

12 Informed consent

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Informed consent is more than getting a patient to sign a consent form. It is a two way communication process which results in the patient feeling confident that they have enough information to agree to undergo a specific medical intervention.

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, thus enabling them to make an informed choice. 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 and inform the patient that they may change their mind

In some areas of medical practice, the concepts involved in treatment are complex and most consumers 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 practitioner must know of every single possible alternative treatment, but she should know about a range of treatments that her colleagues would judge to be reasonably known by a doctor in her position. 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". In these circumstances the doctor should advise the patient of the

evidence base for the respective treatments as far as she knows them, and give the patient clear reasons why she recommends 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 major the procedure, and 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, it is necessary to 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. 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 your patient.

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 the currently recommended and accepted treatment options.

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 mind and withdraw the consent.

The law

There are legal requirements for doctors to undertake the informed consent process prior to beginning treatment. The Code of Health and Disability Services Consumers' Rights 1996 (see Chapter 23) 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 within which a health service will be provided, the results of any tests, and the results of procedures. He has the right to know the identity and qualifications of the provider(s) 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 consumer, only if that consumer 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.

When informed consent is not necessary

There are rare occasions when it is not necessary to get informed consent. Some of these occasions are covered by statutory provisions which take precedent over the Code. These situations are detailed in the publication *Legislative requirements about patient rights and consent* which can be found on the Medical Council web site, www.mcnz.org.nz. The well known examples are under the Mental Health Compulsory Treatment Act 1992, 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 and section 16 of the Children and Their Families Act 1989 (see chapter 4). Right 7 (4) of the Code specifies other circumstances when it is possible to proceed with treatment without consent. This section revolves around a patient's competence, but remember that every consumer 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.

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 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. 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.

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. It is expected that only those treatments that are necessary to preserve life or health will 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.

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 new 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 health practitioners 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

All the issues surrounding consent for the treatment of children have not been settled and doctors will still face dilemmas. New Zealand has had three high profile cases since the year 2000 where 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 new legislation and seek advice from the medical protection society, lawyers, or employers. There are situations where doctors and care givers 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.

In summary, 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. Not all issues in informed consent have simple solutions. Consult with other doctors and professional advisers when you are uncertain.

References

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