

Te Kaunihera Rata o Aotearoa

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# Informed Consent: Helping patients make informed decisions about their care

# Key points about informed consent

The patient has the right to make an informed choice about their care and, in most instances, must give permission to proceed with treatment.

That permission is called informed consent. It is an interactive process between the doctor, the patient and sometimes those close to the patient, such as their family or whānau.

As the doctor, it is your responsibility to ensure informed consent is obtained, and to communicate and work with your patient to help them make the best decision for themselves (Code of Health and Disability Services Consumers' Rights 1996).

The doctor undertaking the treatment is responsible for the overall informed consent process.

The patient has the right to refuse treatment and withdraw consent.

All patients are presumed competent to give informed consent unless established otherwise.

### About our statement on informed consent

### What is informed consent?

Every time treatment is provided, a doctor must have permission to provide that treatment. The process of obtaining that permission is called 'informed consent'. Without informed consent, the treatment may be unlawful. To help the patient decide whether they want a treatment, they first need to be given information, such as the risks and benefits of their treatment options.

In this statement, we use the words 'treat' and 'treatment' to refer not just to one-off or specific clinical encounters and procedures, but also to ongoing care.

### Who is this statement for?

This statement applies to all doctors, and sets out the standards of good medical practice when discussing options for treatment and obtaining consent from patients.

This statement may be helpful for patients and for other health practitioners who need to explain to patients what their rights to informed consent are and what they can expect from their doctors.

This statement may be used by the Medical Council, the Health Practitioners Disciplinary Tribunal and the Health and Disability Commissioner as a standard by which to measure your conduct as a doctor.

While we expect you to meet the standards set out in this statement, there are instances when you will need to use your judgement when applying this statement to the particular situations you face in your practice.

### The key principles of informed consent

- 1 Trust is essential in the doctor-patient relationship. One way to build trust is to provide information openly and honestly to your patient.
- 2 You must comply with the Code of Health and Disability Services Consumers' Rights (the Code), which sets out what patients can expect when they use a health or disability service in New Zealand. Keep in mind the following points:

#### There must be agreement before going ahead with treatment

a In most instances, treatment may only take place if the patient agrees to have the treatment. (See Right 7(1) of the Code.)

#### The patient must be able to make decisions about their care

b Start from the position that every patient can make their own decisions unless there are reasonable grounds to believe otherwise. Recognise that a patient's capacity to make decisions can fluctuate and is specific to each decision the patient makes. (See Rights 7(2) and 7(3) of the Code.)

#### Consent is an interactive process, not a one-off event

c Obtaining consent is a process of shared decision-making where you help the patient understand their medical condition and the options for treating (or not treating) that condition. It is more than signing forms and completing paperwork. Take the time to ask questions so that you understand what matters to your patient, and what their concerns, wishes, goals and values are. (See Right 1(3) of the Code.)

### How you can help your patient make informed decisions

### **Provide the information needed**

- 3 You must give your patient the information they need to help them make a fully-informed decision. Share information that is relevant to them, in a way they understand, and allow reasonable time for the patient to make their decision. Think about whether there is anything else you can do to make it easier for your patient to consider the different options and make a fully informed decision. Cover the options available including those that you may not be able to provide yourself.
- 4 Be open and honest with your patient, and answer their questions accurately.
- 5 Provide information to your patient, such as an explanation of their condition, the options available, and the results of tests and procedures. (See Right 6 of the Code which lists several things to tell your patient.)

### **Communicate effectively**

6 Effective communication is critical in the consent process. Establish what matters to your patient. Share information in a way that helps your patient understand what you are saying. This could include highlighting risks specific to your patient, and giving your patient pamphlets, brochures, or website links that provide more information about their condition. You may need to engage an interpreter if there are language barriers.<sup>1</sup> (See Right 5 of the Code on effective communication.)

If you use an interpreter during the consent process, you should document this in the patient's records, along with the interpreter's name and status (professional interpreter, family member etc). If possible, ask the interpreter to acknowledge in writing that they believe the patient understands the information provided about their care and treatment. See also the chapter about 'Working with interpreters' in *Cole's medical practice in New Zealand*.

### **Treat your patient with respect**

7 Treat your patient with respect. Being respectful includes taking into account your patient's cultural, religious, and social needs, and their values and beliefs. (See Right 1 of the Code on treating patients with respect.)

### Involve others when making decisions

- 8 It is good practice to check with your patient whether they would like to involve others close to them in the informed consent process.
- 9 Sometimes, you may not have all the information required and may need another doctor or health practitioner to provide input on your patient's care. In those situations, you should explain to your patient that you need more information, and work with your colleagues to provide quality care. (See Right 4(5) of the Code about co-operation among providers.)
- 10 Sometimes, your patient may have difficulty making decisions about their care. Where that happens, the doctor obtaining consent should, with the patient's permission, include those close to the patient (such as their family/whānau<sup>2</sup>) in discussions about the patient's care. You must confirm with your patient their final decision before going ahead with treatment.

## Factors to consider before going ahead with treatment

- 11 In most situations, treatment should only go ahead if:
  - a your patient has received all the information that is relevant to their decision, and
  - b you are sure that your patient understands that information and the consequences of their decision.

Questions to consider before going ahead with treatment:

- What is your patient's understanding of their condition and the outcome they are hoping to achieve?
- Have you (or another colleague) explained the different treatment options including the risks and benefits of each option, and the option of not treating (adopting a see what happens with time approach)?
- Have you given your patient relevant information that would influence how they would decide?
- If your patient is unsure about your advice or recommendations, are they aware that they can seek a second opinion?
- If a proposed treatment is new, experimental or lacks scientific evidence, have you explained this to your patient?
- Has your patient had enough time to ask questions and think about how they would like to proceed?
- Does your patient have additional needs (disability, language barriers, low health literacy) and need more support to make a decision?
- 12 If you are worried that your patient is making a decision that is not in their best interests, you should explain your concerns clearly to them and outline the possible consequences of their decision. Where possible, work with the patient (and those they are close to such as family members and whānau) to find a solution that works for the patient.

# **Documenting discussions during the consent process**

- 13 You must keep clear and accurate patient records that note:
  - a the information that was discussed
  - b any specific risks that were highlighted
  - c any request or concerns expressed
  - d any decisions made and the reasons for them.
  - <sup>2</sup> Whānau refers to the extended family and family group.

- 14 Not every aspect of a consultation can be noted in a patient's records. You must record enough information to provide an accurate summary of your discussion with your patient. Check that what you record is enough to guide another doctor or health practitioner if they need to follow up with your patient.
- 15 If you give pamphlets, brochures, or leaflets to your patient, you should note these resources in your patient's records. You should also note any exceptions (to those resources) that relate to your patient. If at a later date your patient requests a copy of their notes, you should include a copy of the resources you provided (where this is practical).

### When a patient declines information about treatment

16 If a patient tells you they do not want information about their treatment, you must record their decision in their notes. You should also explore with the patient why they are declining information about their treatment (including its risks and benefits), and record the patient's reasons in their notes. You should tell the patient that they can let you know if they change their mind, and to contact you in that event.

### When a patient lacks capacity to consent

- 17 You must have reasonable grounds for deciding that your patient lacks capacity to make decisions about their care.<sup>3</sup> When your patient lacks capacity to make their own decisions, you should contact someone who has the legal right to make decisions on the patient's behalf (for example, a legal guardian or someone who holds a current enduring power of attorney for personal care and welfare) for their input on the patient's care.
- 18 If your patient lacks capacity to make their own decisions and there is no one to make decisions on their behalf, you may go ahead with treatment when:
  - a that treatment is in the patient's best interests; and
  - b reasonable steps have been taken to find out what matters to the patient; and
  - c you believe that the treatment is what the patient would have wanted if they were able to decide for themselves; or
  - d you have taken into account the input of others who have an interest in your patient's welfare if you have not been able to find out what your patient's views are.

(See Right 7(4) for more information.)

19 Before going ahead with treatment, you may want to discuss your decision with an appropriate colleague. You should document in your patient's records, the reasons for going ahead with the treatment, and the input you received from those you contacted about your patient.

### Situations when immediate life-saving treatment may be needed

20 Sometimes, a patient may require immediate life-saving treatment because they are acutely unwell. In those time-critical situations, it may not be practical or possible to establish the patient's wishes or to communicate with the patient or their family/whānau before going ahead with treatment. You should take into account what is good practice, and what is in the patient's best interests. You should also document the treatment you provide and discuss it with the patient (and their family/ whānau) at the earliest opportunity.

# Your responsibilities

21 The doctor undertaking the treatment or procedure is responsible for the overall informed consent process. If you are the doctor treating the patient, you need to check that the patient is clear about their decision to have treatment before you go ahead with it.

<sup>3</sup> See also the chapter about 'Mental capacity' in *Cole's Medical Practice in New Zealand*, which discusses capacity assessments carried out to decide whether a person can make certain decisions.

22 In some situations, the doctor who obtains consent from the patient may not be the doctor who treats the patient. A doctor should only manage aspects of the informed consent process for which they have sufficient knowledge. It is not necessary that they are competent to perform that procedure.

### Delegating the patient's care to another doctor or health practitioner

- 23 Sometimes, it could be practical to delegate a patient's care to another doctor or health practitioner. When deciding whether to delegate, you should consider:
  - a the nature of the treatment or intervention, and how any risks and complications will be managed
  - b your relationship with your patient, and how your patient would feel about having treatment with another doctor or health practitioner
  - c whether your patient or anyone else involved in the decision to delegate has been given enough information and time to think it over and to express their views.
- 24 You should also consider whether the person you delegate to:
  - a has the right skills and experience to treat your patient
  - b understands the risks and benefits of the treatment they are providing
  - c understands the patient's needs and their clinical history
  - d recognises that, in some situations, they should contact you or a senior colleague for advice
  - e is clear about which doctor or health practitioner is responsible for obtaining consent from the patient and for checking that the patient is clear about their decision.

### Managing time pressures during the informed consent process

- 25 Managing competing demands is a reality for many doctors. However, time pressures do not remove your obligation to share information with your patient and to support them in making decisions about their care.
- 26 One way of managing time pressures is to consider:
  - a whether other doctors or health practitioners could play a part in explaining information and answering questions before or after you see your patient.
  - b what other sources of information and support are available that you could refer your patient to.

### Special circumstances you may encounter

### When your patient is a child or adolescent

- 27 The Code does not specify any minimum age for consent. It assumes that a patient is able to make their own decisions about their care and treatment unless there are reasonable grounds to think otherwise.
- 28 Legally, someone who is 16 years of age or older who consents or refuses consent to treatment is viewed as though they were an adult (of full age).<sup>4</sup> Someone under 16 is allowed to make their own decisions about their care. But whether they will be viewed as though they were an adult would depend on how mature they are to make their own decisions.
- 29 Generally, if a child or adolescent is able to understand what treatment or procedure they are having and why, along with what would happen if they did not have that treatment or procedure, then they are able to decide for themselves.
- 30 A female of any age has the right to accept or refuse any medical or surgical procedure related to ending her pregnancy.
  - <sup>4</sup> Care of Children Act 2004, section 36. See also section 4 of the Age of Majority Act 1970 that states that a person reaches full age when they turn 20.

### When care is provided in a teaching environment

31 You must have a patient's permission in advance if students or observers attend the consultation or participate in the patient's care. Pay particular attention when sensitive issues are discussed. You must obtain explicit consent for any intimate examination.

Explain to the patient:

- a the status and clinical experience of those attending
- b the role and involvement of those attending (such as whether they will be observing, or participating in the care by taking a clinical history or examining the patient)
- c what is expected of those attending
- d that at any point in time, they have the right to refuse the involvement of those attending.

#### When a patient is anaesthetised

- 32 Sometimes, a patient under anaesthesia needs more investigation or treatment than they have consented to. You must use good clinical judgement and act in your patient's best interests. Sometimes, the treatment may need to be deferred.
- 33 If the situation is urgent, you should proceed on that basis, and discuss with your patient at the earliest opportunity.<sup>5</sup> You should consider discussing with a peer, a clinical head, or your Chief Medical Officer any unexpected findings you come across during the course of treatment. You should document these discussions.

### When a patient participates in research

- 34 Before inviting a patient to participate in research, the research must first be approved by an accredited ethics committee. A patient must provide written informed consent before they participate in research (see Rights 6(1)(d) and 7(6)(a) of the Code). If any part of the research changes after the patient gives their consent, you must disclose this to the patient so that they can decide whether they still want to be involved.
- 35 If the treatment is part of research, the investigating and the treating doctors are responsible for taking all reasonable steps to help the patient understand the full implications of the treatment, especially the risks and uncertainties involved.
- 36 Patients may withdraw their consent to participate in research at any time.

#### When body parts or bodily substances are taken from a patient

- 37 A patient has the right to decide whether they want any body parts or bodily substances taken from them during a procedure to be returned or disposed of (see Right 7(9) of the Code). You should be guided by your patient's wishes.
- 38 Body parts or bodily substances removed or taken during a procedure or after death may only be stored, preserved, or used if:
  - a the patient consents; or
  - b the parts or substances are for research that an ethics committee has approved; or
  - c the parts or substances are for a professionally recognised quality assurance programme; an external audit of services; or an external evaluation of services (see Right 7(10) of the Code).

<sup>5</sup> See also the section on 'Unexpected events' in the chapter on 'Informed consent' in Cole's Medical Practice in New Zealand.

### When a patient is enrolled in an immunisation or screening programme

- 39 You have a special duty of care when enrolling patients into immunisation or screening programmes. This includes making the person aware of any limitations of a screening programme and the uncertainties, in particular the chance of false positive and false negative results. Before obtaining consent you should explain, or give information to the patient that explains:
  - a the purpose of the screening or immunisation
  - b the risks and uncertainties
  - c any significant medical, social or financial implications for immunising against, or screening for that condition, and any follow-up provided, such as counselling and support services.

### When you seek a declaration or Court order because there is disagreement about treatment

- 40 When the patient declines consent or lacks capacity to decide for themselves, this can sometimes cause disagreement between the doctor and patient (or their family/whānau). If that happens, you should ensure that your patient and their family/whānau are given the time, information and support they need to work through their concerns. You should also seek advice from your peers, senior colleagues, your organisation's legal adviser, or an ethics committee.
- 41 Where the disagreement between the different parties is likely to affect the patient negatively, you may need to seek (urgent) approval from the High Court. You may need to seek legal advice on the process for obtaining approval from the Court. Examples include:
  - a a blood transfusion or caesarean section to save life
  - b stopping treatment to allow the patient to die (for example, a patient in a persistent vegetative state)
  - c sterilisation of a patient who does not have the capacity to consent but for whom the family and other carers, supported by medical opinion, request the procedure to improve the patient's quality of life or to prevent the patient's physical or mental health from worsening
  - d a dispute between parents based on their views or religious beliefs about the treatment for their child.

### If you need more advice

If you are unsure about any aspect of this statement, please contact us at the Medical Council. You may find it helpful to seek advice from a trusted colleague, your medical indemnity insurer, or your professional college or association.

## **Related resources that may be helpful**

### **Medical Council of New Zealand**

- Good Medical Practice
- Cole's Medical Practice in New Zealand
- Managing patient records
- Disclosure of harm following an adverse event
- Safe practice in an environment of resource limitation
- Doctors and CAM (complementary and alternative medicine)
- Cosmetic procedures
- Advertising
- Telehealth
- When another person is present during the consultation

### Office of the Health and Disability Commissioner (HDC)

Code of Health and Disability Services Consumers' Rights

The HDC has issued several decisions on informed consent. These are available on https://www.hdc.org.nz/decisions/

### **Other organisations**

*Clinical images and the use of personal mobile devices: A guide for medical students and doctors* (This is a joint publication by the New Zealand Medical Association and New Zealand Private Surgical Hospitals Association Inc.)

### Legislation

Several laws set out requirements about rights and consent, and are available on http://www.legislation.govt.nz/

This statement was updated in September 2019. It replaces the March 2011 statement on *Information, choice of treatment and informed consent*. It is scheduled for review in September 2024. Any changes to the law before that review may make parts of this statement obsolete.