







Discussing benefits and risks with patients

PSA testing

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Obtaining valid consent from patients is good medical practice and a legal necessity. The process of obtaining consent involves shared decision making and a discussion of benefits and risks with patients. This article uses the example of PSA screening to explore the issue of shared decision making and outlines some strategies for general practitioners to use when discussing risks with patients.

Case history

On 19 July 1999, Dr DM saw a 53 year old patient for a general check up. The patient was asymptomatic and had no family history of cancer. Dr DM discussed the importance of colon cancer screening, exercise, diet and sunscreen use. Dr DM also discussed the benefits and risks of screening for prostate cancer. These discussions were documented in the medical records. Some time later, the patient presented to another medical practitioner who ordered prostatic specific antigen (PSA) screening. The PSA level was high and subsequent investigations revealed advanced prostate cancer.

In June 2002, Dr DM was served with court proceedings alleging failure to diagnose prostate cancer. The case proceeded to trial in Virginia, USA, in June 2003.

Medicolegal issues

The patient's solicitor alleged that Dr DM should have simply ordered PSA testing, rather than discussing the benefits and risks of the test with the patient. According to the solicitor, there was little risk involved in performing the test. It was alleged that ordering a PSA test in this patient's case was the appropriate 'standard of care' in Virginia in 1999. The patient's solicitor obtained expert opinions from four physicians practising in Virginia who testified that when they saw male patients over 50 years of age, they had no discussion with the patient about the test and prostate cancer: they simply ordered PSA testing. In his closing submission, the patient's solicitor claimed, 'evidence based medicine' was a cost saving exercise practised by Dr DM's employer. Dr DM's solicitor argued that routine performance of PSA screening in men was not recommended by Dr DM's employer or any of the national health guidelines. Current evidence suggested there was no benefit in undertaking mass screening for prostate cancer. In particular, there was no evidence that screening reduced patient mortality from prostate cancer. Because of the questionable benefits and the associated risks of PSA screening, a shared decision making model was recommended by the professional bodies. In this case, Dr DM had discussed the benefits and risks of PSA testing with the patient and a decision was made not to perform the test in July 1999.

Seven days after the trial commenced, the jury found that Dr DM had not breached his duty of care to the patient. Nevertheless, Dr DM's employer was found liable for failing to diagnose the patient's prostate cancer at an earlier stage. The jury awarded the patient US\$1 million.

Discussion

This case history is based on an American case report. What are the implications for Australian medical practitioners? Could a similar case occur in the Australian courts?

Recent Australian tort law reform has introduced changes to the definition of professional negligence. In New South Wales, the *Civil Liability Amendment (Personal Responsibility) Act* 2002 has introduced the 'peer acceptance defence'. Therefore, a medical practitioner is not negligent if it is established that: 'the medical practitioner acted in a manner that (at the time the service was provided) was widely accepted in Australia by peer professional opinion as competent professional practice – unless the court considers that the opinion is irrational'.

Peer professional opinion does not have

to be universally accepted to be considered widely accepted. The fact that there are differing peer professional opinions widely accepted in Australia concerning a matter does not prevent any one or all of the peer opinions being relied on. However, it should be noted that the peer acceptance defence does not apply to liability arising in connection with failure to warn of risks.

Screening for prostate cancer is controversial. There is still considerable debate as to the potential benefits of PSA screening and concern that it may not improve survival or quality of life.^{2,3} The Royal Australian College of General Practitioners' Guidelines for preventive activities in general practice4 state routine screening for prostate cancer is not recommended and that currently there is 'no evidence that mass screening reduces mortality'. The guidelines conclude 'PSA is unsuitable for screening because of low positive predictive value and known risks or adverse effects of therapies that have unknown effectiveness'. The Cancer Council Australia states that it is 'up to individual men to weigh up the pros and cons of testing and make a decision that they are comfortable with'.5 This raises the challenging and complex issue of discussing the benefits and risks of interventions, including tests, with patients (socalled 'informed' consent or decision making).

Important issues to consider

A common myth surrounding the discussion of benefits and risks is that decisions are based on a rational weighing up of relevant information. However, most patients' assessment of risk is primarily determined not by facts, but by emotions.⁶ Patients want to know whether and how they will be affected as individuals. They do not necessarily equate this with an explanation of risk as derived from population studies and medical research. The way in which information on risks is presented to patients influences their subsequent decisions (see *Resource*). Consider the following examples:

- 'there is a 99% chance of surviving' vs 'there is a 1% chance of death'
- an investigation that reduces a patient's risk of dying from cancer from 2% to 1% can

be said to reduce their risk by 1% or half. Presenting information to patients in natural frequencies (eg. one patient out of every 100) is an effective method of reducing any confusion resulting from the provision of numerical risk information. Additionally, the presentation of both positive and negative frames, rather than only one perspective, contributes to the effectiveness of communicating risk information.

Medical practitioners inevitably have their own biases about the benefits and risks of a particular intervention. This may have an effect on the way information and advice is presented to their patients. For example, many GPs are concerned that they might get sued if they do not perform PSA testing and a patient subsequently develops prostate cancer. This concern is likely to result in GPs recommending and ordering PSA testing.

Risk management strategies

The law demands that a medical practitioner should obtain valid consent from patients before any intervention, including a test or investigation. This process will involve a discussion of benefits and risks with patients. The narrower the margin between the benefits and risks, the more fully should patients be informed. The current climate in which GPs practise is one of shared decision making with their patients. There is a greater recognition of patients' autonomy and a move away from a 'paternalistic' model of medical care. There are a number of factors that have contributed to this change - not least of which is the legal framework within which medical practitioners work. However, the way in which medical practitioners diagnose and treat diseases has become more complex. There is not necessarily a simple or clear cut choice about the most appropriate investigation or treatment for a specific condition. Instead, there may be a range of options, each with their own benefits and risks. Towle and Godolphin have outlined a framework for the competencies that medical practitioners need for shared decision making7:

- 1. develop a partnership with the patient
- 2. establish or review the patient's preferences for information (such as amount or format)

- establish or review the patient's preferences for their role in decision making (such as degree of involvement of self) and the existence and nature of any uncertainty about the course of action to take
- 4. ascertain and respond to the patient's ideas, concerns and expectations
- identify choices (including ideas and information that the patient may have) and evaluate the research evidence in relation to the individual patient
- present (or direct the patient to) evidence, taking into account competencies 2 and 3 and framing effects (how presentation of information may influence decision making). Help the patient to reflect on and assess the impact of alternative decisions with regard to his or her lifestyle and values
- 7. make or negotiate a decision in partnership with the patient and resolve conflict
- 8. agree an action plan and complete arrangements for follow up.

There is no doubt that GPs are well suited to undertake this model of care.

Resource

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Conflict of interest: none declared.





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