The creation of an informed consent form for osteopaths in clinical practice using a consensus process

NCOR Exeter Research Hub

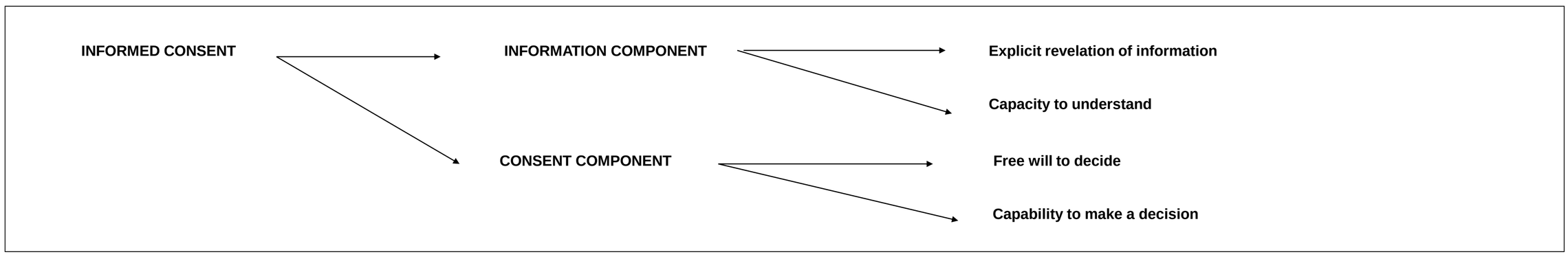
Authors: Fawkes CA, Adams L, Bartlett L, Brierley M, Bury C, Doddrell J, Farwell S, Hands P, Oldham J, Peers C, Spencer P, Welford S.

Introduction

Informed consent is believed to be a relatively new response to growing biotechnological and treatment interventions. Documentation from Greek and Roman periods has been identified that shows the need for patient approval before the intervention of a doctor[1]. The introduction of Fitness to Practise guidelines by the General Osteopathic Council[2] underlined the importance of informed consent within osteopathic practice. A number of osteopaths had started to create their own versions of consent forms and the Exeter research group has examined the literature surrounding consent to create a consensus document that could be helpful to members of the osteopathic profession wishing to use a consent form.

What is informed consent?

Informed consent may be described as ”the voluntary and revocable agreement of a competent individual to participate in a therapeutic or research procedure, based on an adequate understanding of its nature, purpose and implications”[3]. The importance of consent was raised following the revelation of experimental atrocities during the Nuremberg trials in 1945. The components of informed consent can be described in the following way:



Methods

A literature search was undertaken. This examined literature from a variety of health care professions and concentrated on consent associated with clinical practice rather than consent related to research. A number of different electronic databases were accessed including PubMed, AMED, CINAHL, PEDro and OSTMED. Hand-searching of paper copies of the British Osteopathic Journal and the Journal of Osteopathic Medicine was also carried out. Attention was paid to the development of consent forms in other health care professions and the recommendations for key information that should be disclosed as part of the consent process. Members of the Exeter research hub also brought along existing consent forms they used in clinical practice. A draft consent form was created by the hub; this was piloted among the group, refined and then further refined following group discussion[4]. A final version of the consent form was created and is shown below in the results section.

Results

A series of draft consent forms were created and piloted. A completed consent form was created and is shown below.

A consent form for osteopathic practice

What is osteopathy?
Osteopathy is an established system of diagnosis and hands on treatment in which a caring approach to the patient and attention to individual needs are of primary importance. In particular, it is concerned with the inter-relationship between the structure of the body – its muscles, ligaments and joints – and the manner in which the body functions. Osteopathy is a means of detecting and treating damaged parts of the body including those affecting the neuro-musculoskeletal systems.

What should I expect to happen at my first visit to an osteopath?
Your osteopath should make you feel at ease during your first consultation and any subsequent appointments and tell you what is happening throughout. You should feel free to ask questions at any point during the consultation. It is quite acceptable to bring a friend or relative along to the consultation if you prefer to do so. An adult or appointed representative should desirably be present with a patient who is 16 years or younger.

On your first visit, and before examination begins, the osteopath will discuss and record your current and past medical history in detail. It is essential that you inform your osteopath about any health condition or medication that is not discussed during the case history taking process e.g. if you experience fits, have a pacemaker or other electrical implants fitted, if you suffer unaccountable double vision, vomiting or dizziness or have difficulty swallowing. Equally you should inform your osteopath if you are receiving treatment or taking medication for other conditions, particularly diabetes, cancer, osteoporosis, asthma or clotting disorders.

As the consultation progresses, you will then normally be asked to remove some of your clothing so that a series of observations and biomechanical assessments can be made to attempt to identify points of weakness or excessive strain throughout the body. You should ask questions if you have any concerns or discomfort during treatment, and also tell you osteopath if you are not comfortable with certain forms of osteopathic treatment or do not wish to receive other forms of treatment that may be available within the practice e.g. acupuncture.

Is osteopathy safe?
Osteopathy is generally very safe. Osteopaths undergo a long period of training and are regulated by the General Osteopathic Council (www.osteopathy.org.uk). Training prepares osteopaths to examine and screen for potential difficulties that indicate where certain techniques should not be used, thereby avoiding patients being exposed to unnecessary risk. Serious side effects are rare – they have been reported as occurring in between 1 in 400,000 to 1 in 5,85 million patients undergoing cervical spine manipulation. Many patients attending osteopaths for treatment are currently taking non-steroidal anti-inflammatories, an estimated risk of serious side effects for this type of medication (e.g. gastro-intestinal ulcer or death) has, by comparison, been estimated by some researchers to affect 1 in 1000 patients.

What responses can I expect to osteopathic treatment?
Many patients consult osteopaths looking for relief from painful symptoms; some patients experience some initial aching for 24 to 48 hours after treatment but then start to gain relief from their symptoms. Research has been undertaken to look at common responses to manual therapy treatment and this has shown that local discomfort, tiredness, headache or stiffness can occur after treatment in approximately 10-20% patients.

In certain circumstances, further investigations may be suggested which could include an x-ray or blood test. This will allow a full diagnosis of the problem to be made and will enable the osteopath to tailor a treatment plan to your needs. If further medical treatment is needed the osteopath may contact your doctor, with your permission.

I hereby consent to – insert osteopath’s or practice name - to contact my general practitioner, either verbally or in writing, which may involve releasing details of medical information, notes held and/or treatment received at the practice.

GP’s name……..
Surgery ……
Patient’s or guardian’s signature……
Date……

Statement of Consent for adult patients

I confirm that I have read the above information; I confirm that I have had the opportunity to discuss any concerns with the osteopath and have understood what has been explained to me. I consent to receive osteopathic treatment on this occasion, but I understand that I can refuse treatment (or any part of treatment) now or in the future without jeopardising future treatment at this practice. I understand that it is important that I inform my osteopath of any concerns, reactions or discomfort associated with treatment. I understand that I can also request to see another practitioner at this practice (not applicable to single practitioner practices).

Signature ……
Print name in full…… Date……

Statement of Consent for patients aged 16 years or younger

I confirm that I have read and understood the above information, and I consent, as parent, guardian or appointed carer to this patient receiving osteopathic treatment at this time. I understand that they can refuse treatment (or any part of treatment) at any time in the future without jeopardising future treatment at this practice.

Signature……
Print name in full …… Date ……..

What information was identified to be commonly disclosed as part of the informed consent process?

A considerable volume of information now exists concerning what is needed to meet the key requirements of informed consent. This information includes:

- The diagnosis, prognosis and likely prognosis if a condition is left untreated.
- Any uncertainty concerning the diagnosis and further investigations required.
- Management strategies that could be adopted including the possibility of no treatment.
- The proposed techniques to be used in diagnosis and treatment, both osteopathic and adjunctive e.g. acupuncture, heat or ice.
- The intended benefit s of the diagnostic and treatment interventions in balance with the potential risks[5].
- How and when the progress of treatment will be evaluated and re-evaluated. This should include information concerning how side-effects will be monitored and dealt with should they arise.
- Whether any students will be present during the consultation.
- A reminder that patients can change their mind about treatment at any time in the future.
- The costs and any additional charges a patient will have to meet.

Conclusion

The consent form designed in this study is not intended to be prescriptive in any way. It should never be forgotten that **consent is an ongoing process** and completion of a consent form as an isolated event, in the absence of suitable information, completely invalidates the process. Good communication skills and concern for the safety and wellbeing of patients underpins the process of gaining ongoing and valid consent: these qualities have traditionally been at the heart of osteopathic practice.

References:

1. Mallardi V. The origin of informed consent. *Acta Otorhinolaryngol Ital*. 2005;25(5):312-27.
2. *General Osteopathic Council Code of Practise*, May 2005.
3. Sim J. Informed consent: ethical implications for physiotherapy. *Physiotherapy*. 1986;72:584-7
4. Fardy HJ, Jeffs D. Focus groups: a method for developing consensus guidelines in general practice. *Fam Pract*. 1994;11(3):325-9
5. Gibbons P, Tehan P. HVLA thrust techniques: what are the risks? *International Journal of Osteopathic Medicine.* 2006;9(1):4-12