Guidelines

April 2013

Informed consent: Guidelines for osteopaths

1. Introduction

These guidelines have been developed under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law).

The guidelines aim to guide osteopaths about informed consent. See Attachment A of these guidelines for the relevant sections of the National Law.

The guidelines complement the Osteopathy Board of Australia's *Code of conduct for registered health professionals (Code of conduct)* and the *Guidelines for clinical records* and *Sexual and professional boundaries: Guidelines for osteopaths*. These documents have numerous references to consent and are important reading for practitioners.

2. Summary of these guidelines

Good osteopathic practice requires obtaining a patient's informed consent. These guidelines have drawn on a range of sources both within and outside of the osteopathy profession.

As an integral part of a consultation with a patient, it is important that osteopaths follow these guidelines at all times. The guidelines cover the concept of consent as a dynamic, continuous two-way process which must be documented in the patient file. Informed consent is not to be equated with merely obtaining a patient's signature once 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
- how to gain informed consent if there is no capacity to give it
- the continual nature of consent and triggers for renewal, and
- withdrawal of consent.

The Osteopathy Board of Australia (the Board) will investigate an osteopath who is alleged to have breached these guidelines and if the allegations are found to be substantiated, the Board will take action (see section 12 of this guideline). An investigation into informed consent may take place as part of an investigation into other aspects of an osteopath's practice. These guidelines should be read in conjunction with the Board's guidelines on clinical records, sexual and professional boundaries, and the Code of conduct.

3. What is informed consent?

In the practitioner/patient context, informed consent is the valid consent of the patient to proposed examination or treatment or procedure (referred to as '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 inherent risks of the treatment and alternate treatment options.

In order to provide informed consent a patient has a right to sufficient information for his/her understanding of:

1. the diagnosis and likely outcome (prognosis) of the condition
2. an explanation of the recommended treatment
3. the risks of the procedure and common side effects
4. possible complications
5. specific details of the treatment
6. any other options for treatment and their probability of success
7. cost of treatment
8. option to defer treatment, and
9. right to withdraw consent to treatment at any time.

This is discussed further below.

4. Why is 'informed consent' necessary?

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

Patients have a right to know the usual and serious inherent risks of osteopathic treatment and to decide for themselves whether they are prepared to accept those risks.

Practitioners cannot make those decisions for patients or unduly influence their decision.

It therefore follows that an osteopathic practitioner has a legal duty to obtain the 'informed' consent of the patient to proposed treatment.

5. The purpose of this guideline

This guideline reflects the legal right of the patient to make their own decisions about osteopathic 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 to treatment at all relevant times.

While it is recognised that this statement might be consulted in legal proceedings or in the adjudication of a complaint/notification, it is not intended to mandate a particular process for informing the patient. Rather, the guidelines are intended to foster better communication between osteopath and patient, so that patients are able, with their osteopath, to make the best decisions about their osteopathic care.

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

Because of the overlapping issues involved with the ethical obligation and legal duty of informed consent, these guidelines reinforce a number of important themes and principles.

6. Important principles of informed consent

The following is a list of principles of informed consent. It should not be treated as an exhaustive list, but rather an important framework of critical principles which can be added to.

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 decisions.

3. Consent is only valid if the patient is competent to understand and authorise the intervention and makes a voluntary decision to undergo the treatment.
4. The practitioner should provide adequate information on the issue and intervention options on which to make a decision.
5. The information should be provided in a manner which is appropriate in the circumstances, including the osteopath's objective assessment of the patient's ability to understand, as well as subjective factors such as personality, expectations, fears, beliefs, values and cultural background of the patient.
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 has the opportunity to change their decision about interventions / treatment after the commencement of that treatment.
9. A patient's seeming acceptance of interventions/treatment is not necessarily an indication of consent.
10. The obligation to obtain informed consent is ongoing rather than a once off responsibility.

7. How does a practitioner obtain informed consent?

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

The Osteopathy Board of Australia supports a process of obtaining informed consent (outlined below) that osteopaths should use every time they treat a patient.

In the communications process, the osteopath providing or performing the examination, treatment and/or procedure (not another person such as a clinic receptionist), should disclose and discuss with each patient:

1. patient's diagnosis, if known
2. nature and purpose of a proposed examination, treatment or procedure
3. benefits and risks of a proposed examination, treatment or procedure
4. osteopathic alternatives to proposed examination, treatment or procedure
5. benefits and risks of the alternative osteopathic approaches as far as is known. Where the benefits and risks are not known, the patient should be informed of this,
6. if there is another health professional that may deal with the health issue, and
7. cost of treatment.

In turn, the patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that the patient can make an informed decision about whether to proceed or to refuse a particular course of osteopathic intervention.

The information provided to the patient requires both an objective assessment by the practitioner of the inherent risks of the proposed treatment, as well as a subjective assessment of what the patient is likely to regard as important information to their decision making. The information should be presented in plain language that the particular patient is able to understand.

Careful consideration needs to be given to the way information is communicated in relation to potentially sensitive procedures or treatment. If working with patients from a culturally or linguistically diverse background, special care is needed to ensure there is a shared understanding between the osteopath and the patient about the information provided.

The process of obtaining informed consent is both an ethical obligation and a legal requirement.

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

Practical steps in the process of obtaining consent:

1. use words / language that the patient can understand
2. allow the patient to ask questions

3. repeat information if necessary
4. give the patient adequate time to make a decision without any sense of pressure or coercion, and
5. use a qualified competent language or cultural interpreter if the patient does not speak sufficient English or another shared common language (rather than a family member or staff member)
6. communication is a two way process with the need for active listening to determine any specific concerns of the patient.

Some osteopaths may have concerns about advising patients of low risks of serious debilitating outcomes, for which they believe there is little evidence. 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 osteopathic treatment. Explaining risks sensitively and in context will enhance the therapeutic relationship and help patients understand their options and make an informed decision.

Context is everything. The osteopath must make sure that the patient is able to weigh up the balance between the benefits and the low but serious risks of the treatment. If the patient does not want to proceed with the treatment that carries a low but serious inherent risk, they may accept an alternative treatment approach. There are a number of osteopathic techniques from which the osteopath can select according to the needs of the individual patient.

A common example of the importance of providing an adequate explanation of proposed treatment is as follows.

> *Allegations of sexual assault or inappropriate touching of a patient during treatment may arise from inadequate explanation of a treatment technique prior to commencement, and inadequate time for the patient to ask questions and make a decision. For example, in order to treat a patient's hip, the osteopath may need the patient to undress down to their underwear and may then need to palpate the groin area. Unless this treatment is carefully explained to the patient and their consent obtained, the treatment may take the patient by surprise, and expose the osteopath to legal action and/or a notification.*

The ability to explain risks will be an evolving skill, improving over time, but there are some essential elements to a good explanation. These are the things that the patient will want to know:

1. your diagnosis
2. what treatment you recommend
3. why you recommend that examination/treatment/procedure – benefits
4. what is involved
5. the usual risks
6. low risks of serious debility
7. that you have tested for contraindications, and
8. alternative osteopathic treatment (if known).

As an osteopath, imagining yourself as a patient should help with this process. The extra element of explanation need not take very long or be onerous.

9. Documenting the patient's informed consent

While it is not necessary to ask the patient to sign a consent form for the proposed treatment, it is important that the osteopath documents in the patient's notes the fact that informed consent has been provided, together with a summary of the information that was provided to the patient in order to obtain that consent.

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

> *An osteopath performed some soft tissue, articulation and cervical spine manipulation techniques on a patient with persistent neck pain. The patient later complained of stroke-like symptoms and was admitted to hospital for further investigations. The patient claimed the practitioner was negligent as he would not have agreed to these cervical spine techniques had he known there was a risk of suffering stroke-like symptoms. While the practitioner was confident that she always discussed the risk of stroke with her patients, she had not documented consent in this case.*

There is currently no legal requirement in Australia for a signed consent form. Documenting the patient's consent to treatment is not the same as the patient signing a consent form.

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 about their body and health care. It is important that the communication process itself be documented, however this does not necessarily involve the patient signing a consent form.

Forms that attempt to satisfy all legal requirements (stating for example that 'all material risks have been explained to me') may not preclude a patient from asserting that the actual disclosure did not include risks that the patient unfortunately discovered after treatment.

Good documentation can serve as evidence (when 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.

The decision on the use of consent forms is at discretion of the osteopath in conjunction with advice from their professional indemnity insurer.

The Board is not able to provide a standard form of words for warning of risks. Iinformed consent is a process that requires the osteopath to provide adequate information to the patient, taking account of the individual patient's capacity to understand at a particular time. Because patients are all different and because different issues present when tests for contraindications are performed, a standard explanation cannot be appropriate. For the same reason, the Board does not advocate a standard consent form but is not opposed to consent forms that relate the particular risks.

Osteopaths are cautioned against any belief that if they obtain a patient's signature, they have obtained consent. This is not necessarily the case.

Consent is a process in which the osteopath endeavours to ensure that the patient understands the risks. Obtaining a signature does not necessarily mean that this process has been satisfied. Accordingly, the osteopath's contemporaneous notes can be as effective as a consent form. The fact that the osteopath has taken the trouble to write out their advice may better indicate that they have gone through the consent process.

Requiring the patient to sign a consent form given by the osteopath or receptionist as part of the administration process prior to the osteopathic consultation is not valid evidence of informed consent from the patient and demonstrates a fundamental misunderstanding of the osteopath's ethical and legal duty to the patient in obtaining the patient's consent to treatment after an appropriate explanation has occurred and before the treatment commences.

10 Capability of providing consent to treatment

Informed consent for treatment is only valid if the individual has capacity to consent at that time.

All adults (18 years and over) are assumed to have the capacity to consent unless otherwise proven or unless there is some indication that a reasonable practitioner ought to be aware that the patient's capacity is questionable. It does not follow that people under the age of 18 have no capacity to give consent. This may depend on the age and understanding of the person under 18. A person under the age of 18 in some circumstances and for some treatments may be competent to provide informed consent. The legislation in regard to consent by a person under 18 years of age can vary across jurisdictions and can be challenged in court. Given this is a complex area of law across Australia, where practicable it is recommended that persons under 18 are treated with parental consent.

There are no numeric measures or tests that can be done to determine if an individual has capacity to consent. Capacity is a judgement of an individual's ability to understand the consequences and nature of a specific decision.

People with mild intellectual disabilities may still be capable of consenting. Similarly, people with more significant intellectual disabilities may be capable of consenting to simple procedures. Individuals may also lose capacity temporarily, for example while suffering from an illness, but later recover.

Capacity for consent requires that a person must be able to understand the information given, remember the information and analyse it to make a decision to give consent.

In situations where patients have no capacity to consent and are dependent on a third party for their ongoing care, (e.g. persons with an intellectual disability, under a guardianship order), it is important to ensure all appropriate information is provided to the substitute decision-maker for the patient, for example a legal guardian, who may consent to proposed treatment on behalf of the patient. These are broad points only and further professional advice may be needed for different state and territory legislation governing these examples, or where there are conflicting views between parents or the patient and parent/guardian.

11 Duration of informed consent

Gaining a patient's consent to treatment is not a 'one-off' activity when the patient first visits the osteopath'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 or management. Informed consent remains valid until it is withdrawn by the patient.

12 The role of the Osteopathy Board of Australia

All osteopaths practising in Australia must be registered with the Board.

The primary role of the Board is to protect the public by ensuring that only osteopathy practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered.

The Board can investigate concerns about the professional conduct, performance, and/or health of registered osteopathy practitioners[1]. It can also take a range of actions to protect the public.

In cases of serious unprofessional conduct, the Board has the power to suspend a practitioner's registration and/or refer a matter to a tribunal or court, where a practitioner's registration may be cancelled. In cases involving allegations of less serious unprofessional conduct, the Board has the power to impose conditions on the osteopath's registration, require the osteopathy practitioner to undergo counselling, supervision, undertake further education, caution the practitioner or accept an undertaking from the practitioner.

These guidelines can be used in proceedings under the National Law as evidence of what constitutes professional conduct or practice for osteopathy under Section 41 of the National Law.

13. Review

These guidelines will take effect on 10 April 2013. The Board will review these guidelines at least every three years.

[1] *Except in NSW, which has a co-regulatory system where notifications are handled by the NSW Health Care Complaints Commission and the Osteopathy Council of New South Wales*

Attachment A

Extract of relevant provisions from the Health Practitioner Regulation National Law, as in force in each state and territory

Division 3 Registration standards and codes and guidelines

39 Codes and guidelines

A National Board may develop and approve codes and guidelines—

(a) to provide guidance to the health practitioners it registers; and

(b) about other matters relevant to the exercise of its functions.

Example: A National Board may develop guidelines about the advertising of regulated health services by health practitioners registered by the Board or other persons for the purposes of section 133.

40 Consultation about registration standards, codes and guidelines

(1) If a National Board develops a registration standard or a code or guideline, it must ensure there is wide-ranging consultation about its content.

(2) A contravention of subsection (1) does not invalidate a registration standard, code or guideline.

(3) The following must be published on a National Board's website—

(a) a registration standard developed by the Board and approved by the Ministerial Council;

(b) a code or guideline approved by the National Board.

(4) An approved registration standard or a code or guideline takes effect—

(a) on the day it is published on the National Board's website; or

(b) if a later day is stated in the registration standard, code or guideline, on that day.

41 Use of registration standards, codes or guidelines in disciplinary proceedings

An approved registration standard for a health profession, or a code or guideline approved by a National Board, is admissible in proceedings under this Law or a law of a co-regulatory jurisdiction against a health practitioner registered by the Board as evidence of what constitutes appropriate professional conduct or practice for the health profession.