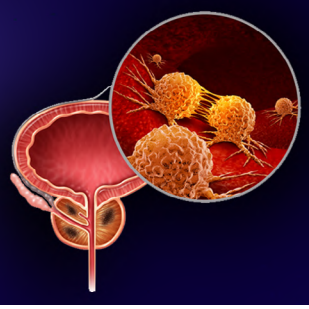
Prostate Cancer Practice Review™



Making Education Easy

Issue 29 - 2025

In this issue:

Abbreviations used in this issue:

ADT = androgen-deprivation therapy; **AI** = artificial intelligence; **AUA** = American Urological Association; **BPH** = Benign Prostatic Hyperplasia; **COSA** = Clinical Oncology Society of Australia; **CPD** = continuing professional development; **GGT** = germline genetic testing; **GRADE** = Grading of Recommendations, Assessment, Development, and Evaluations; **mCRPC** = metastatic castration-resistant prostate cancer; **mHSPC** = metastatic hormone-sensitive prostate cancer; **MOGA** = Medical Oncology Group of Australia; **mpMRI** = multiparametric magnetic resonance imaging; **NCCN** = National Comprehensive Cancer Network Clinical; **NHMRC** = National Health and Medical Research Council; **PBS** = Pharmaceutical Benefits Scheme; **PCFA** = Prostate Cancer Foundation of Australia; **PET** = positron emission tomography; **PGV** = pathogenic germline variant; **PSA** = prostate-specific antigen; **PSMA PET** = prostate-specific membrane antigen; **RECIP** = Response Evaluation Criteria in PSMA-imaging; **RECIST** = Response Evaluation Criteria in Solid Tumors; **SPECT** = single-photon emission computed tomography; **TGA** = Therapeutic Goods Administration; **TTV** = total tumour volume; **USANZ** = Urological Society of Australia and New Zealand.

Welcome to the 29th 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 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,

Dr Janette Tenne
Editor
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Clinical Practice

Draft 2025 clinical guidelines for the early detection of prostate cancer

The PCFA has submitted a draft of the *2025 Clinical Guidelines for the Early Detection of Prostate Cancer* to the NHMRC for approval, aiming to update and replace the 2016 prostate-specific antigen (PSA) Testing Guidelines. These new guidelines reflect significant advances in prostate cancer diagnostics and management, supporting a more structured, evidence-based approach to early detection. Developed through a comprehensive process involving multidisciplinary expert panels, systematic reviews, and alignment with NHMRC and GRADE standards, the guidelines address risk stratification, diagnostic pathways, and management strategies tailored to contemporary clinical practice.

Risk assessment is central, with strong evidence identifying men at higher risk of prostate cancer mortality: those with a brother diagnosed with prostate cancer, a father diagnosed before age 65, or two or more second-degree relatives who died of prostate cancer. Black men of sub-Saharan African ancestry and those with *BRCA2* mutations are also classified as higher risk. For these groups, the risk of prostate cancer mortality is at least double that of the general population. The guidelines recommend biennial PSA testing for men aged 50–69 years, with earlier and more frequent testing (from age 40) for those at higher risk. For Aboriginal and Torres Strait Islander men, recommendations align with the general population, but with added emphasis on embedding PSA testing within annual health assessments and culturally appropriate health promotion to address disparities in awareness and access.

Digital rectal examination is no longer recommended as a routine adjunct to PSA testing in primary care due to limited incremental diagnostic value, though it remains important in specialist assessment before biopsy. For men with elevated PSA, multiparametric MRI (mpMRI) is recommended as the next diagnostic step, guiding the need for biopsy. Targeted biopsies are advised for suspicious mpMRI lesions, with systematic biopsies reserved for equivocal or high-risk cases. The guidelines also endorse active surveillance as the preferred management for low-risk localised prostate cancer, outlining protocols for monitoring with PSA, mpMRI, and selective repeat biopsy to minimise overtreatment.

A risk-adapted, harm-minimisation approach underpins all recommendations, emphasising shared decision-making, patient preferences, and the use of modern diagnostic tools to reduce overdiagnosis and overtreatment. The guidelines are designed to be reviewed by 2030 or earlier as new evidence emerges, ensuring ongoing alignment with best practice and patient outcomes in prostate cancer care.

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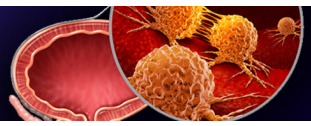

Theranostics in advanced prostate cancer management

USANZ issued a position statement earlier this year outlining the current role of theranostics in the management of advanced prostate cancer, particularly focusing on metastatic castration-resistant prostate cancer (mCRPC). The increasing adoption of prostate-specific membrane antigen positron emission tomography (PSMA PET) imaging has enabled more precise identification of PSMA-expressing lesions, facilitating the use of targeted radioligand therapies. The most extensively studied therapeutic agent in this context is 177Lu-PSMA-617, with 177Lu-PSMA I&T as an alternative. These agents deliver targeted radiation to metastatic sites, using β-emitting isotopes such as lutetium-177, and, in some cases, α-emitters like actinium-225.

Evidence supporting these therapies is drawn from major clinical trials. The phase II TheraP trial compared up to six cycles of 177Lu-PSMA-617 with cabazitaxel in men with mCRPC. The primary endpoint, a ≥50% reduction in PSA, was achieved in 66% of patients receiving 177Lu-PSMA-617 compared with 37% in the cabazitaxel group, with a statistically significant difference. However, overall survival at 36 months was similar between the two groups. The phase III VISION trial evaluated 177Lu-PSMA-617 in patients previously treated with at least one androgen-receptor pathway inhibitor and one or two taxane regimens. This trial demonstrated a significant improvement in both imaging-based progression-free survival and overall survival for patients receiving 177Lu-PSMA-617 plus standard care compared with standard care alone. Updated safety analyses from the VISION study support the use of up to six cycles in patients who are clinically benefiting and tolerating therapy.

Adverse event profiles indicate that 177Lu-PSMA-617 is generally well tolerated, with discontinuation rates due to toxicity ranging from 1% in TheraP to 7% in VISION. In TheraP, grade 3–4 adverse events were less frequent with 177Lu-PSMA-617 than with cabazitaxel (33% vs. 53%), though thrombocytopenia was notable. In VISION, the incidence of grade 3 or higher adverse events was higher with 177Lu-PSMA-617, but quality of life was not negatively affected.

Patient selection criteria for 177Lu-PSMA-617 therapy include confirmed mCRPC, prior treatment with at least one androgen-receptor pathway inhibitor and one taxane regimen, and the presence of at least one PSMA-positive metastatic lesion with no PSMA-negative lesions. An ECOG performance status of 0–2 is required. All cases should be reviewed in a multidisciplinary setting with appropriate imaging.

https://tinyurl.com/umxzxmrv

Evaluation of NCCN prostate cancer clinical practice guidelines for germline genetic testing

A recent study evaluated the effectiveness of the NCCN clinical practice guidelines, specifically version 1.2022, for germline genetic testing (GGT) in patients with localised and locally recurrent nonmetastatic prostate cancer. The primary aim was to determine how well these criteria identify patients with pathogenic or likely pathogenic germline variants (PGVs) in a European cohort, and to compare the diagnostic yield of the 1.2022 criteria with earlier (2.2019) and newer (3.2024) NCCN guideline versions.

A total of 376 consecutive patients with nonmetastatic prostate cancer, either undergoing radical prostatectomy or salvage lymphadenectomy, were prospectively enrolled between 2021 and 2022. All patients met the NCCN 1.2022 GGT criteria, which include indications based on tumour characteristics, family history, and prior personal history of other malignancies. Genetic testing was performed for a panel of genes associated with prostate cancer risk, including *ATM*, *BRCA1*, *BRCA2*, *CHEK2*, *TP53*, *PALB2*, *MLH1*, *MSH2*, *MSH6*, *PMS2*, and *HOXB13*, using next-generation sequencing.

The study found that 12.2% of patients (46/376) harboured PGVs, with the highest detection rate in those meeting the criteria based on tumour characteristics (17.5%). Multivariable logistic regression confirmed that high-risk tumour features were a significant independent predictor of PGVs (odds ratio 2.48, 95% CI 1.03–5.84, p=0.04), while family history and prior malignancy were not independent predictors. Notably, 23.1% of patients fulfilled more than one criterion, and this subgroup also showed a higher likelihood of PGV detection.

When applying the NCCN 2.2019 and 3.2024 criteria retrospectively to the same cohort, the overall detection rates of PGVs were similar (12.5% and 12.6%, respectively), but both would have missed five patients with PGVs who were identified using the 1.2022 criteria. This highlights the increased sensitivity of the 1.2022 guidelines, particularly for nonmetastatic high-risk prostate cancer. The study also observed that the prevalence of PGVs in this nonmetastatic cohort was comparable to rates reported in metastatic prostate cancer populations, supporting the extension of GGT to earlier disease stages.

The authors conclude that the NCCN 1.2022 GGT criteria provide a robust framework for identifying patients with nonmetastatic high-risk prostate cancer who are likely to benefit from genetic testing. The findings support the integration of GGT into routine clinical practice for this population, enabling personalised management and cascade testing for at-risk relatives. The study also underscores the need for further multicentre research to refine subcriteria and assess cost-effectiveness in broader clinical settings.

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PSMA PET or conventional imaging in metastatic hormone-sensitive prostate cancer?

A recent editorial in *Expert Review of Anticancer Therapy* discusses the evolving role of prostate-specific membrane antigen positron emission tomography (PSMA PET) compared with conventional imaging in the staging and management of metastatic hormone-sensitive prostate cancer (mHSPC). Accurate classification of disease volume into low or high categories is critical for guiding treatment decisions, including the use of androgen-deprivation therapy (ADT), androgen-receptor pathway inhibitors, and intensified systemic regimens such as triplet therapy with docetaxel. Conventional imaging methods, including bone scintigraphy and CT, rely on criteria such as CHAARTED to define high-volume disease, but these methods often underestimate metastatic burden by missing small lesions.

PSMA PET has emerged as a more sensitive and specific imaging modality, capable of detecting subcentimeter nodal, bone, and visceral metastases that convetional imaging misses. This increased sensitivity leads to significant upstaging, with studies showing that 30–50% of patients initially classified as low-volume by conventional imaging are reclassified as high-volume by PSMA PET. This reclassification has important implications for treatment intensification and eligibility for metastasis-directed therapy. However, the higher cost, limited availability, and lack of standardised volume thresholds associated with PSMA PET currently limit its widespread adoption.

A promising quantitative biomarker derived from PSMA PET is the PSMA total tumour volume (PSMA-TTV), which sums the volume of all PSMA-avid lesions, providing a more objective measure of disease burden than lesion counting alone. Retrospective analyses from trials such as ENZAMET and ENZA-p have demonstrated that higher PSMA-TTV correlates with poorer progression-free and overall survival, even among patients classified as low-volume by conventional criteria. PSMA-TTV may also predict response to systemic therapies, although no standardised cutoffs exist yet, and variability in measurement methods remains a challenge.

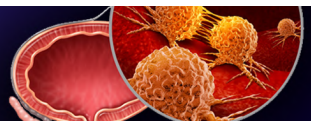
The editorial emphasises that while PSMA PET and PSMA-TTV offer enhanced staging accuracy and prognostic information, their integration into clinical practice faces barriers including a lack of standardisation, limited access, workflow challenges, and absence from current guidelines. Interim approaches include using PSMA-TTV as a supplementary metric alongside traditional staging and adopting semi-standardised protocols locally. Multidisciplinary collaboration and prospective clinical trials incorporating PSMA PET biomarkers are needed to refine treatment algorithms and validate these novel imaging metrics.

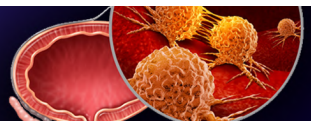
Ultimately, PSMA PET represents a significant advance in the precision oncology of mHSPC, enabling more accurate disease characterisation and potentially more personalised treatment strategies. However, clinicians must interpret PSMA PET findings cautiously within the context of existing trial data and consider individual patient factors, including comorbidities and genomic markers, when deciding on treatment intensification to avoid overtreatment and optimise outcomes.

https://tinyurl.com/ykrdr7e4

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.





Regulatory News

MBS update: Therapeutic nuclear medicine therapy for metastatic castrate resistant prostate cancer

Available from 1 July 2025, the Medicare Benefits Schedule in Australia introduced two new items for Lutetium-177 (177Lu) PSMA therapy, targeting patients with progressive or symptomatic mCRPC who have failed prior treatments. Additionally, a new item for a whole-body PSMA PET scan was listed to determine patient eligibility for this therapy. mCRPC is characterised by prostate cancer that has metastasised and no longer responds to hormone therapy. These changes are significant for specialists, consultant physicians, patients, private health insurers, and hospitals involved in the management of advanced prostate cancer.

The new diagnostic imaging item, 61528, enables a whole-body PSMA PET scan to assess suitability for Lutetium PSMA therapy in patients whose disease has progressed despite chemotherapy and at least one androgen receptor signalling inhibitor. The scan is reimbursed at $1,300, with Medicare benefits of 85% ($1,197.60) or 75% ($975.00) of the schedule fee. For therapeutic intervention, two new items (16050 and 16055) are available. Item 16050 covers the administration of Lutetium-177 PSMA, followed within 36 hours by whole-body Lu-PSMA SPECT, for patients confirmed as PSMA-positive by PET criteria (SUV_{max} >15 at a single site and >10 at all measurable sites) after prior treatment failure. This item allows for up to two cycles during the initial phase, with a schedule fee of $8,000 per cycle and corresponding Medicare benefits. Item 16055 permits up to four additional cycles in patients who have not shown disease progression during initial therapy, using the same administration protocol and reimbursement structure.

Eligibility for continuing therapy (item 16055) requires that no disease progression has occurred during Lutetium-177 PSMA treatment, as defined by a rise in PSA of more than 2 ng/mL confirmed by two tests at least two weeks apart, or new soft tissue or bone metastases on imaging, following established criteria such as RECIST or RECIP. These changes are not limited to a specific Lutetium PSMA product, anticipating future developments in theranostics. Patients may face significant upfront costs, and claims for out-of-pocket payments exceeding $10,000 require submission of a specific Medicare claim form. The Extended Medicare Safety Net will provide additional support for high out-of-pocket expenses. These updates follow recommendations from the Medical Services Advisory Committee and aim to improve access, survival, and quality of life for patients with advanced prostate cancer by expanding the availability of evidence-based nuclear medicine therapies.

https://tinyurl.com/59sttun2

Medicine supply updates

Based on the Medicine Shortage Reports Database from the Therapeutic Goods Administration (TGA), the following supply updates may be of particular interest to clinicians managing prostate cancer. The TGA is monitoring these issues, and alternative products are being sought where possible.

ADT and anti-androgens

- **BI ELIGARD CP®** (leuprorelin acetate + bicalutamide, multiple strengths) has been discontinued, with supply expected to be exhausted by July–October 2025.
- **CALUTEX®, COSAMIDE®, APO-BICALUTAMIDE®** (bicalutamide 50 mg tablets) have been discontinued or are in limited supply, with some shortages resolved as of June 2025.
- **COSAMIDE®** (bicalutamide 50 mg tablets) is anticipated to be available from August to September 2025 following a period of limited availability.

5-alpha-reductase inhibitors and BPH agents

- **APO-Dutasteride®** (dutasteride 500 microgram capsules) shortage resolved as of May 2025.
- **DUTASTERIDE/TAMSULOSIN LUPIN®** (dutasteride 500 microgram / tamsulosin 400 microgram capsules) shortage resolved as of May 2025.
- **FINAPEN® and FINASTERIDE VIATRIS®** (finasteride 1 mg tablets) are in limited supply or anticipated shortage through December 2025.

Supportive and symptom management therapies

- Multiple brands of **solifenacin** (solifenacin succinate 5 mg, 10 mg tablets) are in limited supply or unavailable through August–September 2025.
- Some presentations of **morphine and oxycodone** (various brands, oral and injectable) are in limited supply or discontinued, with alternative brands and Section 19A (unregistered) products approved by the TGA.

This information is current as of 11 July 2025. Clinicians are advised to check the TGA Medicine Shortages database for updates and discuss alternatives with pharmacists as needed

https://tinyurl.com/mrr52z4w

Electronic prescribing

Electronic prescribing is now broadly available in Australia, supporting both clinicians and patients with the choice to use electronic prescriptions instead of paper scripts, while maintaining the option for paper when preferred. This system is integral to the government's digital health and medicines safety initiatives, aiming to improve Pharmaceutical Benefits Scheme (PBS) efficiency, medication safety, and regulatory compliance. The Australian Government has committed over $111 million to support and enhance electronic prescription infrastructure, and legislative changes at both federal and state/territory levels ensure the legal validity of electronic prescribing for PBS medicines nationwide.

For clinicians, electronic prescribing offers a streamlined workflow, potential reduction in prescribing and dispensing errors, and improved safety, which is critical in settings such as hospitals and aged care. The process does not alter core clinical prescribing steps but replaces the tangible paper prescription with a secure digital token (QR code) sent to the consumer via SMS or email, which is then presented at the pharmacy for dispensing. Notably, the Active Script List provides a consolidated view of a patient's active prescriptions, allowing prescribers and pharmacists, with the patient's consent, to more effectively manage medications, particularly for those on multiple therapies.

This model supports telehealth and continuity of care and reduces physical script handling, which lowers infection risks. The government continues refining technical and regulatory standards, and clinicians are encouraged to ensure their clinical software is updated and to participate in available training. Importantly, despite recent cybersecurity concerns with a former provider, current prescription delivery services remain secure and operational. Overall, electronic prescribing enhances patient choice and medication management while supporting national health system efficiency and safety.

https://tinyurl.com/ek2hb4ny

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.

News in Brief

Developing a professional framework for prostate cancer specialist nursing practice

The *Prostate Cancer Specialist Nurse Practice and Capability Framework 2023* was developed through a Real-time Delphi process involving 75 expert nurses. The framework defines standards and competencies across four domains to guide professional and clinical practice, emphasising person-centred, evidence-based care and interdisciplinary collaboration. It aims to improve survivorship outcomes, address fragmented care, and support the professional growth of specialist nurses.

https://tinyurl.com/2tjdw4eh

Artificial intelligence and prostate cancer

UROonco25 took place in Seville, Spain from 19 to 21 June 2025. During the conference, Dr. Giancarlo Marra (Italy) interviewed Prof. Prokar Dasgupta (Great Britain) on the hot topic of artificial intelligence (AI) and prostate cancer, including the challenges and opportunities when integrating AI into daily clinical practice. According to Prof. Dasgupta, while AI will enhance precision and efficiency, it will not replace the judgment and adaptability of surgeons, at least not any time soon. The future lies in collaboration: human intelligence with machine intelligence. The short interview is available to watch on demand.

https://tinyurl.com/59h4tyf9

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

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