

Informed Consent Practice Standard

December 2006

Dental Council
Te Kaunihera Tiaki Niho

Primarily based on the NZDA Code of Practice: Informed Consent

Note: In this document, unless otherwise specified, the term *patient* is used to include both *the person competent to give informed consent* and *any responsible parent/guardian (of a child) or representative (of a non-competent older patient)*.

INTRODUCTION

The oral health practitioner has an ethical and statutory responsibility to communicate effectively and take reasonable steps to ensure that the patient is given all the information necessary to make an informed choice.

The concept of informed consent is embodied in New Zealand consumer law, particularly the HDC Code of Health and Disability Services Consumers' Rights, 1996 (the "HDC Code"). The HDC Code sets out both the rights of consumers (eg, patients), and the duties of providers (eg, oral health professionals) to inform consumers of their rights and enable them to exercise their rights.

Three Rights in particular address the process of informed consent: Right 5 (The right to effective communication), Right 6 (The right to be fully informed), and Right 7 (The right to make an informed choice and give informed consent). However, these Rights must be viewed within the framework of the HDC Code's other Rights, which support the relationship between the patient and the provider. These are:

Right 1 – the right to be treated with respect;

Right 2 – the right to freedom from discrimination, coercion, harassment and exploitation;

Right 3 – the right to dignity and independence;

Right 4 – the right to services of an appropriate standard;

Right 8 – the right to support;

Right 9 – rights in respect of teaching or research; and

Right 10 – the right to complain.

While this practice standard seeks to clarify the process of informed consent, professional judgement and the quality of the provider / patient relationship play a part in this process.

The patient who has received sufficient information on treatment proposals may, on the basis of this, give "informed consent" to what the oral health professional has proposed. The process must involve effective communication (Right 5), and the information provided will be broader than the right to information on treatment proposals alone (Right 6).

Some treatments need more information, detailed and written, than others, which are routine and regular, and may require only verbal discussions and explanation.

Practices or organisations may produce their own forms for recording Informed Consent. Oral health professionals must use common sense when using such forms and deciding whether the form is adequate. Informed consent is the outcome of a process, and not just the signing of a form

CRITERIA FOR THE INFORMED CONSENT PROCESS

- 1 Effective communication (Right 5)
- 2 Provision of information (Right 6)
- 3 Making an informed choice and giving informed consent (Right 7)

“Consenting” then means “giving someone the permission to do something they would not have the right to do without such permission”. The patient must indicate that approval for the particular procedure(s) has been given, or declined.

DEFINITIONS

1 Information

Right 6 of the HDC Code gives every consumer the right to the information that a reasonable consumer, in that person’s circumstances, would expect to receive, in order to make an informed choice or give informed consent.

This includes, but is not limited to:

- An explanation of the patient’s existing condition;
- An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option;
- Advice of timeframes for providing the treatment;
- Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval;
- Any other information required by legal, professional, ethical, and other relevant standards;
- The results of tests; and
- The results of procedures.

In addition, consumers are entitled to honest and accurate answers to any questions about services, including the identity and qualifications of the provider, the recommendation of the provider, how to obtain a second opinion from another provider, and the results of relevant research. If requested, a written summary of the information must be provided.

2 Effective Communication

Right 5 of the HDC Code entitles every consumer to effective communication in a form, language and manner that enables the consumer to understand the information provided, and for this to take place in an environment that enables open, honest, and effective communication. The involvement of family, whanau or other support persons may often help with understanding (Right 8). Where necessary and reasonably practicable, consumers have the right to a competent interpreter.

3 Competence to give consent

Every consumer must be presumed competent to make an informed choice, or give informed consent, unless there are reasonable grounds for believing that the consumer is not competent (Right 7 [2]). The patient’s age can be a relevant factor to take into account when determining competence, but there are several other factors that must also be considered.

These include the person’s level of understanding and maturity, and the seriousness of the procedure. It is important that the provider determines whether the particular individual, regardless of their age, has the capacity to consent to the particular form of treatment proposed.

Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent to the extent appropriate to his/her level of competence (Right 7 [2]).

3.1 Determining competence

In any communication regarding Informed Consent, the oral health professional should try to validate a patient's comprehension, for instance by asking the patient to describe what has been said, in his or her own words. If the patient demonstrates confusion, an inability to reason, or behaviour inconsistent with past behaviour, the oral health professional must consult with an individual who is legally entitled to consent on the patient's behalf. If a person who is legally entitled to consent on behalf of the non-competent consumer is available, consent to treatment should be obtained from that person. Persons who may legally consent on behalf of a consumer include a legal guardian (parent/guardian under the Guardianship Act, or a welfare guardian appointed under the Protection of Personal and Property Rights Act), or a person with an enduring power of attorney for the consumer's personal care and welfare.

This person is not always obvious or easy to contact. In this situation, a provider must go through the process of Right 7 [4] before providing treatment to that patient. This clearly sets out the steps that are applicable where no person entitled to consent on behalf of the non-competent consumer is available, and allow the provider to provide services where:

- 1 It is in the best interests of the consumer; and
- 2 Reasonable steps have been taken to ascertain the views of the consumer; and
- 3 Where either:
 - The consumer's views have been ascertained, and having regard to those views the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
 - The consumer's views have *not* been ascertained, but the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

4 Consent

Consent given by a parent or guardian for the treatment of a child or an impaired adult does not necessarily imply assent to treatment by the patient. Should there be any doubts about consent, care must be exercised in proceeding. The consumer must still be provided with information appropriate to his/her level of ability to understand, and retains the right to make informed choices and give informed consent to the extent appropriate to their level of competence.

5 Voluntary consent

The consumer must be able to give consent freely, without being subject to discrimination, coercion, harassment or exploitation (Right 2). The consumer has the right to refuse services (including the use of particular materials or special tests), and to withdraw consent that has already been given, without prejudice. The consumer is also entitled to express a preference as to who will provide services and have that preference met where practicable (Right 7 [7] and [8]).

Right 7 [9] also states that the consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure. This may be of significance, for example, with regard to extracted teeth.

6 Referral (Right 4)

Where treatment is outside an oral health professional's scope of practice or experience, the practitioner is required to inform the patient fully and frankly of this, and of the significance that referral for care to an appropriately-qualified provider may have for his or her treatment, along with the availability of such referral services. When a referral of this nature is considered appropriate, but is declined by the patient, this should be noted in the patient's records.

ORAL AND WRITTEN CONSENT

Informed consent to a health care procedure must be in writing (Right 7 [6]) if –

- (i) The consumer is to participate in any research; or
- (ii) The procedure is experimental; or
- (iii) The consumer will be under general anaesthetic; or
- (iv) There is a significant risk of adverse effects on the consumer.

A signed consent form can be regarded as evidence that the person has made an informed decision only where it can be shown that the decision is the outcome of discussion about the proposed procedure. It is therefore important for the oral health professional to keep accurate contemporaneous written records of the discussion that has taken place prior to the provision of treatment.

Where the person giving consent is conscious and does not object, oral consent is sufficient for minor procedures, but it is prudent to note this in the patient's record. If the oral health professional is in any doubt about whether a procedure is major or minor, written consent should be obtained.

In all situations, careful, clear, written records should be kept.

TREATMENT FEES AND COSTS

If any costs (fees) are involved in providing dental treatment, prior to providing treatment, the oral health professional should ensure, via the informed consent process, that the consumer has been informed that fees are involved (Right 6 [1(b)]).

It is unwise for an oral health professional to prejudge a patient's ability to afford a particular treatment, or the value that a patient puts on any treatment.