Quality, Error and the Law
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Introduction

The law recognises that medicine is not an exact science. Adverse events will always occur despite our efforts at quality improvement. It's encouraging that the rate of adverse events has decreased as a result of improved safety in healthcare. But the legal system has also played a role. Making health professionals personally responsible for maintaining healthcare standards has led to improved compliance with those standards.

How is a health professional supposed to know whether he/she faces legal action following an adverse event?

- How is a health professional expected to know whether or not he/she has achieved the expected standard?
- Who sets the standard
- Who decides whether it has been met?
- Does the mere fact that an adverse event has occurred mean automatically that the standard of care has not been met? The answer is the most common statement uttered by lawyers: "Well, it all depends".

It all depends on what?

This paper will look at the legal standard expected of health practitioners.

When will a health professional be regarded as negligent?

1. There must be a duty of care. In nearly all cases, health professionals have what is called a non-delegable duty of care. They have the duty and they cannot avoid that duty by blaming those who report to them.
2. The duty must have been breached.
3. The plaintiff must have suffered damage.

Doctors operated to separate two con-joined adult Siamese twins in Singapore a few years ago. Both patients died. Nobody has ever alleged that the medical team was negligent. It was a tragic outcome but the standard of care was very high and no duty was breached.

So when will the duty of care be breached?

Consent and the law: Duty to Warn

Not every adverse event will lead to legal action. Some adverse events are a known complication of a particular treatment or procedure albeit being a low risk in many cases. Provided the patient has been given sufficient information to provide informed consent, which includes drawing to the patient's attention the known complications of the treatment or procedure, the patient will only have a legal remedy where the adverse event was caused by a failure of the health professional to achieve the standard expected.

The law in Australia on medical consent is set out in a famous High Court case[1]. It is not laid down in statute but forms part of the common law.[2] The High Court held that the patient's choice on whether or not to consent to treatment is meaningless unless it is made on the basis of relevant information and advice:

> *"The Law should recognise that a medical practitioner has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.*"[3]

There was no dispute in this case that the procedure was performed with the necessary skill. The adverse event that occurred (sympathetic ophthalmia in the patient's good eye) was a known complication albeit with a 1 in 14,000 chance of occurring. However Dr Rogers was held to have had a duty to warn Mrs Whitaker because the risk of damage to her good eye is something that he ought to have known she would attach significance in deciding whether to consent to the operation. The low risk of it occurring was material to Mrs Whitaker being able to assess the risk and therefore Dr Rogers had a duty to disclose it to her.

The lesson from the case is that medical practitioners must understand that their patients have a right to be warned of material risks <u>according to the patient's perspective</u>.

So what is the legal standard on a duty to warn?

The case made it clear that a paternalistic attitude by medical practitioners - that they know what's best for a patient about to undergo surgery - exposes them to a claim in negligence unless the patient is given all the information that is relevant from the patient's perspective in choosing whether or not to undergo the procedure.

The consent should be in writing and refer to the fact that the risks were made known to the patient and that the patient was accepting the risks. In this way the risk in the procedure (provided it is performed competently) passes to the patient.

Who decides on the standard of care? The medical profession or the courts?

The UK case of Bolam[4] decided that the standard of care given to a patient was a matter for the medical profession. It was summarised by Lord Scarman in Sidaway v Governors of Bethlem Royal Hospital as follows:

> *"The Bolam principle may be formulated as a rule that a doctor is not negligent if he acts in accordance with a practice accepted at the time as proper by a responsible body of medical opinion even though other doctors adopt a different practice. In short, the law imposes the duty of care: but the standard of care is a matter of medical judgement."*[5]

[1] Rogers v Whitaker (1992) 175 CLR 479.
[2] See also Dunn Ian: "What should Doctor tell you? LIJ (1993) 67 No 4
[3] Rogers v Whitaker op cit 490.
[4] Bolam v Friern Hospital Management Committee [1957] 1 WLR 582
[5] [1985] 1 AC 871 at 881

This test has been rejected in Australia. It has been enacted in statute and gives the courts the right to intervene where the opinion of the medical profession is unreasonable. Section 59 of the Wrongs Act 1958 (Vic) provides:

"***59. Standard of care for professionals***

*(1) A professional is not negligent in providing a professional service if it is established that the professional acted in a manner that (at the time the service was provided) was widely accepted in Australia by a significant number of respected practitioners in the field (**peer professional opinion**) as competent professional practice in the circumstances.*

(2) However, peer professional opinion cannot be relied on for the purposes of this section if the court determines that the opinion is unreasonable.

(3) The fact that there are differing peer professional opinions widely accepted in Australia by a significant number of respected practitioners in the field concerning a matter does not prevent any one or more (or all) of those opinions being relied on for the purposes of this section.

(4) Peer professional opinion does not have to be universally accepted to be considered widely accepted.

(5) If, under this section, a court determines peer professional opinion to be unreasonable, it must specify in writing the reasons for that determination.

(6) Subsection (5) does not apply if a jury determines the matter."

In practice however, medical opinions will always weigh heavily on whoever is deciding the facts be it a judge or a jury. A plaintiff who can produce a medical opinion in his or her favour will be at a considerable advantage even if the defendant can produce medical; opinions in support of its defence. Thus the weight of peer professional opinion will still be influential in any negligence action.

In fact the Bolam test was in the process of being modified in the UK with Lord Maurice Saatchi's private member's Bill.[6] The aim of the Bill was to protect doctors who offer innovative treatment for diseases such as cancer where peer professional opinion might be non-supportive. It has caused considerable controversy in the UK and was not supported by the Lib Dems prior to the election on the grounds it permitted substandard medical performance. It will have to start again as the UK Parliament was prorogued in May 2015 for the election and the Bill has therefore lapsed.

Causation and Damage

A plaintiff might be able to persuade a court that the medical practitioner failed to meet the required standard but there are two further hurdles: the plaintiff must show that this deficient standard of care caused the plaintiff's injuries and the plaintiff suffered damage.

This will often be difficult where a patient has a large number of co-morbidities or there is no evidence of any loss or damage due to the deficient treatment.

[6] Medical Innovation Bill

Whether or not negligence can be established, a patient can still complain to AHPRA

The Australian Health Practitioner Regulation Agency (AHPRA) regulates 14 health professions in Australia. It has a Code of Conduct. A member of the public can make a complaint about a registered health practitioner's health, performance or conduct standards. There is no requirement to show that the health practitioner was negligent. Where misconduct is alleged, the health practitioner's conduct will be measured against the AHPRA Code of Conduct.

In addition, all health practitioners covered by AHPRA are required to report "notifiable conduct".

Notifiable conduct by registered health practitioners is defined as:

- practising while intoxicated by alcohol or drugs
- sexual misconduct in the practice of the profession
- placing the public at risk of substantial harm because of an impairment (health issue), or
- placing the public at risk because of a significant departure from accepted professional standards.

AHPRA has extensive powers to discipline health practitioners who it finds to have:

- breached the Code of Conduct or
- carried on their professional practice while unwell; or
- engaged in misconduct.

AHPRA can

- caution the health practitioner
- accept an undertaking
- impose conditions on the health practitioner's practice
- refer the health practitioner to another entity
- refer the health practitioner to a panel or tribunal hearing depending on the degree of misconduct

AHPRA can cause as much embarrassment and career damage to a health practitioner as any finding by a court involving negligence. In fact negligence actions against practitioners in the courts can be masked by the practitioner's employer being named as the defendant based on the principle of vicarious liability. No such protection is afforded to the health practitioner in any matter dealt with by AHPRA.

How does a health professional stay out of trouble? Six steps:

1. Stay up to date with the latest developments in your field. You must know what options are available to your patient. Do more training if that's what's needed to stay at the forefront in your field.
2. Make sure you always get informed consent from a competent patient. Remember the test is whether the information would be significant from the patient's perspective, not your's. Always get consent in writing. It should refer to the fact that you have explained all the risks to the patient and the fact that the patient is accepting these risks.
3. Document all relevant clinical information in the clinical notes.
   Good notes: good defence
   Poor notes: poor defence
   No notes: no defence.

4. Listen to your patients rather than lecturing them. Address their questions. Don't cut them off. Make sure they have no more questions and that they have told you everything you need to know. Be patient. Even if a patient or the family are annoying or downright rude, control yourself and remain professional.
5. Embrace open disclosure following an adverse event. Don't just cover it up or ignore it. Get advice on what to say and what not to say: stick to facts not opinions. Apologise. Often that is all the patient or family wants.
6. Respond fully and openly to any complaint made to AHPRA. You cannot stonewall if AHPRA contacts you with a complaint. If you are worried, get advice, preferably from a lawyer experienced in health law matters.

Bill O'Shea has recently retired after 12 years as the first General Counsel for Alfred Health. He holds degrees in Science and Law from the University of Melbourne.