



# **Communicating risks of treatment and informed consent in osteopathic practice**

A literature review and pilot focus groups



September 2011

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Editor: Janine Leach

Funding: This project was funded by the General Osteopathic Council

Acknowledgements: The author is grateful for the advice from all members of the Research Team, the Steering Group and Advisors for the project, and to the staff and patients at the College of Osteopaths who participated in the study

*Risk is not just about numbers*

## **Executive Summary**

Patient safety is a priority for responsible healthcare professionals, as it is for Government, healthcare providers and regulators. This project was initiated to provide guidance to osteopaths on good practice relating to communicating to patients about any risks of treatment.

The study aimed to address three research questions:

- *What are the most effective ways of communicating risk of adverse effects to patients in the context of osteopathic practice?*
- *What constitutes good practice when seeking informed consent from patients for osteopathic care?*
- *What should osteopaths be aware of in order to understand clinical risk effectively?*

The evidence was gathered through a wide-ranging literature review and narrative synthesis of the findings, drawing out the points of particular relevance for osteopathic practice. Some information material on risks and benefits in osteopathic practice was drafted, based on the recommendations in the literature. This was pilot tested in two focus groups of osteopaths and osteopathic patients.

### **Risks and benefits of osteopathic care**

An essential first stage for the project was to define the risks that osteopaths may need to communicate. This is presented in Chapter 2. The data was drawn mainly from the first NCOR Adverse Events Project (NCOR1), which has since been published (Carnes, Mars et al. 2010).

The inherent risks of osteopathy that need to be communicated are two-fold:

- The risk of mild effects such as a short-term increase in pain or stiffness lasting a few days is high: many patients experience these effects.
- The risk of serious effects, such as damage to nerves or arteries is very low occurring, less frequently than 7-10 in 100,000 treatments.

For musculoskeletal pain, manipulation is comparable in risk to other types of treatment such as exercise or analgesic drugs, and less risky than prolonged use of analgesics.

The risks need to be set alongside the benefits of the manipulation:

- For back pain, manipulation is likely to reduce the level of pain by about 30%.
- For neck pain, manipulation or mobilisation may give immediate or short term relief of pain, especially if combined with exercises.
- Manipulation is equivalent in effect to appropriate medication, acupuncture, and some combined treatments, so patients can choose which they prefer.

No review on the magnitude of the benefits of osteopathic care has been conducted and such a review was outside the scope of this study. The benefits of osteopathy were estimated from recent osteopathic research and research in chiropractic and manipulative medicine.

### **Understanding lay perceptions of risk**

Understanding of how lay people *perceive* risk, summarised in Chapter 3, not only under-pins later research on effective *communication* of risk but is also essential knowledge for osteopaths in order to be aware of how their patients may perceive risk. In summary:

- Lay perception of risk is highly personal and emotional, as well as logical.
- The information will not be communicated (i.e. received, understood, and accepted) unless a trusting relationship has been established.
- Every aspect of the message shapes its emotional impact. These aspects include the words, images (colour, shapes, symbols), and body language.

- The size of the risk needs to be conveyed in both numbers and words. Although people want to be informed about risk, the information is not easily comprehended even by well-educated recipients.
- Very small risks tend to be over-estimated ('amplified') by lay people.
- Risks need to be discussed in the context of the patient's beliefs and values, and benefits also need to be considered.

### **Effective communication of risk in a clinical consultation**

The evidence presented in Chapter 4 addresses the first research question of the project. A systematic search of the literature showed that this area of research within healthcare was extensive and well reviewed: the evidence was drawn primarily from the best expert reviews, focussing on health interventions which were analogous to most osteopathic care in being an active treatment and not screening or prevention, for health conditions that are disabling but not life-threatening. The recommendations as consistently stated by the experts were:

- Discuss risk in a context that conveys competence and care, and engenders trust.
- Present the risks alongside the benefits.
- Present the risks and benefits in both numbers and words.
- Present a range of information in different formats to suit different people.
- Frame the risk in a positive way (x out of N people have **no** side effects) *and* in a negative way (y out of N people **will** suffer side effects).
- Present absolute numbers where possible (e.g. 1 in 10,000). Do not use relative risk (e.g. A is 3 times more risky than B) or percentages.
- Use visual aids to assist understanding and encourage discussion. Make them consistent, and use non-threatening colours, symbols and wording.
- Personalise the message, drawing on your own experiences and the patient's own risk factors, if any.
- Be honest about what we know and do not know; convey uncertainty.
- Explore people's understanding, reactions and opinions about the risk information.

## **Informed consent, shared decision-making and practitioners' communication skills**

Chapters 5 and 6 present the evidence relating to the second research question: good practice when seeking informed consent from patients for osteopathic care.

Chapter 5 presents the main current principles and Chapter 6 presents the limited research relating to communicating and achieving shared decision-making in vulnerable and minority groups. The findings were:

- For consent to be valid, the patient needs to be competent to make the decision and to understand the information given, whatever their age, disabilities, and cultural background.
- Patients must give consent voluntarily without feeling under pressure to make their decision.
- Consent is an ongoing process during treatment, not a one-off event.
- The emphasis for consent has shifted from disclosing information to *sharing* information.
- Partnership and shared decision-making (SDM) are now foremost in the consent process.
- Ethically, patients have a right to understand what is happening to them- their illness, their prognosis and their treatment options, even if they do not wish to participate in treatment decisions.
- Patients generally want more information than they receive from their clinicians.
- A leaflet is helpful but not sufficient because information needs to be explained and personalised.
- Clinicians may need to enhance their communication skills in order to communicate effectively with patients about risks: they need skills in active listening, simplifying complex information, empathy, facilitation and negotiation.
- Special measures may be required to assist when a patient's comprehension or communication is limited, for e.g. due to lack of education, language barriers or mental disability. Interpreters or pictorial aids may be helpful in some settings but research is limited. More research is needed in these specialist areas of communication before firm evidence-based recommendations can be made.

### **What should osteopaths be aware of in order to understand clinical risk effectively?**

In order to understand clinical risk, osteopaths need to be aware of the nature and frequency of mild, moderate and serious risks of treatment, as summarised in Chapter 2. They also need to be aware of the uncertainty inherent in those statistics. An understanding by osteopaths of lay perceptions of risk (Chapter 3) is vital in order to ensure that their verbal communication is sensitive to fright factors and the difficulties of comprehending the size of the risk in an objective sense. The new primary data from the focus groups (Chapter 7) provided a preliminary insight into the attitudes of osteopathic patients, which appeared very consistent with the research evidence in previous chapters. Some key messages relevant to practice were:

- Communicating risk *prior* to the osteopathic consultation is not good practice; a trusting relationship needs to be established first.
- The clinician's role is to discuss and personalise the formal message (as given to the patient in words, numbers and graphically) by drawing on their own experience and knowledge of the patient's own risk factors.
- In the osteopathic context, patients may feel vulnerable when undressed or lying down. Discussion needs to take place when the patient is appropriately dressed and seated to permit eye contact.
- Clinicians may wish to make a record in the case-notes of the nature of the personalised information they have given to the patient.
- Patients welcomed being given clear information on risks and benefits. This finding needs to be confirmed in a larger patient sample.
- Information on the broad treatment options available in the clinic was welcomed as helpful for new patients and those seeing a new practitioner. This finding needs to be confirmed in a larger patient sample.
- Implementation of shared decision-making in osteopathic practice is challenging and requires changes in practice routine and timing. Osteopaths will also need to be prepared to undertake additional skills training in this area.

## **Recommendations for further research**

Further work is recommended to take this work to build on the foundation established through this project.

1. The most pressing need is for further investigation of the views of osteopathic patients in relation to communicating risks and benefits. Further focus groups are recommended.
2. A systematic review of the benefits of osteopathy is needed, analogous to the review by Carnes et al on risks in osteopathy.
3. Research is needed to develop nationally-agreed information materials and guidance for osteopaths, using an inclusive process that allows all sectors of the profession to take part in the development.
4. Research is needed to understand the needs and improve communication with minority groups within the patient population.
5. Research is needed to evaluate any new information material and guidance for widespread use in routine practice.
6. Evidence-based materials for teaching communication skills for shared decision-making need to be developed for practitioners.
7. Future research could undertake the development and evaluation of decision aids for personalising the risk according to the patient's age, gender, and other risk factors.



## **Chapter 1 Background to the project**

### ***Aim and context of proposed research***

This study is one of four pieces of work commissioned by the General Osteopathic Council (GOsC) and developed and coordinated by the National Council for Osteopathic Research (NCOR) relating to adverse events associated with osteopathic care. The ‘Adverse Events’ projects were funded by the General Osteopathic Council, the statutory regulator, in the interests of patient safety. The right of patients to be informed of any known risks associated with the proposed interventions, before consenting to care, is specified in the GOsC Code of Practice for osteopaths.

The primary aim of this study was to review and summarise existing knowledge in order to inform osteopaths on the answers to three questions:

- 1. What are the most effective ways of communicating risk of adverse effects to patients in the context of osteopathic practice?**
- 2. What constitutes good practice when seeking informed consent from patients for osteopathic care?**
- 3. What should osteopaths be aware of in order to understand clinical risk effectively?**

### ***The purpose of the project***

The purpose of the project was to draw together existing knowledge about communicating risk within a healthcare consultation, in order to assist osteopaths in practice and to inform practitioner guidelines for communicating the risks of osteopathic treatment.

At the start of this project, little profession-specific guidance existed to help osteopaths to understand or communicate the current evidence about the risks and benefits of treatment in order to obtain informed consent. When the General Osteopathic Council issued a revised

Code of Practice for osteopaths in 2005 (General Osteopathic Council 2005), it introduced a new clause (Clause 20) which made the requirement more explicit: “*You should not only explain the usual inherent risks associated with the particular treatment but also any low risks of seriously debilitating outcomes*”.

Correspondence in the professional journal, *Osteopathy Today* produced by the professional body, the British Osteopathic Association (BOA), suggested that osteopaths found Clause 20 of the Code of Practice difficult to interpret and implement. Guidance was produced by the BOA (Chorley 2008). Two surveys of registered osteopaths in the UK (Leach and Goodyear 2009) showed that compliance in practice was low. The first survey (in 2006) was conducted by the European School of Osteopathy (ESO) undergraduate Lynne Beckley (Beckley 2008). A questionnaire was sent by post to a random sample of 10% of osteopaths on the UK Statutory Register. Over 200 osteopaths (56% of the sample) responded. Only 7% of respondents communicated the risks at each treatment session and one-third reported having had a technique refused as a result of explaining the risk. The second survey (in 2009) was conducted by the British Osteopathic Association (BOA) using an email questionnaire sent to all 2,200 BOA members who were contactable by email. 459 (21%) members responded to the question relating to Clause 20: 29% of respondents reported they did not fully understand Clause 20. 23% of respondents were fully implementing the clause in practice.

The legal experts on the Project Steering Group (see Appendix 1) advised on the meaning of the terms within Clause 20. They emphasised that the risk of *serious* consequences *must* be communicated, even if the probability of harm is negligibly small. Secondly, the meaning of the words “inherent risks” within Clause 20 was clarified. Inherent risks are those that cannot be fully predicted or foreseen and may be outside of the control of the practitioner. Such risks are present in any therapy, however “natural” the therapy e.g. the lowering of blood pressure, emotional release, and aggravation of symptoms after the session. Common inherent risks of manual therapy include mild, transient pain or stiffness. There are also rare inherent risks such as stroke following neck manipulation. While practitioners may be able to minimise such risks through their assessment of the patient, such events are not wholly predictable. In contrast to inherent risks, some risks are avoidable: for example a broken rib due to inappropriate use of force for the specific patient. Such an event could be considered as due to negligence.

The Research Team commissioned to undertake this project (Appendix 1) comprised researchers with a range of expertise, including risks within osteopathy (Leach 2006), communication within healthcare consultations (Mandy and Gard 2000; Mandy, Lucas et al. 2003), training in communication (Cross, Moore et al. 2004), and communication with patients (Marteau, Hankins et al. 2002; Horne, Graupner et al. 2004; Michie, Thompson et al. 2004; Wright, Whitwell et al. 2009; Mann, Kellar et al. 2010).

### ***Methodologies chosen for this study***

In order to answer the research questions, two types of data were gathered. Firstly, the existing evidence about communicating risk about adverse effects in clinical practice was reviewed. A narrative synthesis of the literature was chosen as the methodology since this permits inclusion of information from both research literature and grey literature, such as consensus guidelines and professional journals (Greenhalgh, Robert et al. 2005; Dixon-Woods, Cavers et al. 2006; Rodgers, Arai et al. 2006). This methodology starts with a systematic search of literature, filtering of studies based on inclusion criteria, and development of preliminary theories. It permits the studies to be grouped conceptually, and then assessed for quality before the final synthesis.

In order to be able to draw out indicators for good practice for osteopaths, the second part of the study used focus group interviews with patients and osteopaths as a preliminary test of the guidance which emerged from the literature about communication of risk and obtaining informed consent. Views on suitability and feasibility of a range of materials were collected from a small sample of patients and osteopaths. The views expressed by users will inform the dissemination of the materials generated by this study.

The search strategy has been recognised as difficult for this diffuse topic, and is a trade-off between precision and comprehensiveness (Matthews, Edwards et al. 1999), with only a few percent of the papers retrieved being relevant. The search results are given in detail in Appendix 2, including the sources used, the number of papers found from the databases, and the number included in the review. In view of the short timescale and small resources for the

project, the highest quality papers were identified and were used as the main sources throughout the report.

### ***Conceptual grouping of the literature on communicating risk***

The topics covered in the subsequent chapters were arrived at after gathering recent research literature and several iterations of reading, extracting themes, further searching and re-reading. The topics are based on the final conceptual groupings identified from the literature as relevant to the research questions. The research questions are quite complex and cover several aspects of the topic of risk communication.

Each chapter is presented as a self-contained distinct literature review:

- Risks and benefits in osteopathy (relevant to research questions 1 and 3)
- Understanding lay perceptions of risk (relevant to research question 1)
- Effective communication of risk in a clinical consultation (relevant to research question 1)
- Informed consent, shared decision-making and communication skills for practitioners (relevant to research questions 2 and 3)
- Communicating with vulnerable and minority groups (relevant to research questions 2 and 3)
- Decision aids (relevant to research questions 2 and 3)

Each subsequent chapter ends with a list of key messages for osteopaths.

## **Chapter 2 The risks and benefits of osteopathic care**

This chapter aims to provide a summary of the findings of a number of recent published reviews of the risks and the benefits of osteopathic treatments. The risks of osteopathic care were reviewed in Project 1 of the NCOR “Adverse events” studies funded by the General Osteopathic Council. No similar review was commissioned relating to the benefits of osteopathic care. Hence, a number of recent published reviews were selected as the basis for the evidence presented in this chapter.

### ***Risks of manual treatment and manipulation***

One of the ‘Adverse Event’ projects commissioned by GOsC produced a valuable systematic review which is used here (Carnes, Mars et al. 2010). A cross-professional definition of the severity of adverse effects in musculoskeletal medicine was also produced (Carnes, Mullinger et al. 2010)

*Mild* adverse effects of osteopathic treatment are experienced by around half of all manual therapy patients after treatment, the majority of these adverse effects occurring within 24 hours after the first treatment and most resolving within 48 hours (Froud, Rajendran et al. 2008; Rajendran, Mullinger et al. 2009; Carnes, Mars et al. 2010).

*Moderate* adverse effects occur in about 1% of patients (Thiel, Bolton et al. 2007; Froud, Rajendran et al. 2008; Strutt, Shaw et al. 2008; Rajendran, Mullinger et al. 2009; Fawkes, Leach et al. 2010). These are more severe effects that last longer than a few days but do not require medical treatment (Carnes, Mullinger et al. 2010).

*Serious* adverse effects of osteopathic treatment are rarely observed. In studies following up patients after manipulative treatments, no serious adverse events were observed in over 22,000 patients and over 40,000 treatments (Carnes, Mars et al. 2010). In this systematic review, there were zero catastrophic adverse events such as stroke or death in any study, zero major adverse events in the RCTs, and 14 “unbearably severe side effects” in the prospective

studies. The risk of a major adverse event was therefore *less than 7* in 100,000 per treatment and 10 in 100,000 per patient. The results were dominated by a large prospective study of chiropractic neck manipulations which gave a very similar estimate of 6 per 100,000 neck manipulations (Thiel, Bolton et al. 2007). However, the available data are limited and other authors (Kerry, Taylor et al. 2008) are of the opinion that the size of both risks and benefits of manual therapies remain uncertain.

Osteopaths use a range of types of manual treatment; manipulation is just one option. Manipulation using high velocity thrust techniques exerts focussed forces on the spinal joints, and is considered most likely to cause serious effects (Gibbons and Tehan 2006). The two most serious complications are (i) stroke including ‘Vertebro-Basilar Accidents’ (VBA) or ‘Cervical Artery Dissections’ (CAD) caused by damage of the arteries in the neck (Kunnasmaa and Thiel 1994; Debette and Leys 2009) and (ii) the collapse of an inter-vertebral lumbar disc causing ‘cauda equina syndrome’ (Snelling 2006). The arteries in the neck are quite vulnerable and damage such as CAD *can* occur (albeit extremely rarely) during everyday activities such as accidental impacts during falls, sport or leisure; turning the head while driving; sneezing; or against the back-wash at the hairdresser. The population-based risk of stroke in those aged under 45 years is about 3 in 10,000 (Feigin, Lawes et al. 2003). Stroke is difficult to prevent and is irreversible. It is often disabling and, more rarely (5-10%), fatal (Debette and Leys 2009). Cauda equina syndrome, (characterised by symptoms such as weakness of the legs, numbness in the buttocks or incontinence) can be treated, although it may sometimes require emergency surgery.

Prevention of stroke is difficult as there is no good test for risk factors. The recommendations for clinicians (Kerry 2002; Magarey, Rebbeck et al. 2004; Thiel and Rix 2005; Gibbons and Tehan 2006; Kerry and Taylor 2009; Leach, Cross et al. 2011) are to screen patients using both history and physical tests. Clinical reasoning should depend mainly on an assessment of vascular risk factors such as smoking, hypertension, and prior headache (Kerry, Taylor et al. 2008). Cervical manipulation, high velocity low amplitude (HVLA) thrust and end-range rotation techniques should not be undertaken if there is evidence of symptoms potentially associated with a raised risk of stroke. A clinician may also assess the patient’s status in relation to the predictors of a good outcome of neck manipulation (Hill, Lewis et al. 2007; Rubinstein, Leboeuf-Yde et al. 2008).

### ***Risks of manual therapy compared to other options***

Carnes et al (2009) pooled data from 31 randomised controlled trials in which manual therapy was compared with a range of other treatment options for musculoskeletal problems. The authors grouped the other treatment options into three categories: exercise therapy; GP or usual care; and drug therapy (which mainly comprised NSAIDs or diclofenac). The risk of mild or moderate adverse events of manual therapy was similar to the risks from exercise therapy, about twice the risk associated with GP or usual care (RR=1.91, 95% CI= 1.39-2.64), and about 20 times lower than the risk from drug therapy (RR=0.05, 95% CI = 0.01-0.20). In comparison, the risk of serious gastric complications from *prolonged* use of NSAIDs may be as high as 100 in 100,000 (Stevinson and Ernst 2002).

### ***Comparable risks in daily life***

Some consideration was given to finding appropriate activities in everyday life that might be comparable to seeking a treatment for a specific problem, where the benefits are potentially great but the risks need to be considered in relation to taking the option of doing nothing.

Seeking osteopathic treatment was considered as having a number of defining characteristics:

- The health problems being treated are not life-threatening, although they may have a profound impact on quality of life; treatment may be highly desirable but is not essential for survival.
- Seeking treatment is a conscious decision, over which the person has control, so the risks are not comparable to natural disasters such as lightning and earthquakes.
- Treatment is not comparable to activities with quite high risks that people choose because they enjoy them e.g. sport or cigarette-smoking.

An everyday activity that may be considered in some ways comparable is travel. We choose to undertake travel, choosing different transport options according to need and availability,

and travel is often necessary but not essential. The risks of serious injury / death vary greatly (Moore, Derry et al. 2008; Evans and Addison 2009):

- Air and rail travel: the risk per 1000 km is about 1 in a million.
- Travel by car: the risk per passenger-kilometre is 7 per billion, and the risk per driver-kilometre is 10 per billion.

This means that for a journey of 1000 km by car, the risk is 7 per million. The risk for an average year of driving of 10,000 km is about 1 per 10 000.

### ***Benefits of manual treatment***

There is quite strong evidence of the benefits of manipulative treatment for back pain. The UK BEAM trial (UK BEAM Trial team 2004) found that spinal manipulation gave back pain sufferers a small but significant benefit at 3 and 12 months after treatment, when added to “best GP care”. Note that in this trial, “manipulation” referred to a package of osteopathic or chiropractic or physiotherapy care.

The evidence-based guidance for the NHS for back pain that has lasted for more than 6 weeks to a maximum of 13 months (NICE 2009) concluded that the evidence was strong enough to recommend a course of manual therapy from an osteopath, chiropractor or physiotherapist as an option for GPs. Acupuncture was another recommended option.

Osteopathic manipulative treatment significantly reduced back pain by 30% (95% confidence interval = 47% -13%) when six randomised controlled trials involving 525 subjects were pooled (Licciardone, Brimhall et al. 2005).

Several Cochrane systematic reviews of treatment options for pain in the cervical spine have been published. However, this evidence is weak due to a lack of high quality trials (Gross, Hoving et al. 2004; Kroeling, Gross et al. 2005; Rubinstein, Leboeuf-Yde et al. 2007; Haines, Gross et al. 2009; Gross, Miller et al. 2010). Some of these reviews found fairly good evidence that manipulation and mobilisation may improve pain, function and satisfaction at short-term and intermediate-term follow-up. There was some evidence that manipulation may



provide immediate and short-term pain relief following 1-4 sessions. There was very weak evidence that manipulation was equivalent to appropriate medication, acupuncture, and some combined treatments. There was strong evidence that a combination of exercise plus another modality was effective.

A chiropractic study of 529 patients with neck pain reported that approximately half the patients considered themselves recovered after 4 treatments, and about two-thirds had recovered at 3 months and 12 months after their first treatment.

### *Translating the scientific evidence into information for patients*

It is helpful to describe the risks in words as well as numbers (Paling 2003). The terminology needs to be consistent and standard terms have not been adopted, as interpretation of words is likely to be culture-specific and context-specific. A cross-professional consensus is likely to be needed in the future to agree standard terms for translating the osteopathic risks probabilities into words. The terms used by Paling have been adopted in this report: the 5 in 10 probability of mild adverse effects from osteopathy is a “very high” risk. The 1 in 100 probability of moderate adverse effects is a “high” risk. The probability of serious effects of osteopathy, at less than 10 in 10,000 is a “very low” risk.

It is interesting that for the purpose of communicating risk to an individual patient, personalised data are required, such as information about the proportions of patients who respond well or not so well, over time. This information is rarely reported in clinical trials, which normally report the scientific efficacy of one treatment compared to another e.g. the mean improvement in each arm of the trial. For the purposes of this study, prospective cohort studies provided more relevant information than clinical trials.

Pilot ‘standardised data’ collected prospectively on 1603 patients attending osteopaths in the UK in 2009, showed that more than 70% of patients (the majority of whom attended with back problems) considered they were improved or much improved after the first appointment (Fawkes, Leach et al. 2010) and more than 80% were improved after an average of 3-4 treatments. In a study in Plymouth, 72% patients with acute low back pain (half of whom

were off work at the inception of the study) considered they were more than 70% improved after a 6 week course of treatment. The main treatment given was spinal manipulation.

To summarise, at present the evidence needed for an informed discussion with patients about risks and benefits of manipulative treatment for back pain and neck pain exists, but is weak. Further research is urgently needed to (1) summarise existing evidence on the benefits of manual treatments (2) provide evidence on the risks associated with different types of manual techniques and (3) determine the risks and benefits of treatment for conditions other than back pain and neck pain.

## KEY MESSAGES FOR OSTEOPATHS

### **THE RISKS AND BENEFITS OF OSTEOPATHIC CARE**

- Patient safety is a priority for responsible healthcare professionals, as it is for the Government, healthcare providers and regulators.
- This project was initiated to provide guidance to osteopaths on good practice relating to communicating risks.
- The inherent risks of osteopathy that need to be communicated are two-fold:
  - The risk of mild effects such as a short-term increase in pain or stiffness lasting a few days is high. Many patients experience these effects
  - The risk of serious effects such as damage to nerves or arteries is very low, occurring less frequently than 7-10 in 100, 000 treatments
- For musculoskeletal pain, manipulation is comparable in risk to other types of treatment such as exercise or analgesic drugs, and less risky than prolonged use of analgesics
- The risks need to be set alongside the benefits of the manipulation:
  - For back pain, manipulation is likely to reduce the level of pain by approximately 30%
  - For neck pain, manipulation or mobilisation may give immediate or short term relief of pain, especially if combined with exercises.
  - Manipulation is equivalent in effect to appropriate medication, acupuncture, and some combined treatments. Patients can choose which they prefer.

## Chapter 3 Understanding lay perceptions of risk

An understanding of how the lay public perceives risk is a pre-requisite to being able to design effective messages and communications about risk. The main sources for this chapter were a Department of Health publication (Bennett and Calman 1999) and a more recent review of numeracy (Nelson, Reyna et al. 2008), plus a number of recent studies of particular relevance that emerged in the literature search.

### *The psychology of risk perception*

People react to risks *emotionally* as well as logically (Slovic, Peters et al. 2005). Some people enjoy taking risks (e.g. gambling, dangerous sports) and some people are risk-averse. Emotional undertones in the language of risk communication can affect the decisions people make (Hilton 2008). The whole design of the message, particularly colour, signal word, surround shape, and the context in which it is framed will affect the perception of the risk. (Williams and Noyes 2007).

Firstly, there are a number of '*fright factors*' that make risks seem bigger than they are (see Box 2.1). An interesting example of fright factors is provided by epidemics such as swine flu, where the fright factor of a rapidly spreading infection was amplified by media hype. The last item in Box 2.1 relates to the most important of all factors: messages are judged first and foremost by the *trust-worthiness of the source*. If the source is not trusted, the message is likely to be disregarded and may even lead to the person's belief that the opposite might be true.

**Box 2.1. The fright factors that make risks seem more worrying**

*(Bennett and Calman 1999)*

Involuntary or unavoidable (e.g. environmental pollution)

Inequitably distributed (e.g. some people suffer more than others)

Inescapable through personal action

Man-made rather than natural

Damage is hidden and irreversible (e.g. causing effects a long time after exposure)

Damaging children, pregnant women or future generations

Causing an illness that carries particular dread

Victims are identified persons rather than anonymous

Poorly understood by science

Conflicting or contradictory messages are issued by authoritative sources

Patients' *beliefs and values* also play a powerful role. Attitudes to risk depend critically on the perceived benefits (Bennett and Calman 1999) and on the wider values held by the individual. Recent research was able to correlate decisions with a utility score derived from patients' values and preferences (Nelson, Reyna et al. 2008). Information which presents bold, isolated facts about risk is likely, therefore, to be difficult to interpret because people need fuller information relating to possible benefit, value, and qualities such as enjoyment and choice. People also differ widely in their beliefs about their control over events and their desire to make their own decisions.

### ***Comprehending the size of the risk***

In order for patients to truly understand the risks posed by a particular treatment, they may require a high degree of *literacy* (Edwards and Rogers 2007) in order to read professionally produced information and a high level of *numeracy* to understand the figures presented (Reyna and Brainerd 2007). However, 22% of adults have below-basic literacy levels and even highly-educated adults (including physicians and medical students) have low numeracy levels; they have difficulty performing basic arithmetic calculations or comprehending risk estimates (Nelson, Reyna et al. 2008). This poses a challenging problem for risk communication (Reyna, Nelson et al. 2009).

Public discussion about risk contains numbers because of the low numeracy of the population generally (including clinicians) (Nelson, Reyna et al. 2008). In a quantitative study (Wright, Bolger et al. 2002), both experts (actuaries) and lay people were quite competent at comparing and ranking the risks of different events but both groups had '*scaling problems*' with risks that were very different in magnitude to those experienced on a normal basis (risks of the order of betting odds like 10 to 1, or 100 to 1). Both groups over-estimated very small risks and under-estimated very large risks. In essence people "shrink" the scale towards the mean, towards odds that they can comprehend more readily.

In 1996, the Chief Medical Officer of the Department of Health (Calman 1996) proposed a new *terminology* to improve and clarify public discussion about risks. He proposed formal terms for levels of probability such as 'negligible' for risks less than 1 per million and 'minimal' for risks less than 1 per 100 000. However, people can interpret these terms differently and modern commentators (Thomson, Edwards et al. 2005) feel that context specific terms are more appropriate. Calman (1996) also identified a number of important *dimensions* that affect how we think about risk: whether or not the risk is avoidable, justifiable in terms of possible benefit, acceptable socially and ethically, and the scale of the risk (serious or mild).

### ***Perspectives on risk***

A key aspect of the *lay perspective* is that it differs radically from a *scientific perspective*. The lay view is concerned with individuals, not the ‘average person’ or population as presented in scientific data. Ideally, risk estimates need to be personalised at least in terms of age and gender to begin to carry meaning (Edwards, Evans et al. 2006). Causality between two events is also attributed by members of the general public if the link seems intuitively reasonable, even though there may be no positive proof of a causal link in scientific terms (Bennett and Calman 1999).

The most recent research in cognitive psychology and decision-making theory (Edwards and Elwyn 2001) uses theoretical models such as the Health Belief Model, the Theory of Social Behaviour and the Prospect model to explain how an individual perceives the value and the threat posed by a given course of action. These could be applied to osteopathy in future research.

Perception of risks is complex and multi-faceted, and highly individualised. Recent research confirms that every aspect of a message affects the perception by the recipient.

## **KEY MESSAGES FOR OSTEOPATHS**

### **LAY PERCEPTIONS OF RISK**

- Lay perception of risk is highly personal, and emotional as well as logical.
- The information will not be communicated (i.e. received, understood, and accepted) unless a trusting relationship has been established.
- Communicating risk prior to the osteopathic consultation is not good practice: a trusting relationship needs to be established first.
- Every aspect of the message shapes its emotional impact: these aspects include the words, images (colour, shapes, symbols), and body language.
- The size of the risk needs to be conveyed in both numbers and words: although people want to be informed about risk, the information is not easily comprehended, even by well-educated recipients.
- Very small risks tend to be over-estimated ('amplified') by lay people.
- Risks need to be discussed in the context of the patient's beliefs and values, and benefits also need to be considered.



## Chapter 4 Effective communication of risk in a clinical consultation

This chapter represents the central topic of the project. The evidence presented here derives from a full systematic search and review of the literature (see Appendix 2). The published literature on communication of risk is extensive and was filtered using the following criteria. The research was eligible for review if it focussed on:

- a **clinical consultation**, rather than public health, legal or ethical considerations or risk management.
- a **health problem that is acute or chronic** but is not life-threatening (i.e. most papers on cancer were excluded)
- an **active treatment intervention** (not prevention or prophylaxis, or lifestyle, environment, genetics or screening).
- concerning **serious but rare risks** of treatment.
- the publication should be peer-reviewed, published in a mainstream journal, and report on original research; books or reports were included only if they were very recent.

The main sources included some highly relevant reviews such as Cochrane reviews by experts in the field (Lipkus and Hollands 1999; Edwards and Elwyn 2001; Edwards, Elwyn et al. 2001; Thomson, Edwards et al. 2005; Edwards, Evans et al. 2006; Lipkus 2007).

### *Introduction*

The research on patients' and clinicians' understanding of risk and on communicating risk effectively to patients has evolved rapidly since 1990. By the late 1990's, doctors in the UK were beginning to move towards a dialogue with the public and with patients about risk, and guidance for doctors started to appear (Department of Health 1998; Bennett and Calman 1999; Calman, Bennett et al. 1999). Professors were appointed in several universities (Edwards and Yahne 1987; Thomson, Edwards et al. 2005; Spiegelhalter 2008). Specialist

networks emerged such as the ESRC network ‘Social Contexts and Responses to Risks’ (SCARR) at University of Kent and similar developments occurred in the North America, with leading figures emerging (O’Connor, Pennie et al. 1996; Paling 2003; Epstein, Alper et al. 2004). Guidelines for clinicians were produced by UK institutions (British Heart Foundation 2005; Royal College of Physicians 2006).

The work of John Paling in the field of commerce has informed the healthcare field (Paling 2003) and forms the basis of the advice given by several clinical bodies such as Bandolier, the Royal College of Physicians and health charities (British Heart Foundation 2005).

Paling’s advice was to:

- Discuss risk in a context that conveys competence and care, and engenders trust
- Present risk in the context of benefits
- Use both words and numbers to describe risk
- Use a standard taxonomy (at least within the profession) for describing risk levels (e.g. ‘common’, ‘very common’, ‘rare’)
- Use a consistent denominator (e.g. compare 30 in 10,000 with 1 in 10,000)
- present both positive and negative outcomes e.g. compare likelihoods of having side-effects and not having side-effects; this is called ‘framing’
- Use absolute numbers where possible; do not use relative risk (such as A is 3 times more risky than B) or percentages, or numbers needed to treat (NNT)
- Use visual aids to assist understanding and encourage discussion

Useful additions to these points, drawn from a paper for the Royal College of Physicians’ journal (Thomson, Edwards et al. 2005) aiming to help clinicians to support patients in decision-making are:

- Be honest about what we know and do not know: convey uncertainty.
- Explore people’s understanding, reactions and opinions about the risk information.

Uncertainty is a difficult concept, comprising both random chance (as in tossing a coin) and uncertainty due to lack of knowledge (Speigelhalter 2008). In medical risk scenarios, there is

always lack of knowledge about the detailed risk factors that might apply when trying to estimate an individual's personalised risk. Different people also have different beliefs about the degree to which events are preordained, or how they view their own risk in comparison with the risk as presented in a specific scientific study, which is averaged across the specific study population (Fagerlin, Zikmund-Fisher et al. 2007).

### ***Types of information to describe risks***

Risk is, technically, the probability of suffering harm or loss. Quantitative data about the risks and benefits of specific treatments are often not available and discussion is then limited to the broad advantages and disadvantages of different options. It is important that numerical data are used if they are available, as evidence suggests most people prefer numerical data (Edwards and Elwyn 2001), although approximately one-third prefer verbal information. The type of information preferred depends on patient characteristics (e.g. age, educational level) and health condition (severity, recent experience of illness).

Presenting single numbers in isolation without others for comparison may lead to “shrinkage” of the risk scale: low risks seem larger and high risks seem smaller.

### ***Framing the risk information***

Framing is defined as presenting logically equivalent information in different ways (Edwards and Elwyn 2001). For example, “the risk of mild side-effects of osteopathic treatment is about 4 in every 10 patients” is *negative* framing. To say that “6 in 10 patients have no side-effects” is *positive* framing. It is similar to saying “glass half full” versus “glass half empty”.

There is substantial evidence (Edwards, Elwyn et al. 2001) that framing is potentially manipulative, especially in respect of choices about treatments (rather than about screening or preventive medicines). Hence, great care must be taken with the way information is presented to ensure that the patient is fully and fairly informed, and is able to make their own autonomous choice. There are several types of framing, including:

1. Negative and positive framing of risk information (as discussed above).
2. Loss and gain framing of possible outcomes (benefits if you do take a particular action and the losses if you do not).
3. Numerical and graphical, and verbal framing.
4. Vivid and abstract framing.
5. Framing by means of manipulating the denominator.
6. Framing by manipulating the volume of information.

The evidence shows that *loss* framing (Edwards, Elwyn et al. 2001) is likely to increase the uptake of screening. *Positive* framing may make individuals more likely to choose risky options. An *increased volume of information* was found to increase an individual's wariness and cautiousness about the treatment options. This applied to all aspects: more data points, having time to discuss options, being presented with a range of verbal and numerical information. Being presented with *numerical* as well as *verbal* data increased knowledge and understanding but also increased cautiousness, particularly in relation to serious risks such as death (rather than less serious effects such as nausea). In terms of the numerical information, relative risks were substantially more "persuasive" than the absolute risk reductions or numbers needed to treat (NNT) in relation to uptake of preventive medication. A vivid or personal vignette is more persuasive than an abstract description. Finally there is good evidence that people exhibit 'base rate neglect' (*manipulating the denominator*), e.g. people rate 1,286 out of 10 000 as more risky than 13 in 100.

The evidence about the potential to manipulate decisions therefore raises important ethical issues about informed choice and patient autonomy. In order to promote patient-centred communication and support patients in coming to their own decision, it is recommended to present a range of information in different formats, and both positively and negatively framed. The use of multiple complementary formats of the same information is supported by psychological research into the biases of human information-processing. The success of the communication should be judged by affective outcomes such as satisfaction, understanding, and certainty that they have made the right choice.

There is strong evidence that people given **personalised risk information** (adjusted for factors such as age, gender and genetic profile) (Edwards, Evans et al. 2006) are more likely to participate in screening but there is not enough evidence to show whether personalised information makes decisions more informed. Providing information in ways that better inform people can sometimes lead to lower participation rates in screening.

The recognised expert on **visual communication** is Isaac Lipkus from Duke University in North Carolina (Lipkus and Hollands 1999; Lipkus 2007). His 2007 paper provides an in-depth discussion of the inherent philosophical problems of trying to convey information in a simple way about something which is complex, personal and ill-defined. Risk is not absolute; he raises questions about how effects of differing severity should be combined into a single estimate, how severity should be assessed, whether risk is an objective likelihood or moderated by personal factors. He also compares the relative merits of numerical, verbal and visual communication.

**Numerical estimates of risks** are appealing: they appear precise, scientific and verifiable – and most individuals tend to prefer them to verbal or other formats. The weakness of numbers is their inability to express value and uncertainty, and the difficulty most people find in understanding numerical data.

**Verbal communication of risk** has the advantage of fluidity of expression: words are natural, and can encourage reasoning. The weakness of verbal messages is the high variability in interpretation, for example “likely” might suggest 60% to some people, 80% to others.

**Graphical displays** have the advantage of being able to summarise a considerable amount of information, reveal patterns, and compare options. They may aid understanding for less numerate individuals. The disadvantages of graphics are that the patterns may distract users from the detail: the graphs may not be very well understood and further, they take time to prepare and design well. Graphs also have the potential to mislead: classic ‘tricks’ being suppression of the zero or the denominator. However, the literature has been reviewed (Lipkus and Hollands 1999) which permits recommendations to be made.

The various **types of graph** have different strengths. Bar charts are good for comparing risk between subgroups; line graphs are good for trends over time; pie charts are good for judging proportions. Arrays of icons (small faces or human figures or even dots) are useful for showing the number in a population likely to be affected or unaffected. The icons should be presented in an array (e.g. 10 x 10). The affected icons can be grouped for ease of comprehending proportions, or distributed throughout the array to convey randomness. For comprehending the scale of the risk, some people have difficulty with pie charts because they cannot estimate the exact proportion being represented; and when using icons in arrays, random displays are best avoided as they decrease the precision of the risk estimate because the relative magnitude is difficult to judge.

The **choice of data** for a graph is important. Graphs that present the negative data only (e.g. numbers harmed) will increase the likelihood of risk-avoiding choices; graphs that presenting the numbers harmed and unharmed will decrease risk-avoiding choices.

The **design of the graph** needs consideration. The ink density on graphs should be concentrated on the data, and other areas should be clear if possible. Increase in risk is conveyed more readily by vertical height (for example a risk ladder) than by a horizontal bar. If several related graphs are shown, they should be consistent in style and colour, and differences between them should be highlighted in the legend and visually, if possible.

The accompanying explanation with graphical presentations should comprise a clear, lay text explanation of meaning. This should be reinforced with a verbal explanation from the practitioner to assist comprehension and for the visually impaired. Graphs represent risks in a population, and users may not identify personally with this population. Clinicians need to discuss the extent to which the individual resembles the population and personalise the message, expressing it as their own personal odds of harm (e.g. saying “*you* would have a risk of 1 in 10”).

Very small probabilities of less than 1 in 100 are difficult to understand. Graphical devices such as a magnifying glass image “blowing up” the lower end of a risk scale avoids the use of a logarithmic scale, which is not suitable for a lay audience, and aids comprehension. The use

of cumulative risks (e.g. over a life-time or over a long course of treatment) can be helpful with a very small risks as it may bring the risks into a more intuitive range. However one of the pitfalls in graphical representation (Nelson, Reyna et al. 2008) is the time-frame: people perceive greater risk of mortality and larger differences in treatment effectiveness when data are presented over 15 years rather than 5 years.

A great deal of the research surrounding risk communication has been conducted for marketing purposes, where the professionals *do* want to manipulate users' decision-making. Although in healthcare, the aim is *not* to manipulate the user, much of the evidence is still relevant. Such marketing research (Lurie and Mason 2007) describes visual representation as a process of encoding information using colour, texture and geometry. The representation only works well if the decision-maker decodes the information accurately and efficiently. Design issues such as colour choice, orientation of shapes and the selection of markers e.g. emotive images such as a skull or crossbones for death can influence a user's decisions. Visual representations draw on the associative rather than the rule-based reasoning system. Hence their use is suited to situations in which intuition plays a part, such as clinical decision-making.

A useful short introduction for clinicians to ways of representing (and mis-representing) risk information (Gigerenzer and Edwards 2003) illustrates how easy it is for clinicians as well as patients to misunderstand the scale of a risk if the above guidelines are not followed.

## KEY MESSAGES FOR OSTEOPATHS

### EFFECTIVE COMMUNICATION OF RISK

- Discuss risk in a context that conveys competence and care and engenders trust.
- Present the risks alongside the benefits.
- Present the risks and benefits in both numbers and words.
- Present a range of information in different formats to suit different people.
- Frame the risk in a positive way (x out of N people will suffer *no* side effects) and in a negative way (y out of N people *will* suffer side effects).
- Present absolute numbers where possible (e.g. 1 in 10,000): do not use relative risk (such as A is 3 times more risky than B) or percentages.
- Use visual aids to assist understanding and encourage discussion. Make them consistent and non-threatening in colour, symbols and wording.
- Personalise the message, drawing on your own experience and the patients' own risk factors, if any.
- Be honest about what we know and do not know - convey uncertainty
- Explore people's understanding, reactions and opinions about the risk information



## **Chapter 5 Informed consent, shared decision-making and communication skills**

This chapter traces the changes in recent years, with emphasis shifting from the didactic stance of providing patients with information (which they may comprehend poorly) and expecting them to sign a consent form, to a model of shared decision-making (General Medical Council 1998; General Medical Council 2008). For clinicians, shared decision-making requires a new way of working and refined communication skills. The implementation of shared decision-making has only recently begun to be evaluated within different settings (Elwyn, Edwards et al. 2001; Edwards, Elwyn et al. 2003).

### ***Informed consent***

Obtaining the informed consent of a patient is a common law requirement in most countries in which osteopaths work (Walker, Cameron et al. 2004) and the legal requirements are clearly defined in a Department of Health document (Department of Health 2009). Further guidance on the legal aspects of informed consent within osteopathy can be obtained from the General Osteopathic Council.

The requirements for fully informed consent include discussion with the patient about their symptoms, the proposed treatment, other reasonable alternative treatments, the risks and benefits of the different options (including declining treatment), and an assessment of the patient's understanding of the information given. Informed consent comprises three ethical principles (i) full information (ii) capacity to understand and (iii) freedom of choice (Department of Health 2009). For consent to be valid, the patient needs to be competent to make the decision and to understand the information given, whatever their age, disabilities, and cultural background, and patients must give consent voluntarily without feeling under pressure to make their decision (Bridson, Hammond et al. 2003). In addition, consent is an ongoing process during treatment, not a one-off event.

Communicating information is only one part of informed consent: partnership and shared decision-making are the hallmarks of recent guidance, as reflected by the updated guidance from the GMC 'Consent: doctors and patients making decisions together' (General Medical Council 2008).

In a survey of 480 Australian physiotherapists to monitor compliance with professional guidelines in 2004, only 33% of respondents sought consent for each cervical manipulation (Magarey, Rebbeck et al. 2004). In a Canadian focus group study of 46 physiotherapists, participants described that the physiotherapists exceeded the professional guidelines in terms of consent, but the fast pace of therapy sessions compromised patient autonomy (Fenety, Harman et al. 2009).

Patient understanding of the information provided as part of the informed consent process for medical and surgical procedures is often poor. The evidence suggests that modest efforts to improve communication can result in significant gains in patient understanding (Schenker, Fernandez et al. 2011). Since there was no evidence to suggest which type of information (written, audio visual, discussion, and feedback) was more effective, the authors recommended to the surgical community clinicians should select those which seem feasible within the clinical setting. However, the medical setting is not wholly parallel to osteopathic private practice: surgical treatment is comparable to osteopathic treatment in being an active intervention but the medical conditions requiring surgery and medical procedures range from life-threatening to cosmetic. In contrast, the conditions treated by osteopaths are not life-threatening and are often self-limiting.

The emphasis in relation to informed consent was on disclosure of risks and until about 2002, too little attention was paid to patients' objectives. Clinicians need to find out what the patient wants from treatment before discussing treatment options, especially in the management of chronic conditions (Bridson, Hammond et al. 2003). In order to achieve patient-centred consent, the emphasis needs to change from *disclosing* information to *sharing* information.

### ***Shared decision-making***

Patient-centred shared decision-making (commonly abbreviated to SDM) is an important development in healthcare. Not all patients wish to be involved in making decisions about their treatment, preferring the clinician to make that decision for them, yet all patients appear to want to be discuss the impact of treatment (Delany 2008). SDM is a challenge to health professionals and the evidence from a range of clinical settings suggests that implementation of SDM requires changes in practice and clinicians to gain new skills (Adam, Khaw et al. 2008; Watson, Thomson et al. 2008). One study found that psychiatrists gave professionally based recommendations to patients who asked “what would you do if you were me?” but used a personal perspective if they were choosing treatment for themselves, showing how difficult it is for a professional to adopt the lay perspective (Mendel, Hamann et al. 2010).

A seminal review of participatory decision-making in the primary care sector was conducted by Epstein and colleagues (Epstein, Alper et al. 2004). The review aimed to identify ways to improve patient understanding and involvement in decisions. In practical terms, informed patients are more likely to participate actively in their care, to make wiser decisions, to come to a common understanding with their clinicians, and to adhere to their treatment.

Communicating evidence can improve the therapeutic relationship and build trust and focuses on the patient not the clinician. Ethically, patients have a right to understand what is happening to them (their illness, their prognosis and their treatment options) even if they do not wish to participate in treatment decisions. Patients generally want more information than they receive from their clinicians.

### ***Clinicians' communication skills***

Epstein et al (Epstein, Alper et al. 2004) proposed that the skills needed by clinicians in order to communicate effectively with patients about risks include:

- Active listening
- Ability to communicate complex information in non-technical language

- Tailoring the amount and pace of the information to the patient's needs and preferences e.g. small "digestible" chunks work well
- Drawing diagrams to aid comprehension
- Considering the patient's values while weighing choices (e.g. whether emotions such as fear of pain or recurrence are uppermost)
- Facilitative skills to encourage patient involvement
- Evaluation of internet information which the patient might bring
- Creating an environment in which the patient feels comfortable asking questions
- Giving patients time to take in the information
- Declaration of equipoise (no evidence that two options are different) when present
- Checking patients' understanding
- Negotiation

Although clinicians are generally positive about shared decision-making, implementation implies changes in ways of working and communicating (Lurie and Weinstein 2001; Edwards and Elwyn 2004; Edwards, Elwyn et al. 2005; Bryant, Bednarski et al. 2006; Lewiecki 2010). The main barriers to change (McIntosh and Shaw 2003; Short, Frischer et al. 2004) appear to be poor quality information or inconsistency of information; information or decision aids that are professional or de-personalised in tone; and the time constraints of the consultation.

Clinicians may also need to acquire new communication skills. The training in communication skills for doctors (Fellowes, Wilkinson et al. 2004) and health professionals (Mandy and Gard 2000) has advanced over recent years but further training has resource implications (Cohen, Longo et al. 2004). The fact that osteopaths work mainly in the private sector precludes the kind of workplace training available to some other health professionals (Cross, Moore et al. 2004), creating an additional challenge for implementation within osteopathy.

### ***The discussion of risk information with patients***

Epstein (Epstein, Alper et al. 2004) suggested five steps for a clinician to use in the consultation:

#### ***Step 1: Understand the patients experience and expectations***

- What they want from the visit, what they value as outcome

#### ***Step 2: Build partnership***

- Show empathy
- Outline the decision to be made, explain that it will be joint

#### ***Step 3: Provide evidence including uncertainties***

- Explanation of the information of risk and benefit
- Present the information with positive and negative framing, and with graphics
- Discuss whether it applies to the patient

#### ***Step 4: Present recommendations***

- Propose a course you think is reasonable

#### ***Step 5: Check for understanding and agreement***

- Ask if it makes sense, ask them to tell you how they see it

The advice given here is wholly consistent with the guidelines for Australian physiotherapy (Delany 2002). Clinicians find it difficult to relinquish their therapist-determined view of what is best for the patient (Langworthy and le Fleming 2005; Delany 2007) and in private practice, were found to give explanation rather than offering choice. Making decisions on behalf of patients is quicker in the streamlined running of practice: a full discussion takes time.

A useful booklet to help clinicians gain communication skills ‘Communicating with patients: a quick reference guide for clinicians’ (Cullins, Plumbo et al. 2004), includes the “Respect” model for good practice and a discussion of cultural competence, the topic of the next chapter of this report.

A more recent development to aid discussion within the clinical consultation is the use of ‘decision aids’. Decision aids can prepare people to participate in decisions that involve weighing benefits, harms, and scientific uncertainty. They usually involve a paper or online questionnaire that enables both the patient and the clinician to work through the necessary steps to arriving at a decision that the patient is happy with. The efficacy of decision aids for people facing health treatment or screening decisions has been reviewed systematically (O'Connor, Bennett et al. 2009). An edited version of the results is given here. Based on 55 RCTs, the review confirmed that:

“Decision aids performed better than usual care interventions in terms of a) greater knowledge (b) lower decisional conflict related to feeling uninformed c) lower decisional conflict related to feeling unclear about personal values d) a reduced the proportion of people who were passive in decision-making and e) a reduced proportion of people who remained undecided post-intervention.”

The same authors have developed a decision aid tool, the ‘Ottawa Personal Decision Guide’, including a web-based version of a PDF available on their user-friendly and well-researched web site <http://decisionaid.ohri.ca/index.html>.

A brief clinical review for the General Medical Council (General Medical Council 2008) provides key pointers to SDM. The authors emphasise that professionals need to turn the raw data into information that supports discussion. They emphasise that the use of manipulative “framing” should be avoided, such as relative risks presented without actual rates’ and they support the use of decision aids. Comparisons with appropriate everyday risks can help patients to understand the information better (General Medical Council 2008)

## **KEY MESSAGES FOR OSTEOPATHS**

### **INFORMED CONSENT AND SHARED DECISION-MAKING**

- For consent to be valid, the patient needs to be competent to make the decision and to understand the information given whatever their age, disabilities, and cultural background.
- Patients must give consent voluntarily without feeling under pressure to make their decision.
- Consent is an ongoing process during treatment, not a one-off event.
- The emphasis for consent has shifted from disclosing information to sharing information.
- Partnership and shared decision-making (SDM) are now foremost in the consent process.
- Ethically, patients have a right to understand what is happening to them- their illness, their prognosis and their treatment options, even if they do not wish to participate in treatment decisions.
- Patients generally want more information than they receive from their clinicians.
- A leaflet is helpful but not sufficient because information needs to be explained and personalised. Clinicians may wish to make a record in the case-notes of the nature of the personalised information they have given to the patient.
- Clinicians may need to enhance their communication skills in order to communicate effectively with patients about risks: they need skills in active listening, simplifying complex information, empathy, facilitation and negotiation.
- The use of decision aids can help patients to choose their preferred option.
- In the osteopathic context, patients may feel vulnerable when undressed or lying down. Discussion needs to take place when the patient is appropriately dressed and seated to permit eye contact.

## **Chapter 6 Cultural competence in communicating risk**

Communication is very culture-specific, and effective and appropriate methods for communication will vary according to the patient's nationality, ethnic group, social group and even age and gender. This creates challenges for the clinician. In addition, communication and comprehension may be limited or impaired by physical factors such as deafness or limited language skills, or by communication disability. Limited comprehension and differences in cultural views of risk and health can seriously challenge the clinician in trying to achieve shared decision-making.

The research in this area was much less developed than for the other chapters (see Appendix 2), even after widening the search to include papers relating to clinical scenarios that were not close to those in osteopathy e.g. life-threatening disease or screening decisions. Only a few relevant studies have been conducted in most of these aspects. These are reported to give an indication of the challenges and potential solutions. Insufficient research exists to provide guidance or recommendations.

### ***Legal considerations***

The legal issues in regard to capacity to consent in the UK are summarised in a clear and helpful fashion on the website of the UK Clinical Ethics Network <http://www.ethics-network.org.uk/ethical-issues/consent/legal-considerations> and the consent guidance from the GMC (General Medical Council 2008) which also covers Northern Ireland.

There definitive Department of Health guidance (Department of Health 2009) cites the Mental Capacity Act 2005 in England and Wales, which applies to persons aged 16 and over. In England, Wales and Scotland, 'children' are aged under 16 years and "young people" are those aged 16-17 years who, although they have not reached the age of majority, are considered in law to have the capacity to consent to their own medical treatment (Department of Health 2009). However, in Northern Ireland children are defined as those under the age of 18 years ([http://www.dhsspsni.gov.uk/public\\_health\\_consent](http://www.dhsspsni.gov.uk/public_health_consent)).



### ***Ethnicity***

According to one review (Dein and Thomas 2002), approaches to truth-telling in the Western world are rooted in the Western concept of individualism and autonomy whereas in many parts of the world such as China, Japan, and India, the individual is firmly situated in a family. The result in terms of decision-making about treatment choices, is that the family may assume responsibility for decision-making. When the news is bad e.g. in terminal cancer, the family may shield the sick person from the truth about diagnosis and prognosis. The breaking of bad news to the patient, when it occurs, is the responsibility of the family. Even in Europe, Italian culture emphasises maintaining hope and tranquillity, and Polish cancer patients are rarely informed. The Jewish tradition is life-affirming and emphasises the need for hope, although at some point a patient must be told of impending death in order to utter the final confession.

The above account is in accord with evidence from a North American survey of 257 Latina, African-American and white breast cancer patients about their decision-making about treatment (Maly, Umezawa et al. 2006; Hawley, Janz et al. 2008). A substantial proportion of the Latina women stated that the final treatment decisions were made by their family. This impacted significantly on the treatment options chosen. Patients were much more likely to receive radical surgery when the family decided.

Culture may change the way risk is perceived (Masuda and Garvin 2006). Cultural differences may also exist in expectations about the language and style of the therapeutic relationship. Israeli breast cancer patients described being treated as a number, a machine, or a stranger rather than as a human being or a friend by staff within the medical culture in hospital (Nicolson, Fawcett et al. 2010) .

### ***Communicating with children***

Communication with children poses additional ethical and social challenges (De Lourdes Levy, Larcher et al. 2003) with tensions around allowing the child to express their

preferences and respecting the role of the parents and family in supporting them and advising them.

Interviews with parents, 11 children with cerebral palsy and 10 physiotherapists (Young, Moffett et al. 2006) about shared decision-making in community-based physiotherapy suggested that decision-making was unilateral, with each party contributing to different areas and children having little involvement.

A study interviewing parents and young people attending a paediatric oncology unit (Young, Dixon-Woods et al. 2003) found that the young people welcomed the parents involvement but found that their presence could inhibit communication and could make the young person feel marginalised in consultations with doctors.

### ***Elderly patients***

Elderly patients are often able to comprehend and decide as well as their younger peers. Clinicians need to be aware that eyesight, hearing or memory may be compromised and adjust the communication accordingly.

A survey of 50 inpatients aged over 75 showed a wide variation in understanding probabilities, using examples based on dice, coins, and pictographs. The results were broadly similar to those in the general population, although eyesight was more problematic (Fuller, Dudley et al. 2001). Elders from minority backgrounds may be at a disadvantage when it comes to decision-making (Byrd, Fletcher et al. 2007).

### ***Gender***

There are differences between men and women in cognitive processes and beliefs, which may also need to be taken into account in communication about risk (Walter, Emery et al. 2004; Höglund and Holmström 2008).

### ***Disability***

Communication disability is particularly challenging in the context of consent and care, yet is frequently met in primary care. A review of current guidelines (Chew, Iacono et al. 2009) stressed how an individualised approach is essential because of the wide variety of communication styles adopted with those with communication barriers. This disabled group may use speech, visual, behavioural or other cues in their communication, and communication can be improved by working with the person and their carer.

In a series of focus groups, general practitioners reported communicating mainly to carers, while people with communication disability objected to staff speaking to carers and not to them (Murphy 2006). This study used picture symbols and ‘talking mats’ as a visual communication framework to assist the disabled participants to communicate. Talking mats are an example of a communication tool (Murphy, Tester et al. 2005; Ferm, Sahlin et al. 2010; Murphy, Oliver et al. 2010) that could be considered for use in osteopathy.

There are other minority groups who may present considerable barriers to communication e.g. refugees and survivors of abuse (Constantino, Crane et al. 2007), and those with mental illness (including children) (Jensen, McNamara et al. 1991; Gustafson, McNamara et al. 1994).

### ***Patients with chronic pain***

Patients with chronic back pain, and other long term musculo-skeletal problems, have often travelled on a protracted pathway trying to seek help through the medical system ‘Being believed’ by a clinician is very important to them as found in a recent study on osteopathic patients’ expectations (Leach, Cross et al. 2011). Their symptoms are often not tangible but may be quite disabling, leading to social isolation and problems at work. These factors make some of the chronic patients seen in osteopathic practice, in a sense, a minority group. Establishing trust and empathy at the start of the consultation is very important.

### ***Culturally-adapted communication strategies***

Cultural differences can affect both parties in a consultation. Cultural differences in professional attitudes to informed consent may impact on health care (Henley, Benatar et al. 1995; Yousuf, Fauzi et al. 2007; Humayun, Fatima et al. 2008; Meeuwesen and Hofstede 2009). Clinicians also have to adjust their style of communication according to the cultural background of the patient (Sze-Mun Lee, Sullivan et al. 2006; Garcia-Retamero and Galesic 2009). When language barriers exist, clinicians may tend to use a family interpreter, non-verbal communication, simplified language or bilingual staff. Compared to the use of professional interpreters, these strategies can lead to inaccuracy, bias and misinterpretation, and potentially to ineffective treatment (Lee, Sullivan et al. 2006).

The patient-physician relationship is strengthened if patients see themselves as similar to their physician ('concordance'). Similarity in personal beliefs, values and patient-centred communication are more important than race or gender in establishing concordance (Street, O'Malley et al. 2008). These findings emphasise the importance of clinicians being able to express their views in lay terms, and from a lay perspective, in order to establish good communication.

The challenge of communicating risk has been outlined in previous chapters. In minority groups the communication challenge may be much more difficult. This is a specialist area requiring sophisticated guidance. The work undertaken within this project aimed to highlight areas where such guidance may need to be developed for osteopaths in the future.

## KEY MESSAGES FOR OSTEOPATHS

### CULTURAL COMPETENCE IN COMMUNICATING RISK

- Communicating about risks and shared decision-making depends on establishing a good patient-physician relationship. This relationship is strengthened if patients perceive concordance between their personal beliefs and values and those of their physician.
- Cultural differences such as race, gender and age may reduce concordance and can be a barrier to understanding of the patient's perspective.
- Clinicians need to be aware that the understanding of concepts that are at the heart of this communication, (such as risk, truth-telling, autonomy and the role of the family in health decisions) vary considerably between cultures and ethnic groups.
- In England and Wales, children (those aged under 16 years) and young people (those aged 16-17 years) are considered in law to have the capacity to consent to their own medical treatment.
- Young people may welcome their parents' involvement but their presence can limit communication and make the young person feel marginalised during consultations with doctors.
- Elderly patients are often able to comprehend and take decisions regarding their care as well as their younger peers. Clinicians need to be aware that eyesight, hearing or memory may be compromised and adjust the communication accordingly.
- Limited comprehension (due to lack of education, language barriers or mental disability) can seriously challenge the clinician in trying to achieve shared decision-making. Special measures may be required to assist when communication is limited. Interpreters may be helpful but can introduce bias. Pictorial aids have been shown to be helpful in some settings but research is limited.
- More research is needed in these specialist areas of communication before firm evidence-based recommendations can be made.

## **Chapter 7 Developing and testing a communication aid for osteopathic practices**

This chapter specifically addresses the research question ‘what constitutes good practice when seeking informed consent from patients for osteopathic care?’

### **Methodology**

In the light of the evidence presented in previous chapters showing that shared decision-making is the accepted approach to obtaining informed consent, it appeared that some supportive material or decision aid was needed to facilitate shared decision-making within an osteopathic consultation. The methods chosen to develop and test a communication aid were:

- 1) to develop a draft set of information material based on the literature outlined in the previous chapters, which could assist a patient to come to a decision about their osteopathic treatment in partnership with their osteopath;
- 2) to pilot test the information material on users, through focus groups of osteopaths and patients.

The information material aimed to define the risks and benefits, and the options open to patients. It utilised evidence-based methods for communication of the information: the use of multiple formats to allow for learning styles e.g. using verbal, numeric, visual information to be communicated both in written and oral form.

The information was tested through user involvement which was conducted within one of the osteopathic training colleges (the College of Osteopaths, a collaborator in this study). Focus groups were conducted, lasting approximately one hour with 4-8 participants and led by two researchers. Separate focus groups were conducted with osteopaths and with patients, in order to obtain osteopathic and lay perspectives. Participants were recruited as a convenience sample. Those invited to participate were given a Participant Information Pack (see Appendix 3) with a Consent Form to sign if they wished to participate. The focus groups took place in a private room within the College premises. One researcher facilitated by explaining the

background to the study and the fact that the discussions would give an osteopathic view on the material presented. Participants were asked to consider this as material given to a patient prior to a course of treatment, to support discussion between patient and osteopath within the consultation. Participants were then asked for views about the information material in terms of value and utility; views on the information about the risks and benefits of osteopathic treatment; and how such information should be presented in the clinic. Their reactions to the information were recorded digitally and also by the second researcher who was acting as an observer. Analysis involved identifying the emergent key messages, identifying differences in views between the osteopaths and patients, and suggesting ways to more clearly articulate the messages, along with any other options and ideas for communication.

### ***Development of the information material***

The information currently given to patients attending the osteopathic clinic at the College of Osteopaths was used as the starting point. This was a short written warning notice provided in each treatment room stating that adverse reactions were possible and listing some serious outcomes, including death. This was expanded using the information in Chapter 2 about the risks and benefits of osteopathic treatment: the facts were translated into short verbal statements in collaboration with several osteopaths (Rachel Ives, Carol Fawkes, and Tracey Stokely). In line with research evidence, the statements provided both verbal and numerical descriptions of the risks, as well as some possible analogies since these can also be very helpful (Edwards 2003). The risks were framed both positively and negatively. The wording and the issues presented were designed for lay acceptability and utility using guidance from the Committee on Safety of Medicine and a review of risk communication for NSAIDs (Moore, Derry et al. 2008). In addition, four broad options for the osteopathic treatment approach were identified so that the patient could choose their preferred approach. The information was then simplified and condensed into material that could form the basis of a leaflet for patients with the aim of clear wording, brevity and within a maximum of 4 A4 pages.

Additional material was prepared comprising (1) graphics in different formats, visually representing the risks and the benefits (2) a decision aid adapted to apply to the osteopathic options and (3) some additional medical facts around the serious risks. The visual

representations were based on guidance from several authors (Edwards, Elwyn et al. 2002; Price, Cameron et al. 2007; Dolan and Iadarola 2008; Carling, Kristoffersen et al. 2009). The decision aid was based on a tool developed in Ottawa (O'Connor, Bennett et al. 2009; Ottawa Hospital Research Institute 2011).

## **Results**

The final information pack as discussed at the pilot focus groups is presented in Appendix 4.

The two pilot focus groups took place at the College of Osteopaths clinic in Borehamwood in March 2011. The first group comprised 5 osteopathic *practitioners* (3 female, 2 male). All had private practices, many years of cumulative experience as clinical tutors, and one worked within the NHS. Their original osteopathic training and their cultural background was varied, reflecting the diversity in osteopathy in the UK.

The second group comprised 3 osteopathic *patients* (2 female, 1 male) with different experiences of osteopathy. The male patient had been attending the clinic for many years for help with a long-term disabling condition, and had also experienced some quite severe adverse effects (severe pain after treatment and collapse in the clinic on at least one occasion). One female patient was mid-way through her first course of treatment, and the other was an NHS health professional returning for a new problem after having a first course of treatment some two years previously.

The field notes from the Focus Groups and edited verbatim transcripts of the discussion are provided, in full, in Appendix 5.

### ***Findings from the Focus Groups***

Several practitioners were initially defensive and critical of the information material and found it difficult to digest. However, as the discussion progressed they became more engaged and positive suggestions were made by all participants.

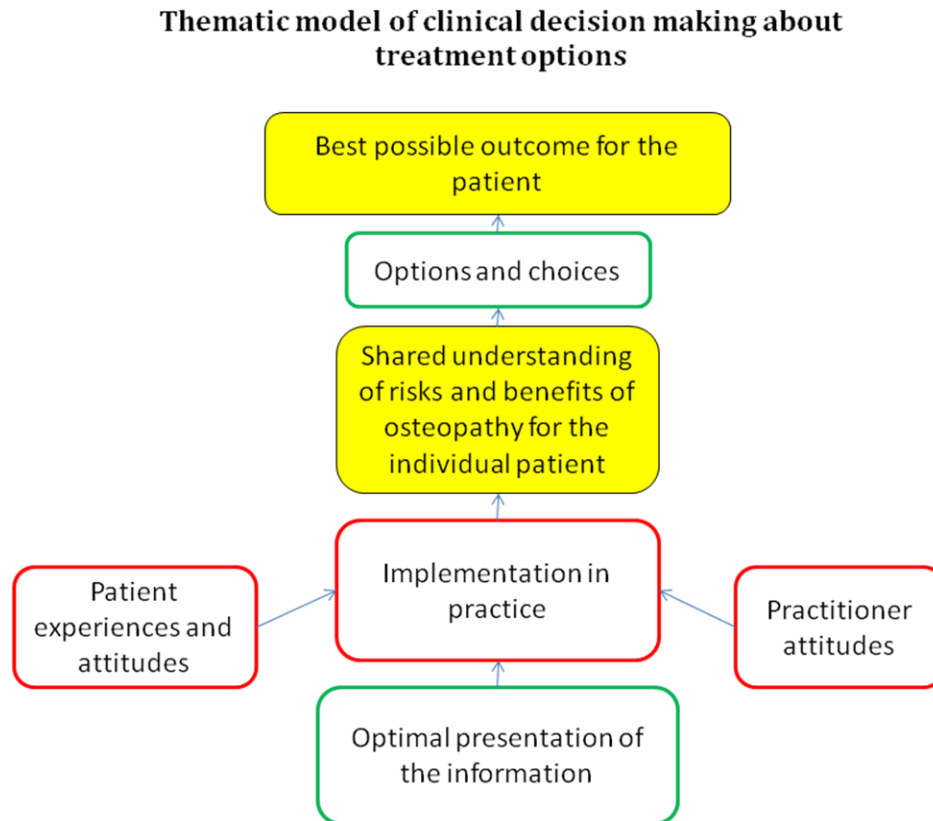


The patients were highly engaged from the beginning: they read through the material with interest, seemed to find it understandable, and were all vocal about the value of the different sections and whether it corresponded to their own experiences. They contradicted the practitioners on a number of key issues. They were surprised that the benefits of osteopathic treatment, as outlined in the leaflet, were so substantial and thought these should be presented before the risk information. They liked the idea of being given options for treatment and found that the way that they were presented was simple and clear.

All the patients were very concerned about getting their full quota of treatment within the time-slot available, perhaps because this is a particular issue in a teaching clinic. They did not want to lose treatment time because of discussions about risk or other factors (such as repeated taking of full case histories which can occur within visits to the teaching clinic). They also varied in the level of detail they wanted about risks and benefits: for some the material was too detailed.

The data collected from the Focus Groups was formally analysed thematically, using a cyclical process to draw out and refine themes and the relationships between them. A model was developed as shown in Figure 7.1 (following page) for the process of coming to a shared decision with a patient within an osteopathic consultation.

**Figure 7.1**



The model represents the fact that both patients and practitioners were aiming at a common goal: the best possible outcome for the patient (top of diagram). The process is initiated by information-giving. The information presented needs to be appropriate and understandable for osteopathic patients (and practitioners). The next step is implementation in practice: the form that implementation takes depends upon both the patients' and the practitioners' attitudes and experience. With effective implementation, the essential stage can be reached of shared-understanding of the risks and benefits for the individual patient in the consulting room. Finally, the patient can be assisted in choosing their treatment options for the best chance of a good outcome.

### ***Theme 1: Optimal presentation of the information***

This theme included the words used, how best to describe osteopathy (much discussed by practitioners), comprehension, contextual framing, and fright factors.

The patients seemed to **prefer words to numbers**. One patient said “I like the words. The graphics highlight the bad things ... but covering them in softer words ...” The practitioners were also aware of the importance of the words used: “You have to talk about risks and benefits together... language are terribly important”. They were concerned about the terms used to differentiate osteopathic approaches: they disliked the term “forceful”, because “we are possibly installing fear, there must be another way of putting it... ” and “forceful conjures up there’s something traumatic”. They pointed out the potential confusion arising from differences in terminology between professions “when a patient has been to a physio, they may say they have had manipulation but it may be soft tissue”.

**Analogies**, such as the needle in a haystack and the football stadium, were helpful for some patients in making risk information seem less frightening “I like the funny bits, it’s a serious thing, but at the same time...” Other patients may not like them: “I think they confuse people”.

**Framing** osteopathic risks in comparison to lifestyle risks like falls or motor accidents was not popular with patients: “I don’t think people can relate to it. The stairs [*falls*]: maybe if you are elderly. It’s not mathematical, it’s bad luck”. The patients preferred comparisons with other treatments for back pain, such as drugs. Both patients and practitioners wanted to avoid generating fear in first-time patients before a degree of trust had been established: as expressed by one patient “it’s quite scary [*the risk information*]. I would rather see the positives first, and then a paragraph on what might happen”, and “the benefits first, otherwise I might think ‘should I be here or not?’ You could frighten the patient before they even get started”. One patient felt that because GPs do not routinely discuss the risks when they prescribe medication, the information “puts you [*osteopaths*] in a bad light because you are highlighting the risk, where they [*patients*] are not used to having the risks highlighted”.

The **choice of graphics** appeared to be very personal and variable. Each of the different styles (bar charts, pie charts or arrays of dots) was preferred by someone within the group although in general the bar charts received more positive comments.

When it came to the serious risks, one patient wanted more information so as to be able to judge if they were personally at risk or not: “I’d want to know the risk factors and I could look and say ‘I don’t apply to that’”.

### ***Theme 2i: Implementation in practice - attitudes of patients***

This theme embraced the way practices might want to present material to patients (e.g. leaflets, posters or verbal advice) and the factors that might influence that choice, particularly establishing trust and rapport, ring-fencing time for treatment, and the type of clinic. The patients’ attitudes may depend on their experience of both osteopathy and the healthcare system in general. Most had tried many types of therapy including the GP, physiotherapy, and acupuncture. All three patients that participated were extremely loyal to the College Clinic, which they believed had helped them a great deal: “95% of the time you get full benefit”.

The patients discussed the **value** the information might hold for them. Some of the patients wanted information about their options, to understand their options and approach advised by the practitioner. Another patient preferred to trust the practitioner rather than obtain information, saying “when I needed [*osteopathic*] treatment, I was desperate to have treatment whatever” and “I don’t think it’s helpful to have more information. If I was having some strange treatment I would look it up on the internet, like when she did that back-twisting thing, that hold”.

All the patients were very **protective of their treatment time**: “I wouldn’t want to lose out on treatment time. The more questions and explanations, the less treatment time and that’s

what you are here for”. The issue of loss of treatment time might be more pronounced in teaching clinics, however.

The patient participants varied in **attitude to the serious risks**. One seemed to have a very pragmatic approach, viewing them as being “worst case scenario” and taking little notice of them: “having seen the list [*risk statement*] in the clinic for my first treatment they just said ‘these are the risks, can you sign that you have read it’, no-one discussed it. My thoughts were that they have got to do that in case something dreadful does happen”. Another patient who had experienced adverse effects was more concerned that the risks were communicated: “the Consent Form spells out the risks involved; you need to be aware of the risks... It’s very difficult because the osteopath does not know how the patient will react... My risks are greater”.

### ***Theme 2ii: Implementation in practice - attitudes of practitioners***

The attitudes of practitioners to discussing the risks of osteopathy with patients initially tended to be very **defensive**: “before I get to the first paragraph, the risk outweighs the benefit in the graphics on the front page: a picture paints a thousand words”.

They discussed **the impression created by such information** in the consultation: “would I show that to my patients? They have already decided to come and see me. It’s better marketing material” and “in hospital, on the morning of the operation, you would see three different people to communicate that risk... you wouldn’t want to see osteopathy bogged down in red tape”. The practitioner with an NHS practice commented that some patients might find it annoying: “they say where we are going with all this Health and Safety? I have a lot of comments about this”.

They discussed **comprehensibility** and **barriers to communication**: “A patient who can’t understand the information, it’s best to start with the gentler stuff [*e.g. treatment style*]... until the trust develops”.

They were concerned about the **time taken** by discussion of the information: “Practices with 15-20 minute appointments are going to struggle with this information”. They discussed whether this could be remedied by introducing it in the reception area so that the patient could choose whether to discuss it: “in the waiting area is very good: those that want clarification can pick it up and ask to talk about it”.

The practitioners also discussed the role of **verbal communication of their own experience** of adverse events: “does experience not count?”

### ***Theme 3: Shared understanding of risks and benefits of osteopathy***

This theme refers to the practitioner’s role in ensuring the information has been communicated and understood, and in assisting the patient to assess their own individual likelihood of benefits and risks.

The concept of shared decision-making in order to optimise outcomes was not unfamiliar to the practitioners, as one emphasised “patients *have* to be involved. The greater the buy-in, the greater the benefit will be”.

**Understanding** of the benefits proved to be challenging, and the material presented did not appear to communicate with either group, although the graphics helped. Patients were positive when asked if they found the information understandable, but some comments revealed that they had misunderstood certain facts.

The patients wanted to know if the information applied to them: they wanted to **personalise their risk** assessment. The patients were concerned that the osteopath should have their medical details and be aware of medications in order to assess their risk in more detail. One patient proposed access to their medical records in order that the osteopath was in possession of all the relevant health issues: “In my/[NHS] job, people might forget about 50% of the things that are relevant ... Patients could ask for a printout for the last year [*from the GP*] before going to the osteopath”. But the experience of another patient suggested that this

might not be easy: “I’ve had my medical details released to the osteopathic clinic but it can take so long it delays your treatment and it’s not a freebie... ”.

One of the patients had experienced a number of adverse events and was vocal about the need to assess individual risk, saying “in my particular back situation- it can never be cured ... Treatment can make it a lot worse ... I have collapsed in the clinic ... my risks are greater”.

#### ***Theme 4: Options and Choices***

Four broad options in relation to the style of osteopathic treatment were presented in the information material, in order that patients could state a preference if they had one.

The practitioners all had strong reservations about presenting the wide spectrum of osteopathic treatment in such a generalised way as four broad options: “it’s very narrow isn’t it? Within each category there is a huge range of what a practitioner can do. It’s not clear that each option covers a huge range”. They also felt that the options omitted aspects of osteopathic care: “hands-on is not the entirety of what they do... There is education, advice, reassurance”. The practitioners made many constructive suggestions for editing the wording, such as “maybe show a sliding scale of options, advice and exercise, gentler techniques ... ”; one practitioner suggested that the information should state “you do have options, please discuss them with your practitioner”.

In contrast, the reactions from the patients were very positive about being given broad options “it’s superb to have that table to look at. When someone comes in the first time, they might be scared to death, not knowing what to expect, but seeing they have got a level of treatment options to go for, that would help them a lot.” At the same time, some were aware that that they personally would not be likely to make use of the options, but would trust the practitioner to decide: “I’m healthy so I don’t bother to read these things”.

#### ***Theme 5: The best possible outcome for the patient***

While practitioners tended to be focussed on getting best results from the osteopathic treatment, patients focussed on a wider perspective and wanted advice from the osteopath on what was the **best route for a good outcome**: “Do the trials say it’s better than going to the GP? What people want to know is ‘what’s the best thing to do to help my condition? Is osteopathy better than physio?’ ... I would have thought it depends on the individual osteopath and physio”. They had all sought help from a variety of health professions and appeared willing to use all the health systems available to them.

Patients were concerned to get prompt treatment with **short waits**: “the doctor said to me “I can offer you it on the NHS”. I said how long is the waiting list? You need to get it sorted”

They were concerned about **cost-effectiveness**: “when I brought my daughter it wasn’t effective, so we went to a private clinic. When you are really pushed for time, you pay twice as much but it’s more effective and it’s worth it”.

Some patients acknowledged it was quite hard to know if osteopathy had been **effective** or if they would have improved without it: “you always say it works, but it’s hard to know.”

One patient emphasised that osteopaths should inform patients about **the possibility of non-response**: “I don’t think there’s enough emphasis on advising the patient that there can be a downside to treatment. A patient may not walk out of the door ten times fitter. I don’t see that highlighted anywhere. People need to be made aware, whether they are young or old, that not everyone is going to obtain what they are hoping to, and it may not work for everybody”.

## **Discussion**

Although these groups were small, the focus group discussions provided a preliminary test of the appropriateness for osteopathy of material that was prepared from evidence arising in other areas of healthcare. The results need to be viewed very much as preliminary, due to the limited number and range of participants. Clearly, before any final conclusions can be drawn, more focus groups are needed. However, on the basis of these pilot studies, some points emerged for the future.



Firstly, it appeared that routinely-presented risk information (at least as currently presented in this particular clinic) did not facilitate a discussion of risks and benefits or shared decision-making with all patients. Better information appears to be necessary for the profession to use in practice.

The new information material developed within the project was well received by patients and facilitated a discussion about options and obtaining the best possible outcome. However, it was clear that much more development of the wording, design and graphics would be required before it was fit for purpose within the profession generally. Many detailed suggestions were made by participants on how the information could be improved (see Appendix 5). In particular, the information needs to make clear that risk of a serious adverse event is associated with *specific* techniques applied to *specific* joints, not to osteopathic treatment as a whole.

Information on risks, benefits and options was welcomed by these patients. Even though they might not always wish to use it, they seemed to feel that osteopaths should have such information available for them should they require it. Patients are well-informed and take a wide perspective when looking to access private healthcare. The risks and benefits of osteopathy need to be presented in this wider context, and compared directly with other treatment options in the musculoskeletal arena.

Patients' emphasis on protecting precious treatment time means that consideration needs to be given to ways of streamlining the discussion of risks and benefits. Options include sending out the material pre-treatment or presenting the material in a three layer format, each layer becoming more detailed, to suit readers who want to "drill down" to varying degrees.

The initial reactions of this group of specialist practitioners suggested that it could be quite challenging to change practice within the wider osteopathic profession towards an explicit discussion of risks with patients, even when risks are presented in the context of benefits. Generalist practitioners may be even more resistant to change. Positive pressures for change are likely to be needed such as patients' voices expecting information about the risks and

benefits; education and training; and nationally-agreed models of this quite specialist information.

Practitioners would benefit from additional written guidance specifically for osteopaths. Their help could possibly be enlisted in improving available information for patients. The practitioners need to understand the concept of shared decision-making as a way to informed consent, and their role within it. They need to be aware of the limitations of the current research evidence on risks and benefits; they need to be confident in drawing on their own experience and on their clinical judgement in relation to the risk factors for an individual patient, and on their ability to advise a patient on the likely benefits so that they can choose from the various options for treatment.

The current project was the first of its kind within osteopathy and was limited in budget and time. There is scope for much further research and development as well as graphic design input. The areas which need particular development are (1) better information about patient factors associated with a good or poor response to osteopathy, and associated with adverse effects; (2) a review of the evidence on the patient characteristics and risk factors for stroke caused by cervical artery dissection (CAD); and (3) further exploration and testing of patient information comparing patient attitudes and needs between the different osteopathic service models. The focus group in this college training clinic shed some light on this (for details see Appendix 5), but further research is needed in this area.

In summary, material for communication about risks and benefits has been proposed and pilot-tested in the course of this project. There is no doubt that patients wish to be adequately informed and that balanced, open and honest communication enhances the therapeutic relationship and outcomes. Building on this project, the next stage would be to design and test guidance for use in practice, incorporating those changes in the material and the presentation suggested by the findings from the focus groups.

## **KEY MESSAGES FOR OSTEOPATHS**

### **FINDINGS FROM THE FOCUS GROUPS**

- The information material developed for the focus groups was evidence-based as far as possible.
- The focus groups represented a pilot of the use of decision aids for shared decision-making in osteopathic practice.
- The numerical evidence on risk and benefits is limited, and some uncertainty needs to be conveyed. Further research is needed to obtain more accurate estimates of benefit in particular.
- The content, design and format of the information and guidance require considerable further development before it is suitable for use in practice.
- .Further focus group research is needed to ensure the future development of the information material is patient-centred.
- The pilot focus groups suggested that osteopathic patients welcome information on the benefits and risks of osteopathy and on their options for treatment, especially at their first visit.
- The patients suggested that benefits should be presented first, followed by the risks of osteopathic treatment. They wanted the information to be quick to read, understand, and discuss with the osteopath.
- Both brief and more detailed information about the risks and risk factors should be available, to cater for patients' different attitudes to risk. The patients suggested the information was prepared as a series of leaflets, increasing in complexity and detail.
- The osteopathic patients agreed with research literature recommendations that the key information should be presented in a variety of formats to allow for patients' learning styles and preferences.
- The patients wanted to personalise the risk information, using information about risk factors, and by discussion with their osteopath. They relied on their osteopath's understanding of how the risks might apply to them in the light of their medical history.
- The osteopaths supported the need for information and guidance about benefits and risks. They suggested that the information should support shared decision-making rather than simply conveying factual information.

- The patients and osteopaths diverged in their interpretation of ‘the best possible outcome for the patient’ when discussing treatment options. The osteopaths’ focus was on the most effective osteopathic care, while the patients’ focus was on finding the most effective and cost-effective multi-professional care, including medical, physiotherapy, chiropractic or other healthcare as required. More research is needed, but if true this finding carries training implications for osteopaths.
- The patients welcomed the idea of being offered choice about the style of osteopathy they would receive. However, the osteopaths felt that the treatment options section needed much more development, in order to reflect osteopathy truthfully yet succinctly.
- Changing practice in the osteopathic profession will be challenging and practitioners are likely to need training in the skills of shared decision-making as a route to informed consent.

## **Chapter 8 Discussion**

Evidence from surveys of osteopaths suggests that a majority of practitioners are not communicating fully or consistently about the risks of treatment. The risks of serious adverse effects in osteopathy are extremely low and largely associated with particular areas of practice such as manipulation of the cervical spine. Nevertheless, osteopaths have a duty to communicate any risks associated with treatment they are proposing.

### ***Main findings***

This project has identified substantial literature on this topic. This report has undertaken to extract the evidence relevant to osteopathy from good quality studies and literature reviews.

Most of the existing literature about risk communication reviewed in the course of this project reflected experience in health disciplines other than osteopathy. However, the issues that arise in osteopathy are not dissimilar to those arising for any active intervention given to treat a health condition that is disabling but not life-threatening.

Risk information is acknowledged as difficult to communicate: patients' comprehension of risk information tends to be poor generally (as detailed in Chapter 3) and the very low risk of a serious adverse event within osteopathy will tend to be perceived as bigger than it is. This poses a problem for the clinician and while there is much guidance on how to facilitate risk communication by way of format, media and style, the final responsibility is with the clinician to engender a caring, trusting relationship in each individual consultation, to invite discussion, and to encourage a partnership approach.

This responsibility makes considerable demands on the clinicians' communication and negotiation skills and understanding of patients. This is particularly true when dealing with vulnerable patients, whether that vulnerability arises due to their age, gender, disability, culture or language skills. Added to this, osteopathic patients potentially may feel vulnerable,

due to their pain, and being in a state of undress, and being in a “lower” position (e.g. supine on the couch).

The osteopathy-specific information material developed through this project and tested in the focus groups could potentially form the basis for the development of general guidance available to all osteopaths, and the development of patient information. Further development and testing would be required if this is recognised as a priority for osteopathic practice.

### ***Limitations of the study***

The evidence for this study drew mainly on the work of notable experts in the field rather than conducting a new systematic review of the many primary studies. The large number of reviews into the mechanics of communicating risks reflected the advanced state of research in that specific area. Emerging areas for research are the development and evaluation of decision aids, and methods for improving clinical skills in communicating risk.

The development of materials for our focus groups highlighted the lack of appropriate statistical data on risks and benefits in osteopathy. The required data are the absolute risks, absolute benefits and percentages of responders and non-responders to different types of treatment. Clinical trials, in particular, rarely provide any measure of benefit other than the relative risks of one treatment compared to another, for the participants as a whole. That is only part of the information that patients need in order to weigh up their risks and benefits equation. There is scope for further research to provide this information.

The focus groups provided a preliminary test of the risk-benefit information, and confirmed the need for such information. However, this was a pilot study with small samples of patients and practitioners drawn from a single location. Further tests with a much wider range of patients and osteopaths will be needed to capture the diversity of views, drawing participants from private and NHS practices, as well as other osteopathic educational institution clinics. The development of patient information for use in practice (e.g. a leaflet) was not part of the remit for this study, and could be the aim of a future project.

## **Chapter 9 Conclusions and recommendations for further research**

The evidence provided in this report in relation to these questions derives from research which is mostly in healthcare areas other than osteopathy. The recommendations need to be tested further within osteopathy, and could then form the basis of official guidance in the future.

The study posed three research questions:

- *What are the most effective ways of communicating risk of adverse effects to patients in the context of osteopathic practice?*
- *What constitutes good practice when seeking informed consent from patients for osteopathic care?*
- *What should osteopaths be aware of in order to understand clinical risk effectively?*

### ***Effective ways of communicating risk of adverse effects to patients in the context of osteopathic practice***

A summary of the evidence on effective communication of risks in a clinical consultation was provided in Chapter 4 of this report. This evidence was drawn from research within healthcare, selecting studies where the health intervention was analogous to most osteopathic care in being an active treatment (not screening or prevention) for health conditions that are disabling but not life-threatening.

To set this evidence in the context of osteopathic practice, the magnitude of the risks and benefits of osteopathic care were quantified, as far as possible, from osteopathic research and research in chiropractic and manipulative medicine in Chapter 2. Finally, the needs of patients for such information, in an osteopathic context, were explored in two pilot focus groups with patients and practitioners in Chapter 7.

***Good practice when seeking informed consent from patients for osteopathic care***

The evidence on current principles of good practice in informed consent and shared decision-making was presented in Chapter 5. The guidance and limited research relating to communicating and achieving shared decision-making in vulnerable and minority groups was outlined in Chapter 6.

***What should osteopaths be aware of in order to understand clinical risk effectively?***

In order to understand clinical risk, osteopaths need to be aware of the nature and frequency of mild, moderate and serious risks of treatment (summarised in Chapter 2). They also need to be aware of the uncertainty inherent in those statistics. An understanding by osteopaths of lay perceptions of risk (Chapter 3) is vital in order to ensure that their verbal communication is sensitive to fright factors and the difficulties of comprehending the size of the risk in an objective sense. Osteopaths also need to be aware of patients' attitudes to risk information; the new primary data from the focus groups (Chapter 7) provides a small insight into those attitudes. The design and content of the draft patient information leaflets developed in the project (Appendix 4) were based on the literature review conducted within the study. The draft leaflets together with the revisions proposed by patients and practitioners in the focus groups may assist osteopaths in communicating risk-related information to patients in the future.

***Recommendations for further research***

Further work is recommended to take this work and to build on the foundation established within this project.

The most pressing need is for further investigation of the views of osteopathic patients in relation to communicating risks and benefits.



1. Further focus groups are recommended aiming to collect opinions from a diverse range of patients, and utilising the information material developed through this project, refined on the basis of the findings to date. Many detailed suggestions were made by participants on how the draft information could be improved (see Appendix 5). The most recent research in cognitive psychology and decision-making theory (Edwards and Elwyn 2001) uses theoretical models such as the Health Belief Model, the Theory of Social Behaviour, and the Prospect model to explain how an individual perceives the values and the threats posed by a given course of action. These could be relevant to this investigation.
2. A systematic review of the benefits of osteopathy is needed, analogous to the review by Carnes et al on risks in osteopathy. The study should aim to quantify benefits in both absolute and relative terms, and estimate the rates of response in the treated populations, as discussed in Chapter 2.
3. Research is needed to develop nationally-agreed information and guidance materials for osteopaths, using an inclusive process that allows all sectors of the profession to take part in the development. On the basis of the limited evidence available, it appears that most of the risk information in current use within the profession does *not* facilitate discussion of risks and benefits or shared decision-making with osteopathic patients. Better information and guidance is much needed for the profession to use in practice. Standard osteopathy-specific terminology corresponding to level of risk (“low”, “very low” etc) needs to be agreed within the profession. The development needs to include not only the wording but also design and graphics. The end product may well comprise multi-media information to cater for different learning styles.
4. Research is needed to understand the needs and improve communication with minority groups within the patient population. The research above will collect some information from minority groups, perhaps sufficient to meet the needs of different socio-economic strata, but further research is needed focussing on patients from minority ethnic groups as well as those with communication barriers, such as communication disability.

5. Any new information and guidance materials for widespread use will need to be evaluated in routine practice, gathering views on barriers and obstacles to implementation, and ways in which these might be overcome. This stage could incorporate educational events for practitioners, where they could share their experiences of shared decision-making. Existing research on evaluating decision aids, mentioned in Chapter 7, could potentially suggest suitable methodologies for this further research.
6. The teaching of communication skills for shared decision-making to practitioners is a specialist area and appropriate material needs to be developed based on current research.
7. The development and evaluation of decision aids for clinical decision-making is an active area of current healthcare research, and an area where computers can be helpful for patients, especially for personalising the risk according to the patient's age, gender, and other risk factors. This is a topic for future research.

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## **APPENDIX 1 The Research Team and Steering Group**

### **Research team**

Janine Leach, University of Brighton	Principal Investigator
Anne Mandy, University of Brighton	Senior Management
Matthew Hankins, Brighton and Sussex Medical School research in communicating risk	Review methodology and
Rachel Ives, College of Osteopaths ( <i>assisted by Julie Thompson</i> )	Professional Education
Vinette Cross, University of Brighton research and adult learning	Practice based education
Mark Cage, University of Brighton Communication	Language and
Kevin Lucas, University of Brighton	Systematic reviewing

### **Steering Group**

Tim McClune, Osteopath and former Member of the GOsC Professional Conduct Committee (PCC) (representing NCOR grants committee)

Bernadette Ranger, Admissions Officer, European School of Osteopathy (representing Service Users)

David Balen, Director of Balens Specialist Insurance Brokers, a provider of professional indemnity cover for osteopaths

Asgar Hassanali, Executive Director, Lockton Affinity, a provider of professional indemnity cover for osteopaths (from September 2008)

### **Advisors**

Paul Grant, Solicitor and Osteopath, BSG Solicitors, London (representing solicitors who represent osteopaths or complainants in court)

Professor Julie Stone, Barrister, consultant on regulatory, legal, and ethical issues to the healthcare sector

Catherine Goodyear, Business Manager, British Osteopathic Association (BOA) (representing the osteopathic professional association)

## **Appendix 2 Search strategy and results**

### *Sources*

#### *Grey literature*

Google searches was used to locate grey literature available on the internet from professional bodies and other sources, such as medical training materials, and best practice documents from professional bodies such as the Royal College of Physicians.

Osteopathic sources such as GOsC, the British Osteopathic Association, and faculty and specialist lecturers for Osteopathic Educational Institutions (OEIs) and CPD events were accessed (lectures delivered by D Balen and Julie Stone, and the complaints course delivered by GOsC).

#### *Research literature*

Evidence was gathered from research databases including Medline, CINAHL, AMED, BNI, SPORTDiscus and PsycInfo, and Science Direct. The main search terms were risk, communication, perception, informed consent and shared decision-making. The full search strategy is given below.

Since practice in this field has advanced rapidly, only information published since 1990 was used. Because of time constraints, only English language and readily available material will be included.

The results were filtered on relevance to a clinical consultation about treatment for non-life threatening conditions. Exclusion criteria included risk communication about genetics, screening, lifestyle, environment, preventive treatments, and public health. Pearl searching and related papers were also used.

The full text of all relevant papers was obtained, and evaluated for strength of study design.

## Formal search strategy

The main topic areas for literature review were (1) communication of risk, as relevant to osteopathic practice, obtaining informed consent for treatment, and shared treatment decision-making and (2) effective interventions to train practitioners in communication.

## Terms for systematic searching of the research databases

### A. RISK COMMUNICATION

The initial search identified papers within this whole domain (risk AND communication), identified time eras within this area of research and any major authors, before focussing the search as below.

The search was step-wise, looking at the results for each term, and then as the additional terms were added.

<b>Top Level Terms</b>	<b>Refining</b>	<b>Subsets</b>
Patients / lay	Not general public / volunteers	Adolescents Elderly Ethnic minorities
Type of complaint <i>e.g. not serious or life-threatening or emergency</i>	Back pain / neck pain / pain patients chronic disease	
Treatment interventions	Manual treatment family practice / GP surgery / outpatient clinic NOT prevention or screening or research	Physio/ Chiro/ Osteopathy cervical manipulation
Type of risk <i>e.g. serious and rare</i>	Risk of treatment; Adverse event; Side effect;	Iatrogenic
Type of communication <i>e.g. in person, face to face</i>	Patient-practitioner, patient-doctor Personal discussion face-to face in clinic NOT postal / telephone	Decision aids, pictures, visual aids, diagrams, models ; Explanation Discussion
Aim of discussion <i>e.g. understanding risks Facilitate discussion Fully informed consent</i>	Shared decision-making about treatment / SDM Informed choice Decision support NOT informed consent for research	Capacity to consent Risk perception Being in control, empowered to decide, consumer involvement

**B. INTERVENTIONS TO IMPROVE PRACTITIONER- PATIENT COMMUNICATION**

<b>Top Level Terms</b>	<b>Refining</b>	<b>Subsets</b>
Practitioners / Doctors	Manual therapists Health professions Complementary therapists	
Effective interventions	Training Videos	Prefer randomised studies
Improved communication	About risk Facilitate informed consent Shared decision-making about treatment	

Communication skills and decisions aids are major topics in their own right, so only recent reviews will be used. It is a topic for future research.

**Results**

As this is a huge area of research, the search was limited by sourcing only the high quality papers on current best within healthcare from Pubmed and Cochrane databases. All the databases were then used to identify papers relevant to the research within the minority areas of manual therapies, young and elderly patients, and ethnic minorities (cultural differences).

**Annual counts of publications on PUBMED (access date 021210):**

Search terms **risk AND communicat\***

<b>Published in the last 1 year</b>	<a href="#"><u>1419</u></a>
<b>Published in the last 5 years</b>	<a href="#"><u>6607</u></a>
<b>Published in the last 10 years</b>	<a href="#"><u>10679</u></a>
<b>Total all years</b>	<a href="#"><u>15953</u></a>

**Effect of Limit to humans, and patients**

<b>Humans</b>	<a href="#"><u>13891</u></a>
<b>Humans, published in the last 1 year</b>	<a href="#"><u>823</u></a>
<b>Patient* , Humans</b>	<a href="#"><u>4979</u></a>
<b>Patient* Humans, published in the last 1 year</b>	<a href="#"><u>310</u></a>

## PubMed Search History

(search 37 includes surgery; final search 38 excluded surgery)

Search	Most Recent Queries	Time	Result
<a href="#">#38</a>	Search ("Patients"[Mesh] OR patient*) AND (risk AND communicat*) AND (("Family Practice"[Mesh] OR "general practice*") OR ("Musculoskeletal Manipulations"[Mesh] OR physiotherap* OR osteopath* OR chiroprac*)) AND ("Decision Support Techniques"[Mesh] OR shared decision making OR informed consent OR informed choice) Limits: only items with abstracts, Humans, English	08:09:31	<a href="#">26</a>
<a href="#">#37</a>	Search ("Patients"[Mesh] OR patient*) AND (risk AND communicat*) AND (("Family Practice"[Mesh] OR "general practice*") OR ("Musculoskeletal Manipulations"[Mesh] OR physiotherap* OR osteopath* OR chiroprac*) OR surg*) AND ("Decision Support Techniques"[Mesh] OR shared decision making OR informed consent OR informed choice) Limits: only items with abstracts, Humans, English	08:06:50	<a href="#">103</a>
<a href="#">#32</a>	Search "Decision Support Techniques"[Mesh] OR shared decision making	07:41:43	<a href="#">47980</a>
<a href="#">#19</a>	Search risk AND communicat* AND patient* Limits: Humans	07:25:31	<a href="#">4979</a>

## Cochrane Database

### [Personalised risk communication for informed decision making about taking screening tests](#)

Adrian GK Edwards, Rhodri Evans, Joanna Dundon, Sally Haigh, Kerry Hood, Glyn J Elwyn

### [Decision aids for people facing health treatment or screening decisions](#)

Annette M. O'Connor, Carol L Bennett, Dawn Stacey, Michael Barry, Nananda F Col, Karen B Eden, Vikki A Entwistle, Valerie Fiset, Margaret Holmes-Rovner, Sara Khangura, Hilary Llewellyn-Thomas, David Rovner

July 2009

### [Interventions for improving the adoption of shared decision making by healthcare professionals](#)

France Légaré, Stéphane Ratté, Dawn Stacey, Jennifer Kryworuchko, Karine Gravel, Ian D Graham, Stéphane Turcotte

May 2010

**Search for minority topics in all databases**

<b>Database (limits)</b>	<b>Risk AND communicat * OR informed consent</b>	<b>AND osteopath*</b>	<b>AND chiropract*</b>	<b>AND physiotherapy*</b>	<b>AND child* OR elder*</b>	<b>AND cultur* OR ethnic*</b>
CINAHL 1986-2101 with abstracts, scientific journals	3187	3(1)	9(1)	13(2)	232(6) ☆	48 (6) ☆
AMED BNI Psycinfo+ Sport discuss  <i>With full text, periodicals only</i> ☆	1444	2 (0)	4(1)	6 (2)	88(6) ☆	139(6) ☆
Science direct Medical and HP journals	604	2(1)	7 (2)	13 (3)	14 (3) 2(0)	1(0)
Pubmed	21709	12 (4)	14 (4)	24 (3)	4200 514	
Pubmed	Full focussed search N=103	0			11(5) 3 (0)	3 (3 +related links)

**Filtering abstracts**

The abstracts were imported to a bibliographic database and screened individually for relevance. The inclusion criteria were that the communication topic had to relate to:

- a clinical consultation (not focussed on public health, legal or ethical considerations or risk management)
- a health problem is that acute or chronic but is not life-threatening (e.g. cancer)
- an active treatment intervention (not prevention or prophylaxis, or lifestyle, environment, genetics or screening)
- concerning serious but rare risks of treatment
- the publication should be peer-reviewed scientific publication about original research; books or reports were included only if a very recent

**Appendix 3 Participant packs inviting those interested to take part in focus groups** (*Note: included as seen*)



**University of Brighton**

Dear Sir/Madam,

**Research on communicating risks of treatment to patients in osteopathic practice**

I am a researcher at the University of Brighton. I am writing to invite you to take part in this study to find out about effective ways of communicating risk of adverse effects to patients, good practice when seeking informed consent, and practitioners' understanding of clinical risk.

The Information Sheet attached tells you about the study. When you have read it, you can decide whether or not you want to take part.

There is also a Consent Form attached. Please can you to let me know whether or not you wish to take part by filling in the Consent Form and returning it to me in the reply-paid envelope.

If you do not wish to take part, that is fine. Just tick the "No" box on the Consent Form.

If you would like more information about the study, call 01273 643457 and ask to talk to me or one of the other researchers on the "Communicating risk" project. We will do our best to answer your questions.

Thank you for taking an interest in our study.

Yours sincerely

Dr Janine Leach  
Senior Research Fellow in Osteopathy

Telephone: 01273 643457  
Email: [c.m.j.leach@brighton.ac.uk](mailto:c.m.j.leach@brighton.ac.uk)





## **Participant Information Sheet**

### **Communicating risks of treatment to patients in osteopathic practice**

#### **Why are we doing this study?**

The research is about effective ways of communicating risk of adverse effects to patients, good practice when seeking informed consent from patients, and practitioners' understanding of clinical risk.

The main part of the study was a review of published scientific papers and clinical guidelines to find evidence of current good practice. We have now reached the final stage which is to discuss the findings with a small group comprising osteopathic patients and osteopaths. These discussions will shape the final recommendations that are made from the study, about communicating risks within osteopathic practice.

#### **Why have I been invited?**

The College of Osteopaths is assisting us with the study, and we are inviting patients and osteopaths associated with the college to attend the discussion group. We would like to talk to a group that varies in age, ethnic group, social background and health problems. Everyone taking part will need to be reasonably fluent in spoken English.

#### **Do I have to take part?**

No, you are free to choose whether to take part or not. When you have read the Information Sheet about the study, it's up to you to decide if you want to take part in the study. Whatever your decision, it will not affect the care that you receive from your osteopath, if you are a patient.

#### **What will happen to me if I take part?**

If you are willing to take part, please send the Consent Form back to the researchers. If you consent, the researchers will telephone you to check if you have any further questions, to make sure you still wish to participate, and to see if the time and place arranged are convenient for you. If you agree to attend, they will also telephone to remind you on the day before the interview.

The discussion group will last about one hour and will be led by two University researchers. It will involve one researcher asking some questions about your views on the risks of osteopathic treatment, and how such information should be presented to you in the clinic. The researcher will invite you and the other people to talk about your views. We hope there will be 4-8 people in the group. The second researcher will take notes on paper. You will not have met the researchers before, and your osteopath will not be there, because we want you to feel free to voice your opinions in full.

The researchers will make an audio-recording of the discussion, so that they can listen to it again later. They will not identify individual voices on the recording, because they are interested in the viewpoints that are expressed, not who they belong to.

**What will come out of the study?**

The researchers will use the views collected from the discussion to help them to make recommendations on how risks should be communicated in osteopathic practice.

We will write a report about the results, and all the data presented in the report will be anonymous. The report will be available from our web site, or you can ask for a printed copy to be sent to you.

**Are there any risks of taking part?**

The researchers will not ask any questions of a sensitive nature, but it is possible that the discussion might introduce issues related to pain or discomfort previously experienced, that you find distressing or disturbing. If you were to become anxious or distressed during the interview, the researchers will be able to comfort you. They will offer you the opportunity to take a break or to go home. With your permission, they would also contact your osteopath or GP, who would advise you about further support if needed.

**Are there any benefits to taking part?**

Taking part in the discussion will not benefit you directly. We will reimburse your travel expenses for getting to the interview, and tea and biscuits will be offered during the interview. We hope that you will find it an interesting experience. Taking part will benefit future patients, by helping us to improve communication in this area.

**Will my details be kept confidential?**

This study was checked carefully by an ethics panel\*, to make sure that we respect participants' rights and ensure their privacy, confidentiality and safety.

All the data collected in the study will be anonymous and will be stored securely at the University of Brighton until the end of the study. No personal data will be collected. The research will not reveal to your osteopath, or to anyone reading the results, who took part in the study or what information they contributed.

The only exception to total confidentiality would be in the unlikely event that information from a patient suggested very serious misconduct by an osteopath. In that case, the researchers would have a legal obligation to trace the practice concerned.

**Who is organising the research?**

The General Osteopathic Council has asked the University of Brighton to conduct the study. The College of Osteopaths is supporting it. Dr Janine Leach is the researcher who is leading the project. She can be contacted at:

Clinical Research Centre for Health Professions

University of Brighton, Aldro Building, 49 Darley Road, Eastbourne BN20 7UR

Telephone: 01273 643457

Email: [c.m.j.leach@brighton.ac.uk](mailto:c.m.j.leach@brighton.ac.uk)

Web site for this project <http://www.patientexpectationstudy.org.uk/>

\*The ethical panel that has checked this study is The Faculty of Health and Social Science Research Ethics and Governance Committee, University of Brighton



**Research on communicating risks of treatment to patients in osteopathic practice**

**PARTICIPANT CONSENT FORM**

*Tick as appropriate*

The researcher has explained to my satisfaction the purpose of the study and the possible risks involved	
The researcher has explained the procedures to me and I have read the Information Sheet and have had the opportunity to ask questions. I fully understand what is involved	
I am aware that the researcher will interview me	
I am aware that the researcher will record the interview	
I understand that any confidential information will be seen only by the researchers and will not be revealed to anyone else.	
I understand that participation is entirely voluntary and that I am free to withdraw at any time	
YES I agree to take part in the study	
NO I do not wish to take part in the study	

**Please sign below**

**Participant**

Signature	PRINT	Date
-----------	-------	------

**Researcher**

Sign	PRINT	Date
------	-------	------

Please sign both copies. One copy is for you to keep.

**Please return one copy in the stamped addressed envelope** to Dr Janine Leach, Senior Research Fellow in Osteopathy, Clinical Research Centre for Health Professions, University of Brighton, Aldro Building, 49 Darley Road, Eastbourne BN20 7UR

**Appendix 4** Information material provided for discussion at focus groups (*Note: included as seen*)

## Risks and benefits of osteopathic treatment for discussion with your practitioner



All activities carry some risk, and osteopathy is no exception. This booklet tries to set out the risks, the benefits, how these compare to other treatments, and tries to help you come to a decision about what kind of osteopathic treatment you want.

The risks of osteopathic treatment are extremely small, and osteopaths can use different techniques to make them as small as possible. Your osteopath will try to minimise any risk that you will be harmed by treatment. They will assess your risk based on your medical history, your family history and clinical tests.

Please discuss with your practitioner how the facts below apply to you, and they will help you decide what kind of treatment you want.

Note for practitioners: the information in this booklet is based on the most recent studies of osteopathic risks and benefits, and on scientific research on how best to present risk in a clinical consultation. It is important that you talk through the information with your patient; advise them using your own clinical judgement; and help them to make a decision that they are happy with.

*Further information about the evidence provided here, as well as the references supporting the statements made, can be found in the NCOR2 report produced from this study, which will be available on the NCOR web site. The author is Dr Janine Leach, University of Brighton, email [c.m.j.leach@brighton.ac.uk](mailto:c.m.j.leach@brighton.ac.uk)*

### What are the risks of osteopathic treatment?

Adverse effects	How often do they occur?
<p><b>Mild effects</b></p> <ul style="list-style-type: none"> <li>○ Tenderness or stiffness</li> <li>○ Headache</li> <li>○ Tiredness</li> <li>○ Light-headedness</li> <li>○ Numbness and tingling in the first 1-3 days after treatment, which then disappear</li> </ul>	<p>Mild effects are common.</p> <p>About <u>half of all patients</u> experience them</p> <p>They are as common as getting “heads” when you toss a coin.</p>
<p><b>Moderate effects</b></p> <ul style="list-style-type: none"> <li>○ more severe pain</li> <li>○ bothersome numbness and tingling</li> <li>○ lasting weeks or months</li> </ul>	<p>Moderate effects are quite common.</p> <p>These are experienced by about <u>1 in 100 patients</u>. And 99 in 100 patients (99%) will not have these effects.</p> <p>The risk is about the same as drawing an ace of spades from a pack of cards, or being injured in a fall on your stairs at home this year.</p>
<p><b>Serious effects</b></p> <ul style="list-style-type: none"> <li>○ requiring emergency medical care</li> <li>○ long term damage</li> <li>○ may be irreversible</li> </ul> <p>Examples are:</p> <ul style="list-style-type: none"> <li>○ Stroke</li> <li>○ Nerve damage</li> <li>○ Muscular weakness</li> <li>○ Bowel and bladder weakness</li> <li>○ Death</li> </ul>	<p>These are rare.</p> <p>Tens of thousands of people have been followed up after manipulative treatment and <u>no</u> serious effects have been observed.</p> <p>A few patients suffering a stroke had a neck manipulation some time before, but stroke also can be triggered by mild neck impact in sport, at the hairdresser, driving or sneezing. More details are on the back page.</p> <p>The best estimate of the risk is <u>1 in 10 000 treatments</u>.</p> <p>This is 1 person in capacity crowd at the football stadium at Southend, Bury or Luton.</p> <p>The risk is like the chance of finding a needle in a haystack</p> <p>The risk is about as rare as dying in an accident at home in one year, or dying in a road accident.</p>



## The benefits from osteopathic treatment

### How much can you expect to improve?

There is strong evidence of the benefit of manipulative treatment for back pain. In an American trial, osteopathic treatment reduced back pain by 30% on average. In a UK study, acute patients were less likely to need hospital treatment. Manipulation is likely to improve neck pain and function following 1-4 sessions, especially if combined with exercise.

### How quickly can I expect to improve?

In a survey of UK osteopathic patients, more than 70% of patients considered they were improved or much improved after the first appointment. After 3-4 treatments more than 80% had improved.

About half the patients with neck pain, treated with chiropractic manipulation, considered they were recovered after 4 treatments, and about two-thirds had recovered at 12 months after their first treatment.

### Does the improvement last?

Back pain sufferers gain small but significant benefit at 3 and 12 months after treatment, compared to GP care.

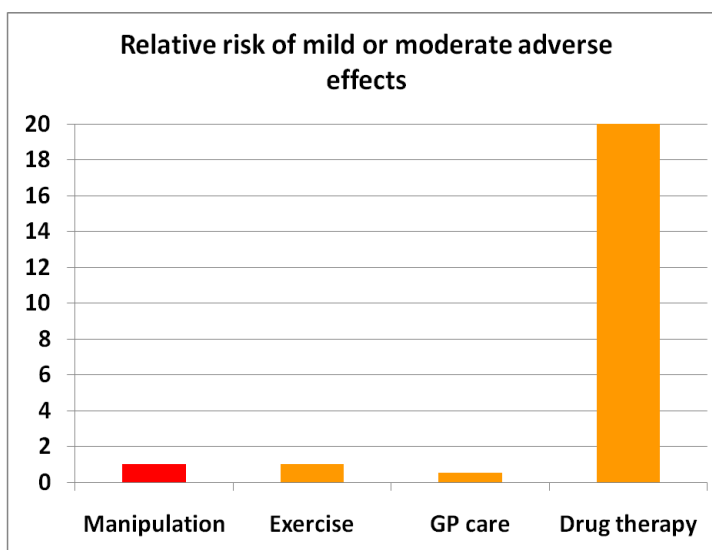
### Will it cure my problem?

In terms of longer term cure, osteopathic treatment tackles the cause of your problem, it does not simply mask the pain like drugs do. Tissues that have been damaged are weakened, and problems do recur sometimes.

## Other treatment options for your symptoms

Other treatment options such as massage, exercises, acupuncture and medication. can be beneficial. But in clinical trials, spinal manipulation (e.g. osteopathy or chiropractic) and acupuncture are more effective than the other options.

All options have a similar (tiny) risk of serious effects. The exception is the long- term use of pain-killers, which carries a much higher risk (of causing bleeding in the stomach).





## **What are my options?**

In order to decide if you want osteopathic treatment and if so, whether you want manipulation, you need to look at the risks and the benefits and decide what seems the best course - for you.

### **Option 1. Do nothing - don't have treatment**

It is possible you will get better in the course of time, even without treatment.

### **Option 2. Have osteopathic treatment without any forceful manipulation**

This means techniques like massage, stretching or cranial will be used. There is limited evidence about the effectiveness; the risks are probably similar to Option 3.

### **Option 3. Have osteopathic treatment without any forceful manipulation of low back or neck**

The results of this course are likely to be that after a course of treatments, you are most likely to feel improved. The risk of serious adverse effects is slightly less than option 4.

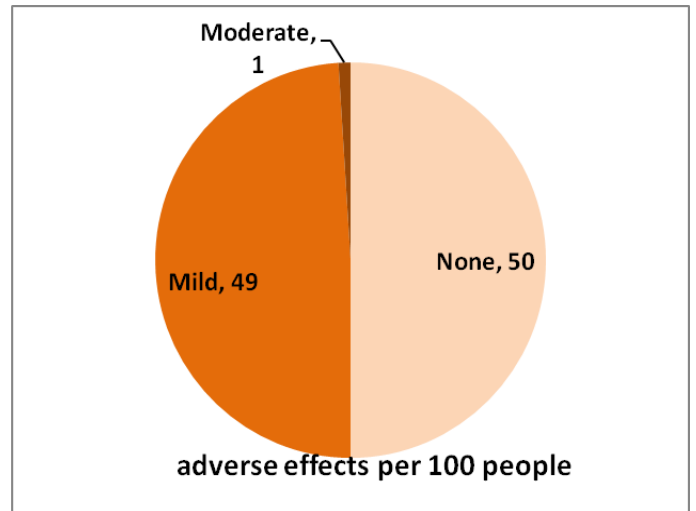
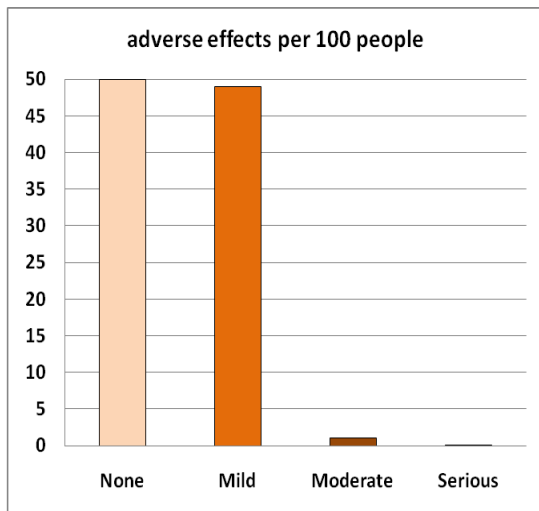
### **Option 4. Have osteopathic treatment including manipulation if your practitioner feels it is appropriate**

Adding manipulation (the most forceful type of osteopathic treatment), means that treatment is a little more likely to be effective, but there is an additional risk of a rare serious adverse effects such as stroke or damage to a disk, which might affect 1 in 10,000 people.

# Risks and benefits of osteopathic treatment for discussion with your practitioner

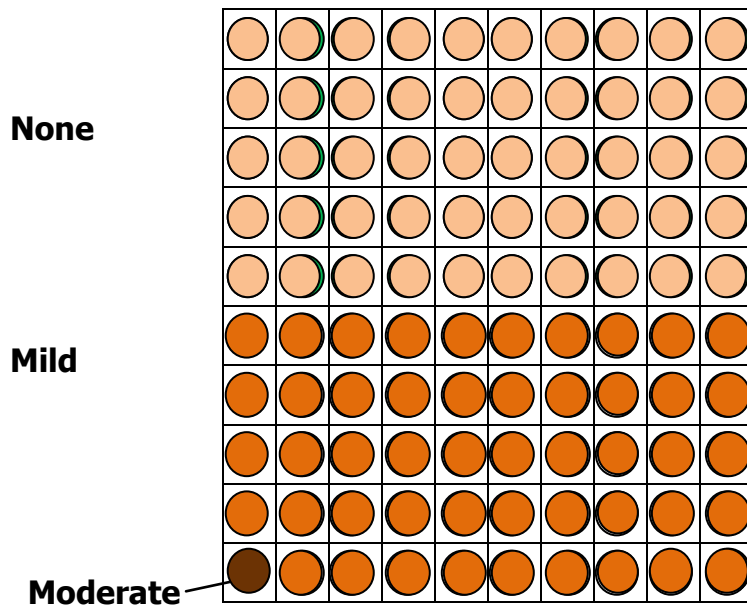


## Part 2 additional information



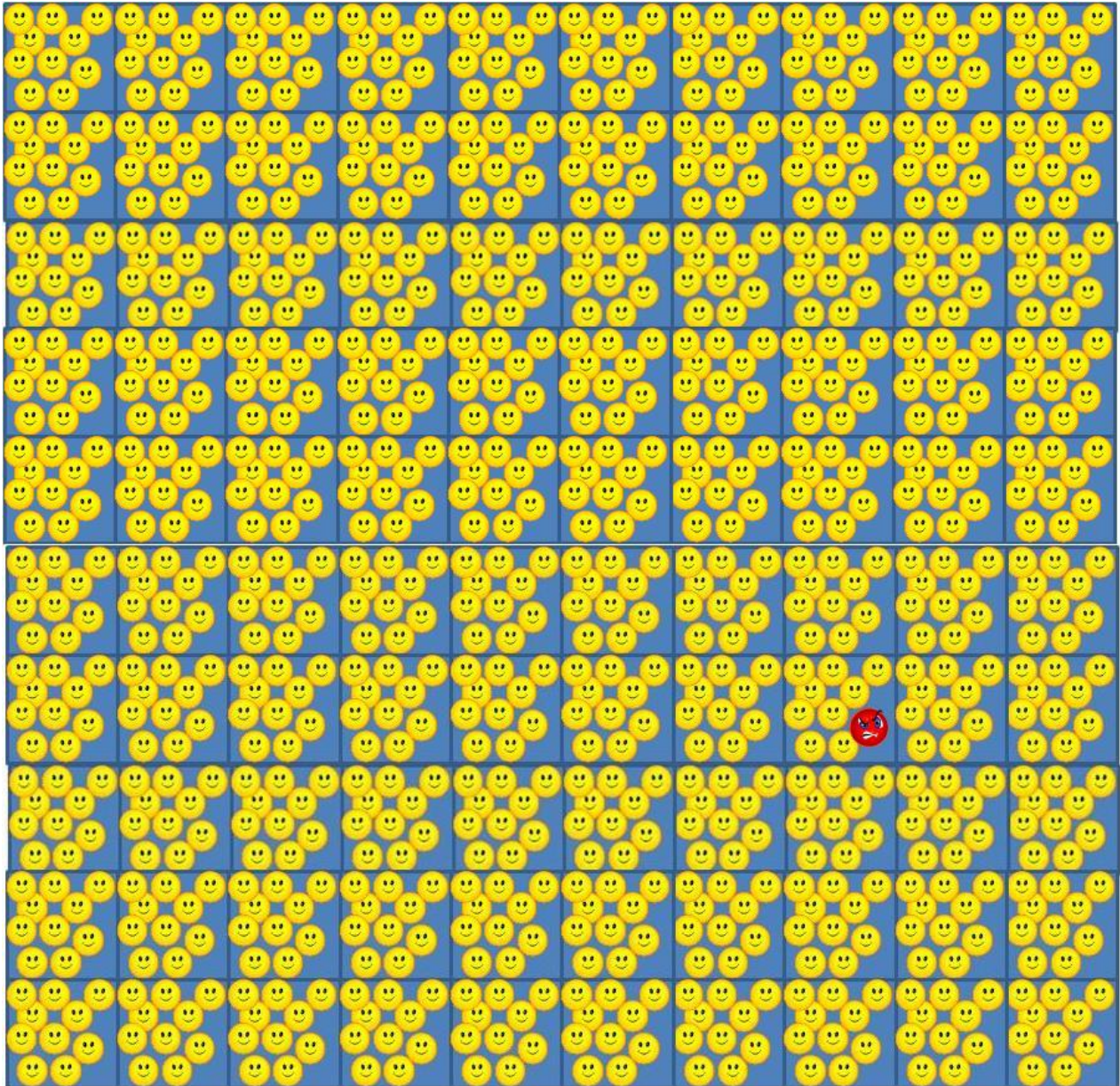
**Graphics explaining the mild and moderate risks of osteopathy:  
which graph do you find most helpful?**

### Adverse effects in 100 people

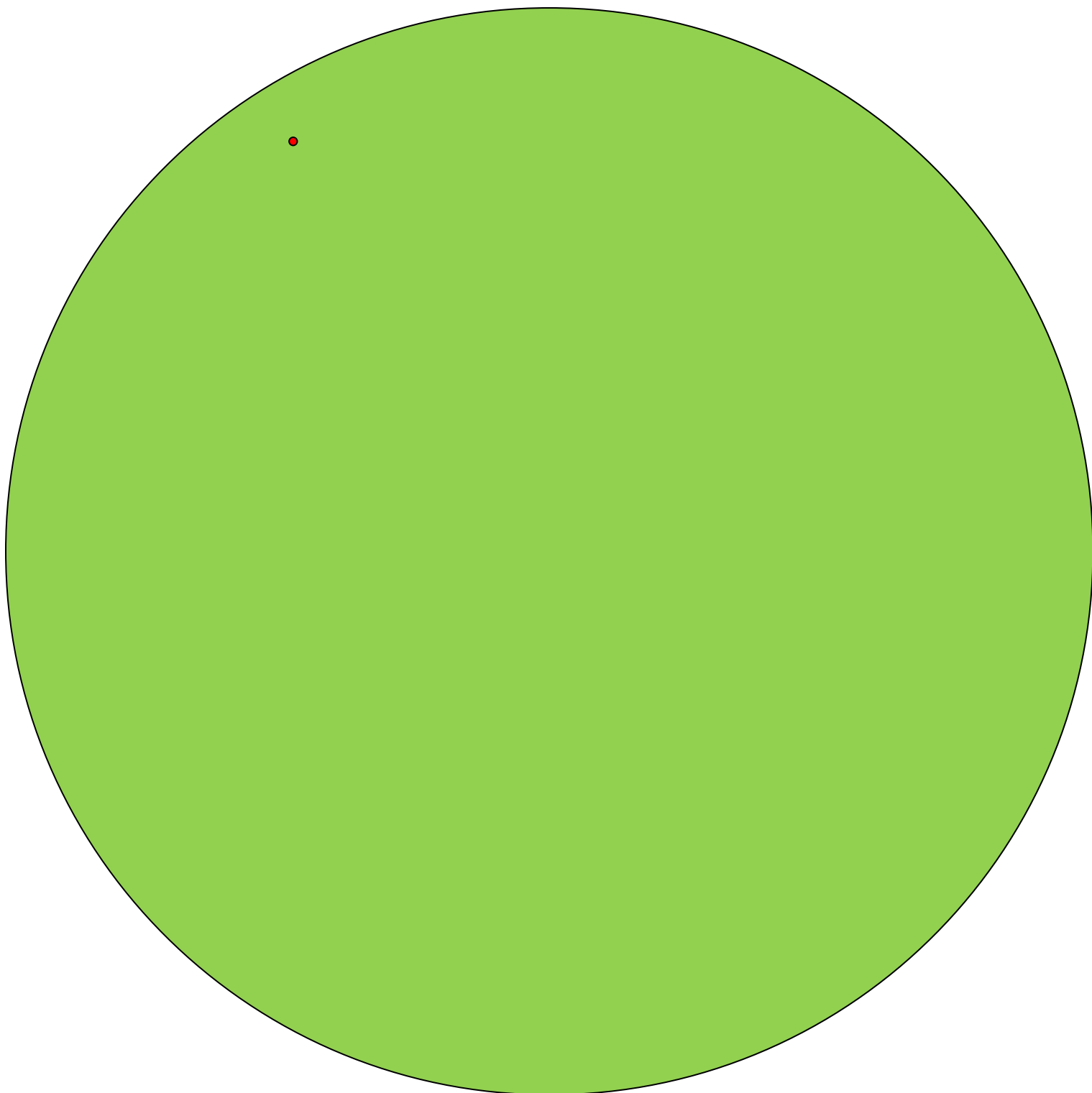


### Graphics explaining serious risks which do you find most helpful?

This risk is so small it is hard to show graphically, but let's have a go! Only 1 person in 10 000 has a serious effect. In the block below there is one red "bad" smiley and 999 happy smileys, 1000 in total. Imagine another 10 blocks full of happy smileys, and then you would have one red one in 10 000.



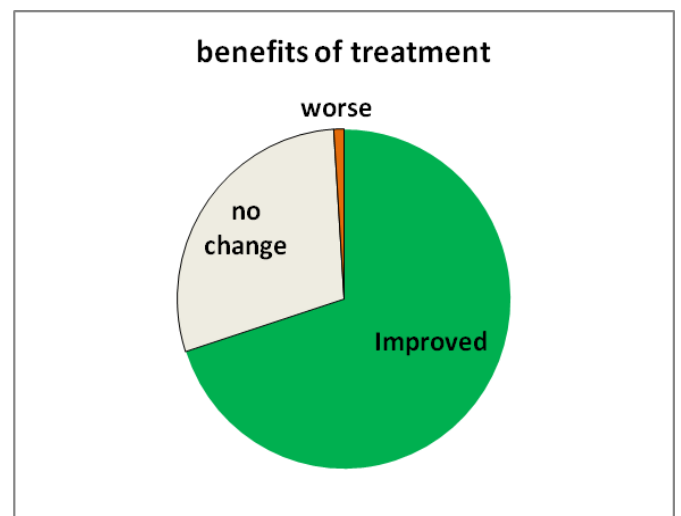
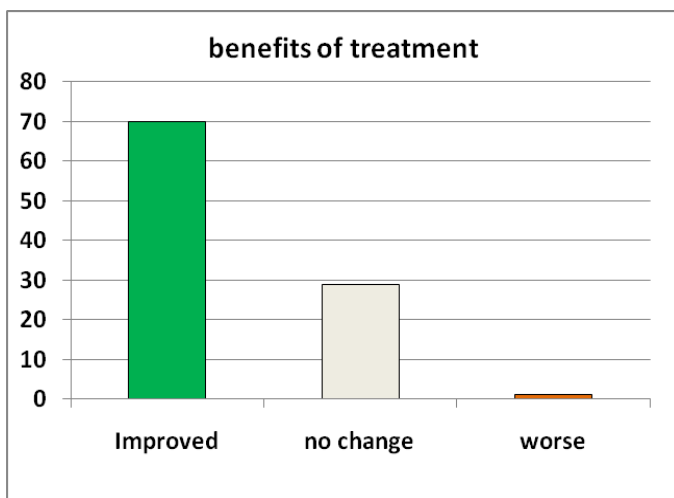
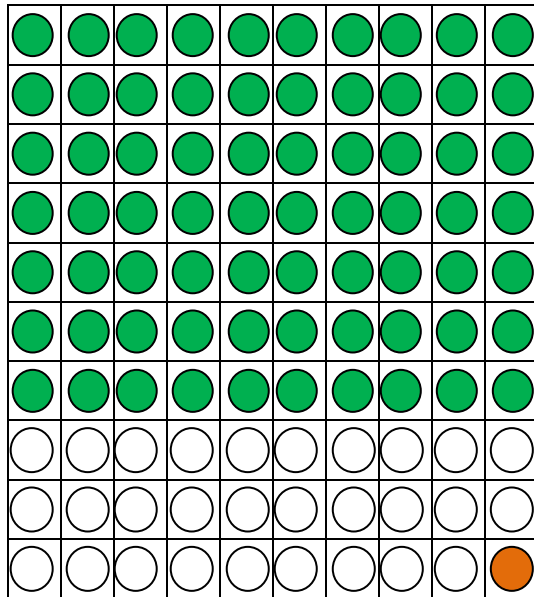
This picture represents the risk of 1 in 10 000 as a grain of sand - the red dot – on an area of beach containing 10,000 grains



**Graphics for benefits of osteopathic treatment:  
which picture do you prefer?**

***Benefits of treatment in 100 people***

Better =green dot ●    Unchanged= white dot ○    Feel worse =orange dot ●



## A decision aid for choosing the type of treatment for your problem

First clarify the decision in the table below.

Write down what you see as the risks and benefits of each treatment option.

Then put \*\*\* to identify which ones matter to you most:

	<b>OPTION</b>	<b>BENEFITS</b> Reasons to chose this option	<b>RISKS</b> Reasons to avoid this option
1	<b>No manual treatment</b>		
2	<b>Osteopathy but don't manipulate at all</b>		
3	<b>Osteopathy including manipulation if appropriate</b>		
4	<b>Osteopathy but don't manipulate my back or neck</b>		

**Are you leaning towards one option?** (which).....

**Which role do you prefer in making this decision?** (tick one)

- To share the decision with (who?) .....
- To decide yourself after talking it over with (who?) .....
- For someone else to decide (who?) .....

**Are you clear about what matters to you most?** **Yes No**

**Are you choosing without pressure from others?** **Yes No**

**Do you feel sure about the best option for you?** **Yes No**

If you have answered "No" to one or more questions, you might regret your choices, it is important to work through the next steps. If you are feeling others are pressurising you, it might help to focus on the views of people who matter most to you, or to find a neutral person to help you.

If you are unsure, list your questions, and delay your decision.

**Do you need support and advice from others?** **Yes No**

**Do you need more information or facts?** **Yes No**

To find out more, and talk to people who have experience or knowledge, maybe a health professional or a counsellor, or read more information.

**Next steps** .....

*(adapted from Ottawa personal decision guide)*

## **Appendix. Additional details about the causes of serious adverse effects**

There are two manual techniques which very rarely might cause a serious adverse effect.

### 1) Neck manipulation

Neck manipulation can damage the arteries in the neck (called "cervical artery dissection") and this can lead to a stroke. The arteries in the neck are quite vulnerable and such damage can occur (equally rarely) during everyday activities such as accidental blows during falls, sport or leisure, turning the head while driving, sneezing, or the back-wash at the hairdresser. Strokes are an irreversible serious effect, often seriously disabling; about 5-10% of all strokes are fatal.

### 2) Manipulation of the low back

Manipulation of the low back in very rare cases may cause damage to a "disc" between the bones of the spine. Very rarely, this can lead to the nerves in the spinal cord being compressed, causing weakness of the legs, numbness in the buttocks, or incontinence. This sometimes requires emergency surgery to rectify it.



## **APPENDIX 5 Focus group field notes and edited transcripts**

**Two Focus groups were held on the same day, one for practitioners and one for patients. Both groups were given the material, the aim of the project and the purpose of the material was explained, and they were asked to look at the material and comment, overall and section by section.**

Observer: Julie Thompson  
Facilitator: Jan leach

### **Practitioner Focus Group**

#### **Practitioner participants**

Female: R, T, C  
Male: P, W

#### **Field Notes**

*All practitioners in private practice and working as college clinic tutors, one also employed within the NHS. Varied in style of osteopathy, prior training, and age.*

Flow through meeting: started defensively, several practitioners with arms crossed, others sitting in open posture but looked anxious.

As meeting progressed, increasing engagement – actual reading and interaction with the materials rather than what they thought were in the materials.

Towards the end of the meeting, positive suggestions were made by all participants.

#### **Practitioner Focus Group: edited verbatim transcript**

##### **Immediate reactions**

W: I already have an objection, even before I get to the first paragraph, the risk outweighs the benefit in the graphics on the front page- a picture paint a thousand words

R: What could this become?... a nationally agreed leaflet?

T: I agree that something is needed especially since Clause 20... As a teaching school we introduced in consultation with the clinic tutors, something to have something available, for patients to talk thru

J: do the students discuss it?

T: The student practitioners will discuss all the adverse effects with patients

T: patients appreciate being informed

W: I think there is a trust

C: In the NHS, the main difference is that patients have a limit on the number of treatments they are given ...

J: Is there a difference in the environment on informed consent?

C: Some patients get annoyed about signing things; they say where are we going with all this Health and Safety ... I have a lot of comments about this

P: These alleged side effects – it's a very grey area – there are so many variables

P: I find this almost offensive “manipulation is the most forceful type of osteopathic treatment”. It does not have to be forceful.. that's mis-leading

T: the word “forceful”?

W : Am I taking it that you are saying you can only use research evidence – anything that is not established facts is wrong- is what he said fictitious then? Does experience not count?

W: a well known orthopaedic surgeon looked at our (risk) data and said any Orthopaedic department would welcome statistics like that – they are such small risks.

W: chiropractic manipulation is entirely different and it's much more dangerous. I have done both ...

P: (the risk data) would cause the patient a lot of confusion reading that, it seems to exacerbate the risk, not minimise it

T : It seems quite clear to me

W: In one way, we want to inform the patient but in another aspect, we are possibly installing fear --- there must be another way of putting it ...

J: how would you explain to a patient what their choices are?

W: a lot of what I do is not an HVT, but an MVT or an LVT ... I would not give them a choice of HVT or MVT or LVT, too much information can overwhelm them – but certainly give them the choice of approach: manual or other techniques ... gentler techniques

R: the use of a diagram is effective, like the histogram on page 3 ... when you see the options compared to drug therapy ... but is the highlighting in red deliberate?

T : it's important to have some kind of nationally agreed wording – patients expect something like that

C: patients respond “so much litigation”

T: if you were going in to hospital ... on the morning of the operation, you would see three different people to communicate that risk ... You wouldn't want to see osteopathy bogged down in red tape ... But it's necessary, it's good, but the ultimate thing as an osteopath is that you want to educate them ... about further injury ... or social change

W : education is good; programming them is not so good. You have to talk about risks and benefits together... language is terribly important

P: Cost effectiveness too ... most patients will go the quick route (*cites some typical costs*)

W: HVT can also be a gentle technique

T : Many times patients have told me about their experiences of the osteopath suddenly clicking their neck ... a slightly brutal approach ... perhaps osteopathic history but ...

T: Option 4 is a bit inciteful [sic], “forceful” conjures up there’s something traumatic ... “HVT is rapid and controlled” is not sounding biased

**Benefits page:** *little comment so moved onto Visuals*

## VISUAL SECTION

Risk diagrams like a “colour blind test”

Serious risk: Smileys preferred, a consensus - they are friendly, they are people, better than the sand. The red face should be sad not snarly.

Benefits diagrams: preferred Pie most, dots least

“All good”

R: would I show that to my patients? They have already decided to come and see me ... its better marketing material

W: not necessarily in the main material ... useful if they were a bit undecided

C: in the waiting area is very good – those that want clarification can pick it up and ask to talk about it

R: Patients will say “is it going to happen to me”

T: teaching schools see a wide diversity of patients, perhaps wider than private clinics. A patient who can’t understand the information, its best to start with the gentler stuff ... till the trust develops ...

W: if a patient is at all concerned, it is best to start with the gentler stuff, until the trust develops

T: Practices with 15-20 minute appointments are going to struggle with this information

### ***Re concept of shared decision-making***

W: patients have to be involved ... the greater the buy-in, the greater the benefit will be

### ***Re Options page***

W: *That not all we do*

T: it’s very narrow isn’t it ... within each category there is a huge range of what a practitioner can do. It’s not clear that each option covers a huge range

W: Doing nothing and not having osteopathic treatment are not synonymous

P: treatment can be to leave it alone

T: And osteopaths, hands-on is not the entirety of what they do ... there is education, advice, reassurance

C: when a patient has been to a physio, they may say they have had manipulation ... but it may be soft tissue

T: I am not happy with the way it (*Options*) is worded

C: could you just say “you do have options, please discuss them with your practitioner”

T: Maybe show a sliding scale of options—advice and exercise, gentler techniques, more subtle...how to word it “speed and control”

### **The Decision Aid**

R: isn't this over-egging the pudding?

T: too many words, too many things going on

P: please attend the clinic at least half an hour before your appointment!

T: condescending

R: was this developed for manual medicine ... yes it may be more suitable for difficult scenarios ...

### **Context of other risks**

J: what lifestyle risks are similar to osteopathy?

P: airplane pilots are much more tightly regulated –osteopaths are more varied in skill

### **Final thoughts**

P: this will be very good when it's finished, and necessary ... it will give a bit of uniformity

P: some of this information, condensed, would be good for the patient. Some is more PR

T: a poster maybe

P: whatever you produce will not be a substitute for rapport with the patient

## **Patient Focus Group**

### **Patient participants**

*Male: P – long term disability, long term user of osteopathy*

*Female: N – Has been having treatment for a range of symptoms for 2 years; C - first treatment course 2yrs ago, now starting new course for another problem, and is employed in NHS.*

*Small sample of patients, but range of ages and educational levels. Two women, one man. N less confident about speaking up, but gradually became more vocal.*

### **Field Notes**

The body language of the patients was positive and thoughtful. Their reactions were expressed in the words.

All wanted to give something back to the college – were satisfied users. They viewed the benefits as much greater than the risks. Even P who had experienced a lot of adverse effects, some quite severe e.g. collapse

They were eager to read the material, but did not have an immediate reaction to it- it did not speak to them, though they said they understood it. But it was clearly a topic they wanted information about.

They were equally concerned to get their full quota of treatment time, in order to have the results and outcomes P was particularly keen on the Options, (perhaps as a way of avoiding those adverse effects, because he knows his body)

## **PATIENT group: edited verbatim transcript**

### **Immediate reactions**

*They had a few minutes to read the information and then were asked for their reactions to it*

C: certainly they have that sheet (*Risk Statement displayed in all cubicles in the College of Osteopaths clinic*) on the tables in the clinic, it's the same as that, it's the worst case scenario, and I didn't take a lot of notice of it

N: yes, I remember signing the form.... There was no discussion (about the sheet)

P... the consent Form (in clinic) highlights the issues involved ... the risks are greater for some people, like myself

P .. in my particular back situation- it can never be cured ... Whenever they work on certain areas, treatment can make it a lot worse ... I have collapsed in the clinic... the Consent Form spells out the risks involved, you need to be aware of the risks ... it's very difficult because the osteopath does not know how the patient will react ... my risks are greater

C: One needs to say worst case scenario ... the doctor puts you on a drug, you are not given a whole lecture, or a consent form to say the small writing in the leaflet ... the doctor never highlights the risks.

In my job (diabetes antenatal care), certain things we do, it's probably best for the patient ... the drug might not be licensed and we have to highlight that to the patient, whereas if you go to the GP, they don't tell you about the drug.

C: Consent as a whole, because the medical profession don't do that ... if the osteopaths as a profession starts to do it, when a patient first comes for treatment it puts you in a bad light because you are highlighting the risk, where they are not used to having the risks highlighted

N: doctors seem to follow their own law

C: having seen the list (*RISK statement*) in the clinic – for my first treatment they just said "these are the risks, can you sign that you have read it", no-one discussed it. My thoughts were that they have got to do that in case something dreadful does happen

C: I don't think it's helpful to have more information. if I was having some strange treatment I would look it up on the internet, like when she did that back-twisting thing – that hold – she said did I mind, I said no, she was being supervised by a senior tutor, I trust him

N You do put your trust in people, don't you?

C: yes I trusted, if she was doing it on her own I might have felt different

N: When it comes to reading the small print, I'm afraid I'm a bit ignorant, I just do it. Like my back operation –I thought I need to do it otherwise I can't do things. So I signed the form and gave it back ... I put my faith in these people. Same when I needed (*osteopathic*) treatment, I was desperate to have treatment whatever

P: before I started coming here the doctor was pumping me full of pills and though the first couple of years was very stressful ... now I can walk straighter and I've cut down the drugs a lot. When I said to my GP I was coming here – there was a certain stigma about osteopathy, and it was not recognised as it is now. And I cannot fault this place; I would recommend it to anybody.

N: the stigma still exists – the doctor said to me "you are being treated privately are you – I can offer you it on the NHS" I said how long is the waiting list ... you need to get it sorted

## **FRONT Page**

C "would it be better if osteopaths had access to your medical notes?... In my job, people might forget about 50% of the things that are relevant. ... Patients could ask for a printout for the last year before going to the osteopath

P: I've had my medical details released to the osteopathic clinic – but it can take so long it delays your treatment and it's not a freebie ...

## **RISK PAGE**

C: it's quite scary, I would rather see the positives first, and then a paragraph on what might happen; the benefits first, otherwise I might think should I be here or not?

### **GRAPHICS PREFERENCES ON FORMATS**

*C likes bar chart*

*N liked Dots, especially if they were smileys*

*P: hurts his eyes looking at the dots, prefers bar chart*

### **Serious risk graphics**

N: (smiley) it's like a 3D puzzle- I would cut this out and put it on my fridge (laughs)

P: it makes my eyes hurt, I like this one (sand), that one's pleasant to look at and puts across what you need to know

### **WORDS, NUMBERS OR GRAPHS?**

N: I prefer words

C: I like the words. The graphics highlight the bad things. I know you've got to cover yourself but covering them in softer words....

### **ANALOGIES?**

N: I chuckled (*about the needle in a haystack and the football stadium*)

P: I think they confuse people

C: I agree

N: I like the funny bits, it's a serious thing, but at the same time...

C: I don't think people can relate to it (*stats on falls/ accidents*). The stairs- maybe if you are elderly, but I can't relate to it. If someone had lost someone in a road accident, they might be quite upset. It's not something statistical. And you might know two people who have been killed in a road accident and I might not know any. It's not mathematical, it's bad luck.

C: I presume if you had a stroke, you would have to have certain risk factors?

C: Where it says risk of stroke, you are not giving an age at treatment, if you were treating an elderly patient or an alcoholic say.... it's not quantified enough. I'd want to know the risk factors and I could look and say I don't apply to that.... you could frighten the patient before they even get started

C: making it more comparable to drug treatment for backache, makes it more comparable to osteopathic treatment. Car accidents and falling down stairs have no relation to osteopathic treatment. You could say like taking pain pain-killers for 10 years and your risk of gastric bleeding

### **Benefits page**

N: it's quite a high risk of improvement; I was surprised when I saw the percentages how high it was

*Long pause (? finding it hard to understand?)*

C: it's just research, there's no data, maybe looking at improvements, and it sounds very subjective

C: when someone asks you do you feel better than last week, it's very difficult because it might have righted itself anyway. When someone asks if the treatment has worked you don't really know.

N: I said I was 70% better this week and the practitioner said you said that last week

C: I had never had back pain before – my spine had tilted and she clicked it back in and my whole posture changed

P: without being a killjoy, I have gone out of here worse than I'd gone in... it depends on the individual and I don't think there's enough emphasis on advising the patient that there can be a downside to treatment. A patient may not walk out of the door ten times fitter. I don't see that highlighted anywhere. People need to be made aware, whether they are young or old, that not everyone is going to obtain what they are hoping to, and it may not work for everybody.

C: you always say it works, but it's hard to know. Do the trials say it's better than going to the GP? What people want to know is: what's the best thing to do to help my condition? Is osteopathy better than physio? I would have thought it depends on the individual osteopath and physio

P: people may not realise that medication causes the osteopath a problem because he can't see what's really going on, you are better off not taking the tablets.

### **Is the information understandable?**

*All the participants thought they understood the information, though some comments showed they mis-understood some information*

C: It (*the Options graph on Benefits page*) makes drug therapy look positive, that big bar

### **Options page**

J: is it *helpful to have options spelt out?*

C: I think it is. People with problems like conduction of the nerves..... they might want to have options. I'm healthy and I haven't got those problems, so I don't bother to read these things

P: yes it's superb to have that table to look at. When someone comes in the first time, they might be scared to death, not knowing what to expect, but seeing they have got a level of treatment options to go for, that would help them a lot.

N: personally – it's important to read about the risks, I've never heard of the “middle Way”

J: that's me trying to give them simple names

P: it really comes across well and helps understanding

N: I felt I've had the middle way – very slow; I think I'm about halfway...



### **Any other issues**

C: the whole thing about being here at the College, it's very different to a private clinic. I do sometimes think that working with students, there might be more risk, and that risk isn't always pointed out... I've never experienced anything but some students are much better than others like in any work. One student when I brought my daughter it wasn't effective, so we went to a private clinic. When you are really pushed for time – you pay twice as much but it's more effective and it's worth it

C: Also they use different year students here, and it's not always apparent. I always ask, but it's not like you get any choice.

N: You might like to see the same person again, but it's not like that, it's the luck of the draw.

P: I try and see someone who knows me- otherwise you lose about half your treatment time. I know you have to teach the students somehow, but I think there should be someone in with the newer person that could answer questions for them, to cut down on the time you lose....

N: yes, I feel I lost out on 20 minutes on Wednesday because he did not know my case

P: I phone up and ask who's in and pick and chose who I see on the day

N: You can do that, can you?

J: what makes it worth coming to the college clinic?

N: it's nice here; I feel more at ease here than I would at a private clinic

P: it's like a family atmosphere, a lovely reception; you're relaxed before you go for your treatment

J: should they be more open about what level the student is?

C: if people know what level the student is, like a 5th Year, then you feel more confident. You are more likely to look at risks if they are not skilled

C: well I wouldn't want to lose out on treatment time; the more questions and explanations, the less treatment time and that's what you are here for

P: I lost 35 minutes last time. I told L (clinic manager) it's not acceptable

P: Losing treatment time, you are paying for nothing. I get less time for my money, where they could have done so much. .. It's not about wasting my time.

J: is it about getting full benefit?

P: 95% of the time you get full benefit

### **NOTES FOLLOWING THE FOCUS GROUPS (JL)**

The defensive reaction of the practitioners, even though the participants were all confident, multi-skilled trainers, suggests strongly that changing professional practice and persuading

practitioners to use this type of material is likely to need personal engagement in an education learning process.

A separate sheet for practitioners is needed, containing the points below in some form. Practitioners seem to be keen on visual presentations.

The Ottawa Decision Guide may be a useful structure to explain to practitioners what they are doing within shared decision-making.

**Points for practitioners:**

This is an osteopathic pilot of shared decision-making

Explain that the information has to be based on research evidence as far as possible, but that they can present their own experience

The evidence on risk derives from spinal manipulation by different operators – possibly with different interpretations of manipulation

It is hard to find data in the right form for benefits

They needed reassurance that their own evidence (of long clinical experience and no adverse effects) is also valid and valued by the patient

They need to know their role: personalising the information to fit the patient's own risk factors - the patient wants to know if it will happen to them

Cost effectiveness may be useful additional material for practitioners

**Re-design of the material:**

Many patients want material in its simplest form, so a multi-layer design may be better: (1) a poster or leaflet with the basics, (2) a more detailed leaflet more like the one prepared here, but simplify the front page, for those that want it and (3) some further in depth information for those people who need a lot of information; it is important to prepare this because it's not easy for patients or practitioners to find accurate information on the internet.

The Options Section may be better as a separate poster/ Leaflet.

The benefits section proved more difficult, both groups needed to be talked through it with the graphics. Maybe it needs to be redesigned to show a spectrum of improvement and address the question- what's best for me.

Specialist help with the graphics would improve the look of the final product.

Certain evidence was beyond the scope of this study but would be very helpful: (1) best evidence on the benefits of osteopathy in the form proposed here and (2) the risk factors for stroke caused by Cervical Artery Dissection (CAD).