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Informed consent is performed well by the majority of medical and dental practitioners but it is still a primary factor when discussing your patient's healthcare with them.

Notwithstanding this, MIPS does see allegations concerning inadequate informed consent on the part of a practitioner in:

- civil legal proceedings where the patient seeks compensation for alleged medical malpractice; and
- disciplinary or regulatory cases before AHPRA or a State healthcare complaints body.

In both instances, it is rare to for informed consent to be the sole basis of a complaint or allegation of malpractice.

What is informed consent?

Informed consent, as a commonly recognised term in healthcare practice, arises from the High Court decision in *Rogers v Whitaker* [1992] 175 CLR 479.

Leaving aside the circumstances giving rise to that claim, the High Court was asked to decide if the *Bolam principle*, which was applied in the United Kingdom, had application in Australian law. At its core, the issue was did the practitioner's failure to advise and warn Mrs Rogers of risks inherent in her ophthalmic operation constitute a breach of duty?

The *Bolam principle* (see *Bolam v Friern Hospital Management Committee* (1957) 1 WLR 582), described by Lord Scarman in *Sidaway v Governors of Bethlem Royal Hospital* (1985) AC 871 as:

> *"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."*

Dr Roger's argued that the *Bolam principle* should apply in Australian law.

In their majority judgement in *Rogers v Whitaker*, judges rejected the *Bolam principle*, and in so doing addressed standard of care, peer professional opinion and the duty to warn of risk. The High Court held, in relation to:

Standard of care: that

> *...the standard of care to be observed by a person with some special skill or competence is that of the ordinary skilled person exercising and professing to have that special skill ..., but that standard is not determined solely or even primarily by reference to the practice followed or supported by a responsible body of opinion in the relevant profession or trade...*

This interpretation is incorporated in civil litigation legislation in each state and territory.

Peer professional opinion: following the decision in *F v R* (1983) 33 SASR 189 that,

> *....particularly in the field of non-disclosure of risk and the provision of advice and information, the Bolam principle has been discarded and instead, the courts have adopted the principle that, while evidence of acceptable medical practice is a useful guide for the court, it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to "the paramount consideration that a person is entitled to make his own decision about his life".*

Duty to warn (Informed Consent): that

> *...the law should recognise that a doctor has a duty to warn a patient of t**he 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 be reasonable aware that the particular patient, if warned of the risk, would be likely to attach significance to it.*

As can be seen this decision reflects the then contemporary view of what society and a reasonable person at large expected of a person exercising and professing to have a special skill. Fortunately, the majority of practitioners then, as now, practice to the standard expected of them.

Whilst that 1992 decision is still relevant, it needs to be understood that the information world has changed. In 1992 the internet was in its infancy and the extent to which

information from a wide range of sources would be available had likely not been envisaged. With the internet, TV shows and other media on medical procedures, general practice and pharmacology comes generations of people who are more informed (not necessarily correctly) and with information comes an increase in patient expectation. Add to that the challenges of diversity and language in the Australian population and the issue of informed consent, depending on the circumstances, can become equally challenging. As can the distinction between inferred consent, consent and informed financial consent which is a topic for another day.

How then does a practitioner deal these expectations and still meet his/her duty to warn a patient of a material risk and obtain the patient's informed consent?

Obtaining a patient's informed consent

Before we get to the ways to approach informed consent, consider this; properly obtaining the informed consent of your patient not only means that you have met your obligation to your patient but, conversely, you have significantly reduced the risk of your patient either complaining about you or commencing legal proceedings against you. That is not to say that will not happen, however if you have a proper consent process, have documented what you have said and your interaction with your patient it goes a long way to demonstrating that you have met your obligation.

There is no one way to approach informed consent, however, there can be no informed consent if the practitioner responsible does not communicate with the patient. Given that we live in a world where patients have greater access to information it is sometimes a good idea to start with what they already know (you can almost bet that in most instances they have consulted Dr Google). Understanding what the patient knows gives you the opportunity to get into the hard discussion about patient expectations and what the material risks of a procedure are. More importantly it lets you identify the risks that the patient is most concerned about. These are the material risks that matter to that patient; if the risk is 1:10 or 1:1000 do not be scared to disclose it. More often than not the outcome will be good.

It is not possible to identify all the aids and tools that are at a practitioner's fingertips to assist them in explaining a procedure and discussing the risks of that procedure with a patient. Possibly some of the best communicators in this area are those practitioners who work with children; yes you can explain to a parent what is going on but to get the same level of engagement with a child takes a bit of skill and the use of different aids and tools. However, just as the patient has information available to them via the internet, you more likely than not, have access to better and more relevant information.

Bear in mind that the use of aids and tools is very much secondary to proper communication between you and your patient, but they are a good tool to stimulate communication.

Just giving your patient a handout from your College or professional association does not meet your informed consent obligations notwithstanding that the patient may sign a form saying that they have received it; whether they read, understood and were given to opportunity to question you about what is in the handout is an entirely different matter that goes to informed consent. Drawing a picture and discussing that in addition to other aids or tools often draws out the concerns that a patient may have (the benefit is the drawing can go in your notes).

Whatever you do;

- if you use aids or tools to assist in informing a patient when obtaining informed consent, make those aids or tools part of your usual practice (bearing in mind that usual practice changes with time);
- communicate openly with the patient; and
- document what has been discussed or any other pertinent issues.

As a starting point, the following elements, which are by no means exhaustive, may be considered when assessing the materiality of a risk to a patient.

Element	Questions to consider
Nature of the matter to be disclosed	How likely and how serious is the potential risk? • Highly probable and more serious injuries to which the patient is likely to attach significance require disclosure • Consideration of co-morbidities and the risks
Nature of the proposed procedure	How complex is the intervention? • Complicated procedures may require more detailed explanation • Is there likely to be a consequential disability or impairment which may not be avoided? Will this be permanent? • What support services are there? • Does the procedure involve a multi-disciplinary team and how involved are they?
Desire for information	How eager is the patient to learn about the risks involved? • Patients who ask many questions demonstrate a desire for information and these should be addressed • What does your patient already know from their own research? • What is your patient's expectation from the procedure etc? • What is the recovery time? • Cost and impediments to activities of daily living (ie you cannot drive the car for 6 weeks)

Patient's distinctive characteristics	What are the patient's personal attributes, mental or physical health problems? • Patients with anxiety, underlying health issues or other compromising circumstances may need more information • Does the patient require an interpreter and if so is the interpreter a family member (some family members find it hard to talk about death or serious consequence and will not interpret accurately but skirt around an issue and unless you speak the language you will not know) • What is the patient's level of comprehension? Do they have capacity? • Is the patient a minor? Does the Gillick competency test come into question?
General surrounding circumstances	Where/When is the procedure taking place and how does this affect its risk level? • Information required for elective procedures, where several consultations are possible, may differ from • Is it possible that the patient may require, given the procedure and any co-morbidities, admission to ED and does the hospital have that capability

Table 1: Important factors in assessing material risks. Adapted from Skene and Smallwood (2002) Informed consent: lessons from Australia. Bmj. 2002 Jan 5;324(7328):39-41[4].

Lennox and Wright (Lennox A, Wright B. How can we improve informed consent processes? Briefing Document. Melbourne, Australia: Behaviour Works Australia, Monash University. May 2019) conducted a series of interviews with a panel of stakeholders in the Australian healthcare context, to learn about their experiences with obtaining informed consent and thus inform future improvements to current practice in Australia.

The lessons learned from this research highlight the following steps you can take to increase the engagement of your patients in the informed consent process:

Understand your role

- The responsibility to obtain consent is on the clinician who performs a procedure or investigation.

Ensure your patients are informed of and understand their rights to information

- Make clear it is their right to choose and discuss the procedure and any concerns in a two-way conversation.

Provide information objectively and accurately to address expectations

- Convey information about diagnosis, relevant procedures, associated risks and benefits, potential outcomes, what to expect after the procedure.

Be mindful of how information is presented

- Remain flexible and present the information in a variety of different ways, for example you may use graphics, icon arrays, decision aids, framing in the positive and negative, bar charts, risk ladders, percentages, etc.

Timing

- Have the conversation early in the therapeutic process and ensure enough time is given to address any concerns.

Information should address the patient's individual circumstances

- Consider what matters to your patients and tailor the information provision accordingly.

Is your patient able to comprehend what is being said and does he/she openly engage?

Bear in mind, a patient will likely only understand part of what you say;

- Ask patients explain their understanding of what they have been informed of;
- Talk through their decisions and what they consider important;
- If there is any uncertainty clarify it then and there and give the patient the opportunity to rationalise the information (bearing in mind it is not always what they want to hear);
- Be prepared to discuss the difficult issues.

Record all information in the patient's health record (this is your primary protection)

- Keeping contemporaneous records of informed consent can significantly assist to defend an allegation of negligence or complaint which may be made against you (it is an old mantra but "if it is not documented it did not happen"). The courts and regulators expect to see notes on informed consent in the patient records.

The expectation from Rogers v Whitaker on the question of "Informed Consent" is that healthcare information be a collaboration between practitioner and patient.

From MIPS' experience this collaboration ensures optimum patient outcomes, a lower risk exposure both to the patient and practitioner and perhaps more importantly a patient who is happy to recommend the practitioner to someone else.

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