Chinese Medicine Council of New Zealand

Informed consent guidance

Purpose

The purpose of the informed consent practice standard is to set minimum standards for the process of obtaining informed consent in Chinese medicine (CM) practice. This guidance document supplements and expands on the Standard and should be read in conjunction with the Standard and the Chinese Medicine Council of New Zealand's (The Council) Standards of Professional Conduct, Clinical and Cultural Competencies and other relevant standards and policies.

The standards set by the Council are minimum standards which are used by the Council, the public of New Zealand, competence review committees, professional conduct committees, the Health and Disability Commissioner (HDC), the Health Practitioners Disciplinary Tribunal, and the courts to measure the competence, performance, and conduct of practitioners.

These standards may also be helpful for tangata whai ora (person/s seeking health) and other health practitioners who need to explain what their rights to informed consent are, and what they can expect from their CM practitioner. A failure to meet the Council's standards and adhere to the principles contained within could result in Council involvement and may impact on the practitioner's practice.

CM practitioners are legally and ethically obliged to obtain informed consent before providing care. These obligations are set out in the Health and Disability Commissioner Code of Health and Disability Consumers' Rights Regulation 1996 (HDC Code of Rights), the Council's standards framework, and the Council's informed consent standard. The HDC Code of Rights provides that every consumer has the right to effective communication; the right to be fully informed; and the right to make an informed choice.

Defining and understanding informed consent

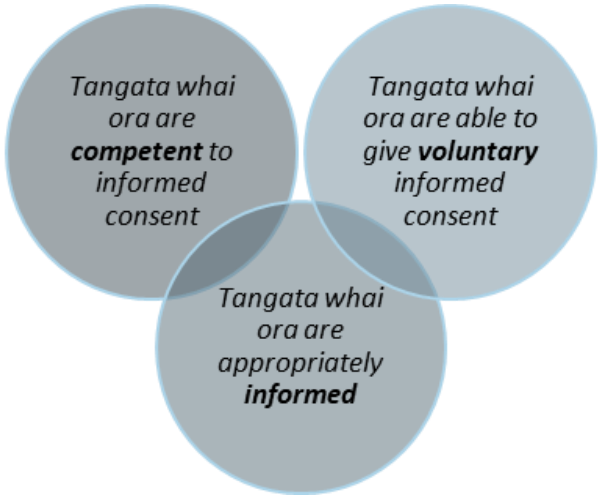

Figure 1 Legally valid informed consent consists of three key components.

Informed consent is a person's voluntary decision about healthcare that they make with knowledge and understanding of all the relevant information, including the risks, benefits, and costs of their treatment options.

It is the responsibility of a CM Practitioner to ensure that informed consent is obtained, and to communicate with, and work with tangata whai ora to ensure they have sufficient information to make

an informed decision. Without informed consent being provided, the CM treatment provided may be unlawful.

Informed consent is an integral part of CM consultations. Therefore, it is important that CM practitioners always follow these guidelines. The guidelines cover the concept of informed consent as a dynamic, continuous two-way process which must be documented. Obtaining informed consent is a process of shared decision-making where the practitioner ensures that tangata whai ora understand their condition and the options for treating (or not treating) that condition. It is more than signing forms and completing paperwork.

Informed consent Practice Guidance

Effective communication

Tangata whai ora are entitled to effective communication in a form, language and manner that enables them to understand the information provided. Effective communication covers everything from informed consent, active listening, written notes, appropriate communications with other service providers etc. Effective communication also includes the use of appropriate language and detail, use of appropriate verbal and non-verbal cues and confirming that the tangata whai ora has understood.

Effective communication means the ability to adapt to the situation and context, and with those people who are communicating with each other. It is good practice to check with the tangata whai ora whether they would like to involve whānau, family, or other support persons in the informed consent process. Encourage tangata whai ora to ask questions and give them the opportunity to discuss with you the various options for care, and their preferences and concerns.

Always give tangata whai ora the time they need to consider the information you have given them, and your discussions; and allow them the time they need to make an informed choice. Where necessary and reasonably practicable, clients have the right to a competent interpreter.

Effective communication guidance

- Approach the process of informed consent as a partnership where communication enables tangata whai ora to understand their options for care, and genuinely exercise their autonomy
- Listen to tangata whai ora and treat them as individuals. Take their specific communication needs and preferences into account, respecting cultural values and differences
- Give information in a form, language, and manner that enables them to understand it. Use simple and easy to understand plain language, that avoids technical terms and medical jargon, and is pitched at a level where the words are easily known; and use visual aids, diagrams, or models as appropriate.

Examples in clinical practice

CM has a unique language that many tangata whai ora may not be familiar with. If you are unsure that tangata whai ora have understood your explanations, allow them to give you feedback using methods such as the ‘teach-back’ method whereby they explain their understanding back to you. If you cannot confirm understanding you may wish to engage support people, or if needed, an interpreter.

Provide information about your services in a variety of ways such as a Frequently Asked Questions (FAQ) page on your website, brochures and posters in your clinic, a poster clearly showing the HDC (Health and Disability Commissioner) Code of Rights, and relevant public information.

In your clinic, clearly display your registration certificate and Annual Practising Certificate, alongside any relevant CM qualifications. Ensure that all information provided is current, evidence informed where appropriate, and does not downplay risks and limitations, over-emphasise benefits, or unduly criticise other treatment options.

Provide a written summary of the information provided to tangata whai ora when this is requested, or when you consider that this would be helpful; for example, when the care is complex and/or the timeframe for care is long. Make sure that tangata whai ora are aware of their right to seek a second opinion and to consult with support people if they do not clearly understand the treatment options.

Obtaining Informed consent

CM practitioners must obtain informed consent before providing, and during, any CM services. They must ensure the informed consent is freely given and appropriately documented. Care must be taken by the CM practitioner to determine, as much as possible, whether tangata whai ora understand the explanation/s about the proposed treatment/s.

Informed consent is not a one-off event. It is an ongoing process of communication between tangata whai ora and CM practitioners which provides multiple opportunities to make informed decisions about their treatment, both before and within a period of care; and to give, withhold, affirm, or withdraw their informed consent.

Tangata whai ora must be able to give informed consent freely, without being subject to discrimination, coercion, harassment, or exploitation. They have the right to refuse services and to withdraw informed consent that has already been given, without prejudice. They are also entitled to express a preference as to whom will provide services and have that preference met where practicable.

CM practitioners must clearly and adequately inform tangata whai ora of the purpose and nature of the CM intervention to enable their informed choice. To provide informed consent tangata whai ora have the right to sufficient information for their understanding of:

- the CM diagnosis and possible responses to treatment
- an explanation of known evidence that supports the proposed CM treatment
- an explanation of the CM treatment including
    - an explanation of the condition
    - an explanation of the known options available, including a discussion, if known, about the expected risks, side effects, benefits
    - the advice about treatment frequency, and estimated numbers of treatments
    - any explanation about any proposed participation in teaching or research, including ethical approval requirements
- any other information required by legal, professional, ethical, and other relevant standards
- specific details of the treatment including when procedures are being given in an area of a sensitive or personal nature
- any other known options for treatment
- cost of treatment
- the right to complain and the complaints process
- option to defer treatment, and
- right to withdraw informed consent to treatment at any time.

It is also important for a CM practitioner to tell tangata whai ora if they do not have the relevant information or knowledge to answer questions, that may influence informed consent. This may mean CM practitioners need time to find information or consult with colleagues, or they may need to advise tangata whai ora to seek further information from other sources before providing consent.

Tangata whai ora are entitled to honest and accurate answers to any questions about services, including the identity and qualifications of the CM practitioner; the recommendations of the CM practitioner; 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, this may be requested in English and if so, must be provided. Where records are maintained in a language other than English, on occasion it may be necessary to provide translated information tangata whai ora or to a third party, if so, it should be translated by a certified translator or by a practitioner with no conflict of interest;

CM practitioners must seek prior informed consent for an additional person(s), not directly involved in the care of tangata whai ora, attending an assessment; and/or (Involvement of an additional person during a consultation).

This includes but is not limited to:

- a chaperone, supervisor, or peer reviewer
- an observer for education, peer review or research purposes, and
- an interpreter.

If a person needs more time to think about their options before commencing treatment, they are entitled to request to return later, or refuse treatment.

Obtaining Informed Consent Guidance

Informed consent is typically given either orally or via written informed consent. Oral informed consent is sufficient for routine assessments and treatments, where any perceived risk to tangata whai ora (or practitioner) is minimal. Care must be taken with ongoing informed consent when treatment involves procedures, including palpation, which are being given in an area of perceived sensitive or personal nature.

Written informed consent is required when:

- there is a significant risk of adverse effects for the client, or when there is any doubt about the associated risk with an assessment or treatment
- where a CM student in an approved educational programme is involved in clinical practice, the initial informed consent for any assessment and /or treatment must clearly identify that this is occurring with a CM student under supervision
- explicit written consent is also required every time that a student is involved in a sensitive examination or procedure, or
- there is involvement in any research or teaching/clinical supervision.

Written informed consent should include the discussed treatment options and risks and be part of the informed consent signed by the tangata whai ora. All oral, electronic, and written informed consent must be clearly documented, dated, and include an explanation of the information provided. Avoid the use of standardised forms or templates when obtaining written informed consent, particularly those

from international sources where the legal requirements for informed consent may differ from those in New Zealand.

Examples in clinical practice

Informed consent needs to take place prior to and throughout the consultation and treatment process. This may mean that a general informed consent form is issued prior to, or when a booking takes place. This form could outline the general nature of CM treatment and the associated risks.

Following this, the next informed consent point is during the consultation process, ensuring understanding of what the treatment may involve and confirming informed consent. Further, prior to the intervention's application, informed consent should be obtained again. This is especially relevant when sensitive areas of the body need to be exposed, palpated, or treated with CM interventions, such as tuina, needling, moxa, or cupping.

What is perceived as 'sensitive' may differ between practitioner and tangata whai ora, clear descriptions of areas to be palpated or treated need to be discussed prior to informed consent being obtained. Informed consent must be given freely, and at no time can the practitioner coerce the tangata whai ora into treatment, such as using language that implies the treatment must be carried out, or that there are no alternatives.

Be sure that the care you obtained informed consent for is the care you provide. If treatment is provided that has not been informed consented to, the informed consent that was obtained is not considered valid. For example, if you decide to change acupuncture points, or add cupping or any hands-on techniques during the treatment, but these were not discussed prior or informed consented during, these must be clearly stated in the file of tangata whai ora and time must be allowed for the person to ask questions and refuse any aspect of the changed treatment.

Whilst it is not always necessary for the practitioner to discuss point selection with tangata whai ora, it is reasonable to expect the practitioner to discuss where on the body they would be placing the needles or applying other allied techniques during the treatment and any cautions appropriate to the areas to be needled (for example points over the lungs). Historically, several complaints received by the HDC and the voluntary regulators regarding CM practise, relate to a lack of informed consent for components of treatment being added during the treatment process or not being adequately explained prior to treatment taking place.

Be sure to keep records of the informed consent received, either written or verbal, and the explanations given with each.

Resources

The following links are to useful resources which provide further information:

- Informed consent. Healthify He Puna Waiora, 2022
- Informed consent – helping patients make informed decisions about their care. Medical Council, NZ, 2019
- Without informed consent, tread warily to protect the person's legal rights. Health & Disability Commissioner, NZ, 2018
- Informed consent for consumers who are not competent. Health & Disability Commissioner, NZ
- Patient informed consent for treatment by trainees. Health & Disability Commissioner, NZ, 2017

- Informed consent. Starship Children's Hospital, NZ, 2018
- Ministry of Health. Informed consent in Child and Youth Health: Information for Practitioners.
- Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996

Acknowledgements

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