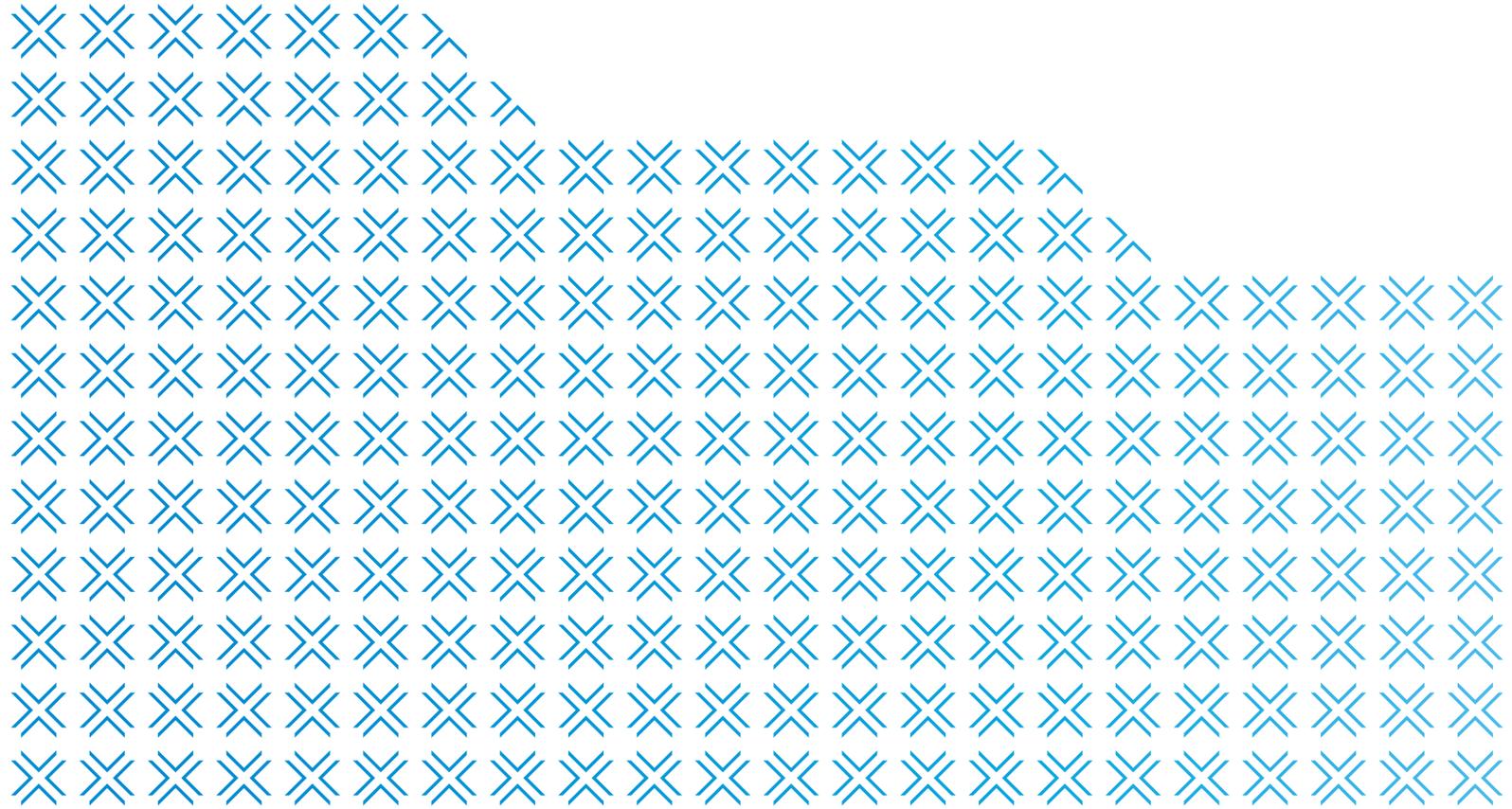


PSA TESTING AND EARLY MANAGEMENT OF TEST-DETECTED PROSTATE CANCER

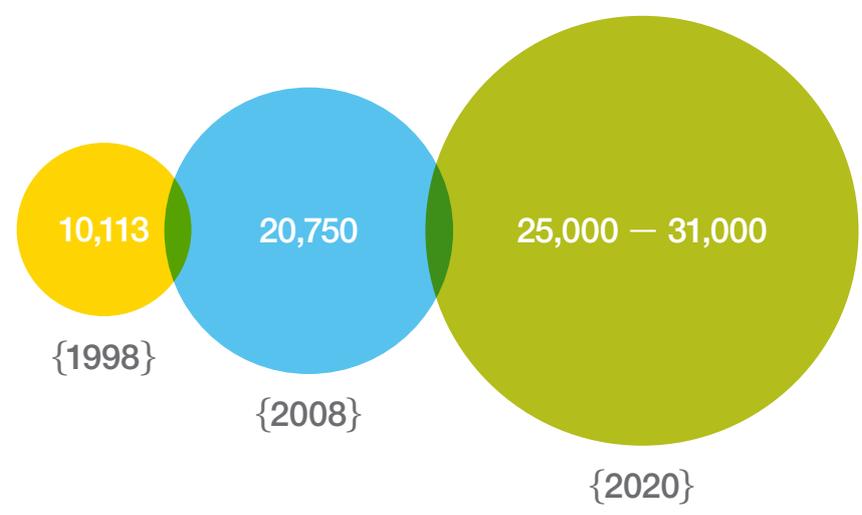
CLINICAL PRACTICE GUIDELINES

An overview of the recommendations approved by the National Health and Medical Research Council



- Prostate cancer is the second most commonly diagnosed cancer in Australian men (after skin cancer) and accounts for approximately 33% of male cancers diagnosed each year.
- The risk of being diagnosed with prostate cancer increases with age. For Australian men the risk of being diagnosed by age 75 is 1 in 7, and by age 85 this increases to 1 in 5.[†]
- In Australia, prostate cancer is the second most common cause of male cancer deaths and the sixth most common cause of male deaths overall.^{††}
- It is estimated that by 2017 there will be more than 185,000 Australian men – or 1.6% of the projected male population – living with prostate cancer.
- Compared to other cancers, prostate cancer has one of the highest five-year survival rates. In the period 2006 to 2010, Australian men who were newly diagnosed with prostate cancer had a 92% chance of surviving for at least 5 years compared to the general population.^{†††}
- PSA testing carries both benefits and harms.
- A significant number of men treated for prostate cancer experience ongoing side effects of treatment that impact on their quality of life.

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Prostate cancer diagnoses
 doubled between 1998 and
 2008, and numbers are
 expected to rise by 2020



[†]Australian Institute of Health and Welfare (AIHW) 2014. Australian Cancer Incidence and Mortality (ACIM) books: Prostate cancer. Canberra: AIHW. <<http://www.aihw.gov.au/acim-books>>.
^{††}Australian Institute of Health and Welfare 2013. www.aihw.gov.au/deaths/leading-causes-of-death/.
^{†††}Australian Institute of Health and Welfare 2013. Prostate cancer in Australia. Cancer series no. 79. Cat. no. CAN 76. Canberra: AIHW.

The measurement of Prostatic Specific Antigen (PSA) concentration in the blood has become the primary method of testing for prostate cancer. However, PSA is not specific to cancer and thus is not a reliable marker for presence of the disease. Currently, the only way to diagnose prostate cancer is to perform a biopsy, and even biopsy is not perfect in finding prostate cancer when it is present.

While PSA testing is widely used, there is still debate over whether it offers men net benefit. A proportion of prostate cancers detected as a result of PSA tests would never have bothered the men in whom they were detected had they not been tested. Such cancers are commonly referred to as over-diagnosed cancers. Over-diagnosis is estimated to be as high as 20-40% of prostate cancers diagnosed following a positive PSA test.

Treatment of prostate cancer is quite frequently the cause of adverse side effects. These harms are usually seen as justified by the cure or amelioration of the disease from treatment. However, in the case of an over-diagnosed cancer, the harms will be unjustified.

The major adverse effects following prostate cancer treatment are:

- urinary incontinence and other urinary problems, which are common soon after treatment and persist in some men treated by radical prostatectomy or radiotherapy
- erectile dysfunction in men treated by radical prostatectomy, radiotherapy or androgen deprivation therapy. This is common soon after treatment and persists in some 70% of men, but is not attributable to therapy in all cases
- bowel problems, which are most common after external beam radiotherapy and affect some 20% of men.

Whilst there is agreement amongst health professional bodies that current evidence does not support a population-based PSA screening program for prostate cancer, there is a lack of consensus on what advice to offer doctors, or men who request a PSA test. This causes widespread confusion for men and their health advisers.

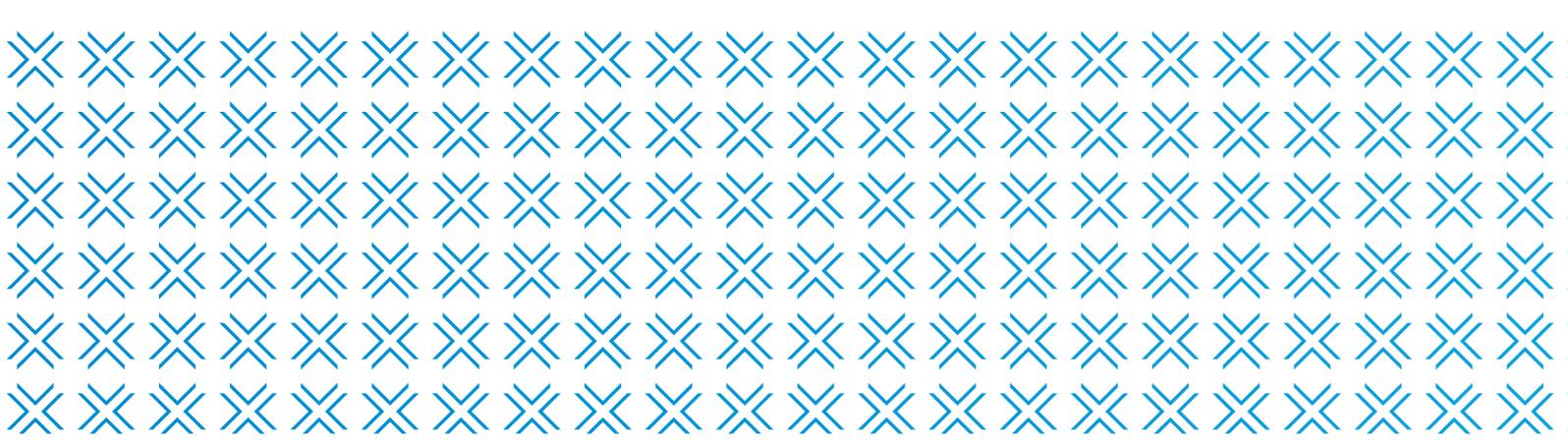
Despite the fact that PSA testing is not recommended as a population-based screening program, current rates of PSA testing in Australia are similar to the participation rate of eligible women in the BreastScreen program.

- There is evidence that many men undergo PSA testing without the opportunity to be fully informed about the risks and benefits of testing.
- Many men are undergoing PSA testing outside the recommendations contained in these guidelines; either too frequently, too young, too old or with a short life-expectancy.
- There is no consistent approach to determining what PSA concentration should prompt further investigation after a positive initial PSA test.
- There is no clear guidance on testing for men in known high risk groups, such as men with a family history of prostate cancer.

Thus there is a need for evidence-based clinical practice guidelines for prostate cancer testing from informed decision making about whether to be tested through to decision making and actions following a positive result.

The primary audiences for the guidelines are:

- health professionals in primary care, such as general practitioners, advising men who are considering testing or have decided to be tested
- urologists and other health practitioners advising men who have a positive PSA test, have had a prostate biopsy or have been diagnosed with localised prostate cancer and are considering their management options.



The **guidelines** are intended for use in the present PSA testing context; that is interactions between men and their doctors in which a man might request a PSA test or his doctor might offer one. They do not recommend a national PSA screening program (a program that offers testing to all men of a certain age group), as there is no evidence to support such an approach.

The guidelines are also intended to support the appropriate use of PSA testing, ensuring men and their doctors are able to openly discuss testing, and men are able to make informed decisions based on the latest available evidence.

For men who decide to be tested, there is guidance on matters such as what age to start testing; how frequently to be tested; when to stop testing; the PSA level which should prompt further investigation; family history; and the role of the digital rectal examination.

The main recommendations contained in the guidelines are as follows:

- Men who are considering having a PSA test require information about the benefits and harms of testing to support their decision to test or not.
- A PSA testing decision aid for use by men and their doctors is under development, however these guidelines will support health professionals to help men make an informed decision.
- Men who are 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, should be offered PSA testing every 2 years from age 50 to 69. Further investigation should be offered if the total PSA concentration is greater than 3 ng/mL.

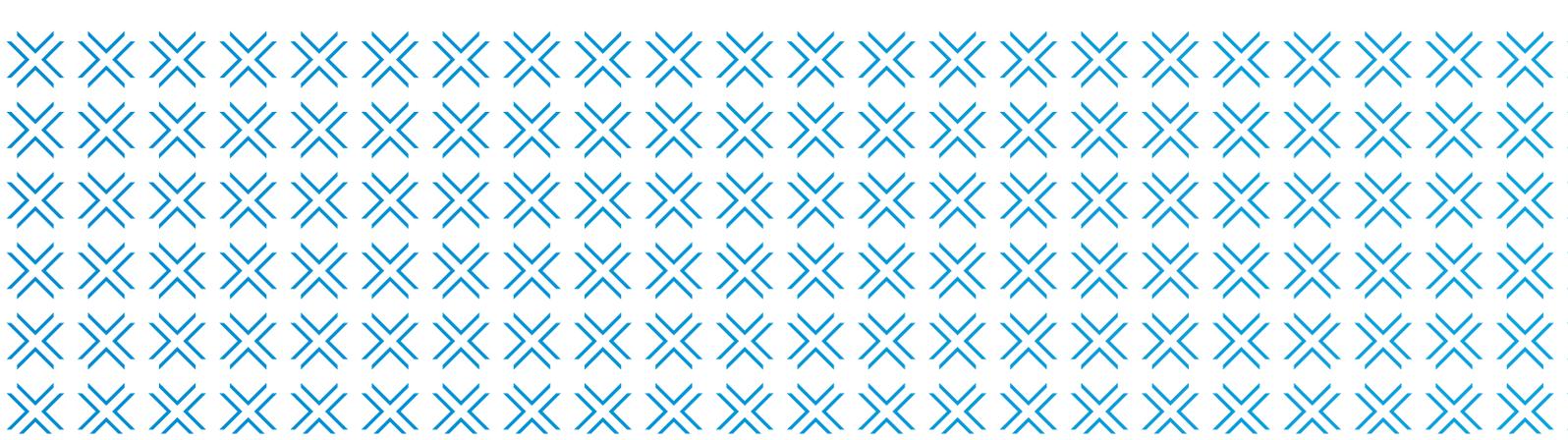
- Advise men 70 years or older who have been informed of the benefits and harms of testing and who wish to start or continue regular testing that the harms of PSA testing may be greater than the benefits of testing in men of their age.
- Men who have a father or one brother who has been diagnosed with prostate cancer have 2.5 to 3 times higher than average risk of developing the disease. Such men who have been informed of the benefits and harms of testing, and who decide to undergo regular testing for prostate cancer, should be offered PSA testing every 2 years from age 45 to 69.
- Men who have a father and two or more brothers who have been diagnosed with prostate cancer have at least 9 to 10 times higher than average risk of developing the disease. Such men who have been informed of the benefits and harms of testing, and who decide to undergo regular testing for prostate cancer, should be offered PSA testing every 2 years from age 40 to 69.
- Digital rectal examination is not recommended for asymptomatic men as a routine addition to PSA testing in the primary care setting. Note, however, that on referral to a urologist or other specialist, digital rectal examination remains an important assessment procedure prior to consideration for biopsy.
- Since any mortality benefit from early diagnosis of prostate cancer due to PSA testing is not seen within less than 6 to 7 years from testing, PSA testing is not recommended for men who are unlikely to live another 7 years (subject to health status).

Other recommendations contained in the guidelines cover further investigations if the PSA concentration is above 3 ng/mL; prostate biopsy and multiparametric MRI; active surveillance; and watchful waiting.

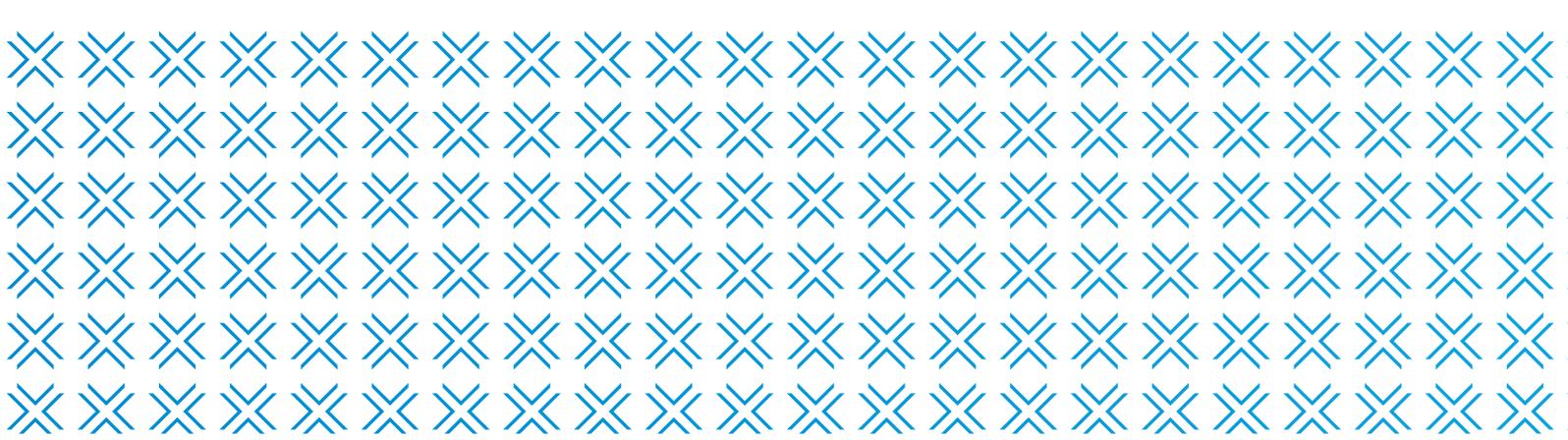
The full text of the guidelines can be found at:

pcf.a.org.au/psa-testing-guidelines

wiki.cancer.org.au/psaguidelines



- Men should be offered the opportunity to consider and discuss the benefits and harms of PSA testing before making the decision whether or not to be tested.
- The harms of PSA testing may outweigh the benefits, particularly for men aged 70 and older.
- Men at average risk of prostate cancer who decide to undergo regular testing should be offered PSA testing every 2 years from age 50 to 69.
- Men with a family history of prostate cancer who decide to be tested should be offered PSA testing every 2 years from age 40/45 to 69, with the starting age depending on the strength of their family history.
- Digital rectal examination is not recommended for asymptomatic men as a routine addition to PSA testing in the primary care setting, but remains an important part of specialist assessment.
- The recommendations in the guidelines are approved by the CEO of the National Health and Medical Research Council (NHMRC). In granting approval NHMRC is satisfied that the guideline recommendations are systematically derived, based on the identification and synthesis of the best available scientific evidence, and developed for health professionals practicing in an Australian health care setting.



EXPERT ADVISORY PANEL

Name	Position	Specialty
Emeritus Professor Willis Marshall AC, Chair Expert Advisory Panel	Consultant Urologist, SA	Urology
Professor Sanchia Aranda	Chief Executive Officer, Cancer Council Australia, NSW (from 3 August 2015)	Cancer Control
Professor Bruce Armstrong AM	Emeritus Professor, School of Public Health, The University of Sydney, NSW	Epidemiology
Dr Joseph Bucci	Radiation Oncologist, Prostate Cancer Institute, St George Hospital, NSW	Prostate Brachytherapy
Professor Suzanne Chambers	Professor of Preventative Health, Griffith Health Institute, QLD	Psycho-oncology
A/Professor Pauline Chiarelli JP	School of Health Sciences (Physiotherapy), The University of Newcastle, NSW	Rehabilitation
Professor Chris Del Mar	Professor of Public Health, Bond University, QLD	General Practice
Professor Mark Frydenberg	Chairman, Department of Urology, Monash Medical Centre, Southern Health, VIC	Urology
Professor Robert 'Frank' Gardiner	AM Centre for Clinical Research, University of Queensland, QLD	Urology
Professor Paul Glasziou	Professor of Evidence Based Medicine, Bond University, QLD	General Practice
Dr Keen-Hun Tai	Chair, Faculty of Radiation Oncology Genito-Urinary Group, VIC	Radiation Oncology
A/Professor Anthony Lowe	Chief Executive Officer, Prostate Cancer Foundation of Australia, NSW	Cancer Control
Dr David Malouf	Consultant Urologist, Prostate Cancer Institute, St George Hospital, NSW	Urology
A/Professor Paul McKenzie	Senior Staff Specialist Tissue and Pathology Diagnostics, Royal Prince Alfred Hospital, NSW	Pathology
Professor Robert McLachlan	Director, Andrology Australia, VIC	Male Reproductive Health
Professor Dianne O'Connell	Senior Epidemiologist, Cancer Research Division, Cancer Council NSW	Epidemiology
Professor Ian Oliver AM	Chief Executive Officer, Cancer Council Australia, NSW (until 31 December 2014); Director, Sansom Institute, Chair of Translational Cancer Research, University of South Australia (from 23 February 2015)	Cancer Control
Dr Ian Roos OAM	Consumer Advocate, Cancer Voices Australia, VIC	Consumer Advocacy
Mr David Sandoe OAM	National Chairman, Prostate Cancer Foundation of Australia, NSW (retired as National Chairman on 31 March 2015)	Consumer Advocacy
A/Professor Ken Sikaris	Director of Chemical Pathology, Melbourne Pathology, VIC	Pathology
Professor Martin Stockler	Oncology and Clinical Epidemiology Medicine, The University of Sydney, NSW	Medical Oncology
Professor Phillip Stricker AO	Consultant Urologist, St Vincent's Clinic, NSW	Urology
Mr Peter Teiermanis	Consumer Advocate, Frankston, VIC	Consumer Advocacy
Ms Elizabeth Watt	Head of School of Nursing, Austin Campus, La Trobe University, VIC	Nursing
Professor Simon Willcock	Director of Primary Care Services, Macquarie University Hospital, NSW	General Practice

The guidelines were developed by a multi-disciplinary Expert Advisory Panel which included general practitioners, public health experts, urologists, radiation oncologists, pathologists, medical oncologists, allied health professionals and consumer representatives. They are supported by Prostate Cancer Foundation of Australia and Cancer Council Australia.

The recommendations in the guidelines were approved by the CEO of the National Health and Medical Research Council on 2 November 2015.

Prostate Cancer Foundation of Australia (PCFA) is a broad based community organisation and the peak national body for prostate cancer in Australia. PCFA is dedicated to reducing the impact of prostate cancer on Australian men, their partners and families, recognising the diversity of the Australian community.

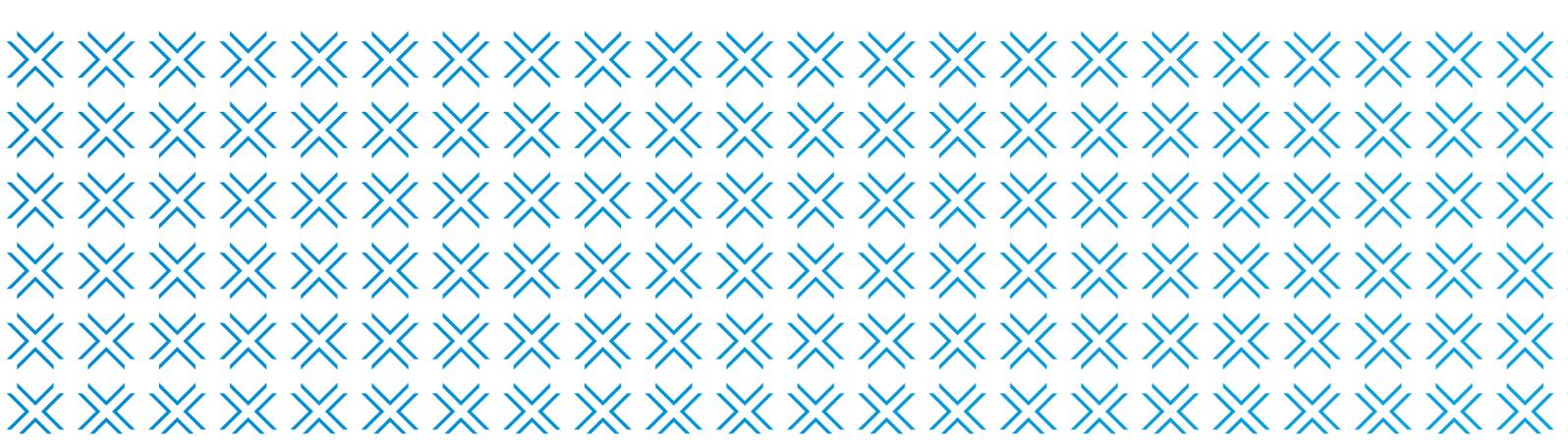
PCFA does this by:

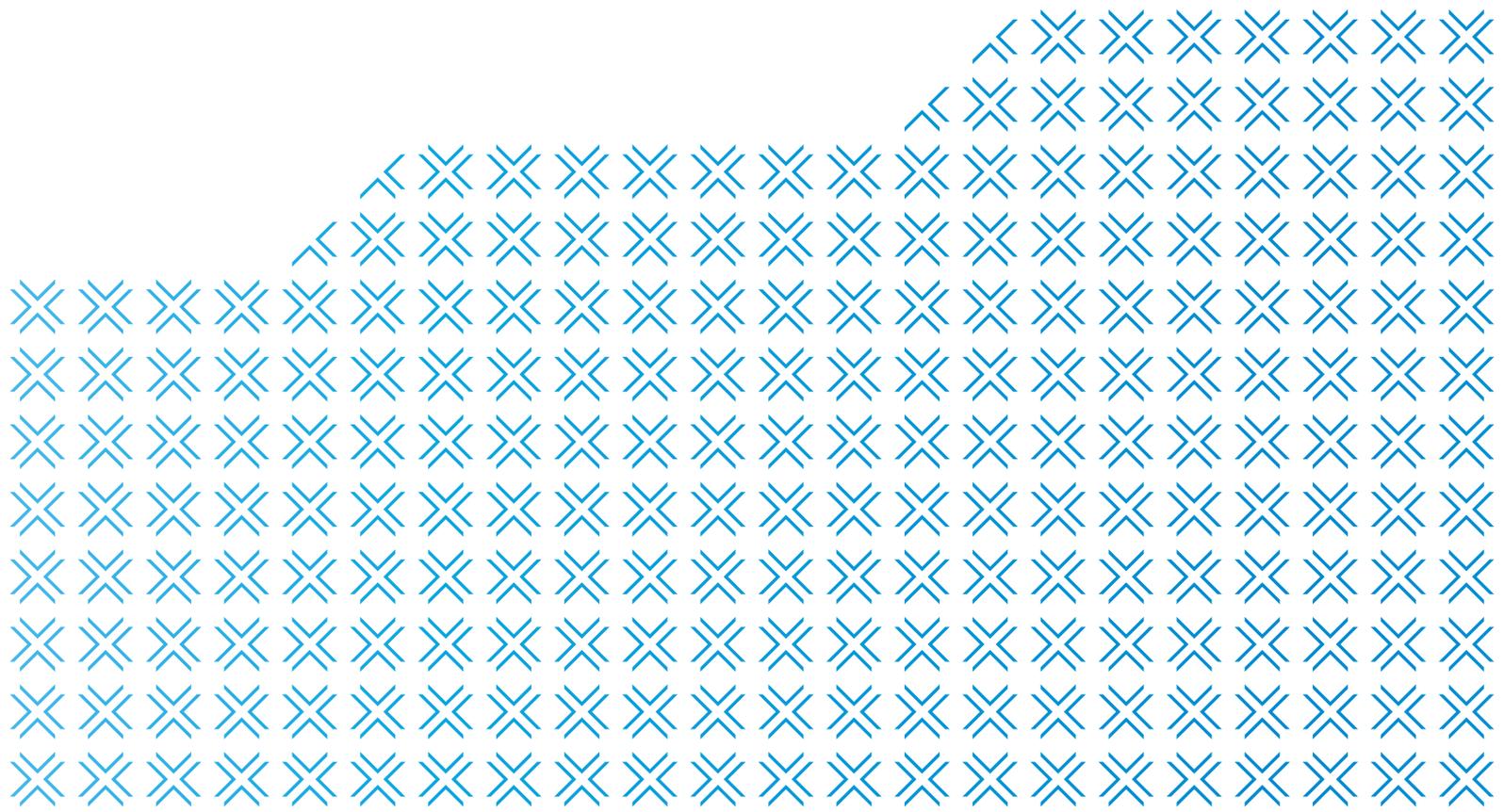
- promoting and funding world leading, innovative research into prostate cancer
- implementing awareness campaigns and education programs for the Australian community, health professionals and Government
- supporting men and their families affected by prostate cancer, through evidence-based information and resources, support groups and Prostate Cancer Specialist Nurses.

Cancer Council Australia is the nation's leading non-government cancer control organisation. Cancer Council Australia develops and promotes evidence-based information on cancer prevention, detection, treatment and care for health professionals and provides education about all aspects of cancer to patients, their families and carers, and the general community.

Cancer Council Australia works with members, the eight state and territory cancer organisations, to:

- undertake and fund cancer research
- prevent and control cancer
- provide information and support for people affected by cancer.





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