CHAPTER 10

Informed consent

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Informing and obtaining consent

Informed consent is more than getting a patient to sign a consent form. The consent form is merely the written acknowledgment of a process that provides the patient with sufficient information in order to make an informed decision about their treatment. It is a two way communication process between a doctor and patient which results in the patient feeling confident that they have enough information to agree to undergo a specific medical intervention. It is also more than a one off action. It is a process throughout all stages of treatment or procedure.

Informed consent to medical treatment has long been an ethical obligation, and more recently a legal requirement. It is a fundamental patient right. The process of obtaining informed consent acknowledges the independence of the patient and the fact that the interaction between the doctor and the patient is for the patient’s benefit.

In the modern world of medical practice much is known about the risks, benefits and costs of treatments. Most of these risks, benefits and costs have been quantified to the degree that meaningful information can be given to patients, enabling them to make an informed choice. However this informed choice can be made only to the level of comprehension and competence that the patient possesses. It is therefore necessary to be aware of this level of understanding in your patient. There can be no suggestion of coercion and the patient must make choices voluntarily. Patients will sometimes need time after the consultation to consider matters and possibly discuss these matters with family/whānau or others who are near to them before they can make a decision. Sometimes, after considering all of the information, patients can still be unsure about what to do. They may ask their doctor what he or she would do if he or she were the patient. It is reasonable in this circumstance to give an honest answer to this question.

In addition patients may waive the right to discuss the details of a treatment. You should record this decision. Sometimes patients maintain that they do not want a lot of detail about possible complications from the proposed treatment. In this situation, you must decide whether or not the patient has in fact received sufficient relevant information to make an informed choice. If not, then you may need to consider declining to perform the procedure under discussion. In such circumstances it is vital to seek collegial support or refer the patient to another doctor.

In some areas of medical practice, the concepts involved in treatment are complex and most patients will be able to grasp only some of the considerations surrounding the recommended treatment or procedure. In these areas of treatment or investigation, it is wise for the doctor to make a specific recommendation based on his or her experience. The final choice about whether to accept or reject such a recommendation is the patient’s.

In addition to discussing the risks and benefits of any proposed treatment, the patient has the right to know of alternative treatments and their risks and benefits. This does not mean that a doctor must know of every single possible alternative treatment, but they should know about a range of treatments that their colleagues would judge to be reasonably known by a doctor in their position. This includes informing the patient of treatment options that might be available outside of the publically funded health service.
Patients sometimes raise the possibility of a treatment that the doctor does not agree with or does not know about. This is especially true of "alternative therapies" (see chapter 24). In these circumstances the doctor should advise the patient of the evidence base for the respective treatments as far as they know them, and give the patient clear reasons why they recommend one treatment over another.

It is not necessary to have a signed consent form for every treatment; this would be impractical, for example, for every prescription written in general practice. However, the more invasive the procedure, or the more risks it involves, the more prudent it is to have the patient sign a consent form.

In the absence of a signed consent form, you should include an annotation in the patient record that the patient has consented to this treatment. You should do this in every case because it provides evidence that you engaged with the patient in an appropriate discussion. When an interpreter or other third party has been used to assist in obtaining the patient's consent you should note this in the patient record. Other than in extreme emergencies it is a requirement of the World Health Organisation Patient Safety Checklist to ensure a written and signed consent form is completed prior to any operative procedure. The checklist is likely to be introduced into all New Zealand hospitals.

If a treatment is part of research or is experimental, or the consumer will be under general anaesthetic, or there is significant risk of adverse effects to the consumer, then the consent must be in writing.

Doctors have a special duty of care when enrolling apparently healthy asymptomatic persons in screening programs. Particular attention must be paid to explaining the uncertainties and limitations of the screening and implications of false positive and false negative findings for their patient. This must be explained prior to obtaining consent.

Where medical trainees are involved in the treatment or care of a patient the patient should be informed about the extent of the involvement of the trainee and the trainee's experience. Consent should be obtained from the patient if the care or treatment is part of the trainee's education.

There are rare occasions when a doctor does not wish to discuss a particular treatment with a patient because that treatment conflicts with the values or beliefs of the doctor. An example of this might be termination of pregnancy. In this case the doctor must inform the patient of this conflict and refer the patient forthwith to a doctor who can discuss all the currently recommended and accepted treatment options.

When a proposed treatment is expensive or in any way innovative, particular care should be taken to ensure that the patient is aware of this.

In summary, there must be a discussion with your patient about the proposed treatment, during which the patient must be given the opportunity to ask questions and gain a better understanding, and you, (and not a delegated representative) should disclose and discuss with your patient:

- The diagnosis as far as it is known
- The nature and purpose of the proposed treatment or procedure
- The risks and benefits of the proposed treatment or procedure
• Alternatives to this treatment or procedure (regardless of their cost or availability in the New Zealand public health system)

• The risks and benefits of the alternative treatment or procedure as far as you know them; and

• The risks and benefits of not receiving or undergoing a treatment or procedure.

The patient has the right to:

• Consider the information given

• Ask for clarification and ask for time to consider the information

• Consult with family and others

• Give consent or decline to give consent

• Waive the right to discuss the details of treatment

• After having given consent, change his or her mind and withdraw the consent.

The standard for informed consent is that which a reasonable patient might expect rather than what a reasonable doctor might think (Rogers v Whitaker 1992), and failure to fulfil requirements may be considered as professional misconduct. All doctors must be familiar, and comply with, the Code of Health and Disability Services Consumers’ Rights.

The Code of Health and Disability Services Consumers’ Rights 1996

There are legal requirements for doctors to undertake the informed consent process prior to beginning treatment. The Code (see chapter 29) makes explicit reference to informed consent, especially in Rights 5, 6, and 7. It is important that every practitioner working in New Zealand is fully conversant with this Code. Among other things the Code makes it clear that the patient must be informed of any proposed research or teaching associated with their treatment, and whether such research requires and has received ethical approval. The Code says that the patient must also be informed about the estimated time in which a health service will be provided, the results of any tests, and the results of procedures. The patient has the right to know the identity and qualifications of the providers of the service, how to obtain an opinion from another provider, and the results of the research.

The Code is also explicit that health services can be provided to a patient, only if that patient has made an informed choice and given informed consent. General consent may be given by a patient in advance of the knowledge that any treatment will be necessary. This can be in the form of an advance directive and must be in writing and is covered by common law. Retention and or storage of body parts or bodily substances can be done only with the informed consent of the patient.

Many of the complaints made under the Code are essentially about the lack of proper communication between doctor and patient.
When informed consent is not necessary

There are rare occasions when it is not necessary to get informed consent and the health practitioner has immunity. Some of these occasions are covered by statutory provisions which take precedence over the Code. These situations are detailed in the Medical Council’s statement Information, choice of treatment and informed consent which can be found on its website, www.mcnz.org.nz. The well-known examples are under the Mental Health (Compulsory Treatment) Act 1992 (see chapter 9), and under the Health Act 1956—to prevent the spread of infectious disease. Other examples are the Alcoholism and Drug Addiction Act 1966, the Land Transport Act 1998, Criminal Investigations (Bodily Samples) Act 1995, Criminal Procedures (Medically Impaired Persons) Act sections 36 to 38 Care of Children Act 2004 and the Children, Young Persons and Their Families Act 1989 (see chapter 28). Right 7(4) of the Code specifies other circumstances when it is possible to proceed with treatment without consent. This section involves a patient’s competence, but remember that every patient must be presumed to be competent unless there are reasonable grounds for believing that they are not. The common circumstances where a patient is not competent are where they are a young child, where they are unconscious, or where they are suffering from dementia, or have an intellectual disability.

If in emergency, immediate action must be taken to preserve the life or health of a patient, then you can provide the key services without consent. Only those treatments that are necessary to preserve life or health should be done at this time. Any procedure that can reasonably be delayed should be delayed until an opportunity can be given for the patient to consent.

Occasionally, when a patient is unable or refuses to consent to treatment, a legal opinion should be sought with a view to seeking authority from the High Court.

Who can give consent on behalf of another?

The only individuals who are entitled to grant consent on behalf of a patient are legal guardians (welfare guardians under the Protection of Personal and Property Rights Act, or parents/guardians under the Care of Children Act 2004 or someone with enduring power of attorney). A spouse or next of kin cannot consent to or refuse medical treatment on behalf of an incompetent person unless they hold enduring power of attorney or are their welfare guardian. The individual with that authority can make all health care decisions, except they do not have the legal ability to refuse consent for lifesaving treatment or medical experimentation. Section 18(1)(c) of The Protection of Personal and Property Rights Act 1988 specifically forbids the person who has enduring power of attorney from refusing consent “to the administering … of any standard medical treatment or procedure intended to save [the patient’s] life or to prevent serious damage to that person’s health” (see chapter 28). It is important to ask someone who has enduring power of attorney, if they have powers in relation to property, or personal care, or both. Personal care is the applicable authority in regard to giving consent for health care.
Care of Children Act 2004

This Act came into force on 21 July 2005 and replaced the Guardianship Act 1968. It states that all persons over the age of 16 are regarded as adults for the purposes of determining competence to give informed consent. People under the age of 16 are not automatically prohibited from consenting to medical, surgical, or dental procedures so judgment is needed in each instance. This Act has changed the way a court order may be sought in cases where the parents or guardians refuse to consent to treatment for children in circumstances where the child's life is at risk.

It also covers how the consent of children should be obtained for medical procedures and the right of doctors to administer blood transfusions to children without consent in certain conditions (to save life being the principal condition). Section 38 of the Act addresses the issue of obtaining consent for abortion for children (a female of any age has the right to consent to or refuse to consent to any medical or surgical procedure for the purpose of terminating her pregnancy).

Ethical dilemmas

Doctors need to be aware of decisions made by the Courts. Decisions are made on a case by case basis and are circumstance dependent. While a particular medical act may be considered ethical in one situation in another situation a similar act can be unethical and illegal.

Not all the issues surrounding consent for the treatment of children have been settled and doctors will still face dilemmas. New Zealand has had three high profile cases since 2000 when parents withheld consent for medical treatment for their children under circumstances that resulted in all three children dying of their diseases. The way the police and the courts treated these cases was inconsistent and in the first of these cases, the lack of a police prosecution followed intense nationwide public support for the parent's decision to decline to accept conventional medical treatment. In the other two cases the parents were prosecuted. The courts imposed a suspended sentence on the parents in the second case, and sentenced the parents in the third case to 5 years in prison. It would appear, for the time being at least, that the ability to persuade the court will be the most significant factor in determining outcomes. Doctors should regard court orders against parents as an absolute last resort, and all other means to persuade parents should be exhausted first.

Professor Don Evans, director of Otago University’s Bioethics Centre has stated “There is a huge price to be paid for that last step. It pretty well destroys any collaboration for the future between parents and health carers”. If you are likely to find yourself in conflict with a child’s guardian about the treatment of serious life threatening conditions, you should read this legislation and seek advice from your medical protection insurer, lawyers, or employers. There are situations where doctors and caregivers may jointly seek a court order for consent, for example to terminate treatment to allow a patient to die peacefully, or sterilisation of a patient who is unable to consent but for whom the family and other carers, supported by medical opinion, request the operation to enhance the quality of life or to prevent deterioration in physical or mental health.
Current legal authority “consent” decisions

In *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402 (HL) it was held that “parental rights” did not exist other than to safeguard the best interests of a minor (under 16). In some circumstances a minor could consent to treatment, and that in those circumstances a parent had no power to veto treatment. The test is can the child fully understand the medical treatment proposed and give consent. This is referred to as “Gillick competency”. A child who is deemed “Gillick competent” is able to prevent parents viewing their medical records.

In *Rogers v Whitaker* (1992) 175 CLR 479 High Court Australia the decision affirmed that a doctor has a duty to warn a patient of any material risk involved in a proposed treatment. A risk is considered material if a reasonable person in similar circumstances would attach significance to the risk, or if the doctor is, or should be, cognizant that the particular patient would express concerns about the risk. This approach is similar to the standards which the Medical Council of New Zealand has set. The “mature minor” principle is considered and discussed by the Supreme Court of Canada in *Manitoba (Director of Child & Family Services) v C (A)*. 2009.

In *B v Medical Council of New Zealand* [2005] HC 3NZLR 810 the High Court stressed the importance of assessing the adequacy of information conveyed by a doctor to a patient from the viewpoint of the patient and warns that inadequate information will almost always be professional misconduct.

In conclusion, informed consent, long an ethical obligation, is in New Zealand a legal requirement. It is one of the cornerstones of good patient care, and recognises that the doctor patient relationship is for the benefit of the patient. Informed consent begins with the patient’s first appointment and continues until the procedure is completed. Not all issues in informed consent have simple solutions. It can be a matter of what is reasonable under the circumstances and the reasonableness is from the point of view of the patient rather than the doctor. It is advisable to consult with other doctors and professional advisers when you are uncertain. The Medical Council’s statement *Information, choice of treatment and informed consent* is a reliable primary source.

Resources

Disclosure of harm

Ian St George is a Wellington general practitioner and has been an elected member of the Medical Council, Chair of its Education Committee, and Chair of the International Physician Assessment Coalition (IPAC).

Poison is in everything, and no thing is without poison. It is the dosage that makes it either a poison or a remedy — Paracelsus.

Disclosure of harm is a subset of informed consent, so is dealt with here. We know now that Hippocrates’ “First do no harm” is not going to work all the time. Nearly all treatments carry the potential for harm, and all of us will do harm, so an honest doctor should talk openly about it — before (informed consent) and after (open disclosure).

Open disclosure is the discussion of incidents that result in harm from health care. The elements of open disclosure are:

• an apology or expression of regret
• a factual explanation of what happened
• an opportunity for the patient to relate their experience of the incident
• a discussion of the potential consequences of the adverse event
• an explanation of the steps being taken to manage the incident and prevent recurrence.

In New Zealand open disclosure is a right under the Code of Health and Disability Services Consumers’ Rights and is a requirement of the Health and Disability Service Standards.

Principles

The patient and their support people should be told about adverse events in a timely, open and honest manner. Further information should be provided as it emerges.

There should be an early apology or expression of regret for any harm that results from an adverse event. An apology or expression of regret should include the words “I am sorry” or “we are sorry”, but should not contain speculative statements, admission of liability or apportioning of blame. The patient and their support people should be fully informed of the facts surrounding an adverse event and its consequence, treated with empathy, respect and consideration and supported appropriately.

Staff should be encouraged to report adverse events, educated to participate in open disclosure and supported through the process. A staff member must not become a “second victim”.

Investigation of adverse events and harm should be conducted through good clinical governance covering risk management and systems improvement. The information obtained should be used in quality improvement.

Procedures should consider privacy and confidentiality for patients, support people and clinicians, fully, and in compliance with privacy law.
Resources
