Risk Management for Chiropractors and Osteopaths: Informed Consent. A Common Law Requirement.

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Abstract

Obtaining the informed consent of a patient before undertaking chiropractic or osteopathic treatment is a common law requirement in Australia. This paper outlines the essential elements of informed consent and provides some practice tips on streamlining the process.

What is informed consent?

If a health professional treats a patient without the patient's consent, or without the consent of someone lawfully authorised to consent on behalf of the patient, such as a parent or a guardian, or without other lawful justification, such as an emergency, then the patient may sue the practitioner[1].

This section will discuss not just 'consent' but what 'informed consent' means.

Informed consent is the process by which a fully informed patient can participate in choices about his or her health care. It originates from the legal and ethical right the patient has to direct what happens to their body, and from the ethical duty of the practitioner to involve the patient in his or her health care. In Australia, to consent or refuse treatment is a fundamental common law right of the patient[2-8].

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What are the essential elements of full informed consent?

The most important goal of informed consent is that the patient has an opportunity to be an informed participant in his or her health care decisions. It is generally accepted that complete informed consent includes a discussion of the following elements:

1. The symptoms being treated;
2. The nature of the decision/procedure;
3. Reasonable alternatives to the proposed intervention;
4. That the treatment may not be successful;
5. The relevant risks, benefits, and uncertainties related to the treatment offered and each alternative;
6. Assessment of patient understanding;
7. The acceptance of the intervention by the patient.

In order for the patient's consent to be valid, he or she must be considered competent to make the decision at hand and his or her consent must be voluntary. It is easy for coercive situations to arise in health care. Patients may often feel powerless and vulnerable[9]. Laypeople always stand in danger of being disempowered by expert professionals, to the extent that the professionals' claim to expertise is through their ownership of technical skills and expert knowledge which are seen as superior (as well as different from) the skills and knowledge of the layperson[10]. To encourage the voluntary nature of the transaction, the practitioner should make clear to the patient that he or she is participating in a decision, not merely signing a form or giving verbal agreement. Offering the patient relevant alternatives to the proposed intervention facilitates the participation of decision making.

With this understanding, the informed consent process should be seen as an invitation to the patient to participate in their health care decisions. The practitioner is also generally obligated to provide a recommendation and share their reasoning process with the patient. Comprehension on the

part of the patient is equally as important as the information provided. Consequently, the discussion should be carried on in layperson's terms and the patient's understanding should be assessed along the way.

Basic consent entails letting the patient know what you would like to do, and asking them if that will be all right. Basic consent is appropriate, for example, when performing an examination. Decisions that merit this sort of basic informed consent process require a low level of patient involvement because there is a high level of community consensus.

In the modern field of health law and bioethics, the doctrine of informed consent is about as classic a doctrine as we have. Essentially, it means that a practitioner must present the patient with alternatives, along with balanced and factual information about the pros and cons of the alternatives, and then proceed with the option that the patient selects. In theory, there is always an alternative: Even where there is only one recognised treatment or approach, the patient may choose to do nothing.

How much information is considered 'adequate'?

How do you know when you have said enough about a certain decision? Most of the literature and law in this area suggest one of three approaches:

1. **Reasonable practitioner standard:** what would a typical practitioner say about this intervention? This standard allows the practitioner to determine what information is appropriate to disclose. However, it is probably not enough, since most research in this area shows that the typical practitioner tells the patient very little[11,12]. This standard is also generally considered inconsistent with the goals of informed consent, as the focus is on what the practitioner thinks the patient needs to know, rather than on what the patient actually needs to know.

2. **Reasonable patient standard:** what would the average patient need to know in order to be an informed participant in the decision? This standard focuses on considering all that a patient would need to know in order to understand the decision at hand.

3. **Subjective standard:** what would this patient need to know and understand in order to make an informed decision? This standard is the most challenging to incorporate into practice, since it requires tailoring information to each patient.

What sorts of interventions require informed consent?

Most tertiary health care institutions have policies that state which health interventions require a signed consent form. For example, surgery, anaesthesia, and other invasive procedures are usually in this category. When used well such signed forms are the culmination of a dialogue required to foster the patient's informed participation in the clinical decision.

For a wide range of decisions, written consent is neither required nor necessary, but some meaningful discussion is needed. For instance, a patient contemplating having an x-ray should know the relevant arguments for and against this test, discussed in lay terms.

In a chiropractic or osteopathic setting, procedures that have potential to cause harm other than temporary nuisance pain should be included in the consent process. For example, mild pain after a soft tissue technique does not usually constitute a significant adverse event, however pain and disability after lumbar spine manipulation does. Another example that requires informed consent is the application of any physical therapy apparatus using electricity. Modalities such as ultrasound, interferential, high voltage galvanism and the like can potentially cause burns and even electrocution.

When is it appropriate to question a patient's ability to participate in decision making?

In most cases, it is clear whether or not patients are competent to make their own decisions. Occasionally, it is not so clear. Patients are under an unusual amount of stress during a painful illness and can experience anxiety, fear and depression. The stress associated with illness should not necessarily preclude one from participating in one's own care. However, precautions should be taken to ensure the patient does have the capacity to make good decisions. For instance, has a patient ever said to you 'I don't care what you do, just fix it! This sort of statement is a red flag or danger sign to future litigation.

There are several different standards of decision making capacity. Generally you should assess the patient's ability to:

1. Understand his or her situation;
2. Understand the risks associated with the decision at hand and;
3. Communicate a decision based on that understanding.

When this is unclear, or a patient refuses a treatment, it does not in itself mean the patient is incompetent. Competent patients have the right to refuse treatment, even if those treatments seem simple procedures with low risk. Treatment refusal may, however, be a flag to pursue further the patient's beliefs and understanding about the decision, as well as your own. This exploration of patient values is an essential element of modern evidence-based practice[13].

What should occur if the patient can not give informed consent?

If the patient is determined to be incapacitated/incompetent to make health care decisions, a surrogate decision maker must speak for them. There is a specific hierarchy of appropriate decision makers defined by law, eg a parent of a minor under the age of 18. If a patient is under 18 a legal guardian should sign.

What you need to know about the current state of law in Australia regarding informed consent.

Rogers -v- Whitaker[14] was decided by the High Court of Australia on the 19th November 1992. The case concerned a patient who undertook elective ophthalmic surgery to the right eye. The patient was blind in the right eye and the elective surgery was largely cosmetic in nature to that eye. When considering whether to have the surgery, the patient questioned her doctor closely about possible complications, including possible damage to her left eye. There was a remote risk, of which she was not told, that the operation to the right eye could affect her left eye. The risk eventuated. She was left totally blind. She brought an action for negligence on the basis of a failure to warn. She succeeded at trial, and in the Court of Appeal of New South Wales, and in the High Court. None of the judges who considered the matter found in favour of the doctor. The principal issue was whether the doctor should have informed the patient of the risk. The surgery was elective. The outcome was catastrophic.

In *Rogers -v- Whitaker* , the High Court was sympathetic to the need for patients to be properly informed in order to make their own medical decisions. The Court's decision was virtually unanimous with five judges delivering a joint judgment (only six heard the case). They were determined that the patient's desire for information should be the determinant in deciding what risks were material.

The state of the law after *Rogers -v- Whitaker* is:

The law recognises that a doctor has a legal duty to inform and warn a patient of a material risk inherent in the proposed treatment before the patient consents to undergo a medical procedure.

A risk is material if -

(a) in the circumstances of a particular case, a reasonable [or ordinary] person in the patient's position, if warned of the risk, would be likely to attach significance to it ('the objective limb'); or

(b) the medical practitioner is, or should be, reasonably aware that the particular patient, if warned of the risk, would be likely to attach significance to it ('the subjective limb').

It is important to note that under both limbs of the test, the words "likely to attach significance to it", occur and in assessing those matters the extent or severity of potential injury and the likelihood of it coming to pass, are inter-related and considered together. A slight risk of serious harm might satisfy the test, while a greater risk of a small harm might not. Or, to put it another way, there will be duty to warn of a slight risk of catastrophic harm, but there may not be a duty to warn of a moderate risk of negligible harm (unless, of course, the patient communicated to the practitioner the patient's concerns about the negligible harm)[6].

By way of example, a chiropractor or osteopath wishes to carry out cervical manipulation in a patient with neck pain. It may not be necessary to warn the patient that they may have some short term minor discomfort in an area treated, but it is necessary to warn of disc damage, stroke, death, quadriplegia and sequelae of this nature even though the risk is low. The same would go for possible complications of thoracic and lumbar manipulation such as impotence, loss of bowel and bladder function and broken ribs.

As time has passed since *Rogers -v- Whitaker*, the Courts have become more skeptical, especially when assessing causation. If informed of the risk, would the patient have refused the procedure and therefore not suffered the injury? The test for causation is subjective in Australia, that is, determined by reference to what the *actual patient* would have done- not a 'reasonable' patient[15].

In *Rosenberg v Percivel*[16] Chief Justice Gleeson observed that:

> 'In the way in which litigation proceeds, the conduct of the parties is seen through the prism of hindsight. A foreseeable risk has eventuated, and harm has resulted.

> The particular risk has become the focus of attention. But at the time of the allegedly tortious conduct, there may have been no reason to single it out from a number of adverse contingencies, or to attach to it the significance it later assumed.'

Since *Rogers -v- Whitaker*, the Courts have expressed changing expectations for the behaviour of patients and doctors. While the pendulum may be swinging back towards the health professions, the message is that the patient needs to be informed of all material risks prior to undergoing treatment.

Is it necessary to have patients sign a consent form?

It is not strictly necessary to have a written consent form, but informed consent must still be obtained. From a practical point of view, if a patient sues, you the defendant professional will have little or no independent recollection of giving any particular warning to a patient, whereas a patient will almost inevitably claim to have a clear recollection[5]. For this reason, it is necessary for a health professional who does not use informed consent form(s) to keep comprehensive and clear notes about what was said[5]. This is likely to be time-consuming and fraught with errors. In addition, this process is likely to take longer than using some special purpose forms. It is not enough to just record in the notes "Patient advised of risks" or "informed consent given", or indeed even a form that is signed by the patient that says they have been advised of the risks and have accepted them.

Therefore, the use of special and comprehensive forms is recommended. It should be noted that it is virtually impossible to cover all pertinent and material risks in one form for all body areas.

The practitioner should complete the form during the consultation and before the decision to undergo the procedure is made. While the patient can read the form in the waiting room, the practitioner who will undertake the intervention procedure must witness it. If there is a trial arising from litigation, the practitioner will have actual knowledge of the consent being obtained and will be able to give evidence of it. Also, having the practitioner witness the consent removes the problem of finding the witness to the document at some later time when the witness might have left the practitioner's employ and moved elsewhere.

In the case of written consent, after complying with all of the elements of informed consent listed above and before the patient signs, the practitioner should ask the patient; a) Did you read the consent form? b) Do you understand it? c) Do you have any questions?

If the practitioner has any doubt whatsoever about the informed consent process they should seek independent legal advice. In addition the Chiropractic & Osteopathic College of Australasia provides a risk management module on informed consent, which provides model consent forms for use by practitioners[17].

Conclusion

In summary, obtaining informed consent is a common law requirement in Australia before undertaking chiropractic or osteopathic manual therapy, or indeed any other treatment with potential risk. Chiropractors and osteopaths cannot continue to ignore that written informed consent is an essential part of modern day practice and are encouraged to review this process.

Acknowledgments

The authors would like to thank Michael El Moussalli BAppSc (Chiro), FACCS, LLB, for his review of this paper.

References

1. Skene L. Law and Medical Practice - Rights Duties, Claims and Defences. Butterworths, Australia, 1998:38.
2. Benjamin DM. Informed Consent. 1996 [Online] Available: http://www.channel1.com/users/medlaw/prm/informed.htm Accessed: June 1, 2004.
3. Edwards KA. 1998, Ethics in Medicine: Informed Consent. University of Washington, [Online] Available: http://eduserv.hscer.washington.edu/bioethics/topics/consent.html Accessed: June 1, 2004.
4. Mehlman MJ. 1999, Informed Consent. [Online] Available: http://www.thedoctorwillseeyounow.com/articles/bioethics/consent_3/ Accessed: June 1, 2004.
5. Merz JF. 2002, An Empirical Analysis of the Medical Informed Consent Doctorine: Search for a 'Standard' of Disclosure. [Online] Available: http://www.fplc.edu/RISK/vol2/winter/merz.htm Accessed: June 1, 2004.
6. Pope M. 2002, Written advice brief from barrister assisting COCA on the issue of informed consent.
7. American Medical Association, Office of the General Counsel, Division of Health Law, 1998; Informed Consent. AMA, [Online] Available: http://www.ama-assn.org/ama/pub/category/4608.html Accessed: June 1, 2004.
8. Hartley M. The law of patient consent. Its relevance to chiropractors and osteopaths. Australasian Chiro Osteo 1996; 5(1):8-11.
9. Doehring C. Power dynamics in pastoral care and counseling, Chapter 4, In: Taking care. Abingdon Press: Nashville, TN, 1995.
10. Mitchell A, Cormack M. The therapeutic relationship in complementary healthcare. Edinburgh: Churchill Livingstone 1998: 111.
11. Meryn S. Improving doctor-patient communication. Not an option but a necessity. Br Med J. 1998; 316:1922.

12. Beckman HB, Markakis KM, Suchman AL, Frankel RM. The doctor-patient relationship and malpractice: Lessons from plaintiff depositions. Arch Intern Med. 1994; 154:1365-70.
13. Haynes RB, Devereaux PJ, Guyatt GH. Clinical expertise in the era of evidence-based medicine and patient choice. ACP J Club 2002; 136(2):A11-4.
14. *Rogers -v- Whitaker* (1992) 175 CLR 479.
15. Skene L. Doctor's duty to inform: debates pre- and post Rogers v Whitaker: swings, roundabouts and pendulums. Health Law Bulletin 2002; 11(3):33-6.
16. *Rosenberg v Percival* [2001] HCA 18
17. Chiropractic & Osteopathic College of Australasia 2004, [online] http://www.coca.com.au/default.htm Accessed June 1, 2004.