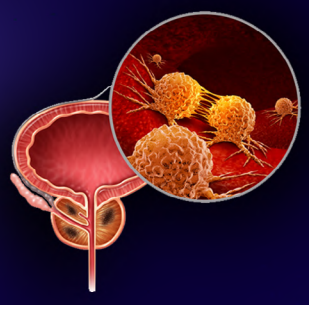
Prostate Cancer Practice Review™



Making Education Easy

Issue 28 - 2025

In this issue:

Abbreviations used in this issue:

ADT = androgen-deprivation therapy; **ARTG** = Australian Register of Therapeutic Goods; **EAU** = European Association of Urology; **mCRPC** = metastatic castration-resistant prostate cancer; **mHSPC** = metastatic hormone-sensitive prostate cancer; **MRI** = magnetic resonance imaging; **PBAC** = Pharmaceutical Benefits Advisory Committee; **PBS** = Pharmaceutical Benefits Scheme; **PCFA** = Prostate Cancer Foundation of Australia; **PSA** = prostate-specific antigen; **TGA** = Therapeutic Goods Administration.

Welcome to the 28th issue of Prostate Cancer Practice Review.

This Review covers news and issues relevant to clinical practice in prostate cancer. It will bring you the latest updates, both locally and from around the globe, in relation to topics such as new and updated treatment guidelines, changes to medicines reimbursement and licensing, educational, professional body news and more. Finally, on the back cover you will find our COVID-19 resources, and a summary of upcoming local and international educational opportunities including workshops, webinars and conferences.

We hope you enjoy this Research Review publication and look forward to hearing your comments and feedback.

Kind Regards,

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Clinical Practice

2025 update to EAU prostate cancer guidelines

A limited update to the 2024 iteration of the European Association of Urology (EAU) prostate cancer guideline has been published, providing clinicians with up-to-date evidence-based recommendations for the management of prostate cancer based on a structured appraisal of novel additions to the literature.

The following key changes to last year's iteration of the guidelines were made:

- The EAU intermediate-risk group for biochemical recurrence of localised and locally-advanced disease was divided into two groups – favourable and unfavourable
- Several new tables were added including
  - Definition of familial and hereditary malignancy
  - Sources of error in PSA value assessment
- Instead of providing general recommendations for the management of prostate cancer, disease stage-specific advice is now given
- The 'Magnetic resonance imaging (MRI) in population-based screening protocols' section was significantly updated
- Several new recommendations were included that endorse:
  - Combination androgen deprivation therapy (ADT) + darolutamide, or ADT + abiraterone or darolutamide and docetaxel as first-line treatment options for metastatic hormone-sensitive prostate cancer (mHSPC) in patients deemed fit for the regimens
  - Multidisciplinary team discussion of all patients with mHSPC
  - The use of bone protecting agents in men with mHSPC on long-term ADT with or without an androgen receptor pathway inhibitor (ARPI)

The full guidelines, as well as a quick reference document (Pocket guidelines), can be downloaded from the EAU website here. Pocket Guidelines, interactive algorithms and calculators, as well as clinical decision support tools, are also available on the EAU Guidelines App.

Draft 2025 Australian Clinical Practice Guidelines for the early detection of prostate cancer

The Australian Clinical Practice Guideline for prostate-specific antigen (PSA)-based prostate cancer screening for health professionals was published almost 10 years ago (available on the Cancer Council Australia website and here). Now, the Prostate Cancer Foundation of Australia (PCFA) have released a draft of modernised clinical guidelines for the early detection of prostate cancer, designed to provide general practitioners and urologists a structured evidence-based protocol to inform the timing and frequency of testing as well as appropriate screening methods. These new guidelines will supersede the previous recommendations. Developed via a rigorous systematic method by a Guideline Review team comprised of a Project Steering Committee, two Advisory Groups, an Expert Advisory Panel made up of general practitioners plus a representative from the Royal Australian College of General Practitioners, 12 Expert Advisory Panel Working Groups and an Executive Team, significant changes to the screening process are outlined. Notably, higher risk for screening purposes is redefined as at least double the risk specifically for clinically significant prostate malignancy or mortality, as opposed to risk of any prostate cancer. While the decision to initiate PSA testing still requires an individual clinical discussion, advancements in both diagnostics and treatments since the previous guideline iteration, as well as evidence on the use of active surveillance in certain cases after cancer diagnosis, have enabled refinement of advice on balancing of risks and benefits of screening according to age. Greater refinement of PSA test result interpretation is also provided.

In a world-first, consensus recommendations suggest that males interested in their prostate health may undergo a once-off PSA test from 40 years of age, and regular PSA testing may be offered to geriatric individuals (≥ 70 years of age) based on clinical evaluation. The new draft guidelines strongly advocate for biannual (every two years) PSA testing in males aged between 50 and 69 years with repeat testing within three months if total PSA ≥ 3.0 µg/L and referral to a urologist if PSA remains elevated on repeat test. Earlier initiation of biannual PSA testing (from 40 years of age) is also suggested for males at higher risk of clinically significant prostate cancer such as:

- individuals with a family history of prostate cancer, breast or ovarian cancer
- Black males of sub-Saharan African ancestry
- individuals with a confirmed germline *BRCA2* mutation

AND

- priority groups, such as Aboriginal and Torres Strait Islander men

Note that PSA threshold levels for retesting vary by age and by risk category.

Other salient advice in the 2025 draft guideline directs:

- Avoidance of digital rectal examination as an adjunct to PSA testing in asymptomatic males in the primary care setting.
- To consider other risk factors for prostate cancer such as metabolic syndrome, diet and smoking and to take care when interpreting PSA levels in individuals taking 5-alpha-reductase inhibitors (5-ARIs) and transgender women on gender-affirming hormones, both of which may artificially lower PSA values
- Use of pre-biopsy multiparametric MRI as the next diagnostic test in the specialist setting for men with confirmed elevated PSA levels

Finally, it is highlighted that while other informal models of discretionary testing are available, these Australian guidelines represent the world's first organised program to detect prostate cancer on a national scale, in-line with the goal of zero prostate cancer deaths.

The draft guidelines are available online. More information about the development of the new guidelines can be found in a PCFA webcast with experts Professor Jeff Dunn AO, PCFA Chief of Mission and Head of Research, Associate Professor David Smith, Interim Deputy Director and Prostate Cancer Stream Lead at the Daffodil Centre and Adjunct Professor Peter Heathcote, one of Australia's leading urologic surgeons for prostate cancer (available on YouTube and Spotify). Following refinement of the draft considering input submitted during the consultation period, the document will be submitted to the National Health and Medical Research Council for final approval later this year.

Actively avoiding prostate cancer screening risks death

Findings from an analysis of the European Randomised study of Screening for Prostate Cancer (ERSPC) suggest that men who actively avoid prostate cancer screening are at an elevated risk of both developing advanced disease and of mortality. Analysis of 20 years of follow-up data from more than 160,000 men aged 55-69 years in seven countries - Finland, the Netherlands, Italy, Sweden, Switzerland, Belgium and Spain – showed that men who declined all invitations to participate in screening had a roughly 40% increased risk of death from prostate cancer compared to both men who attended screening appointments and, surprisingly, a control cohort of men not invited to undergo screening.

This study was presented at the recent 2025 EAU Congress (EAU25 website). Abstracts from the Congress are available in a supplement to *European Urology* (requires a subscription). Full results from the study will be published later in the year.

BARCODE 1: targeted screening guided by genetic profiling may improve prostate cancer detection

Results from the UK BARCODE1 study suggest that integrating a polygenic risk score into a multimodality prostate cancer screening program alongside standard risk evaluation, PSA testing and MRI may improve the detection of clinically significant disease. Researchers at the prostate risk clinic at the Royal Marsden NHS Foundation Trust first utilised genetic single-nucleotide polymorphism (SNP) profiling to non-invasively identify men with a predisposition for prostate cancer via analysis of 130 gene variants (~ 170 single-nucleotide polymorphisms) with known association to prostate cancer risk in DNA extracted from saliva, and subsequently offered this group targeted prostate cancer screening with multiparametric MRI and transperineal biopsy. In a cohort of almost 6,400 Caucasian men aged 55 to 69 years who underwent genetic profiling, roughly 12% were found to have a high genetic risk score (polygenic risk score in the 90th percentile or higher; n=745) and were offered imaging and biopsy screening, regardless of PSA level. In the subgroup of men with high genetic risk score who consented to further screening, the incidence of prostate cancer was 40%, more than half of which was clinically significant disease requiring treatment (intermediate or higher risk according to the 2024 National Comprehensive Cancer Network criteria). Alarmingly, more than 70% of clinically significant prostate cancer cases identified using this targeted screening protocol would have escaped detection via standard PSA and imaging screening methods.

N Engl J Med. 2025;392(14):1406-17

Earn CPD

Nursing and Midwifery Board of Australia (NMBA) Journal reading and watching videos (including Research Reviews') may be considered a self-directed activity set out in the NMBA Registration Standard: Continuing Professional Development. One hour of active learning will equal one hour of CPD. Details at NMBA CPD page.

What is the optimal interval to evaluate PSA post-prostatectomy?

Although persistence of detectable PSA levels after radical prostatectomy has been linked to a worse prognosis with poorer survival in prostate cancer in multiple studies, the optimal timing of post-surgical PSA testing remains unclear. An international research group retrospectively analysed pre- and post-surgical PSA levels and outcomes in more than 40,000 men who received a radical prostatectomy for non-metastatic prostate cancer at the University Hospital Hamburg-Eppendorf, in Germany or at a US Johns Hopkins Medical Institution over an almost 30-year period to elucidate how long after surgery PSA should be monitored to accurately identify disease recurrence, inform treatment decisions and avoid overtreatment. The study first reported a paradoxical association between PSA and mortality after prostatectomy in patients with persistent post-surgical PSA, finding a lower risk of both all-cause and prostate cancer-specific mortality associated with higher pre-surgical PSA levels (> 20 ng/mL vs ≤ 20 ng/mL). Further analysis of the data however, revealed that this unexpected finding may be attributable to PSA levels being evaluated too soon after surgery, especially for men with higher pre-operative PSA levels, which may take three or more months to clear from the serum and become undetectable (54.7% undetectable at a median of 2.68 months). The authors also speculated that with longer post-surgical follow-up a greater proportion of patients with higher pre-surgical PSA levels may achieve undetectable post-surgical PSA status. When PSA levels were assessed at the standard interval of approximately two months after prostatectomy, significantly more patients with higher pre-operative PSA levels had persistent detectable PSA (14% vs 3.6%) and their PSA level was higher (0.65 vs 0.3 ng/mL). In addition, this group more frequently received salvage radiotherapy and/or hormonal therapy and initiated it sooner, often prior to the median time to undetectable PSA, indicating that a longer duration of PSA monitoring post-surgery is required to base salvage therapy decisions on. Current clinical guideline recommendations for PSA testing in the post-surgical setting may require updating to reflect these novel findings.

JAMA Oncol. 2025;11(5):502-10

Regulatory News

TGA approves export only abiraterone acetate products

Late in April the Therapeutic Goods Administration (TGA) approved the addition of six **abiraterone acetate products** to the Australian Register of Therapeutic Goods (ARTG) specifically for export only. The TGA has not approved the sale/supply of these products within Australia. All products are made by Nova Pharmaceuticals Australasia and include 250 mg and 500 mg strength abiraterone acetate tablets under the brand names Novazet™, Vostig™ and Zyron™ as follows:

- Novazet™ 250 mg tablet bottle (ARTG ID 449611)
- Novazet™ 500 mg tablet blister pack (ARTG ID 449612)
- Vostig™ 250 mg tablet bottle (ARTG ID 449615)
- Vostig™ 500 mg tablet blister pack (ARTG ID 449616)
- Zyron™ 250 mg tablet bottle (ARTG ID 449613)
- Zyron™ 500 mg tablet blister pack (ARTG ID 449614)

Per the ARTG listings, all formulations of the Novazet™, Vostig™ and Zyron™ branded abiraterone acetate medications are intended, in combination with prednisolone, for the treatment of:

- newly diagnosed high-risk mHSPC in combination with ADT
- metastatic castration-resistant prostate cancer (mCRPC) in patients who are asymptomatic or mildly symptomatic after failure of ADT
- mCRPC in patients who have received prior chemotherapy containing a taxane

In Australia, there are both branded and generic single-agent abiraterone acetate tablets available including Zytiga™ (500 mg film-coated tablet blister pack & 250 mg tablet bottle; Janssen-Cilag Pty Ltd), Abiraterone-Teva, Abiraterone Sandoz and Abiraterone Dr. Reddy's, as well as a fixed combination product with methylprednisolone (Yonsa® Mpred). Product and Consumer Medicine Information about these medications can be found here.

PBS listing of abiraterone acetate + prednisolone under evaluation

On the agenda for the Pharmaceutical Benefits Advisory Committee (PBAC) meeting scheduled for July 2025 is a request from Actor Pharmaceutical for a General Schedule Authority Required (Telephone/Online) Pharmaceutical Benefits Scheme (PBS) listing of a composite pack containing **abiraterone acetate and prednisolone** (Andriga-10; 56 tablets each of abiraterone acetate 500 mg and prednisolone 5 mg) for the treatment of patients with mCRPC.

The outcome will be published online after the meeting and recommendations provided to the Federal Government for a final decision on public funding.

Consumer comments on the impact of PBS subsidy of this product submitted prior to 28 May 2025 will be considered by the PBAC. Input can be submitted via the online survey on the Office of Health Technology Assessment (OHTA) Consultation Hub.

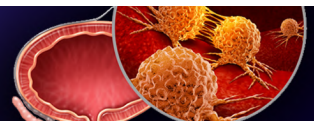
Dual medicine labelling requirement ends in May for some drug ingredients

In order to mitigate confusion regarding new medication names following the international harmonisation of ingredient names effort in 2016, the TGA implemented a transient dual labelling period. This required labels on medications released in Australia between May 2020 and 30 April 2023 to display impacted ingredients by both their old and new names. A subsequent three-year grace period – until 30 May 2026 - was given to manufacturers to transition to sole labelling with the new drug name. Product Information and Consumer Medicine Information documents will also be updated to reflect the new names.

A select few ingredients with substantial changes to their name have an extended dual labelling period timeframe, with sole new name labelling not mandated until the 1st May 2028 but the compulsory double labelling period ending on the 30th April 2025. Clinicians should therefore be familiar with the new names now, as some medications may cease using the old ones imminently. Old names for the following ingredients (in bold) may no longer be seen on labels from May:

- dosulepin (**dothiepin**) hydrochloride
- hydroxycarbamide (**hydroxyurea**)
- tetracaine (**amethocaine**)
- tetracaine (**amethocaine**) hydrochloride
- trihexyphenidyl (**benzhexol**) hydrochloride.

A full list of affected names being updated to internationally recognised versions can be found online here.



News in Brief

App-based lighting intervention promising for cancer-related fatigue

A 12-week US trial has reported promising preliminary results for a personalised light intervention informed by circadian rhythms for cancer-related fatigue. A total of 139 patients with cancer undergoing stable systemic therapy - including 42 with prostate cancer – were enrolled in the trial. Those allocated to the intervention arm received daily individualised light exposure recommendations such as seek bright light or wear blue-light blocking glasses based on heart rate data gathered from an Apple smartwatch and an algorithm via the Sync mobile application. Patients randomised to the control arm used a sham app and clear glasses. Reductions in fatigue, anxiety and sleep disturbances, as well as improvements in physical functioning were noted in the intervention cohort.

Cell Rep Med. 2025;6(3):102001

Former US President Biden diagnosed with metastatic prostate cancer

On Sunday 18th May, the office of Former President Joseph R. Biden Jr released a statement announcing his recent diagnosis with incurable stage 4 prostate cancer. According to follow-up statements, the disease has disseminated to his bones. Reportedly, Biden had not undergone PSA screening in more than 10 years. This is consistent with US guidelines that recommend against screening in men 70 years of age or older (Biden is now 82 years old). Both the American Cancer Society (ACS) and the American Cancer Society Cancer Action Network (ACS CAN) issued statements supporting the Former President and acknowledging his anti-cancer efforts while in office, including prioritisation of government funding of cancer research and the launch of the Cancer Moonshot Initiative.

Multiple news sites, including CNN, are providing regular updates.

PCFA's Walk for Him event on during Men's Health Week

During Men's Health Week – Mon 9th June to Sunday 15th June – the PCFA is hosting a fundraising and awareness campaign named, "Walk for Him" with all proceeds supporting research and support services for men with prostate cancer and their families.

Individuals wishing to participate can sign up online at www.walkforhim.org.au

Improved prostate cancer detection with transperineal biopsy

Local anaesthetic ultrasound-guided transperineal biopsy improves the detection of clinically significant prostate cancer compared to traditional transrectal biopsy, but may be more painful and embarrassing, according to results from the UK multicentre TRANSLATE trial. A randomised controlled head-to-head comparison of the two biopsy techniques was undertaken in a cohort of 1,126 men suspected of having prostate cancer based on PSA levels or digital rectal examination. A 6% increase in clinically significant prostate cancer (defined as the presence of Gleason Grade Group ≥2 prostate cancer) was reported with the transperineal versus transrectal method (60% vs 54%; odds ratio 1.32), as well as a lower incidence of infections requiring hospitalisation.

Lancet Oncol. 2025;26(5):583-95

COVID-19 Resources

Royal Australasian College of Surgeons
European Urology Journal
British Association of Urological Surgeons
European Society of Medical Oncology

Conferences, Workshops, and CPD

Please click on the links below for upcoming local and international prostate cancer meetings, workshops and CPD.

AUA - Meetings & Education
COSA – Events
MOGA – Events
USANZ – Events

Research Review Publications

Prostate Cancer Research Review with Professor Niall Corcoran
Urology Research Review with Professor Eric Chung

Earn CPD

Royal Australasian College of Physicians (RACP) MyCPD participants can claim the time spent reading and evaluating research reviews as CPD in the online MyCPD program. Please contact MyCPD@racp.edu.au for any assistance.

Royal Australian & New Zealand College of Radiologists (RANZCR) members can claim reading related to their practice as a CPD activity under the category 'journal reading and web based no certificate *reflection required'. More info.

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