

Informed Consent in Chinese Medicine Clinical Practice



**Chinese Medicine Council
of New Zealand**



Formal Welcome from the Chair

Paddy McBride

CMC Competencies and Standards

Clinical Competencies

Domain 2: Communication and collaboration

Demonstrate the ability to obtain, and maintain informed consent, explaining the purpose, risks, and benefits of the proposed assessment and/or treatment as well as alternative options.

Standards of Professional Conduct

Principle 3: Work in partnership with tangata whai ora, whānau and families, and respect their dignity, individuality, and rights.

Standards: iv, vi, viii, ix, and x.

Compliance with the **‘Informed Consent Standard’**
and **‘Professional Boundaries Standard’**



Presentation Outline

- ❖ Definition and types of informed consent
- ❖ Legal obligations and the Health and Disability Commissioner's (HDC) Code of Health and Disability Services Consumer's Rights.
- ❖ Components of informed consent (Rights 5,6 and 7)
- ❖ Determining Competency
- ❖ Process of obtaining informed consent
- ❖ Examples in clinical practice
- ❖ Legal Cases, Complaints and Notifications
- ❖ Resources and further reading
- ❖ Questions and answers.



Definition

Informed consent is a fundamental ethical and legal principle in various fields, particularly in medicine and research.

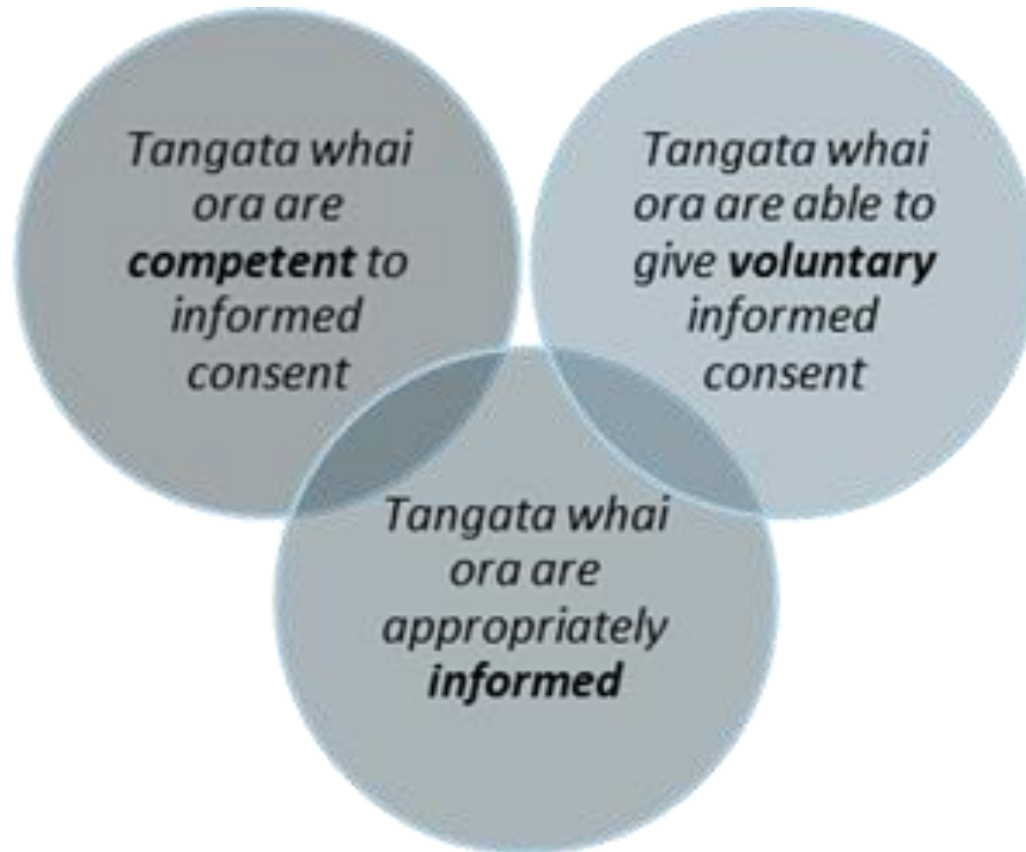
It refers to the process by which an individual voluntarily agrees to participate in a particular procedure, treatment, or research study after being fully informed of all relevant aspects.

These aspects typically include the nature of the procedure, its purpose, potential risks and benefits, alternatives, and the right to refuse or withdraw from the process at any time without penalty.

***Informed consent is ongoing,
not a one-off occurrence.***



Components of informed consent





"Informed consent means that before we go ahead with your treatment, I want to make sure you fully understand what we're planning to do, why we're doing it, the benefits, and any possible risks.

I'll also tell you about other options you might have. It's important that you feel comfortable and have all the information you need to make the best decision for yourself. If you have any questions or concerns, please let me know.

You have the right to say yes or no, and you can change your mind at any time."



Though he stinks at darts, Howie discovers that he has a hidden skill as an acupuncturist.

Scenario:

A patient new to acupuncture seeks treatment for migraines. The practitioner does not inform the patient that some individuals may experience bruising or pain at needle insertion sites.

Solutions:

- ✓ Comprehensive disclosure of possible immediate side effects like pain, bruising, or bleeding.
- ✓ Reassuring patients about the normalcy of these side effects and how to manage them.
- ✓ The importance of open communication about any discomfort experienced during or after the session.

Acupuncture and Pain or Bruising

Scenario:

A patient with a history of hemophilia seeks acupuncture. The practitioner fails to ask about bleeding disorders or inform the patient about the increased risk of bleeding and bruising due to their condition.

Solutions:

- ✓ The necessity of taking a thorough medical history to identify conditions that may affect treatment.
- ✓ Informing patients about how their specific health conditions might influence the risks associated with acupuncture.
- ✓ Customizing consent discussions based on individual patient health profiles.

Acupuncture and Pre-existing Conditions

Scenario:

A patient requests a deep tissue massage to relieve muscle tension. The therapist does not explain that deep tissue techniques can sometimes cause soreness or bruising, especially in sensitive individuals.

Solutions:

- ✓ Discussing the potential for soreness, discomfort, or bruising after deep tissue massage.
- ✓ Providing aftercare instructions to manage post-treatment soreness.
- ✓ Ensuring patients are aware of what to expect and consent to the intensity of the treatment.

Tuina Massage and Deep Tissue Techniques

Scenario:

During an acupuncture session, a practitioner leaves needles in place for a prolonged period, leading to patient discomfort. The practitioner had not informed the patient about how long needles would be retained or the potential discomfort associated with it.

Solutions:

- ✓ Clearly explaining the duration needles will be retained and what sensations to expect.
- ✓ Monitoring patient comfort throughout the session and adjusting as needed.
- ✓ Ensuring patients know they can request needle removal at any time if they feel discomfort.

Acupuncture and Needle Retention

Legal obligations and the Health and Disability Commissioner's (HDC) Code of Health and Disability Services Consumer's Rights.

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.



The Code of Rights means that you should have:

Mā tēnei Ture Tiaki i ōu Tika, ka ahei kia u nga tikanga:

- 1** Respect
Mana
 - 2** Fair treatment
Manaakitanga
 - 3** Dignity and independence
Tū rangatira motuhake
 - 4** Appropriate standards
Tautikanga
 - 5** Effective communication
Whakawhitiwhitinga whakaaro
 - 6** Information
Whakamōhio
 - 7** Choice and consent
Whakaritenga mōu ake
 - 8** Support
Tautoko
 - 9** Rights during teaching and research
Ako me te rangahau
 - 10** Your complaints taken seriously
Amuamu
- 

Language

Form

Manner

Environment

Open

Honest

Effective

Culturally
safe

Access to
interpreter

Right 5 - Right to effective communication

Communication tips

- Use clear, jargon-free language, allow for two-way communication, and time for questions and answers.
- Have written or electronic consent forms.
- Use visual aids to assist explanations.
- Use the teach-back method to ensure understanding.
- Ensure the treatment plan is based on shared decision making.
- Use interpreters, as necessary.
- Have your complaints process clearly visible which may include a poster of the HDC code of Rights.



Right 6 - Right to be fully informed

- the patient's condition or current situation
- the different service options available
- possible risks, benefits, alternatives and costs**
- being realistic about outcomes**
- advice about service timeframes
- any proposed participation in teaching or research
- the results of all tests and treatments.

People have the right to honest and accurate information and to ask any questions about the services you provide. This includes your qualifications, your recommendations, and how to source a second opinion from another provider.

All information must be provided as a written summary, if requested.



**The most common
questions asked**

How does it work?

Is it safe?

What conditions
can it treat?

What can I expect
during a session?

How many sessions
will I need?

What can I expect
to feel after a
treatment?

What qualifications
should a
practitioner have?

Is there any pre or
post care?

Will it interact with
my current
medications or
treatments?

How much does it
cost and is there
any funding
available?

Are there any
contraindications?

What's the
difference between
acupuncture and
dry needling?





Right 7 - Right to make an informed choice and give informed consent

The Right to choose is central to informed consent.

A patient has the right to choose. This includes the right to refuse services, and to withdraw consent that has already been given, without prejudice.

As a provider you are obligated to uphold your patient's right to make an informed choice and give their informed consent.

"As a patient, you have certain rights that are protected under the Health and Disability Commissioner's Code. These rights are designed to ensure you receive high-quality and respectful care. Some of your key rights include being treated with respect and dignity, receiving care that meets proper standards, and being fully informed about your treatment options.

For example, you have the right to understand all the information about your condition and treatments, so I will explain everything in simple language or we can use an interpreter if necessary. You also have the right to make informed decisions about your care, meaning I will discuss the benefits and risks of each option with you.

If you ever feel that your rights are not being respected or you have concerns about your care, you have the right to make a complaint and have it addressed promptly and fairly.

Please feel free to ask any questions you might have about your rights. I want to ensure you feel comfortable and well-informed. If you'd like more detailed information, I can give you a pamphlet or guide you to the Health and Disability Commissioner's website"





"On the plus side, you've cured my back pain."

Determining competency

Tangata whai ora are presumed competent to make an informed choice or give informed consent, regardless of age, unless there are reasonable grounds for believing that they are not competent.

Practitioners need to confirm that the individual has the capacity to make the decision. This involves assessing their mental and cognitive ability to understand the information and make an informed choice.

Determining a patient's competence to give informed consent involves evaluating their ability to understand and process information about their treatment or procedure.



Checking the level of understanding involves asking yourself:



Can they clearly communicate their understanding about their condition or situation?



Can they understand the consequences of their choices?



Can they weigh the relative risks and benefits of their options?

Obtaining informed consent



CM practitioners must obtain informed consent before providing, and during, any CM services.



Informed consent is not a one-off event.



Informed consent needs to take place prior to and throughout the consultation and treatment process.



They have the right to refuse services and to withdraw informed consent that has already been given, without prejudice.



If requested, a written summary of the information must be provided.





Legal Cases,
Complaints
and Notifications

HDC Case 01307 - Tuina

A woman had a 90-minute Tui Na massage. The woman had purchased an online promotional voucher for the treatment. The voucher did not describe Tui Na in any detail and the patient was under the impression that the massage would be a relaxation treatment.

Findings

Given the nature of the treatment, the practitioner should have clearly explained and communicated to the patient, a new client, that Tui Na massage was a deep tissue massage and could potentially be uncomfortable and painful for her. That is information that a reasonable consumer would need to receive to give informed consent. The absence of information given about what the treatment would entail meant that she did not have the information she required in order to give informed consent. Therefore, the practitioner **breached Right 6(2) of the Code.**

Right 7 of the Code provides that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. Due to the lack of information provided to the patient, she was unable to make an informed choice or give informed consent. It follows, therefore, that the practitioner also **breached Right 7(1) of the Code.**



Misleading
signage

No health history
taken

No explanation
of treatment
provided

Inadequate
English to discuss
treatment plan

No provision to
ask questions

No aftercare
provided

Inadequate
clinical records

Unclear
complaints
procedure



Recommendations

- Written apology to be issued to the patient
- Peer review of initial assessments and intake documentation to be conducted. Provide the HDC with a feedback document on the changes and improvements made, including a copy of the client questionnaire
- Independent review of record-keeping for the last six months
- Produce a brief pamphlet of written information about Tui Na to give to potential new clients, and for use in any advertising or promotional material

HDC follow up included

- A copy of the report naming the practitioner was sent to the DHB
- A copy of this report, with details identifying the parties removed, was sent to ACC, and the New Zealand College of Chinese Medicine, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.



Case 19HDC00788 – Treatment of Sensitive areas

A massage therapist provided massage therapy to a woman's breasts without first clearly ensuring that the woman consented to this treatment.

Findings

The massage therapist failed to **inform the woman adequately** and, accordingly, breached Right 6(1) of the Code.

It follows that the woman was **not able to give informed consent** and, accordingly, the massage therapist also breached Right 7(1) of the Code.

The massage did not meet accepted standards. The practitioner did not meet professional and ethical standards and breached Right 4(2) of the Code.




Failure to communicate
adequately

Failure to obtain informed
consent

Treatment did not meet
professional standards

It is not sufficient to assume
that a client has given
informed consent because
the client does not object
to specific actions.



Recommendations

- Written apology to be issued to client
- Professional mentoring for 18 months
- **Supervision on informed consent**
- Review of draping techniques
- Attend training on communication techniques
- Training on treatment of sensitive areas
- **Develop an informed consent process**

HDC follow up included

- Recommendation to professional body that a requirement for supervision and monitoring be put in place for all members as a condition of registration.



HDC Case 00442 – Bilateral apical pneumothorax secondary to acupuncture

A woman was receiving acupuncture treatment for a left arm and wrist injury. At an appointment, her wrist pain had decreased, but her notes record that she was also **experiencing pain at the jian jing (GB21) area on both sides, and shortness of breath.**

The acupuncturist said that prior to treatment she explained the treatment and risks to the woman verbally, including that the location of the jian jing point is close to the lung's apex and there is a possibility of a pneumothorax, as well as general precautions of acupuncture. However, this discussion was not documented. **The acupuncturist acknowledged that the woman did not sign a written consent form on this date.**



- There were discrepancies between the reports from both parties.
- Most of these were about the consent process including information provided before the treatment.
- There were concerns about the management of the treatment injury and the provision of after care.

Your written notes, policies, and procedures are often your only evidence in notifications....



Discrepancies and Pitfalls



Symptoms were recorded in notes but there were different recollections of the events.



Verbal consent was obtained but not documented, again there were discrepancies of the events.



Information brochure was provided within the clinic – patient was not aware.



Consent form for initial visits outlining risks available but was not signed in this case.



Patient stated they were not aware of the risks.



Needling technique did not consider patients low BMI



Practitioner failed to recognize the signs of pneumothorax.



Clinic had no formal consent policies and procedures in place.

Practitioner failed to provide patient with information that a reasonable consumer needed to make an informed choice or give informed consent.

Practitioner did not take appropriate care, punctured both lungs of her patient, and failed to recognise the signs of a possible pneumothorax.

Clinic did not have any formal policies and procedures regarding informed consent



Recommendations

- Conduct a consumer audit on **consent processes** in clinic and provide HDC with a report including any changes made.
- Undertake further training on acupuncture needling techniques and provide HDC with evidence of having completed such training.
- **Develop formal policies and procedures in relation to obtaining consent from consumers.**
- Case to be used as a learning opportunity for the profession.



Informed consent means



- Full information is provided including the nature and purpose, risks, side effects, alternatives, and expected outcomes.
- The patient fully understands the information provided.
- The patient has consented voluntarily.
- The patient has the capacity to make an informed decision.
- Consent has been documented



- Lack of full disclosure, information is omitted.
- Technical or jargon filled explanations.
- Patient is pressured into consenting.
- Patient does not understand.
- Inadequate time for decision making
- Ignoring the patients' questions or concerns.

Take home messages

1. Provide clear and comprehensive information regarding your treatments.
2. Ensure that the patient understands the information provided.
3. Ensure that the patient's decision to undergo treatment is voluntary and respect the patient's right to decline or discontinue treatment at any time.
4. Assess the patient's capacity/competence to make an informed decision about their care.
5. Keep thorough records of the consent process, including the information provided, questions asked by the patient, and their responses.
6. Recognize that informed consent is an ongoing process. Monitor the patient's consent throughout the course of treatment to ensure continued understanding and agreement.
7. Be aware of and respect cultural differences. Provide information in a culturally sensitive manner and consider using translators or cultural mediators when necessary.



Resources and further reading

1. CMC Competencies and Standards

Standards of Clinical Competence

Standards of Professional Conduct

Informed Consent Standard and Guidance Document

Professional Boundaries Standard and Guidance Document

2. HDC Online module “What you need to know about informed consent”.

[Online learning — Health & Disability Commissioner \(hdc.org.nz\)](#)

3. HDC cases - [18hdc00442.pdf](#), [13hdc01307.pdf](#), [19hdc00788.pdf](#)

4. Further reading

[We must do better on informed consent](#)

[Without informed consent, tread warily to protect the person's legal rights](#)

[What Does the Evolution From Informed Consent to Shared Decision Making Teach Us About Authority in Health Care?](#)





Questions?

How to get in touch



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Opening Hours



Mon - Fri



8:30 am – 5:00 pm



Meetings by appointment only