NZASA Guidelines for Informed Consent

Terminology

The term *acupuncture treatment* incorporates needling techniques but also adjunctive techniques such as electro acupuncture, bleeding and plum blossom techniques, laser acupuncture, moxibustion, cupping, gua sha, and tuina.

The term *patient* can be interchanged with client.

The term *practitioner* refers to an NZASA registered member.

1. The purpose of this guideline

NZASA guidelines complement the NZASA Standards of Professional and Ethical Conduct and the Code of Safe Practice. These documents include numerous references to consent and are essential reading for NZASA registered members.

These guidelines reflect the legal right of the patient to make their own decisions about acupuncture treatment and their right to grant, withhold or withdraw consent before or during examination or treatment. In the same way, this statement also reflects the legal duty of the practitioner to obtain the patient's informed consent at all appropriate stages within a treatment cycle.

Not every eventuality can be envisaged, so developing an understanding of key concepts and how they may be applied in practice will help acupuncture practitioners manage issues of consent as they arise.

Because issues of ethical obligation and legal duty overlap within the context of informed consent, these guidelines reinforce several important themes and principles.

New Zealand Law

The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 states every patient has the right to effective communication[1]; the right to be fully informed[2]; and the right to make an informed choice and to give informed consent[3].

[1] Right 5(1) Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996
[2] Right 6 Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996
[3] Right 7(1) Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996

The Care of Children Act 2004 (Section 36) states that children 16 years and over can give consent as if they are adults.

2. Summary of guidelines

These guidelines cover the concept of consent as a dynamic, continuous two-way process which should be documented in the patient's clinical record.

Informed consent is not to be equated with merely obtaining a patient's signature on a single occasion on a form in the first consultation.

These guidelines cover:

- the definitions of informed consent and why it is necessary;
- the important principles and practical steps to obtaining informed consent;
- how to document informed consent;
- consent of minors and vulnerable patients;
- the continual nature of consent and triggers for renewal; and
- withdrawal of consent.

3. What is informed consent?

In the practitioner/patient context, informed consent is the valid permission of the patient to a proposed examination or treatment, after appropriate advice and information has been provided by the practitioner.

Consent is not 'informed' or valid if treatment is agreed to by the patient without them first being informed of the nature of the treatment, the reason for its recommendation and other information they would regard as relevant to their decision, such as any risks of the treatment (both common and minor, as well as rare but potentially more serious), the evidence[4] which supports the treatment approach, and alternate treatment options.

The following is a list of principles of informed consent. It should not be treated as a complete list, but rather a guideline.

1. The patient is entitled to make their own decisions about their treatment and management.
2. The patient should be given adequate information on which to base their decision(s).
3. Consent is only valid if the patient is competent to understand and authorise the intervention/treatment, and makes a voluntary decision to undergo the treatment.
4. The practitioner should provide adequate information on the issue and treatment options to enable the patient to make a decision.
5. The information should be provided in a manner which is appropriate in the circumstances, including the practitioner's objective assessment of the patient's ability to understand; subjective factors such as personality, expectations, fears, beliefs, values and cultural background of the patient.

[4] Evidence to be provided to the patient in the clinical setting can include clinical experience, evidence-based research, and non-evidence-based research. It should be made clear to the patient which type of evidence you are providing and explain any associated limitations of the evidence.

6. Consent obtained by coercion or undue influence is not valid.
7. The patient is free to accept or reject the practitioner's advice.
8. The patient retains the right to change their decision about interventions/treatment after the commencement of that treatment, i.e. at any point within a treatment or treatment cycle.
9. A patient's apparent acceptance of interventions/treatment is not in and of itself an indication of informed consent.
10. The obligation to obtain informed consent is ongoing rather than a one-off responsibility.

4. Why is 'informed consent' necessary?

Right 6 (2) of the Code of Health and Disability Services Consumers' Rights states that "Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent."[5]

The patient's autonomy in making decisions is the key principle of informed consent.

Patients have a right to know both the possible common and minor adverse effects and the rare but serious adverse events that could occur as a result of acupuncture treatment. The discussion will be dependent on the proposed treatment and points.

5. How does a practitioner obtain informed consent?

Consent **cannot be viewed** as an event that occurs at any one point in time when a form is signed. Instead, the practitioner has an ongoing responsibility to ensure that informed consent is obtained throughout the treatment cycle.

NZASA recommends the following process of obtaining informed consent (outlined below).

The practitioner who will examine and provide treatment (not another person, such as a clinic receptionist or assistant), shall disclose and discuss with each patient:

1. the patient's diagnosis/explanation of condition from a traditional Chinese medicine perspective;
2. the nature and purpose of a proposed examination or treatment;
3. the option for a chaperone or support person where appropriate;
4. an explanation of the treatment options available, the benefits, possible side effects and risks of a proposed treatment, including adjunctive treatments such as electro acupuncture, moxibustion, gua-sha. (Note: this is not an exhaustive list);
5. the alternative techniques or therapies to the proposed treatment, e.g. applying cupping or gua-sha to a point rather than needling it or vice versa;
6. benefits and risks (this includes probable or likely outcomes such as marking to the skin as the result cupping or gua sha) of the alternative techniques or therapies. Where the benefits and risks are not known, the patient should be informed of this;
7. answer any questions the patient has regarding cost of treatment; and
8. advice about recommended treatment frequency, and estimated numbers of treatments required, or time frame for review of progress and prognosis.

[5] Right 6(2) Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulation, 1996.

Effective communication is essential in the consent process.

The information must be delivered at a level the patient understands and presented in plain language. Information can be supported by leaflets and/or simple explanations about conditions and treatment options.

In turn, the patient should have an opportunity to ask questions in order to clarify their understanding of anything from the above list. The patient should be given adequate time to make a decision without any sense of pressure or coercion, as consent is paramount to treatment

If uncertain of the patient's understanding of information presented, it may be necessary to test whether the patient understands the explanation(s) about the proposed treatment/s, by asking the patient to clarify their own understanding of what has been discussed. This provides the opportunity for the practitioner to offer additional explanation(s) as necessary.

Right 5 (1) of the Code of Health and Disability Services Consumers' Rights states that "Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter."[6]

If there are language barriers that require the use of an interpreter during the consent process, you should document this in the patient's health record, 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 you have provided.

6. How to explain the proposed treatment and risks to patients

Some practitioners may have concerns about advising patients of the low risks of rare, or serious outcomes associated with needling vulnerable points (such as pneumothorax or penetration of other organs, arteries or nerves). Concerns may include that the patient might refuse to accept beneficial treatment or that an explanation would take too long.

It is ultimately up to the patient whether they accept acupuncture treatment. Context is everything. The practitioner must make sure that the patient is able to weigh up the balance between the benefits and the risks of the proposed treatment (both the common and mild adverse effects, and the rare but serious risks associated with certain vulnerable points).

Time taken to explain risk until each patient has a clear understanding is an essential component of informed consent and a key part of the consultation that must not be rushed.

If the patient does not want to proceed with the proposed treatment that carries a low/rare but serious risk (i.e. the needling of a vulnerable point), they may accept an alternative treatment approach offered. There are a number of acupuncture points and techniques from which the practitioner can select according to the needs and consent of the individual patient.

Imagining yourself as the patient (and what you would wish to know) should help with this process.

7. Documenting the patient's informed consent

While it is not necessary to ask the patient to sign a consent form for every proposed treatment, it is important that the acupuncturist documents in the patient's health record, the fact that informed consent (verbal or written) has been given by the patient, together with a summary of the information that was provided to the patient in order to obtain that consent. All oral and written informed consent must be clearly documented and dated.

[6] Right 5(1) Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulation, 1996.

Failure to document consent can lead to disputes about what was discussed. For example:

An acupuncturist needled Small Intestine 14 (Jianwaishu), on a patient with shoulder and scapular pain. The patient later complained of pain in the chest and difficulty breathing and was sent to hospital for further investigation. The patient claimed the practitioner did not inform him that needling this acupuncture point carried a small risk of a pneumothorax as the lungs lie beneath this point, nor did the practitioner inform him not to move during the treatment due to the risk of moving the needle deeper into the body. While the practitioner was confident that he always discussed the small but possible risk of injury to the lung when needling this point and the need to remain still whilst the needles were in place, he had not documented this discussion or that the patient had given consent in this case.

Practitioners should be mindful that consent cases generally centre on whether the consent was 'informed', i.e. whether the patient was given sufficient information to make a decision receiving the health intervention. It is important that the communication process itself be documented in the patient's clinical notes.

Clear and thorough documentation can serve as evidence (if the advice and treatment is scrutinised at a later stage) that the practitioner did engage the patient in an appropriate discussion and obtain informed consent to treatment. Such documentation will receive greater credibility if the practitioner can demonstrate the habit and custom of such documentation in all medical notes for all patients.

Where the patient refuses treatment, this must be documented in the patient's record also, together with the information provided to the patient and notes on the discussion had.

Requiring the patient to sign a consent form given by the practitioner or receptionist as part of the administration process prior to the acupuncture consultation is not valid evidence of informed consent from the patient. It also demonstrates a fundamental misunderstanding of the practitioners' ethical and legal duty to the patient in obtaining the patient's consent to treatment **after** an appropriate explanation has occurred specific to that patient and the proposed treatment. You must not delegate the obtaining of consent to a receptionist or assistant.

You must record any subsequent explanation and consent obtained if the course of treatment extends beyond the original projection, if treatment continues beyond an agreed review date, or if the treatment itself involves significant changes in point locations or techniques.

8. Consent of minors

Under the Care of Children Act (Section 36), children over the age of 16 years may give consent as if they are adults.

You must seek the consent of a parent or guardian if the patient is under the age of 16. You must also be aware that the refusal of treatment by a child under the age of 16 may carry legal force and override the consent, even though properly given, of a legally authorised adult.

Make every effort to encourage and enable patients of any age to be involved in the informed consent process; they retain their right to make informed choices and give informed consent to the extent appropriate to their level of competence, regardless of age.

You should consider having the parent or care giver stay with the minor throughout the treatment. If you are in any doubt you should contact NZASA or seek legal advice before you perform any treatment.

9. Competency for providing consent to treatment

Right 7(2) of The Code of Health and Disability Services Consumers' Rights states that "every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the patient is not competent."[7]

When a patient is not competent or has diminished competence, the HDC Code of Rights requires that practitioners seek to involve someone in the informed consent process who has the legal right to make decisions on the patient's behalf.

Being a relative of the patient does not in itself give legal authority to consent on behalf of the patient.

Where a patient has diminished competence, that patient retains the right to make informed choices and give informed consent, to the extent appropriate to their level of competence; regardless of age.[8]

This means that while someone with legal authority needs to be involved in the informed consent process and provide their consent, practitioners need to make every effort to encourage and enable the continued involvement of the patient in the informed consent process, to the extent their level of competence allows.

10. Duration of informed consent

Gaining a patient's consent to treatment is not a 'one-off' activity when the patient first visits the acupuncturist's practice. It should be repeated when a patient returns after a period of absence and when their condition or proposed treatment plan changes.

The process of informed consent should occur as close as possible prior to the patient receiving the proposed treatment.

11. When a student, observer or assistant is present

You must have a patient's permission in advance if a student, observers, or assistant is to attend the consultation or participate in the patient's treatment.

Be mindful if sensitive issues may be discussed in the consultation.

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 treatment session in any way)

c) that at any point in time, they have the right to refuse the presence or involvement of the student or observer. For example, if sensitive issues arise during the consultation, it would be appropriate to check whether the patient would prefer to not have other parties present.

[7] Right 7(2) Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996

[8] Right 7(3) Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996

12. When involved in research

All research must be approved by an accredited ethics committee. A patient must provide **written informed consent** before they participate in research. Refer to Rights 6(1)(d) and 7(6)(a) of the Code of Health and Disability Services Consumers' Rights.

Patients may withdraw their consent to participate in research at any time.

13. Further reading

1. Health and Disability Commissioners – The Code of Health and Disability Services Consumers' Right

2. Osteopathic Council of New Zealand: Informed consent: Guidelines for osteopaths. 2014

3. Informed Consent Standard. Physiotherapy Board of New Zealand. 2018

4. Medical Council of New Zealand. Informed Consent: Helping patients make informed decisions about their care. 2019

14. Acknowledgements

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