Informed Consent

Purpose

To ensure CDHB and WCDHB follow an approach to informed consent which:

- is patient-centred and supports people to make an informed and voluntary choice about their care; and
- complies with relevant legal, ethical and professional standards regarding informed consent.

Policy

Informed consent is part of all clinical service and must be obtained from a patient before any treatment is provided, except where:

- specific legislation allows the treatment to be provided without consent;
- the common law allows services to be provided without consent (for example, in an emergency); or
- the patient is incompetent.

The informed consent process involves four elements including:

- checking to ensure the person is **competent** to make the decision to undergo or refuse the proposed treatment;
- effective communication;
- providing the person with **sufficient information** to enable to them to make an informed decision about the proposed treatment; and
- the person giving consent **voluntarily.**

Informed consent is not the act of filling out a form, but rather a process of exchange of information so that an informed decision can be made by that person.

Competence

Every person is presumed competent unless there are reasonable grounds for believing that the person is not competent.

The person must be capable of understanding the essential nature of their condition along with the treatment proposed, its intended benefits, risks and possible side effects.

A competent person has the right to refuse treatment or services, even if it is not in their best interests, results in significant harm, or even death.

Medication, intellectual disability, mental illness, the influence of alcohol or other substances or physical injuries all may affect the informed consent process, and may amount to reasonable grounds for believing the person is not competent. In each case reasoning outlining why the person is not considered competent must be documented.

A decision which seems unwise to others is not reasonable grounds for believing the person is incompetent.

Information about Capacity, and assessing Capacity, can be found on Hospital HealthPathways under *'Legal and Ethical'.*

Treatment of an incompetent person

Except in case of emergency, if the patient is rendered temporarily incompetent, the planned health care procedure should be delayed until the patient is able to provide informed consent. See pages 5 and 6 regarding treatment of an incompetent patient.

Competence and children

The health professional must assess competence of a child as with an adult. Capacity includes the ability to understand and to make a decision in relation to the particular treatment. The assessment and the child's decision must be documented in the clinical notes.

Children 16 years and over: Under the Care of Children Act 2004, a child who is 16 years or over, or is or has been married, in a civil union, or living in a de facto relationship can consent, assuming he or she is competent, to any medical procedure (including blood donation and surgical and dental procedures). Consent to medical treatment and procedures expressly includes the right to refuse consent.

Children under 16 years: It is generally agreed that children under 16 years of age can consent to their own treatment if they are competent to make a decision about the particular treatment.

Incompetent children: If a child is incompetent to make an informed choice and give informed consent, services may be provided:

- With the consent of the child's legal representative; or
- In an emergency, to save the child's life or prevent serious risk to his or her health;
- Without consent, provided the treatment is in the child's best interests and the requirements set out in Right 7 (4) of the Code have been satisfied.

Effective communication

Information is to be provided in a form, language and manner that enables the person to understand the information provided to them. Where necessary and reasonably practicable, this must involve arranging for an independent interpreter to be present in person or by phone. Interpretation by family members or other personal support persons should not be relied upon. This is because the lack of independence creates an inherent risk to the accurate exchange of information.

The Booking and Requesting Interpreters procedure gives information on the limited circumstances when family, friends and untrained staff members can interpret.

The environment must be one in which the person and the provider of the health and disability services feels that they are able to communicate openly, honestly, and effectively.

Sufficient information

Every person has the right to information that a reasonable person, in that person's circumstances, would expect to receive, including:

- An explanation of their condition;
- An explanation of the options available, including an assessment of the expected risks, side effects, benefits and cost of each option (including no treatment);
- The estimated duration for the service
- The possibility of additional treatments or procedures that can be anticipated,
- 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.

Other relevant information may include private treatment options, the option of a second opinion, implications of existing advance directives, issues related to the use of blood products, issues related to body parts, precautions following the procedure, recovery and planned follow-up.

In many situations, a patient would expect to be informed of which clinician will be performing or leading their treatment. For example, in some cases a patient will consent to a procedure at a pre-admission clinic but enter a pooled waiting list for a theatre booking with the next available surgeon. In this situation, the patient should be informed of the process for allocating theatre bookings and advised who their surgeon will be prior to their procedure.

The discussion should include an opportunity for the individual to ask questions and have their questions answered.

The discussion must take place with a person who is suitably qualified and experienced and has sufficient knowledge of the individual's condition and the proposed services.

Voluntary choice

The individual must be allowed to make a decision (either to accept or decline healthcare services) freely, without any form of coercion or constraint.

Documentation of consent

Consent (oral or written), must always be recorded in the patient's clinical notes. If written consent is required, it must be obtained using one of the forms associated with this policy or another form which has been approved as an exception by the legal team and the Chief Medical Officer.

Written consent

Consent must be obtained in writing if:

- General anaesthetic or conscious sedation is to be used;
- There is a significant risk of adverse effects;

- The patient is to participate in any research;
- The procedure is experimental.

Recordings and imaging

Where recordings and imaging are made as part of patient treatment or management, informed consent is required.

These recordings and imaging may only be used for education and research purposes if appropriate consent is given *(see Agreement to Clinical Imaging form).*

Refusal or withdrawal of consent

Every competent patient has the right to refuse service and withdraw consent for service for any reason (including religious beliefs).

- This decision must be respected (noting the few exceptions regarding decisions on behalf of children and incompetent persons).
- The person should be informed of the implications their refusal may have on their clinical outcome.
- The best standard of care and support possible in the circumstances is to be offered to that patient.
- No undue influence or pressure is to be brought to bear on that patient.

Appropriate members of the clinical team must be informed of the decision.

The following should be documented in the patient's clinical notes;

- A full account of what happened (including date and time);
- What the patient was told, his or her response;
- Whether any relatives or witnesses were present;
- An assessment of the patient's competence.

It may sometimes be appropriate, if the risks are unusually high, to ask the patient to provide a written acknowledgment of their refusal and their acceptance of the risks involved. This record is not to be framed as a waiver of responsibility or liability by CDHB or WCDHB. CDHB and WCDHB remain responsible for the quality of care we provide and our actions.

When this decision is made by one or more people on behalf of a child or incompetent person, there may be provision for the decision to be legally challenged. For example, a person holding an enduring power of attorney for an incompetent adult cannot refuse treatment intended to save the person's life or prevent serious damage to their health. When situations such as this occur, advice should be sought from the Clinical Director / Corporate / Legal.

How long is the consent valid for?

The validity of consent is variable. If any of the following situations are fulfilled the patient's consent should be considered invalid and retaken:

- The nature of the procedure changes

- There is progression of the condition
- Change in the health status of the individual (prognosis)
- Change in the individual's competence
- Change in the expected outcome or side effects
- Change in treatment options
- Elapse of more than 3 months between consent and the beginning of the treatment.

Advance directives

Every person has the right to use an advance directive under Right 7 (5) of the Code of Rights.

An advance directive is made by the person, while they are competent, about a possible future health care service that is intended to be used only when the person is incompetent. An advance directive can be made orally or in writing but for clear communication and evidentiary purposes a written advance directive is preferred.

A valid advance directive is binding on health professionals and should be followed unless there are reasonable grounds for believing it is not valid.

An advance directive is valid when the person:

- Was competent;
- Anticipated and intended his or her decision to apply to the prevailing circumstances;
- Had been sufficiently informed to make the decision; and
- Reached their decision without undue influence or coercion.

Persons legally entitled to give consent on a person's behalf

A welfare guardian or an Enduring Power of Attorney (EPOA) for personal care and welfare can consent on behalf of an incompetent adult.

- They cannot refuse treatment intended to save a person's life or prevent serious damage to a person's health.
- An EPOA is activated when a health practitioner has certified that the patient is mentally incapable. This "activation" must occur before an attorney can act in respect of a "significant matter".
- An EPOA for property cannot consent to personal care or treatment decisions.

A person cannot consent on behalf of an incompetent adult simply because they are that person's next of kin, a member of their family or a close friend.

Treatment without consent under Right 7(4)

Where a person is not competent to make an informed choice and give informed consent, and no person who is legally entitled to consent on the patient's behalf is available (and it may not be an emergency), right 7(4) allows a health professional to administer treatment without consent where:

- It is in the best interests of the person;
- Reasonable steps have been taken to ascertain the views of the person; and

Either:

a) If the person's views have been ascertained, and having regard to those views, the health professional believes, on reasonable grounds, that the provision of services is consistent with the informed choice the patient would make if he or she were competent; or

b) If the patient's views have not been ascertained, the health professional takes into account the views of other suitable persons who are interested in the welfare of the patient and available to advise the health professional. The suitable persons are not being asked to give informed consent. Rather it is a matter of taking their views into account in deciding whether the proposed treatment is in the patient's best interests and the patient would have consented.

Treatment without consent where permitted by legislation

Some specific legislation overrides an individual's right to refuse treatment. This includes:

- *The Mental Health (Compulsory Assessment and Treatment)* Act 1992, where statutory criteria are met for treatment of mental disorder.
- *The Substance Addiction (Compulsory Assessment and Treatment)* Act 2017, where a court has ordered detention for the treatment of alcohol or drug dependence.
- *The Health Act 1956* provides for compulsory treatment in specified circumstances, e.g. some Infectious Diseases.

Students and teaching

Informed consent must be gained for the presence or involvement of students or other staff who do not have a direct role in the treatment team during the health care procedure. The reasons for the presence or involvement must be explained to the patient.

The clinician is expected to exclude any students during the discussion to allow the patient to make a decision without undue pressure (real or perceived).

Additional treatments or procedures

If an unexpected event occurs and the person has not given their prior informed consent to any additional treatments, no further treatment can be undertaken without first pausing to obtain consent, unless those treatments are required in an emergency situation or immediately for the preservation of life.

Applicability

Applies to all CDHB or WCDHB staff (permanent or casual/temporary), including contractors, visiting health professionals and students working in any CDHB or WCDHB facility and to all organisations providing services and treatment on behalf of CDHB or WCDHB.

Roles and Responsibilities

Obtaining consent

The registered health professional who is responsible for the service/treatment being proposed has duty of care to enable an informed choice to be made about that treatment before any treatment begins.

This responsibility may be delegated provided that delegated person is suitably qualified and experienced and has sufficient knowledge of the individual's circumstances, condition and the proposed service/treatment.

Legal advice

The legal team is responsible for advising on informed consent when requested.

The legal team will oversee legal obligations and potential concerns and complaints relating to consent for CDHB and WCDHB.

Training

Education on informed consent is professionally and clinically based. CDHB and WCDHB's informed consent processes and divisional practice will be included as part of clinical staff induction and ongoing training within their department as required.

Governance

Divisional quality teams monitor informed consent processes through customer feedback and regular reporting processes, escalating concerns to clinical governance committees when necessary.

Clinical governance committees will ensure that compliance with this policy is monitored. The focus of monitoring is to verify that the:

- Informed consent process occurs.
- A written consent is obtained when appropriate.
- Consent and the discussions between the health professional and person are recorded in the clinical notes.

Policy measurement

Incidents and complaints relating to poor compliance with the policy are reported using the Incident Management Reporting System.

Patient experience feedback will provide data about informed consent.

Area or topic specific audit will occur as per local audit schedules.

Associated material (inclusive)

Related documents

- Agreement to Treatment form
- Request for Treatment form
- Treatment without consent form
- Agreement to Clinical Imaging Form
- General photography/ Video Filming consent
- Electronic Interpreter Booking form
- Interpreter Services Patient Information

Legislation and standards

- Code of Health and Disability Services Consumers' Rights 1996 Rights 5, 6 and 7.
- Health and Disability Services Standard 2008: 1.10
- Medical Council of New Zealand Statement on information, choice of treatment and informed consent, March 2011

Contents