Prostate Cancer Practice Review



Making Education Easy

Issue 25 - 2024

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Abbreviations used in this issue:

¹⁷⁷Lu = lutetium-177; ADT = androgen-deprivation therapy;

ARPI = androgen receptor pathway inhibitor:

ARSI = androgen receptor signalling inhibitor;
APCCC = Advanced Prostate Cancer Consensus Conference;

CRPC = castration-resistant prostate cancer;
FDA = US Food & Drug Administration; HRR = homologous recombination repair;

ISUP = International Society of Urological Pathology; MBS = Medicare Benefits Schedule:

mCRPC = metastatic castration-resistant prostate cancer; mHSPC = metastatic hormone-sensitive prostate cancer;

MRI = magnetic resonance imaging; PARP = poly(ADP-ribose) polymerase; PBS = Pharmaceutical Benefits Scheme; PET = positron emission tomography;

PSA = prostate-specific antigen; PSMA = prostate-specific membrane antigen; TGA = Australian Therapeutic Goods Administration.

Welcome to the 25th 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. And 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,

Dr Janette Tenne

Editor

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Clinical Practice

Management of patients with advanced prostate cancer. Report from the 2024 Advanced Prostate Cancer Consensus Conference (APCCC)

Advanced Prostate Cancer Consensus Conferences (APCCCs), hosted biennially by the Advanced Prostate Cancer Society, aim to support clinical decision-making in areas where a paucity of high-quality evidence or diametric trial findings preclude definitive clinical practice guidelines. The consensus statements constitute a supplement to evidence-informed guidelines by capturing the majority expert view of expert physicians including medical, clinical and radiation oncologists plus urologists, on key areas of advanced prostate cancer management in an ideal real-world situation in the current era of multiple efficacious but potentially expensive and toxic therapeutic options and where imaging techniques, biomarker identification and analysis, molecular characterisation and genetic assays are rapidly evolving.

During the 5th APCCC – held in Lugano, Switzerland in April – more than 100 interdisciplinary prostate cancer experts from across the globe discussed and voted on 183 pre-determined multiple-choice questions across eight contentious areas of advanced prostate cancer care, namely management of various advanced disease states (high-risk localised and locally advanced, metastatic hormone-sensitive and metastatic castration-resistant) plus prostate-specific antigen (PSA) persistence and biochemical recurrence, radioligand therapy with lutetium-177 (177Lu)-labelled prostate-specific membrane antigen (PSMA) ligands, side-effects from hormonal therapy, bone protection and genetics and genomics.

After deletion of one poorly-worded question, given a hypothetical scenario of ready availability of all diagnostic procedures and therapies in a patient without contraindications for whom no clinical trial is available, voting achieved consensus on just over one-fifth of questions, including 11 with a strong consensus (≥90% agreement). In addition, in approximately one-third of questions that did not reach consensus most panellists agreed that the best alternative was between two options.

Strong consensus (≥90% agreement) was attained for the following:

High-risk localised and locally advanced disease

- For patients with localised prostate cancer and clinically T2 (digital rectal examination positive) cN0 cM0 and International Society of Urological Pathology (ISUP) grade group ≥3 carcinoma and clear evidence of T3 disease on magnetic resonance imaging (MRI), treatment as per T3 disease is preferred over treatment for T2 disease
- For patients with newly diagnosed cN1 (pelvic lymph nodes) on conventional imaging and no distant lesions, prostate plus pelvic radiation therapy plus long-term androgen deprivation therapy (ADT) and two years of abiraterone is the preferred treatment
- For continent patients with pT3b pN0 following radical prostatectomy with extended pelvic lymph node dissection (ISUP grade group 4–5 and R0 and with undetectable postoperative PSA) most experts employ a monitoring plus early salvage therapy strategy rather than initiating adjuvant therapy

PSA persistence and biochemical recurrence

 For patients with a confirmed rising PSA after radical prostatectomy and a PSA-doubling time ≤1 year or pathological ISUP grade group 4 or 5 and no or negative PSMA-positron emission tomography (PET) imaging, salvage therapy with radiotherapy and/or systemic therapy is preferrable to monitoring

Metastatic hormone-sensitive prostate cancer (mHSPC)

 For systemic therapy in a patient with metachronous lowburden mHSPC on conventional imaging, therapy with ADT plus an androgen receptor pathway inhibitor (ARPI) is preferred over either alone, or both plus docetaxel

Metastatic castration-resistant prostate cancer (mCRPC)

- Somatic genetic testing for aberrations in DNA damage repair genes prior to initiating poly(ADP-ribose) polymerase (PARP) inhibitor therapy is recommended
- For patients with mCRPC progressing on ADT plus an ARPI, cabozantinib and atezolizumab is NOT recommended
- For patients with BRCA2 mutated mCRPC who received ADT ± docetaxel for mHSPC, first-line ARPI plus PARP inhibitor is preferred over an ARPI alone, taxane chemotherapy or ¹⁷⁷Lu-PSMA therapy

177Lu-PSMA therapy

- For chemotherapy fit patients with PSMA imaging-positive mCRPC who meet relevant PET criteria for ¹⁷⁷Lu-PSMA therapy and who have received one line of ARPI and one line of taxane-based chemotherapy and have no actionable molecular alteration, most physicians utilise ¹⁷⁷Lu-PSMA, instead of cabazitaxeI, radium-233 or an alternate ARPI
- It is not appropriate to recommended ¹⁷⁷Lu-PSMA therapy for mHSPC outside of a clinical trial

Side effects of systemic therapy and ARPI selection in special situations

 The blood pressure of patients undergoing abiraterone therapy should be monitored

The publication was careful to note that these consensus statements were not based on a literature review or meta-analysis and reflect only standard expert practices in complex situations where best practice is debatable. Finally, areas where consensus could not be reached emphasise the need for quality trials to inform treatment decisions.

Eur Urol. 2024; Oct 10. Online ahead of print



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PBS: Pharmaceutical Benefits Scheme; QOL: quality of life; ADT: androgen deprivation therapy; mHSPC: metastatic hormone sensitive prostate cancer; HRQOL: health related quality of life; mCRPC: metastatic castration resistant prostate cancer; QLQ-C30: European Organisation for Research and Treatment of Cancer – Quality of Life Questionnaire





References: 1. PBS Handbook 1 March 2024. 2. Fizazi K, et al N Engl J Med 2017;377:352-360. 3. Chi K, et al. Lancet Onc 2018;19: 194-206. 4. Thiery-Vuillemin A, et al. Eur Urol 2020;77:380-387 (including supplementary appendix). 5. Thiery-Vuillemin A, et al. ESMO Open 2018;3:e000397.doi:10.1136/esmoopen-2018-000397. 6. Gotto G, et al. Can Urol Assoc J 2020;14:E616-20.

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Management of advanced prostate cancer in the Asia-Pacific region: Summary of the 2023 Asia-Pacific APCCC

The 2022 APCCC resulted in a series of expert consensus statements to inform clinical decision making regarding the management of mHSPC, non-metastatic CRPC and mCRPC specifically in domains not guided by high-quality evidence or absent in clinical practice guidelines. Subsequently, given the expanding burden of prostate cancer in the Asia-Pacific plus the high mortality risk, in 2023 the Asia-Pacific APCCC satellite symposium was convened to examine the real-world area-specific relevance and implementation of these consensus statements considering cultural differences as well as drug pricing, availability and regulatory approval, and to identify issues unique to the region. Almost 30 prostate cancer experts from 14 countries in the region - including Australia, Hong Kong, India, Malaysia and Singapore - attended the 2023 APAC APCCC in Singapore in July and provided insight into current practices in their country.

Availability of drugs and technologies in the Asia-Pacific region

The delegates commented on the radical changes in the management of advanced prostate cancer that have come about recently, driven by novel treatment innovations plus new diagnostic and other technologies. While access to medications and testing was fairly uniformly high, government subsidy of both was heterogenous, with reimbursement for next-generation imaging such as PSMA-PET, genetic testing and counselling reported to be not available by more than half of the participants. Similarly, a high proportion of experts reported a lack of subsidy for many medications - including cabazitaxel, enzalutamide, apalutamide, darolutamide, olaparib, 177Lu-PSMA and radium-223.

Use of next-generation imaging

While most experts acknowledged that the APCCC consensus statement that advocated for adoption of a molecular imaging TNM staging system (over staging based on conventional imaging) for metastatic prostate cancer allowed for greater sensitivity and specificity, in real-world clinical practice universal adoption is hindered by fiscal considerations as well as availability. Routine use of PSMA PET-CT may be thwarted by lack of an appropriately experienced nuclear physician to interpret results and the same issues of availability and cost influence decisions regarding how to manage discordant results between PSMA PET-CT and conventional imaging, as well as PSMA PET tracer selection. The experts further noted that given these hurdles they tended to restrict use of molecular imaging to cases of clinically localised disease at high-risk of metastasis. It was concluded that treatment of the primary tumour should be prioritised, regardless of whether small lymph node metastasis is identified solely by molecular imaging. Experts further generally agreed that whole-body MRI for distant staging of clinically localised high- or intermediate-risk disease is not appropriate.

Management of intermediate- and high-risk locally advanced prostate cancer

Of four possible management strategies for intermediate- and high-risk locally advanced (not localised) prostate cancer - namely, radiation therapy to the primary tumour, systemic therapy with radiation therapy, salvage versus adjuvant radiation therapy and additional systemic therapy - experts from the Asia-Pacific region tended to concur with the APCCC consensus preferring ADT plus abiraterone for high- or very high-risk disease. Consistent with the range of opinions at APCCC, experts from the Asia-Pacific region could not agree on the optimal fractionation schedule for prostate radiation or on whether to add systemic therapy. Early salvage therapy prior to PSA level exceeding 0.2 ng/mL was favoured.

Management of newly diagnosed mHSPC

Experts practicing in the Asia-Pacific area mostly concurred with APCCC consensus regarding optimal management of mHSPC, specifically that treatment selection regarding combination regimens and sequencing should consider disease volume and timing of metastatic disease presentation (synchronous or metachronous). Experts mostly utilised ADT plus an androgen receptor signalling inhibitor (ARSI) and/or docetaxel, with greater use of doublet versus triplet systemic combinations due to unclear survival benefits and cumulative toxicity concerns. Cases of knowingly utilising less favourable therapies (such as ADT monotherapy) were relatively uncommon, and attributed to lack of ARSI subsidy. One commonly employed cost mitigation strategy was the prescribing of low-dose abiraterone, although this practice may become obsolete after the introduction of the 500 mg tablet. Chemophobia was highlighted as an issue unique to the Asia-Pacific area that significantly impacts the use of docetaxel in certain populations. Radiation was reported to be readily available and accessible even in low-resource settings with high use reported for both primary tumour and metastases.

Management of non-metastatic CRPC

There was considerable variation in the management of patients with non-metastatic CRPC with a short PSA doubling time who have not undergone local therapy, with experts in the region equally opting for observation, prostate-directed radiotherapy or local therapy plus ARSi. It was noted that asymptomatic patients are inclined to be complacent regarding treatment escalation and frequently opt for deferral. In patients with non-metastatic CRPC undergoing ARSI therapy, serial PSA monitoring alone was frequently employed despite evidence suggesting imaging is required to accurately evaluate disease progression. This practice was chalked up to lack of evidence of a survival benefit as well as pragmatic considerations.

Genetic testing

The use of genetic testing is increasing across the Asia-Pacific region, with almost one-quarter of patients identified as carrying therapeutically targetable genomic aberrations such as *BRCA* mutations. A need to further disseminate knowledge regarding genetic testing for homologous recombination repair (HRR) deficiencies to practitioners was noted and experts assented that testing is appropriate as the clinical setting approaches mCRPC.

Management of mCRPC

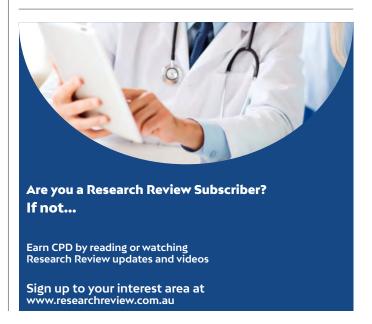
Considerations such as the presence of a *BRCA* mutation or other HRR aberration and prior therapy drive treatment decisions in this space. Almost one-third of experts admitted to switching between ARSIs in cases of disease progression and no actionable mutations, despite APCCC consensus not to, predominantly driven by fiscal considerations and the strong patient preference in certain areas for non-chemotherapy therapies. Radionuclide therapy use is increasing but is not widespread, due primarily to cost. Use of immune checkpoint inhibitor therapy for mismatch repair deficient/high microsatellite instability (dMMR/MSI high) phenotypes is mostly still restricted to clinical trials or compassionate access programs.

Asia Pac J Clin Oncol. 2024;20(4):481-90

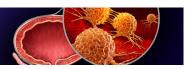
Prostate cancer survivorship of Australian men living with prostate cancer: Patient support programs in Australia

This publication is a valuable resource to inform General Practitioners regarding the support programs available in Australia for men with prostate cancer. A total of 13 different patient support programs run by the government, organisations and pharmaceutical companies are listed that offer various educational materials, treatment decision support tools and relevant referrals to specialised services including continence advice, sexual health counselling and psychological support.

Aust J Gen Pract. 2024;53(10):773-76



Prostate Cancer Practice Review™



Regulatory News

First Nations Closing the Gap Program expanding

The Closing the Gap Pharmaceutical Benefits Scheme (PBS) Co-payment Program was implemented by the Australian Government in 2010 to ensure that fiscal considerations did not prevent Aboriginal and Torres Strait Islander people from obtaining medication they need to manage a chronic condition. In conjunction with the Remote Area Aboriginal Health Service Program, this underserved population can access a range of heavily subsidised or free medications (reduces medications to the concession rate, or to nothing if usually eligible for the concession rate) through community pharmacies, approved medical practitioners and private hospitals. Certain PBS listed medications can also be obtained without paying for a consultation or a prescription directly from the Remote Area Aboriginal Health Service. To date, over 1,300 general schedule (section 85) and section 100 PBS items - including drugs on the Highly Specialised Drugs Program, the Efficient Funding of Chemotherapy Program and the in vitro fertilisation Program such as treatments for opioid dependence, hepatitis B and HIV antiretrovirals - are accessible through pharmacies, general practitioners and private hospitals. Further expansion of the initiative in January 2025 will enable access to all section 85 & 100 section PBS medicines dispensed by public hospitals.

Health professionals who deem Medicare registered First Nation patients reliant on regular medication eligible for the program can register them via the Services Australia Health Professional Online Services (HPOS) portal here or by telephone on 132 290.

Further information is available on the PBS website

Changes to MBS chronic disease management arrangements delayed

Alterations to the Medicare Benefits Schedule (MBS) items for chronic disease management originally planned for November this year have been delayed until July 2025. The changes - recommended by the MBS Review Taskforce and announced in the 2023—24 budget - provide a framework to support patients with chronic conditions by consolidating the GP Management Plan and the Team Care Arrangements into a single plan and aim to simplify and improve arrangements for both clinicians and patients. Potential improvements in care may be seen in the realms of continuity of care, regular reviews and communication between multidisciplinary care team members.

More information can be found here

TGA approves Illuccix® PSMA-PET radiotracer to identify patients with mCRPC eligible for PSMA-targeted therapy

Following the recent Therapeutic Goods Administration (TGA) approval of ¹⁷⁷Lu-vipivotide tetraxetan (¹⁷⁷Lu-PSMA-617; Pluvicto®; 1000 MBq/mL solution for injection vial; Novartis Pharmaceuticals Australia; <u>Australian prescription medicine decision summary</u>) for the treatment of PSMA-positive mCRPC after failure of ARPIs and taxane-based chemotherapy, indications for the diagnostic PSMA-targeting PET radiopharmaceutical Illuccix® (kit for the preparation of gallium-68 [⁶⁸Ga]-labelled PSMA-11 injection; Telix Pharmaceuticals) have been expanded to include determination of eligibility of patients with mCRPC for ¹⁷⁷Lu vipivotide tetraxetan (<u>Prescription medicines registration</u>).

Currently, MBS funding subsidises PSMA PET-CT imaging with the ⁶⁸Ga-PSMA-11 tracer for initial staging of intermediate to high-risk patients with prostate cancer and the re-staging of patients with recurrent prostate cancer (items 61563 and 61564). ¹⁷⁷Lu-PSMA-617 radionuclide therapy is not yet listed on the PBS.

A joint re-application from academic specialists and the Australasian Association of Nuclear Medicine for public funding of both \$^{177}Lu-PSMA-617\$ therapy for patients with progressive mCRPC and whole-body PSMA PET-CT imaging to identify appropriate patients for such treatment was appraised by the Medical Services Advisory Committee (MSAC) at their April 2024 meeting but a decision was not reached (Application No. 1686.1). As with the previous application requesting the same, and despite accepting the safety and efficacy of treatment plus the clinical need as a last-line option, economic concerns including an unacceptably high incremental cost-effectiveness ratio of approximately \$100,000 per quality-adjusted life year precluded a positive recommendation. The application will be reconsidered after remodelling of the economic evaluation. Similarly, an application from Telix Pharmaceuticals Ltd for MBS funding of the Illuccix® kit (Application No. 1720) for evaluating patient eligibility for PSMA targeted therapy was deferred due to cost concerns.

More information regarding MSAC Applications 1686 and 1720 can be found $\underline{\text{here}}$ and $\underline{\text{here}}$

FDA grants Fast Track designation to ⁶⁴Cu-SAR-bisPSMA diagnostic for PET imaging in prostate cancer

In August the US Food & Drug Administration (FDA) granted Fast Track Designation to 64Cu-SAR-bisPSMA, a copper-based theranostic radiopharmaceutical developed by Clarity Pharmaceuticals for the PET detection of PSMA-positive prostate cancer lesions in patients with suspected metastasis deemed suitable for initial definitive therapy. Aimed to expedite regulatory approval of the novel PET tracer, the designation was based on a strong diagnostic performance in the phase 1 PROPELLOR trial, with higher maximum standardised uptake values and potentially improved detection of primary disease versus 68Ga-PSMA-11 in patients prior to radical prostatectomy. The registrational single-arm phase 3 CLARIFY trial will further examine the diagnostic ability of a single intravenous administration of 200 MBg ⁶⁴Cu-SAR-bisPSMA within the pelvic gland as well as pelvic and regional nodal metastases in patients with previously untreated high-risk (clinical stage \geq T3a, grade group \geq 4, or PSA level > 20 ng/mL) adenocarcinoma of the prostate planned for radical prostatectomy with pelvic lymph node dissection. A second registrational phase 3 imaging trial will assess the performance of ⁶⁴Cu-SAR-bisPSMA for detection of lesions in patients with biochemical recurrence. Compared to currently available diagnostic radiopharmaceuticals, such as ⁶⁸Ga-PSMA-11, ⁶⁴Cu-SAR-bisPSMA may have several advantages including a longer half-life and shelf-life, higher tumour uptake and retention and ability to detect smaller lesions.

Relevant press releases from Clarity Pharmaceuticals can be read $\underline{\text{here}}$ and $\underline{\text{here}}$

J Clin Oncol 2023; 41 (suppl 6; 318)

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News in Brief

Non-invasive liquid biopsies could revolutionise prostate cancer detection

An international collaborative research effort utilising a 3D Mueller-matrix image reconstruction technique to visualise polycrystalline structures in dehydrated blood smears reports validity of this approach to diagnose prostate cancer, suggesting it may offer a non-invasive and accurate screening alternative to PSA evaluation. Comparison of multiple optical anisotropy parameters in partially depolarising dry blood smears enabled differentiation between healthy individuals and patients with prostate cancer with an accuracy rate of over 90%.

Sci Rep. 2024;14(1):13679

Incisionless robotic-MRI fusion surgery in development

The US National Cancer Institute has provided researchers affiliated with the Case Western Reserve and Vanderbilt Universities a US\$3.7 million grant to develop a novel prostate cancer surgery technique comprised of robotics combined with low-field MRI. Designed to enable real-time and accurate visualisation of localised prostate lesions during surgery by employing Promaxo Inc.'s low-field MRI scanner, the technique utilises a modified Virtuoso Surgical Inc robot to only remove cancerous tissue, omitting whole-gland prostate removal.

More information can be found here

Men confused about prostate cancer screening

A recent American Cancer Society survey has found that more than half of adult American men hold erroneous views regarding prostate cancer screening and many do not undergo screening, resulting in recent increases in the diagnosis of advanced-stage disease. In the sample of nearly 1,200 men, rectal exam, rather than a blood test, was commonly believed to be the first step in screening and contributed to reluctance to undergo screening. A high proportion of participants stated that they didn't need to be screened, but factors influencing cancer predisposition as well as symptoms of cancer and the importance of screening in the absence of symptoms were widely unknown.

To address these gaps in knowledge the Know Your Score campaign will be launched soon.

More findings from the survey can be found here

COVID-19 Resources

Royal Australasian College of Surgeons

European Urology Journal

British Association of Urological Surgeons

American Urological Association

European Society of Medical Oncology

American Society of Clinical Oncology

Conferences, Workshops, and CPD

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

COSA - Events

MOGA - Events

USANZ - Events

COMS - Conferences and Meetings on Urology

Research Review Publications

Prostate Cancer Research Review with Professor Niall Corcoran and Professor Nathan Lawrentschuk

Urology Research Review with Professor Eric Chung

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