBR | 2.2 | 3.3 |
| For men younger than 50 years who are concerned about their risk for prostate cancer, have been informed of the benefits and harms of testing, and who wish to undergo regular testing for prostate cancer, offer testing every 2 years from age 45 to age 69 years.<br><br>If initial PSA is at or below the 75th percentile for age, advise no further testing until age 50.<br><br>If initial PSA is above the 75th percentile for age, but at or below the 95th percentile for age, reconfirm the offer of testing every 2 years.<br><br>If a PSA test result before age 50 years is greater than the 95th percentile for age, offer further investigation.<br><br>Offer testing from age 50 years according to the protocol for all other men who are at average risk of prostate cancer. | CBR | 2.2 | 3.1 |
| Advise men 70 years or older who have been informed of the benefits and harms of testing and who wish to start or continue regular testing that the harms of PSA testing may be greater than the benefits of testing in men of their age.[ii] | CBR | 2.2 | 3.1 |

| Recommendation | Type (and grade, if applicable) | Section | PICO question # |
|---|---|---|---|
| **Chapter 2: PSA Testing Strategies** | | | |
| For men whose risk of prostate cancer is estimated to be at least 2.5–3 times higher than average due to the presence of risk factors (e.g. a brother diagnosed with prostate cancer, particularly if younger than 60 years at diagnosis), and who decide to undergo testing after being informed of the benefits and harms, offer testing every 2 years from age 45–69 years.<br><br>For men whose risk of prostate cancer is estimated to be at least 9–10 times higher than average due to the presence of risk factors (e.g. father and two brothers diagnosed with prostate cancer), and who decide to undergo testing after being informed of the benefits and harms, offer testing every 2 years from age 40–69 years.<br><br>If initial PSA is at or below the 75th percentile for age, advise no further testing until age 50.<br><br>If initial PSA is above the 75th percentile for age, but at or below the 95th percentile for age, reconfirm the offer of testing every 2 years.<br><br>If a PSA test result before age 50 years is greater than 95th percentile for age, offer further investigation.<br><br>Offer testing from age 50 years according to the protocol for men who are at average risk of prostate cancer. | CBR | 2.2 | 3.1 |
| In asymptomatic men interested in undergoing testing for early diagnosis of prostate cancer, digital rectal examination is not recommended as a routine addition to PSA testing in the primary care setting. | EBR (C) | 2.3 | 4 |
| 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. | PP | 2.3 | 4 |
| Since any mortality benefit from early diagnosis of prostate cancer due to PSA testing is not seen within less than 6–7 years from testing, PSA testing is not recommended for men who are unlikely to live another 7 years. | EBR (C) | 2.4 | 5 |

| Recommendation | Type (and grade, if applicable) | Section | PICO question # |
|---|---|---|---|
| **Chapter 2: PSA Testing Strategies** | | | |
| When discussing the benefits and harms of PSA testing with older men or those with a potentially fatal chronic illness, explain each of the following:<br><br>— Testing can only be expected to prevent prostate cancer death that would have occurred more than 7 years in the future.<br><br>— If prostate cancer is diagnosed after the test, medium- to long-term quality of life may be better due to diagnosis and treatment of a cancer that could have become advanced in less than 7 years.<br><br>— If prostate cancer is diagnosed after the test, quality of life in the immediate short term may be poorer due to the harmful effects of treatment.<br><br>The percentage of men of a given age, and average health status for their age who are expected to live for another 7 years is as shown in the table below:<br><br>**Age / Percentage of men remaining alive after 7 years**<br>50 — 97%<br>55 — 96%<br>60 — 94%<br>65 — 91%<br>70 — 85%<br>75 — 74%<br>80 — 57%<br>85 — 37%<br>90 — 19% | PP | 2.4 | 5 |
| For men aged 45–69 years whose risk of prostate cancer is at least double the average risk and with total PSA 2.0–3.0 ng/mL, consider offering prostate biopsy if free-to-total PSA is less than 25%. | EBR (D) | 2.5 | 6.1 a |
| Do not use PSA velocity or the PHI test as adjuncts to total PSA testing in determining whether or not to offer prostate biopsy, except in the context of research conducted to assess their utility for this purpose. | CBR | 2.5 | 6.2 a, 6.3 a |
| For men aged 50–69 years with initial total PSA greater than 3.0 ng/mL, offer repeat PSA within 1–3 months.<br><br>For those with initial total PSA greater than 3.0 ng/mL and up to 5.5 ng/mL, measure free-to-total PSA percentage at the same time as repeating the total PSA. | EBR (D) | 2.6 | 6.1 b, 6.4 |

# SUMMARY OF CLINICAL PRACTICE RECOMMENDATIONS

| Recommendation | Type (and grade, if applicable) | Section | PICO question # |
|---|---|---|---|
| **Chapter 2: PSA Testing Strategies** | | | |
| For men aged 50–69 years with initial total PSA greater than 3.0 ng/mL who have undergone repeat total PSA and free-to-total PSA percentage tests at follow-up 1–3 months later, offer prostate biopsy:<br>— if repeat total PSA is greater than 5.5 ng/mL, regardless of free-to-total PSA percentage<br>— if repeat total PSA is greater than 3.0 ng/mL and less than or equal to 5.5 ng/mL **and** free-to-total PSA is below 25%. | CBR | 2.6 | 6.1 b, 6.4 |
| For men aged 50–69 years with a previous total PSA test result greater than 3.0 ng/mL who are not offered prostate biopsy (or do not accept prostate biopsy when offered) after follow-up PSA testing, explain that there is a small chance of missing a significant cancer and advise them to return for PSA testing within 2 years. | CBR | 2.6 | 6.1 b, 6.4 |
| Measurement of PSA velocity is not recommended to increase specificity of a total PSA test result of 3.0 ng/mL or greater. | EBR (D) | 2.6 | 6.2 b |
| Do not use the PHI test to increase specificity of a total PSA test result of 3.0 ng/mL or greater, except in the context of research conducted to assess its utility for this purpose. | CBR | 2.6 | 6.3 b |
| **Chapter 3: Prostate biopsy and multiparametric MRI** | | | |
| Take 21–24 cores in initial biopsies for the diagnosis of prostate cancer. In addition to the sextant biopsies, direct 15–18 additional biopsies to the peripheral zones of the prostate. | EBR (B) | 3.1 | 7 |
| Before offering biopsy after an elevated total PSA test result, take into account a man's family history of prostate cancer *(see Chapter 1 Risk)* and the results of further investigations *(see 2.5 Testing with variants of PSA to improve sensitivity after an initial total PSA ≤ 3.0 ng/mL and 2.6 Testing with variants of PSA or repeat PSA testing to improve specificity after an initial total PSA > 3.0 ng/mL).* | PP | 3.1 | 7 |
| Transrectal and transperineal biopsy approaches are both acceptable with respect to rates of cancer detection. The approach taken should be based on the man's wishes, the surgeon's experience, risk of sepsis and other morbidity, and practical issues such as cost and access to the necessary facilities. | PP | 3.1 | 7 |
| Advise men whose initial biopsy is negative for prostate cancer that they should continue to be followed.<br>Monitor more closely men with abnormal findings on pre-biopsy digital rectal examination, and those whose biopsy findings included either atypical small acinar proliferation or high-grade prostatic intra-epithelial neoplasia.<br>In addition to further PSA testing and digital rectal examination, consider prostate imaging with investigations that can help to localise the site of cancer within the prostate, and repeat biopsy using a targeted approach. | EBR (D) | 3.2 | 8.1, 8.2 |

# SUMMARY OF CLINICAL PRACTICE RECOMMENDATIONS

| Recommendation | Type (and grade, if applicable) | Section | PICO question # |
|---|---|---|---|
| **Chapter 3: Prostate biopsy and multiparametric MRI** | | | |
| Consider multiparametric MRI (using T2- and diffusion-weighted imaging) for men with a negative transrectal ultrasound-guided biopsy to determine whether another biopsy is needed. Do not offer another biopsy if the multiparametric MRI (using T2- and diffusion-weighted imaging) is negative, unless any of the following risk factors are present: — atypical small acinar proliferation on initial biopsy — abnormal digital rectal examination before the initial biopsy — high-grade prostatic intraepithelial neoplasia on initial biopsy. | EBR (D) | 3.2 | 8.1, 8.2 |
| Multiparametric MRI should be used only in centres with experienced radiologists appropriately trained in the use of multiparametric MRI to aid urologists in the management of individual patients.[iii] | PP | 3.2 | 8.2 |
| Clinicians and other staff performing multiparametric MRI should do so in accordance with appropriate standards and guidelines for its use.[iv] | PP | 3.2 | 8.2 |
| The recommendations for multiparametric MRI apply only to its use in patients who have already undergone biopsy. Primary healthcare professionals should not order multiparametric MRI in the initial investigation of suspected prostate cancer in men with raised PSA levels. | PP | 3.2 | 8.2 |
| Advise patients not undergoing repeat biopsy after a normal multiparametric MRI that there is a 10–15% chance of missing a significant cancer and that further follow-up is recommended. | PP | 3.2 | 8.2 |
| For men at average risk for prostate cancer whose initial biopsy is negative for prostate cancer, and who have a life expectancy of less than 7 years (e.g. due to their age or due to other illness), advise that no further action is recommended unless they develop symptoms that suggest prostate cancer. | PP | 3.2 | 8.2 |
| **Chapter 4: Active surveillance** | | | |
| Offer active surveillance to men with prostate cancer if all the following criteria are met: — PSA ≤ 20 ng/mL — clinical stage T1–2 — Gleason score 6. | EBR (C) | 4.1 | 9 |
| Consider offering active surveillance to men with prostate cancer if all the following criteria are met: — PSA ≤ 10.0 ng/mL — clinical stage T1–2a — Gleason score ≤ (3 + 4 = 7) and pattern 4 component < 10% after pathological review. For men aged less than 60 years, consider offering active surveillance based on the above criteria, provided that the man understands that treatment in these circumstances may be delayed rather than avoided. | CBR | 4.1 | 9 |

# SUMMARY OF CLINICAL PRACTICE RECOMMENDATIONS

| Recommendation | Type (and grade, if applicable) | Section | PICO question # |
|---|---|---|---|
| **Chapter 4: Active surveillance** | | | |
| Consider offering definitive treatment for:<br>— men with clinical stage T2b-c prostate cancer<br>— men with biopsy-diagnosed prostate cancer with PSA 10.0–20.0 ng/mL who do not meet the other criteria for active surveillance.<br>If the man strongly prefers active surveillance, offer repeat biopsy to ensure that disease classification is accurate. | CBR | 4.1 | 9 |
| Consider offering definitive treatment to men aged less than 60 years with either of the following:<br>— clinical stage T2b-c prostate cancer<br>— PSA 10.0–20.0 ng/mL and biopsy-diagnosed prostate cancer which does not meet the other criteria for active surveillance.<br>If the man strongly prefers active surveillance, offer repeat biopsy. | CBR | 4.1 | 9 |
| For men with prostate cancer managed by an active surveillance protocol, offer monitoring with PSA measurements every 3 months, and a physical examination, including digital rectal examination, every 6 months. | CBR | 4.1 | 10 |
| Offer a reclassification repeat prostate biopsy within 6–12 months of starting an active surveillance protocol.<br>Offer repeat biopsies every 2–3 years, or earlier as needed to investigate suspected disease progression: offer repeat biopsy and/or multiparametric MRI (in specialised centres) if PSA doubling time is less than 2–3 years or clinical progression is detected on digital rectal examination. | CBR | 4.1 | 10 |
| During active surveillance, offer definitive treatment if pathological progression is detected on biopsy, or if the patient prefers to proceed to intervention. | CBR | 4.1 | 10 |
| Advise men with low-risk prostate cancer that, if they choose active surveillance, their risk of death due to prostate cancer over the next 10 years would be low, and would probably be no greater than if they were to choose immediate definitive treatment. | PP | 4.1 | 9 |
| When considering active surveillance, take into account other factors that may be associated with risk of future pathological progression but for which evidence is inconsistent (e.g. total cancer length at biopsy, tumour volume, PSA doubling time < 3 years and PSA density). | CBR | 4.1 | 9 |
| In centres where staff have skills and experience in the use of multiparametric MRI for prostate examination, consider using it to help identify foci of potentially higher-grade disease, aid targeting at reclassification biopsies and aid determination of interval tumour growth. Clinicians and other staff performing multiparametric MRI should refer to appropriate standards and guidelines for its use.[v] | PP | 4.1 | 10 |

| Recommendation | Type (and grade, if applicable) | Section | PICO question # |
|---|---|---|---|
| **Chapter 5: Watchful waiting** | | | |
| For men with potentially curable prostate cancer who are considering watchful waiting, advise that:<br>— the risk of developing more advanced prostate cancer and dying from it is higher with watchful waiting than with immediate definitive treatment<br>— watchful waiting is unlikely to diminish wellbeing and quality of life in the medium-to-long term. | EBR (C) | 5.2 | 11 |
| Offer watchful waiting to men diagnosed with potentially curable prostate cancer who, for reasons other than prostate cancer, are unlikely to live for more than another 7 years. | CBR | 5.2 | 11 |
| Offer watchful waiting to men diagnosed with potentially curable prostate cancer who choose not to accept potentially curative therapy when it is offered to them. | CBR | 5.2 | 11 |
| For all men choosing watchful waiting, discuss the purpose, duration, frequency and location of follow-up with the man and, if he wishes, with his partner or carers.[vi] | CBR | 5.2 | 12 |
| Specialists should consider referring men without advanced incurable prostate cancer back to their general practitioners for follow-up in primary care according to a protocol the specialist suggests and/or these guidelines.<br>If there is no evidence of significant disease progression (as indicated by 3–4 monthly PSA levels over 1 year and absence of relevant symptoms), continue monitoring by 6-monthly PSA levels.<br>If there is evidence of significant disease progression (that is, relevant symptoms and/or rapidly-rising PSA level), refer to a member of the treating team (urologist, medical oncologist or radiation oncologist) for review. | CBR | 5.2 | 12 |
| For men whose prostate cancer is advanced and is not curable with local treatments, follow guidelines for the management of locally advanced or metastatic prostate cancer. If no treatment is offered or accepted, monitor clinically and by PSA testing and reconsider androgen deprivation therapy if any of the following occur:<br>— symptomatic local disease progression<br>— symptomatic or proven metastasis<br>— a PSA doubling time of < 3 months, based on at least three measurements over a minimum of 6 months (this should warrant consideration of further clinical investigations). | PP | 5.2 | 12 |

[i] *National Health and Medical Research Council. PSA testing for prostate cancer in asymptomatic men. Information for health practitioners [PDF document on web]. Last updated 2014; Available from: https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/men4d_psa_testing_asymptomatic_men_140304.pdf.*

[ii] *This Consensus-based recommendation assumes testing with the criterion for further investigation a PSA of ≥ 3 ng/mL. This recommendation will be a high priority for reconsideration when the Australian model of PSA testing has been completed. For example, use of the 95th percentile for age in place of ≥ 3 ng/mL might improve appreciably the balance of harms to benefits of testing in men 70–74 years of age.*

[iii] *Refer to Urological Society of Australasia position statement: Status of mp-MRI prostate 2012: report from the MRI Prostate Working Party (available at www.usanz.org.au).*

[iv] *See Moore CM, Kasivisvanathan V, Eggener S et al. Standards of reporting for MRI-targeted biopsy studies (START) of the prostate: recommendations from an International Working Group. Eur Urol 2013;64(4):544-552.*

[v] *See Moore CM, Kasivisvanathan V, Eggener S et al. Standards of reporting for MRI-targeted biopsy studies (START) of the prostate: recommendations from an International Working Group. Eur Urol 2013;64(4):544-552.*

[vi] *Source: adapted from [UK] National Collaborating Centre for Cancer. Prostate cancer: diagnosis and treatment. National Collaborating Centre for Cancer; 2014.*

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