

# Reviews

## Informed consent for anaesthesia in Australia and New Zealand

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### SUMMARY

*The legal and ethical requirements related to an anaesthetist's communication with patients in preparing them for anaesthesia, assisting them in making appropriate decisions and obtaining consent in a formal sense are complex. Doing these things well takes time, skill and sensitivity. The primary focus should be to adequately prepare patients for surgery and to ensure that they are sufficiently well informed to make the choices that best meet their own needs. This is just an affirmation of the importance of patient-centred care.*

Key Words: anaesthesia, informed consent, risk, information, ethics, medicolegal

Informed consent is fundamental to modern anaesthesia<sup>1-3</sup>, but there is debate over what constitutes reasonable practice in various clinical contexts. A recent review<sup>4</sup> in a speciality surgical unit in Australia found that few consent forms described procedures using plain language (18.5%), documented relevant risks (4.1%) or provided information about alternative treatment options. The researchers commented that “provision of appropriate information is an issue of social responsibility” and contrasted their findings unfavourably with the information typically received by consumers of products or services in other settings. This research supported our anecdotal observation that compliance with the process of informed consent is variable. There are, without doubt, many factors which may impede meeting the legal standard of informed consent (Table 1).

TABLE 1  
*Factors which may contribute to failure of obtaining the legal standard of informed consent*

Systemic factors	Time pressures associated with workload. Lack of private areas in which to communicate with patients. Increasing day of surgery admissions. Under-utilisation of pre-admission clinics for anaesthetic consultations.
Anaesthetic factors	A perception held by some anaesthetists that discussing material risks will unduly increase patient anxiety and fear. A perception held by some anaesthetists that the consent process is excessively onerous and time consuming. Insufficient knowledge of the medicolegal requirements for informed consent of some anaesthetists. Lack of departmental policies on informed consent for anaesthesia. The use of medical jargon.
Patient factors	Cultural and social factors: levels of education, language and literacy, perceptions of the relative importance of individual autonomy and consensus of groups, such as extended families. Varying degrees of competence.

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The final arbiter of acceptable practice is the law, but the law is subject to interpretation and may not always be well understood. Therefore, in this paper we review key conceptual, ethical and legal issues relevant to informed consent for anaesthetists in Australia and New Zealand.

## ANAESTHESIA AND RISK

Anaesthesia today is generally perceived as safe<sup>5</sup>, but carries a diverse constellation of risks. Each risk is difficult to quantify accurately and varies with patient factors and the type of surgery.

The purpose of anaesthesia is to facilitate surgical or medical procedures; anaesthesia usually has no therapeutic value in itself<sup>6-8</sup>. However, many modern procedures are impossible without anaesthesia and the risks associated with anaesthesia contribute to and sometimes exceed those of the facilitated procedure. It follows that these risks need to be factored into the primary decision to undergo any procedure that requires anaesthesia. The view that consent for anaesthesia is required separately from consent for surgery has wide authoritative support<sup>1-3,9</sup>.

Conveying the risks of anaesthesia appropriately depends on successful communication between anaesthetists and their patients. Many patients know little about anaesthesia or the roles and responsibilities of anaesthetists<sup>10</sup>, and many are unconscious or amnesic during much of their time with their anaesthetist. The most successful anaesthetics are those that have the least impact on patients, leaving them lucid, pain-free, without nausea and sometimes slightly euphoric, so it is understandable if patients occasionally fail to appreciate the importance of the care they have received and therefore the context of the associated risks. The preoperative consultation provides opportunity not only for disclosure of risks but also for explanations, reassurances and the development of rapport.

## THE CONTEXT OF INFORMED CONSENT

Anaesthetists' approach to disclosure and consent is influenced by diverse factors, including relationships with surgeons, the hospital environment, the peripatetic nature of their work (in some cases), progressive changes in the law over time and the cultural diversity which characterises Australia and New Zealand. The modern operating theatre environment is complex and dynamic. Patients are often admitted to hospital on the day of surgery where they are processed by a succession of clerical, nursing and medical staff, and required to read and sign a number of forms. By this stage, patients may already have formed impressions about their anaesthetic from ideas imparted by others (e.g. nurses, midwives, surgeons, junior doctors), which may not be accurate. Anaesthetists sometimes have little alternative other than to see their patients for the first time in the operating suite. These areas are typically hectic, noisy and lacking in privacy. It is far from ideal for informed consent for anaesthesia to

be obtained in such settings, or immediately prior to induction of anaesthesia, but production pressure to increase operating theatre efficiency is a strong disincentive for anaesthetists to take sufficient time and care in communicating adequately with their patients<sup>11</sup>.

Anaesthetists often have more transient and fleeting relationships with their patients than surgeons. Patients are typically referred to a specific surgeon but rarely to a specific anaesthetist. For most elective operations, patients are seen by their surgeon well before admission to hospital, often more than once and usually in a private, well-appointed consulting room. Surgeons also routinely conduct postoperative and post-discharge consultations with their patients, whereas comparable postoperative assessments by anaesthetists are still relatively infrequent. Even in hospital, many surgeons dress formally and see their patients at scheduled times accompanied by retinues of attendants. In contrast, anaesthetists tend to visit their wards alone, dressed in scrubs and when opportunity arises. It is therefore not surprising that few patients can recall the name of their anaesthetist<sup>12,13</sup>. This is not to say that the surgeon's approach is ideal: while patients typically prefer doctors to dress formally<sup>14-16</sup>, the clothing worn by anaesthetists does not seem to affect patient satisfaction<sup>17,18</sup>. Formal dress may actually hinder effective communication by emphasising steep authority gradients and by making doctors appear intimidating and unapproachable. In the United Kingdom, infection control departments are discouraging physicians from wearing neck-ties, on the grounds that these are a potent source of cross infection<sup>19,20</sup>. The allocation of enough time for the consultation is probably more important than attire and so is the timeliness of the consultation. A hurried, last-minute interaction is unsatisfactory for both parties.

Specialist and trainee anaesthetists often move within and between Australia and New Zealand and may struggle with local nuances of law and culture. The law may, understandably, often seem threatening, complex and inscrutable. The broad legal principles and bioethical foundations of good practice are generally understood, but many doctors are uncertain about their precise (current) legal obligations<sup>21</sup>.

## AN HISTORICAL PERSPECTIVE

Times have changed: in 1871 the American physician Professor Oliver Wendell Holmes Sr, addressing the graduating class of the Bellevue Hospital Medical College, said, "your patient has no more right to all the truth than he has to all the

medicine in your saddle-bags ... He should get only just so much as is good for him"<sup>22</sup>.

The term "informed consent" was coined by attorney Mr Paul G. Gebhard in a 1957 medical malpractice case in California<sup>23</sup>, and entered the zeitgeist in the latter half of the 20th century. It has been defined as follows<sup>24</sup>: "An informed consent is an individual's *autonomous authorization* of a medical intervention or of participation in research." However, Australian law has taken a different view of the concept of informed consent from the American law. In *Rogers v Whitaker*<sup>25</sup>, the High Court of Australia said (at para [15]) that "the phrase 'informed consent' is apt to mislead as it suggests a test of the validity of a patient's consent". The Court said that the question is not whether the patient has consented (the basis of an action in trespass), but rather whether the doctor has taken reasonable care in providing information to enable the patient to make an informed decision (the basis of an action in negligence). This emphasis on the patient is a reflection of the fundamental shift that has occurred in most Western cultures in the doctor-patient relationship from a physician-oriented paternalistic approach to a patient-centred model which emphasises autonomy and self-determination<sup>26</sup>. There is increasing recognition that competent, adult patients are entitled to refuse medical procedures, even procedures which are clearly in their best medical interests. There has also been an increased emphasis on documentation. Formal documentation of consent with the use of a checklist in the operating room may reduce the chance of operating on the wrong side or even the wrong patient, and so contribute to safety<sup>27</sup>. However, we believe that appropriate and ongoing communication with patients over time is the central requirement<sup>28</sup> and that undue emphasis on documentation may be unhelpful, if only through the implication that the provision of informed consent is a discrete event.

#### PHILOSOPHICAL CONSIDERATIONS

Beauchamp and Childress<sup>24</sup> described four bioethical principles fundamental to medical ethics: autonomy, nonmaleficence, beneficence and justice. Sometimes these principles conflict and, in ethical discourse, there is no agreed hierarchy for resolving such conflict. In fact, Beauchamp and Childress went to considerable lengths to qualify the principles and emphasise the importance of context. Furthermore, there are several alternative philosophical approaches to medical ethics. Virtue ethics is particularly helpful, being less constrained by the idea of principle and more accommodating

of the complexity of the ethical challenges often faced in healthcare. A virtue ethicist might take the view that these principles are better understood as virtues, to be considered in the context of other virtues, such as honesty and compassion. However, the law has placed particular emphasis on autonomy<sup>29</sup>. This does not necessarily reflect the view of all cultures. Many Maori and Indigenous Australians might have a more collective view of decision-making, and so may people from a number of other countries around the world.

#### Autonomy

Autonomy is derived from the Greek *autonomia*, meaning self-rule. Applied to individuals, autonomy may be defined as personal freedom or freedom of the will<sup>30</sup>. The doctrine of informed consent is founded on respect for autonomy. In 1914, the American judge, Justice Benjamin Cardozo said<sup>31</sup>:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."

In his essay "On Liberty"<sup>32</sup>, John Stuart Mill said: "The only purpose for which power can be rightly exercised over any member of a civilised community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so ..."

Respect for autonomy in the medical context implies that patients, and not their doctors, have the right to decide about their medical treatment. Doctors may comprehend the medical issues, "but only the patient knows the patient's own values, which will ultimately determine the treatment the patient is prepared to undergo: the willingness to take risks, bear pain or physical restrictions and the like. Neither the state, 'the community', nor a paternalistic, if well-meaning health professional, is entitled to dictate the medical treatment that a competent adult patient will undertake"<sup>33</sup>.

Thus patients have the right to consent to treatment that is offered, or to refuse it. However, they have no legally enforceable right to demand treatment that is inappropriate or not medically indicated<sup>33</sup>. A patient who is hesitant to take advice or consent to treatment has the right to seek a second opinion, and the primary clinician should facilitate this if possible.

#### Nonmaleficence

The principle of nonmaleficence "asserts an obligation not to inflict harm on others"<sup>24</sup>. It must

be balanced with the principle of beneficence, to which it is closely related.

### *Beneficence*

The principle of beneficence noted in the writings of Aristotle<sup>34</sup> refers to “a moral *obligation* to act for the benefit of others”<sup>24</sup>. Positive beneficence is the requirement to provide benefit, whereas utility beneficence requires a balance of benefits and risks to produce the best overall results, usually in a wider, community-oriented context<sup>24,35</sup>. Many factors, including religious beliefs and the views of family, friends and the media, may influence patients’ decisions<sup>36</sup>. The principles of beneficence and respect for autonomy may conflict when patients decline treatment thought to be appropriate (e.g. a blood transfusion in a haemorrhaging patient who is a Jehovah’s Witness).

### *Justice*

The principle of justice may be defined as “fair, equitable treatment in light of what is owed or due to an individual”<sup>35</sup>, and might include rationing of scarce resources, ensuring that all patients are treated alike, without discrimination, and considering the rights of health professionals.

When a clinician suffers a needle-stick injury, and the patient is anaesthetised, the principle of respect for patient autonomy conflicts with the need for justice. The clinician urgently needs to know the patient’s infectious disease status for his or her own welfare, but the patient is unable to consent to serological testing. In many Australian and New Zealand hospitals, the chief medical officer will authorise serological testing. This pragmatic compromise provides considerable legal and ethical protection for the involved practitioners. In some institutions, explicit consent for testing under such circumstances is routinely obtained before surgery.

## INFORMED CONSENT AND THE LAW

The law relating to the information to be provided before a patient agrees to a medical procedure varies in detail between jurisdictions in Australia, and between Australia and New Zealand, but the underlying principles tend to be consistent. Statutory law, common law, professional guidelines<sup>9</sup> and ethical codes<sup>33,37</sup> all apply. In Australia, a doctor’s duty to provide information to patients before undertaking a medical procedure derives principally from the law of negligence, but the law of trespass and contract are also relevant and the common law principles have been stated in legislation in some jurisdictions. In New Zealand, the Code of Health

and Disability Services Consumers’ Rights<sup>37</sup> is particularly relevant.

Anaesthetists are the best qualified to provide information and advice about anaesthesia. Certain risks fall clearly within the anaesthetic domain. The responsibility for explaining other risks (e.g. an adverse drug reaction to an antibiotic requested by a surgeon but administered by an anaesthetist) may be less clearly delineated. If more than one person assumes this responsibility, contradictory messages may be given. The key is communication; providers need to liaise, and it is important to ask patients what they have been told by others.

### *The tort of trespass (battery and assault)*

If a patient has not consented to a medical procedure at all, then he or she may have an action in trespass. The law of trespass to the person includes battery, which is any “touching” of a person, and assault, which is conduct that puts a person in apprehension of a battery<sup>33</sup>. The law of trespass “protects a person’s right to bodily inviolability: the right not to be touched without consent or other lawful authority”<sup>33</sup>. Many things done to patients in healthcare would constitute trespass in the absence of consent (or other lawful authority). Examples of typical actions in trespass relate to wrong-sided procedures or procedures on the wrong patient. Here, there is no consent. The issue is not whether the doctor has failed to provide adequate information about the procedure. All that a patient would have to prove is that the procedure was done without his or her consent. It is not necessary to prove any injury or loss, or that the doctor was at fault. Also, the fact that the doctor had made a reasonable mistake or acted in the patient’s best interests would be no defence, though that may be relevant to the amount of compensation awarded. However, these situations are rare, tend to be quickly settled and are

TABLE 2

#### *An example of trespass*

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In a prominent Canadian case<sup>77</sup>, a young female patient was scheduled for spinal surgery because of backache. She was otherwise fit and well, and had repeatedly requested general anaesthesia and refused spinal anaesthesia. After prolonged discussion with her anaesthetist and the administration of sedation, the anaesthetist convinced her to have a spinal anaesthetic for her surgery, as was the usual practice in that institution. After the procedure she was paralysed from the waist down and successfully sued the anaesthetist. In testimony, a witness said that the patient “refused [the spinal anaesthetic], but they continued to offer it to her; finally she became tired and said: ‘You do as you wish’ or something like that.” The judge stated that the patient’s agreement to the spinal anaesthetic was involuntary, because it rested on “words which denote defeat, exhaustion, and abandonment of the will power”<sup>743</sup>.

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not usually publicised. In other cases, consent may be vitiated (have its validity diminished or nullified) because it was obtained by fraud, deception or duress (Table 2), but again, these cases are rare.

Procedures may sometimes be undertaken lawfully without consent, notably in emergencies. Consent need not always be explicit: it may be implied from the circumstances. A person other than the anaesthetist, such as another practitioner or a nurse, may obtain consent from a patient, although this is less than ideal. Also, a third party, such as a parent or other relative, a guardian or a guardianship body or court may consent on behalf of an incompetent patient in certain circumstances.

#### *The tort of negligence*

Where a patient has consented to a procedure, but later alleges that he or she would not have consented if properly informed about what the procedure involved, and the potential risks and alternatives, an action in trespass is not available in Australian law<sup>25</sup>. The only legal actions available to the patient in such circumstances are in negligence or for breach of contract.

Negligence is conduct that falls below the standards of behaviour established by law for the protection of others against the unreasonable risk of harm. In order to make a successful claim in negligence against a doctor, a patient must prove that: 1) the doctor owed the patient a duty of care, 2) this duty of care was breached because of behaviour falling below the standards required to satisfy the duty of care, and 3) this breach caused physical, emotional or financial harm to the patient (Table 3).

In *Rogers v Whitaker*, the High Court of Australia said (page 490<sup>25</sup>) that it is part of a doctor's general duty of care to inform patients about "material" risks

TABLE 3  
*Claims in negligence*

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There have been only a few legal cases involving doctors not disclosing anaesthetic risk<sup>78-81</sup>. Furthermore, in tort, there are a number of requirements (described below) for liability to be imposed. Complaints are more likely to gain traction, notably in New Zealand, where the Health and Disability Commissioner has high expectations for patient-centred care (including informed consent).

Liability in tort would only be imposed if:

- The anaesthetist did not disclose a material risk (breach of the duty of care – failure to inform); and
  - The risk in fact eventuated so that the patient suffered harm (injury or loss); and
  - The patient was able to persuade the court that he or she would not have agreed to the procedure if informed of the risk in question (causation).
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of a procedure before they agree to undergo the procedure.

#### *Breach of contract*

A patient who alleges that he or she has not been adequately informed about a proposed procedure may sue in contract as well as in negligence. A contract is defined as an enforceable agreement between two or more individuals and the relationship between doctors and patients is contractual. The contract, which is generally implied rather than specific, will require the doctor to take reasonable care, so the duty in contract is the same as the duty in negligence. Contracts between doctors and patients occasionally require the doctor to achieve a particular outcome, such as to sterilise a patient. One may imagine an unwritten contractual obligation for anaesthetists to ensure that their patients remain safe, as comfortable and free of pain as practicable, and unconscious or amnestic during the operation (depending on whether general anaesthesia or sedation is provided). However, if a patient alleges that one of these obligations was not met during his or her procedure, those matters are more likely to be pleaded as an indication of the anaesthetist's failure to take reasonable care in the procedure, rather than a breach of implied terms in the contract between them.

#### *Other avenues of complaint*

Some patients may not wish to take legal proceedings against their medical practitioners, or they may not be entitled to bring an action, because they have not suffered any injury or loss. In such cases, they may complain to a medical registration body, such as a medical practitioners' board, or a "health ombudsman" (e.g. in Victoria this could be the Victorian Health Services Commissioner). This may lead to disciplinary action against the doctor, an apology to the patient or an agreement to pay some compensation, even if the patient has suffered no injury or loss. In New Zealand, the Health and Disability Commissioner deals with complaints against the Code of Rights<sup>37</sup>, and might find a breach of the relevant rights even in the absence of injury or loss.

### THE ELEMENTS OF INFORMED CONSENT

Beauchamp and Childress<sup>24</sup> describe the process of informed consent as having several elements: 1) threshold elements, 2) information elements, and 3) consent elements. We have modified this framework to include the explanation of alternatives and refusal elements (Table 4).

TABLE 4  
*The elements of informed consent*

<i>Threshold elements (pre-conditions)</i>	
1. Competence (to understand and decide)	
2. Voluntariness (in deciding)	
<i>Information elements</i>	
3. Disclosure of material information	
4. Explanation of alternative treatments	
5. Recommendation of a plan	
6. Understanding of 3-5	
<i>Consent elements</i>	<i>Refusal elements</i>
7. Decision in favour of a plan	9. Decision against a plan
8. Authorisation of a plan	

Modified after Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. New York: Oxford University Press, 2001.

### *Competence (to understand and decide)*

Competence and capacity have similar meanings in the context of consent to medical procedures, and the terms may be used interchangeably. Competence is defined as the “*capacity to understand the general nature and effect of the proposed treatment*”<sup>38</sup>.

Competence and incompetence represent extremes of a continuous spectrum. Persons aged 18 years or older in some jurisdictions in Australia, 14 or 16 years or older in other Australian jurisdictions, and 16 years or older in New Zealand, are generally presumed to be competent, though it is possible to rebut this presumption by showing that an individual lacks the level of competence to make the decision in question. Also, a child under these ages may be competent to consent if he or she is sufficiently mature to understand what is involved in a particular procedure<sup>39,40</sup>. Patients whose competence is in doubt should be assessed individually, and those with minor impairment should be encouraged to make their own decisions and have their autonomy respected. A patient may be assessed as competent even if the patient’s reasons for making a particular decision “are rational, irrational, unknown or even non-existent”<sup>41</sup>. The definition of a person who is “incapable of giving consent” has been given as: “incapable of understanding the general nature and effect of the proposed procedure or treatment or of communicating consent or refusal”<sup>33</sup>. Competence is specific to particular decisions: invasive procedures may require a higher level of competence than simple ones. For example, a person may be competent to consent to being examined by a neurosurgeon, but not to consent to neurosurgery.

Anaesthetists are often involved in the care of patients when competence to consent to medical treatment may be fluctuating as a result of acute

illness or the use of analgesic and sedative medications.

If a patient does not have sufficient capacity to make a decision, then the law may allow a substitute decision-maker to decide. Substitute decision-making effectively acknowledges “the right of incompetent patients not to be treated ‘paternalistically’ by a doctor”<sup>33</sup>, and thus respect for their autonomy. The explicit aim of substitute decision-making is to “replicate the decision the patient would make if he or she were still capable”<sup>42</sup>, so the wishes of adult patients who expressed their wishes before becoming incompetent will be important. Relatives have no legal authority to decide about treatment at common law (except parents deciding for their under-age child) but many jurisdictions now have legislation that formally authorises relatives and carers to make medical decisions in this context (e.g. *Guardianship Act 1987 (NSW) s 33A*; *Guardianship and Administration Act 1986 (Vic) ss 37, 39* (“person responsible”)). Decisions may also be made by a guardian, a guardianship body or a court. The law on the appropriate person to consent for an incompetent patient varies and practitioners need to be familiar with the law in their own jurisdiction. Medical defence organisations and insurers are a helpful resource for answering particular queries that arise in day-to-day practice.

Substitute decision-makers are entitled to be given sufficient information to make an informed choice. They are also required to act in the patient’s best interests and decisions that appear not to be in a patient’s best interests may be legally challenged in a guardianship body or a court (note that conflicts of interest may occasionally arise in relation to substitute decision-making).

In practice, a parent can consent to anaesthesia for an under-age child and, if an adult patient is not competent to consent to anaesthesia and a close relative is present, that person can usually decide for the patient. The anaesthetist should give the parent or relative the same kind of information as a patient and recommend the appropriate procedure. The consent of a parent or relative is lawful authority to proceed. If the parent or relative does not wish to take this role, it may be necessary for a court or a guardianship body to appoint someone else to make the decision. This may take some time, and if the procedure is medically necessary and cannot be deferred, then reasonable treatment may be administered without consent (this is a principle of the common law and, in some jurisdictions, is also in legislation: for example, in New South Wales, the *Guardianship Act 1987 (NSW) s 37*; and in Victoria,

the *Guardianship and Administration Act* 1986 (Vic) ss 42L, 42M).

#### *Voluntariness (in deciding)*

Voluntariness is an important pre-condition to decisions about medical procedures, and refers to “a patient’s right to make healthcare choices free of any undue influence”<sup>43</sup>. However, the ability of a patient to make voluntary choices prior to anaesthesia is often affected by internal factors such as inter-current illness, emotional stress and anxiety, pain and by external factors which may include manipulation, coercion and force that may be imposed by clinicians, or the influence of family members with pecuniary interests. Manipulation, coercion and force are a spectrum of behaviours which vitiate (diminish or nullify) consent. Manipulation is defined as “the deliberate distortion or omission of information in an attempt to induce the patient to accept a treatment”<sup>43</sup>. Equally, manipulation could involve attempting to induce a patient to choose one alternative over another, or indeed to refuse treatment altogether. Manipulation may take many forms and may be subtle. For example, a trainee wishing to improve his or her skills in awake intubation might persuade a patient who does not really need this to believe that it is in fact indicated, whereas a less manipulative approach would be to explain the situation honestly and seek explicit consent. Even then, a patient might be influenced by a sense of needing to please the doctor, and a high degree of awareness of this possibility is sometimes required to avoid unconscious manipulation.

Coercion involves “the use of explicit or implicit threats to ensure that a treatment is accepted”<sup>43</sup>. There may be a fine line between coercion and giving patients the information that they really ought to receive (for example, informing a patient of the potentially fatal consequences of refusing a laparotomy to deal with an acute abdomen seems reasonable, even though it could be construed as coercive). The key, of course, is to leave open the possibility that a properly informed patient might still refuse. We believe that serious coercion is unusual in hospitals in Australia and New Zealand, in part because of the obvious risk of a complaint and the high likelihood that a complaint would be upheld. Force “involves the use of physical restraint or sedation to enable a treatment to be given”<sup>43</sup>. Premedication and gentle physical restraint during induction of anaesthesia are frequently employed in paediatric patients. In these circumstances, force may be justified because the child cannot understand what is involved and the child’s parents have lawful

authority to consent to treatment for their child. However, a slightly older child who is able to articulate opposition to proceeding with an anaesthetic to which his or her parents have consented may present a difficult problem. The use of force in the administration of anaesthesia may also be justified if a patient is given involuntary treatment for a psychiatric condition that is authorised under mental health legislation.

#### *Disclosure (of material information)*

Most of the cases that have come before the courts in relation to consent to medical procedures have focused on the doctor’s duty to provide information about “material” risks (“the duty to warn”). Exactly which risks require explanation and disclosure has been the subject of much debate. The previous standard accepted by the courts was that of the so-called “Bolam test”<sup>44</sup>. This test, as stated in another case, is that “a doctor is not negligent if he (or she) 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”<sup>45</sup>. This means that a doctor who failed to disclose a particular risk would ordinarily have a defence if the practice of some other doctors (or specialists in the field) would be not to discuss that risk.

In 1992, in *Rogers v Whitaker*<sup>25</sup> (discussed above), the High Court of Australia delivered a landmark judgment, in which it rejected the Bolam test and stated a test focussed on individual patients rather than accepted medical practice:

“It is a doctor’s duty to disclose material risks. 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.”

This principle requires doctors to provide information that a *reasonable patient* (an objective test) or, in some cases where the doctor knows more about the patient’s desire for information, the *particular patient* (a subjective test) could be assumed to want, in order to decide whether to agree to the procedure in question. This principle was not changed by the civil liability legislation (“tort law reform”) that has later largely reinstated the Bolam standard for doctors’ negligent conduct other than negligent non-disclosure; and cases alleging negligent failure to inform continue to come before the courts, some involving anaesthetic risks<sup>46</sup>. The

law is similar in New Zealand, as set out in Right 6 (Right to be Fully Informed) of the Code of Health and Disability Services Consumers' Rights Regulation. It extends to disclosing proposed participation in research and teaching and answering questions about a practitioner's qualifications<sup>47</sup> and experience.

In a case alleging negligent non-disclosure, the most difficult matter for a patient to prove is typically causation. The patient must prove that, if the anaesthetist had given the patient the information in question, then the patient would not have consented to the procedure and so would not have suffered the injury or loss. In Australia, the test for determining causation is subjective (i.e. based on what the particular patient would have done if adequately informed) and is decided as a matter of common sense, as the High Court of Australia said in *Chappel v Hart*<sup>48</sup>. After the development of a complication, the patient is more likely to say that he or she would have attached significance to that risk if warned about it in advance, and so the outcome tends to be considered through hindsight, as the High Court observed in *Rosenberg v Percival*<sup>33,49</sup>, and that possibility is taken into account in deciding the outcome of a claim by the patient.

The practice of risk disclosure was further clarified in guidelines published in 1993 (later reissued in 2004) by the Australian National Health and Medical Research Council<sup>50</sup>, which reflected the principles of *Rogers v Whitaker*<sup>25</sup>:

"Doctors should give information about the risks of any intervention, especially those that are likely to influence the patient's decisions. Known risks should be disclosed when an adverse outcome is common even though the detriment is slight, or when an adverse outcome is severe even though its occurrence is rare."

Risk is most accurately described in terms of numerical probability, although research has shown that people often find difficulty in comprehending

such measures<sup>51</sup>. When explaining the probabilities of different risks in anaesthesia, it may be helpful to place these risks in perspective by reminding patients of the risks they are subjected to in daily life.

In *Rogers v Whitaker*<sup>25</sup>, the High Court of Australia considered five factors to be important in deciding whether a risk is material and must be mentioned to a patient and these factors were also accepted by the National Health and Medical Research Council Committee (Table 5).

#### *Explanation of alternative treatments – the concept of informed choice*

Fair progress has been made in the practice of risk disclosure prior to medical procedures. However, more emphasis needs to be placed upon explanation of alternative treatments, including the choice not to proceed. This is part of the principle that doctors should disclose relevant information that patients need in order to make an informed decision.

Often, patients are advised only of a recommended anaesthetic plan and it is less common for other anaesthetic options to be discussed. Typically, the patient is offered a single choice, to proceed or not to proceed, after explanation of possible risks. Thus, a patient who was not told about different anaesthetic options might have grounds for an action in negligence if he or she became paralysed after epidural anaesthesia for a procedure that might have been performed under general anaesthesia, which the patient might have preferred for other reasons as well.

An informed choice is defined as "one that is informed, consistent with the decision-maker's values, and behaviourally implemented"<sup>52</sup>, and provides real choice to patients in the diagnostic and treatment options offered<sup>53</sup>. Any option likely to be given serious consideration by the particular patient should be discussed. In New Zealand, the right to be fully informed includes "an explanation

TABLE 5  
*Factors which anaesthetists should consider when disclosing risks to patients*

1. The nature of the matter to be disclosed	More likely and more serious risks require disclosure.
2. The nature of the proposed procedure	Complex interventions typically require more information, as do procedures where the patient has no illness.
3. The patient's desire for information	Patients who ask questions make known their desire for information and should be told.
4. The temperament and health of the patient	Anxious patients and patients with health problems or other relevant circumstances that make a risk more important for them (such as their medical condition or occupation) may need more information.
5. The general surrounding circumstances	The information appropriate for elective procedures, where several consultations are possible, may be different from that required in emergency settings.

Adapted from Skene L, Smallwood R. Informed consent: lessons from Australia. *BMJ* 2002; 324:39-41.



of the options available, including an assessment of the expected risks, side-effects, benefits, and costs of each option”<sup>37</sup>.

### EMERGENCIES

In an emergency, treatment may be given without prior consent provided that the treatment is limited to what is reasonably necessary to preserve the patient’s life or prevent serious damage to the patient’s health, and the patient has not previously specifically refused the treatment. This principle justifies emergency procedures, including anaesthesia, if there is an unexpected development during other treatment, or if the patient is unable to communicate and there is no-one present with authority to consent on the patient’s behalf.

### CHILDREN

In Australia, where a patient is a child, either parent will usually be legally authorised to consent to medical procedures for that child, including anaesthesia, until he or she is 18 years old (though, in some states, children can consent to medical procedures from ages as low as 14 years). Parents’ general authority arises from their “parental responsibility” for the child under the federal *Family Law Act 1975* but some states have specific legislation on consent for medical procedures. In New Zealand, children aged 16 years or older can make their own medical decisions under the *Care of Children Act 2004*; for children under that age, medical decisions may be made by the child’s guardian and both parents are generally joint guardians. In both Australia and New Zealand, the child’s interests and welfare are paramount. Parents are required by law to act in their child’s best interests and, if they unreasonably withhold consent to a medical procedure, that decision can be challenged in court (and doctors may continue with reasonable treatment until the court has reviewed the matter). An example relevant to anaesthetists would be that of a paediatric patient who urgently requires a blood transfusion, contrary to the wishes of the child’s parents who are Jehovah’s Witnesses. The anaesthetist may treat such a child with a blood transfusion under human tissue legislation in Australia, or under the *Care of Children Act 2004* in New Zealand, and also under the common law doctrine of emergency care (in both Australia and New Zealand, this principle applies to patients up to 18 years of age). However, there may be far-reaching consequences for future doctor-patient relationships in discounting the parents’ wishes in such a situation (see “Other avenues of complaint” above), and perhaps for relationships

within the family, so the justification for giving blood must be well-founded. Parental authority to consent ceases when the child is 18 years old (or younger in some jurisdictions), but children who are under that age and can understand what is involved (a “mature minor”) may consent on their own behalf to medical treatment. This is particularly relevant in situations involving conflict between teenage children and their parents, but situations of this type are very difficult, and consultation with a colleague would usually be prudent. More generally, it is appropriate for children to be provided information and to contribute to the process of consent to the degree reasonable for their stage of cognitive development. This does not normally imply excluding parents, and hospitals often require parental consent as well as consent from the child. In elective circumstances that do not involve explicit conflict between the child and the parent, involvement of both parents and children is obviously desirable.

### TREATMENT AUTHORISED BY LEGISLATION OR A COURT

Where treatment is authorised by legislation or a court order, it may be given without consent and without the need for formal information to be given. A common example involves general anaesthesia for electroconvulsive therapy for the treatment of involuntary psychiatric patients. However, even in such cases, it is good clinical practice to provide appropriate information to patients. Patients place high importance on meeting with anaesthetists prior to anaesthesia<sup>54-56</sup>, and in other areas of medicine, provision of information has been shown to improve functional status<sup>57</sup> and patient satisfaction<sup>58</sup>.

### PATIENTS WHO DO NOT WANT FULL INFORMATION

Competent adult patients are entitled to waive their right to be fully informed. The High Court of Australia recognised this right in *Rogers v Whitaker*<sup>25</sup>. However, there is considerable risk to an anaesthetist in this situation if a complication that has not been discussed actually does occur. Even patients who say that they trust their doctor and do not want to know what might go wrong should be told the basic details of the procedure to which they are consenting, and the most obviously material risks<sup>59</sup>. As always it is a matter of degree and of judgement. In such circumstances, documentation would be particularly advisable.

## DISCLOSURE, ANXIETY AND THE RETENTION OF INFORMATION

Many anaesthetists are fearful that providing detailed risk information just prior to surgery may increase anxiety and stress during an already emotional time. A recent survey<sup>60</sup> by the American Society of Regional Anesthesia and Pain Medicine examined the risk disclosure practices of 801 members. The risks of regional anaesthesia most commonly disclosed to patients were benign, while severe complications were far less commonly disclosed. However, there is evidence (including from studies in Australia) that patients appreciate and desire information prior to surgery and that this does not typically result in any measurable increase in preoperative anxiety. Patients under 50 years of age tend to want more information than those who are older<sup>54,55,61</sup>.

The pain of labour may make it more difficult to communicate successfully with a patient, but in a prospective survey, 60 labouring women indicated that they wanted all risks of epidural analgesia disclosed in the informed consent process, although they did not want the incidences quoted<sup>62</sup>. The survey's authors suggested that labouring patients are as able to give informed consent as any other patients. The recall of preoperative risk information is variable, in anaesthesia and also in other specialties<sup>63-65</sup>.

Ninety-five percent of a group of Chinese patients had satisfactory recall of information provided preoperatively at an interview on the day of surgery<sup>66</sup>. Similarly, in a recent Australian survey of 150 women presenting for elective or emergency caesarean section under regional anaesthesia, recall of preoperative information was generally satisfactory, with most women being able to recall at least four risks<sup>67</sup>. A survey of 40 primiparous labouring women following epidural insertion found that overall recall of information was poor, but was significantly better in patients who had attended antenatal epidural education classes<sup>68</sup>. The information and risks which are regarded by the patient as important (material risks) may change if they actually suffer a complication or in light of new information they may receive<sup>69</sup>.

Printed information has been shown to increase patient knowledge of anaesthesia without usually causing a significant change in patient anxiety<sup>69</sup>. Patients can read the information at their leisure, returning to ask questions later if they wish. Providing written information will not, however, necessarily be a defence to a claim, even if it includes diagrams and photographs. Printed information cannot be

substituted for a verbal explanation in which the patient is encouraged to ask questions and raise any concerns because this standardised approach may not take into account those risks to which the particular patient would be likely to attach significance.

## DOCUMENTING THE PROCESS OF INFORMED CONSENT

Although a signed consent form is not a legal requirement in Australia, it is important to document the process of providing information and obtaining consent from each patient. In New Zealand, the Code of Health and Disability Services Consumers' Rights stipulates that some procedures (including general anaesthesia) require written consent<sup>37</sup>. Patients must be competent when signing consent forms for any procedure, including anaesthesia.

Although the doctor's notes of the consultation may take any form, the format of the consent form is most often a matter of institutional policy. One possibility is a pro forma sheet, headed with the patient's name, the proposed procedure and the date, and a list of the relevant risks in simple terms, which anaesthetists could tick off as the risks are explained. If a patient has expressed concern about a particular issue, that could be highlighted with a note that the anaesthetist has discussed that issue in more detail. There could be a section to record the other anaesthetic options that have been explained (e.g. epidural versus patient controlled analgesia), that the patient was offered the opportunity to ask questions, to involve someone else in the decision making process, to delay the decision or to seek another opinion (if appropriate), and other relevant matters. The patient could then be asked to sign the form to indicate that the points have been covered.

Even if a patient has signed a form of this kind, his or her signature is, at most, prima facie evidence, although legible and contemporaneous documentation may improve the doctor's credibility. It would still be possible for a patient to challenge the assertion that the relevant information was in fact provided in an appropriate manner. A patient may, for example, prove that he or she does not speak English, or allege that he or she was not given an opportunity to read the form or answer questions. It makes no difference that the form was witnessed, as the role of a witness to a signature is merely to confirm that a document was signed in his or her presence; although a witness may testify that the doctor did, in fact, talk to the patient and offered the patient an opportunity to ask questions.

## INFORMED FINANCIAL CONSENT

Informed financial consent is the dialogue undertaken between a doctor or his/her representative and a patient so that the patient understands the potential fee for the medical procedure, the potential rebate for the services provided by the health system (Medicare or District Health Board) and/or the patient's private health insurer<sup>70,71</sup>. The provision of this information should ideally occur prior to admission to hospital; however, in some circumstances, it may take place during the pre-operative consultation and may distract patients from the medical issues. Because medical costs, insurance and government rebates can be complex and difficult to understand, informed financial consent is strongly promoted by the Australian Medical Association and Australian Society of Anaesthetists as a way of providing patients with a clear understanding of the likely anaesthesia and other medical fees prior to entering hospital.

## CULTURAL CONSIDERATIONS

Australia and New Zealand are multicultural societies that have diverse migrant populations and national, religious and cultural sub-groups. The principle of sensitivity in general to the range of norms and expectations that this implies is universally applicable. It may not be practical to expect doctors to have an intimate knowledge of every culture that they might come across, but it is reasonable to expect that they know something about the main cultures, including the cultures of Indigenous populations of the countries in which they practise. Such an understanding provides a framework of wide applicability and is likely to increase sensitivity to important issues in any culture.

In New Zealand, the rights of the Maori are enshrined in law through the Treaty of Waitangi<sup>72</sup>, the country's founding charter. This does not diminish the rights of others, but makes explicit the special situation of the Indigenous people. No equivalent provisions exist in Australia. In the Australian context, the recognition of the rights of Indigenous people has primarily occurred through the political and policy process.

A requirement to consult with Maori representatives is explicit in the process of obtaining institutional approval for research in New Zealand. In the broadest sense this may be seen as extending the conversation around obtaining consent for the proposed research at an early stage in its planning to members of the community well placed to provide

comment and advice. In practice, the thrust of the advice provided is usually to ensure inclusion and to promote awareness of matters important to Maori (notably ethnic disparities in health access and outcomes). In Australia a parallel development has occurred. In 2003, the National Health and Medical Research Council issued "Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research"<sup>73</sup>. The guidelines are framed by key values including reciprocity, respect, equality, survival and protection, responsibility, spirit and integrity. As is the case with Maori, these guidelines emphasise a dual approach to consent that includes community level processes. In the clinical context, extra sensitivity is needed in dealing with people from any culture different from the anaesthetist's own, and the principle that one should consider the expectations and anxieties of any particular patient with respect to communication and the process of informed consent applies. For example, traditional Maori culture places more emphasis on the family than the individual when making important decisions. In traditional Australian Aboriginal culture all internal community relationships are framed by reciprocal expectations of distinct types of kinship. On the other hand there is great variation between individuals in this matter, so as always there is no simple rule. The implication might be a need to provide the opportunity for patients to include family members in the discussions about anaesthesia, and time for the family to come to a collective decision.

As with any culture, there are certain practices that might offend Maori (for example, sitting on a patient's bed) and certain practices that are desirable (for example, asking patients if they want another person to be present) and for those working in New Zealand it is highly desirable to be informed in this regard. There is nothing particularly exceptional in this: the underlying concepts apply to any cultural group. For example, in some situations, it is culturally insensitive in the extreme to inform a patient of an impending fatal condition. The cultural way to deal with this is for the family or senior male relative to be informed but never the patient. In other cultures, the head is regarded as sacrosanct and patients will object to having their face touched. In such settings it is imperative that patients are provided with adequate information so they may consent to head manipulation, face-mask ventilation and intubation, for example.

Cultural sensitivity is a matter of placing oneself in the position of the patient and of seeking permission in relation to any aspect of

communication. Communication is a two-way process, and involves testing one's assumptions and (in this context) checking that one's patient is comfortable with the proceedings, as well as providing information. In Australia, many hospitals with significant numbers of Aboriginal patients will employ Aboriginal hospital liaison officers who can assist hospital staff in framing their communication and understanding the Aboriginal patients' needs and preferences.

The primary point of distinction between Australia and New Zealand is that, in New Zealand, the Treaty creates a particular onus in relation to Maori, which is not explicitly present in relation to other cultures, and which does not have its counterpart in Australia. Thus, New Zealand doctors may be obliged to accommodate the expectation of the extended family to be present for much of the time a Maori patient is in hospital, and for the extended family to participate in decision making. This may be helpful to many non-Maori patients who may also appreciate similar opportunities.

Many patients need the information about their anaesthetic to be translated into their own language. This applies to some Indigenous people in Australia. A recent census showed that approximately 12% of Indigenous Australians spoke an Indigenous language at home, although 83% of these were also proficient in English<sup>74</sup>. Health professionals should take reasonable steps to ensure that patients understand what is proposed.

#### IMPROVING THE PROCESS OF INFORMED CONSENT

It has been repeatedly shown that most patients place high importance on seeing an anaesthetist prior to surgery<sup>54-56</sup>. Preadmission anaesthesia clinics are one way of ensuring that this occurs in a timely and positive way, and of ensuring that the elements of informed consent may be met. As well as improving communication and the process of consent, pre-admission clinics have been shown to improve the flow of patients through theatre<sup>75</sup>, to decrease the number of cancellations just prior to surgery and to improve operating theatre efficiency<sup>76</sup>. Cancellation of patients on the day of surgery can be a deeply distressing and disruptive experience and economically wasteful for the healthcare system. Some cancellations may be avoided with timely preoperative assessment and optimisation of patients and anaesthesia pre-assessment clinics have been shown to be helpful in this regard.

#### CONCLUSION

Informed consent for anaesthesia is a complex process, which ideally should be driven by considerations of good practice rather than with the primary aim of avoiding litigation. The law does take account of the circumstances in which treatment is provided, but this is more likely to manifest through allowing some latitude in an emergency or in under-resourced situations than in accepting an argument that a busy private or public hospital can not provide adequate time and facilities for a process as fundamental as informed consent. The objective should be to have a conversation with one's patient in which explanations are given, risks explained, alternatives outlined, questions answered and advice provided. There should be enough time for the patient to reflect, consult with others if required and to come back with more questions. The conversation should not end with signing of a form but should continue as care continues, with new information being provided as events progress. For major surgery or patients who suffer complications of anaesthesia, the process may become quite protracted. Over time, mutual trust and rapport should grow, and the doctor-patient relationship should strengthen. This is an ideal which may seem impossible to achieve for many busy anaesthetists.

The hospital may be regarded as a complex system with many participants playing roles which at times have conflicting or competing priorities. Managing the process of informed consent in such an environment takes time, skill and sensitivity. The primary focus should be to adequately prepare patients for surgery and to ensure that they are sufficiently well informed to make the choices that best meet their own needs. The best medicolegal defence is good medical practice grounded in patient-centred care.

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