

# National Cancer Prevention Policy

2007–09



## Screening to detect cancer early

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### Prostate cancer



## Prostate cancer

*Cancer of the prostate is a common and important health problem. Its early diagnosis and subsequent treatment present a dilemma for medical practitioners and consumers. Since advantages of testing and treatment are not clear-cut, individual men who decide to be tested for prostate cancer should be able to do so on the basis of informed consent, having access to full information about the potential benefits and risks associated with testing. Preliminary findings suggest that introduction of a national education program for general practitioners to improve decision-making relating to the use of prostate-specific antigen testing would be cost-effective.*

### Prostate cancer in Australia

In 2005, prostate cancer is projected to be the most common cancer (apart from non-melanoma skin cancer) diagnosed in Australian men, with an estimated 12,529 new cases (AIHW, AACR, NCSG & McDermid 2005).

Prostate cancer mainly affects men in older age groups. Over 85% of new cases and over 96% of deaths occur in men over 60 years of age. It is rare in men under 45 years.

Although the incidence of prostate cancer increases with age, the threat to life from prostate cancer decreases with age because the disease generally develops and progresses slowly. This means that men diagnosed with prostate cancer who are older than 75 years or have fewer than 10 years life expectancy are considered to be least at risk of dying of prostate cancer.

Men who are diagnosed at an earlier age (e.g. in their 50s) are most at risk of dying from prostate cancer (Baade, Steginga et al. 2005). This is because it is probable that they will live long enough for their prostate cancer to progress to a life-threatening stage and are less likely to die from competing causes. It is also important to note that, irrespective of the risk it poses, a diagnosis of prostate cancer at any age can have a major impact on a man's quality of life.

The incidence of prostate cancer was relatively stable until 1989 but, between 1990 and 1994, there was a dramatic rise in the number of new cases reported (AIHW & AACR 2004). This has been attributed to increased detection of the disease due to many more investigations, particularly case-finding using PSA testing, which was introduced around 1990 (see below). However, between 1994 and 1997 the age-standardised prostate cancer incidence rate fell by 30%. Since then, there has been little change between the 1998 and 2005 rate, indicating that the surge-effect from the previously undetected cases has been accommodated and the practice of early detection has stabilised.

The mortality rate from prostate cancer, which is significantly lower than the incidence rate, decreased by 1.9% per annum between 1991 and 2005, when 2,946 deaths were reported (ABS 2007).

The burden of prostate cancer is likely to increase with the ageing of the Australian population, and this has major public health and economic implications (Weller et al. 1998).

## Can prostate cancer be prevented?

The causes of prostate cancer are poorly understood. Geographical and racial differences in rates of prostate cancer provide compelling evidence that environmental and lifestyle factors are involved (Weller et al. 1998). Age and family history are the strongest risk factors in Australia. Researchers continue to examine other possible risk factors, including diet, weight and physical activity. An effective approach to primary prevention of prostate cancer has not yet been identified (Harris & Lohr 2002).

Chemoprevention is being investigated but is not in routine use. A trial examining selenium and vitamin E (The SELECT trial) is in progress, with results not anticipated until 2013 (Klein 2004). An analysis of the screening arm of the prostate, lung, colorectal and ovarian (PLCO) cancer trial does not show a benefit for supplementation with the micronutrient antioxidants vitamin E, beta-carotene and vitamin C (Kirsh et al. 2006).

An Australian review noted that there is little evidence that could define risk groups sufficiently for targeted screening activities (Weller et al. 1998). One possible exception is men with a strong family history of prostate cancer. Men with a first-degree relative diagnosed with prostate cancer have a two-and-a-half times greater risk of being diagnosed, with some evidence that the risk is higher if the relative was diagnosed before the age of 60 years (Johns & Houlston 2003). The genetic basis has not been identified, though men carrying mutations of the breast cancer susceptibility genes BRCA1 or BRCA2 gene have an increased risk of several types of cancer, including prostate cancer (Liede et al. 2000). The questions of whether, when and how often such people should be monitored have yet to be addressed.

## Tests for prostate cancer

### **Prostate-specific antigen test**

The prostate-specific antigen (PSA) test is commonly used to try to detect prostate cancer. It measures the amount of PSA in blood.

PSA levels can be raised due to a range of conditions. In studies of men aged 45 to 80 years, 7% to 13% had a PSA level greater than 4 ng/ml; of these, 10% to 30% were identified as having prostate cancer on biopsy (USPSTF 2005). The level of PSA used to justify biopsy is commonly set at 4 ng/ml. Some have advocated a cut-off of 2.5 ng/ml (Punglia et al. 2003), since it is estimated that 25% to 30% of prostate cancers are detected with a PSA between 2.5 and 4 ng/ml (Pepe et al. 2006). However, increased sensitivity by use of a lower level will decrease specificity, leading to a higher rate of unnecessary biopsies and an increase in over-diagnosis (see below).

Accuracy may be improved by taking into account a man's age, since PSA levels increase with age due to benign enlargement of the prostate. It may also be improved by measuring the proportion of free to total or complexed PSA, since men with prostate cancer tend to

have lower levels of free PSA than men who don't have prostate cancer. However, there is no consensus yet on either of these measurements (Harris & Lohr 2002; Stenman 1997).

### Digital rectal examination

Another form of testing is digital rectal examination. This test involves manual examination of the prostate gland through the rectum. Some abnormalities may be felt but it is not possible to feel all of the prostate. A cancer that is in a part of the prostate gland out of the doctor's reach—estimated to be 25% to 35% of the prostate—may be missed (USPSTF 2005). In addition, small (stage A or T1) cancers cannot be felt. Wide variations in reporting occur between doctors (AHTAC 1996).

### Transrectal ultrasound and biopsy

Neither the PSA test nor DRE, alone or together, is a truly accurate test for prostate cancer. If abnormalities are detected by a PSA test or DRE, tissue specimens will be needed for diagnosis, usually via transrectal ultrasound (TRUS) imaging to permit spatial positioning of biopsy needles. The needle biopsy procedure involves eight to 10 or more cores of tissue being removed for examination under a microscope. Even though tissue is taken from a number of locations, and most malignant cancers will be detected, it is not possible to say with complete certainty that a negative result excludes the presence of cancer. The test carries risks of infection and bleeding (AHTAC 1996).

### Test limitations and implications

The sensitivity and specificity of the screening tests available for prostate cancer cannot be determined with certainty (i.e. confirmed by pathology tests on tissue samples) because biopsies are generally not done on people with negative screening tests (USPSTF 2005). Only the positive predictive value—the probability of cancer when the test is positive—can be calculated with any confidence, but this also is subject to methodological difficulties from the needle biopsy (USPSTF 2005).

A recent study where 2950 men with 'normal' PSA values (<4 ng/ml) were subjected to biopsy found that 15% had prostate cancer on biopsy (Thompson et al. 2004).

There is no single test or combination of techniques that can detect prostate cancer and predict which cancers, if left untreated, are likely to:

- result in few, if any symptoms, require no treatment and have no effect on life expectancy
- progress to a stage of widespread and aggressive cancer.

Recent research has focused on the PSA test, particularly to improve its sensitivity and specificity. Various derived measures, including free-to-total PSA ratio, PSA density and age-specific ranges, have been suggested (Bangma et al. 1995) but have not become established as superior to total PSA (Ciatto et al. 2001). The question remains whether measurement of PSA provides benefits to patients in terms of treatment and quality of life outcomes. Studies so far have been subject to methodological difficulties.

Randomised controlled trials of screening for prostate cancer are underway (European Randomized Study of Screening for Prostate Cancer: ERSPC), Canada and the US (PLCO cancer screening trial), but results in terms of differences in death rates are not expected to be available until about 2008 (Schroder et al. 1999).

These uncertainties over the specificity and sensitivity of the PSA test are important ingredients in a discussion balancing the potential good and harm resulting from the test.

Participants in the ERSPC trial completed a questionnaire on health before screening and then twice subsequently if they were diagnosed with prostate cancer. Mental and self-rated overall health worsened significantly immediately after diagnosis ( $P \leq 0.04$ ), but months later no longer differed significantly from the pre-diagnosis score (Korfage et al. 2006). If radical treatment results from screening with PSA, the complications of treatment—including possible impotence (up to 79.3% at five years) and severe urinary incontinence (15.4% in one population-based longitudinal cohort of 901 men)—need to also be balanced against the outcomes if the PSA test had not been performed (Potosky et al. 2004).

### **Future prospects for screening tests**

Other candidate biomarkers are being investigated, including novel tests for human kallikrein 11 from seminal plasma (Luo et al. 2006). Genetic tests are also being investigated.

### **Who has been tested?**

There is widespread community concern about prostate cancer, reflected in the high rates of PSA testing in general practice. In a South Australian study, 20% of men aged 40 and over reported having a PSA test in the preceding 12 months (Pinnock, Weller & Marshall 1998), while in a NSW study, 22% men over 55 years had undergone testing in the same period (Ward et al. 1997). A national study reported that 27% of Australian men 50 years and over had had at least one test in 1995–96 (Smith & Armstrong 1998). The age-standardised rates of PSA testing were lower in rural than urban areas by 16% in 2002–03 (Coory & Baade 2005).

It is important that men understand what decisions they will face if a PSA test is abnormal. Certainly men regard undisclosed screening as inappropriate and favour education about screening so they can make informed choices (Gattellari & Ward 2005).

## **The policy context**

Population screening for prostate cancer, as opposed to individuals deciding to have a PSA test, is widely debated. All screening programs cause some harm. This could include false alarms, inducing anxiety, and the treatment of early disease that would not otherwise have become a problem.

The Cancer Council supports expert reviews (AHTAC 1996; Selley et al. 1997; Weller et al. 1998; Harris & Lohr 2002) that current evidence does not support population screening of well men for prostate cancer.

Recommendations of the Australian Health Technology Advisory Committee report (1996) included that:

- men being offered or requesting the PSA test be fully informed of the limitations of the available tests and the possible further diagnostic and treatment choices they may face if they have the test
- research into prostate cancer continues to be targeted as a high priority funding area by the National Health and Medical Research Council and other funding bodies
- a mechanism be established to ensure that new technologies for screening, diagnosis and treatment of prostate cancer are rigorously trialled before being introduced into routine clinical practice, or, alternatively, that they are introduced under trial conditions involving appropriate professional bodies

- a monitoring mechanism be put in place to ensure that the Australian Health Technology Advisory Committee position on screening is reviewed when significant developments occur
- a comprehensive education program on the risks and benefits of prostate cancer testing be introduced for GPs, their patients and the community.

The Cancer Council Australia and state and territory cancer councils were active in the establishment in 1998 of the National Prostate Cancer Collaboration to foster clinical, laboratory and epidemiological research, as well as research and programs in education. In 1999 the group became the Australian Prostate Cancer Collaboration. Its aim is to develop strategies for the control of prostate cancer to decrease mortality and increase quality of life.

### **The role of general practice**

Recent reports suggest that GPs are poorly resourced to assist their patients making an informed choice on prostate cancer testing. Only half or less of the GPs who responded to a survey were aware of guidelines published by the Royal Australasian College of General Practitioners and The Cancer Council Australia—both of which recommend against population screening (Ward, Young & Sladden 1998).

A meeting about informed choice for prostate cancer testing in general practice (Pinnock 2004) reported that:

- studies on how patients make medical decisions indicate that non-systematic factors such as old beliefs, anecdotes and salient experiences are more common than a systematic weighing up of pros and cons (see also Farrell, Murphy & Schneider 2002; Steginga et al. 2002)
- testing is often requested for medico-legal reasons. The process and content of an informed choice discussion needs to reflect medico-legal obligations
- criteria have been developed to assess which decision aids are likely to be most effective in helping patients become informed and make decisions
- the barriers GPs face in fully informing patients with diverse backgrounds and knowledge need to be better understood
- particular skills are needed in order to communicate complex issues such as uncertainty and risk to patients
- complicating factors are men's lack of access to primary care services, particularly in rural areas, poor general knowledge of male health in the community and high prevalence of anxiety about urinary symptoms.

Preliminary findings suggest that the introduction of a national education program for GPs to improve decision-making relating to the use of PSA testing would be cost effective (Stone et al. 2005). Evaluations of the GP education workshops have shown that as participants' knowledge about PSA testing and level of understanding increased, they were more likely to initiate discussions with patients about the risks and benefits of testing, and they were more confident in doing so (Metcalfe et al. 2006; Steginga et al. 2005).

## Potential benefits and adverse effects of prostate cancer screening

Refer to the introduction to Section Two for the World Health Organization criteria that need to be satisfied before population screening for a disease may be introduced. Central to this is the need for evidence that screening for the disease, with subsequent early treatment, is effective in improving health outcomes. In relation to prostate cancer, the question is whether detection of tumours using currently available tests will result in benefits for most patients.

The difficulty regarding early detection of prostate cancer is that first, depending on the age of the patient, many cancers found through screening will not be life threatening. Second, it is currently not possible to distinguish with certainty those cancers that will be life threatening. It has been estimated that prostate cancer is present in 30% to 40% of men aged more than 50 years, but only one in four of these cancers will result in clinical symptoms and one in 14 will cause death (Weller et al. 1998).

### **Would population screening be of benefit at this stage?**

The current state of knowledge does not satisfy the World Health Organization criterion that there should be an accepted treatment for patients with recognised disease. It is possible that intervention through early detection will cause more harm than good, for example in the risks posed by treatment (see below).

### **The problem of over-diagnosis**

A major concern with screening is that it will diagnose cancers which, if left undetected, would never have caused morbidity or mortality. This is known as over-diagnosis. One estimate using mathematical modelling puts the over-diagnosis rate as high as 50% (Draisma et al. 2003). It has been estimated that most prostate cancer detected by commonly promoted testing strategies would not have caused morbidity or mortality (McGregor et al. 1998; Draisma et al. 2003). Over-diagnosis results in unnecessary treatment with high risks of urinary incontinence, bowel problems (especially following radiation) and erectile dysfunction (Begg et al. 2002).

### **Prostate cancer treatment issues**

The major treatment options following detection of prostate cancer are active treatment (surgical removal of the prostate or radiation therapy) or observational treatment (watchful waiting) (AHTAC 1996).

Our knowledge of which prostate cancers are life threatening and which are not is limited. In the European Randomised study of screening for prostate cancer, the patients in the Rotterdam section were screened by PSA, DRE and transrectal ultrasound. A subset of patients who would have qualified for a surveillance program were identified: those with a Gleason score less than or equal to 3+3, PSA density less than 0.2 and a maximum PSA level of 15 ng/ml. Those who met the above arbitrary criteria who chose watchful waiting did not do worse than those who had active treatment at a mean follow-up to 80.8 months (Roemeling et al. 2006).

Limitations of studies comparing the effectiveness of treatments occur because most information on treatment by surgical removal of the prostate comes from uncontrolled case series and cohort studies that indicate survival following surgery is high. However,

because surgical patients are usually younger and have less advanced disease, it is difficult to separate out the effects of treatment efficacy and selection bias.

In practice there is a wide variation in treatment decisions. Treatments for early prostate cancer differ in the proportion of patients who are likely to experience side effects such as erectile problems, incontinence and bowel symptoms.

Current clinical practice supports active intervention, particularly among men whose life expectancy exceeds 10 years with aggressive and early onset of disease.

Randomised controlled trials comparing options are difficult to conduct, but a recent study compared watchful waiting with immediate radical prostatectomy in 695 men with newly diagnosed early stage prostate cancer. Prostatectomy led to a significant reduction in both metastatic disease and disease-specific mortality, and, after eight to 10 years, overall mortality (Holmberg et al. 2002; Bill-Axelsson et al. 2005).

Radiation therapy is widely practised in Australia, particularly among older patients and those with more aggressive or later stage (high-risk) cancers. Newer techniques, delivering radiation therapy aimed at increasing the radiation dose while minimising effects on adjacent tissues, are becoming increasingly available. An analysis of 60,290 men with low and moderate grade organ-confined prostate cancer, on the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) Program showed better survival for men under and over 60 years if they received surgery or brachytherapy rather no definitive treatment (Tward et al 2006).

Because it has not been possible to prove definitively that treatments differ in effectiveness (NHMRC 2003), the incorporation of patient preference into treatment decisions is widely endorsed (Weller et al. 1998; NHMRC & ACN 2003).

## Aims

The Cancer Council Australia supports:

- advocating for and contributing expert advice to the development of decision-making tools for informed choice about prostate cancer testing, for medical practitioners and consumers, based on the best available evidence
- contributing to the development and implementation of community education relating to the prostate and prostate cancer
- monitoring and supporting research on population screening and testing for prostate cancer to inform the development of policy and communication strategies
- seeking opportunities to work with health related agencies, health professionals and consumers to increase understanding of the prostate and prostate cancer
- addressing the issues which cause inequities in access and outcomes in prostate cancer, such as living in rural and remote Australia, by developing models where information and multidisciplinary care can be accessed by those groups.

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