

Clinical Risk Osteopathy and Management Scientific Report



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Glossary

| | |
|-----------------------------------|---|
| AE | Adverse Event: Any untoward occurrence that may present associated with treatment, but which does not necessarily have a causal relationship with treatment |
| AUC | Area Under the Curve; or specifically in this thesis, the area under the ROC curve. |
| BSO | The British School of Osteopathy: An osteopathic education and research institution. |
| CI | Confidence Interval; The range around the point estimate that is likely to include the population parameter. The chance of it including this parameter is expressed as a percentage (eg the 95% CI). |
| CPD | Continuing professional development: Professional learning activities aimed at enhancing practice and keeping abreast of current knowledge. Current expectations for osteopaths in the UK include completing 30 hours per year of such activity, some of which should be undertaken in the context of learning with others. |
| Cranial techniques | Cranial techniques: Application of light touch and low force often conceptualised as influencing inherent rhythms within the body, interosseous function and connective tissue function. |
| CROaM | clinical Risk Osteopathy and Management study: Shortened title of one of four studies commissioned by the General Osteopathic Council concerning adverse events. |
| ES | Effect size; see standardised mean difference (SMD). |
| Functional techniques | Functional techniques: Slow application of movement to articulations of the body with aim of seeking a position of ease and low resistance of a joint and associated soft tissues |
| GOsC | General Osteopathic Council: The regulator of the practice of osteopathy in the UK |
| HVT | High Velocity Thrust: A manipulative procedure associated with cavitation of a joint. |
| LBP | Low Back Pain. |
| MET | Muscle energy technique: An exercise based procedure involving active contraction of muscles by patients with resistance being applied by the practitioner. |
| NHS | National Health Service; the public sector health service in the UK. |
| NICE | National Institute for health and Clinical Excellence; an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill-health. |
| Non-specific low back pain | Low back pain not thought not due to specific identifiable pathology. |
| NRS | Numerical Rating Scale; a discrete scale usually running from 0 to 10 (11 points) measuring a latent health construct that is marked by patient usually before and after treatment. |
| NSAIDs | Non Steroidal Anti Inflammatory Drugs. |
| P | - value; the probability of observing the result reported, or a more extreme result, if the null-hypothesis is true (ie no difference in score between groups). A <i>P</i> value of < 0.05 is interpreted as evidence for the intervention having an effect on the outcome being measured. |
| QALY | Quality Adjusted Life Year; a year of life adjusted for quality. A year in perfect health is considered equal to 1.0 and the |

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| | | | |
|-------------------------------|--|--------------------------------|--|
| | value of poor health is subtracted from 1.0. For example, a year spent with LBP might have a value equal to 0.8. | | |
| RCT | Randomised Controlled Trial. | | |
| Red flag | A sign or symptom that is associated with an increased risk of serious pathology and is an indicator for clinicians to be alert to the possibility of an underlying serious pathology | STT | Soft tissue technique: Direct application of stretching to a muscle often using massage and cross fibre type approaches. |
| Regression to the mean | Regression To the Mean; the tendency of extreme scores to ‘fall back’ toward the mean on remeasurement. | TQ | Transition Question; a single question asking a patient if he/she has experienced improvement or deterioration since beginning treatment. |
| ROC curve | Receiver Operator Characteristics curve; a plot of sensitivity (true positive rate) and 1-specificity (false positive rate). | UI | Unique Identifier: A individual number and or barcode used to identify participants whilst protecting their anonymity |
| SAE | Serious adverse event: Major adverse event associated with treatment, but not necessarily caused by treatment. These were defined in the practitioner questionnaire as serious treatment reactions that involved the onset of severe new symptoms or the worsening of existing symptoms after treatment leading to hospital referral and/or permanent disability and/or incapacity or death. | VAD | Vertebro arterial dissection: Damage to one of the arteries in the neck that is anatomically related to the cervical spine. Dissection is associated with hind brain stroke |
| SD | Standard Deviation; a measure of the variability or dispersion of data. | Vertebro basilar stroke | A rare type of ischaemic stroke associated with vascular pathology and dissection of the vertebral artery. |
| SE | Standard Error; the standard deviation (see SD) of the sampling distribution. | Visceral technique | Visceral technique: Manipulative procedures applied directly or indirectly to the viscera, often conceptualised as affecting associated connective tissue and the functional position of the organ concerned |
| SMD | Standardised Mean Difference; also referred to as the effect size (ES), this is the | | |

Key Summary Points

What we already know: There is an ongoing debate about the possible link between manipulation and negative outcome in patients. This has focussed on manipulation of the neck and stroke. In addition, there is a growing interest in other treatment reactions, such as increased pain and the appearance of new symptoms after treatment. To date, the evidence about manipulation is contradictory and there is little existing published information about these types of outcomes in osteopathy.

What we did: A survey to all UK practising osteopaths was carried out, followed by in-depth interviews of selected osteopaths. Osteopaths also invited patients to provide information about their experience of osteopathic care and its outcomes. Patients were surveyed before treatment, one day and two days after treatment and at six weeks. Selected patients were interviewed.

1,082 (27.8%) osteopaths completed the practitioner survey. Interviews took place with 24 osteopaths. 2,057 patients, recruited from 212 osteopaths, completed questionnaires before their treatment. 1782 patients (86.6%) agreed to be followed up at 6 weeks; of these, 1,387 (77%) patients returned six week follow-up questionnaires. Interviews took place with 19 patients.

What we found: Four percent of patients reported that they had experienced temporary disability that was attributed to their osteopathic treatment. Ten of these patients were interviewed and only two described serious problems, neither of which were stroke.

Osteopaths reported that they had seen patients who had experienced serious problems after treatment. A range of events occurring in the preceding year were described by 4% of osteopaths. The most common event described was the occurrence of pain associated with a trapped nerve. There were also 7 reports of stroke like symptoms.

Between 10% and 20% of patients experienced increased symptoms/pain related to their main complaint in the days immediately following treatment, and this was highest amongst

new patients. At six weeks, 10% of the patients had seen another healthcare practitioner because of the worsening of their main complaint, which they associated with the osteopathic care that they had received.

The comparison between those that received manipulation and those that did not suggests that manipulation was not linked to outcomes.

Osteopaths reported obtaining consent from patients less often than is required by osteopaths' Standards of Practice. This was especially low in returning patients and for techniques familiar to the patient. Patients reported being asked for their consent less often than the frequency with which osteopaths reported receiving consent. About one-third of patients reported that they had received information about risks and about 40% reported that they had received information from their osteopaths about alternative or no treatment options.

Over half of the patients (55%) achieved at least a 30% decrease in symptoms/pain by day two post treatment. Similar improvement was seen at 6 weeks. Those with widespread pain were least likely to improve. New patients and those returning with a new episode of pain improved most.

The majority of osteopaths favoured the establishment of an adverse events register.

What this means for practice and policy: The evidence suggests that serious problems following osteopathic care are rare, but do occur. Whilst the link between any specific treatment technique and these outcomes was not supported, osteopaths should be aware of the possibility of serious events occurring during or after treatment. With respect to stroke associated with neck and head pain, osteopaths should be vigilant about known risk factors and presenting symptoms of vascular pain arising from the neck.

Osteopaths should inform patients about the possibility that they may experience increases in symptoms/pain associated with their main complaint shortly after treatment. This information should be given to all patients regardless of the site of presenting complaint and the nature of the treatment the osteopath proposes.

There is a need to develop further guidance and educational materials for osteopaths regarding the process of consent.

Further activity is indicated to assess the cost and feasibility of a reporting and learning system for adverse events and treatment reactions in osteopathy.

Part I

Scientific report

1

Background and need for the study

1.1 Background

There has been debate in the medical, scientific, and popular press concerning the benefits and risk profile of manual therapy. Much of this has focussed on the safety of chiropractic manipulation of the neck¹⁻⁵ and on a high profile legal case concerning the claims made for the benefits of chiropractic.⁶ The risks and adverse events associated with manipulation of the neck and increased expectations for accurate information needing to be given to patients about risk and adverse events have provoked concerns from osteopaths.

1.1.1 Adverse events

Retrospective case control studies and case reviews have come to mixed conclusions about the association between physical treatments and cervical artery dissection and stroke.⁷⁻¹¹ Although some authors reviewing the literature have concluded, on balance, that there is a causal relationship between manipulation and stroke, the need for large-scale prospective studies has been acknowledged.¹² Arguably, the strongest methodological study to date concluded that increased risks of vertebro-basilar stroke associated with visits to primary care physicians and chiropractors was likely to be due to patients with neck pain and headaches caused by vertebro arterial dissection seeking treatment. No evidence was found of excess risk relating to seeing a chiropractor compared to seeking care in a family practice setting.¹³ Judicial review in the State of Connecticut in the USA in 2010 delivered a declaratory ruling about chiropractic. The Board found that the evidence was not sufficient to conclude that stroke or cervical artery dissection is a risk or side-effect of joint mobilisation or manipulation of the cervical spine and as such that chiropractors were not required to address these issues as part of informed consent of patients.¹⁴

Large scale prospective studies have been conducted in chiropractic and have not identified major adverse events and conclude that benefits outweigh risks.^{15,16} Recent systematic reviews have called for further research and identified the weaknesses of existing research about adverse events associated with cervical manipulation and mobilization¹⁷ and have identified very low risk of major adverse events related to manual therapy in general.¹⁸ There are few studies relating to adverse events associated with osteopathic treatment. Those that exist in osteopathy are pilot studies,¹⁹ or studies whose primary purpose was not focussed on describing adverse events.^{20,21} There is, therefore, little published information directly addressing risk and adverse events which osteopaths may use to inform the delivery of their treatment or the information they give their patients.

1.1.2 Characteristics of osteopathic practice, risk assessment and management

Describing the nature and frequency of adverse events and treatment reactions tells us little about the clinicians' behaviour and attitudes with respect to assessing risk and managing perceived risks. There is little published information available about the nature and scope of the practice of osteopathy in the UK. Recent large-scale UK survey work of osteopathic practice suggests that back pain accounts for half of an osteopath's workload²⁰ and that musculoskeletal-type presentations make up the majority of the rest of a typical case load. Other data that have been reported should be treated with some caution as they are either dated,²² based on teaching clinics,^{23,24} single practices,^{25,26} or single-day surveys with low response rates.^{27,28} The same critique applies to descriptions of osteopathic approaches to treatment for particular complaints. In addition to the limited information about practice there is also a paucity of evidence of effectiveness of UK-practised osteopathy. There are notable exceptions, mostly in relation to back pain,²⁹⁻³¹ and osteopathy has been included as a suitable manual therapy in national guidance.³² There is a need to provide a context for possible therapy-related adverse events or treatment reactions by providing additional information about benefits of treatment.

1.1.3 Regulation and governance

Osteopaths and the quality of their treatment are regulated by statute in the UK. The General Osteopathic Council (GOsC) is the organ of regulation. It promotes patient safety, helps patients with concerns and complaints, determines osteopaths' fitness to practice, as well as assuring educational standards and adherence with osteopaths' obligations to participate in continuing professional development. Accordingly, the GOsC is responsible for articulating Standards of

Proficiency and Codes of Practice to which osteopaths are obliged to meet and adhere.³³⁻³⁵ The Code of Practice provides guidance and standards which cover the behaviour of osteopaths. These include expectations concerning communicating with patients and the process of receiving consent. In order to enhance knowledge concerning risk related to osteopathy and to provide more coherent and relevant information for osteopaths and patients, the GOsC commissioned, via an open call, four research projects broadly concerned with adverse events. These projects covered the following topics:

1. Adverse events associated with physical interventions in osteopathy and relevant manual therapies
2. Communicating risk and obtaining consent - good practice for osteopaths
3. Insurance claim trends and patient complaints to the regulator
4. Investigating osteopaths' attitudes to managing and assessing risk in clinical settings and patients' experiences and responses to osteopathic treatment

The first three of the projects have been made available to the osteopathic profession via the GOsC's website.³⁶⁻³⁸ Carnes et al.³⁶ provide an overview and review of definitions of adverse events as well as systematically reviewing the literature relating to manual therapy and adverse events. As part of their work they developed a taxonomy of adverse events³⁹ which categorises adverse events into Major, Moderate and Mild/"not adverse" events and incorporates the context and description of the event along with the severity and duration of the event. This work has been welcomed, but criticised for not including patient views in its development and not addressing the standardisation of terminology. Further work is called for to agree standard terminology across professions using physical therapy for describing harms.⁴⁰ Leach et al.³⁸ reviewed and summarised information related to communicating risks of treatment and informed consent within the context of osteopathic practice. Pilot work was carried out to test material for communicating risk and benefits to patients. Leach et al.³⁷ also led the other GOsC commissioned project that reviewed complaints and claims against osteopaths and contextualised these with other professions. The study included interviews with individuals involved in processing claims and complaints. The fourth study is the subject of the current report.

1.1.4 Summary and research aims

In summary, although considerable advances have been made by the osteopathic profession in terms of increased acceptance and regulation, there is a need for further information about professional practice, the effectiveness of treatment, and patients' perceptions and expectations of their treatment. The increased expectations for clinical governance, the use of research evidence and the need for shared decision making with patients means that it is timely to research risk in osteopathic clinical settings, and patients' experiences and responses to osteopathic treatment. Therefore the overall purpose of the study was to provide a description of UK osteopaths' risk assessment and risk management, including processes and content related to receiving consent; to document reported adverse events and treatment reactions in patients; to develop a model of practitioners' and patients' perceptions and beliefs about adverse events and treatment reactions. In addition, using short-term follow up of patient outcomes, we aimed to provide a narrative evaluation of the comparative risks and benefits of osteopathic treatment.

The specific aims of the research were to:

- provide nationally generalisable information about risk management and assessment from patients' and practitioners' perspectives;
- determine the frequency and impact of adverse events;
- provide a framework to interpret adverse events from the perspective of patients and practitioners;
- provide a baseline for guidance in this area and provide a risk versus benefit context for osteopathic practice.

2

Research approach

2.1 Mixed methods

Mixed methods research involves the use of more than one type of research method and different types of data.⁴¹ This type of approach is gaining popularity and involves some integration of quantitative and qualitative methods.⁴² Using mixed methods enhances the ability to provide insights into different aspects of complex questions and to triangulate information. It also enables researchers to draw on the results of one approach to develop further phases of a study.⁴³

The CROaM study used a mixed methods approach for a number of different but linked reasons. Our research questions were both quantitative and qualitative in nature. We wanted to gain quantitative data from practitioners and patients by using survey methods to generate large datasets for both populations, but we also wanted to explore in depth topics covered superficially in the surveys. For example, literature in manual therapy has identified a range of minor to moderate adverse events relating to treatment. There has, however, been little work exploring patients' and practitioners' views and interpretations of these types of events. In order to recruit participants for interview who would represent an effective range of views on our areas of interest, there was a need to select interviewees purposefully. Thus we elected to use sequential linked methods where survey results enabled us to determine our sampling frames for interviews. In order to obtain patient data we also needed a linked strategy that invited practitioners to indicate their willingness to give out patient questionnaires to the people attending their clinics. Thus there were both theoretical and pragmatic reasons for adopting a mixed methods approach. In addition to this, one of the characteristic features of mixed methods research is the integration of the reporting of quantitative and qualitative results.^{44,45} For the CROaM study, juxtaposing qualitative and quantitative results by topic area was anticipated as enabling a deeper view of

the results to be obtained, an opportunity to triangulate results and create a narrative which produced more useful information as a whole than the individual parts treated separately.

The CROaM study adopted an embedded design where the qualitative studies were designed to provide new insights and context to the quantitative data.^{44,46} A sequential approach was used where quantitative survey methods were followed by qualitative interview methods. These approaches were developed into three distinct but interlinked stages:

Stage one, practitioner survey: Cross sectional postal census with a single postal follow up.

Stage two, patient survey: Observational prospective postal survey with a single postal follow up at six weeks with one postal follow up to non-responders.

Stage three, patient and practitioner interviews: Semi-structured interviews with participants drawn from responders to stages one and two.

Figure 2.1 shows a summary of the stages and methods used in the study, illustrating how these were integrated.

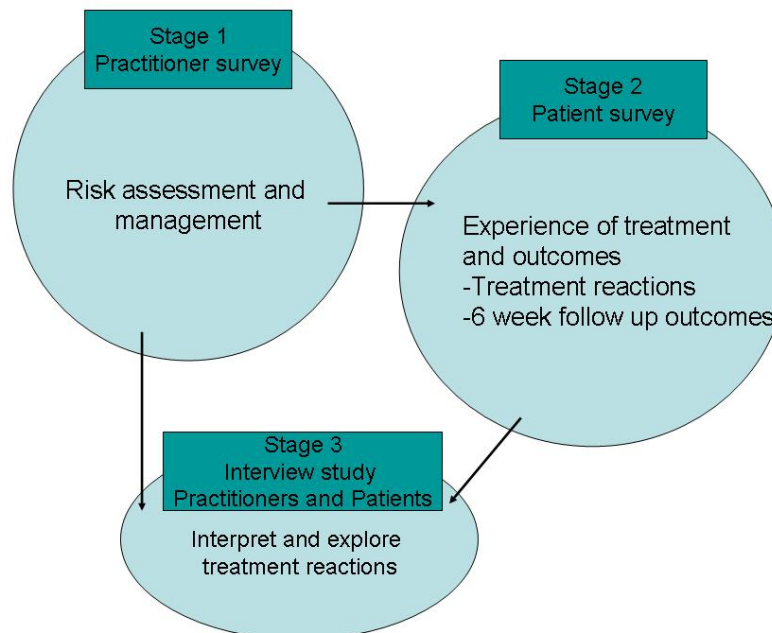


Figure 2.1: Summary of mixed methods and sequential sampling - The sequential nature of the sampling is indicated by the arrows.

2.2 Engaging with participants

We recognised that the topic of our work was sensitive and that there would be considerable burden placed on participants in taking part. Therefore we employed ideas from social exchange

theory and leverage salience theory⁴⁷ along with best evidence from systematic reviews^{48,49} in an effort to maximise response rates to each stage of the research. This included promoting engagement by emphasising the individual and professional significance of participation, appealing to a broad range of potential motivations for participation, emphasising the “branding” of the project and maximising the number of participant contacts.

2.3 Development of instruments and piloting

For all stages of the study we developed instruments drawing from the existing literature, using research team consensus and user consultations which included cognitive interview techniques.⁵⁰ The consultation involved completion of the instruments in the presence of one of the researchers and providing feedback about interpretability, usability and perceived burden of completion along with the time taken to complete the survey. Measurement scales were developed by the research team using best practice principles.^{47–49,51–54} Draft instruments were reviewed by co-applicants and the Steering Committee at various stages.

Rather than individual piloting within stages, in keeping with the integration of the stages of the study, we used a large pilot phase running across stages one and two. Those practitioners in the pilot phase for stage one also formed the basis of the recruitment base for patients in the pilot phase for stage two.

2.4 Data storage and protection

Hard copies of completed survey instruments, transcribed interviews and consent forms were placed in secure storage for the duration of the study. These will be kept securely for six years after completion of the study and then destroyed. Electronic data was stored on the BSO’s secure servers. Only members of the research team directly involved in the study had access to these password protected folders. Data was encrypted using TrueCrypt software (version 7.0a) for transportation to Barts and The London for statistical analysis.

2.5 Ethical approval

Ethical approval was granted for all stages of the research by the University of Bedfordshire’s Research Ethics Committee. The National Research Service helpdesk confirmed that NHS research ethics approval was not required for the study.

3

Methodology, research design and data collection methods

3.1 Stage 1, Practitioner survey

3.1.1 Methods

Stage one of the study was a survey of UK osteopaths. It was designed as a cross-sectional postal census of osteopaths registered as practising in the UK, using one postal follow-up to non-responders.

3.1.1.1 Survey content

The main aims were to identify which techniques osteopaths most use, what they think is important for identifying the risk of adverse events and their reported information giving and consent recording procedures.

The final questionnaire instrument is reproduced in Chapter 7. The questionnaire includes content areas and items covering the following: Practitioner characteristics

- Age
- Sex
- Year of qualification
- Average number of new patients/week by NHS, home, private clinic
- Average number of returning patients/week by NHS, home, private clinic

3.1 Stage 1, Practitioner survey

- Practitioner seeing patients alone or in a group with no discussion or in a group where discussion takes place
- New patient appointment time based on past month
- Returning patient appointment time based on past month

Osteopathic interventions: Frequency of use

- Percentage of patients on whom practitioner used of techniques by eight categories in past month
- Use of non-manual techniques/approaches
- Percentage of patients on whom practitioner used non-manual techniques by nine categories in past month
- Percentage of patients on whom practitioner has used HVT in the past month

Attitudes toward mild adverse events

- Agreement with statement about deterioration as an essential response
- Agreement with statement about exacerbation of symptoms being a positive sign
- Agreement with statement about experience of new symptoms being a positive sign
- Agreement with statement that it is predictable who will benefit from manipulation/HVT
- Agreement with statement that it is predictable who will have minor or transient reactions following manipulation/HVT
- Agreement with statement that it is predictable who will have a major treatment reaction following manipulation/HVT

Risk assessment

- Importance of age in assessment of risk of treatment reaction when treating the cervical spine
- Importance of gender in assessment of risk of treatment reaction when treating the cervical spine

- Importance of recurrence of symptoms in assessment of risk of treatment reaction by six categories when treating the cervical spine
- Importance of recurrent or current minor injury/mild whiplash in assessment of risk of treatment reaction when treating the cervical spine
- Importance of recurrent or current significant injury/moderate or severe whiplash in assessment of risk of treatment reaction when treating the cervical spine
- Importance of anti-coagulant consumption in assessment of risk of treatment reaction when treating the cervical spine
- Importance of oral contraceptive consumption in assessment of risk of treatment reaction when treating the cervical spine
- Importance of steroid consumption (past or present) in assessment of risk of treatment reaction when treating the cervical spine
- Importance of inflammatory disease status in assessment of risk of treatment reaction when treating the cervical spine
- Importance of congenital disorders in assessment of risk of treatment reaction when treating the cervical spine
- Importance of previous treatment practitioner has given in assessment of risk of treatment reaction when treating the cervical spine
- Importance of smoking status in assessment of risk of treatment reaction when treating the cervical spine
- Importance of other factors in assessment of risk of treatment reaction when treating the cervical spine

Conveying information about risk

- Difficulty discussing unpleasant treatment reactions when preparing new patients to receive HVT to cervical spine
- Difficulty discussing unpleasant treatment reactions when preparing new patients to receive osteopathic treatment in general

- Difficulty discussing unpleasant treatment reactions when preparing returning patients to receive osteopathic treatment in general

Risk management

- Practitioner rating of risk of minor reaction by eight treatment approaches
- Practitioner rating of importance of six factors in considering referral to GP
- Practitioner-reported frequency of obtaining consent prior to initial examination
- Practitioner-reported frequency of obtaining consent prior to each successive examination
- Practitioner-reported frequency of obtaining consent prior to initial use of osteopathic technique
- Practitioner-reported frequency of informing patients about treatment benefits
- Practitioner-reported frequency of informing patients about treatment risks
- Practitioner-reported frequency of informing patients about outcomes of no treatment or alternative treatment
- Practitioner-reported frequency of obtaining consent prior to successive usage of osteopathic technique
- Practitioner-reported method of obtaining consent by nine technique categories, relating to the cervical spine
- Practitioner-reported method of obtaining consent by nine technique categories, relating to the thoracic and lumbar spine
- Received guidance on consent processes
- Source of received guidance
- Rating of received guidance
- Question on whether it is desirable that practitioners receive guidance on consent process
- Source of proposed guidance

Self-reported serious treatment reactions

- Practitioner-reported Serious Adverse Events (SAEs) over whole career
- Practitioner-reported SAEs in past twelve months
- Description of last SAE

Attitudes toward an adverse events register

- Question on whether practitioner believes this is a good idea
- Elaboration
- Question on whether practitioner would contribute to an adverse events register

The last section of the questionnaire invited participants to amend their contact details and to indicate whether they might be willing to hand out questionnaires to patients and/or be willing to be interviewed as part of further stages of the study.

3.1.1.2 Data collection methods and procedures

Osteopaths listed as practising by the GOsC on 28/05/2010 were used as the sampling frame. The spreadsheet supplied by the GOsC was checked for overseas addresses which were removed (n=33). Practitioners involved in the development of the survey instrument were also removed from the sample (n=16). The remaining records (n=3896) were transferred into an Access 2003 database, where each one was assigned a unique identifier (UI). Script was developed using Visual Basic to use the UI to generate personalised questionnaires at given points in time for the duration of the study.

The final version of the practitioner questionnaire and associated documents were converted into a rich text format to allow for them to be automatically generated from within Access. The instruments included the UI as a barcode and the associated number. Questionnaire instruments were formatted for data capture using Remark Optical Data Mark Recognition Software (version 7). We used a hand-held barcode scanner to log the time points of the questionnaires at dispatch and return. The scanning of the barcodes enabled the automatic generation of personalised instruments for those requiring follow-up.

The pilot phase began on 07/06/2010 and included 500 randomly selected practitioners from the main GOsC database. The main phase began on 06/07/2010 and included 3,396 practitioners. All data collection for stage one ceased on the 20/10/2010. Survey instruments and associated materials were sent out using second class post; prepaid return envelopes were included along with participant information sheets. A postcard reminder at two weeks and

one postal follow-up to non-responders at three weeks were also sent to participants. Those who declined to take part were invited to give brief reasons for their decision and to provide their age, sex and years since qualification. Minor changes were made to the questionnaire post pilot phase. These included the removal of items offering an “other” option which were left largely incomplete in the pilot phase. The questionnaire items asking practitioners about their experience of serious adverse events were amended to include the definition of serious adverse events in each questionnaire item as well as appearing in an explanatory box above the items.

Table 3.1 shows the questionnaires distributed to practitioners by phase.

Table 3.1: Stage 1 instruments distributed by phase

| Phase | Initial | Follow-up | Total |
|-------|---------|-----------|-------|
| Pilot | 500 | 399 | 899 |
| Main | 3,396 | 2,648 | 6,044 |
| Total | 3,896 | 3,047 | 6,943 |

3.1.1.3 Data reduction

Outcome variables The responses to questions regarding the percentage of patients on whom practitioners had used different techniques (Items 7a-7g) showed medium to strong correlations ($r = 0.37$ to 0.45 ; where small $r = 0.1$, medium $r = 0.3$ and strong $r = 0.5$)⁷ between cranial, functional, and visceral; and medium to very strong (0.4 to 0.7) between HVT, joint articulation, and soft tissue. Whereas MET had only small correlations with everything else (0.09 to 0.27). Based on this, and with consideration of the clinical context, we decided to group outcome variables into 1) Articulation, HVT, and Soft tissue technique, 2) Cranial, functional, and visceral, and 3) MET. We also decided to investigate HVT alone as a separate outcome.

For “other approaches”, whilst there were medium correlations between use of dry needling or acupuncture, homeopathy, herbal medicine, and between prescription of medication and injections, there were only small correlations between electrotherapy and any other variables, and kinesiology and other variables. Moreover, since the prevalence of use was low for these approaches, we elected to use the binary outcome whether or not “other approaches” were used (No=583, Yes=463) for logistic regression as per the option outlined *a priori* in the analysis plan (version 1.4).

The binary variable for whether adjunctive treatments were used was used as both a predictor variable in linear regressions and as an outcome in the logistic regression. “Yes” values were imputed in the case where the prevalence of treatments was greater than zero.

Predictor variables There was a strong correlation (0.67) between number of new patients seen in the NHS and number of repeating patients seen (though only 59 participants who saw at least one); after discussion we decided that these should be combined. The number of new and repeating patients seen per week in private settings and in the home were kept separate. For all six of these variables, zeros were imputed where practitioners had checked “N/A”. There was a small correlation between appointment times for new patients and returning patients (0.25); however, stratified by graduating year (cut point=1998) there was a medium correlation between new and returning appointment times for more recent graduates. After discussion, it was decided to model these variables separately. Similarly, correlation between the number of new patients and returning patients seen in home settings was small, but large when restricted to recent graduates (0.7). These variables were also kept separate.

There were medium to strong correlations between practitioners’ views on: patients needing to get worse before they get better, exacerbation being positive, and appearance of unpleasant new symptoms being positive; we combined these. Similarly, there were medium to strong correlations between belief about who will benefit from treatment being predictable, who will have minor, and who will have major reactions to HVT, and we combined these.

There were at least medium (smallest=0.25) correlations between the perceived risks of minor reactions when using any two treatments on the thoracic and lumbar spine, but the strongest correlations were between cranial, visceral, and functional; and between HVT, STT, articulation, and MET. These were grouped as per the outcome variable, for structural technique (*i.e.* risk from HVT, STT, articulation) and MET, but kept separate for functional and cranial due to there being too few responses to compute a “functional” variable. Also, because of a high number of missing values and low reported usage, risk of visceral was dropped from the modelling.

Variables regarding use of HVT to specific areas were omitted *a priori* when testing the first hypothesis as these would clearly correlate highly with use of structural technique.

There were medium to very strong correlations between any two of the eleven importance of referral (in different circumstances) variables; from these we computed a single combined (*i.e.* the mean) variable: importance of referral. Similarly, there were medium to strong correlations between frequency of informing patients of benefits, risks, and alternative treatments, and we combined these into a single variable: frequency of informing patients about benefits,

risks, or alternative treatments. Likewise, for the four frequency of obtaining consent variables (correlation range: 0.30 to 0.67), we computed a single variable: frequency of obtaining consent.

The correlations between the levels of consent required for using different techniques on the cervical spine and the thoracic/lumbar spine were nearly 1. Furthermore, the aforementioned pattern of strong correlations was evident between HVT, STT, and articulations; and visceral, functional, and cranial. MET was strongly correlated to everything; there was no correlation between any two of these variable of < 0.4 . For simplicity, clinical interpretability, and in light of strong correlations, we grouped by 1) HVT, STT and articulatory techniques; and 2) MET but due to a high number of missing values, consent levels for cranial and functional techniques for the thoracic and lumbar spine were dropped, as was visceral on either the thoracic and lumber or cervical spine, but corresponding variables for level of consent for these techniques on the cervical spine were not as affected by missing values and therefore retained.

After discussion, we decided to group “importance of anti-coagulants in assessing risk of treating the cervical spine”, with hypertension with which there was a strong correlation (0.53) (*i.e.* “underlying cardiac risk”), rather than with the importance of contraceptives, and steroids (which formed a separate group, “drugs”) with which there were small to medium correlations. Importance of neck pain and importance of neurological symptoms were strongly correlated (0.54) and we combined these. Importance of minor injury and importance of significant injury were strongly correlated; we also combined these. Importance of inflammatory disease and of congenital disease were highly correlated and again we combined these. The importance of headache and migraine was very high (0.78) and we also combined these. This leaves importance of previous treatment, importance of anxiety, importance of age, and of gender and importance of smoking; whilst there were small to medium correlations with almost everything, we decided to keep these variables separate.

We computed a single variable “difficulty discussing treatment reactions” as an average of the four variables enquiring about difficulty talking to patients about unpleasant treatment reactions when preparing new and returning patients for HVT to the cervical spine and treatment in general. Finally, we used only career reported number of SAEs in modelling use of technique.

The team considered these reduced variables and whilst these were thought appropriate for crude (exploratory) modelling, they selected the following variables *a priori* for modelling the relationship between technique use and risk assessment and risk management, and practitioner characteristics.

1. Appointment time (a combination of new and continuing)

2. Years since graduation
3. Gender
4. Predictability of benefit/minor/major reactions (as per the reduction above)
5. Perceived risk of neck/neurological symptoms (as per reduction)
6. Perceived risk of drugs (as per reduction)
7. Perceived risk of headaches/migranes (as per reduction)
8. Perceived risk of anxiety
9. Difficulty discussing treatment reactions (as per reduction)
10. HVT risk perception
11. Frequency of informing patients of benefits, risks, and outcomes (as per reduction)
12. Consent taken prior to each successive examination
13. Consent taken prior to initial use of an osteopathic technique
14. Consent taken prior to each use of an osteopathic technique
15. Serious treatment reaction since graduation

Consent Two new *a priori* selected variables were included in the model recording consent when treating necks and when treating backs. They were scaled from 0 (practitioner does not seek consent for any treatment on the neck/back) to 8 (practitioner does seek consent for all treatments on the neck/back). We defined two different categorisations for level of consent:

Definition 1:

- 0 = consent not discussed
- 1 = consent either verbally discussed, verbally discussed and noted or written and signed

Definition 2:

- 0 = consent not discussed or only verbally discussed
- 1 = consent verbally discussed and noted or written and signed

Definition 2 is a more strict definition requiring written recording of consent.

3.1.1.4 Data analysis techniques

The full analysis plan was developed without reference to the dataset. Descriptive statistics were used to summarise the demographic characteristics of practitioners as well as their behaviours and attitudes towards risk. Regression analyses were used to explore whether consent practices and the experience of serious adverse events predict the use of certain techniques. The final dataset was analysed using Stata (Version 10.1).

The outcomes for prevalence of use of an osteopathic technique in the past month are measured on a 10-point scale and were treated as continuous. One unit on the β scale corresponds to 1% change in the prevalence of use of the technique. The outcome for the use of adjunctive techniques (e.g. electro-therapy, nutrition therapy, dry needling/acupuncture, homeopathy, herbal medicine, applied or clinical kinesiology, prescription of medication, injections, etc...) is binary (yes/no for at least one reported adjunctive technique). The odds ratio (OR) represents the relative increase in odds per unit increase or decrease beyond the average of the predictor variable, if the predictor variable is on a continuous scale.

After describing crude estimates from simple regression analyses we fitted linear regression models for continuous outcomes (e.g. length of appointment time or prevalence of structural technique use), while using logistic regression models for binary outcomes (e.g. use of adjunctive techniques).

All significance testing was done at the 5% significance level. For each model with *a priori* selected predictor variables, we reported sample size, (pseudo) R-statistic and F statistic. To ensure that we only reported models where the proportion of variance in outcome explained was likely to have any clinical relevance in this situation, we only present models in which at least 10% of the variance or deviance is explained. The complete set of models, including those with an R-statistic of less than 10%, are available in the Statistical Report.

To further evaluate the quality of the linear models, residuals were checked for normal distribution, linearity and homoscedascity using graphical methods and where needed transformations were applied. To assess the influence of individual datapoints Cook's distances were computed. For logistic regression models the area under the ROC curve was used to assess the discriminative ability. Pearson and deviance residuals were computed to find data points with high leverage.

Free text responses were analysed by sorting and categorisation of data using content analysis strategies.^{55,56} We used NVivo 9 Computer Assisted Qualitative Analysis Software and Microsoft Excel 2003 to manage and code the data. Categories were updated and restructured through retrospective analysis of all the responses to free text questions. As categories emerged and

accumulated, we developed a classification for the content of the free text responses. Themes which emerged across the respondents were noted and constant comparisons made utilising the process of axial coding. In some instances frequencies of responses by theme or content were calculated. Two coders were used to assess the data and maximise reliability of data and themes generated.⁵⁷ The coding framework was discussed with a third member of the team and thematic analysis with all co-applicants. The final classifications of the free text data were cross-checked and errors of omission and commission were discussed and categorised by agreement between two coders.

The free text responses concerning osteopaths' experience of serious adverse events were noted in the pilot phase to include responses that did not fulfil our *a priori* definition of a serious adverse event. Two independent research physiotherapists coded these responses into those that fulfilled our definition, those that they were unsure about and those that did not fit our definition. They also coded these data into responses that they attributed to treatment, were unsure of and did not attribute to treatment. Quotations used in the results section were amended to ensure anonymity of individuals described by practitioners, whilst ensuring that the key clinical points in the descriptions were maintained.

3.1.1.5 Data entry, cleaning and quality assurance

On return, surveys had both the front and back pages containing personal details of respondents and reasons for non-participation removed. These were stored separately and this ensured anonymity of respondents. Fully completed questionnaires were scanned into a database using Remark Software version 8.4. The front pages which indicated an unwillingness to participate in the study were also scanned. Finally, back pages were processed in order to create a database which was then used to inform stage two of the study.

All survey data was then manually checked for errors of registration and scanning and free text fields were entered by hand. Quality assurance was carried out on 5% of the data, with an error rate of 0.001 in the final dataset.

3.2 Stage 2, Patient survey

3.2.1 Methods

Stage two of the study was a survey of osteopathic patients. It was designed as a prospective observational cohort study of patients attending osteopathic clinics in the UK. The target population was new and returning patients attending osteopathic clinics. Measurement points

were immediately prior to treatment, one day after treatment, two days after treatment and at six weeks after treatment. One postal follow-up was sent to non-responders to the six week questionnaire.

3.2.1.1 Survey content

The main aims were to identify the characteristics of patients consulting osteopaths, what forms of treatment they receive from osteopaths, whether they experience additional/worsening symptoms following their visit to an osteopath, which patients are most likely to experience additional/worsening symptoms and which patients report positive outcomes.

The questionnaire was structured in four sections: Section A - Pre-treatment, Section B - Day one, Section C - Day two and Section D - Six week. All the patient survey questionnaires are reproduced in Chapter 7.

The final questionnaire instruments included areas and items covering the following: Section A - Pre-treatment, patient-reported

- Area of main complaint
- Length of current episode
- Time since one month without symptoms
- Average four week pain/symptom intensity
- Current pain/symptom intensity
- Troublesomeness of main pain/symptom in past four weeks
- Troublesomeness of pain/symptom by body areas
- Intensity of symptoms in past fourteen days
- Frequency of symptoms in past fourteen days
- Presence of flu/cold-like symptoms in past fourteen days
- Consumption of pain killers in past seven days
- Health state (EQ5D)
- Point at which questionnaire completed

Practitioner-reported

- Techniques used and area of application
- Use of cranial/IVM/visceral
- Other approaches

Section B - Day one, patient-reported

- Age
- Sex
- Age upon leaving full-time education
- Employment status
- Smoking status
- Current health problems
- Consumption of medication
- First visit to an osteopath
- First visit to an osteopath for current symptoms
- Number of previous visits to an osteopath
- Visit to another healthcare professional about current symptoms
- Visit to GP in past six months
- Ability to work because of current symptoms
- Number of days off this episode
- Number of days off due to symptoms in past twelve months
- HVT received
- Different treatment approaches
- Discussion of need for examination, benefits, risks, and outcomes
- Agreement with statement about importance of permission to examine

- Agreement with statement about importance of permission to treat
- Permissions sought by osteopaths
- Troublesomeness of symptoms by area
- Intensity of symptoms in past day
- Current intensity of symptoms
- Troublesomeness of main pain/symptoms in past day
- Intensity of symptoms in past day
- Change in symptoms since yesterday
- Visit to GP or medical practitioner because of worsening or new symptoms in past day
- Satisfaction with treatment
- Recommendation of treatment to others with similar symptoms
- Point at which questionnaire completed

Section C - Day two, patient-reported

- Intensity of symptoms in past two days
- Current intensity of symptoms
- Troublesomeness of main pain/symptoms in past two days
- Troublesomeness of symptoms in past two days
- Intensity of symptoms in past two days
- Change in symptoms in past two days
- Visit to GP or medical practitioner because of worsening or new symptoms in past two days
- Satisfaction with treatment
- Recommendation of treatment to others with similar symptoms
- Point at which questionnaire completed

- Contact details and willingness to be involved in further research and willingness to be interviewed

Section D - Six week, patient-reported

- Date
- Number of osteopathic treatments in past six weeks
- Visit to GP or medical practitioner because of worsening or new symptoms in past six weeks
- Inability to work because of current symptoms
- Number of days off in past six weeks
- Consumption of pain killers in past seven days
- Presence of flu/cold-like symptoms in past fourteen days
- Health state
- Troublesomeness of symptoms in past two days
- Intensity of symptoms in past four weeks
- Current intensity of symptoms
- Troublesomeness of main pain/symptoms in past four weeks
- Intensity of symptoms in past fourteen days / Frequency of symptoms in past fourteen days
- Change in symptoms in past six weeks
- Visit to GP or medical practitioner because of worsening or new symptoms
- Experience of temporary incapacity or disability attributed to osteopathic treatment
- Satisfaction with treatment

3.2.1.2 Sampling procedure

The study used an opportunistic sampling method. Practitioners responding to stage one who indicated that they might be willing to hand out questionnaires to patients (n = 507) were sent an information pack containing a cover letter providing information in the following areas: survey aims, practicalities, giving questionnaires to patients, telling existing patients and new patients about the study, selecting patients and a section on what to do next. A draft version of all the instruments which would be given to patients was also included (questionnaires, participant information sheets, patient cover letters,) as well as an opt-out form for practitioners to use should they decide that they would like no further involvement in this stage of the study. Information packs were sent to practitioners in the pilot phase on 15/07/2010 (n=63) and to those in the main phase on 31/08/2010 (n = 444).

After a period of two weeks to allow for opt-outs, patient packs were distributed to practitioners. The number of questionnaires sent to practitioners was calculated using the numbers of patients being seen as reported by individual practitioners in stage one. For the pilot phase this was 75% of the calculated total number of patients estimated as being seen over a two week period.

For the main phase this strategy was adjusted. The pilot phase indicated that we had more practitioners wanting to take part than resources allowed. In order to involve all the practitioners who were willing to distribute questionnaires and to reduce the complexity of the recruitment process for practitioners, volumes of patient packs sent to individual practitioners were reduced to 55% of those patients seen in a single week in an individual practice. This calculation was used to send individualised numbers of patient packs to practitioners.

Table 3.2 shows the patient survey information packs and patient survey packs distributed to practitioners by phase.

Table 3.2: Stage 2 instruments distributed by phase

| Phase | No. Info Packs to Practitioners | No. opted out | No. agreeing to distribute to patients | Total packs distributed to practitioners |
|-------|---------------------------------|---------------|--|--|
| Pilot | 63 | 19 | 44 | 2,300 |
| Main | 444 | 89 | 355 | 7,144 |
| Total | 507 | 108 | 399 | 9,444 |

3.2.1.3 Data collection methods and procedures

A similar process to that used in stage one was implemented to enable information packs to be automatically generated for all practitioners who indicated a willingness to take part. Opt-out forms were scanned on return to enable a final database of practitioners willing to take part to be constructed.

Patient questionnaire sections were colour coded and sequentially barcoded and marked with a UI. The sequence of patient questionnaires sent to each practitioner was recorded based on the practitioners' UI from stage one. This allowed anonymous reporting of responses by practitioner.

Individual packs containing a cover letter and FAQ sheet were dispatched along with separate sealed patient questionnaire packs and pens were supplied. Practitioners were asked to give out their questionnaires sequentially and to unselected consecutive patients.

Patient packs included a cover letter, participant information sheet and relevant sections of the questionnaire. The front page of Section A included the opportunity for those who declined to take part to give brief reasons for the decision and to provide their age, sex and whether this was their first visit to this osteopath.

On receipt of a response the date was logged using a barcode scanner along with whether there was an indication of an unwillingness to take part (front page) or whether completed sections A (baseline), B (day one) and C (day two) had been returned. Contact details were extracted to create a separate database to generate section D questionnaires (six week follow-up). Section D was also scanned on receipt.

Those participants who returned completed questionnaires were sent section D, six week questionnaires, at between five and six weeks from initial appointment with their osteopath. Non-responders to the six-week questionnaire were followed up by post two weeks later.

To ensure a mean time of follow-up as close to six weeks as possible, the date on which questionnaires were filled out (section B, item 3) was inputted to a system that drew upon the database of patient contacts to automatically generate the section D questionnaire with its UI five weeks post completion. These were then printed and dispatched. Responses to section D were logged immediately on receipt and data entered as above.

Table 3.3 shows the patient survey information packs and patient survey packs distributed by phase.

3.2.1.4 Data entry, cleaning and quality assurance

All completed questionnaire sections were scanned into a master database using Remark OMR software. All survey data was manually checked for errors of registration and scanning and free

Table 3.3: Stage 2 instruments distributed by phase

| Phase | No. Initial patient packs | No. of six week questionnaires | Follow-ups to six week questionnaire | Total |
|-------|---------------------------|--------------------------------|--------------------------------------|--------|
| Pilot | 2300 | 183 | 108 | 2,591 |
| Main | 7,144 | 1,599 | 1,415 | 10,158 |
| Total | 9,444 | 1,782 | 1,523 | 12,749 |

text fields were entered by hand. Quality assurance was carried out on 5% of the data with an accuracy rate of 0.003 in the final dataset. The final dataset was analysed using Stata (Version 10.1).

3.2.1.5 Data reduction

Outcome variables The responses to questions regarding the intensity and troublesomeness of patients’ main presenting symptoms and side effects were reduced in a number of ways to predict AEs or improvement in patients.

Adverse events: An adverse event was defined using eight binary variables indicating whether a patient worsened from baseline to a time point after treatment. Firstly, questions A5, B25, C2 and SW11 were used to describe a worsening of current intensity in reported main pain/symptoms by at least 30% from baseline to day one or day two (variable 1) and baseline to six weeks (variable 2).

Secondly, to describe an increase in average intensity by at least 30% of at least one non-musculoskeletal symptom we compared baseline questions A8a-m to day one and day two questions B27a-m and C5a-m respectively (variable 3) and baseline to six weeks questions SW13a-m (variable 4). The third definition of an adverse event was defined as the appearance of one or more new musculoskeletal symptoms with intensity at least 2 (questions A8, B27, C5 and SW13 a-m) or non-musculoskeletal symptom that was reported as at least slightly troublesome (questions A7, B23, C4, SW9 a-n). Two variables each were created comparing baseline to day one/day two and baseline to six weeks follow-up (variables 5-8).

Improvement at six weeks: Three binary variables were used to indicate whether a patient got better by six weeks. Improvement was defined as a reduction in current main pain/symptom intensity by at least 30% or by at least 2 points. The third indicator concerned a global health transition question and showed if a patient had at least “much improved”.

Long term adverse events: To indicate patients deteriorating by six weeks in terms of their main symptom we defined two binary variables coded as yes if the patient worsened by at least 30% or 2 points respectively.

Treatment satisfaction: Treatment satisfaction was averaged over the follow-up time points. If the value at one of the time points was missing, the average of the observed ones was used. Hence, this variable is only missing if none of the three time points was observed.

Health status EQ-5D: The change in health status was defined as the difference between the baseline and six weeks EQ-5D value.

Predictor variables Some of the variables anticipated as being predictive were represented by a large number of individual items in the questionnaires. This would bias the regression models. To cut down on the number of variables in each model we decided to reduce them as described below. These reduction rules were set up a priori and summarized in table 3.4.

Presenting area: Instead of using fourteen variables to indicate the presenting area we computed the variables creating three categories: 1. Head/face/neck or shoulder; 2. Upper back/lower back or hip; 3. Extremities (elbow, wrist, hand, knee, ankle, foot). Other non-defined areas were coded as missing. Episode duration was dichotomised into sub-acute and chronic, where chronic is defined as the current episode being present for at least four months or the last time a whole month was symptom free being at least four months ago.

Baseline symptoms: We included a combined measure of the baseline intensity and troublesomeness (questions A4-6). Troublesomeness was rescaled to fit the intensity scale (0-11) and the average of the three measurements was taken. If a value was missing the mean of the observed values was calculated.

Number of pain sites: The presence of multi-site pain was computed as a continuous count of the number of areas of pain/symptoms that were at least “moderately troublesome” (Question A7a-m).

Use of HVT: The binary variable for whether HVT was used (as reported by practitioners) was coded yes if the osteopath reported using it on at least one area.

Comorbidities: To check for comorbidities a binary variable was produced using questions B7a-p. It shows if the patient reported at least one of the health problems listed.

Information giving and permission asking: Finally, we wanted to include a variable that shows how much information patients reported as being given by the osteopath (question B19a-d) and for how much permission the patient reported being asked for by the osteopath for treatment and examination (question B22a-d). Both parts consist of four questions and we awarded one point for each question answered with yes. This resulted in two variables with a scale 0-4.

Table 3.4: Data reduction

| Variable | Reduction rules |
|--|--|
| Presenting area | 1 Head / Face / Neck / Shoulder 2 Upper back / lower back / hip 3 Extremity (elbow / wrist / hand / knee / ankle / foot) |
| Episode duration | 0 sub-acute (<3 months) 1 chronic (>3 months) |
| Baseline intensity and troublesomeness | Average of main symptom intensity over time, intensity right now and troublesomeness right now (rescaled to 0-10) |
| Presence of multi-site pain | Number of other areas of the body that are least moderately troublesome |
| Practitioner used HVT | Osteopath reported use of HVT on any part of the body (binary y/n) |
| Presence of comorbidity | At least one other health problem (binary y/n) |
| Information giving | Amount of information given by osteopath on scale 0-4 (1 point per: reason for examination, benefits of treatment, risks of treatment, outcome of no or alternative treatment) |
| Permission asking | Amount of permission asked by osteopath on scale 0-4 (1 point per: first examination, successive examination, first treatment, successive treatment) |

Treatment naivety The patients were asked to answer three questions regarding whether they had visited this osteopath before and how often. We combined those questions and defined treatment naivety using the following categorisation:

1. Patients who were visiting the osteopath for the first time (“New pat”)

3.3 Stage 3, Patient and practitioner interviews

2. Patients who were not new to the osteopath, but were returning for the first time for the current symptom/pain (“Rtn pat/new symp”)
3. Patients who were returning to the osteopath and were in ongoing treatment for their symptom/pain (“Rtn pat/ongoing”)

In patient models we used the variable “First treatment for current symptoms” which is a combination of the first two categories.

3.2.1.6 Data analysis techniques

Descriptive statistics were used to summarise patient characteristics as well as their experiences of treatment, treatment reactions and treatment outcomes. A number of different statistical regression models were then used to explore whether these characteristics can predict the types of response that patients have to osteopathic treatment.

After describing crude estimates from simple regression analyses we fitted linear regression models for continuous outcomes (e.g. EQ-5D), while using logistic regression models for binary outcomes (e.g. adverse events).

All significance testing was done on the 5% significance level. For each model with *a priori* selected predictor variables we reported sample size, (pseudo) R-statistic and F statistic. To ensure that we only reported models where the proportion of variance in outcome explained was likely to have any clinical relevance in this situation we only present models in which at least 10% of the variance or deviance is explained. The complete set of models done including those with an R-statistic of less than 10% is available in the Statistical Report.

To further evaluate the quality of the linear models, residuals were checked for normal distribution, linearity and homoscedascity using graphical methods and where needed transformations were applied. To assess the influence of individual datapoints Cook’s distances were computed. For logistic regression models the area under the ROC curve was used to assess the discriminative ability. Pearson and deviance residuals were computed to find data points with high leverage.

3.3 Stage 3, Patient and practitioner interviews

3.3.1 Methods

Stage three of the study was a series of interviews. It was designed as a qualitative study using semi-structured interview guides. The target populations were patients and practitioners who were identified for interview purposefully using data generated from stages one and two.

3.3.1.1 Interview schedule development and content

An initial interview schema for patient and practitioner interviews was constructed as part of the original proposal. This was amended to include a fuller introduction and follow-up prompts in order to test the acceptability, flow and interpretation of the interview guide.

Seventeen user consultations took place to develop the patient interview guide and nine for the practitioner interview guide. Some amendments were made to clarify questions and to enhance the flow of the interview. The interview guides are reproduced in Chapter 7. A high degree of flexibility was retained in response to participants' experiences⁵⁸ and prompts were included where required to further explore responses. Each interview guide began with an introduction and some background questions about the participant. Practitioner and patient guides covered some overlapping content areas such as experience of serious treatment reactions and common treatment reactions, their interpretation and an exploration of the participants' understanding of what characterises such events. Issues around consent, information giving and the acceptability of treatment reactions were also explored. Practitioners were additionally asked about their views of the Code of Practice in relation to consent. All participants were asked if they would like to check the transcription of their interview.

3.3.1.2 Data collection methods and procedures

Practitioners were selected for invitation using the following variables from the practitioner survey:

- Willingness to be interviewed
- Sex
- Years since graduation
- Primary location in which patients are seen (NHS, home, private clinic)
- Discussion of treatment decisions with others
- Use of HVT in the past month
- Practitioner-reported SAEs
- Description of last SAE

3.3 Stage 3, Patient and practitioner interviews

The sampling strategy aimed to include a wide range of characteristics of practitioners who had and had not reported experience of a SAE in their practice. Responses to stage one were used to create an Access database of all practitioners who indicated a willingness to be interviewed. These were then divided into those who had reported a patient experiencing an SAE (n=65) and those who had not (n=436). The SAE group was then divided into those who had reported a patient experience an SAE in the past year (n=20) and those who had not (n=45). Queries were used to further subdivide the two groups reporting SAEs into the following categories: whether the practitioner was male or female; whether the majority of patients were seen in an NHS setting, at home or in a private clinic; whether decisions regarding treatment were made alone or in discussion with others; whether HVT techniques had been used in the past month; whether the practitioner was inexperienced, experienced or very experienced.

Practitioners who reported SAEs were selected for interview based on different combinations of the above categories. Where a particular combination of characteristics included more than one practitioner, descriptions of their most recent SAE were used to determine which practitioner was the most suitable for interview. Having identified a range of interviewees, we matched characteristics across to a sample who had not reported a SAE. The numbers in this group were large and therefore we randomly sampled to give an equal number to match our SAE group. A total of 63 practitioners were invited for interview with 30 agreeing to be interviewed. We ceased recruitment when the interviewers agreed that little or no new content was emerging from the interviews. This occurred after a total of 24 interviews.

Patients were selected for invitation using the following variables and data from the patient cohort:

- Willingness to be interviewed
- Experience of temporary incapacity or disability attributed to osteopathic treatment by self report
- Three point worsening of primary symptoms between pre treatment and two days post treatment

The sampling strategy aimed to include a mix of patients who reported experiencing treatment reactions. Responses to stage two were used to create an Access database of all patients who indicated a willingness to be interviewed. Of these, those reporting temporary incapacity or disability attributed to osteopathic treatment were invited for interview (n=38). Additionally, we sampled from those patients reporting a three point or greater increase on the current

3.3 Stage 3, Patient and practitioner interviews

pain/symptom intensity scale between pre-treatment baseline and two days post treatment. A total of 74 respondents were invited.

Potential interviewees were sent information about the study by post. This information included a cover letter, participant information sheet, copies of the consent forms and an availability form which gave the option to indicate whether a face-to-face or telephone interview was preferable. A prepaid return envelope was also included. Those who replied indicating availability were telephoned to arrange an interview.

All interviews were audio recorded using Retell (Model 957 Pro) for telephone interviews and two digital Dictaphones for face-to-face interviews. Digital audio files were transcribed verbatim using a DSS Player Pro Transcription Module (version 5.0.5.0).

3.3.1.3 Data entry, cleaning and quality assurance

Audio files were transcribed verbatim. Transcriptions were identified by participant number to preserve anonymity and checked for accuracy and for information that may identify participants or others. Amendments were made and then transcripts were returned to those participants who had requested a copy to check for accuracy of transcription and of the representation of their views. All transcripts were then uploaded to NVivo 9 for analysis.

3.3.1.4 Data analysis techniques

Initial stages of data analysis included the sorting and categorisation of data using content analysis strategies.^{55,56} Categorisation of data allowed us to contextually define and conceptualise the participant dialogue. This occurred during the data collection stages, with some ongoing analysis informing future data collection. We used NVivo 9 Computer Assisted Qualitative Analysis Software to manage and code the data. Categories were updated and restructured through retrospective analysis of all the transcripts. As categories emerged and accumulated, we identified potential themes. Themes which emerged across the transcripts were noted and constant comparisons made utilising the process of axial coding. Data was collected and analysed until a point of saturation had been reached, where no new themes were emerging from the data. Two coders were used to assess the data independently to develop the initial coding framework through discussion and consensus. A third member of the team reviewed the framework and definition of codes and categories.⁵⁷ Transcripts were coded and then cross checked and errors of omission and commission discussed iteratively. This process led to a finalised coded dataset. Agreed themes were then extracted and discussed between three members of the team. Finally a fourth member of the team was involved in grouping themes together in the context

3.3 Stage 3, Patient and practitioner interviews

of the survey data results and to structure the results section. Emergent results and coding frameworks were discussed with all applicants at various time points.

4

Results

4.1 Response rates to the practitioner survey

The total number of osteopaths available for the postal sample was 3,896. Table 4.1 shows the numbers of questionnaires sent out in the pilot and main phase of the practitioner survey and their associated response rates.

Table 4.1: Response rates to the practitioner survey

| | Practitioners surveyed | Complete questionnaires received | Response rate % |
|-------|------------------------|----------------------------------|-----------------|
| Pilot | 500 | 152 | 30.4 |
| Main | 3,396 | 930 | 27.4 |
| Total | 3,896 | 1,082 | 27.8 |

Forty three individual addresses were not found or returned as not known at that address (1.1%). An additional 75 responses (1.9%) were received indicating that they felt unable to take part. The largest number of these was due to being non-practising (n=38) and osteopaths reporting being on maternity leave (n=38).

We received 392 responses (10.1% survey sample) indicating that they did not want to take part in the study. Of the 344 who gave a reason for this, 86.4% indicated not having sufficient time, 11.7% felt the research was not useful to the profession, 7.6% indicated not being interested in research and a small proportion (3.2%) thought that they had not been given sufficient information. Those osteopaths who returned information indicating that they did not want to take part were similar to osteopaths in the sample who made no response at all

in terms of their sex but tended to be older (\bar{x} difference = 4.9 years) and had been qualified longer (\bar{x} difference = 4.8 years).

4.1.1 Characteristics of responders and non-responders

The mean age of the 1,082 responders ($\bar{x} = 45.1$, $SD = 9.7$) was similar to the 2,810 non-responders ($\bar{x} = 45.2$, $SD = 9.7$). Figure 4.1 shows a comparison of the distribution of ages between responders and non-responders.

A greater proportion of female osteopaths (53.6%) returned questionnaires compared males. The GOsC register at the time of the survey included 48.4% female osteopaths, thus female osteopaths may be slightly overrepresented in the respondents. Male osteopaths were slightly underrepresented, with 46.4% taking part as compared with 51.6% in the GOsC register.

Respondents and non-responders had similar lengths of time since qualification ($\bar{x} = 14.1$, $SD = 9.9$, $\bar{x} = 13.8$, $SD = 9.7$ respectively).

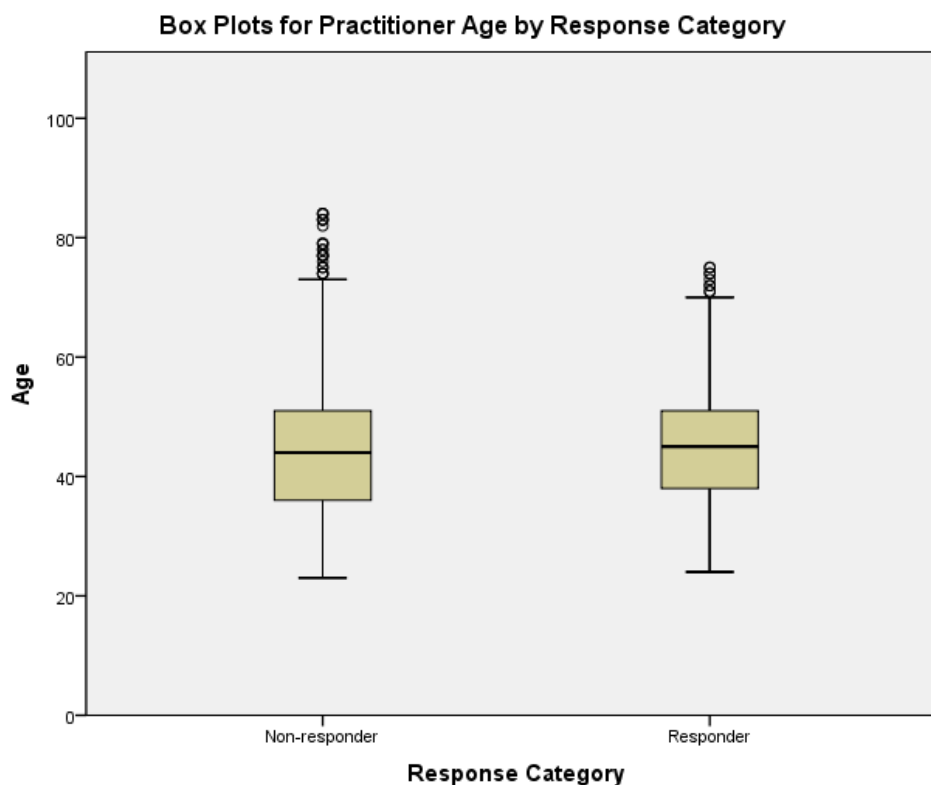


Figure 4.1: A box plot for age, by response category - The figure shows median ages, by response to the practitioner survey for 1,082 responders and 2,810 non-responders, as well as 25th and 75th percentiles; 1.5 times the inter-quartile range, and outliers

4.2 Response rates to the patient survey

Figure 4.2 summarises the recruitment and responses to the patient survey.

The practitioner survey included an item which asked whether practitioners might be willing to give out questionnaires to patients as part of being involved further in the study. Of the 1082 respondents, 507 (46.9%) responded positively and received an information pack.

Table 4.2 shows the numbers of information packs sent out in the pilot and main phases of the survey, the number of osteopaths who opted out and the numbers of patient packs sent out to practitioners.

Table 4.2: Distribution of information packs and patient baseline questionnaire packs

| | Info Packs Sent to Practitioners | Practitioners opted out | Practitioners agreeing to distribute questionnaires | Total patient packs sent to practitioners |
|-------|----------------------------------|-------------------------|---|---|
| Pilot | 63 | 19 | 44 | 2300 |
| Main | 444 | 89 | 355 | 7144 |
| Total | 507 | 108 | 399 | 9444 |

In total 399 practitioners were sent survey instruments for their patients. This represents 10.2% of the register of UK practising osteopaths used in the original practitioners' survey and 36.9% of the 1,082 responders to the practitioner survey. Of these we received at least one completed patient questionnaire from 212 practitioners, representing 5.4% of the UK practitioner population and 19.6% of respondents to the practitioner survey.

Table 4.3 provides further details of the responses to the patients' survey.

Table 4.3: Responses to baseline pilot and main phases

| | Pilot phase | Main phase | Total |
|--|-------------|-------------|-------------|
| Practitioners with one or more responses (%) | 22 (50.0) | 190 (53.5) | 212 (53.1) |
| No. questionnaires returned (%) | 209 (9.1) | 1848 (25.9) | 2057 (21.8) |
| Average returned per osteopath taking part | 9.5 | 9.7 | N/A |

Of the 2,057 baseline questionnaires returned by patients, 18 were incomplete and excluded, giving 2,039 usable responses. 1,782 (86.6%) provided contact details for the six week follow-up questionnaire. For the pilot phase 183 patients were contacted and 138 (75.4%) returned

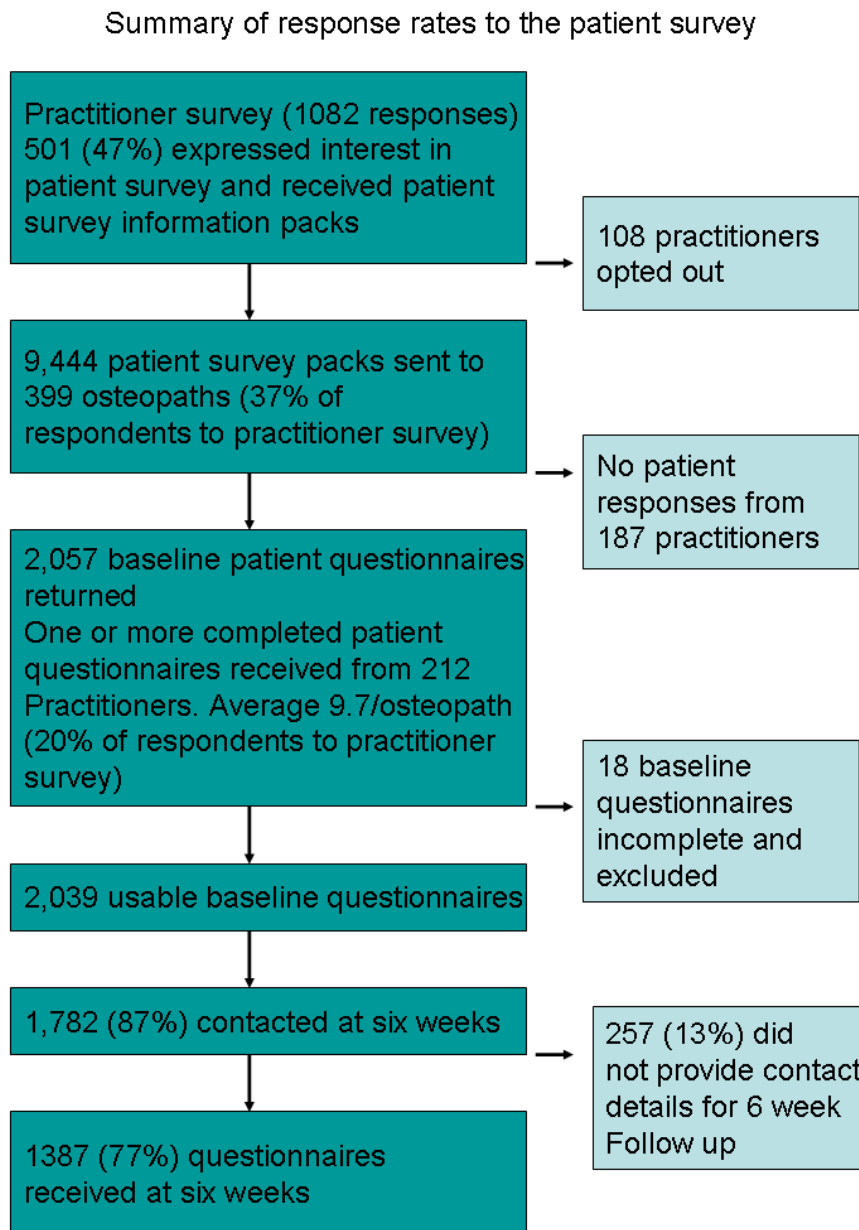


Figure 4.2: Summary of recruitment and response rates for the patient survey -

4.3 Response rates to the practitioner interviews

questionnaires at six weeks. In the main phase 1,599 patients were surveyed with follow-up questionnaires and 1,249 responses (78.1%) were received at six weeks. Thus the overall response rate for the six week follow-up questionnaire was 77.4%. The mean time taken from the baseline appointment to completion of the six week follow-up questionnaire was 6.3 weeks (SD = 1.9).

The baseline questionnaire was completed by 1,266 (62.1%) patients before their treatment, 531 (26.0%) completed it on the same day but after treatment and 156 (7.7%) completed the questionnaire the day after. 86 (4.2%) did not say when they completed the questionnaire.

The day one questionnaire was filled in one day after the appointment by 1,688 (82.8%) patients, on the treatment day but after the consultation by 52 (2.6%) patients, two days after the treatment by 147 (7.2%) patients and more than two days after the appointment by 94 (4.6% of patients. 58 (2.8%) participants did not say when they filled in the questionnaire or did not return it.

The day two questionnaire was completed two days after the appointment by 1,520 (74.6%) patients, three days after the appointment by 279 (13.7%) patients and more than three days after appointment by 168 (8.2%) of patients. 72 (3.5%) did not say when they filled in the questionnaire or did not return it.

4.2.1 Baseline comparison of responders and non-responders at six weeks follow-up

Out of the total of 2,039 participants 652 (32.0%) were lost to follow-up at 6 weeks. Comparisons between the baseline characteristics of non-responders and those who completed six week questionnaires revealed that the following were found to be equally distributed between the two groups: Age, Sex, Education/Job, Medication, Attitude towards the practitioner giving information or asking permission, Presenting area, Symptoms and troublesomeness at baseline.

Two characteristics were found to be different between those who responded at six weeks vs those who did not. These were consultation of other health care professional (responders 43% vs non-responders 50%, $\chi^2=6.97$ $p=0.008$) and visit to the GP in the last six months (responders 70% vs non-responders 75%, $\chi^2=3.69$ $p=0.055$)

4.3 Response rates to the practitioner interviews

A total of 63 practitioners were invited for interview with 30 agreeing to be interviewed. We ceased recruitment when the interviewers agreed that little or no new content was emerging from the interviews. This occurred after a total of 24 interviews.

4.4 Response rates to the patient interviews

Seventy-four patients were identified as fulfilling our selection criteria for interview (see methods section for further details) and indicated that they would be willing to be contacted for interview in response to the stage two patient survey. All these patients were contacted with information about the interview phase, a consent form, and indicative times for interview. Twenty patients replied and were willing to be interviewed. Nineteen patients were interviewed and we failed to arrange a convenient time for interview with one patient.

4.5 Characteristics of the respondents to the practitioner survey

The median age of practitioners was 44 (IQR 37 to 50) and the median years since qualification was 12 (IQR 6 to 21). Forty six percent of respondents were male (n=499), 53% were female (n=576), and 7 sex identifiers were missing (1%).

Male and female practitioners responding to the survey were broadly similar in terms of their age and the time since graduation. The median reported graduation year was 1998 (IQR 1989 to 2004). This reflects the increase in numbers of osteopaths graduating in the last two decades. Figure 4.3 illustrates the age and sex of respondents and figure 4.4 shows the distribution of respondents by sex and years of experience since graduation.

4.5 Characteristics of the respondents to the practitioner survey

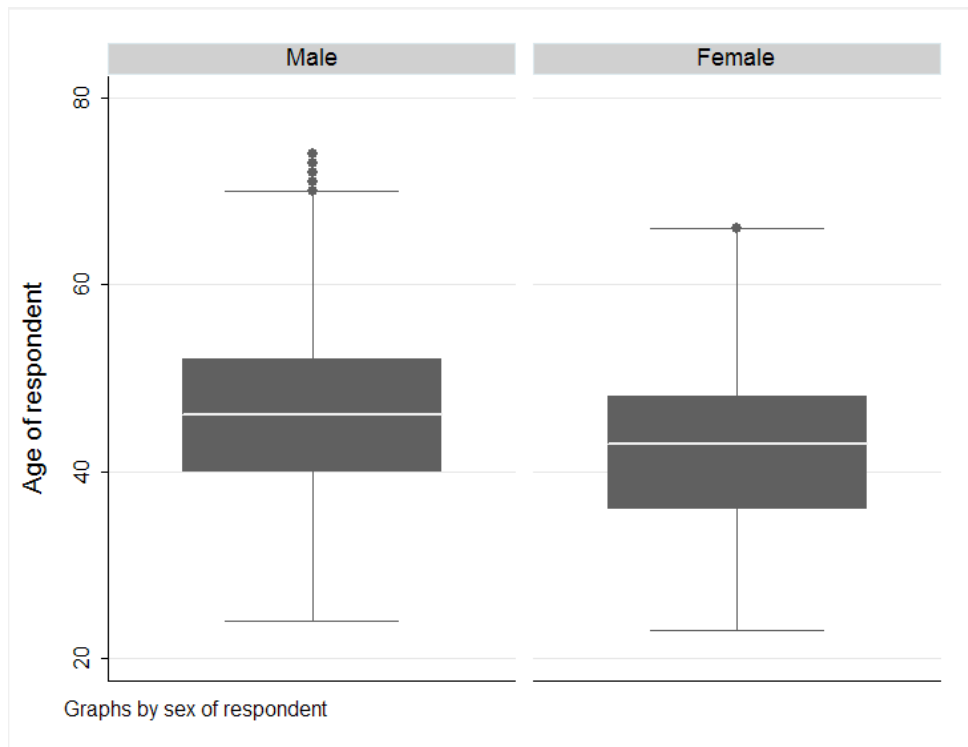


Figure 4.3: A box plot of respondent age by sex - The figure shows median ages, by sex, as well as 25th and 75th percentiles; 1.5 times the inter-quartile range, and outliers

4.5 Characteristics of the respondents to the practitioner survey

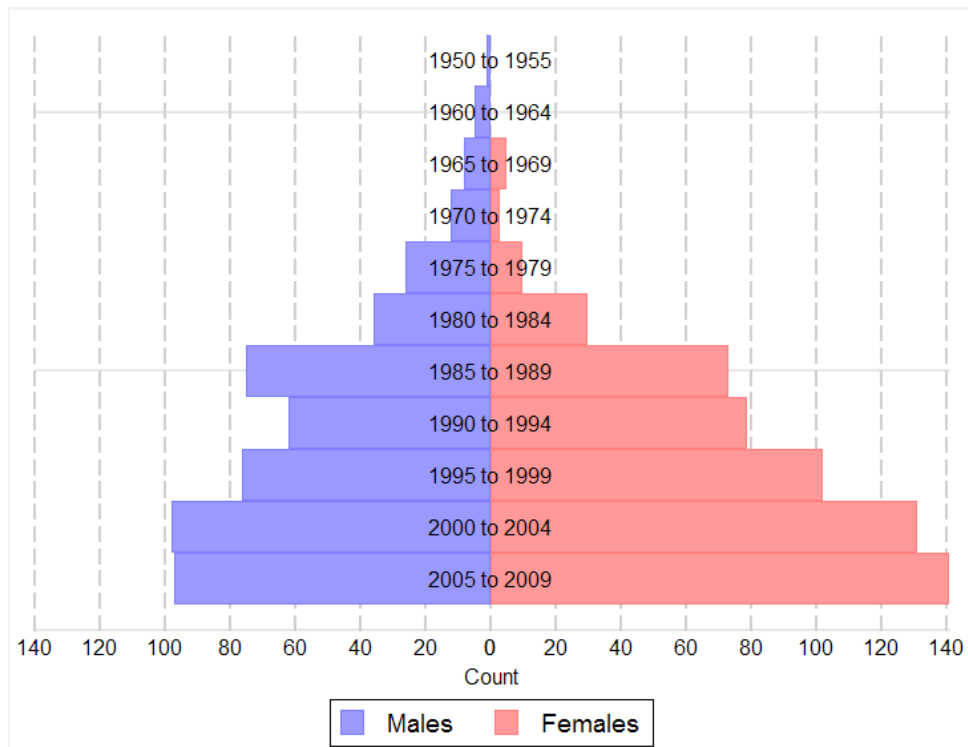


Figure 4.4: Population pyramid: graduation year, by sex - The figure shows the prevalence of participating osteopaths graduating in different year categories, by sex

4.6 Characteristics of respondents to the patient survey

4.6.1 Demographic and socioeconomic characteristics

Of the 2,039 responses from adults to the baseline survey, more were female (n=1,323, 64.9%) than male (n=661, 32.4%). Fifty-five sex identifiers were missing (2.7%). The median age for females and males was similar at 56 (IQR 45 to 65) and 57 (IQR 45 to 65) respectively (figure 4.5). Fifty patients did not supply their age (2.5%). Patients between 45 and 64 years of age accounted for 50% of respondents. Figure 4.6 shows a population pyramid of patients' ages and sex, indicating that men and women were similarly distributed across the age categories. Table 4.4 provides the frequency distribution across the age categories.



Figure 4.5: A box plot of patient age by sex - The figure shows median ages, by sex, as well as 25th and 75th percentiles; and 1.5 times the inter-quartile range

Similar proportions of respondents left school at 16 or younger (35.9%) and at 19 or older (34.5%). A small number were still in full time education (0.7%). Table 4.5 shows the frequency distribution across the categories for the 1,981 respondents (2.9% missing).

Most respondents were employed (57.1%) or retired (28.6%). Table 4.6 shows the frequency distribution across the categories.

Of the 1,945 participants who responded to the question whether they were a current smoker, 197 participants identified themselves as smokers (10.1%) and 1,748 (89.9%) as non-smokers.

4.6 Characteristics of respondents to the patient survey

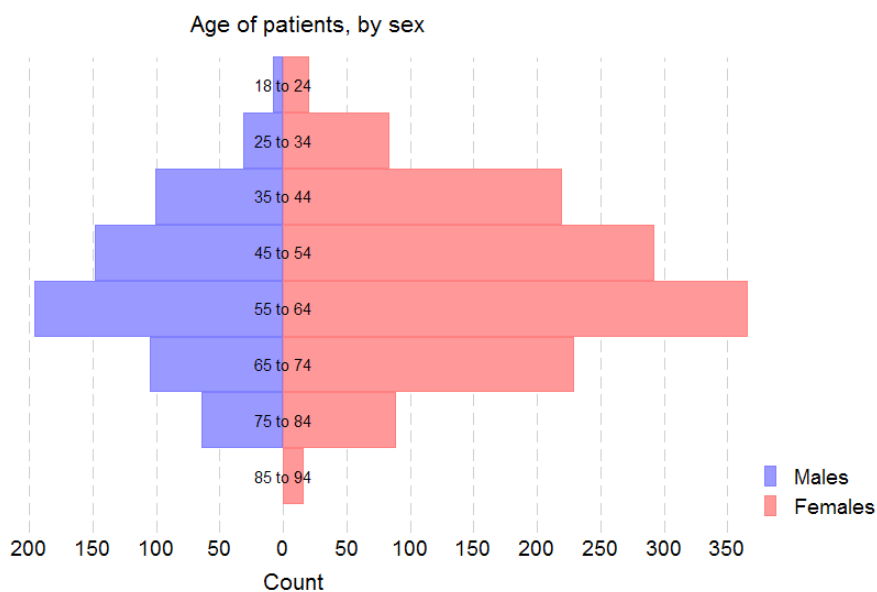


Figure 4.6: Population pyramid: age, by sex - The figure shows the prevalence of patients of different ages, by sex

Table 4.4: Age by category and sex

| Age category | Males (%) | Females (%) | Total (%) |
|--------------|-------------------|---------------------|--------------------|
| 18 to 24 | 8 (1.2) | 21 (1.6) | 29 (1.5) |
| 25 to 34 | 31 (4.7) | 84 (6.4) | 115 (5.8) |
| 35 to 44 | 101 (15.3) | 220 (16.7) | 321 (16.2) |
| 45 to 54 | 148 (22.4) | 293 (22.2) | 441 (22.3) |
| 55 to 64 | 196 (29.7) | 366 (27.8) | 562 (28.4) |
| 65 to 74 | 105 (15.9) | 229 (17.4) | 334 (16.9) |
| 75 to 84 | 64 (9.7) | 89 (6.8) | 153 (7.7) |
| 85 to 94 | 7 (1.1) | 16 (1.2) | 23 (1.2) |
| Total | 660 (33.4) | 1,318 (66.6) | 1,978 (100) |

Table 4.5: Age on leaving full-time education

| Age category | Freq. | Percent | Cum. |
|------------------------------|-------|---------|-------|
| 16 or less | 711 | 35.9 | 35.9 |
| 17 to 18 | 572 | 28.9 | 64.8 |
| 19 or older | 684 | 34.5 | 99.3 |
| Still in full time education | 14 | 0.7 | 100.0 |

4.6 Characteristics of respondents to the patient survey

Table 4.6: Employment status of responding patients

| Category | Freq. | Percent |
|--|-------|---------|
| Employed - full or part time + self employed | 1,124 | 57.1 |
| Retired from paid work | 563 | 28.6 |
| Looking after your home/family | 146 | 7.4 |
| Unable to work due to long term sickness | 61 | 3.1 |
| Unemployed and looking for work | 19 | 1.0 |
| At school or in full time education | 12 | 0.6 |
| Other | 42 | 2.1 |

4.6.2 Comorbidities

Of the 1,959 participants who responded to the question asking whether they currently suffered from a number of listed health problems, 57.3% (n=1,123) responded positively. Table 4.7 lists the health problems, along with the frequency distributions of reported health problems. The denominator for percentages in table 4.7 is 2,037; this is 2 fewer than the total sample since 2 patients' demographic data were missing.

4.6 Characteristics of respondents to the patient survey

Table 4.7: Reported comorbidity

| Health complaint | | Freq. | Percent* |
|--------------------------------------|---|-------|----------|
| <i>Painful joints</i> | Rheumatoid arthritis | 124 | 6.1 |
| | Ankylosing Spondylitis | 43 | 2.1 |
| | Osteoarthritis | 311 | 15.3 |
| | Other joint problem | 221 | 10.9 |
| <i>Bone problems</i> | Osteoporosis | 94 | 4.6 |
| | Other bone problem | 85 | 4.2 |
| <i>Difficulties with breathing</i> | COPD, chronic bronchitis or Emphysema | 47 | 2.3 |
| | Other cause of breathing difficulty | 86 | 4.2 |
| <i>Heart problems</i> | Heart disease, Congestive Heart Failure, or Hypertension | 278 | 13.7 |
| | Angina | 32 | 1.6 |
| | Other heart problem | 40 | 2.0 |
| | | | |
| <i>Digestive or stomach problems</i> | Hiatus Hernia, Reflux/Heartburn | | |
| | Recurrent Indigestion, or Ulcers | 324 | 15.9 |
| | Other digestive or stomach problem | 76 | 3.7 |
| <i>Diabetes</i> | Diabetes | 104 | 5.1 |
| <i>Mental health problems</i> | Depression, or anxiety | 224 | 11.0 |
| | Other mental health | 25 | 1.2 |

* Where $n=2,037$

4.6.3 Medication

Of the 1,950 participants responding to the question about medication use, 1,211 (62.1%) indicated using medication in the past seven days. Table 4.8 shows the types of drugs participants selected from choices from the following categories: anti-depressants, anti-coagulants, blood thinning drugs, blood pressure lowering drugs, anti-angina drugs, cholesterol lowering drugs, steroids, and osteoporosis drugs.

Table 4.8: Drug use in the past week

| Drug class | Freq. | Percent* |
|---------------------------|-------|----------|
| Anti-depressants | 189 | 9.3 |
| Anti-coag./Blood thinning | 205 | 10.1 |
| Blood pressure lowering | 390 | 19.2 |
| Anti-angina | 77 | 3.8 |
| Cholesterol lowering | 289 | 14.2 |
| Steroids | 42 | 2.1 |
| Drugs for Osteoporosis | 93 | 4.6 |

* Where $n=2,037$

Out of the 1,934 participants who answered the question, 518 (26.8%) reported having cold or flu symptoms in the past two weeks. From 1,914 who responded to the yes/no question, 1,365 (71.3%) reported taking painkillers in the past week. From 2,019 who responded to the section on the use of specific painkillers in the last 7 days, 775 (38.4%) reported using anti-inflammatories, 758 (37.5%) reported using mild painkillers such as paracetamol, 433 (21.5%) reported using moderate painkillers, and 76 (3.8%) reported using strong painkillers.

4.6.4 Baseline clinical data

4.6.4.1 Characteristics of patients' site and duration of main symptoms/pain at baseline

Figure 4.7 and Table 4.9 show the distribution and frequency of distributions of the main area of symptoms/pain that caused the participants to visit an osteopath. The lower back area accounted for 41.3% of main problems, followed by the neck (16.7%) and shoulder (12.8%). Together these areas accounted for 70.8% of the main areas of symptoms/ pain presented by patients for treatment.

Table 4.10 shows the length of the participants' main pain/symptoms for which they were seeking osteopathic treatment. This question was answered by 1,984 (97.3%) of patients. Approximately half of the respondents (53.5%) reported a symptoms/pain duration of less than

4.6 Characteristics of respondents to the patient survey

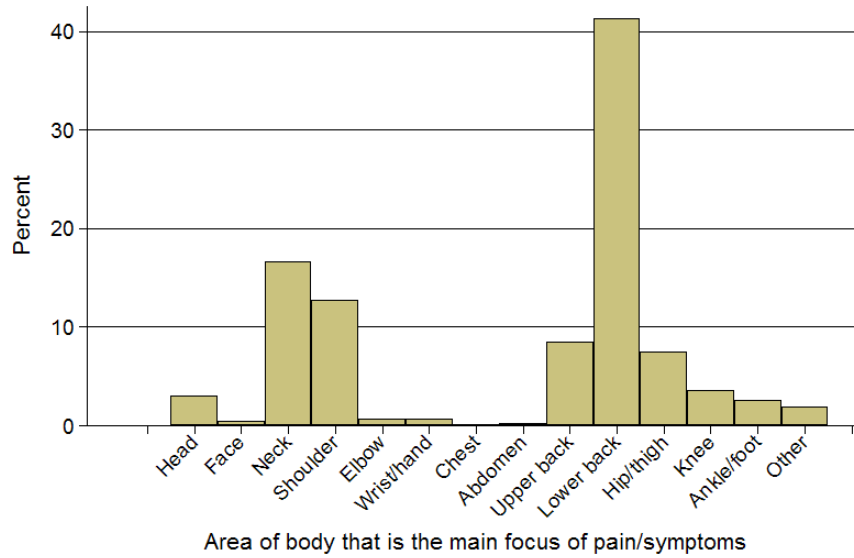


Figure 4.7: Area of main complaint - The figure shows the prevalence of area of main symptoms/pain

Table 4.9: Area of main focus

| Area | Freq. | Percent | Cum. |
|------------|-------|---------|-------|
| Head | 55 | 3.1 | 3.1 |
| Face | 8 | 0.5 | 3.5 |
| Neck | 298 | 16.67 | 20.2 |
| Shoulder | 228 | 12.8 | 33.0 |
| Elbow | 12 | 0.7 | 33.7 |
| Wrist/hand | 13 | 0.7 | 34.4 |
| Chest | 3 | 0.2 | 34.6 |
| Abdomen | 5 | 0.3 | 34.8 |
| Upper back | 151 | 8.5 | 43.3 |
| Lower back | 737 | 41.3 | 84.6 |
| Hip/thigh | 133 | 7.5 | 92.0 |
| Knee | 63 | 3.5 | 95.5 |
| Ankle/foot | 46 | 2.6 | 98.1 |
| Other | 34 | 1.9 | 100.0 |

4.6 Characteristics of respondents to the patient survey

three months. Thirty-six percent of participants reported that the pain had been present for more than seven months and of these 53.6% reported pain of greater than three years' duration.

Table 4.10: Length of bout/episode

| Length | Freq. | Percent | Cum. |
|---------------------|-------|---------|-------|
| Less than one month | 578 | 29.1 | 29.1 |
| 1-3 months | 483 | 24.3 | 53.5 |
| 4-6 months | 207 | 10.4 | 63.9 |
| 7 months to 3 years | 332 | 16.7 | 80.7 |
| More than 3 years | 384 | 19.4 | 100.0 |

Table 4.11 shows the time since participants had had a whole month without the pain/symptoms for which they were seeking osteopathic treatment. In total, 1,961 (96.2%) patients answered this question.

Table 4.11: Time since having a whole month free of symptoms/pain

| Length | Freq. | Percent | Cum. |
|---------------------|-------|---------|-------|
| Less than one month | 447 | 22.8 | 22.8 |
| 1-3 months | 387 | 19.7 | 42.5 |
| 4-6 months | 317 | 16.2 | 58.7 |
| 7 months to 3 years | 429 | 21.9 | 80.6 |
| More than 3 years | 381 | 19.4 | 100.0 |

4.6.4.2 Use of osteopathy for the main complaint, health care utilisation, impact on ability to work

Of the total 2,039 patients, 49 (2.4%) gave no indication about previous treatments. The majority of respondents, 1,467 (71.9%), returning the baseline questionnaire were in ongoing treatment. Twelve percent of respondents were new patients (n=244) and 13.7% were not new to the osteopath (n=279) but were presenting with a new episode of symptoms/pain.

Of the 1,205 who gave information about the number of treatments they had received, the median was 5 (IQR 2 to 10) and the mean was 11.9 (skewness = 16.9). The data was highly skewed with 55.3% of patients reporting that they had received five or fewer treatments for their current complaint, a further 20.4% had received between six and ten treatments, and 1.1% reported 100 or more treatments (maximum = 1000 treatments)

4.6 Characteristics of respondents to the patient survey

Most patients had visited their GP in the last 6 months (71.8%) and 45.2% had seen another healthcare practitioner about the symptoms/pain for which they were seeking osteopathic treatment.

A small proportion of patients were unable to work due to their symptoms (n=133, 7.2%). For those who had taken time off work on “this occasion”, the period of time was relatively short (median days 7.5, IQR 2 to 21.5; mean 37.6, skewness = 6.2). For the 1,076 participants who answered the question about time off due to their symptoms/pain over the last year, the time taken was also on average low. Of those who had taken time off, 52.9% had taken seven days or less, 84.7% had taken thirty days or fewer and only 4.0% had taken six months or more in the last twelve months. The median number of days off in the past year was 0 (IQR 0 to 1) (mean = 6.9, skewness = 7.84). A quarter of respondents (24.5%, n=455) indicated that being currently off work was not applicable to their situation.

4.6.4.3 Main complaint symptoms/pain intensity and troublesomeness

Figure 4.8 shows the distribution of average symptom/pain intensity over the past month. Table 4.12 shows the frequency distribution, median and IQR in the 1,995 participants who responded to this question.

Table 4.12: Intensity of symptoms/pain in the last month

| Symptom intensity | Freq. | Percent | Cum. |
|-------------------|-------|---------|-------|
| 0 | 44 | 2.2 | 2.2 |
| 1 | 53 | 2.7 | 4.9 |
| 2 | 111 | 5.6 | 10.4 |
| 3 | 210 | 10.5 | 21.0 |
| 4 | 234 | 11.7 | 32.7 |
| 5 | 276 | 13.8 | 46.5 |
| 6 | 278 | 13.9 | 60.5 |
| 7 | 313 | 15.7 | 76.1 |
| 8 | 286 | 14.3 | 90.5 |
| 9 | 100 | 5.0 | 95.5 |
| 10 | 90 | 4.5 | 100.0 |

0 = “No symptoms/pain” and 10 “Worst possible symptoms/pain”, Median=6 (IQR 4 to 7)

Figure 4.9 shows the distribution of current symptom/pain intensity. Table 4.13 shows the frequency distribution, median and IQR in the 1,998 participants who responded to this question.

4.6 Characteristics of respondents to the patient survey

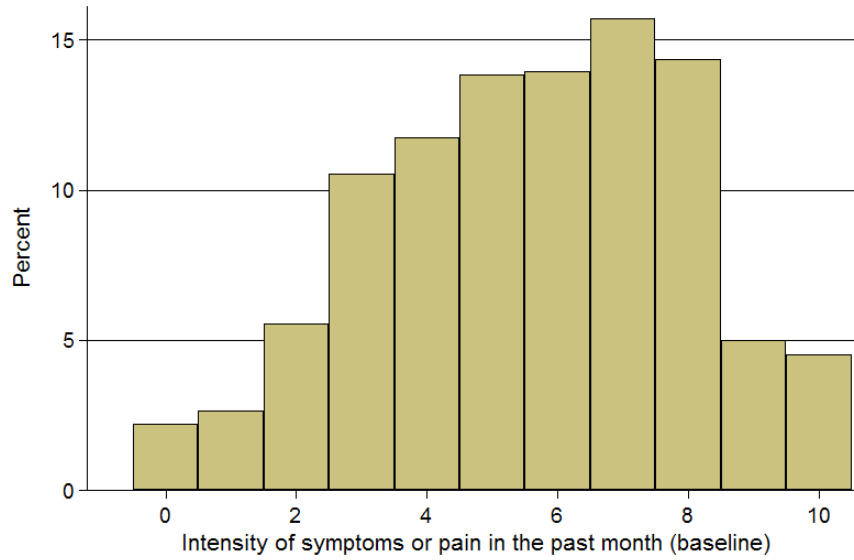


Figure 4.8: Intensity of symptoms/pain in the last month - The figure shows the distribution of intensity of symptoms/pain in the last month

Table 4.13: Current symptoms/pain intensity

| Symptom intensity | Freq. | Percent | Cum. |
|-------------------|-------|---------|-------|
| 0 | 108 | 5.4 | 5.4 |
| 1 | 178 | 8.9 | 14.3 |
| 2 | 242 | 12.1 | 26.4 |
| 3 | 325 | 16.3 | 42.7 |
| 4 | 263 | 13.2 | 55.9 |
| 5 | 242 | 12.1 | 68.0 |
| 6 | 182 | 9.1 | 77.1 |
| 7 | 208 | 10.4 | 87.5 |
| 8 | 166 | 8.3 | 95.8 |
| 9 | 62 | 3.1 | 98.9 |
| 10 | 22 | 1.1 | 100.0 |

0 = "No symptoms/pain" and 10 "Worst possible symptoms/pain", Median=4 (IQR 2 to 6)

4.6 Characteristics of respondents to the patient survey

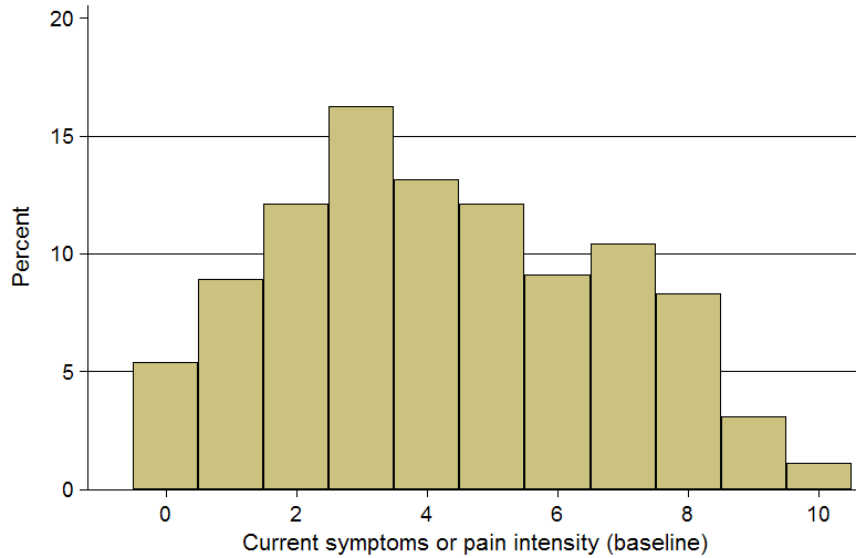


Figure 4.9: Current symptoms/pain intensity - The figure shows the distribution of current symptoms/pain intensity

Table 4.12 and Table 4.13 suggest that overall, patients rate their symptom/pain intensity higher over the last month than when reporting their current symptoms/pain.

Figure 4.10 shows the distribution of symptom/pain troublesomeness over the past month. Table 4.14 shows the frequency distribution, median and IQR in the 1,985 participants who responded to this question.

Table 4.14: Troublesomeness of symptoms/pain over the past month

| Troublesomeness | Freq. | Percent | Cum. |
|------------------------------|-------|---------|-------|
| No symptoms/pain experienced | 26 | 1.3 | 1.3 |
| Not at all troublesome | 68 | 3.4 | 4.7 |
| Slightly troublesome | 374 | 18.8 | 23.6 |
| Moderately troublesome | 826 | 41.6 | 65.2 |
| Very troublesome | 556 | 28.0 | 93.2 |
| Extremely troublesome | 135 | 6.8 | 100.0 |

Median=4 (IQR 4 to 5)

4.6 Characteristics of respondents to the patient survey

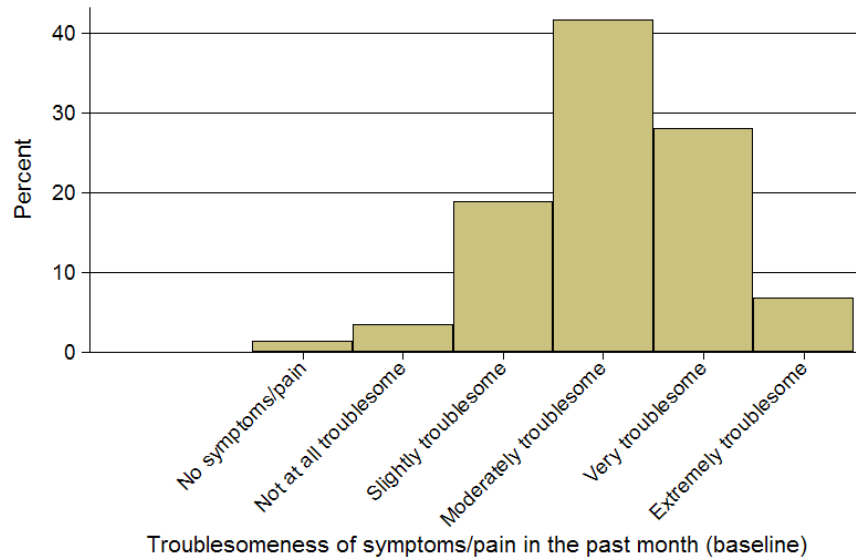


Figure 4.10: Troublesomeness of symptoms/pain over the past month - The figure shows the distribution of troublesomeness symptoms/pain over the past month

4.6.4.4 Symptoms/pain troublesomeness in other areas of the body

The neck, shoulder, upper back and lower back had median scores of 3 on the troublesomeness scale where 1 = “No symptoms/Pain” and 6 = “Extremely troublesome”. All other areas of the body had low median scores of 1 indicating that for these areas the prevalence of troublesome symptoms/pain was relatively low. Details of the distribution and frequency of scores for troublesomeness in all areas of the body may be seen in the Statistical Report.

4.6.4.5 Intensity and frequency of other non-musculoskeletal symptoms

Respondents were asked to rate the intensity of a range of broadly non-musculoskeletal symptoms, which have previously been reported as associated with adverse events in manual therapy. The scale was framed as on average, over the last fourteen day period and used an eleven point scale where 0=“no symptoms” and 10=“worst possible” symptoms.

The only non-musculoskeletal symptoms that had a median value above 0 were fatigue/sleepiness (Median = 3, IQR 0 to 6) and headaches (Median = 1, IQR 1 to 3). The percentage of respondents reporting an intensity above 0 was approximately 30% or under for all symptoms excepting headaches, where approximately 50% of the respondents reported some symptoms of an intensity of greater than 0.

4.6 Characteristics of respondents to the patient survey

Table 4.15: Percentage reporting zero symptom intensity, median and IQR of all respondents' intensity of non-musculoskeletal symptoms over the last 14 days

| Symptom | Percent zero intensity | Median | IQR. |
|-------------------------------|------------------------|--------|--------|
| Fatigue - sleepiness | 30 | 3 | 0 to 6 |
| Dizziness - lightheadedness | 67 | 0 | 0 to 1 |
| Nausea | 83 | 0 | 0 to 0 |
| Vomiting | 97 | 0 | 0 to 0 |
| Headache | 49 | 1 | 1 to 3 |
| Ringing in the ears | 78 | 0 | 0 to 0 |
| Confusion - disorientation | 90 | 0 | 0 to 0 |
| Fear - anxiety | 69 | 0 | 0 to 1 |
| Depression | 70 | 0 | 0 to 1 |
| Bruising | 85 | 0 | 0 to 0 |
| Skin rash | 90 | 0 | 0 to 0 |
| Numbness-tingling: arms-hands | 69 | 0 | 0 to 1 |
| Numbness-tingling: legs-feet | 73 | 0 | 0 to 1 |

Details of the distribution and frequency of scores for the intensity of all non-musculoskeletal symptoms measured may be seen in the Statistical Report.

Respondents were asked to rate the frequency of symptoms in the last fourteen days on an 11 point scale, where 0 = “not at all” and 10 = “every day”. The percentage of patients (approximately 70%) who reported 0 (not at all) was similar to those who reported 0 intensity (no symptoms) on the scale measuring intensity of symptoms. Details of the distribution and frequency of scores for the frequency of all non-musculoskeletal symptoms measured may be seen in the Statistical Report.

4.6.4.6 Health status: EuroQol score

The mean EuroQoL score at baseline (calculated for a UK population)⁵⁹ was 0.673 (95% CI 0.662 to 0.684). Table 4.16 shows the frequency and distribution of responses to the EQ5D at baseline, Figure 4.11 shows a histogram of its distribution.

4.6.4.7 Comparison of new and returning patients

Out of 1,954 patients who answered the question about whether this was the first time they had visited the osteopath, 244 (12.5%) replied positively indicating that they were new patients. For those who may have already consulted their osteopath we asked whether they were visiting for the first time for their current symptoms/pain. 351 (19.7%) out of 1,782 patients indicated

4.6 Characteristics of respondents to the patient survey

Table 4.16: EQ5D baseline scores

| Domain (n) | | Freq. | Percent |
|-----------------------------------|---|-------|---------|
| Mobility (1,933) | No problems walking around | 1,219 | 63.1 |
| | Some problems walking around | 713 | 36.9 |
| | Confined to bed | 1 | 0.05 |
| Self-care (1,898) | No problems with self-care | 1,721 | 90.7 |
| | Some problems with self-care | 173 | 9.1 |
| | Unable to wash or dress | 4 | 0.21 |
| Usual Activities (1,936) | No problems performing usual activities | 923 | 47.7 |
| | Some problems performing usual activities | 934 | 48.2 |
| | Unable to perform usual activities | 79 | 4.1 |
| Pain discomfort (1,946) | No pain or discomfort | 208 | 10.7 |
| | Moderate pain or discomfort | 1,518 | 78.0 |
| | Extreme pain or discomfort | 220 | 11.3 |
| Anxiety/depression (1,886) | No anxiety/depression | 1,324 | 70.2 |
| | Moderate anxiety/depression | 526 | 27.9 |
| | Extreme anxiety/depression | 36 | 1.8 |

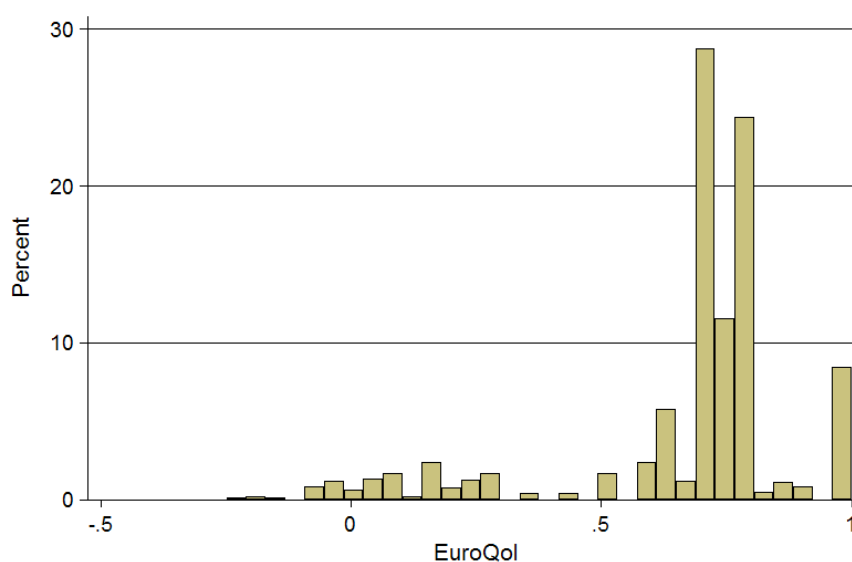


Figure 4.11: Histogram of EuroQol baseline scores - The figure shows a Histogram of EQ5D scores at baseline

4.6 Characteristics of respondents to the patient survey

positively. These patients had seen the osteopath before but were presenting with a new episode of symptoms/pain. Finally those who were under ongoing care were asked to indicate the number of treatments they had received for their current symptoms/pain; 18 (0.9%) patients said zero, 1,187 (58.2%) patients gave a number greater than zero and 834 (40.9%) patients did not answer the question. The median number of previous appointments was 5 (IQR 2 to 10)($\bar{x} = 11.9$; skewness 16.9). By cross-checking the replies for the three questions some of the answers could be imputed, and in this way we identified 523 “new” and 1,473 “returning” patients.

In returning patients the average age was 55.6 years (n=1,456, SE=0.36, 95%CI [55.0 to 56.3]) and in new patients it was 54.0 years (n=520, SE=0.64, 95%CI [52.7 to 55.2]).

The proportion of male patients was 32.3% in returning and 36.4% in new patients (n=1,454 and n=517 respectively). The χ^2 test showed no evidence of a significant difference (p=0.09).

The employment status is compared in table 4.17. The Kruskal-Wallis test showed no significant difference between the two groups (p=0.06).

Table 4.17: Employment status of new and returning patients

| Employment status | Returning | | New patient | |
|--|-----------|---------|-------------|---------|
| | Freq. | Percent | Freq. | Percent |
| Employed | 807 | 56.0 | 311 | 60.3 |
| Retired | 430 | 29.9 | 128 | 24.8 |
| Looking after family | 102 | 7.1 | 44 | 8.5 |
| Unable to work due to chronic sickness | 45 | 3.1 | 16 | 3.1 |
| Unemployed | 14 | 1.0 | 5 | 1.0 |
| Still in education | 6 | 0.4 | 6 | 1.2 |
| Other | 36 | 2.5 | 6 | 1.2 |

* Returning patients: n=1,440 and new patients: n=516, Kruskal-Wallis $\chi^2=3.5$, p=0.06

There were 82 (8.1%) returning patients currently off work because of their symptoms/pain and 50 (13.2%) new patients. This is significantly different on the 5% level ($\chi^2=8.3$, p=0.004). New patients were more likely to be off work which is consistent with their higher baseline pain scores.

Table 4.18 shows how many patients took medication in seven days prior to their baseline appointment. There is no significant difference except for steroidal drugs. Twice as many new patients had taken steroids in the previous week.

Overall, 48.2% of new patients reported at least one comorbidity, which is significantly lower than the 58.5% of returning patients ($\chi^2=16.5$, p<0.001). Table 4.19 shows how many patients

4.6 Characteristics of respondents to the patient survey

Table 4.18: Medication of new and returning patients

| Drug class | Returning | | New patient | | p-value (χ^2 test) |
|------------------------------|-----------|---------|-------------|---------|-----------------------------|
| | Freq. | Percent | Freq. | Percent | |
| Anti-depressants | 140 | 9.5 | 48 | 9.2 | 0.832 |
| Anti-coagulants | 36 | 2.5 | 20 | 3.8 | 0.101 |
| Blood thinning | 110 | 7.5 | 39 | 7.5 | 0.991 |
| Blood pressure lowering | 285 | 19.4 | 104 | 19.9 | 0.795 |
| Anti angina | 54 | 3.7 | 23 | 4.4 | 0.457 |
| Cholesterol lowering/statins | 209 | 14.2 | 80 | 15.3 | 0.540 |
| Steroids | 24 | 1.6 | 18 | 3.4 | 0.013 |
| Drugs for osteoporosis | 74 | 5.0 | 19 | 3.6 | 0.197 |

* Returning patients: n=1,472 and new patients: n=523

reported each health complaint.

Returning patients suffer significantly more often from painful joints (excluding Rheumatoid Arthritis), also from other bone problems (excluding osteoporosis) and other digestive and stomach problems (excluding Hiatus Hernia, acid Reflux/Heartburn, Recurrent Indigestion, Ulcers).

4.6 Characteristics of respondents to the patient survey

Table 4.19: Reported comorbidities of new and returning patients

| Health complaint | Returning | | New patient | | p-value (χ^2 test) |
|---|-----------|---------|-------------|---------|-----------------------------|
| | Freq. | Percent | Freq. | Percent | |
| Rheumatoid Arthritis | 88 | 6.0 | 35 | 6.7 | 0.560 |
| Ankylosing-Spondylitis | 37 | 2.5 | 5 | 1.0 | 0.033 |
| Osteo-Arthritis | 256 | 17.4 | 53 | 10.1 | <0.001 |
| Other painful joints | 174 | 11.8 | 42 | 8.0 | 0.017 |
| Osteoporosis | 75 | 5.1 | 18 | 3.4 | 0.123 |
| Other bone problems | 69 | 4.7 | 12 | 2.3 | 0.017 |
| COPD, Chronic bronchitis, Emphysema | 32 | 2.2 | 15 | 2.9 | 0.369 |
| Other difficulties with breathing | 65 | 4.4 | 20 | 3.8 | 0.565 |
| Heart Disease, Congestive Heart Failure, Hypertension | 210 | 14.3 | 67 | 12.8 | 0.408 |
| Angina | 25 | 1.7 | 7 | 1.3 | 0.574 |
| Other Heart Problems | 31 | 2.1 | 8 | 1.5 | 0.412 |
| Hiatus Hernia, acid Reflux/Heartburn, Recurrent Indigestion, Ulcers | 242 | 16.4 | 80 | 15.3 | 0.541 |
| Other Digestive and Stomach Problems | 63 | 4.3 | 12 | 2.3 | 0.040 |
| Diabetes | 78 | 5.3 | 24 | 4.6 | 0.527 |
| Depression, Anxiety | 176 | 12.0 | 47 | 9.0 | 0.064 |
| Other Mental Health Problems | 17 | 1.2 | 8 | 1.5 | 0.508 |

* Returning patients: n=1,472 and new patients: n=523

4.7 Characteristics of the practitioner interviewees

The 23 practitioners interviewed for the study were fairly homogeneous in terms of the patients they treat. They reported that they treat a range of ages, predominantly adult, though very few stated that they specialise in a particular age group. The most common presentations that they reported seeing were broadly categorised as musculoskeletal conditions, with a number of practitioners specifically mentioning sports injuries as a specialism or interest. A few practitioners referred to other conditions of particular interest, including ME, migraine, headache and breathing problems. There was little specialisation in terms of acute or chronic patients, with most practitioners describing having a mix of both. Of those who reported a focus one way or the other, the majority had more chronic patients.

More men (n=16) than women (n=7) were interviewed and their experience varied from those with fewer years in practice (1-5 years, n=4) through to practitioners with greater than 25 years of experience (n=9). Interviewees were all older than 30, with the most common age category being between 50 and 59 (n = 12) and one practitioner was greater than 70 years of age. Only one of the interviewees reported patient volumes less than 20 per week, ten saw between 20 and 39 and, nine between 40 and 59. Three interviewees said that they saw more than 60 patients per week. There was a mix of practice environments with six interviewees describing themselves as working alone, thirteen with other health care practitioners and four with other osteopaths.

4.8 Characteristics of the patient interviewees

Patients were invited for interview based on their experience of temporary incapacity or disability attributed to osteopathic treatment by self-report, and by their experience of a three point worsening of primary symptoms between pre-treatment and two days post treatment.

Of the nineteen people interviewed, ten reported that they had experienced temporary incapacity or disability that they attributed to their osteopathic treatment. Four interviewees were male. The age range of interviewees was between 38 and 86; there were five people aged between 50 and 60, six people between 61 and 70 and five people between 71 and 86. Two people were 47 years of age and one 38. Ten of those interviewed described themselves as retired, one as not working due to long-term sickness, and six reported a range of occupations.

4.9 Osteopathic setting, consultation time and treatment techniques used

4.9.1 Practice settings and volumes

Osteopaths were asked to refer to their appointment schedules to estimate the volumes of new and returning patients they saw on average over a week in NHS, home settings and in dedicated private clinic/practices. The majority of patients (80.1%) are seen by the osteopaths in dedicated private clinics/practices, 15.0% are seen in home settings and 4.9% were reported as seen in an NHS setting. Table 4.20 shows the volume of patients and proportions by site of new and returning patients seen in different practice settings. Overall, an average of 33.3 patients were seen per osteopath per week.

Table 4.20: Number of patients reported as seen per average week

| | NHS (%) | Home (%) | Clinic (%) | Total (%) |
|-----------|--------------|--------------|---------------|---------------|
| New | 374 (21.1) | 867 (16.0) | 3,876 (13.4) | 5,117 (14.2) |
| Returning | 1,398 (78.9) | 4,550 (84.0) | 25,014 (86.6) | 30,962 (85.8) |
| Total | 1,772 (100) | 5,417 (100) | 28,890 (100) | 36,079 (100) |

The highest proportion of new patients per practice setting was seen in the NHS (21.1%) followed by home settings (16.0%) and then private dedicated clinics (13.4%).

Of the 1,082 osteopaths, 110 (10.2%) had seen at least one new or continuing patient in either a GP practice, hospital, or other NHS setting in the past month; there was no evidence of a difference between male and female practitioners in terms of their likelihood to see patients in an NHS setting (Table 4.21). The median number of new adult patients seen in NHS settings per week was 2 (IQR 1 to 4). The median number of continuing patients seen per week was 9 (IQR 5 to 16).

Table 4.21: Counts of participants who reported seeing patients in NHS settings

| At least one patient in NHS setting | Male | Female | Total |
|-------------------------------------|------|--------|-------|
| No | 440 | 525 | 965 |
| Yes | 59 | 51 | 110 |
| Total | 499 | 576 | 1,075 |

$$\chi^2 = 2.57, p = 0.109$$

4.9 Osteopathic setting, consultation time and treatment techniques used

Of the 1,082 respondents, 309 (28.6%) had seen at least one new or continuing patient in their own home or the home of the practice principal; females were more likely than males to see patients in this setting (Table 4.22). The median number of new adult patients seen in home settings per week was 2 (IQR 1 to 3). The median number of continuing patients seen per week was 10 (IQR 5 to 20).

Table 4.22: Counts of participants who reported seeing patients in their home or the practice principal's home

| At least one patient in home settings | Male | Female | Total |
|---------------------------------------|------|--------|-------|
| No | 379 | 387 | 766 |
| Yes | 120 | 189 | 309 |
| Total | 499 | 576 | 1,075 |

$$\chi^2 = 10.02, p = 0.002$$

For the 892 (82.4%) osteopaths who had seen at least one new or continuing patient in private practice settings, males were more likely than females to see patients in this setting (Table 4.23). The median number of new adult patients seen by these practitioners in private settings per week was 4 (IQR 2 to 5). The median number of continuing patients seen per week was 25 (IQR 14 to 40).

Table 4.23: Counts of participants who reported seeing patients in private practice settings

| At least one patient in private settings | Male | Female | Total |
|--|------|--------|-------|
| No | 71 | 114 | 185 |
| Yes | 428 | 462 | 890 |
| Total | 499 | 576 | 1,075 |

$$\chi^2 = 5.8, p = 0.016$$

n.b sex data absent for two practitioners

Of the 1,065 osteopaths, responding to the question, 549 (51.6%) reported seeing most of their patients working in a setting where they did not discuss patients with others.

These patterns of practice suggest that NHS and home settings are lower volume and are likely to reflect a more part-time model of delivery. Women are more likely to deliver more care in home settings and men in private dedicated premises. There is no sex difference between those delivering care in NHS contexts.

4.9 Osteopathic setting, consultation time and treatment techniques used

4.9.2 Consultation times

The average appointment time for new patients was 50 minutes and 4 seconds (95% CI 49.22 to 50.90). This differed by gender ($t_{1056} = -5.35, p < 0.001$), with females spending on average 4 minutes and 34 seconds longer with new patients compared to males (95% CI 2.88 to 6.22). The average appointment time for continuing patients was 33 minutes and 32 seconds (95% CI 33.07 to 34.02), with evidence of a difference between the continuing appointment times of male and female practitioners ($t_{1058} = -3.44, p < 0.001$), but these differences were of little clinical significance, with females spending on average 1 minute and 40 seconds longer with new patients compared to males (95% CI 0.71 to 2.61). Table 4.24 summarises the differences between male and female consultation times.

Table 4.24: Consultation time in minutes by male and female practitioners for new and returning patients expressed in mean and median values

| | Mean (SD) | | | Median (IQR) | | |
|-----------|-------------|-------------|-------------|--------------|------------|------------|
| | Male | Female | Total | Male | Female | Total |
| New | 47.6 (13.5) | 52.2 (14.1) | 50.1 (14.0) | 45 (36-60) | 60 (45-60) | 60 (40-60) |
| Returning | 32.6 (7.9) | 34.3 (7.8) | 33.5 (7.9) | 30 (30-30) | 30 (30-40) | 30 (30-38) |
| All | 40.1 (9.1) | 43.3 (9.2) | 41.8 (9.3) | 41 (30-45) | 45 (38-45) | 45 (35-45) |

4.9.2.1 Predictors of length of consultation

Regression analyses exploring the predictors of the length of appointment time were performed using two different definitions for consent explained (see section 3.1.1.3 for definition). We present here the model explaining the largest amount of the variance. It used the stricter definition of consent recording. For both new and returning patient appointment times 9.9% of the variance of appointment length was explained in the regression model which included 879 observations. Table 4.25 shows the summary model.

Table 4.25: Modelled estimates: variables' effects on patient appointment lengths in past month

| Explanatory variable | β | SE | 95% CI | p-value (Wald) |
|---|---------|-------|------------------|----------------|
| Gender (Effect of male) | -2.037 | 0.641 | -3.295 to -0.780 | 0.002 |
| Graduation year | 0.122 | 0.033 | 0.057 to 0.186 | <0.001 |
| Osteopath uses functional/ Continued on next page... | 0.067 | 0.016 | 0.036 to 0.099 | <0.001 |

4.9 Osteopathic setting, consultation time and treatment techniques used

Table 4.25 – Continued

| Explanatory variable | β | SE | 95% CI | p-value (Wald) |
|--|---------|-----------|------------------|-----------------------|
| cranial techniques | | | | |
| Osteopath uses structural techniques | -0.052 | 0.015 | -0.082 to -0.021 | 0.001 |
| Frequency of informing patients about treatment benefits | -0.330 | 0.291 | -0.901 to 0.242 | 0.258 |
| Frequency of informing patients about treatment risks | 0.241 | 0.251 | -0.252 to 0.733 | 0.338 |
| Frequency of informing patients about outcome of alternate or no trt | -0.326 | 0.215 | -0.748 to 0.095 | 0.129 |
| Obtaining successive consent for examination | 0.144 | 0.196 | -0.242 to 0.530 | 0.463 |
| Obtaining consent before initial treatment | 0.244 | 0.256 | -0.258 to 0.745 | 0.340 |
| Obtaining successive consent for treatment | -0.112 | 0.230 | -0.564 to 0.340 | 0.627 |
| Consenting behaviour when treating the neck: Def 2 (0...never, 8...always) | -0.986 | 0.388 | -1.747 to -0.224 | 0.011 |
| Consenting behaviour when treating the back: Def 2 (0...never, 8...always) | 7.996 | 3.056 | 1.998 to 13.994 | 0.009 |

Six variables were predictive of the length of consultation. Sex is predictive of shorter consultation time, where being a male osteopath is associated with a shorter appointment by two minutes ($p = 0.002$). The length of time an osteopath has been practising since graduation also predicts appointment time, where those in practice longer have shorter appointments. Eight years of time in practice predicts a shorter appointment by one minute. The variable “functional technique” used in the model was a combined variable. It included functional technique/counterstrain, visceral and cranial approaches and predicted a very slightly longer appointment time (4 seconds). “Structural technique”, also a combined variable made up of HVT, soft tissue

4.9 Osteopathic setting, consultation time and treatment techniques used

and articulatory techniques, also predicted appointment length, but in the opposite direction. Structural technique use was associated with shorter appointments by 3 seconds. Whilst these variables predicted statistically significant changes in appointment times, they are small and unlikely to be clinically meaningful. Consent being verbally discussed and noted or written and signed, also had an impact on appointment time; when treating the neck this was associated with shorter consultations by one minute per individual technique consented, whereas for back pain, the length of appointment increased by 8 minutes for each technique consented. Notably variables concerning information giving about risks, benefits, alternatives and the reported frequencies of obtaining consent prior to initial or successive treatments or examinations were not predictors.

4.9.3 Use of osteopathic techniques and adjunctive approaches

4.9.3.1 Osteopathic techniques

Osteopaths were asked to estimate the percentage of their patients over the last month on whom they had used a range of osteopathic techniques. Figure 4.12 shows a table of histograms illustrating how the use of different techniques is distributed over the percentage of patients treated by osteopaths and Table 4.26 shows the median percentages and inter-quartile ranges.

Table 4.26: Median percentage of patients treated by osteopaths, by technique

| Technique | Median | 25 th centile | 75 th centile |
|--------------------------|--------|--------------------------|--------------------------|
| Cranial/IVM | 10 | 0 | 50 |
| Functional/counterstrain | 20 | 10 | 40 |
| HVT | 50 | 30 | 70 |
| Joint articulation | 90 | 70 | 100 |
| Soft tissue | 90 | 80 | 100 |
| MET | 40 | 20 | 70 |
| Visceral | 10 | 0 | 10 |

Across the scope of techniques used, there is evidence of considerable variation in the extent of use of different techniques. Some practitioners report using each individual technique on 100% of their patients and some practitioners report not using particular techniques at all. For example, 3 practitioners (0.3%) reported using visceral techniques on 100% of their patients over the last month whereas 497 (49.5%) reported not using it on any patients over the last month. Only 2 practitioners reported using each technique listed on 100% of all their patients over the last month. Overall joint articulation and soft tissue are used on most patients by most

4.9 Osteopathic setting, consultation time and treatment techniques used

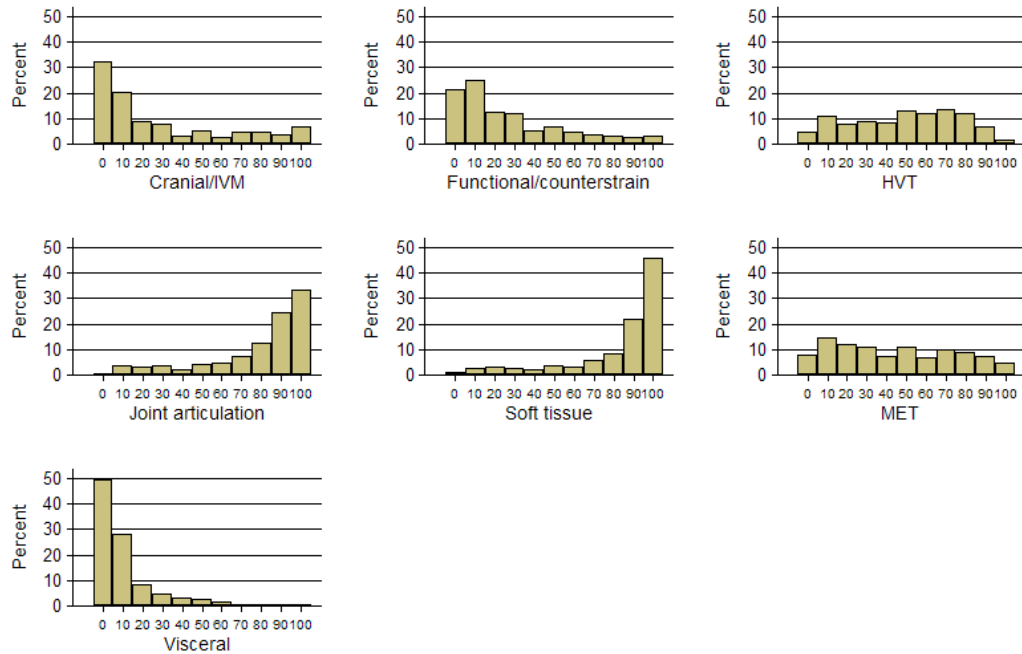


Figure 4.12: Technique use by osteopaths - The figure shows a table of histograms illustrating how use of different techniques is distributed over the percentage of patients treated by osteopaths

osteopaths (median = 90% of patients). Visceral overall is used on the least number of patients followed by cranial and then functional. However HVT and MET are spread across the range of proportionate use.

4.9.3.2 HVT use in cervical, thoracic and lumbar spinal regions

Osteopaths were asked to estimate the percentage of patients over the last month on whom they had used HVT for the cervical, thoracic and lumbar regions of the spine. Table 4.27 shows the distributions of HVT use by osteopaths on the cervical, thoracic, and lumbar spine. Figure 4.13 shows box-plots of these. The median percentage for use of HVT on the cervical spine was 20% (IQR 10 to 40), for the thoracic spine it was 50% (IQR 30 to 70), and for the lumbar spine it was 40% (IQR 20 to 60).

HVT use is highest in the thoracic region followed by the lumbar and cervical regions. Only 16.2% of practitioners did not use HVT of the neck on any patient in the last month. Three practitioners reported using HVT on all patients seen in the last month. Only 5.9% osteopaths did not use HVT of the thoracic spine, whereas 7 practitioners reported its use on all patients.

4.9 Osteopathic setting, consultation time and treatment techniques used

Table 4.27: Frequencies of HVT use (%) on the cervical, thoracic and lumbar spine

| HVT use (%) | Cervical | | Thoracic | | Lumbar | |
|-------------|----------|------|----------|------|--------|------|
| | n | % | n | % | n | % |
| 0 | 172 | 16.2 | 63 | 5.9 | 99 | 9.3 |
| 10 | 275 | 25.8 | 77 | 7.2 | 105 | 9.8 |
| 20 | 176 | 16.5 | 77 | 7.2 | 100 | 9.4 |
| 30 | 149 | 14.0 | 115 | 10.8 | 154 | 14.4 |
| 40 | 77 | 7.2 | 106 | 9.9 | 131 | 12.3 |
| 50 | 77 | 7.2 | 127 | 11.9 | 155 | 14.5 |
| 60 | 39 | 3.7 | 150 | 14.1 | 111 | 10.4 |
| 70 | 44 | 4.1 | 134 | 12.6 | 99 | 9.3 |
| 80 | 32 | 3.0 | 130 | 12.2 | 67 | 6.3 |
| 90 | 21 | 2.0 | 81 | 8.0 | 43 | 4.0 |
| 100 | 3 | 0.3 | 7 | 0.7 | 3 | 0.3 |

Cervical: Median=20 (IQR=10 to 40), Thoracic: Median=50 (IQR=30 to 70), Lumbar: Median=40 (IQR=20 to 60)

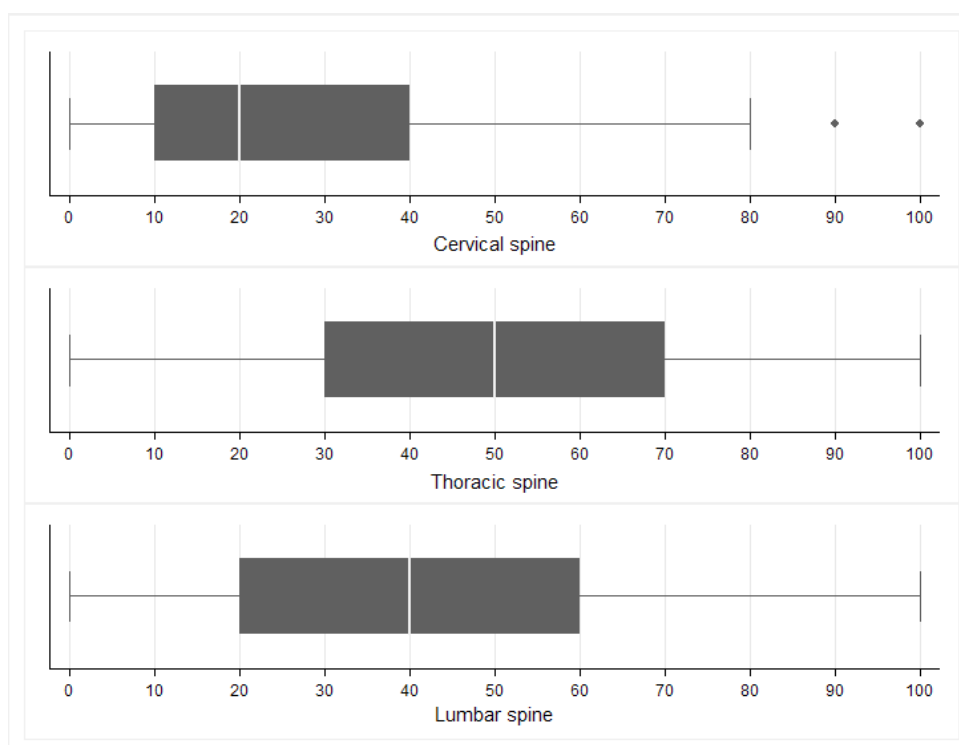


Figure 4.13: Box-plots of HVT application to spinal areas - The figure shows distributions of HVT use by osteopaths on the cervical, thoracic, and lumbar spine

4.9 Osteopathic setting, consultation time and treatment techniques used

4.9.3.3 Predicting osteopathic technique usage

Regression analyses were used to explore the predictors of technique use by osteopaths, as defined by the proportion of patients on whom osteopaths reported using a particular technique in the past month. The regression model for HVT explained 10.1% of the variance of HVT use and contained 903 observations. Table 4.28 shows the adjusted estimates.

Table 4.28: Modelled estimates: effects on reported use of HVT in the past month

| Explanatory variable | β | SE | 95% CI | p-value (Wald) |
|--|---------|------|----------------|----------------|
| Average time for new and returning patients | -0.50 | 0.09 | -0.69 to -0.32 | < 0.001 |
| Believing it is predictable who will benefit or react to treatment | 1.41 | 0.67 | 0.09 to 2.73 | 0.036 |
| Difficulty discussing treatment reactions | -1.26 | 0.61 | -2.46 to -0.05 | 0.040 |
| Frequency of informing patients about benefits, risks, or alternative treatments | -0.08 | 0.87 | -1.79 to 1.63 | 0.927 |
| Gender (Effect of male) | 5.69 | 1.75 | 2.26 to 9.13 | < 0.001 |
| Graduation year | 0.30 | 0.09 | 0.12 to 0.47 | 0.001 |
| Self-reported Serious Adverse Events (Effect of ever reporting) | -0.88 | 2.59 | -5.98 to 4.21 | 0.733 |
| Obtaining consent before initial treatment | 1.09 | 0.67 | -0.23 to 2.42 | 0.106 |
| Obtaining successive consent | -0.15 | 0.55 | -1.23 to 0.94 | 0.793 |
| Perceived importance of anxiety when treating the cervical spine | -0.27 | 0.81 | -1.86 to 1.32 | 0.736 |
| Perceived importance of cardiac risk when treating the cervical spine | 2.87 | 1.13 | 0.66 to 5.08 | 0.011 |
| Perceived importance of | -2.61 | 0.90 | -4.37 to -0.85 | 0.004 |
| Continued on next page... | | | | |

4.9 Osteopathic setting, consultation time and treatment techniques used

Table 4.28 – Continued

| Explanatory variable | β | SE | 95% CI | p-value (Wald) |
|---|---------|-----------|----------------|-----------------------|
| drugs when assessing risk of treating the cervical spine | | | | |
| Perceived importance of headache/migrane when assessing risk of treating the cervical spine | 0.19 | 0.88 | -1.53 to 1.92 | 0.825 |
| Perceived importance of injury when treating the cervical spine | -2.18 | 1.09 | -4.31 to -0.05 | 0.045 |
| Perceived importance of neck and upper arm neurological symptoms when treating the cervical spine | -0.34 | 0.95 | -2.21 to 1.53 | 0.718 |
| Perceived risk of HVT treatment for thoracic and lumbar episodes | -1.56 | 0.65 | -2.85 to -0.28 | 0.017 |

The prevalence of HVT use is 5% lower in practitioners whose patients consultation time is 10 minutes longer ($p < 0.001$). This is consistent with the model above where structural technique which included HVT predicted a shorter appointment duration. Practitioners use HVT 1.4% more for each additional point on the seven-point agreement scale about statements regarding knowing which patient is going to benefit from or react to treatment ($p = 0.036$). Thus those with stronger beliefs about the predictability of benefit use HVT more. However, reporting difficulty discussing treatment reactions with patients is associated with HVT use decreasing by 1.3% for each point increase on the seven point difficulty scale from extremely easy to extremely difficult ($p = 0.040$). Gender and graduation year are also predictors. The prevalence of HVT is 5.7% higher in male practitioners ($p < 0.001$) and 3% higher if the practitioner graduated 10 years later ($p = 0.001$).

A 1 point increase in perceived importance of cardiac factors in the risk of treatment reactions when treating the neck is associated with a 3% increase in the use of HVT, indicating that practitioners who perceive cardiac risk as more important when treating the cervical spine use HVT more often ($p = 0.011$). The importance of drugs (anti-coagulants, oral contraceptives and

4.9 Osteopathic setting, consultation time and treatment techniques used

steroids) in the assessment of risk of treatment reactions when treating the cervical spine shows a trend in the opposite direction. The prevalence of using HVT is 2.6% lower if the importance of drugs was rated 1 point higher, showing that practitioners will use HVT less often if they believe these drugs to be important in the assessment of treatment risk (p=0.004).

Also predictive is the perceived importance of injury when treating the cervical spine, where a 1 point increase is associated with a 2.2% lower use of HVT (p=0.045) and the perceived risk of HVT treatment for thoracic and lumbar episodes, where 1 point increase is associated with a 1.6% lower use of HVT (p=0.017). Those who view treating the lumbar spine and thoracic spine as more risky use HVT less. For each point on the seven-point scale from extremely low risk to extremely high risk there is a decrease in use of HVT by 1.6%.

The regression model for “functional technique” explained 12.8% of the variance of ‘functional technique’ use and contained 823 observations.

Table 4.29 shows the adjusted estimates.

Table 4.29: Modelled estimates: effects on reported use of functional technique in the past month

| Explanatory variable | β | SE | 95% CI | p-value (Wald) |
|--|---------|------|----------------|----------------|
| Average time for new and returning patients | 0.35 | 0.07 | 0.21 to 0.49 | < 0.001 |
| Believing it is predictable who will benefit or react to treatment | 0.79 | 0.51 | -0.22 to 1.81 | 0.123 |
| Difficulty discussing treatment reactions | -0.56 | 0.47 | -1.49 to 0.36 | 0.234 |
| Frequency of informing patients about benefits, risks, or alternative treatments | 0.61 | 0.67 | -0.71 to 1.93 | 0.366 |
| Gender (Effect of male) | -6.6 | 1.34 | -9.27 to -4.01 | < 0.001 |
| Graduation year | -0.08 | 0.07 | -0.22 to 0.06 | 0.241 |
| Self-reported Serious Adverse Events (Effect of ever reporting) | 0.47 | 2.00 | -3.45 to 4.38 | 0.815 |
| Obtaining consent before initial treatment | -0.43 | 0.52 | -1.46 to 0.60 | 0.414 |

Continued on next page...

4.9 Osteopathic setting, consultation time and treatment techniques used

Table 4.29 – Continued

| Explanatory variable | β | SE | 95% CI | p-value (Wald) |
|---|---------|-----------|---------------|-----------------------|
| Obtaining successive consent | -0.03 | 0.42 | -0.86 to 0.80 | 0.938 |
| Perceived importance of anxiety when treating the cervical spine | -0.25 | 0.61 | -1.45 to 0.96 | 0.689 |
| Perceived importance of cardiac risk when treating the cervical spine | -0.54 | 0.86 | -2.22 to 1.15 | 0.532 |
| Perceived importance of drugs when assessing risk of treating the cervical spine | 0.62 | 0.69 | -0.73 to 1.96 | 0.367 |
| Perceived importance of headache/migrane when assessing risk of treating the cervical spine | 1.72 | 0.66 | 0.42 to 3.03 | 0.010 |
| Perceived importance of injury when treating the cervical spine | 1.05 | 0.83 | -0.58 to 2.68 | 0.205 |
| Perceived importance of neck and upper arm neurological symptoms when treating the cervical spine | -0.63 | 0.73 | -2.05 to 0.80 | 0.388 |
| Perceived risk of HVT treatment for thoracic and lumbar episodes | 2.04 | 0.51 | 1.05 to 3.03 | < 0.001 |

The prevalence of functional technique use is 3.5% higher in practitioners whose patient consultation time is 10 minutes longer ($p < 0.001$). Again this is consistent with the previous modelling of consultation time. Gender is also highly predictive. The prevalence of functional technique is 6.6% lower in male practitioners ($p < 0.001$). A one point increase in seven-point scale measuring perceived importance of headaches and migraines is associated with a 1.7% increase in the use of functional techniques, indicating that practitioners who perceive headaches as more important as a risk factor when treating the cervical spine use functional techniques more often

4.9 Osteopathic setting, consultation time and treatment techniques used

($p=0.010$). Also predictive is the perceived risk of HVT treatment for thoracic and lumbar episodes, where a one point increase on the seven point scale is associated with a 2.0% higher use of functional techniques ($p<0.001$).

4.9.3.4 Adjunctive approaches

Of the 1,046 osteopaths who responded to the question asking whether they use other approaches (e.g. acupuncture and electrotherapy etc) in addition to manual osteopathic techniques, 463 replied in the affirmative (44.3%) and 583 in the negative (55.7%). There were 36 missing values. However, of those who replied in the negative or who did not reply, 122 responded either in part or in full to the question eliciting the proportion of patients on whom adjunctive approaches had been used in practice over the last month mostly (i.e. in 78 cases) to indicate 0%; however, 16 practitioners responded in such a way that they were categorised as using adjunctive approaches. Therefore a total of 1,062 observations were included, where 479 (45.1%) were confirmed as using adjunctive approaches and 583 (54.9%) who do not use these approaches. Figure 4.14 shows frequency distributions for the reported use of these other approaches and Table 4.30 shows the frequency distributions for each adjunctive approach. Table 4.31 shows the median and interquartile range for all osteopaths responding to the question about the use of adjunctive techniques and Table 4.32 shows the median and interquartile range for the sub-group of osteopaths who do use adjunctive approaches in their practice.

Table 4.30: Frequencies and percentage of reported use of adjunctive approaches (%) in the past month

| Technique | 0% | | 1-25% | | 26-50% | | 51-75% | | 76-100% | |
|------------------------------|-----|------|-------|------|--------|------|--------|-----|---------|-----|
| | n | % | n | % | n | % | n | % | n | % |
| Electrotherapy | 282 | 55.4 | 144 | 28.3 | 45 | 8.8 | 24 | 4.7 | 14 | 2.8 |
| Nutrition therapy | 280 | 56.2 | 161 | 32.3 | 36 | 7.2 | 15 | 3.0 | 6 | 1.2 |
| Dry needling/ acupuncture | 232 | 43.2 | 152 | 28.3 | 86 | 16.0 | 48 | 8.9 | 19 | 3.5 |
| Homeopathy | 413 | 89.6 | 40 | 8.7 | 5 | 1.1 | 3 | 0.7 | 0 | 0.0 |
| Herbal medicine | 417 | 90.1 | 38 | 8.2 | 5 | 1.1 | 2 | 0.4 | 1 | 0.2 |
| Kinesiology | 430 | 91.7 | 23 | 4.9 | 4 | 0.9 | 7 | 1.5 | 5 | 1.1 |
| Medication | 412 | 88.4 | 40 | 8.9 | 9 | 1.9 | 3 | 0.6 | 2 | 0.4 |
| Injections | 440 | 95.2 | 16 | 3.5 | 5 | 1.1 | 1 | 0.2 | 0 | 0.0 |

Of the adjunctive approaches, dry needling/acupuncture, electrotherapy and nutrition therapy are the approaches most used on patients and account for the percentage of reported use of adjunctive approaches (45.1%). However, the majority of practitioners reporting use of these

4.9 Osteopathic setting, consultation time and treatment techniques used

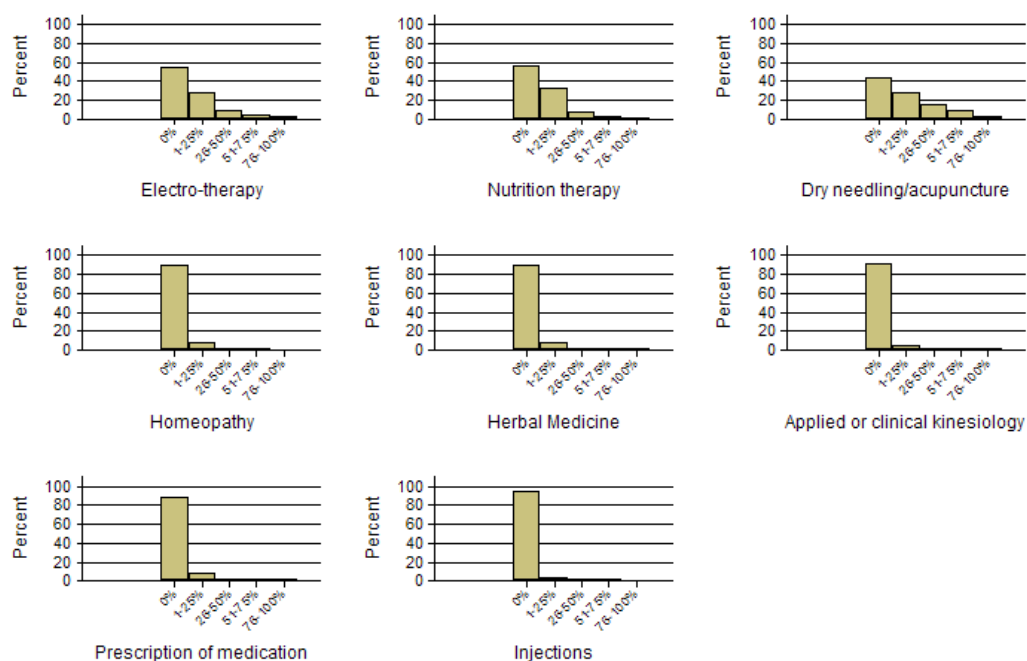


Figure 4.14: Adjunctive approaches used by osteopaths - The figure shows a table of histograms illustrating the distributions of use of adjunctive treatment approaches

Table 4.31: Median percentage category of adjunctive treatment use, by technique

| Technique | Median | 25 th centile | 75 th centile |
|---------------------------------|--------|--------------------------|--------------------------|
| Electro-therapy | 0 | 0 | 1-25 |
| Nutrition therapy | 0 | 0 | 1-25 |
| Dry Needling/Acupuncture | 1-25 | 0 | 26-50 |
| Homeopathy | 0 | 0 | 0 |
| Herbal Medicine | 0 | 0 | 0 |
| Applied or Clinical Kinesiology | 0 | 0 | 0 |
| Prescription of medication | 0 | 0 | 0 |
| Injections | 0 | 0 | 0 |

4.9 Osteopathic setting, consultation time and treatment techniques used

Table 4.32: Median percentage category of adjunctive treatment use %in osteopaths who use adjunctive treatments, by technique

| Technique | Median | 25 th centile | 75 th centile |
|---------------------------------|--------|--------------------------|--------------------------|
| Electro-therapy | 1-25 | 0 | 1-25 |
| Nutrition therapy | 0 | 0 | 1-25 |
| Dry Needling/Acupuncture | 1-25 | 0 | 26-50 |
| Homeopathy | 0 | 0 | 0 |
| Herbal Medicine | 0 | 0 | 0 |
| Applied or Clinical Kinesiology | 0 | 0 | 0 |
| Prescription of medication | 0 | 0 | 0 |
| Injections | 0 | 0 | 0 |

approaches tended to use them in a low proportion of patients. Considering the population of osteopaths responding as a whole, only dry needling/acupuncture had a median value above 0 (median = 1-25%, IQR 0% to 26-50%).

4.9.3.5 Predicting use of adjunctive approaches

Regression analysis was used to explore the predictors of use of adjunctive approaches by practitioners. The model is reported in full in the Statistical Report. It explained only 4.1% of the deviance.

4.9.4 Technique use reported in the patient survey

The sections above report use of technique estimates and models derived from the practitioner survey. In the patient survey both patients and practitioners returned information on technique experienced (patients) and delivered (osteopaths) for a single treatment.

4.9.4.1 Technique experience reported by patients

Of the 1,941 participants who answered the question about whether they had received a movement to the neck, mid back or low back where they may have heard a click, 996 (51.5%) indicated that their osteopath put their neck/back into a position and performed a quick movement during which they heard a “click”. Table 4.33 shows frequency distributions by body area.

Of the 1,944 participants who answered a question about the use of adjunctive approaches, 260 (13.3%) indicated their osteopath used either dry needling/acupuncture, injections, homeopathy, prescription of medication, electro-therapy, herbal or other supplements, or gave specific advice about diet. Table 4.34 shows frequency distributions for each category.

4.9 Osteopathic setting, consultation time and treatment techniques used

Table 4.33: Frequency of “click” by area as reported by patients

| Area “clicked” | Freq. | Percent | <i>n</i> |
|----------------|-------|---------|----------|
| Neck | 509 | 32.2 | 1,581 |
| Mid back | 654 | 40.0 | 1,637 |
| Low back | 522 | 32.9 | 1,588 |

* Where $n=2,037$

Table 4.34: Additional treatment approaches as reported by patients

| Treatment approach | Freq. | Percent | <i>n</i> |
|------------------------------------|-------|---------|----------|
| Dry needling/acupuncture | 120 | 5.9 | 2,036 |
| Injections | 9 | 0.4 | 2,037 |
| Homeopathy | 18 | 0.9 | 2,038 |
| Prescription of medication | 9 | 0.4 | 2,038 |
| Electro-therapy | 96 | 4.7 | 2,037 |
| Use of herbal or other supplements | 30 | 1.5 | 2,036 |
| Specific advice about diet | 32 | 1.6 | 2,037 |

4.9.4.2 Technique delivered reported by practitioners completing a subsection of the patient survey

Of the 1,935 patients who returned questionnaires with the treatment section completed by their treating osteopath, functional/counterstrain techniques were indicated as being delivered to 492 (25.4%) patients; HVT on 835 (43.2%) patients; joint articulation on 1,668 (86.2%) patients; soft tissue techniques on 1,763 (91.1%) patients and MET on 415 (21.5%) patients. Table 4.35 shows the number of patients out of 1,935 that received a treatment technique on a specific area of the body. Each patient can receive more than one treatment technique on a body area or have a treatment technique applied to multiple body parts. Therefore, the frequencies in table 4.35 add up to a total of 12,237 treatment techniques applied to 1,935 patients. The table shows that the most used treatment is soft tissue technique on the lumbar spine (57.0%).

Practitioners were also asked to indicate whether they had used cranial osteopathic/IVM techniques and visceral techniques. These questions were not linked to areas of the body. Of the 1,820 participants who responded to the item on cranial/IVM, 558 (30.7%) reported its use. 1,591 participants responded to the question about visceral technique, with 63 (4.0%) reported its use. There was also an “other approaches” section which offered a list of adjunctive approaches such as electrotherapy and nutrition therapy. Of the 1,818 participants who responded, 348

4.9 Osteopathic setting, consultation time and treatment techniques used

Table 4.35: Technique application by area: frequencies reported by practitioners

| Number of patients receiving osteopathic treatments (% of total 1,935) | | | | | |
|--|------------------------------|------------|-----------------------|--------------------------|-----------|
| Body area | Functional/ Counterstrain | HVT | Joint Articulation | Soft Tissue Technique | MET |
| Cervical spine | 294 (15.2) | 264 (13.6) | 863 (44.6) | 971 (50.2) | 144 (7.4) |
| Thoracic spine | 153 (7.9) | 625 (32.3) | 951 (49.2) | 1,095 (56.6) | 58 (3.0) |
| Lumbar spine | 152 (7.9) | 351 (18.1) | 1,021 (52.8) | 1,102 (57.0) | 159 (8.2) |
| Shoulder girdle | 75 (3.9) | 18 (0.9) | 407 (21.0) | 528 (27.3) | 56 (2.9) |
| Upper extremity | 29 (1.5) | 14 (0.7) | 212 (11.0) | 232 (12.0) | 28 (1.5) |
| Pelvic girdle | 119 (6.2) | 60 (3.1) | 486 (25.1) | 576 (29.8) | 127 (6.6) |
| Lower extremity | 79 (4.1) | 25 (1.3) | 403 (20.8) | 455 (23.5) | 105 (5.4) |

(19.1%) reported using ‘1adjunctive’ techniques. Table 4.36 shows the frequency distributions for each listed technique.

Table 4.36: Adjunctive techniques used

| Treatment approach | Frequency | Percent* |
|------------------------------------|-----------|----------|
| Dry needling/acupuncture | 86 | 4.3 |
| Injections | 6 | 0.3 |
| Homeopathy | 5 | 0.3 |
| Prescription of medication | 7 | 0.4 |
| Electro-therapy | 85 | 4.2 |
| Use of herbal or other supplements | 4 | 0.2 |
| Specific advice about diet | 19 | 1.0 |
| Applied or clinical kinesiology | 26 | 1.3 |

* Where $n=2,016$

In line with the data from the practitioner survey, the two most commonly delivered adjunctive approaches were dry needling/acupuncture and electrotherapy. However these were at relatively low frequencies and represent a small proportion of treatment given. The responses from patients and practitioners are not directly comparable for the use and experience of HVT. Patients were asked about whether their osteopath put them in a position and performed a quick movement during which they may have heard a click and osteopaths about whether they had performed an HVT or not. However, it appears that patients report higher levels of manipulation than osteopaths particularly in the neck region.

4.10 Risk management and assessment

4.10.1 Osteopaths' beliefs about the predictability of the benefit of manipulation, reactions to treatment and attitudes to reactions to treatment

As part of stage one, the practitioner survey, osteopaths were asked a series of questions exploring their beliefs about the predictability of the benefit from manipulation, the predictability of both minor and serious treatment reactions and their attitudes towards treatment reactions in the process of osteopathic care. Each of these items on the scale were statements followed by a seven point scale where 0 = “Completely disagree” and 6 = “Completely agree”.

Figure 4.15 shows the distributions of osteopaths' beliefs about whether it is predictable who will benefit from HVT.

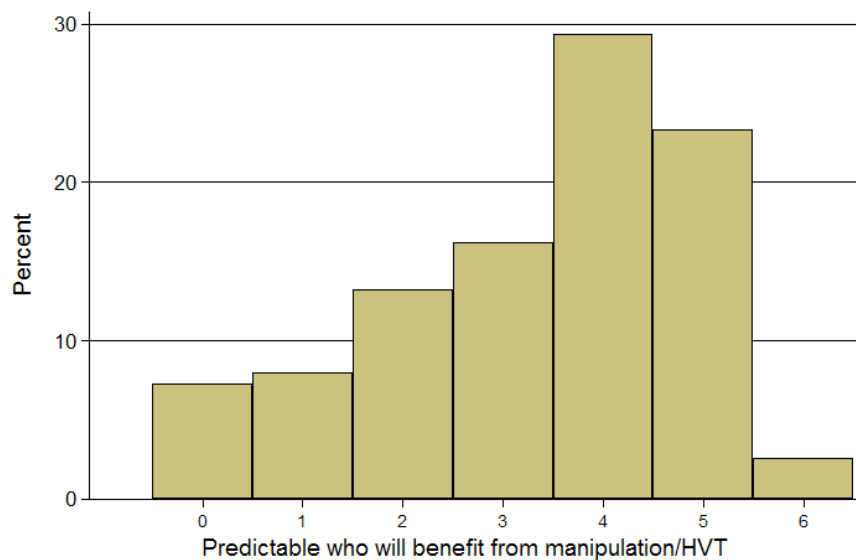


Figure 4.15: Histogram of osteopaths' agreement with statement that it is predictable who will benefit from HVT - The figure shows the distributions of osteopaths' beliefs about whether it is predictable who will benefit from HVT.

The distribution of responses was skewed positively towards agreement, where osteopaths consider it is predictable who will benefit from HVT, and the median value was 4 (IQR 2 to 5). However, 306 (28.5%) responses fell towards the disagreement side of the seven point scale, indicating that more than a quarter of osteopaths were uncertain about the predictability of who will benefit from HVT.

There was more variability with respect to practitioners' agreement about statements concerning the predictability of minor or transient treatment reactions and major or adverse treat-

ment reactions in response to HVT. Figure 4.16 show the distributions of osteopaths' responses. The statements that they were asked to consider were respectively "It is predictable who will get minor or transient treatment reactions from a manipulation/high velocity thrust" and "It is predictable who will get major or adverse treatment reactions from a manipulation/high velocity thrust". The median rating for the first statement was 3 (IQR 3 to 4) and for the second statement it was also 3 (IQR 3 to 5); however, the wider interquartile range illustrates that there was more spread in the responses to the second statement. This suggests more uncertainty about the predicatibility of major treatment reactions.

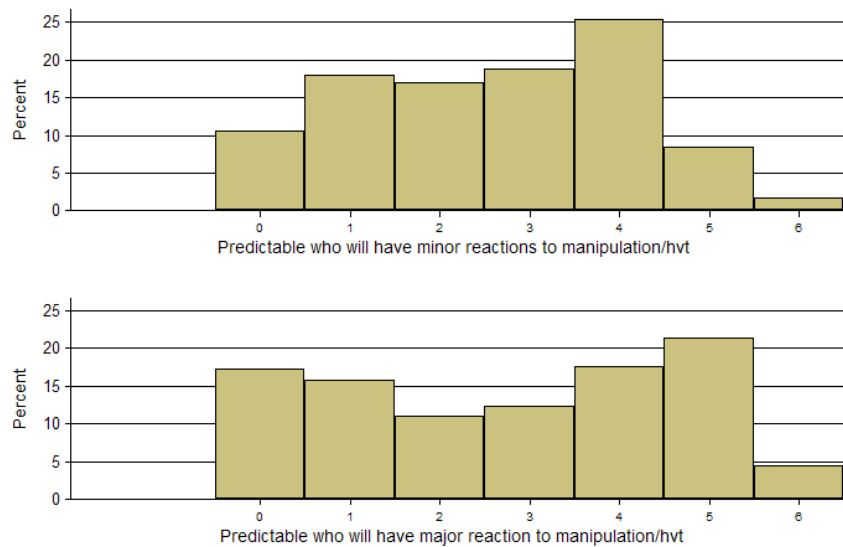


Figure 4.16: Predictability of treatment reactions following HVT - The figure shows a histogram of the distributions of osteopaths' beliefs about whether it is predictable who will have a minor/transient (top) or major/adverse (bottom) treatment reaction following HVT.

Figures 4.17 and 4.18 show a box plot and histogram representing the distribution of participants' agreement with three statements: 1) "An essential response to osteopathic treatment is that patients get worse before they get better" (Median = 1, IQR 0 to 3); 2) "Patients experiencing an exacerbation of their presenting symptoms after osteopathic treatment is a positive sign" (Median = 2, IQR 1 to 3); 3) "Patients experiencing the appearance of unpleasant new symptoms after treatment is a positive sign" (Median = 1, IQR 0 to 2). Whilst the majority of practitioners disagreed with the construct that patients should get worse or that an increase in current or the appearance of new symptoms is positive, a notable number of practitioners agreed with these statements. Ninety five (8.9%) practitioners scored 4 or above on the scale for "an essential response patients get worse before they get better", 154 (14.3%) for the

item “... exacerbation ofpresenting symptoms is positive...” and 59 (5.5%) agreed with the statement “... appearance of unpleasant... new symptoms is positive”.

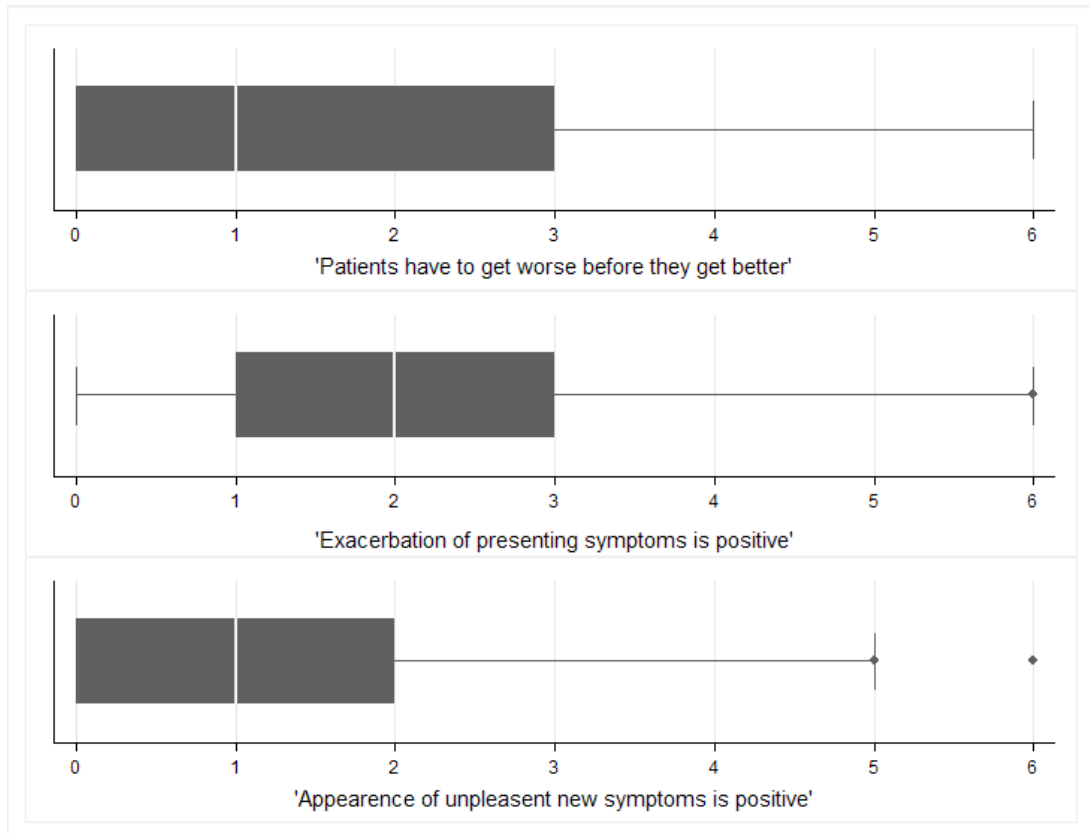


Figure 4.17: Box-plots of osteopaths’ agreement with three statements about beliefs about adverse symptoms - The figure shows distributions of osteopaths’ beliefs about deterioration needing to take place prior to improvement (top), the worsening of existing symptoms (middle), and the appearance of unpleasant new symptoms (bottom).

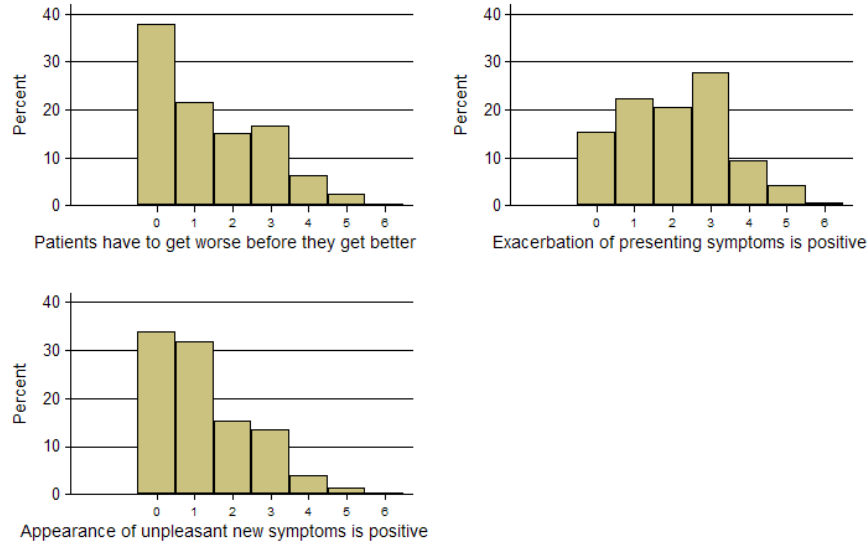


Figure 4.18: Histograms of osteopaths’ agreement with three statements about beliefs about adverse symptoms - The figure shows distributions of osteopaths’ beliefs about deterioration needing to take place prior to improvement (top left), the worsening of existing symptoms (top right), and the appearance of unpleasant new symptoms (bottom left); where 6=Completely agree and 0=Completely disagree.

4.10.2 Osteopaths’ perceptions of risk of minor transient treatment reactions associated with osteopathic techniques on the lumbar and thoracic spine

Osteopaths were asked to rate risk of minor reactions occurring when applying techniques to the lumbar and thoracic spine using a seven point scale where 0 = “Extremely low risk and 6 = ‘Extremely high risk”. Figure 4.19 shows the distribution of risk ratings per technique. The number of responses for each technique varied by use of technique. Most responses were for soft tissue and articulatory techniques and least were for visceral techniques. This was in line with the prevalence of use of techniques from other questions in the survey. The majority of osteopaths perceived osteopathic techniques to be low to medium risk; the highest perceived risk was for HVT (median = 3, IQR 2 to 4). Table 4.37 shows the frequency and proportion of ratings for perceived risk of minor reactions from HVT.

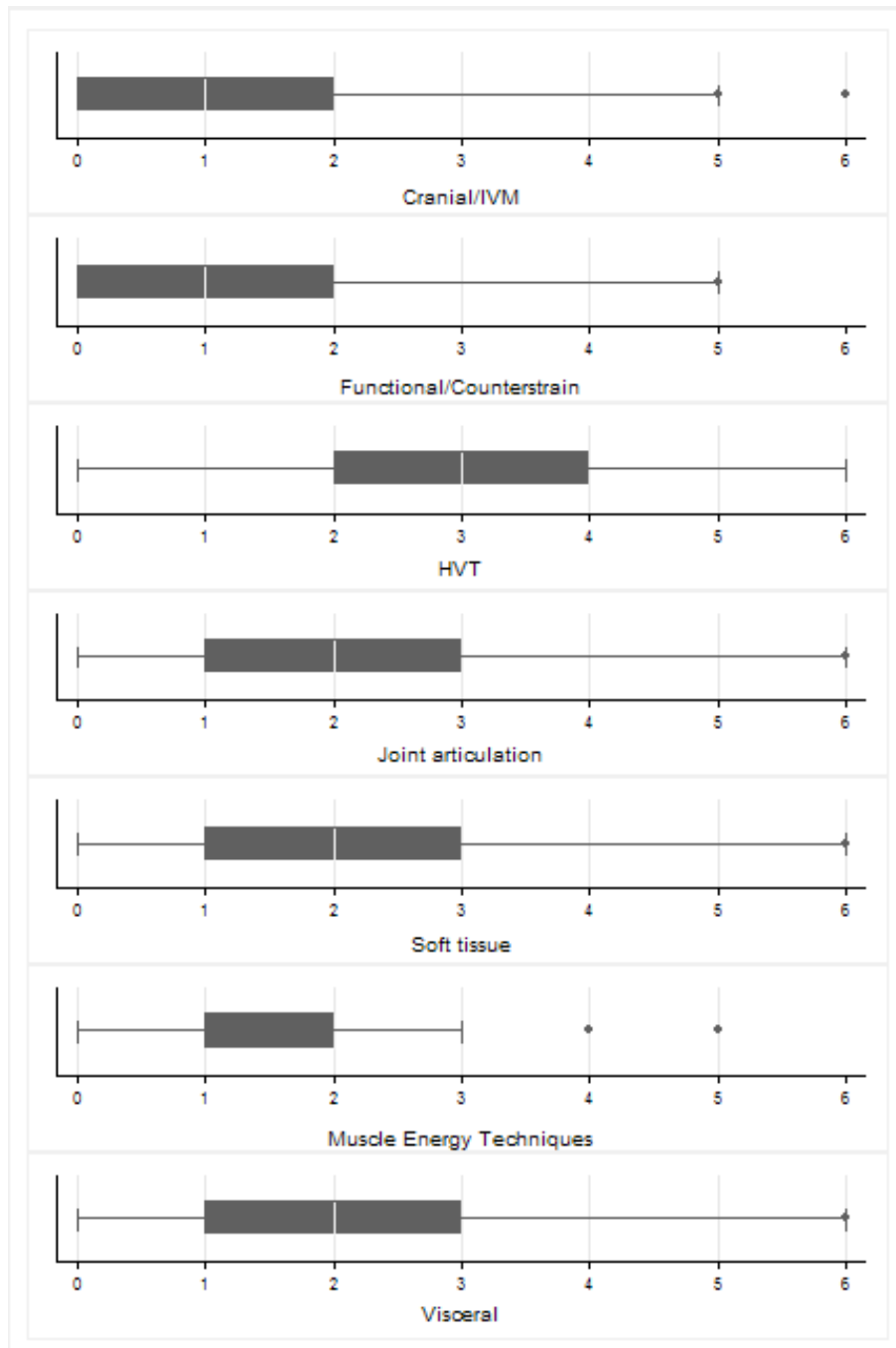


Figure 4.19: Perceived risk of minor reactions, by technique - The figure shows the distributions of the risk osteopaths perceive is associated with using different osteopathic techniques; where 0=extremely low risk and 6=extremely high risk.

Table 4.37: Frequencies of ratings for perceived risk of minor reactions from HVT

| | Rating | Freq. | Percent | Cum. |
|---------------------|--------|-------|---------|--------|
| Extremely low risk | 0 | 23 | 2.24 | 2.24 |
| | 1 | 75 | 7.30 | 9.54 |
| | 2 | 177 | 17.23 | 26.78 |
| | 3 | 286 | 27.85 | 54.63 |
| | 4 | 295 | 28.72 | 83.35 |
| | 5 | 131 | 12.76 | 96.11 |
| Extremely high risk | 6 | 40 | 3.89 | 100.00 |

Median=3 (IQR=2 to 4)

4.10.3 Osteopaths’ assessment of the importance of factors associated with vertebro-basilar stroke when treating the cervical spine

Osteopaths were asked to rate how important they considered a list of factors in their assessment of the risk of treatment reactions when treating the cervical spine. These factors have been reported as associated with vertebro-basilar stroke, though this was not made explicit in the survey. A seven point scale was used where 0 = “Extremely unimportant” and 6 = “Extremely important”.

Overall, osteopaths reported rating these factors as important in their assessment of risk of treatment reactions. All median values were above the mid point of the scale, except for gender where the median value was 3. Table 4.38 shows the ranked median values and IQRs (25th and 75th centiles) for each factor.

4.10.3.1 Importance of factors when referring for further care

Osteopaths were asked to rate the importance of a list of factors relating to referring patients to a GP or other health care professionals for further care using a seven point scale where 0 = “Extremely unimportant” and 6 = “Extremely important”. Figure 4.20 shows that most osteopaths perceived all the suggested factors as important in consideration of patient referrals; the most important factor was “Indicators of undiagnosed pathology or structural deficit” (Median = 6, IQR 6 to 6). Table 4.39 provides median scores and interquartile ranges for the questionnaire items and Figure 4.21 shows histograms of the distribution of the importance of each item.

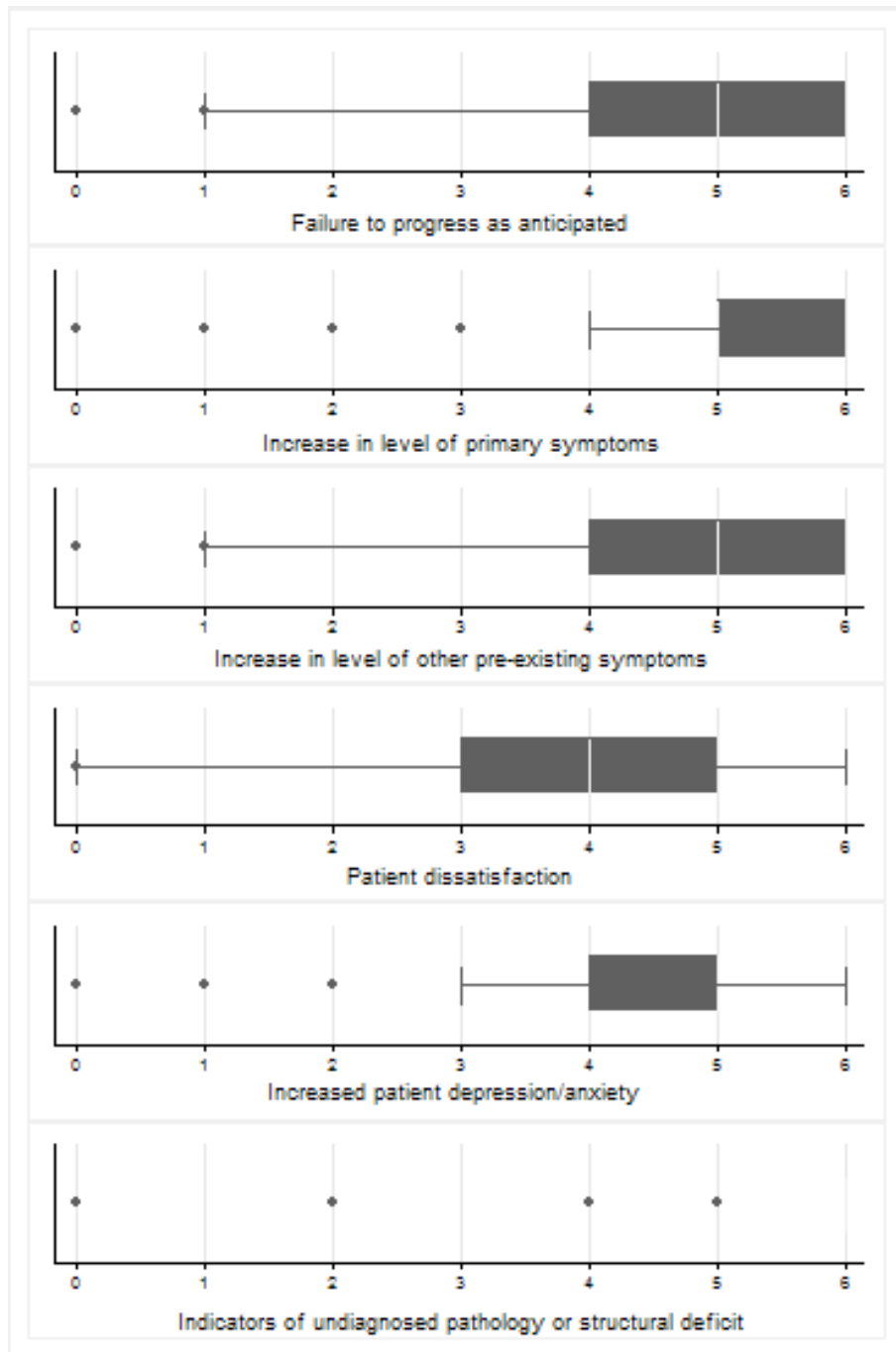


Figure 4.20: Important factors in referral - The figure shows the importance placed on different factors for patient referral; where 0=Extremely unimportant and 6=Extremely important. Examples of undiagnosed pathology or structural deficit suggested to participants were Carcinoma, Ankylosing Spondylitis, or fracture. As all the centiles converge on the sixth rating (for the importance undiagnosed pathology), there is no visible box or whiskers.

4.10 Risk management and assessment

Table 4.38: Ranked importance of factors in the risk of treatment reactions when treating the cervical spine

| Assessment factor | Median | 25 th centile | 75 th centile |
|--|--------|--------------------------|--------------------------|
| Inflammatory Disease e.g. Rheumatoid Arthritis or Ankylosing Spondylitis | 6 | 6 | 6 |
| Previous treatment given by yourself for similar symptoms leading to a negative reaction | 6 | 5 | 6 |
| Significant Injury / Moderate or Severe Whiplash | 6 | 5 | 6 |
| Congenital disorders e.g. Marfans or hypermobility | 6 | 5 | 6 |
| Anti-coagulants | 6 | 5 | 6 |
| Age | 6 | 5 | 6 |
| Hypertension | 5 | 4 | 6 |
| Headache | 5 | 4 | 6 |
| Level of Anxiety | 5 | 4 | 6 |
| Neurological Symptoms in arm | 5 | 4 | 6 |
| Minor injury / mild whiplash | 5 | 4 | 6 |
| Steroids (past or current) | 5 | 4 | 6 |
| Migraines | 4 | 3 | 5 |
| Neck Pain/Stiffness | 4 | 3 | 5 |
| Recent or Current Smoker | 4 | 3 | 5 |
| Oral Contraceptives | 4 | 2 | 4.5 |
| Gender | 3 | 1 | 4 |

Table 4.39: Important referral factors

| Factor | Median | 25 th centile | 75 th centile |
|---|--------|--------------------------|--------------------------|
| Failure to progress as anticipated | 5 | 4 | 6 |
| Increase in level of primary symptoms | 5 | 5 | 6 |
| Increase in level of other pre-existing symptoms | 5 | 4 | 6 |
| Patient dissatisfaction | 4 | 3 | 5 |
| Increased patient depression/anxiety | 5 | 4 | 5 |
| Indicators of undiagnosed pathology or structural deficit | 6 | 6 | 6 |

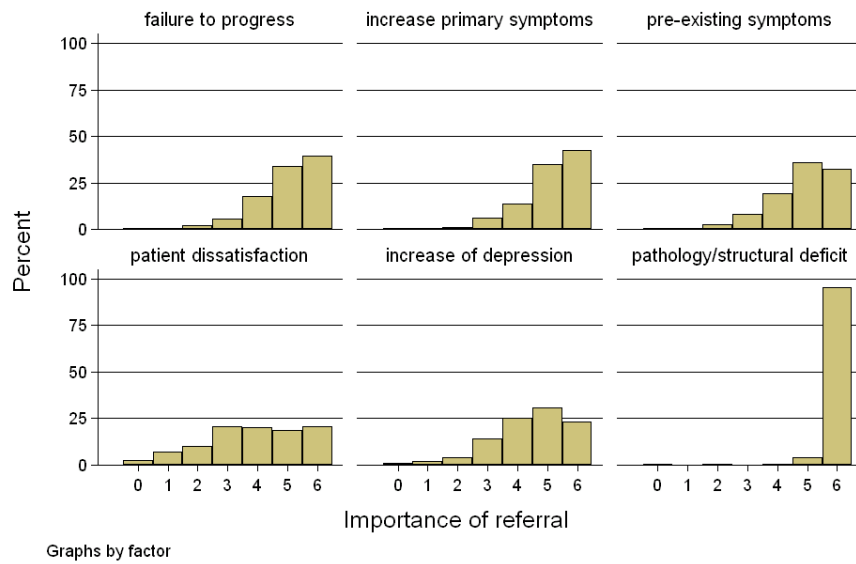


Figure 4.21: The importance of referral factors - The figure shows the distribution of the importance placed on six factors in referral; where 0=“Extremely unimportant” and 6=“Extremely important”.

4.11 Consent and information giving

4.11.1 Perceived difficulty of discussing risk with patients, information giving, frequency of gaining and methods of recording consent

4.11.1.1 Osteopaths' perception of difficulty of talking to patients about unpleasant treatment reactions

Osteopaths were asked several questions about their perception of the difficulty of talking to patients about unpleasant treatment reactions. These questions were in the context of new patients and returning patients and also distinguished between treating the cervical spine and osteopathic treatment in general. Responses were on a seven point scale where 0 = "Extremely easy" and 6 = "Extremely difficult".

Figure 4.22 summarises the distribution of osteopaths' ratings of the perceived difficulty in talking to new patients and returning patients about unpleasant treatment reactions that may be associated with HVT to the cervical spine. For new patients, osteopaths' responses were approximately uniformly distributed, with a median of 3 (IQR 1 to 5) indicating that osteopaths did not have a majority view. Near equal proportions of osteopaths completed each interval of the response scale. Table 4.40 shows the frequency and proportion of responses with respect to new and returning patients. The median rating for returning patients was 2 (IQR 1 to 4). Osteopaths find discussing treatment reactions associated with cervical spine HVT less difficult with returning patients (Kruskal wallis $\chi^2 = 70.43$, $p < 0.001$).

Table 4.40: Frequencies of ratings for difficulty of talking to new and returning patients about unpleasant treatment reactions that may be associated with HVT to the cervical spine

| | Rating | New patients | | Rtn patients | |
|---------------------|--------|--------------|------|--------------|------|
| | | n | % | n | % |
| Extremely easy | 0 | 140 | 13.5 | 188 | 18.1 |
| | 1 | 147 | 14.2 | 232 | 22.4 |
| | 2 | 152 | 14.6 | 189 | 18.2 |
| | 3 | 151 | 14.6 | 156 | 15.0 |
| | 4 | 178 | 17.2 | 136 | 13.1 |
| | 5 | 168 | 16.2 | 97 | 9.4 |
| Extremely difficult | 6 | 102 | 9.8 | 39 | 3.8 |

New patients: Median=3 (IQR=1 to 5), returning patients: Median=2 (IQR=1 to 4)

Figure 4.23 shows how difficult osteopaths perceive this discussion to be in general (*i.e.* not specifically in relation to cervical HVT) with new (median = 2 (IQR 1 to 3)) and returning

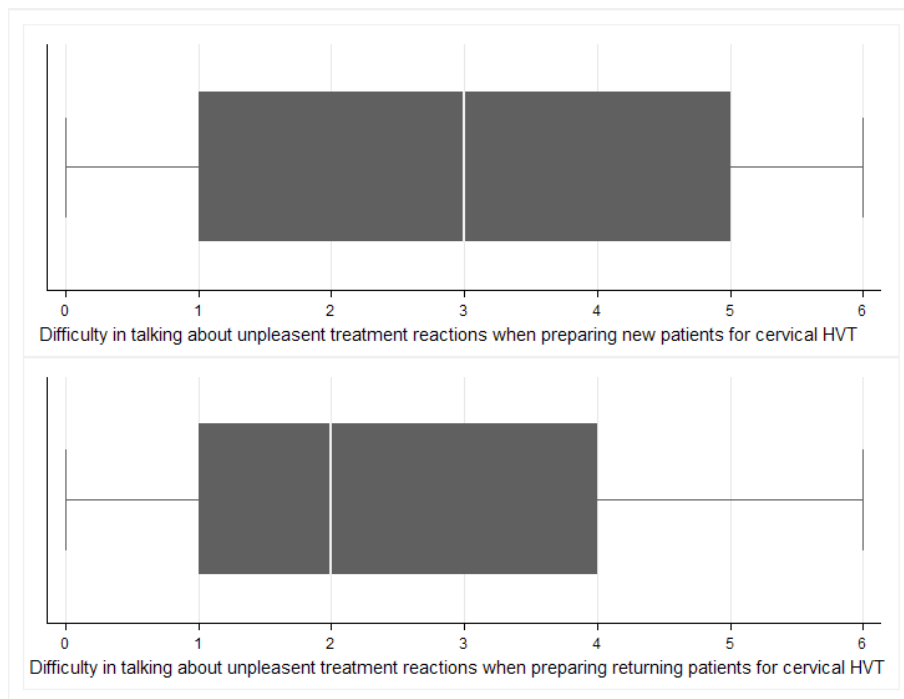


Figure 4.22: Discussion of unpleasant treatment reactions associated with cervical HVT
- The figure shows the distributions of osteopaths' ratings of difficulty associated with talking to new and returning patients about unpleasant treatment reactions that may be associated with HVT to the cervical spine, before administering the HVT.

(median = 1 (IQR 0 to 2)) patients. Again there is a significant difference where osteopaths perceive talking to new patients about unpleasant treatment reaction as more difficult (Kruskal wallis $\chi^2 = 50.07$, $p < 0.001$). However, overall osteopaths tend not to rate talking to patients about unpleasant treatment reactions whilst preparing patients for osteopathic treatment in general as difficult. Tables 4.41 shows the frequencies and proportions of responses.

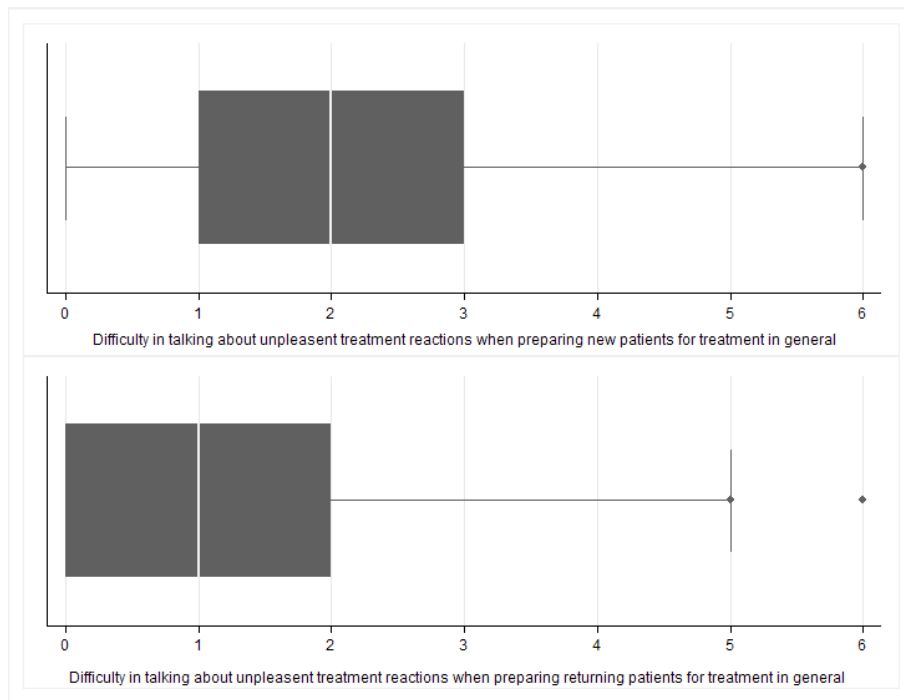


Figure 4.23: Discussion of unpleasant treatment reactions in general - The figure shows the distributions of osteopaths’ ratings of difficulty of talking to new patients about unpleasant treatment reactions associated with osteopathic treatment in general(top) and in returning patients (bottom)

Osteopaths find discussing unpleasant treatment reactions associated with HVT and the cervical spine more difficult than discussing unpleasant treatment reactions with patients in general. This is most evident where osteopaths are preparing new patients for HVT/manipulation of the cervical spine.

4.11.1.2 Informing patients about benefits, risks and alternatives

Osteopaths were asked to indicate how frequently they informed their patients about the benefits of their recommended treatment, the risks of their treatment and the outcomes of no treatment or alternative treatments. Responses were recorded on a seven point scale where 0 = “Never” and 6 = “Always”. Figure 4.24 shows that most osteopaths report that they frequently inform

4.11 Consent and information giving

Table 4.41: Frequencies of ratings for difficulty associated with talking to new and returning patients about unpleasant reactions that may be associated with treatment in general

| | Rating | New patients | | Rtn patients | |
|---------------------|--------|--------------|------|--------------|------|
| | | n | % | n | % |
| Extremely easy | 0 | 226 | 21.1 | 314 | 29.3 |
| | 1 | 274 | 25.6 | 350 | 32.6 |
| | 2 | 228 | 21.3 | 181 | 16.9 |
| | 3 | 167 | 15.6 | 132 | 12.3 |
| | 4 | 107 | 10.0 | 55 | 5.1 |
| | 5 | 51 | 4.8 | 34 | 3.8 |
| Extremely difficult | 6 | 17 | 1.6 | 7 | 0.7 |

New patients: Median=2 (IQR=1 to 3), returning patients: Median=1 (IQR=0 to 2)

their patients about the benefits of their recommended treatment (Median = 5, IQR 4 to 6). The majority of osteopaths report that they frequently inform their patients about the risks of their recommended treatment (Median 5, IQR 3 to 6), and to a lesser extent, the majority of osteopaths report that they inform their patients about the outcomes of no treatment or alternative treatment (Median = 4 , IQR 2 to 5). Frequency distributions and proportions of responses are provided in table 4.42. It is notable that 12.8% of osteopaths completed the risks of recommended treatment scale between 0 and 2, below the mid point, suggesting that they infrequently informed patients about the risks of treatment. A larger proportion (26.4%) of osteopaths completed the outcomes of no treatment or alternative treatments scale between 0 and 2, below the mid point, suggesting that they infrequently gave information in this area.

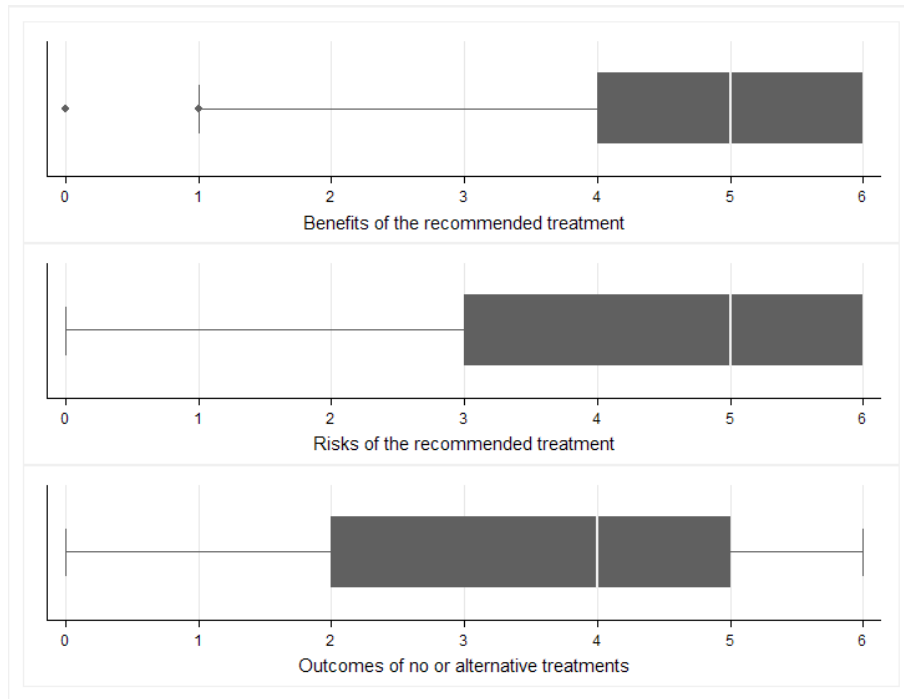


Figure 4.24: Informing patients about risks and benefits - The figure shows the reported frequency with which osteopaths report informing their patients of the benefits of their recommended treatment (top), the risks of their recommended treatment (middle), and the outcomes of no treatment or alternative treatment (bottom); where 0=“Never” and 6=“Always”.

Table 4.42: Frequencies of ratings for informing patients about benefits, risks and outcome of no or alternative treatment

| | Rating | Benefits of recommended treatment | | Risks of recommended treatment | | Outcome of no or alternative treatment | |
|--------|--------|-----------------------------------|------|--------------------------------|------|--|------|
| | | n | % | n | % | n | % |
| Never | 0 | 5 | 0.5 | 9 | 0.9 | 28 | 2.7 |
| | 1 | 7 | 0.7 | 35 | 3.3 | 98 | 9.3 |
| | 2 | 27 | 2.5 | 91 | 8.6 | 153 | 14.5 |
| | 3 | 95 | 9.0 | 146 | 13.8 | 203 | 19.2 |
| | 4 | 149 | 14.0 | 211 | 19.9 | 219 | 20.7 |
| Always | 5 | 284 | 26.8 | 255 | 24.1 | 195 | 18.5 |
| | 6 | 494 | 46.6 | 312 | 29.5 | 161 | 15.2 |

Benefits: Median=5 (IQR=4 to 6), Risks: Median=5 (IQR=3 to 6), Alternatives: Median=4 (IQR=2 to 5)

4.11.1.3 Consenting behaviour

Osteopaths were asked how frequently they obtain consent for examination and treatment from new and returning patients. They were also asked how frequently this took place prior to the initial examination or treatment and prior to each successive examination or treatment. Responses were recorded on a seven point scale where 0 = “Never” and 6 = “Always”. Figure 4.25 shows that most osteopaths report always obtaining consent prior to the initial examination (Median = 6, IQR 5 to 6), with many fewer reporting frequently taking consent prior to each successive examination (Median = 3, IQR 1 to 5). Similarly, most osteopaths report always taking consent before initial use of an osteopathic technique (Median = 6 IQR 4 to 6), but many fewer report frequently gaining consent prior to each successive use of an osteopathic technique (Median = 3, IQR 2 to 5). The frequencies are shown in table 4.43.

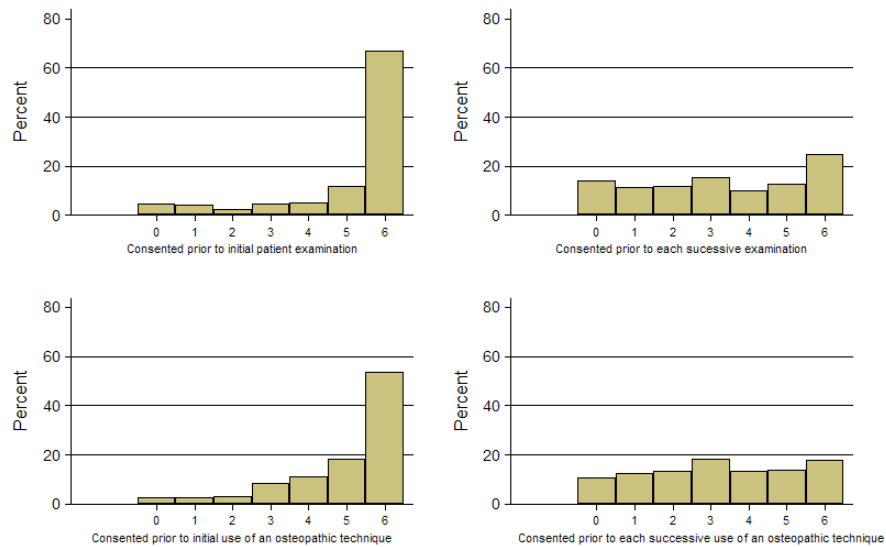


Figure 4.25: Frequency of obtaining consent - The figure shows histograms of the reported frequency with which osteopaths obtain consent before the initial examination (top left), before each successive examination, before initial use of an osteopathic technique, and before each use of an osteopathic technique (bottom right); where 0=“Never” and 6=“Always”.

As with giving information about benefits, risks and alternatives, a proportion of osteopaths completed the scale below the mid point, suggesting that they infrequently sought consent. For receiving consent prior to initial examination, 120 (11.3%) osteopaths marked 2 or below and for prior to initial treatment 90 (8.6%) osteopaths marked 2 or below.

Table 4.43: Frequencies of ratings for consenting before initial examination

| Rating | examination | | | | technique use | | | | |
|--------|-------------|-----|------------|-----|---------------|-----|------------|-----|------|
| | initial | | subsequent | | initial | | subsequent | | |
| | n | % | n | % | n | % | n | % | |
| Never | 0 | 50 | 4.7 | 147 | 14.0 | 27 | 2.6 | 110 | 10.5 |
| | 1 | 43 | 4.1 | 119 | 11.3 | 29 | 2.8 | 132 | 12.6 |
| | 2 | 27 | 2.6 | 127 | 12.1 | 34 | 3.2 | 141 | 13.4 |
| | 3 | 50 | 4.7 | 160 | 15.2 | 87 | 8.3 | 191 | 18.2 |
| | 4 | 52 | 4.9 | 108 | 10.3 | 118 | 11.2 | 142 | 13.5 |
| | 5 | 127 | 12.0 | 133 | 12.6 | 193 | 18.3 | 147 | 14.0 |
| Always | 6 | 709 | 67.0 | 259 | 24.6 | 565 | 53.7 | 189 | 18.0 |

Init exam: Median=6 (IQR=5 to 6), Sub exam: Median=3 (IQR=1 to 5), Init trt: Median=6 (IQR=4 to 6), Sub trt: Median=3 (IQR=2 to 5)

4.11.1.4 Recording of consent when treating the cervical spine

Osteopaths were asked how they record consent when treating the cervical spine using a range of osteopathic techniques. Response options were “N/A” (indicating that the osteopath did not use that technique), “Consent not discussed” (ND), “Verbal but not noted by practitioner” (V), “Verbal and noted by practitioner” (V&N), and “Written and signed by patient” (W&S). Figure 4.26 shows a similar pattern of consent practice for using techniques on the cervical spine: most osteopaths take only verbal consent regardless which technique they use. There appear to be two notable exceptions to this behaviour; 1) prior to using HVT on the cervical spine, consent is noted by most practitioners, and 2) prior to using adjunctive therapies, where more practitioners note consent than for other osteopathic techniques (with the exception of HVT). Table 4.44 and Table 4.45 provide frequency distributions by category, median scores and IQRs.

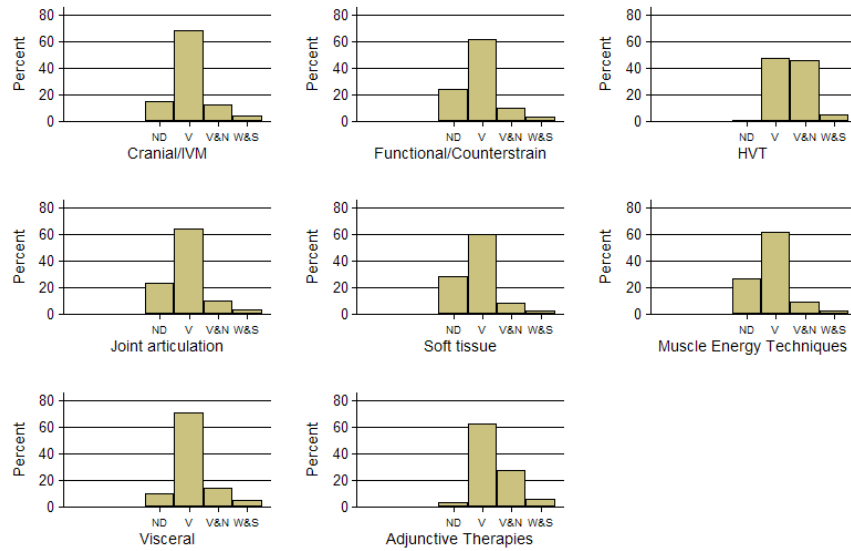


Figure 4.26: Method of obtaining consent to use techniques on the cervical spine, by technique type - The figure shows the methods with which osteopaths report recording consent to use techniques on the cervical spine, by the type of technique.

Table 4.44: Medians and IQR for consenting behaviour by techniques used on cervical spine

| Technique | n | Median | 25 th centile | 75 th centile |
|--------------------------|-------|--------|--------------------------|--------------------------|
| Cranial/IVM | 706 | 2 | 2 | 2 |
| Functional/Counterstrain | 800 | 2 | 2 | 2 |
| HVT | 956 | 3 | 2 | 3 |
| Joint articulation | 1,024 | 2 | 2 | 2 |
| Soft tissue techniques | 1,028 | 2 | 1 | 2 |
| MET | 939 | 2 | 1 | 2 |
| Visceral techniques | 508 | 2 | 2 | 2 |
| Adjunctive techniques | 466 | 2 | 2 | 3 |

1 = “Not discussed”, 2 = “Verbal but not noted by practitioner”, 3 = “Verbal and noted by practitioner” and 4 = “Written and signed by patient”

Table 4.45: Consent behaviour by techniques used on cervical spine

| Technique | ND (%) | V (%) | V&N (%) | W&S (%) |
|--------------------------|------------|------------|------------|----------|
| Cranial/IVM | 105 (14.9) | 481 (68.1) | 91 (12.9) | 29 (4.1) |
| Functional/Counterstrain | 194 (24.3) | 494 (61.8) | 84 (10.5) | 28 (3.5) |
| HVT | 10 (1.1) | 455 (47.6) | 441 (46.1) | 50 (5.2) |
| Joint articulation | 240 (23.4) | 653 (63.8) | 100 (9.8) | 31 (3.0) |
| Soft tissue techniques | 292 (28.4) | 616 (59.9) | 89 (8.7) | 31 (3.0) |
| MET | 249 (26.5) | 579 (61.7) | 83 (8.8) | 28 (3.0) |
| Visceral techniques | 53 (10.4) | 360 (70.9) | 71 (14.0) | 24 (4.7) |
| Adjunctive techniques | 17 (3.6) | 290 (62.2) | 130 (27.9) | 29 (6.2) |

ND = “Not discussed”, V = “Verbal but not noted by practitioner”, V&N = “Verbal and noted by practitioner” and W&S = “Written and signed by patient”

4.11.1.5 Recording consent when treating the thoracic and lumbar spine

Figure 4.27 shows a very similar situation for consent-taking practices when using techniques on the thoracic and lumbar spine; however, the increase in noting consent when performing HVT is not as marked. Table 4.46 and Table 4.47 provide frequency distributions by category, median scores and IQRs.

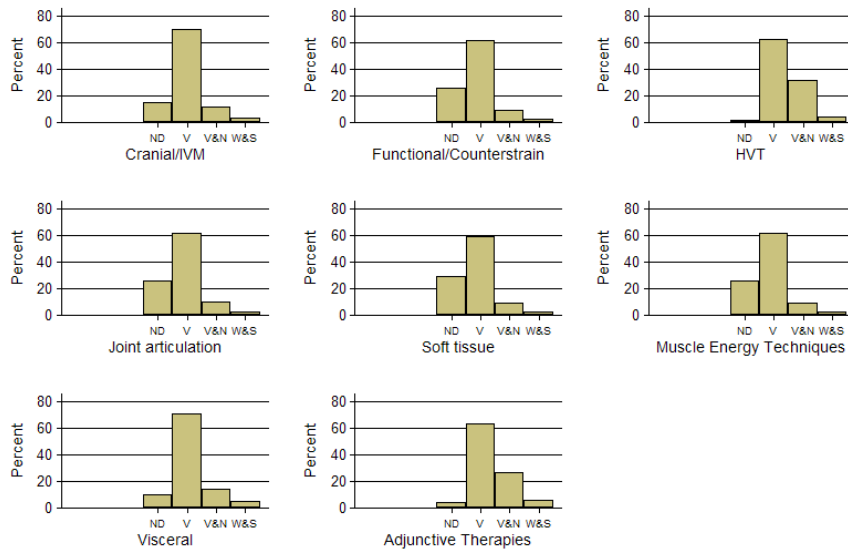


Figure 4.27: Method of obtaining consent to use techniques on the thoracic and lumbar spine, by technique type - The figure shows the methods with which osteopaths report recording consent to use techniques on the thoracic and lumbar spine, by the type of technique.

4.11 Consent and information giving

Table 4.46: Medians and IQR for consenting behaviour by techniques used on thoracic and lumbar spine

| Technique | n | Median | 25 th centile | 75 th centile |
|--------------------------|-------|--------|--------------------------|--------------------------|
| Cranial/IVM | 690 | 2 | 2 | 2 |
| Functional/Counterstrain | 787 | 2 | 1 | 2 |
| HVT | 981 | 2 | 2 | 3 |
| Joint articulation | 1,030 | 2 | 1 | 2 |
| Soft tissue techniques | 1,028 | 2 | 1 | 2 |
| MET | 946 | 2 | 1 | 2 |
| Visceral techniques | 515 | 2 | 2 | 2 |
| Adjunctive techniques | 480 | 2 | 2 | 3 |

1 = “Not discussed”, 2 = “Verbal but not noted by practitioner”, 3 = “Verbal and noted by practitioner” and 4 = “Written and signed by patient”

Table 4.47: Consent behaviour by techniques used on thoracic and lumbar spine

| Technique | ND (%) | V (%) | V&N (%) | W&S (%) |
|--------------------------|------------|------------|------------|----------|
| Cranial/IVM | 104 (15.1) | 481 (69.7) | 81 (11.7) | 24 (3.5) |
| Functional/counterstrain | 205 (26.1) | 483 (61.4) | 76 (9.7) | 23 (2.9) |
| HVT | 17 (1.7) | 610 (62.2) | 312 (31.8) | 42 (4.3) |
| Joint articulation | 267 (25.9) | 631 (61.3) | 102 (9.9) | 30 (2.9) |
| Soft tissue techniques | 301 (29.3) | 606 (59.0) | 91 (8.9) | 30 (2.9) |
| MET | 247 (26.1) | 586 (62.0) | 86 (9.1) | 27 (2.9) |
| Visceral techniques | 53 (10.3) | 364 (70.7) | 72 (14.0) | 26 (5.1) |
| Adjunctive techniques | 21 (4.4) | 304 (63.3) | 128 (26.7) | 27 (5.6) |

4.11.2 Consent guidance and quality

Osteopaths were asked about the adequacy (seven point scale) and sources of information that they had received in the past about consent processes. Osteopaths were also asked from where guidance about consent should originate.

Of the 1,039 osteopaths who responded to the question asking if they had received guidance about consent processes, 844 (81.2%) indicated that they had and 195 (18.8%) that they had not. Figure 4.28 shows the prevalence of sources from which these osteopaths reported receiving such information. 10 osteopaths indicated a source, but indicated that they had not received any guidance. The most common source of guidance was the GOsC (n = 681). The BOA (n = 428) and pre-registration training (n = 359) and CPD (n = 388) were also common sources of information. In response to the question about where osteopaths think guidance should come from, the most frequent response was the GOsC (n = 915), closely followed by pre-registration training (n=813). Responses for all categories increased (BOA n = 631, CPD n = 561), but this was most marked for the pre-registration training category, suggesting that osteopaths in practice see scope for enhancing the curriculum in this area.

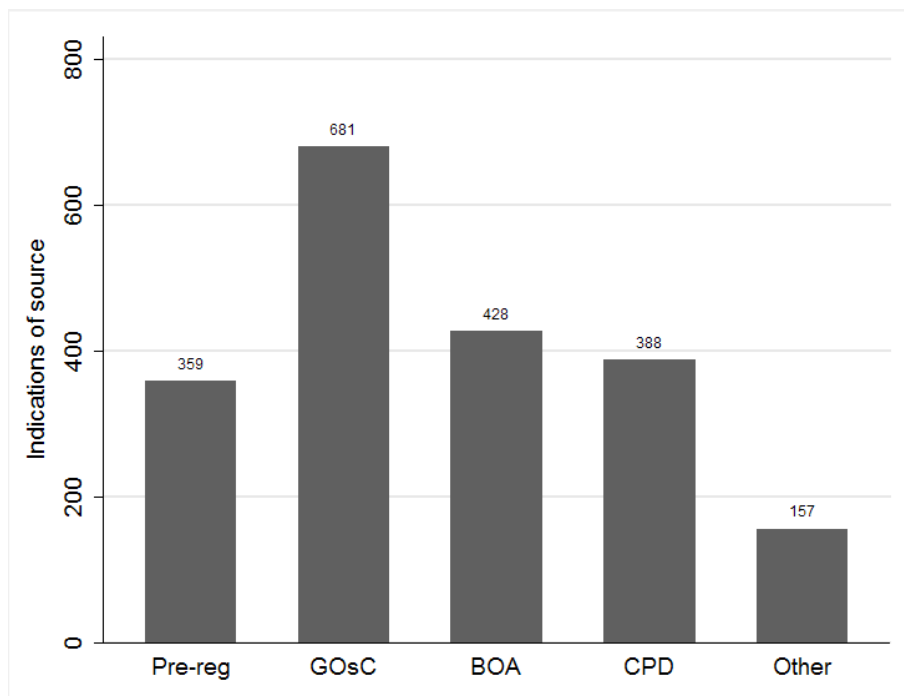


Figure 4.28: Bar chart showing the prevalence of guidance sources - The figure shows which sources osteopaths report receiving guidance about consent processes.

The distribution of responses concerning osteopaths' views of the adequacy of consent guid-

ance information that they had received was normally distributed, with a mean of 3.2 (SD 1.7), suggesting that approximately a third of osteopaths thought that the guidance was between slightly and completely inadequate. Nearly all osteopaths (98.0%) endorsed the idea that it is desirable that practitioners receive guidance about consent.

4.11.3 Patient experience of information given by the osteopath, perceptions of the importance of giving permission by the patient and experience of permission giving

Patients were asked about whether they had been given information about the reasons for examination, the benefits, risks and outcomes of no treatment or different treatment approaches. Their views of the importance of their osteopath gaining permission before examination and treatment were elicited using two statements and a seven point scale of agreement where 0 = “Completely disagree” and 6 = “Completely agree”. Patients were also asked if they had been asked permission to proceed prior to their “First examination”, “Each successive examination in the consultation”, “Treatment” and “Each successive technique in the consultation”.

4.11.3.1 Information received, importance of giving permission and experience of giving permission - whole population of patients

Of the 1,799 participants who answered, 1,157 (64.3%) reported that their osteopath discussed the reasons why he/she needed to examine them; of 1,846, 1,337 (72.4%) reported that their osteopath discussed the likely benefits of treatment; of 1,686, 606 (35.9%) reported that their osteopath discussed the likely risks of the recommended treatment; and of 1,699, 648 (38.1%) reported that their osteopath discussed the likely outcomes of having no, or different, treatment.

Figure 4.29 shows the distribution of participants’ ratings for the perceived importance of an osteopath asking permission prior to examination. The median value was 4 (IQR 2 to 6). Whilst over 40% of patients completely agreed, nearly 30% disagreed. Figure 4.30 shows the distribution of participants’ ratings for the perceived importance of an osteopath asking permission prior to treatment. Again over 40% of patients agreed but 28.0% of patients disagreed.

Of the 1,829 participants who answered the question, 1,385 (75.7%) reported that their osteopath asked permission prior to the first examination; of 1,768, 1,035 (58.5%) reported that their osteopath asked permission prior to each successive examination in the consultation; of 1,825, 1,223 (67.01%) reported that their osteopath asked permission before treatment; and of 1,794, 1,046 (58.3%) reported that their osteopath asked permission before each successive technique in the consultation.

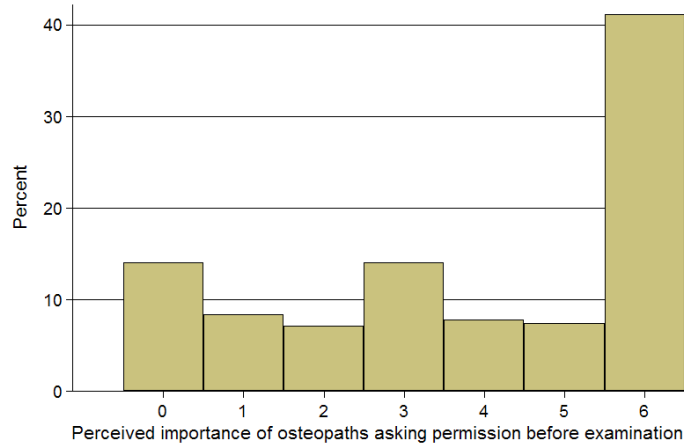


Figure 4.29: Importance of permission to examine - The figure shows the distribution of ratings of agreement with the statement “I think it is extremely important that my osteopath asks my permission before I am examined”; where 0=Completely disagree and 6=Completely agree

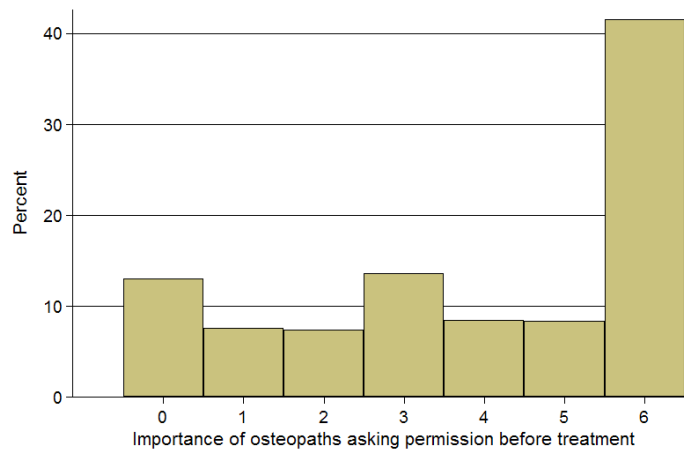


Figure 4.30: Importance of permission to treat - The figure shows the distribution of ratings of agreement with the statement “I think it is extremely important that my osteopath asks my permission before I am treated”; where 0=Completely disagree and 6=Completely agree

4.11.3.2 Information received, importance of giving permission and experience of giving permission - by treatment naivety

We investigated the relationship between treatment naivety and information reported as received by patients related to the consent process. Table 4.48 shows different categories of information and how often it was reported as received by patients.

Table 4.48: Information receipt by treatment naivety

| Did the osteopath talk about: | | Yes | | No | | Total |
|---|------------------|-----|------|-----|------|-------|
| | | n | % | n | % | |
| Reasons for examination | New pat | 195 | 86.3 | 31 | 13.7 | 226 |
| | Rtn pat/new symp | 174 | 68.5 | 80 | 31.5 | 254 |
| | Rtn pat/ongoing | 781 | 59.7 | 527 | 40.3 | 1,308 |
| Likely benefits of treatment | New pat | 190 | 84.1 | 36 | 15.9 | 226 |
| | Rtn pat/new symp | 201 | 78.5 | 55 | 21.5 | 256 |
| | Rtn pat/ongoing | 938 | 69.3 | 416 | 30.7 | 1,354 |
| Likely risks of treatment | New pat | 107 | 50.0 | 107 | 50.0 | 214 |
| | Rtn pat/new symp | 81 | 34.9 | 151 | 65.1 | 232 |
| | Rtn pat/ongoing | 414 | 33.6 | 817 | 66.4 | 1,231 |
| Likely outcome of no treatment or alternative treatment | New pat | 103 | 48.4 | 110 | 51.6 | 213 |
| | Rtn pat/new symp | 98 | 41.5 | 138 | 58.5 | 236 |
| | Rtn pat/ongoing | 443 | 35.7 | 798 | 64.3 | 1,241 |

See section 3.2.1.5 for the definition of treatment naivety

A summary score was created by summing the scores for the 4 questions, with each question scoring 0 if the answer was no, 1 if the answer was yes. 234 new patients reached an average score of 2.62 (median 3), 268 patients with new symptoms had an average score of 2.15 (median 2) and the 1,199 returning patient had a mean score of 1.89 (median 2). On average, patients that are new to their osteopath receive more information than patients who had seen the osteopath before (but present with a new episode) or patients who were in ongoing treatment.

Table 4.49 shows how much importance patients assign to an osteopath asking permission before examination. The average scores for this question were: 235 new patients 4.65 (median 6), 268 patients with new symptoms 3.57 (median 4) and 1,411 returning patients 3.71 (median 4). New patients rate the importance of their osteopath asking permission most highly.

Table 4.50 shows how much importance patients assign to an osteopath asking permission before treatment. The average scores for this question were: 237 new patients 4.8 (median 6), 267 patients with new symptoms 3.64 (median 4) and 1,411 returning patients 3.8 (median 4).

4.11 Consent and information giving

Table 4.49: Perceived importance of osteopath asking permission before examination

| | Number of patients (% of total) | | | |
|---------------------|---------------------------------|------------|----------------------|---------------------|
| | | New pat | Rtn pat/ new symp | Rtn pat/ ongoing |
| Completely disagree | 0 | 16 (6.8) | 45 (16.8) | 208 (14.7) |
| | 1 | 12 (5.1) | 25 (9.3) | 124 (8.8) |
| | 2 | 13 (5.5) | 22 (8.2) | 100 (7.1) |
| | 3 | 22 (9.4) | 35 (13.1) | 211 (15.0) |
| | 4 | 11 (4.7) | 22 (8.2) | 117 (8.3) |
| | 5 | 22 (9.4) | 18 (6.7) | 103 (7.3) |
| Completely agree | 6 | 139 (59.2) | 101 (37.7) | 548 (38.8) |
| Total | | 235 | 268 | 1,411 |

Table 4.50: Perceived importance of osteopath asking permission before treatment

| | Number of patients (% of total) | | | |
|---------------------|---------------------------------|------------|----------------------|---------------------|
| | | New pat | Rtn pat/ new symp | Rtn pat/ ongoing |
| Completely disagree | 0 | 11 (4.6) | 46 (17.2) | 191 (13.5) |
| | 1 | 12 (5.1) | 15 (5.6) | 118 (8.4) |
| | 2 | 8 (3.4) | 26 (9.7) | 107 (7.6) |
| | 3 | 27 (11.4) | 37 (13.9) | 197 (14.0) |
| | 4 | 13 (5.5) | 22 (8.2) | 128 (9.1) |
| | 5 | 20 (8.4) | 21 (7.9) | 120 (8.5) |
| Completely agree | 6 | 146 (61.6) | 100 (37.5) | 550 (39.0) |
| Total | | 237 | 267 | 1,411 |

Table 4.51 shows different categories of permission and the frequencies that patients reported that practitioners ask for each.

Table 4.51: Frequencies of patients reporting that osteopath had asked for permission by treatment naivety

| Did the osteopath ask permission for: | | Yes | | No | | Total |
|---------------------------------------|------------------|-----|------|-----|------|-------|
| | | n | % | n | % | |
| First examination | New pat | 204 | 88.7 | 26 | 11.3 | 230 |
| | Rtn pat/new symp | 190 | 74.8 | 64 | 25.2 | 254 |
| | Rtn pat/ongoing | 980 | 73.6 | 352 | 26.4 | 1,332 |
| Successive examination | New pat | 162 | 75.5 | 52 | 24.3 | 214 |
| | Rtn pat/new symp | 140 | 59.8 | 94 | 40.2 | 234 |
| | Rtn pat/ongoing | 726 | 55.5 | 582 | 44.5 | 1,308 |
| First treatment | New pat | 186 | 83.4 | 37 | 16.6 | 223 |
| | Rtn pat/new symp | 174 | 69.9 | 75 | 30.1 | 249 |
| | Rtn pat/ongoing | 854 | 63.7 | 486 | 36.3 | 1,340 |
| Successive treatment | New pat | 160 | 74.8 | 54 | 25.2 | 214 |
| | Rtn pat/new symp | 149 | 61.6 | 93 | 38.4 | 242 |
| | Rtn pat/ongoing | 728 | 54.9 | 597 | 45.1 | 1,325 |

A summary score was created by summing the scores for the four questions, with each question scoring 0 if the answer was no, 1 if the answer was yes. 209 new patients had an average score of 3.21 (median 4), 230 patients with new symptoms had an average score of 2.61 (median 4) and 1,272 returning patients had a mean score of 2.44 (median 3).

4.11.4 Practitioner information sharing and consent-related views and processes - Interview data

Practitioners were asked to respond to a series of questions about their views and experience of the process of consent in practice. This was within the context of common treatment reactions and explored their views about the type of information and manner in which consent was received as well as their general attitudes to the expectations of the Code of Practice with respect to consent. Practitioners described diverse approaches to receiving consent from patients. These ranged from formal to informal methods, with individual practitioners emphasising different types of information they shared with patients. Practitioners described a number of modes that they considered as receipt of consent from their patients. These included implied consent by attendance for treatment, verbal, written and embodied forms of consent.

4.11 Consent and information giving

Five themes were drawn from the interviews and are presented in detail below. The themes included practitioners' concerns about managing uncertainty and the implications of the lack of clear evidenced information about risk to give their patients. They also recognised the difficulties in ensuring that patients have understood the information given to them. Giving information and the process of consent was seen as a method for managing patient expectations around diagnosis, treatment, risks and the use of other treatments and/or referral. Information giving and receiving consent were also construed of as an important part of communicating with patients and setting up a framework for the extent of partnership and shared decision making in a consultation. Some practitioners placed greater value on patient-led decisions, some on a more shared decision-making process and some thought that the role of the practitioner was to use their experience and expertise to filter information and to make some decisions on behalf of patients.

The experience of patients was an important factor to practitioners; new patients were seen as needing more information and greater levels of consent were required than for patients who were familiar with the osteopath and osteopathic treatment. This finding was congruent with both the patient and practitioner survey data. Similarly several practitioners mentioned actions around the use of HVT which was thought of as needing specific information and consent processes.

Negative views of the consent process centred on perceptions of a loss of professional autonomy, that there was a risk that the process becomes practitioner or regulator focussed rather than in the interest of patients and that in some ways giving risk-related information and receiving consent could interfere with the process of care by changing the techniques used by for example avoiding certain techniques through concerns about giving risk information that was perceived as potentially disturbing to patients. Some practitioners were concerned that information about risk could cause fear and stress in patients and may be an obstacle to establishing a trusting relationship between patient and practitioners. Some osteopaths had a personal reluctance to share information about more serious potential harms from treatment and there was some reference to other professional groups not having such stringent consent expectations as osteopaths. The Code of Practice was endorsed by a small number of interviewees as positive, however many had negative perceptions about the Code and these included pragmatic concerns about the delivery of information, the methods of receiving consent and the lack of guidance received in this area of practice.

4.11.4.1 Theme 1: Uncertainty about risk and patients' understanding of information

Practitioners voiced their uncertainty about the risk of harm from treatment, particularly with respect to serious harm. Practitioners identified that there was a lack of research into risks and harm from osteopathy, and where research was available this was often not from the UK and involved other disciplines delivering the treatment.

“it’s still uncertain as to what the risk is, erm, because of the, well, the statistics don’t necessarily relate to osteopathic treatment and certainly don’t relate to much else apart from HVT” (4711)

There was also concern about the ability to predict which individuals might be vulnerable to suffering from harm from treatment and whether it was known what aspects of care actually could cause harm.

“... it’s very difficult, you know, consent if you don’t really have any appreciation of what the risks are, um, you know, the relative rate of those risks, so you know giving someone some tangible erm idea of how how erm likely something is to happen or erm how severe it’s going to be is very difficult....” (1208)

In addition to the uncertainty about what information to give to patients, there was also an appreciation of the challenge of ensuring that patients had understood the information they were given.

“They didn’t actually realise, or they didn’t take it in, maybe it was just too much information on the first one but, they didn’t take it in and what they didn’t realise was that at that time, what I was doing was getting consent from them to proceed....” (2936)

4.11.4.2 Theme 2: Information about the nature of treatment, diagnosis, risks, benefits and alternatives

When discussing the information that osteopaths gave patients in the context of the process of consent, practitioners recurrently described informing patients about what they should expect from osteopathic care. This focussed on improving the patients’ understanding of their condition and what osteopathic care involved. The diagnosis, nature of treatment and potential benefits of

treatment were most frequently described and practitioners integrated information about these areas when they spoke to patients. Beyond describing the process and their views, practitioners aimed to enhance patient understanding and some described this as part of building confidence and establishing their relationship with their patient.

“Never treat without consent, I always inform the patient what it is I think is wrong with them, how I’m going to approach that in treatment, and I give them options....” (2810)

“I think the trust comes from talking to you as a practitioner and you being able to put your finger on the spot and identify the problem, if I can localise it, then they feel happier about it, if it’s referred pain and I can localise it back up into the back and can tell them why, then they’re also happy about that because it makes sense, because I talk to them about how it happens and what happens.” (1185)

Some practitioners were careful to ensure that patients’ expectations were realistic about what osteopathic treatment could achieve:

“I mean I think a typical sort of er way would be to discuss my findings with a patient, say what I’ve found, a sort of diagnosis if that’s you know within reason, er you know as much as er patients like a nice neat little you know er phrase sometimes, it’s not always possible but to at least explain what’s going on and what I will do to try and improve the situation for them, erm and go through the types of treatments we’ll use, erm why we would do that, er and you know what we would look to achieve, if we feel that you know they should get 100% better or whether we feel you know there’s other issues, and that we can give them a certain amount of relief and respite” (1208)

Giving information about alternative treatments or no treatment was not commonly described as part of the initial process of consent in terms of a patient’s treatment options. More often practitioners described that they would suggest to patients they would make a judgement about the suitability of treatment for the patient or that they try treatment to see if the outcomes were sufficient to continue, and where benefits were not realised discussions would take place about other treatment options or referral back to their general practitioner or other healthcare professionals.

“Yes, so when patients come in, if they’re coming for the first time, when I’m going through my initial sort of discussing whether, have they seen an osteopath, do they know what an osteopath does, do I need to explain as I go through, and then I talk about obviously risks of treatment, I also say to them, listen, after I’ve examined you, it may well be that I decide that actually that osteopathic treatment is not appropriate for you and if that’s the case, it won’t be a case of no sorry, it will be a case of I will either recommend what I think you should be looking for, treatment-wise, or I’ll send you back to the GP with a report of what I’ve done and why I don’t think it’s acceptable to treat you” (2609)

Risk-related information was given to patients about short-term increases in pain. Some practitioners made specific mention of HVT as an important technique to tell patients about with respect to gaining their consent and in the context of the practitioners’ increased awareness of risk with this particular technique.

“When I talk about the patient plan and what I want to do with the patient, I will tell them what is commonly a reaction to treatment, if it’s HVT I then go into a bit more detail about vascular accidents and, but then I will often compare it with other modes of treatment” (3489)

Practitioners were concerned about how they described risk in relation to treating the neck. Practitioners were uncertain about the potential for harm and particularly mentioned strokes and serious injury in this context whilst being interviewed. Some practitioners found the issue so difficult to talk to patients about that while they were aware of the potential for serious harm were unable to share this with patients.

“Well, for example say I want to do an HVT on someone’s neck, ok, I explain what I’m going to do, ok, and I don’t tell them that this is going to, has a risk of causing a stroke, I don’t tell them the risks, ok, because that’s, I feel very occasionally I might, I might say I think this is a good idea but there may be a small chance that it would make you a little worse, I might say that, ok, but I think it’s my job to assess the person in terms of what, you know, if there’s a, if I think there’s a serious risk to that patient obviously I wouldn’t suggest doing the technique, anyway, that’s how I handle it....” (2925)

“but I do warn people, you might get an, what I call an incidental manipulation, where I’m moving things around and there’s a little light pop or click, I said that’s not, that’s what I call

an incidental manipulation, I haven't set you up to do an HVT on someone's neck I will then say, I find it difficult to actually give them all the details and I probably to be honest I withhold some of the information about what might happen, in the sense of this could kill you or make you paralysed from the neck down, I just don't tell them that to be honest" (1773)

Some practitioners described a process of selection with respect to risk. Characteristics of the patient were taken into account and practitioners made their own decisions about the suitability for a particular treatment intervention and did not share this with their patients. Some practitioners also described avoiding techniques because of their perception of risk of harm associated with a particular technique.

"Well, I like to tell patients exactly what I find as I'm finding it, and I like to discuss my diagnosis as I'm going along, so as to get them fully onboard, and then I like to suggest um the, what seems to be the best treatment option, and depending on their age and physical fitness and erm you know, I may, I will obviously alter the treatment plan according to what is, what I think is correct" (4183)

"I always run through that there's a risk of everything from a sore neck to stroke to paralysis to dizziness to giggling to crying, anything and I wouldn't, and I say to them I wouldn't do that if you were in the risk categories, the high risk categories for any of those I wouldn't manipulate your neck, but I legally have to verbalise that to you" (4415)

4.11.4.3 Theme 3: Communication and patient partnership

Practitioners appeared to have different views about their role in the process of information giving and the receipt of consent. These were complex in their formulation and did not seem to be fixed traits with practitioners adapting their approach depending on the context with an individual patient. Practitioners mostly described a shared decision-making process which is ongoing and builds their partnership with patients.

"... though logically patient consent is important, it's important actually, apart from the sort of, the legal side of things, it's important in terms of patient cooperation and trust" (4711)

4.11 Consent and information giving

“nowadays I start consenting them as soon as they walk in the door and I say if there’s anything they don’t want to talk about or positions that they don’t want to be in or anything I’m doing that worries them would they please tell me at once and we can change it, so there is an ongoing consent and erm the permission to stop what I’m doing at any time” (1832)

Some felt that it was their role to provide information for the patient to use to make their own decisions about care.

“Erm, well I do my best to explain what is going to happen and predict what is er the potential downside as well I hope you will feel better for this, and therefore if they are, it is important that they make a judgement am I prepared to accept that or not.” (4711)

One practitioner appeared to share this view with their patients using firm wording and expecting compliance:

“I ask them who’s in charge, me or them, and if they don’t say I am, you know if they don’t say the patient’s in charge, I’ll go through it again, who’s in charge, me or you, and they say I am, say can I trust you, yes, so that means that I’m not allowed to hurt you, I’m not going to do anything you don’t like, can we trust you to say stop, yes, so once they’re prepped in that line, we proceed, if I feel they’re nervous, I just go through it again really” (4275)

Practitioners described a range of different modes used to receive consent. Some practitioners used an initial information sheet to inform patients in order to address their concerns about patients being able to understand information during the consultation. The information sheet was followed by further verbal checking of understanding. Participant 1208 described the process and form that they used in their practice. The detailed excerpt is produced in full below:

“well, the form’s quite long and again it came back to this thing that we didn’t feel necessarily people were taking on board what we were, what we were saying in the room, you know if people are in pain, they’re anxious, they’re maybe not taking it all in, so they get the chance to read it, you know, when they come in, before treatment, but they’re you know encouraged to take it away with them as well, erm and that gives them something they can look over, it’s got all the contact numbers and so on on it, as I say if need be it’s got details of our complaints procedure and various things like that as well, but basically it says I suppose it’s yeah it’s very similarly,

..... but you know it says it's not uncommon to feel you know some discomfort, you know, a day or so after, your osteopath will explain about this, erm there has been some er you know recent er research erm you know linking er you know risk of stroke to um you know treatment or certain treatment techniques, er the neck, and you know it basically says that you're not, you're not obliged to have any sort of treatment you don't want, so again they're pre-warned about that so we try and give them as much advance warning so that you're not leaning over their their erm sort of top end saying right, now I'm just going to adjust your neck here, just going to manipulate this section, oh there's a risk of stroke by the way, you know, so again it's kind of forewarning them, and that gives them I think a bit more confidence in bringing it up, erm you know er if they're not erm comfortable with that you know at the later point when we obviously again ask them if this is ok, so it's a fairly brief summary, I mean now it's a tricky one, you don't want to kind of frighten people off, and make it look like there, you know you commonly get erm very severe kind of detrimental reactions from osteopathic treatment, you know, I don't believe you do, but um yeah it's as I say just to try and er get the message across in a hopefully non-threatening sort of way" (1208)

This process of giving written information and following it up with a discussion was somewhat different to the use of a blanket type written consent form. These forms appeared to be given to patients at the beginning of a consultation and used as an ongoing form of consent:

"Um, every patient that comes to my clinic signs a form to the effect that they're consenting to the treatment, and the mere fact that they have presented and come in voluntarily is an implied assent, sorry, consent." (3256)

The same practitioner was not alone in taking account of the attendance of their patients as being part of implying consent. This was more commonly described in the context of patients who were familiar with osteopathy and were in the middle of a course of treatment or who attended regularly for osteopathic treatments.

".... patients should trust osteopaths and the osteopath should trust the patient, and that if they present for treatment then they are giving their consent, they wouldn't be there if they weren't consenting to treatment, and if they didn't want treatment they would say so...." (3600)

Most practitioners described verbal consent as the most frequently used mode. Information was given about treatment and consent received verbally.

“... I think personally that’s really all I would say in the way of informed consent, and I’d just be very happy to give that verbally, I don’t think one has to pull out a bit of paper and get them to read through it, think about it, come back a day or two later and say yes I’m going to go ahead with this, or sign here....” (4542)

“... it’s only verbal, I don’t get anything written down, but I do it all the time with every patient that walks through the door....” (2810)

Verbal consent was followed by some with attention to body language and the patients’ behaviour. This was seen as an important secondary source to check understanding as part of a commitment to consent being an ongoing process.

“Um, well I think it’s very important, you know, how I do consent, ok, is basically, um, I think there’s verbal consent, where the person says yes I’m happy to be treated, or you know, ok, and then you have to follow that up with non-verbal, so that the person has to say yes with their body as well, so their facial response has to be congruent with their response, so someone might say yes, but they don’t feel good about it, ok, and you have to check that person’s physical, you know, you have to check their body language and their facial expression and all the information that you get about them has to agree, so that if someone says yes I’m happy but you can see that they’re not, you take a step back,....” (2925)

As part of reflecting on consent being an ongoing process some practitioners described attempts to embody consent by allowing patients to experience graded application of techniques in order for the patient to have a clearer idea of what was being proposed. Several practitioners used this idea of a progressive exposure to technique before receiving consent and delivering the proposed technique.

“As long as one’s sensitive to the patients, and you’d very soon know, you know, if they don’t want it done. Before we ever had to, actually had to ask them, and I would always explain what I was hoping to do, erm, get the joints and, you know, side bends and rotations and

so on, and even now, as I did then, would ask them whether it was uncomfortable, um,....” (1361)

The idea that exposure to technique and patients’ experience of osteopathy was important influenced many of the osteopaths who were interviewed. Many practitioners expressed the view that new patients needed more information than ongoing patients.

“On subsequent um treatments, consent is very much more, well it’s different because I, I kind of hammer it home at the first one.....because often the patient will ask you to desist from asking that or saying that or, you know they’ll go look you’ve told me this a hundred times...” (2936)

“ it just depends on the patient, er my older patients who have been with me for years, well I mean usually we don’t hardly talk about anything other than you know what’s been happening in their life and my life and chat chat chat, whilst I treat them, because they know what’s coming and they know what I’m going to do, the new patient will have much more information given to them” (1185)

Ongoing dialogue and discussion of the aims and approaches used by osteopaths along with checking acceptability and progress with patients was seen as helpful. However there were osteopaths who described more formal iterative checking and repetition of information around risk to gain consent at each encounter. This was, at times, seen as a source of frustration to patients and practitioners.

“And that way, you know, they get pissed off enough as it is when you go through the rigmarole about the neck, um, you know, if we’re going to ask for permission to do that we should be asking for permission to articulate them, or indeed to touch them at all, erm, there’s implied consent of course when they come to see us, I would think, and indeed that’s what they think, they keep telling me, “well if I didn’t want you to do it, I wouldn’t be here” ” (1361)

In addition to the recognition that there were differences between the needs of new patients and those more familiar with osteopathic treatment, practitioners acknowledged that the introduction of new techniques required them to revisit the information patients had been given and that a new form of consent was needed.

“Yes they definitely are different, they are er, they definitely assume a familiarity with the process in the patient, you know if it’s someone who’s been to this practice twenty times in ten years, for example, or even more um then you know I feel that I’m justified in assuming their familiarity, because they’re very much choosing to come back and um I have conversations with them that would be exactly the same if I were to be introducing something that they hadn’t experienced before, but even if it was something that they had experienced before, there are certain things that I always stop and ask for explicit consent for, and that involves, that includes acupuncture and spinal manipulations, for mobilisations, soft tissue techniques, or if they’re a repeat cranial osteopathic treat, sorry a repeat cranial osteopathic patient, then I um I talk through what I’m going to do but there’s a certain amount of understanding that they have familiarity with the processes” (1719)

4.11.4.4 Theme 4: Negative perceptions of the consent process

Some practitioners had concerns that expectations surrounding consent affected their professional autonomy to make decisions. These views were commonly associated with concerns about losing valued modes of intervention such as HVT.

“hundreds and hundreds and thousands of patients benefit from having their neck thrust every year, how many deaths do we get, or how many strokes, I mean I don’t think we even know properly, and er if people are so frightened of giving treatments and you make the patient so frightened of having perfectly valid treatment, then you know we just lose so much....” (3669)

“but I mean in the past, I’ve done work on people’s coccyxes by going through er through the rectum which we don’t do anymore, we had to get their consent, but it wasn’t a sort of, you know it wasn’t a sort of big deal, there wasn’t a sort of whole load of erm you know stuff around it, you just asked them, you explained to them why you were going to do it and you did it” (1185)

Some practitioners also had concerns that expectations surrounding consent diverted the focus from the needs of patients to the requirements of osteopaths or served the interests of the legal profession.

“ you know sometimes I think people think when you’re getting consent from them they want, you want them to sign something and they think consent is about you protecting yourself,

and it's not about you protecting them, do you see what I mean?" (3936)

"and I know people have to have a kind of, almost like a medico-legal arse-covering antennae nowadays..." (2416)

These views were aligned to concerns about the impact of information on the process of care with respect to selection of techniques and creating fear and tension in patients.

"this is where I possibly might differ to younger, or the way in which they teach osteopathy at colleges these days, and perhaps it's all to do with health and safety, as this, you know, recent world in which we live, I think you can give them too much, no, I might have to qualify this, you could give patients too much information so that they're immediately worried, so that if, having told them that, you know, all the worst things that can happen, they're then immediately worried that you're even going to touch them, so that rather defeats the object." (1185)

"and the most powerful reactions are as a result of touch, so really in terms of consent if we're going to go down that line we've really got to say to people, listen, if I touch you, you may react and you may react in a way that you're not happy with, end of, so if you do not want to react and you want to be certain that you're not going to react, then don't have treatment" (2416)

The practitioners who acknowledged that there was some information about risk of treatment that they chose not to share with patients explained that for them the cost of giving the information was not equivalent to the benefit.

"I think that the cost of introducing the notion of risk into the treatment far outweighs the potential benefit." (2925)

"... the kind of common treatment reactions people get to osteopathic treatment are generally short-lived and mild, and I don't explain, I just don't explain to patients all the adverse treatment reactions that could happen, I refuse to do it, I think it er, it leads to a potential in a sense a neglecting of patients because you instill so much fear in them that they are, they find it very difficult to accept treatment which is completely safe and valid for them." (3669)

Concerns about creating fear in patients was linked to the potential impact of setting negative expectations around the outcomes of care.

“... I would always wonder how much of the reaction is led by my suggestion, or rather what they tell me, anyway, is led by that, if I'd told them they were going to be in pain for a week, would they be more likely in pain for a week, I don't know...” (4711)

Several practitioners compared their practice with other disciplines and thought that the level of information giving and consent was lower in other contexts and referred to higher risk associated with other treatments. The risk of death from using non-steroidal anti-inflammatories was commonly mentioned.

“does a dentist tell you the risk of serious, does a doctor when he gives you a pill tell him that, one in a million people might actually have an anaphylactic reaction to this and die, they don't, they tell you maybe the usual side effects and not the very very rare ones, and I think that's what we should do, is to tell them the usual ones, but the very rare ones, that could lead to death or severe paralysis, I don't think we should tell them” (3689)

4.11.4.5 Theme 5: Use and value of information concerning consent in the Code of Practice

A minority of practitioners expressed high level of support of the Code of Practice in the context of consent. Concerns reflected issues identified in other themes in this section. These included difficulties in knowing how to adhere to the guidance when there was limited information about risks in response to osteopathic treatment, knowing the extent of information that should be given to patients and concerns about professional autonomy. Practitioners appeared to interpret the guidance around consent in different ways. Some accepted the content and worked towards implementation, whilst others felt that the Code was unrealistic and had been produced without sufficient guidance for osteopaths about how they should adhere to the Code in practice.

“I think the Code of Practice sets a very high standard, and it ought to set a very high standard, and I'm happy with all of it in practice, and I try to be good at following it in every respect, but I wouldn't, I'm sure that at times I've been lax and not followed it absolutely, to the spirit or to the letter, but I do think that it is appropriate and um correct, you know.” (1719)

“ the Code of Practice is doing what does need to be done but they’re doing it in a way that’s more likely to protect themselves than protect the patients” (3600)

“there’s a lot of things in the Code of Practice that have been perhaps well-intentioned but not um you know perhaps fully thought out, erm at times, not just regarding consent but erm I think a lot of osteopaths feel very apprehensive er about this area, erm because they really don’t know what to say and how to say it....” (1208)

“I just think it creates, it’s going to create an unworkable erm, an unworkable position to have to explain every er every procedure and any possible reaction or response” (2416)

4.11.5 Patients’ views of information sharing and consent - Interview data

Patients were asked a series of questions exploring the information given to them during their osteopathic treatment. Questions focussed on the content of information associated with informed consent such as information about the nature of treatment, potential risks, the benefits, discussion of alternative or no treatment and information about examinations that the osteopath carried out. Patients were asked what information that they recalled they had been told by their osteopath and what their views were about the importance of being given information in these areas. Further questions explored patients’ views about the need for osteopaths to seek their permission prior to treatment and examination.

Three broad categories were created from the responses: 1. Patients’ recall of information about the nature of treatment, benefits, risks and alternatives. 2. Moderators of patient expectations about information giving and consent. 3. Purpose and style of information exchange and the consent process. The content of these categories is summarised below along with a description of themes identified where appropriate.

4.11.6 Patients’ recall of information about the nature of treatment, benefits, risks and alternative - Interview data

For many of the patients recall of the information that they were given by their osteopaths was affected by the length of time they had been seeing the osteopath. Patients in longer term treatment had limited memory of information being given at early stages of their treatment with the osteopath, and what they could remember typically related to risk and the nature of the examination and treatment. Their perception of their relationship with their osteopath

appeared to affect their recall, with patients affirming their positive regard for their osteopaths.

“It’s so long ago, um, I, hmm, I honestly don’t remember, no, but, but I’d be surprised if I hadn’t been told.... and I’m sure, I’d be very surprised if he hadn’t, because he’s usually very good at explanations” (17091)

Whilst most patients recalled initial and ongoing discussions about the nature of treatment and the potential benefits and outcomes of treatment, many patients did not recall having been given information about risk.

“I don’t, no he’s never said anything about risk of treatment, no, no” (11483)

Some of these patients explained this in terms of their own situation and their perception that there were no risks associated with treatment and that trust and faith in the practitioner were intimately related to their views about the amount of information given to them as patients.

“Erm, I think I’ve been fairly lucky in the sense that I’ve not had any problems that have been er, how shall I put it, you know, serious enough, where it could really do me any serious harm, you know what I mean, but sometimes I can, you know, it’s, you know occasionally it’s been a case of well we can try something and erm, you know, and then it’s sort of you have to enter a contract, don’t you, with them, you have to trust them and say ok” (13571)

“I can’t remember. Probably did at the beginning but I can’t remember. Don’t think there is any risks.” (9974)

Those patients who recalled information being shared with them about risk described specific information relevant to their condition or concerning specific techniques such as HVT. This commonly related to being informed about the possibility of short term increases in pain and stiffness.

“She kind of said you know you need to go home, you need to rest, because [unclear] and what you’re telling me and the manipulations I’ve done, the chances are that you will get quite a bad headache that will last a few days, I did.” (13702)

“He does tell me that well you might be stiff in a couple of days” (14415)

Some recalled being given written information but did not recall the contents and some were unsure whether information about responses to treatment were equivalent to information about risk.

“Well the first, the very first time I went, I was given some written information and I’m a great one for reading things, so I went through all that, and I read that.” (13262)

“Well, I’m trying to think now whether he did actually say anything about a risk, I don’t think he did at the time because I think he felt that there wasn’t really any risk involved, either he was going to be able to ease the muscles or he wasn’t, the only risk was that the treatment wouldn’t achieve the result he’d hoped it would” (14344)

When recalling information given by osteopaths for the reasons for examinations, most patients recalled the context and process of the examination rather than having the reasons for the examination explained.

“Er, that’s going back a bit now, we’ve got a sort of routine now where we do, we sort of check posture and things like that when we meet, erm, but again that was part of the talking through of how the muscles and how the ligaments and the other stuff works, you know, how it all fits together and how this, corny but the knee bone’s connected to the leg bone etc” (13571)

“Um, well I, he, I think I was just told well just put this gown on and therefore we’re just going to look um at your, you know your body posture, um, and that was it really” (8715)

Some patients felt that an examination was part of the process and did not expect detailed information about the reasons for the examination.

“I don’t.... I mean I kind of expected they would so....perhaps they didn’t feel they needed to.” (12049)

Most patients did not recall receiving information about other potential treatments or having no treatment for their condition. This was interpreted as understandable as the patient had

attended for osteopathic treatment and the osteopath had offered information that suggested that there would be benefit from osteopathic treatment. Patients mentioned information about other treatment options being discussed when they had been told that the limits of what the osteopath could offer had been reached, or in the context of needing another opinion about diagnosis.

“Erm, probably didn’t because I’ve actually gone saying this is what I want, and she knows what other treatments I’ve had and I was having, so I probably didn’t have that discussion” (13702)

“I don’t think there was an issue really that he wouldn’t be able to do something” (13262)

4.11.7 Moderators of patient expectations about information giving and consent

Patients described a range of factors that appeared to moderate the expectations they held with respect to receiving information and giving permission for treatment and examinations. Four themes emerged from the data.

4.11.7.1 Theme 1: Beliefs about osteopathy and experience of osteopathic care; new patient to regular user of osteopathy

Many patients felt that asking permission to treat and gaining permission to examine was particularly important when they were new to osteopathy. The need to be given information was seen as important if the nature of treatment and examination was unknown as opposed to when patients were experienced and had a good sense of what to expect.

“No I think if you just do a one-off when you first go there um and that should suffice for the whole thing” (8175)

Whilst most patients thought it was key at an initial consultation some did feel that information should be reviewed regularly and the individual context of the person should be taken into consideration.

“I think again I don’t think there’s a hard and fast rule on that really, I think it depends on the relationship between the osteopath and the patient, and the, how long they’ve known one

another and all that kind of stuff, I mean I, you know, when I go and see him now I just want him to get on with it, I know what the score is, I know what he's doing, I know what his job is, I know what I'm there for, um, let's just get on with what [unclear] to get on with." (13571)

4.11.7.2 Theme 2: Relationship with osteopath - the role of faith and confidence

Some patients described high levels of faith and confidence in their osteopath. This was related to the establishment of a good relationship with the osteopath over time and overlapped with their views about their own role in making decisions about their care. Faith and confidence seemed to diminish the need for information and for the osteopath having to ask permission to treat or examine the patient. The need to know about risks of treatment was also particularly affected by the patients' relationship with the osteopath. For example, interviewees when replying to whether they had received information about risk expressed their trust in the osteopath and the strength of their relationship.

"... I don't, no he's never said anything about risk of treatment, no, no.... And I've never asked, because I just trust it" (11483)

"Umm.... no, not particularly, no. No, he might have said it to somebody else, but not me because.... No. We've always had an understanding and got on terribly well." (10509)

Others described their osteopath as knowing "quite what to do and what to leave alone" (14415) and assuming that their osteopath would tell them about risk if needed.

"Umm.... no, I don't, but I think that, had I had any condition that might be really risky for his treatment, he would tell me in advance." (8736)

4.11.7.3 Theme 3: Perceptions about osteopathy as a profession

The perception of osteopathy as a profession was described by some patients as part of enhancing their confidence and somewhat diminishing their expectations in terms of being asked permission about elements of treatment. It appeared that the reputation of the profession was interpreted as leading to high standards of practice and thus faith in the individual osteopath that they would not do anything untoward during treatment.

“Well I think it would depend on the osteopath, but in the particular circumstances the last couple of times I’ve met osteopaths, met recently, to be erm, you know to use a phrase, they’ve got a good bedside manner, they’re obviously quite professional, and they know what they’re doing, and er they, you know they make you feel comfortable and you feel relaxed, and then they have a look to see what the problems are, and then they try to address them, you know as far they’re able to, given the, you know the constraints I outlined earlier” (13571)

For some this was important particularly in the context of choosing alternative treatments.

“Um, I don’t think it, again I don’t think it’s important because if I weren’t there with um pain and such a sore leg, I chose the osteopath route, I do know that I could go to a chiropractor or a physio or a GP and therefore um, I’d chosen that, and I’d expect them to say to me um I can help and I’m going to be able to do this, I think it might take a certain amount of time, um, rather than to, yeah because if they can’t help they should just say so” (8175)

4.11.7.4 Theme 4: Specific contexts where additional information or permission is valued by patients

In addition to being new to a practitioner or to osteopathy, patients identified a number of contexts where they thought that the osteopath should offer specific additional information or seek specific permission to act. These included the introduction of new treatments and some mentioned needing to be asked prior to receiving HVT. Undressing and the intimacy of treatment was also mentioned as an important consideration when giving information to patients. In this context some mentioned sex differences between the osteopath and patient and the need to give information about chaperone availability. The whole body approach used by osteopaths was also described as potentially an area that needed particular explanation, especially for patients who were unfamiliar with osteopathic treatment.

“but when you go for something new, like obviously various things, like I had an accident and hit my knee and I went for that, and so it’s a different thing, isn’t it” (11483)

“I think when you’ve got your kit off and you’re standing there in front of somebody, you’ll always feel slightly vulnerable don’t you, that’s just human nature, so if at that point once you’re going to start doing something, you know all they have to say is you know is it ok if we

you know, maybe get to that point, that just seems like the obvious moment to say is it ok if we get, have a look round, you know, see what's going on." (13571)

"....but I should imagine if you were going to have bones clicked and that it would be more important." (9173)

"I think they need to ask permission in that um I was, I was asked if I minded stripping down to my bra and pants, some people aren't very happy about doing that, are they, especially if it's a male osteopath and a female patient or vice versa" (9173)

"Otherwise doesn't need that but if he's going to have a special discussion of a person's health, it might be always wise or vice versa, if it's a female osteopath, someone else male in there, just a question of chaperoning really." (14415)

4.11.7.5 Theme 5: Attendance and choosing osteopathic treatment and implied consent

Although patients tended to give preferences for receiving information and identified particular contexts for when they thought that it was important for information to be given and permission to be granted for action by the osteopath, many voiced the view that they were attending voluntarily and indeed paying for a service that they expected and that this meant that the osteopath seeking permission to examine and treat them was to some extent superfluous.

"I think my assumption is, I mean as I say I'm a psychologist, if somebody comes to see me and sits down in the room with me, they've given their consent to work with me, the fact that I choose to go and sit in this room with the osteopath and I've said I've come to you for treatment, then I kind of think what is the point of them asking permission, it's a question that you've already answered by being there and saying please treat me, I'm paying you this money for a service, erm, I think ethics and consent and things like that in some respects just get a little bit too politically correct....It is, and I think on some levels you kind of have to assume that if I've taken my top off and I've laid on the bed, I've given permission, it doesn't need to be verbalised. If I don't want treatment, then I don't want treatment, and I would say...." (13702)

“Um, again I think I would accept that the fact that I’ve gone along to see somebody, they can’t do their job unless I give them permission to do their job, by going there as it were, so the fact that the osteopath would say to me I need, I’m going to have a look to see or I need to examine this or I need to, then I would find that perfectly adequate and acceptable, I wouldn’t expect a big song and dance about it really, that this is why I’ve gone there and this is the person doing their job” (13262)

4.11.8 Purpose and style of information exchange and the consent process

Patients reflected on the role of information-giving and consent in the consultation, with three themes emerging from the data. Patients identified that the process of information giving and ongoing dialogue with the osteopath promoted confidence and built their relationship with the osteopath. There were a range of styles of using information to make decisions about treatment, but nearly all patients voiced the view that information helped them to have realistic expectations about the process of care and how to react to the results of treatment. This was particularly evident in relation to treatment reactions.

4.11.8.1 Theme 1: Establishing rapport and relationship with the osteopath

Many of the interviewed patients valued their relationship with their osteopath and articulated that the information giving process helped to build confidence and trust with their practitioner. Patients valued information about the benefits and outcomes of treatment and for some this helped them feel more able to ask questions.

“Because I like to understand what’s going on and how it’s, you know how things are working, um, I don’t, I only have a layman’s knowledge of the body and um, but I’m interested and you know I want to, I would, well I would ask the questions I suppose if I wasn’t given the information, I would ask questions anyway, but yes I think that is very important, to know what’s happening and I would say quite a lot of it he initiated, you know this is what I think is happening and this is what I’m doing, and then I felt quite at ease to ask any further questions to sort of clarify or give me a bit more information really” (13262)

Several patients also noted that it was simply courteous to explain what was likely to happen during and after treatment and that it was an important aspect of building trust.

“so I think just, it’s always nice just to be asked so that you can just [unclear] think oh yes um am I actually happy, otherwise it just feels that they’re just dictating to you right, you know, um get on the bed I’m going to examine you, get undressed, do that, and I think it’s more courteous and just gives you a little bit of ease that actually you do have a choice here yourself, and I think you have got to take those choices yourself” (8175)

“I think it is, umm ... for ... what’s the word ... umm ... if there’s explanation it makes or can make the patient feel less sort of guinea-pig-like or mucked about with, you know, if you know why somebody’s doing something, then that’s a whole lot different to not knowing why.... Again it’s a matter of sort of settling patient’s in and developing that trust with reassurance.” (9640)

4.11.8.2 Theme 2: Making decisions - collaboration, autonomy and letting the osteopath decide

Patients’ accounts of how they used information and viewed giving consent in the context of making decisions about their care was complex. There appeared to be evidence of patients using three approaches: a collaborative or partnership approach, using information to make autonomous decisions and instances where patients appeared to leave the decision making to their practitioner. However, these modes of decision making were not consistent within individual patients, rather patients appeared to adopt a strategy that was relevant to them within the context of the information given. For example, one patient described a collaborative approach to making decisions in the following manner:

“And the osteopath that I’ve been seeing is somebody who umm is very very gentle, very caring and very understanding, very empathetic, and always explained to me what she would like to do and why, so we would agree that treatment and because she knew that I didn’t really have the sort of strength and energy to take a great deal of treatment” (9046)

However, these views were followed by the patient saying that there were elements of treatment that they left up to the osteopath to decide:

“sometimes she would say well I’m not going to do this today, or I’m not going to do any more of that because umm you know it might be a bit too much for you, so I really very much

left things up to her judgement.” (9046)

Another patient had similarly divergent views initially pointing out the need for information in the context of consultations with doctors and then seemingly adopting a passive stance to accepting decisions made by their osteopath.

“Well you need to know how to do things for yourself. You’ve got to look after yourself and if he says don’t do this, or do that, it’s like a doctor says you need to know. I mean we are not inclined to accept everything on the surface. We like to ask questions. We say why this and why that. Doctors tend to often expect you to agree, simply because they are telling you, but we don’t always do that, what’s the point of this treatment....” (14415)

“I think the osteopath is the one who’s got the information so he should be able to tell you whether you need a thing or you don’t.” (14415)

Accepting that there are a range of modes of using information and making decisions, many patients endorsed partnership approaches which involved discussion, often revisited at separate visits, and leading to agreed decisions about the right actions for them.

“I suppose he didn’t sort of, I don’t recall him saying well this, this looks like this, this and this, I think it was more an ongoing conversation as he um, I mean each time I had to sort of stand in front of him while he looked, I mean he got me to do various things like obviously to bend and that sort of thing, and um when it was specifically for my shoulder raising my arm in different directions etc, and he would, he was just watching then, but it was more like an ongoing conversation as he was massaging or whatever it is he’s doing, um, as to what’s going on, you know, and what I’m trying to do” (13262)

“But an examination sure, because I mean the first thing he will do is to, is to feel around my neck, look at it, get me to move my head, bend, the various things to show how the mobility is going, so he’s doing that each time, he’s checking on what the situation is, comparing that with what I’m telling him about how I feel about it, and then he’s shaping his specific treatment, the detail of his treatment, to that.”

Some patients clearly felt that the control of the decisions was within their hands and that the onus was on the patient to use information to decide what was best for them.

“So I could make the decision whether I went ahead or not basically” (13262)

“Whether you want to be um put yourself at that risk, choose between the option of having the treatment or, you’ve got to weigh up risk or benefits haven’t you?” (9713)

4.11.8.3 Theme 3: Forewarning and setting expectations

Information received by patients was seen as helping to inform their expectations with respect to the outcome and benefits of treatment. Often this was within the context of patients valuing information about prognosis and the anticipated length of treatment required.

“I didn’t expect to ever walk out after one treatment and the person I saw was very good and explained to me this will probably take um, I mean he didn’t sort of say it’ll take five treatments or anything like that, but I was aware that it was going, it wasn’t a, the issue with my back he felt wasn’t a major problem, but I, he was going to be able to deal with it and it was going to be dealt with relatively quickly” (13262)

“Well, if he tells you that it’s not going to, you might go to an osteopath and think you’re going to get very quick results, so at least you can be forewarned that you’re probably not going to get anything too quick, um, yes so they should communicate to a certain extent what they’re trying to do and what the problem is, or what they see the problem as.” (14819)

Having information about the nature of treatment and likely reactions was seen as helpful. It enabled patients to normalise their experience and to worry less about how they felt.

“But because he explained what he was trying to do, and you know reasons why, he was putting me in that position, and he said you’ll just hear something, it won’t hurt, and he said I just need you to relax and I’ll just do this, but if he was just lying me down and pushing on me, I’d have freaked out I suppose, you know, I would not have gone again. I’d have been out that door. Because he explained I thought oh right, that’s what you’re doing, I thought right,

okay, you're doing it for a reason." (9974)

Treatment reactions were also understood and accepted if a patient had expected them through the receipt of prior information.

"Well I suppose when you get home, if you get any symptoms and neck ache or pains round that area, if they explain that that might happen, or what he's doing, then you won't go rushing back saying oh you've made me worse.... You know what to expect then, so you won't be ringing up saying you've made me worse. I think you've got to know what to expect definitely." (9082)

4.11.9 Perceptions of risk - Interview data

Patients were asked about how they weigh up risks and benefits of treatment. This section of the interview followed a discussion of the nature and acceptability of common treatment reactions. Patients generally regarded their osteopathic treatment as having very low or no risk.

"I don't feel there's any risks.... I don't know why, I just wouldn't, I wouldn't, no it doesn't enter my head, there's no risk to me and that's it, and benefits, without it I wouldn't be able to do what I do, so to me it's a necessity" (11483)

Patients described their views of risk in the context of perceived benefit; they tended not to think of risk in terms of hazards and harms from treatment, but instead regarded risk as the possibility of achieving no benefit.

"Er, I didn't actually, I, the treatment I'm having's non-invasive and so I didn't perceive any risks having talked to the osteopath, and erm my thing was, it will either improve or it won't, but the benefit is that actually I'm going to have an increased quality of life, the risk is nothing's going to get better, so it was kind of worth trying, and giving it a go for a while, erm, but I'd also, because I'd been recommended by somebody that I really trust, and I'd spoken to my GP, [unclear] about the difference between osteopaths and chiropractors and stuff like that, and my GP had said no way go for a chiropractor, but yes osteopathy would be good for your, it was kind of well I don't really see a risk" (13702)

“I don’t think too much about the risks of it, erm, and the benefits, if it gets better, you know, you feel you’ve had benefit, um, so that’s how I’d weigh that one up” (14819)

Some patients acknowledged that there was inherent risk with all interventions and compared osteopathy with other treatments.

“Um, well there’s always, I’d say there’s always a risk when you go somewhere, you, I mean I’d say that’s the case anyway, whether you’re going to a doctor in a hospital or any of these other um chiropractors or osteopaths, you’re putting your faith in them” (8175)

Perception of risk was mitigated by the faith and trust patients placed in their osteopaths and in their osteopaths’ professional knowledge and experience.

“Umm... well I mean if he’s a qualified man at his job, the same as when you go to a doctor, if he’s qualified, you trust that person, and you’ve got to trust, you know, it’s like anybody, trust is very important, so you trust the man that’s going to be doing the treatment to you.” (10509)

“I think, if you’re in the hands of a real skilled practitioner, there aren’t any major risks. I trust this man so much, he is incredibly knowledgeable, and I really don’t think he would try anything that would have major risk involvement. I think one has to have real trust in the practitioner which I do and the more I go to him and the more I hear from my friends what he’s done for them, the more confidence and amazement and thankfulness I have for him. I think he’s outstanding.” (8736)

For the patients interviewed, the majority thought that the benefits clearly outweighed any risks they perceived. Some patients explicitly said that they made a judgement about treatment without considering risks.

“To be quite honest I really didn’t care. I had... I’d had so much pain and so many general day-to-day things that I wasn’t allowed to do, the benefits certainly outweighed the risks with that.” (13713)

4.12 Patient outcomes

4.12.1 Patient improvement

4.12.1.1 Decrease in intensity of main complaint symptoms/pain

At baseline, mean pain intensity was 4.28 (95% CI 4.17 to 4.40) on the eleven point NRS scale; after one day it had fallen to 3.40 (3.30 to 3.50), at two days it had fallen further to 2.76 (2.66 to 2.86), and at six weeks it was 2.56 (2.44 to 2.67). The change from baseline to six weeks was -1.63 (-1.77 to -1.49) (SD=2.61); a standardised effect size of -0.62 (medium to large).

A 30% decrease on an eleven point NRS pain intensity scale has been reported as a clinically meaningful change.^{60,61} Using this 30% decrease in symptoms/pain change as a threshold on the eleven point NRS scales of symptom/pain intensity, 56.6% or above of all patients achieve this threshold at the six week time point. New patients and returning patients with a new episode consistently achieve better outcomes than those patients in ongoing treatment. Generally, the highest improvement can be seen in the group of patients returning to an osteopath with a new episode of symptoms/pain.

Figure 4.31 and figure 4.32 show by how much patients improved from baseline to six weeks. Comparing graph 4.31 and 4.32 also shows that new patients rated their current symptom intensity (“right now”) higher than their average rating (“over last four weeks”). For returning patients with new symptoms/pain this was reversed and only returning patients who presented with recurrent symptoms/pain rated their average and current symptoms/pain intensity similarly.

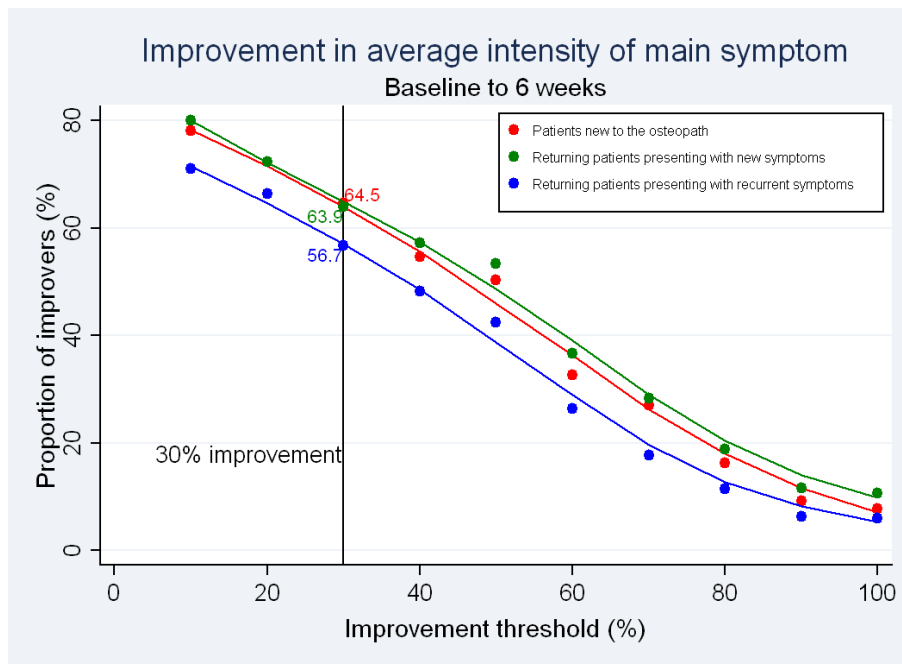


Figure 4.31: Improvement in average intensity of main symptom/pain by treatment naivety - The figure shows the percentage of patients improving from baseline to six weeks follow-up by a range of improvement thresholds. The lines represent least-squares smoothing plots of the data

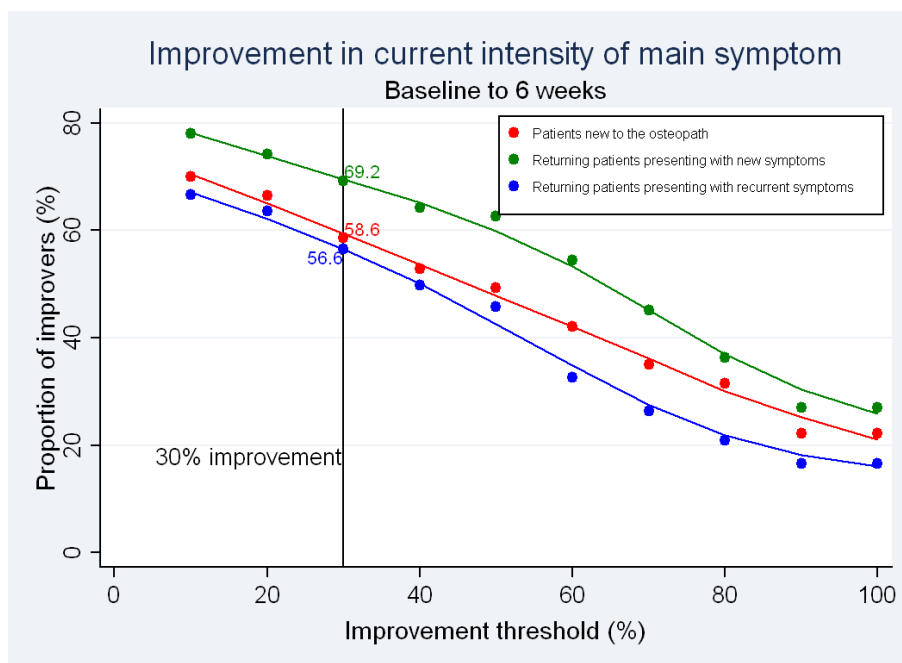


Figure 4.32: Improvement in current intensity of main symptom/pain by treatment naivety - The figure shows the percentage of patients improving from baseline to six weeks follow-up by a range of improvement thresholds. The lines represent least-squares smoothing plots of the data

4.12 Patient outcomes

Table 4.52 shows how many patients experienced a 30% improvement in the current intensity of their main symptoms/pain from baseline to each time point. Data are presented by the patients' baseline pain score.

Out of the patients observed at each time point 773 (39.7% of 1,949) improved by day one, 1,067 (55.3% of 1,929) got better by day two and 751 (56.4% of 1,332) patients experienced a decrease in their main symptom intensity six weeks after treatment. Using the 30% improvement threshold shows similar overall treatment effects at day two and six weeks. Out of the 838 patients who improved by 30% in the first 48 hours and were observed at six weeks, 578 (69.0%) were still at least 30% improved compared with their baseline score at six weeks. Of the 478 patients who did not decrease their symptoms/pain intensity by 30% within 48 hours, 197 patients (41.2%) were improved at six weeks. Out of the 838 patients who improved by 30% in the first 48 hours and were observed at six weeks, 88 (10.5%) had an increase in the intensity of their main symptoms/pain by at least 30% compared with their baseline score at six weeks.

Table 4.52: Number of patients who experience decrease in current intensity of their main symptom by at least 30%. Number of patients is presented at each follow-up point by baseline symptoms/pain intensity

| Pain score at Baseline | n at Baseline (% of total 2,039) | Number of patients (% of baseline) | | | |
|-------------------------------------|-------------------------------------|------------------------------------|------------|--------------|------------|
| | | Day 1 | Day 2 | 6 weeks | |
| no symptoms/ pain | 0 | 108 (5.3) | 0(0.0) | 0 (0.0) | 0 (0.0) |
| | 1 | 178 (8.7) | 37 (20.8) | 42 (23.6) | 42 (23.6) |
| | 2 | 242 (11.9) | 92 (38.0) | 123 (50.8) | 88 (36.4) |
| | 3 | 325 (15.9) | 159 (48.9) | 218 (67.1) | 146 (44.9) |
| | 4 | 263 (12.9) | 94 (35.7) | 143 (54.4) | 86 (32.7) |
| | 5 | 242 (11.9) | 100 (41.3) | 140 (57.9) | 118 (48.8) |
| | 6 | 182 (8.9) | 85 (46.7) | 120 (65.9) | 78 (42.9) |
| | 7 | 208 (10.2) | 92 (44.2) | 130 (62.5) | 82 (39.4) |
| | 8 | 166 (8.1) | 75 (45.2) | 105 (63.3) | 69 (41.6) |
| | 9 | 62 (3.0) | 27 (43.6) | 33 (53.2) | 32 (51.6) |
| worst symptoms/pain | 10 | 22 (1.1) | 12 (54.6) | 13 (59.1) | 10 (45.5) |
| score missing (% of total 2,039) | | 41 (2.0) | 90 (2.4) | 110 (3.4) | 707 (32.7) |
| Total (% of observed) | | 1,998 | 773 (39.7) | 1,067 (55.3) | 751 (56.4) |

The proportion of patients whose pain score decreased by at least two points is lower than the proportion using the 30% threshold of improvement criterion and represents a more conservative analysis of these data. Out of the observed patients, 666 (34.2%) improved by day one, 884 (45.8%) by day two and 639 (48.0%) show a pain score at least two points lower by six weeks

compared to baseline. Again the number of patients who improved from baseline by at least two points is similar after two days or six weeks, suggesting that the main improvement was achieved after day two.

Figure 4.33 shows the raw difference in points on the NRS scale for the intensity of symptoms/pain for all patients from baseline to six weeks. Figure 4.34 shows the same data but separated by those in ongoing treatment and those presenting for the first time for their current problem. This gives an illustration of the scope of improvement and shows more clearly that those presenting with a new episode had greater decreases in pain than those in ongoing treatment.

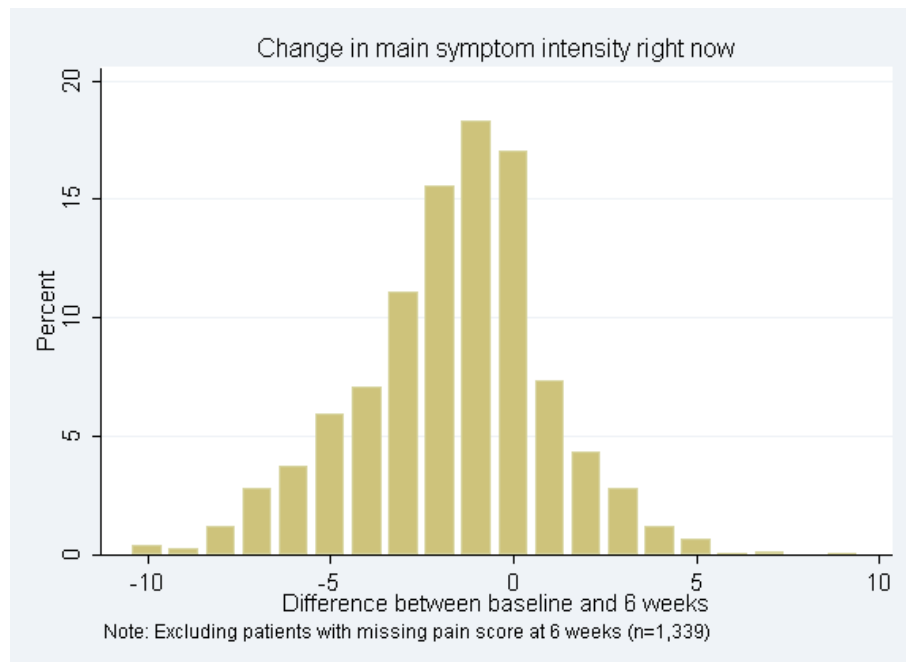


Figure 4.33: Change in current main symptom intensity for all patients - The figure shows the distribution of change between baseline and six weeks follow-up

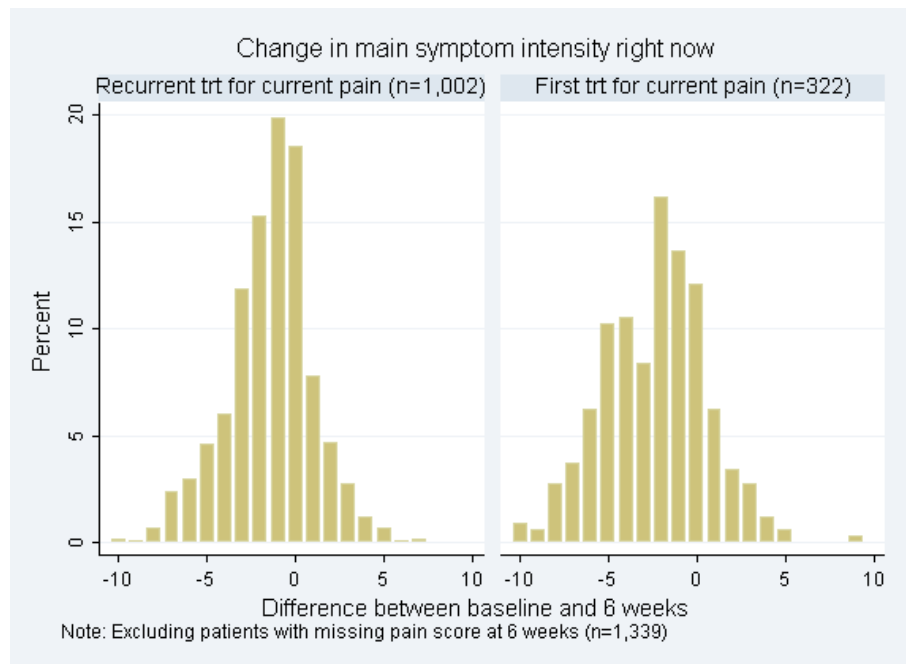


Figure 4.34: Change in current main symptom intensity for new and returning patients
 - The figure shows the distribution of change between baseline and six weeks follow-up separated for new and returning patients

Figure 4.35 shows the patients' current pain score intensity at six weeks against the pain score intensity at baseline. The size of the dots represents the number of patients showing a specific change in score. For example, fewer than 10 patients had a baseline score of 2 and a six weeks score of 7. The red line represents the patients with no change in their pain score. Above that line are the patients that experienced a worsening of their pain (score increased over time) and below the line are the patients whose pain improved (score decreased over time).

Figure 4.36 and figure 4.37 show the same data separated by those who are presenting as a new patient or with a new episode of pain vs those in ongoing treatment. They illustrate the larger improvement made by those with new presentations to an osteopath and demonstrate that patients presenting with new symptoms tend to have higher baseline scores.

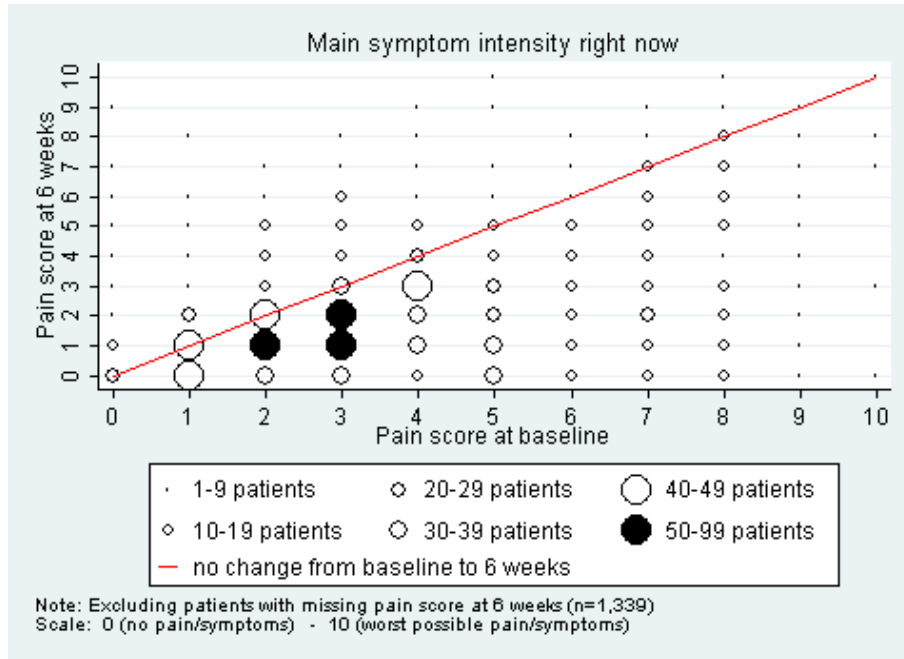


Figure 4.35: Current main symptom intensity (all patients) - The figure shows the change of pain intensity between baseline and six weeks follow-up

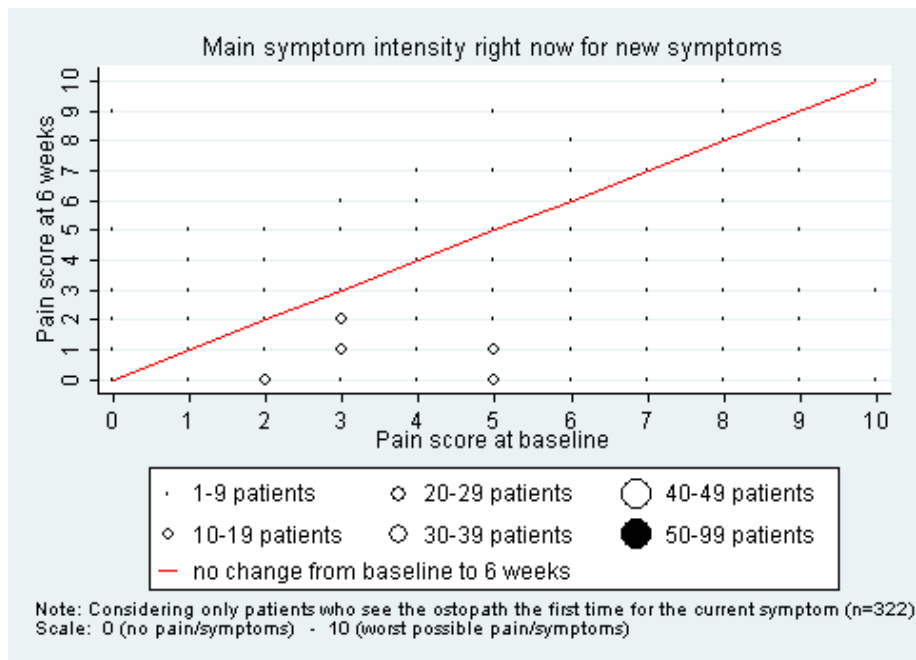


Figure 4.36: Current main symptom intensity (new patients) - The figure shows the change of current pain intensity between baseline and six weeks follow-up for new patients

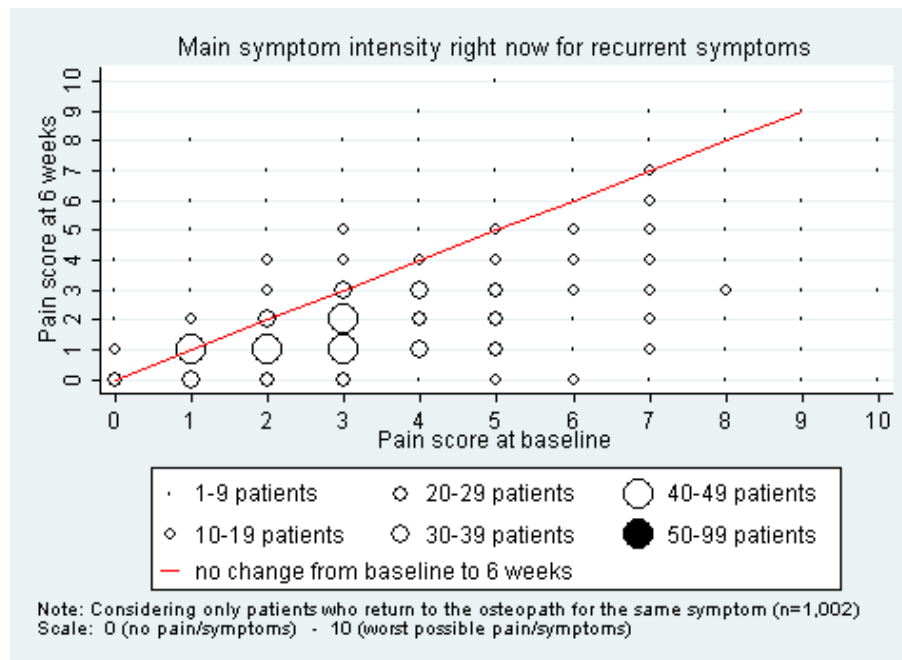


Figure 4.37: Current main symptom intensity (returning patients) - The figure shows the change of pain intensity between baseline and six weeks follow-up for returning patients

At baseline, mean pain intensity (average over past four weeks) was 5.60 (95% CI 5.50 to 5.70) on the 11-point NRS scale, and at six weeks it had fallen to 3.44 (3.32 to 3.57). The change from baseline was -2.07 (-2.21 to -1.92) (SD=2.64); a standardised effect size of -0.78 (large).

Table 4.53 shows changes with respect to patients' judgement of average intensity of symptoms/pain judged over the previous four weeks at baseline and at six week follow up. It also includes results of patients' judgement of intensity of their main symptoms/pain at day one and day two since treatment. The average intensity results show slightly larger proportions of patients meeting the 30% threshold of improvement but follow a similar pattern to the current intensity of pain results. A trend is evident suggesting that baseline higher levels of symptoms/pain lead to higher chance of improvement at the 30% threshold.

Figure 4.38 shows the pain score at six weeks against the pain score at baseline as averaged by patients over four weeks. The size of the dots represents the number of patients showing a specific change on score. For example, fewer than 5 patients had a baseline score of 2 and a six weeks score of 10. The red line represents the patients with no change in their pain score. Above that line are the patients that experienced a worsening of their pain (score increased over time) and below the line are the patients whose pain improved (score decreased over time).

Figure 4.39 and figure 4.40 show the same data separated by those who are presenting as a new patient or with a new episode of pain vs those in ongoing treatment. They further illustrate

Table 4.53: Number of patients who experience decrease in average intensity of their main symptom by at least 30%. Number of patients is presented at each follow-up point by baseline symptoms/pain intensity

| Pain score at Baseline | n at Baseline (% of total 2,039) | Number of patients (% of baseline) | | | |
|-------------------------------------|-------------------------------------|------------------------------------|------------|--------------|------------|
| | | Day 1 | Day 2 | 6 weeks | |
| no symptoms/ pain | 0 | 44 (2.16) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | 1 | 53 (2.60) | 16 (30.2) | 17 (32.1) | 5 (9.4) |
| | 2 | 111 (5.44) | 37 (33.3) | 51 (46.0) | 37 (33.3) |
| | 3 | 210 (10.30) | 100 (47.6) | 133 (63.3) | 88 (41.9) |
| | 4 | 234 (11.48) | 85 (36.3) | 116 (49.6) | 83 (35.5) |
| | 5 | 276 (13.54) | 120 (43.5) | 156 (56.5) | 108 (39.1) |
| | 6 | 278 (13.63) | 145 (52.2) | 168 (60.4) | 131 (47.1) |
| | 7 | 313 (15.35) | 116 (37.1) | 164 (52.4) | 124 (39.6) |
| | 8 | 286 (14.03) | 136 (47.6) | 154 (53.9) | 109 (38.1) |
| worst symptoms/pain | 9 | 100 (4.90) | 46 (46.0) | 63 (63.00) | 42 (42.0) |
| | 10 | 90 (4.41) | 59 (65.6) | 58 (64.4) | 40 (44.4) |
| score missing (% of total 2,039) | | 44 (2.2) | 100 (4.9) | 124 (6.1) | 714 (35.0) |
| Total (% of observed) | | 1,995 | 860 (44.4) | 1,080 (56.4) | 767 (57.9) |

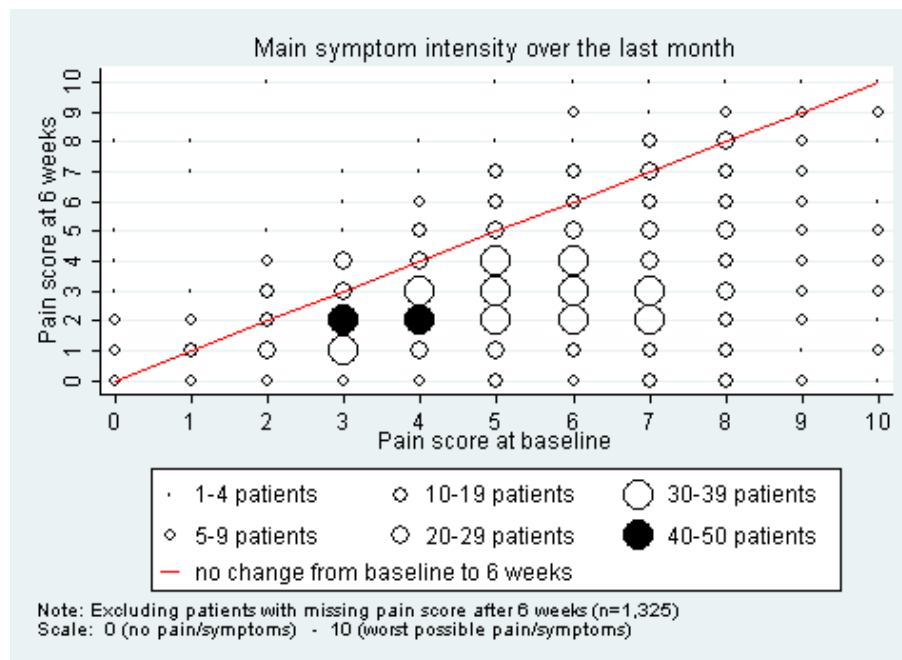


Figure 4.38: Main symptom intensity over the last four weeks (all patients) - The figure shows the change of pain intensity between baseline and six weeks follow-up

the larger improvement made by those with new presentations to an osteopath and demonstrate that patients presenting with new symptoms tend to have higher baseline scores.

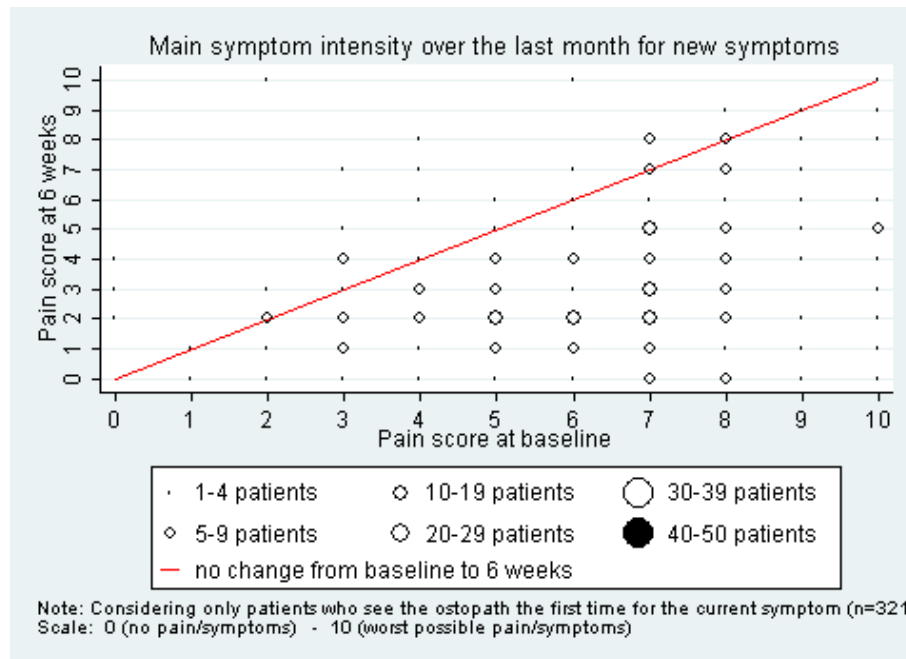


Figure 4.39: Main symptom intensity over the last four weeks (new patients) - The figure shows the change of pain intensity between baseline and six weeks follow-up for new patients

4.12.1.2 Predictors of decrease in intensity of symptoms/pain

Regression analyses exploring the predictors of a decrease in current symptoms/pain intensity are available on request. The results of a logistic regression with a two point change on the NRS scale used as the threshold to create a binary outcome are shown in table 4.54. The model explained 12.3% of the variance and included 787 observations.

Three variables were predictive of improvement. Patients with more sites of pain have a lower chance of improvement. For each additional pain site reported as at least moderately troublesome there is a 11.6% lower chance of improvement by two points on the scale ($p = 0.010$). Higher baseline pain intensity and troublesomeness predicts improvement. There was a 66.9% higher chance of decreasing two points on the NRS scale with an increase in one point on the composites baseline score for intensity and troublesomeness ($p < 0.001$). New presenting episodes were also predictive of a decrease in pain intensity by two points. These patients are 67.8% more likely to have decrease in their pain intensity. The model fits with the descriptive results and supports the findings described above.

Table 4.54: Modelling which patients improve by six weeks (two points decrease in main symptom)

| Explanatory variable | odds ratio | SE | 95% CI | p-value |
|---|-------------------|-----------|----------------|----------------|
| Age | 1.006 | 0.008 | 0.990 to 1.021 | 0.469 |
| Gender (Effect of male) | 0.943 | 0.166 | 0.667 to 1.333 | 0.740 |
| Presenting area (Effect of back/hips vs head/shoulder) | 0.878 | 0.152 | 0.625 to 1.234 | 0.453 |
| Presenting area (Effect of extremity vs head/shoulder) | 1.034 | 0.293 | 0.593 to 1.801 | 0.907 |
| Episode duration (Effect of more than 3 months) | 1.073 | 0.190 | 0.759 to 1.518 | 0.689 |
| Number of pain sites | 0.884 | 0.043 | 0.804 to 0.971 | 0.010 |
| Baseline intensity and troublesomeness | 1.669 | 0.094 | 1.494 to 1.863 | <0.001 |
| Practitioner used HVT | 1.167 | 0.198 | 0.837 to 1.628 | 0.362 |
| Practitioner used cranial osteopathic/IVM | 0.845 | 0.149 | 0.597 to 1.195 | 0.340 |
| Practitioner used dry-needling/acupuncture | 0.938 | 0.426 | 0.385 to 2.287 | 0.888 |
| Presence of comorbidities | 0.761 | 0.133 | 0.540 to 1.073 | 0.119 |
| First treatment for current symptom | 1.678 | 0.319 | 1.156 to 2.435 | 0.006 |
| Current ability to work (Effect of not off work vs off work) | 1.136 | 0.392 | 0.578 to 2.233 | 0.712 |
| Current ability to work (Effect of not applicable vs off work) | 0.911 | 0.358 | 0.422 to 1.969 | 0.814 |
| Information (0...none given, 4...all given) | 1.040 | 0.057 | 0.934 to 1.158 | 0.477 |

$\chi^2=134.17$, $p<0.001$, Area under the ROC curve = 0.7297

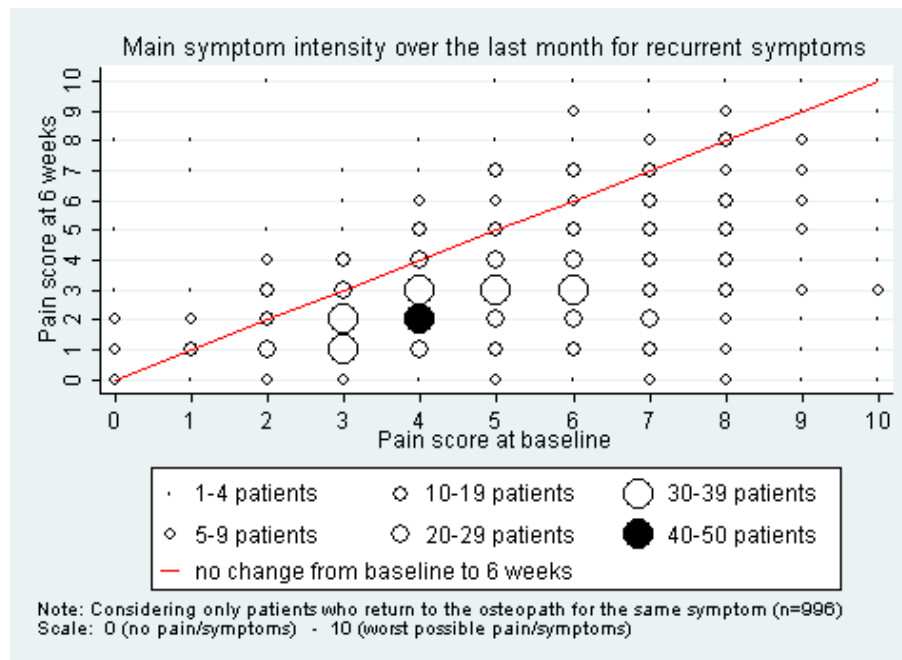


Figure 4.40: Main symptom intensity over the last four weeks (returning patients) - The figure shows the change of pain intensity between baseline and six weeks follow-up for returning patients

4.12.1.3 Decrease in troublesomeness of main symptoms/pain

Patients reported the extent of troublesomeness their main area of symptoms/ pain was causing on a 6 point scale from “No symptoms/pain experienced” to “Extremely troublesome”. Out of the 1,985 patients observed at baseline, 23.6% fell into the first three categories of the scale, with no symptoms or low levels of troublesomeness. At six weeks this had changed to 65.8% out of the 1,329 patients completing the item.

Table 4.62 shows the results of applying a 30% threshold of decrease in troublesomeness score from baseline to day one, day two and six weeks. At day one 31.0% of patients have a decrease of 30% on the troublesomeness scale. A higher proportion at day two (37.2%) decrease by the threshold, but this falls back to similar levels at six weeks where 30.8% of patients have made a decrease in their troublesomeness score of 30%. As with the intensity scores reported above, patients with the highest two levels of troublesomeness at baseline account for the largest proportion of improvers. At day one this was 54.9%, day two 53.1%, and at six weeks 56.6% of those improving.

Table 4.55: Number of patients who experience decrease in average troublesomeness of their main symptom by at least 30%. Number of patients is presented at each follow-up point by baseline symptoms/pain troublesomeness

| Troublesomeness at Baseline | n at Baseline (% of total 2,039) | Number of patients (% of baseline) | | |
|-------------------------------------|-------------------------------------|------------------------------------|------------|------------|
| | | Day 1 | Day 2 | 6 weeks |
| no symptoms/pain | 26 (1.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| not at all troublesome | 68 (3.3) | 16 (23.5) | 17 (25.0) | 10 (14.7) |
| slightly troublesome | 374 (18.3) | 131 (35.0) | 167 (44.7) | 72 (19.3) |
| moderately troublesome | 826 (40.5) | 119 (14.4) | 151 (18.3) | 92 (11.1) |
| very troublesome | 556 (27.3) | 234 (42.1) | 285 (51.3) | 177 (31.8) |
| extremely troublesome | 135 (6.6) | 90 (66.7) | 94 (69.6) | 50 (37.0) |
| score missing (% of total 2,039) | 54 (2.7) | 134 (6.6) | 121 (5.9) | 738 (36.2) |
| Total (% of observed) | 1,985 | 590 (31.0) | 714 (37.2) | 401 (30.8) |

4.12.1.4 Changes in overall perceived improvement and satisfaction with treatment

At day one, 1,972 participants answered the question about their overall change in symptoms/pain since their treatment. The scale used had seven verbal categories from “Very much worse” to “Very much improved”. Categories “much improved” and “very much improved” (6 and 7) were regarded as a substantial improvement. At day one after treatment 923 (46.8%) had at least “much improvement”. At day two out of 1,951 patients 1,020 (52.3%) had at least “much improved” and after six weeks 811 (61.0%) out of 1,330 reported substantial improvement in their overall symptoms. The proportion of patients reporting improvement increases at each time point.

Table 4.56 compares day one and day two responses and Table 4.57 contrasts day two and six week follow up results. There is a small number of patients who reported substantial improvement at day one but not at day two (7.4% of the total population observed). There were also a number of patients who had not improved at day one, but had at day two (12.8%). Similarly comparing, day two and the six week levels of reported overall improvement, 13.3% who had reported improvement at day two fell below the improvement threshold at six weeks, however 21.9% were improved at six weeks but had not reached this threshold at day two.

The regression analysis investigating predictors of global improvement produced a poor fitting model, explaining only 7.2% of the variance of global improvement and is available on request.

At day one, the mean satisfaction rating was 5.51 (95% CI 4.70 to 5.50) on the seven point

Table 4.56: Number of patients who report at least much improvement in their overall symptoms: comparing day one and day two after treatment.

| | | Number of patients improved at Day 2 (% of 1,921) | | |
|---|-----|---|------------|--------------|
| | | yes | no | Total |
| Number of patients improved at Day 1 (% of 1,921) | yes | 752 (39.1) | 143 (7.4) | 1,026 (53.4) |
| | no | 246 (12.8) | 780 (40.6) | 895 (46.6) |
| Total | | 998 (52.0) | 923(48.0) | 1,921 |

$\chi^2=690.45$, $p<0.001$

Table 4.57: Number of patients who report at least much improvement in their overall symptoms: comparing day two and week 6 after treatment.

| | | Number of patients improved at 6 weeks (% of 1,305) | | |
|---|-----|---|------------|------------|
| | | yes | no | Total |
| Number of patients improved at Day 2 (% of 1,305) | yes | 511 (39.2) | 174 (13.3) | 685 (52.5) |
| | no | 286 (21.9) | 334 (25.6) | 620 (47.5) |
| Total | | 797 (61.1) | 508 (38.9) | 1,305 |

$\chi^2=110.95$, $p<0.001$

(0 to 6) NRS scale, at day two it was 5.46 (5.415 to 5.50), and at six weeks it was 5.40 (5.35 to 5.46); the change between baseline and six weeks was -0.14 (-0.19 to -0.09) (SD=0.03), or a standardised effect size of -0.14 (*i.e.* small).

Patients reported high levels of satisfaction. Out of 1,982 at day one 1,341 (67.7%) reported the highest level of satisfaction (6 on a seven point scale from 0 - 6). This high level of satisfaction was consistent at each time point. Out of 1,966 patients, at day two, 1,290 (65.6%) patients had a score of 6. At six weeks of 1,364 patients, 852 (62.5%) also had a score of six. Taking the two highest points (scores 5 and 6) on the seven point scale, 85.5% of patients were highly satisfied at six weeks. Very few patients reported being dissatisfied. Including all scores below the mid point of the scale, only 1.7% reported being dissatisfied at six weeks (n=23).

The regression analyses investigating predictors of satisfaction produced poorly fitting models, explaining only 7.5% and 2.2% of the variance of satisfaction respectively. This is likely to be due to the highly positively skewed distribution of the satisfaction data. The models are available on request.

4.12.1.5 Changes in health status EuroQol

At baseline, mean EuroQol score was 0.673 (95% CI 0.662 to 0.684), and at six weeks it had risen to 0.802 (0.792 to 0.811); a change of 0.114 (0.102 to 0.126) (SD=0.218), or a standardised effect size of 0.52 (*i.e.* medium).

Table 4.58 shows the regression model exploring the factors that predict change in the health status of patients on the EQ5D. The model explained 13.0% of the variance and included 865 observations.

Five variables were predictive of health status. Age predicted health status change. Increasing age by ten years is predictive of a lower EQ5D score by 0.02 ($p = 0.009$). The area of complaint also influenced the EQ5D outcome, where a patient presenting with back/hip symptoms/pain will have a larger improvement in health status by 0.05 on the EQ5D scale ($p = 0.002$) compared with head/shoulder symptoms/pain. Higher baseline pain intensity and troublesomeness predicts improvement in the EQ5D by 0.03 points ($p < 0.001$). Patients presenting with a new episode of symptoms/pain predicted better improvement in health status by 0.04 on the EQ5D scale ($p = 0.009$). Work status during treatment predicted change in health status at six weeks; taking time off work predicted a better change in health status compared to those who were not taking time off work by 0.08 points ($p = 0.009$). All the significant predictor variables related to patient characteristics. The three variables in the model which related to the treatment given to patients by osteopaths were not significant and did not predict health status change.

4.12.2 Patient deterioration

4.12.2.1 Increase in main complaint intensity of symptoms/pain

We conceptualised an increase of symptoms/pain by 30% on the eleven point NRS scale as indicating a minor to moderate adverse event, as has been reported elsewhere.⁶²

Out of 1,949 patients observed at day one, 361 (18.5%) experienced a 30% increase in their main symptoms/pain. At day two, out of the 1,929 observed patients; 235 (12.2%) and after six weeks 189 (14.2%) of 1,332 observed patients had an increase of 30%. Out of the 280 patients who had an increase in their current symptoms/pain by 30% in the first 48 hours and were observed at six weeks, 96 (34.3%) still had an increase of at least 30% in intensity compared with their baseline score at six weeks. Of the 1,022 patients who did not increase in their symptoms/pain intensity by 30% within 48 hours, 88 patients (8.6%) showed an increase at six weeks. Out of the 280 patients who had an increase in their current symptoms/pain by 30% in the first 48 hours and were observed at six weeks, 117 (41.8%) showed at least 30% decrease in

Table 4.58: Change in health status (EQ-5D) at 6 weeks

| Explanatory variable | β | SE | 95% CI | p-value |
|---|---------|-----------|--------------------|----------------|
| Age | -0.002 | 0.001 | -0.0033 to -0.0004 | 0.009 |
| Gender (Effect of male) | -0.023 | 0.015 | -0.052 to 0.006 | 0.125 |
| Presenting area (Effect of back/hips vs head/shoulder) | 0.046 | 0.015 | 0.017 to 0.074 | 0.002 |
| Presenting area (Effect of extremity vs head/shoulder) | -0.001 | 0.024 | -0.049 to 0.046 | 0.956 |
| Episode duration (Effect of more than 3 months) | -0.028 | 0.015 | -0.057 to 0.001 | 0.058 |
| Number of pain sites | -0.002 | 0.004 | -0.010 to 0.006 | 0.670 |
| Baseline intensity and troublesomeness | 0.029 | 0.004 | 0.021 to 0.037 | <0.001 |
| Practitioner used HVT | 0.001 | 0.014 | -0.027 to 0.029 | 0.960 |
| Practitioner used cranial osteopathic/IVM | -0.001 | 0.015 | -0.031 to 0.028 | 0.928 |
| Practitioner used dry-needling/acupuncture | 0.010 | 0.038 | -0.064 to 0.084 | 0.791 |
| Presence of comorbidities | -0.011 | 0.015 | -0.040 to 0.017 | 0.446 |
| First treatment for current symptom | 0.041 | 0.016 | 0.010 to 0.073 | 0.009 |
| Current ability to work (Effect of not off work vs off work) | -0.076 | 0.029 | -0.132 to -0.019 | 0.009 |
| Current ability to work (Effect of not applicable vs off work) | -0.052 | 0.033 | -0.116 to 0.012 | 0.109 |

$F^{(14,850)}=9.06, p<0.001$

intensity compared with their baseline score at six weeks. As part of our sensitivity analyses, we also examined an increase in symptoms/pain using an absolute increase of symptoms/pain by two point on the 0 to 11 NRS scale as a threshold. At day one, 12.2% of patients had an increase in symptoms/pain, at day two 6.3%, and at six weeks 9.3% of patients met the threshold.

An increase in symptoms/pain is associated with having a low level of symptoms/pain at baseline. Table 4.59 shows that low scoring symptoms/pain intensity patients at baseline (3 and under on NRS) account for 79.5% of those getting a 30% increase at day one. Similarly at day two, 78.7% of patients at or below three points at baseline account for the majority of those with an increase in symptoms/pain. At six weeks, 87.8% of those with increase of 30% were in the low group at baseline.

Table 4.59: Number of patients who experience increase in current intensity of their main symptom by at least 30%. Number of patients is presented at each follow-up point by baseline symptoms/pain intensity

| Pain score at Baseline | n at Baseline (% of total 2,039) | Number of patients (% of baseline) | | | |
|-------------------------------------|-------------------------------------|------------------------------------|------------|------------|------------|
| | | Day 1 | Day 2 | 6 weeks | |
| no symptoms/ pain | 0 | 108 (5.3) | 63 (58.3) | 50 (46.3) | 37 (34.3) |
| | 1 | 178 (8.7) | 74 (41.6) | 46 (25.8) | 38 (21.4) |
| | 2 | 242 (11.9) | 73 (30.2) | 50 (20.7) | 44 (18.2) |
| | 3 | 325 (15.9) | 77 (23.7) | 39 (12.0) | 47 (14.5) |
| | 4 | 263 (12.9) | 31 (11.8) | 16 (6.1) | 14 (5.3) |
| | 5 | 242 (11.9) | 32 (13.2) | 22 (9.1) | 5 (2.1) |
| | 6 | 182 (8.9) | 11 (6.0) | 12 (6.7) | 4 (2.2) |
| | 7 | 208 (10.2) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | 8 | 166 (8.1) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| worst | 9 | 62 (3.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| symptoms/pain | 10 | 22 (1.1) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| score missing (% of total 2,039) | | 41 (2.0) | 90 (2.4) | 110 (3.4) | 707 (32.7) |
| Total (% of observed) | | 1,998 | 361 (18.5) | 235 (12.2) | 189 (14.2) |

Table 4.60 shows the results in patients' ratings of symptoms/pain intensity over four weeks with respect to average intensity of symptoms/pain judged over the previous four weeks at baseline and at six week follow up. It also includes results of patients' judgement of intensity of their main symptoms/pain at day one and day two since treatment. These results are similar to those above, in that they show a peak in incidence of an increase in symptoms/pain greater than 30% at day one following treatment. However, overall the proportion of patients reporting such an increase is smaller. At all three post treatment assessments, two thirds of all patients

with an increase of at least 30% were in the low categories of pain at baseline (0-3 score on the NRS).

Table 4.60: Number of patients who experience increase in average intensity of their main symptom by at least 30%. Number of patients is presented at each follow-up point by baseline symptoms/pain intensity

| Pain score at Baseline | n at Baseline (% of total 2,039) | Number of patients (% of baseline) | | | |
|-------------------------------------|-------------------------------------|------------------------------------|------------|-----------|------------|
| | | Day 1 | Day 2 | 6 weeks | |
| no symptoms/ pain | 0 | 44 (2.16) | 33 (75.0) | 30 (68.2) | 23 (52.3) |
| | 1 | 53 (2.60) | 20 (37.7) | 12 (22.6) | 12 (22.6) |
| | 2 | 111 (5.44) | 35 (31.5) | 24 (21.6) | 22 (19.8) |
| | 3 | 210 (10.30) | 51 (24.3) | 30 (14.3) | 32 (15.2) |
| | 4 | 234 (11.48) | 19 (8.1) | 13 (5.6) | 12 (5.1) |
| | 5 | 276 (13.54) | 37 (13.4) | 20 (7.3) | 17 (6.2) |
| | 6 | 278 (13.63) | 16 (5.8) | 12 (4.3) | 10 (3.6) |
| | 7 | 313 (15.35) | 0 (0.0) | 0 (0.0) | 1 (0.3) |
| | 8 | 286 (14.03) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| worst symptoms/pain | 9 | 100 (4.90) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | 10 | 90 (4.41) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| score missing (% of total 2,039) | | 44 (2.2) | 100 (4.9) | 124 (6.1) | 714 (35.0) |
| Total (% of observed) | | 1,995 | 211 (10.9) | 141 (7.4) | 129 (9.7) |

Of the several regression models which were run to explore the predictors of a 30% increase in symptoms/pain, only one was sufficiently predictive to report. Table 4.61 shows the regression model exploring the factors that predict 30% increase in current symptoms/pain intensity from baseline to six weeks. The model explained 11.2% of the variance and included 754 observations.

Three variables were predictive of an increase in current symptoms/pain. For each additional pain site reported as at least moderately troublesome there is a 15.5% higher chance of increasing symptoms/pain by 30% on the eleven point NRS scale ($p = 0.035$). Higher baseline pain intensity and troublesomeness predicts increase in symptoms/pain. There was a 42.1% lower chance of an increase in symptoms/pain associated with an increase of one point on the composites baseline score for intensity and troublesomeness ($p < 0.001$). Patients who reported visiting their GP within the last six months were 79.9% more likely to have an increase in symptoms/pain by 30% ($p = 0.030$). The model fits with the descriptive results and supports the findings described above. It is notable that site of presentation and the osteopathic intervention variables were not predictive of an increase in the intensity of the main symptoms/pain.

Table 4.61: Modelling 30% increase in main symptoms after six weeks

| Explanatory variable | odds ratio | SE | 95% CI | p-value |
|---|-------------------|-----------|----------------|----------------|
| Age | 0.999 | 0.009 | 0.982 to 1.018 | 0.955 |
| Gender (Effect of male) | 1.347 | 0.343 | 0.817 to 2.219 | 0.243 |
| Presenting area (Effect of back/hips vs head/shoulder) | 1.042 | 0.260 | 0.639 to 1.700 | 0.869 |
| Presenting area (Effect of extremity vs head/shoulder) | 0.669 | 0.328 | 0.257 to 1.747 | 0.412 |
| Episode duration (Effect of more than 3 months) | 0.947 | 0.253 | 0.562 to 1.598 | 0.840 |
| Number of pain sites | 1.155 | 0.079 | 1.010 to 1.320 | 0.035 |
| Baseline intensity and troublesomeness | 0.579 | 0.046 | 0.495 to 0.678 | <0.001 |
| Symptoms of flu | 1.300 | 0.328 | 0.793 to 2.131 | 0.299 |
| Practitioner used HVT | 0.775 | 0.191 | 0.478 to 1.260 | 0.303 |
| Practitioner used cranial osteopathic/IVM | 0.857 | 0.214 | 0.525 to 1.399 | 0.538 |
| Practitioner used dry-needling/acupuncture | 1.207 | 0.806 | 0.326 to 4.467 | 0.778 |
| Patient visited GP in last 6 months | 1.799 | 0.485 | 1.060 to 3.053 | 0.030 |
| Information (0...none given, 4...all given) | 0.997 | 0.094 | 0.828 to 1.200 | 0.977 |
| Permission (0...none asked, 4...all asked) | 0.912 | 0.071 | 0.782 to 1.062 | 0.235 |

$\chi^2=66.57$, $p<0.001$, Area under the ROC curve = 0.7423

4.12.2.2 Increase in main complaint troublesomeness of symptoms/pain

Patients reported the extent of troublesomeness their main area of symptoms/ pain was causing on a 6 point scale from “No symptoms/pain” experienced to “Extremely troublesome”. Out of the 1,985 patients observed at baseline 34.8% fell into the highest two categories. At six weeks the proportion was lower at 9.3% (n = 124) out of 1,329 patients completing the item.

Applying a threshold of a 30% increase on the 6 point scale shows that low levels of increase in troublesomeness are present in the sample. These data follow the pattern seen in the intensity outcomes, where lower levels of troublesomeness on the scale account for the largest proportion of those meeting the 30% threshold. However, there is a ceiling effect that applies to the scale which may limit the ability to discriminate and identify those at the highest end of the scale at baseline who deteriorate further. Table 4.62 presents the results of patients experiencing a 30% increase in troublesomeness by baseline score. At day one 4.6%, at day two 3.0% and at six weeks 5.6% of the patients observed had experienced a 30% increase from baseline in troublesomeness.

Table 4.62: Number of patients who experienced increase in average troublesomeness of their main symptom by at least 30%. Number of patients is presented at each follow-up point by baseline symptoms/pain troublesomeness

| Troublesomeness at Baseline | n at Baseline (% of total 2,039) | Number of patients (% of baseline) | | |
|----------------------------------|----------------------------------|------------------------------------|-----------|------------|
| | | Day 1 | Day 2 | 6 weeks |
| no symptoms/pain | 26 (1.3) | 17 (65.4) | 17(65.4) | 10 (38.5) |
| not at all troublesome | 68 (3.3) | 27 (39.7) | 20 (29.4) | 21 (30.9) |
| slightly troublesome | 374 (18.3) | 39 (10.4) | 18 (4.8) | 39 (10.4) |
| moderately troublesome | 826 (40.5) | 4 (0.5) | 2 (0.2) | 3 (0.4) |
| very troublesome | 556 (27.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| extremely troublesome | 135 (6.6) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| score missing (% of total 2,039) | 54 (2.7) | 134 (6.6) | 121 (5.9) | 738 (36.2) |
| Total (% of observed) | 1,985 | 87 (4.6) | 57 (3.0) | 73 (5.6) |

4.12.3 Changes in additional areas to the main complaint and other non-musculoskeletal symptoms

4.12.3.1 Changes in symptoms/pain troublesomeness in other areas of the body

There were low levels of increase in troublesomeness by greater than 30% on the 6 point scale across all time points. Where increases occurred these tended to be highest from baseline to six

weeks but below 10% of patients except for in the wrist/hand area (10.7%, $n = 110$). All areas of the body were similar in the proportions of the respondents who reported an increase. This suggests that no particular area was more vulnerable to an increase in troublesomeness. The face and chest areas had the lowest proportion of patients decreasing troublesomeness (approximately 8% to 11%). The lower and upper back regions showed the largest proportion of patients with a decrease in troublesomeness (28% to 38%).

Table 4.63 show the increase and decrease scores by 30% thresholds for all areas and time points.

4.12.3.2 Changes in intensity and frequency of other non-musculoskeletal symptoms

There were low numbers of patients who had an increase in intensity of non-musculoskeletal symptoms across all categories at day one and day two using the threshold of a 30% change on the eleven point scale. These data shortly post treatment suggest that there is a lower level of increase in symptoms post treatment compared with the longer term follow up at six weeks. At six weeks the proportion of patients reporting a 30% increase in intensity of fatigue, dizziness and headaches rises to above 10%. The proportion of patients with decreases in the intensity of all symptoms was larger in all cases than increases at each time point. In the majority of cases this was by a factor of at least 2. Table 4.64 shows the distribution of increases and decreases in symptom intensity by 30% from baseline at day one, day two and at six weeks. Fatigue and headaches show the largest proportion of change, both for increase and decreases in symptom intensity.

Table 4.65 reports the numbers and proportions of patients having a 30% increase or decrease in the frequency of non-musculoskeletal symptoms over the last two-week period by baseline and six weeks. This shows a similar pattern to the intensity results.

Regression analyses were used to explore which factors predicted a 30% increase in intensity of non-musculoskeletal symptoms or the appearance of such a symptom of an intensity of at least 2 on the eleven point scale. These models are available on request. Variables entered into the model were not good predictors of intensity or production of new symptoms.

4.12.4 Healthcare utilisation, impact on ability to work and use of osteopathy for the main complaint at six weeks

Of the 1,352 patients who completed the question concerning the number of treatments that they had received since their baseline appointments six weeks ago, 35% had not been for further

Table 4.63: Number of patients who experience increase or decrease in current troublesomeness in other areas of the body by at least 30%. Number of patients observed and how many improve or worsen is presented for each follow-up point

| Area of the body | Number of patients whose symptom/pain changed by at least 30% from baseline to: | | | | | | | | | | | |
|------------------|---|------------|------------|-------------------|----------|-------------|---------------------|------------|------------|--|--|--|
| | Day 1 (% of n) | | | Day 2 (% of n) | | | 6 weeks (% of n) | | | | | |
| | n | increase | decrease | n | increase | decrease | n | increase | decrease | | | |
| Head | 1,484 | 101 (6.8) | 236 (15.9) | 1,517 | 63 (4.2) | 283 (18.7) | 1,034 | 80 (7.7) | 196 (19.0) | | | |
| Face | 1,409 | 63 (4.5) | 113 (8.0) | 1,462 | 57 (3.9) | 141 (9.6) | 988 | 55 (5.6) | 97 (9.8) | | | |
| Neck | 1,644 | 103 (6.3) | 478 (29.1) | 1,659 | 67 (4.0) | 627 (37.8) | 1,141 | 85 (7.5) | 359 (31.5) | | | |
| Shoulder | 1,562 | 86 (5.5) | 432 (27.7) | 1,584 | 43 (2.7) | 571 (36.1) | 1,062 | 94 (8.9) | 336 (31.6) | | | |
| Elbow | 1,444 | 53 (3.7) | 176 (12.2) | 1,486 | 39 (2.6) | 228 (15.3) | 1,014 | 58 (5.7) | 130 (12.8) | | | |
| Wrist/hand | 1,461 | 59 (4.0) | 222 (15.2) | 1,511 | 45 (3.0) | 294 (19.5) | 1,024 | 110 (10.7) | 159 (15.5) | | | |
| Chest | 1,433 | 55 (3.8) | 132 (9.2) | 1,483 | 39 (2.6) | 155 (10.5) | 1,012 | 64 (6.3) | 94 (9.3) | | | |
| Abdomen | 1,419 | 57 (4.0) | 142 (10.0) | 1,463 | 42 (2.9) | 168 (11.56) | 999 | 72 (7.2) | 100 (10.0) | | | |
| Upper back | 1,453 | 124 (8.5) | 402 (27.7) | 1,486 | 84 (5.7) | 510 (34.3) | 1,023 | 62 (6.1) | 359 (35.1) | | | |
| Lower back | 1,676 | 111 (6.6) | 466 (27.8) | 1,699 | 78 (4.6) | 644 (37.9) | 1,157 | 106 (9.2) | 401 (34.7) | | | |
| Hip/thigh | 1,525 | 111 (7.30) | 339 (22.2) | 1,557 | 64 (4.1) | 439 (28.2) | 1,055 | 96 (9.1) | 294 (27.9) | | | |
| Knee | 1,466 | 93 (6.3) | 305 (20.8) | 1,510 | 55 (3.6) | 390 (25.8) | 1,032 | 95 (9.2) | 246 (23.8) | | | |
| Ankle/Foot | 1,481 | 75 (5.1) | 266 (18.0) | 1,523 | 62 (4.1) | 328 (21.5) | 1,041 | 93 (8.9) | 209 (20.1) | | | |
| Other | 1,128 | 37 (3.3) | 68 (6.0) | 1,192 | 34 (2.9) | 91 (7.6) | 791 | 46 (5.8) | 73 (9.2) | | | |

Table 4.64: Number of patients who experience increase or decrease in non-musculoskeletal symptom intensity over time by at least 30%. Number of patients observed and how many improve or worsen is presented for each follow-up point

| Symptom | Number of patients whose symptoms change by at least 30% from baseline to: | | | | | | | | | | | |
|----------------------------------|--|-----------|------------|----------------|----------|------------|------------------|------------|------------|------------------|------------|------------|
| | Day 1 (% of n) | | | Day 2 (% of n) | | | 6 weeks (% of n) | | | 6 weeks (% of n) | | |
| | n | increase | decrease | n | increase | decrease | n | increase | decrease | n | increase | decrease |
| Fatigue/sleepiness | 1,855 | 144 (7.8) | 826 (44.5) | 1,846 | 96 (5.2) | 943 (51.1) | 1,290 | 169 (13.1) | 579 (44.9) | 1,244 | 128 (10.3) | 301 (24.2) |
| Dizziness/light headedness | 1,780 | 58 (3.3) | 470 (26.4) | 1,779 | 51 (2.9) | 483 (27.2) | 1,239 | 80 (6.5) | 161 (13.0) | 1,225 | 26 (2.1) | 32 (2.6) |
| Nausea | 1,780 | 36 (2.0) | 251 (14.1) | 1,783 | 28 (1.6) | 259 (14.5) | 1,261 | 183 (14.5) | 430 (34.1) | 1,239 | 87 (7.0) | 159 (12.8) |
| Vomiting | 1,767 | 10 (0.6) | 45 (2.6) | 1,766 | 11 (0.6) | 48 (2.7) | 1,228 | 36 (2.9) | 93 (7.6) | 1,242 | 118 (9.5) | 260 (20.9) |
| Headaches | 1,817 | 70 (3.9) | 763 (42.0) | 1,813 | 51 (2.8) | 804 (44.4) | 1,243 | 111 (8.9) | 255 (20.5) | 1,235 | 52 (4.2) | 148 (12.0) |
| ringing in the ears | 1,785 | 41 (2.3) | 249 (14.0) | 1,784 | 47 (2.6) | 246 (13.8) | 1,232 | 61 (5.0) | 81 (6.6) | 1,234 | 121 (9.8) | 262 (21.2) |
| Confusion/disorientation | 1,772 | 24 (1.4) | 154 (8.7) | 1,774 | 24 (1.4) | 155 (8.7) | 1,241 | 108 (8.7) | 206 (16.6) | 1,241 | 108 (8.7) | 206 (16.6) |
| Fear/anxiety | 1,788 | 42 (2.4) | 441 (24.7) | 1,789 | 38 (2.1) | 469 (26.2) | 1,242 | 118 (9.5) | 260 (20.9) | 1,242 | 118 (9.5) | 260 (20.9) |
| Depression | 1,794 | 31 (1.7) | 418 (23.3) | 1,789 | 32 (1.8) | 425 (23.8) | 1,243 | 111 (8.9) | 255 (20.5) | 1,243 | 111 (8.9) | 255 (20.5) |
| Bruising | 1,770 | 40 (2.3) | 219 (12.4) | 1,775 | 39 (2.2) | 230 (13.0) | 1,235 | 52 (4.2) | 148 (12.0) | 1,235 | 52 (4.2) | 148 (12.0) |
| Skin rash | 1,775 | 18 (1.0) | 135 (7.6) | 1,775 | 20 (1.1) | 153 (8.6) | 1,232 | 61 (5.0) | 81 (6.6) | 1,232 | 61 (5.0) | 81 (6.6) |
| Numbness/tingling: arms/hands | 1,796 | 47 (2.6) | 435 (24.2) | 1,793 | 50 (2.8) | 458 (25.5) | 1,234 | 121 (9.8) | 262 (21.2) | 1,234 | 121 (9.8) | 262 (21.2) |
| legs/feet | 1,801 | 66 (3.7) | 327 (18.2) | 1,793 | 52 (2.9) | 363 (20.3) | 1,241 | 108 (8.7) | 206 (16.6) | 1,241 | 108 (8.7) | 206 (16.6) |

Day one and Day two are intensity since treatment. Baseline and six weeks are intensity over the last four weeks

Table 4.65: Number of patients who experienced increase or decrease in non-musculoskeletal symptom frequency over the last two weeks by at least 30%.

| Symptom | Number of patients with 30% change from baseline to six weeks | | |
|----------------------------|---|-------------------|-------------------|
| | n | increase (% of n) | decrease (% of n) |
| Fatigue/sleepiness | 1,279 | 174 (13.6) | 576 (45.0) |
| Dizziness/light headedness | 1,227 | 109 (8.9) | 279 (22.7) |
| Nausea | 1,239 | 74 (6.0) | 150 (12.1) |
| Vomiting | 1,226 | 19 (1.6) | 34 (2.8) |
| Headaches | 1,251 | 177 (14.2) | 422 (33.7) |
| ringing in the ears | 1,240 | 74 (6.0) | 156 (12.6) |
| Confusion/disorientation | 1,232 | 31 (2.5) | 88 (7.1) |
| Fear/anxiety | 1,244 | 118 (9.5) | 250 (20.1) |
| Depression | 1,247 | 110 (8.8) | 231 (18.5) |
| Bruising | 1,234 | 51 (4.1) | 138 (11.2) |
| Skin rash | 1,237 | 55 (4.5) | 76 (6.1) |
| Numbness/tingeling: | | | |
| arms/hands | 1,248 | 117 (9.4) | 269 (21.6) |
| legs/feet | 1,238 | 97 (7.8) | 216 (17.5) |

treatment ($n = 470$). Those who had received between one and three treatments made up a further 52.2% of responses. Figure 4.41 shows a histogram of the distribution of the number of appointments received since the baseline measurement (*i.e.* additional to the initial consultation).

At baseline, 45.5% had seen another practitioner concerning their main complaint. At six weeks, of the 1,348 who responded, only 14.4% had consulted another practitioner since their treatment six weeks previously.

Of the 1,333 participants who answered the question concerning time off work at six weeks, there was a small fall from the baseline figure of 7.2% to 5.5%, suggesting some patients were able to return to work within the time period. The median number of days off sick since the initial appointment was 2 (IQR 0 to 30). Of those who took time off work ($n = 33$), 18 reported being off work for four weeks or longer.

There was a fall in analgesic medication use from baseline to six weeks. Table 4.66 shows the use of analgesic medications by respondents at baseline and at six weeks, along with the percentage change.



Figure 4.41: Subsequent treatment visits to initial consultation - The figure shows the distribution of the number of subsequent treatment visits to the initial consultation

Table 4.66: Change in use of painkillers from baseline to six weeks

| Painkillers | Baseline | | 6 weeks | | Percentage change |
|-------------|------------------|--------------|------------------|------------|-------------------|
| | No. of responses | Freq (%) | No. of responses | Freq (%) | |
| overall | 1,914 | 1,365 (71.3) | 1,339 | 568 (42.4) | -28.9% |
| mild | 2,019 | 758 (37.5) | 1,373 | 272 (19.8) | -17.7% |
| moderate | 2,019 | 433 (21.5) | 1,373 | 190 (13.8) | -7.7% |
| strong | 2,019 | 76 (3.8) | 1,373 | 19 (1.4) | -2.4% |
| NSAID | 2,019 | 775 (38.4) | 1,373 | 282 (20.5) | -17.9% |

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4.13.1 Practitioner description of common treatment reactions - Interview data

For the purposes of this analysis a “common treatment reaction” was defined as a recognisable patient experience associated with osteopathic treatment and/or management that was not considered by the practitioner as unusual. A common treatment reaction may be interpreted by the patient or practitioner as adverse but not serious, as these reactions may not be immediately associated with patient therapeutic benefit.

Practitioners were invited to reflect on their recent clinical experiences and in particular on the patient response to their osteopathic treatment. The osteopaths were asked to report the types of common treatment reactions that they had seen on a regular basis.

A number of substantive themes emerged from these data, with practitioners describing a range of common reactions associated with a spectrum of osteopathic techniques. However, some clinicians had difficulty in distinguishing “common treatment reactions” from the generally positive patient experiences after osteopathic treatment.

Practitioners reported that common treatment reactions were not unusual, that they were frequently evident during and often shortly after osteopathic treatment and were of short duration.

4.13.1.1 Theme 1: General descriptions of common treatment reactions

Common treatment reactions frequently occurred locally to the site of the osteopathic treatment. They were felt to be manageable by the osteopathic practitioner without the need for referral and were generally associated with medium and long-term positive patient outcomes. A range of reactions were selected for description by osteopaths, including headache, lightheadedness, flu-like symptoms, emotional reactions and fatigue. Increased pain or soreness was most commonly described by practitioners. A number of quotations from practitioners are reproduced below to illustrate types of common treatment reactions.

“if I’m you know doing a reasonable amount of work say in the neck that it’s possible that they might have a headache” (1028)

“one thing that I would say were commonly seen is a little bit of lightheadedness after a treatment where, whether it’s been structural or cranial or acupuncture, after lying down, and

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even with, given a couple of minutes to come round, a patient might say they just feel a little bit spacy or a little bit lightheaded when they sit up.” (1179)

“oh there can be sort of flu-like um symptoms sometimes.” (1382)

“other people just feel better straightaway and they feel better all the time, or they might just feel grotty for a few hours, bit like going to the dentist, you know, when the, you know, when the local anaesthetic wears off it feels a bit bruised.” (1815)

“the first question I ask is how are you and how were you after treatment, and it's very rare I get anything else apart from yeah I was sore after treatment.” (2069)

“they'll often swear at me, call me, question my parentage and erm or, and then they'll burst out laughing er and be profusely apologetic because what I'd done to them hadn't hurt them but they'd just, it just brought about an emotional outburst which, that sometimes happens as a reaction.” (2146)

“sometimes they feel very tired, erm, sometimes they report feeling energized but I would say on the whole probably more people talk of feeling very tired and relaxed and er say they want to go to bed and have a kip rather than go back to work, erm, in sort of subsequent days in terms of reactions, erm probably those first couple of days is the more consistent thing, where people might say yeah, I felt a bit battered and bruised and er I'm a bit stiff and achy and I often find that is more common in the first one or two sessions than in subsequent er sessions, erm” (2146)

“and when you ask the following time she says oh it was a bit sore for 24 hours but then it feels much better, and I suppose that's what I often see in clinic.” (3849)

4.13.1.2 Theme 2: The incidence of common treatment reactions

Practitioners estimated the incidence of common treatment reactions based on their recollection and experience. The incidence was commonly estimated at between 30% and 50% of patient encounters for increases in short-term pain or soreness and was perceived as being more commonly occurring in patients who were new to osteopathic treatment. Other reactions such as

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lightheadedness or fatigue were less common and practitioners tended not to summarise their frequency, preferring to describe them as less common or occasional.

“I would say off the top of my head, and I tell this to all patients as well, I'd say about 50% of the people I see would get what I call a treatment reaction, and that means they notice erm an increase of their symptoms, often it's the day after though, so whatever they've come with, say they've come with a low back pain, they might walk out feeling, you know, noticeably improved erm, but a few hours later, and more often the day after, their symptoms will have got slightly worse, but only in about 50% of my patients off the top of my head” (1773)

“I think you know, very occasionally I mean really probably one or two a year, if I've worked on someone's neck they feel a bit lightheaded perhaps, bit of vertigo and you know slight nausea.” (1773)

4.13.1.3 Theme 3: The timing and duration of common treatment reactions

Practitioners described reactions that normally arose directly after or within 48 hours of treatment.

“it's the sort of you know day or two post-treatment erm you know ache, discomfort, um that people quite regularly report” (1028)

“Well I think almost everybody erm feels a little bashed about the next morning, a little bruised or a little sore after treatment the next morning, sometimes um if they're treated in the morning they'll feel that in the evening.” (4813)

These types of symptoms typically lasted for one to two days.

“I very, very, very rarely have patients who experience symptoms outside of that 48 hours, sorry an aggravation or a worsening of symptoms outside of that 48 hours” (2069)

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4.13.1.4 Theme 4: Positive patient outcomes associated with common treatment reactions

Practitioners tended to construe of common treatment reactions as part of a process leading towards eventual benefit for the patient. Reactions were implied to be part of the process of therapeutic benefit. Some practitioners were unable to give examples of common treatment reactions that had any connotation of negativity for the patient.

“No, it’s purely improvement, I haven’t had bad reactions, not recently. It’s usually, to be perfectly honest, the patient feels better, symptoms reduce, pain reduces, and they come back for a second treatment.” (3060)

More commonly, practitioners tended to describe an initial reaction followed by improvement.

“quite often patients feel worse after treatment for 24 hours before they start to improve, um that’s probably the most common.” (4562)

“you know the next morning, then they started to feel better and then they seemed to get quite a bit better on the whole” (4569)

4.13.2 Practitioners' explanations of common treatment reactions - Interview data

Practitioners were asked to select a specific example of a common treatment reaction and relate their understandings of why it had occurred. The data revealed that osteopathic practitioners have a variety of distinctive individual explanatory models within which they conceptualise the role of osteopathic treatment and healthcare in the restoration and maintenance of patient well-being. These models informed their interpretation of the mechanisms by which common treatment reactions occur. The underlying and often overlapping constructs that practitioners described included structural and mechanical conceptualisations, models based on physiological and psychological principles and a variety of fluid or energy theories. The individual practitioner explanations of common treatment reactions revealed in the data are, in each case, congruent with the individual and specific model of osteopathic healthcare endorsed by each practitioner. Some practitioners also acknowledged their uncertainty and found it difficult to articulate reasons why common treatment reactions occur.

4.13.2.1 Theme 1: Uncertainty of aetiology of common treatment reactions

A number of practitioners expressed uncertainty about the origin of common treatment reactions. Some described difficulties defining common treatment reactions and the difficulties of predicting reactions where a similar treatment has different outcomes for no clear apparent reason.

“I am not entirely sure why people get a worsening of the symptoms.” (2609)

“I don't think you can account for that, I honestly don't think you can account for the unexpected, if I do a treatment on similar conditions on similar people and 99 times out of a hundred people have, you know the 24 hours ache and then they get better, the one person that has the hyper-reaction and ends up in hospital I don't think you can account for” (2810)

4.13.2.2 Theme 2: Physiological explanations of common treatment reactions

Physiological explanations, often associated with references to inflammatory processes or provocative local mechanical tissue stresses or trauma, were particularly evident in the explanation of common treatment reactions local to the site of manual treatment. These local common treatment reactions were frequently describes as “soreness” or “a feeling of being worked on”.

“the treatment, um er you know, soft tissue mobilisation, manipulation, all cause some you know tissue reaction, erm, some degree of inflammation, and er if that's exacerbated then yeah that's maybe when we get more problems.... When people sort of report how they felt you know yeah they're feeling sore perhaps for a day or so after treatment but it's worse you know first thing, worse after periods in the same position, so it has that sort of inflammatory pattern certainly.” (1208)

“we call DOMS, a delayed onset muscular stiffness, and my interpretation of this is that when you're doing this kind of soft tissue techniques, you're going to be, you're going to be stretching out the sarcomeres and you're going to be possibly breaking some of the cross-bridges that have formed between the muscle fibres and this is a, it's an intensely physical process, and it's a mechanical process, and I think it's like a change in the blood flow, so there might be more turgor in the muscles initially before things then go into the next phase of healing and settle down” (1179)

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Some practitioners used neurological concepts including the idea of “hypersensitivity” to explain treatment reactions.

“Some of it will be, because some of them are allodynic, so some of them will have allodynia or hyperesthesia and they will have a facilitated area which will overreact to a seemingly innocuous input, that will be part of it, the other part of it will be, you know sometimes a cigar is just a cigar, sometimes by pushing our thumb in we actually make the problem worse before it gets better, it's the reaction we're after, hopefully, the long-term reaction, so we take them back through that acute pathway and then we shove them down another pathway, which will be the repair and recovery” (2810)

“Erm, I think, the way I would understand it is that working on muscles which have been shortened, they are already sensitised because of the possible slight ischemia of the muscles because they have been tight, blood doesn't flow as well, and therefore when one works firmly on a muscle which is already sensitive, the free nerve endings are going to react more and more rapidly and that causes discomfort, presumably it also has an ongoing tissue effect, for it to be 24 hours or so, there is some physical tissue effect locally which then, because the nerves are sensitised, they will feel it for longer” (4711)

4.13.2.3 Theme 4: Explanations of non-musculoskeletal common treatment reactions

Non-musculoskeletal symptoms such as tiredness were sometimes explained in terms of psychological factors such as the dissipation of stress or by reference to a variety of other models, including those describing energy transfers or releases.

“sometimes that armour is there for a good reason and I've found that to, I've had experiences of that um in terms of treatment reaction, that's something that's informed my practice really, looking at it in terms of the psychological body armouring that we can carry” (2416)

“I often tell my patients, particularly if they're very acute when they come in, that if we've been able to release a lot they will probably go home and want to sleep, and I suggest that they do sleep and let the treatment work through their body, erm, because it just releases the energy,

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erm, so there's that, there's the general aches and pains..." (1185)

In one instance, the elimination of toxins was cited as the reason for post-treatment skin eruptions.

"These complaints can easily be explained. Nausea is due to usually to the liver having to cope with extra toxins draining via the lymphatic drainage to the blood, that is why we advise, we may advise people to take milk thistle extract and drinking plenty of water. We also tell them to take ginger sometimes as well, to help the liver.... Another unpleasant symptom when the drainage is being improved is the appearance of spots, boils and other skin eruptions. Until the lymphatic channels are properly working, the toxins have to go somewhere and their quickest way out is often through the skin." (3689)

4.13.2.4 Theme 5: Method and intensity of treatment

Several practitioners reflected on their role in causing common treatment reactions. The methods or intensity of treatment was often mentioned as a probable reason for patients having increased pain or soreness after treatment. Practitioners felt that they may have misjudged the amount of treatment an individual needed.

" Yes, it could be a combination of all of those things, I treated too long is probably a big risk, erm, I was too firm on tissues which were more reactive than I thought." (4711)

" And usually it happens because I sort of try to do too much in a session, a sort of, you know it's usually enthusiasm that does it, I should not get it, but you know it does happen every now and then" (4275)

4.13.2.5 Theme 6: Explanations of common treatment reactions referencing post treatment patient activity, lifestyle and behaviours etc.

The role of patient lifestyle, work-related and environmental factors were acknowledged as putative causative factors in common treatment reactions that often occurred sometime after the treatment intervention when the patient had left the osteopathic practice. Similarly, a failure of patients to follow the self-management or after-care advice given by the osteopathic practitioner

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was frequently cited as a reason for delayed common treatment reactions.

“He'd done that but unfortunately he was a taxi driver and was going back to work so erm I suspect that the driving position you know was just putting a fair bit of pressure on his sort of LS area, and um yeah, you know he felt quite sore and achy erm just afterwards, obviously not ideal.” (1208)

“Basically her personality, she's not the kind of person who would sit down and then get up and exercise and then resume sitting, she'd be on the go all the time doing something, rushing somewhere.” (3600)

4.13.3 The acceptability or unacceptability of common treatment reactions - Interview data

The clinicians were asked their views about what made common treatment reactions acceptable to them and their patients. Interviewed practitioners considered that common treatment reactions were not unusual and were characterised by transience. Some practitioners considered that it was the patient view rather than their professional opinion that was a significant determinant of the acceptability or unacceptability of common treatment reactions.

“ Erm, that's really put me on the spot, because my immediate reaction there is, well maybe the judge of what is acceptable is the patient, the judge of what is acceptable is the patient” (2416)

However, practitioners considered that there was considerable variation between patients in their perceptions of acceptability and unacceptability. A number of practitioners reported that some patients consider that common treatment reactions such as tissue “soreness” were a positive indication of “something being worked on”.

“ and it might have been a treatment response that someone else might have tolerated or even felt was a positive sign, because sometimes patients think, they sort of express that ‘oh I could tell it was working, I could tell that you'd done something’ ” (1719)

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Some practitioners recognised a need to take these types of views into account to provide appropriate care for the patient.

“ I think what makes a, you never know whether it's going to be acceptable or not, that shouldn't be a question for me, that should be a question for the patient, but most patients will, there are some who are in a lot of pain and say I don't care what you do, and that's not *carte blanche* for us to have a go at doing anything, it means we have to act or react more sensibly towards the patient and their needs, because they're desperate” (2180)

“ I think it shows you that some patients will endure quite a lot based on a belief that it must be good for them if so-and-so says it is, and I think therefore it does behove the practitioner to take responsibility and to go into what actually happened to the patient, not just say well as long as you're better now it doesn't matter what happened last week, sort of thing, I think it is important, I think you need to document that and chart that and make sure that your techniques are as acceptable as they can be” (4452)

There was recognition by some practitioners that patients seemed to have an implicit understanding that the process of healing was sometimes associated with a degree of unpleasantness.

“it's really how the person reacts, you know, because everyone's different, you know I think most people are relatively sanguine about that and say well I thought it would get a bit worse before it got better, sort of thing, it's almost ingrained in our culture, like you know, good medicine tastes bad or something like that” (4542)

There were variations in what the individual practitioners considered to be the determinants of acceptability or unacceptability. There was most agreement about the characteristics of unacceptable reactions. Practitioners reported that the post treatment appearance of neurological signs and symptoms, central nervous system symptoms such as changes in vision, and intense increases in pain and loss of function were unacceptable. Increases in symptoms and pain that were thought to be disproportionate to either the patient presentation or the intensity of the administered treatment were also noted as unacceptable. Significant post treatment deterioration in patient functional status was also considered to be problematic. Some practitioners also mentioned that negative psychological reactions were not acceptable.

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“... it shouldn't be something that's creating neurological symptoms, it shouldn't be something that's creating dizziness or any psychological or emotional response or problems, and it should be contained to something like this muscular stiffness that patients do commonly report” (1719)

With respect to increases in the intensity of pain, whilst practitioners tended to agree that high levels of post treatment pain was not acceptable, many practitioners used the duration of post treatment reactions as an important criterion for differentiating between unacceptable and acceptable reactions. Short-term responses between 24 and 48 hours were acceptable whereas longer-term responses were not.

“ so what would make it reasonable I suppose, I suppose that 24 hour reaction, because that's very common, and there is some research to suggest that that's a normal reaction across the board for physios, because that's where the research came from, and probably the same for us and chiropractics, but any more than that 24, 48 hours and we have to start thinking perhaps that isn't a normal reaction, perhaps that isn't um acceptable” (2180)

“ Right, well a certain amount of discomfort I think is quite acceptable, though that of course is a matter of degree, erm, unacceptable certainly neurological embarrassment, um, certainly I would say headaches that would last more than the following day,” (1361)

A small number of practitioners mentioned that the intensity and chronicity of a patient's problem also affected the acceptability of a reaction. Patients presenting with low levels of pain would not find high levels of pain post treatment acceptable, whereas patients with high pain and longer term problems were more likely to accept that post treatment reactions could be quite strong.

“ as I say if it's been a severe kind of ongoing problem I think people do accept more of a reaction or a more severe reaction perhaps um say as opposed to people with milder symptoms who maybe feel well I came in and it wasn't that bad and I've had two days now and it's really been quite sore so again just trying to manage expectations you know on what may happen.” (1208)

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The idea that acceptability was mediated by ultimate benefit for the patient was also voiced by practitioners. Short-term unpleasant reactions were acceptable if patients made sufficient progress and benefited overall from treatment.

“it’s a question of whether the overall benefit is greater than the short-term discomfort” (3526)

Patient and practitioner expectations were also an important determinant of acceptability or unacceptability. If patients, based on their previous treatment experiences or on the information given to them or obtained by them from their osteopathic practitioner or other sources, were aware that a common treatment reaction was possible or predictable then it seemed to be considered to be more acceptable than if it was unanticipated.

“a lot of people um I think are expecting soreness even before they’ve had any treatment, they often say, oh well you know, I’ve heard it normally hurts for a day or two before I start getting any better” (2416)

“so when they come in and I talk to them, and when I talk about treatment reaction I normally say to them what have you got planned for the next few days, as a pre-cursor to talking about the reaction and if they understand that they may have some kind of reaction to treatment then that for me is an acceptable reaction” (2609)

Similarly, practitioners described reactions that were surprising or unexpectedly troubling as less acceptable.

“I think the unacceptable ones are the ones I don’t expect” (1832)

Practitioners’ views that common treatment reactions were more acceptable if patients had been informed about their likelihood before rather than after the event informed their approach to managing these events.

“I’ve found that as long as people are aware erm you know what may happen and if it does happen they’re you know almost expecting it and we always tell them they can phone in, they can contact us even if I’m not in the practice patients can get in touch with me or speak to one of

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my colleagues who is in to get a bit of advice if need be if it's anything more than you know a bit achy, a bit sore or a bit tender, but I find if people are pre-warned about it it's not too much of an issue. I think probably thinking back in the past I probably, you know just having graduated, probably not as good erm communication you know with patients in that regard and you know that changed quite quickly because people would be saying well actually I felt really sore after treatment and if you tell them that beforehand you know that's ok, if you say to them afterwards, well actually that's not uncommon, you know you get a slightly different response" (1028)

4.13.4 Patients' description of benefits of treatment - Interview data

Patients were asked to describe in what ways they benefited from their osteopathic treatment. Immediate and somewhat delayed relief of pain predominated (in accordance with the survey data), while individual patients derived a number of additional different benefits from their therapeutic encounters.

"Erm, sometimes um I have gone in in agony and walked out relatively pain-free, but in general it's usually the next day and the next again day, before it eases off totally"(10791).

For some the pain relief was contextualised with a sense of acceptance of their condition.

"but there's no pain whatsoever now, um, and it's, most of the time I'm not aware of it either, you know, I just treat it as any other part of my body, you know, forget it's there most of the time"(13262).

Similarly, improvements in patients' ability to move were described:

"Oh yes, yes, nothing but benefit, umm, and you know great improvement and certainly much more flexibility umm you know in my movements and things." (10621).

Patients distinguished between improvements in local pain and function and more generalised feelings of wellbeing and global improvement.

" In fact, I really wondered sort of, you know, at one time, whether it was beneficial or not, but umm ... she really has its made such an improvement to my life, I can't explain

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it.”(13713)

“having that sort of work done on your body, it’s actually makes you feel better, feel more alive, you feel more in control of your body”(13571)

Treatment also facilitated a return to normality, allowing patients to partake in a full range of daily activities.

“I feel that it benefits me so I can live more of a normal life than if I didn’t see them” (9173)

The process of care was also seen as beneficial, with patients deriving benefit from reassurance and feeling more positive about their condition. This was in terms of receiving information, leading to a clear path of action for the patient and what appeared to be an increase in their sense of control of the situation and being able to act more independently to help themselves.

“what’s good is, I think is to have a diagnosis of what the problem is, so that you can then you know, if you feel able to make the necessary lifestyle modifications or behaviour modifications, but if you haven’t got a diagnosis, you can’t make those, you can’t make those changes, can you, because you don’t really know what you’re doing and what’s causing it and what’s going on”(13571)

Some patients also felt that natural and non-medicinal treatment was particularly advantageous and that a decrease in medication was a good outcome.

“I’m not taking medication from the doctor so often now. I’ve got migraine tablets. I was taking in fact he used to send for me and give me reviews on how many I was taking and now he’s noticed that I’m not taking so many so its definitely helped.”(9082)

Relaxation in and of itself was regarded as a benefit. This was seen as a result of the osteopathic hands-on treatment and also in the context of the interpersonal relationship with the osteopath.

“Oh the first time I went to the new one it was ooh, you know, in fact um, no, I have great faith in it, um, and at that time I was really struggling, really struggling, so I was very, I was just

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delighted that I could go to somebody, somebody I felt confident in because I knew he'd worked with my friend and um, so again conversation was very easy because there's lots of other chat, not about me but you know we could chat around things, which again was very relaxing" (10791)

"and then that night I always get a very good night's sleep, which is always wonderful, and the neck pain especially is not as bad to start with, for the next few weeks" (9173)

4.13.5 Patients' understanding and interpretation of benefits of treatment - Interview data

Having described the benefits, patients were asked to offer their interpretation of the mechanisms underlying these benefits. Patients tended to interpret their experiences of benefit using more than one set of explanations. These appeared to be informed both by their practitioners' views and by their own beliefs. Four themes emerged from the data. Explanations relating to physical mechanisms and processes were the most common. Patients also recognised the value of the therapeutic space offered during treatment as well as the importance of the information and guidance they received from the osteopath. Finally a small number of patients expressed their uncertainty about the mechanisms by which they had derived benefit.

4.13.5.1 Theme 1: Physical explanations

Patients drew on a number of different physical explanations to account for aspects of the benefit they perceived from treatment. These included the specific effect of hands-on treatment

"although it's discomfoting slightly, and having it, having that sort of work done on your body, it's actually makes you feel better, feel more alive" (13571)

and the more general notion of having the mechanics of the body and normal movement restored.

"A few days after I've been functioning more normally than before I went, so there's obviously been an improvement, as if... since the body has then settled into that new way of working, its been happy about it." (9640)

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Some patients attributed benefit they received to ongoing treatment that they construed as maintaining their body and keeping symptoms at bay.

“No, I’m not at all worried about it, you know, because I always feel, when I have been to the osteopath, that I feel a lot better, and I certainly feel that going every three months avoids you know having to go for umm a whole umm pile of treatments when something’s happened.” (10621)

The movement and exchange of energy and lymphatics was also described by a small number of patients as a way of understanding the outcomes of treatment.

“Well, it’s all about that, the energy pathways and um how your nerves are reacting, and about things needing to settle down, and doing this sort of thing helps you settle down and this will open this pathway and it’s actually, the information given on a really, really good level, without the technical stuff and um and kind of talking about how the inside of your body works and your chakras and stuff like that, it’s yeah, good” (13702)

“ uhh... as I understand it it really does get your whole circulation going, so it’s umm working on the lymph nodes as well” (10509)

4.13.5.2 Theme 2: Information facilitating recovery, healing and selfcare

Patients identified the value of the information and advice they received as a means of increasing their awareness of their condition and their ability to adjust their behaviour to incorporate effective self care strategies. The focus of self care was exercise and postural or ergonomic adjustments. Having a diagnosis or explanation of their condition was also seen as a route to improvement and increasing the scope for coping effectively.

“I understand better now what’s, because the good thing about the osteopath, well this particular osteopath anyway, is you get to find out what’s causing the problem, and because it’s behavioural, because it’s caused by the way you live and work and what you do and how you do things, you can modify your behaviour or you can have an exercise regime that changes your behaviour” (13571)

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The same interviewee explained how having a diagnosis was an important component:

“if you haven't got a diagnosis, you can't make those, you can't make those changes, can you, because you don't really know what you're doing and what's causing it and what's going on.” (13571)

4.13.5.3 Theme 3: Therapeutic space

Therapeutic space and the relationship between the practitioner and patient was recognised as an important part of facilitating recovery. Patients construed of this in terms of the interpersonal relationship:

“I feel very comfortable with um his um, he's very good at talking and explaining and relaxing erm, yeah anyway, and I mean obviously over the years I've got to know him anyway, so you know I tend, you know that in itself's relaxing when you know somebody, and you feel comfortable” (10791)

Trust and demeanour were identified as important to mediate confidence in treatment as well as other more tangible aspects of the process of care:

“I think it has to be a partnership, a relationship between the patient and the osteopath, or the osteopath and the person seeking the treatment, and I think building up that relationship is very important, because then there's a trust element and you say well you know he's right, if I don't do this it's just going to get worse, if I don't do this it's going to get better, you know, I think that's quite crucial” (13571)

“I just thought, as I walked in the door, oohh this is going to help I think, umm, and it was just his manner as well, very quiet, and polite and his whole attitude as well, you know, gentle touch, none of this yanking you about and what have you, you know, yeah, just the whole approach, yeah.” (9082)

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4.13.5.4 Theme 4: Uncertainty - "but I know it works"

For some patients the mechanisms underlying the effectiveness of treatment were unknown and/or unimportant. The clear focus was on the experience of benefit and that experience predominated when patients neither understood or wanted to understand how the treatment was working.

"... maybe it's psychological the fact, you know, I don't know, but it seems to be, the back's definitely behaving"

" then at the end they just hold your head and just don't do anything, well it feels like obviously they're doing nothing.... That's what people would (IF THEY WERE WATCHING)... They would think, but I know that's not true, because I know they're doing something." (11483)

Attendance and perceived benefit were not contingent on understanding the way in which treatment was working or even having some theoretical understanding of the mechanism of treatment effectiveness.

"I think we have, yeah, I guess the, I think there are issues, the issues that aren't important to me, erm, you know, I required a service, I researched what I wanted, I found somebody, I paid for the service, so a lot of the issues that you're raising with me I feel are quite irrelevant to me, erm, the issue for me is that I pay to see my osteopath and I get a good outcome, if I wasn't getting a good outcome, I wouldn't pay to see my osteopath, I would say this is not for me and I'd do something else, but I have had a good outcome, erm, I think, I actually think she's amazing, but I mean all of what [unclear] of osteopaths, I'm just going to twiddle this little bit very gently for five minutes and I'm going to feel wonderful for four weeks, it's very clever, but I ask questions, that's the thing, I'm fascinated..." (13702)

" I may take more notice of my posture now which could have an effect, but there's no sort of concrete reason that I can see for it not to be as bad as it was." (9640)

4.13.6 Patients' descriptions of common treatment reactions - Interview data

Patients were asked to describe a response to treatment where they had had a specific treatment reaction. Most patients responded by indicating a range of mildly unpleasant sensations of

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short duration which they attributed to their osteopathic intervention. However, two patients responded by describing only positive experiences from treatment or no change, and in some cases what might be regarded as negative reactions were interpreted by the patient in a positive way. These responses were grouped into four categories: musculoskeletal symptoms, fatigue and relaxation, lightheadedness and balance, headache.

4.13.6.1 Musculoskeletal symptoms

Over half of the interviewees described a broad range of symptoms, including local increase in pain and stiffness, more widely distributed aching and in a small number of cases an altered sense of their physical body:

“...having the sort of work on the muscles to ease the stresses and strains does make you, you know, initially makes you more conscious of them in a sense, er, and makes you more sensitive to er how fragile everything is, it's all held together with string sort of thing, then after a couple of days you get back to normal and you feel your same, you know, you become the same lazy old slob you was, you know, two days earlier” (13571)

These reactions to treatment were all of short-term duration, lasting between thirty minutes and two days' duration. The onset of these types of symptoms was variable; some patients described an increase in discomfort while being treated:

“... (held) my arm and rotated it, and that really, really hurt when he did it. Got home, just sat quietly for a while and um I suppose after about an hour it began to ease off.” (14417)

For others, their symptoms appeared shortly after treatment:

“What I usually find is that um I have a slight reaction from the treatment in terms of ache, pain, the following day” (14344)

“Sometimes you feel not so good the day after and then you start to improve a little bit after that, so generally, after the treatment, a not so good day, and then I start to improve” (12049)

In a few cases patients described the appearance of an increase in symptoms several days after treatment which they attributed to the osteopathic intervention:

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“he does tell me well you might be stiff, but sometimes it kicks in ... some minor reaction kicks in about three days afterwards” (14415)

4.13.6.2 Fatigue and relaxation

Fatigue was a commonly reported response to treatment and as such was in accord with the patient survey data as the most frequent non-musculoskeletal symptom to increase after treatment. Symptoms of fatigue were reported as occurring straight after treatment and/or later in the same day. Fatigue was often associated with a positive sense of relaxation and improved ability to sleep. This category of treatment reaction highlighted the difference between patients' and practitioners' constructions of treatment reactions. Practitioners were more likely to interpret this kind of symptom as a common treatment reaction and thus frame it negatively, whereas for patients the reactions, whilst often not directly related to their goals of treatment, were often seen as beneficial and part of an ongoing healing process.

“... I suppose just feeling really tired afterwards...” (11483)

“ I certainly would say that that evening, that sort of late afternoon, evening, each time I've had treatment I have probably felt more tired than normal, umm, a sort of, in a way a relaxed sort of tired, umm, not, I mean you can sometimes feel tired and feel quite stressed about it, can't you, but it wasn't like that at all.” (13262)

4.13.6.3 Lightheadedness and balance

Patients described a series of sensations which appeared to be distinct from relaxation, and which were most frequently reported as feeling lightheaded, dizzy or with a disturbed sense of balance. Some described a “different state of mind” (11483), while others compared it to a meditative state.

“...but then, um, on the way home, I walk because it's only fifteen minutes down the road, I quite often feel woozy-headed.... um, sort of thick-headed, as if you're going to get a bad cold but you're not, you don't have any of the cold symptoms, but it's that thick head sort of feeling, so I often go home and sit down and have a cup of coffee or a drink of water or something, and

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then that night I always get a very good night's sleep, which is always wonderful..." (9173)

"sometimes when, when they treat you standing up I nearly fall over backwards, I feel like I'm falling, going to fall back." (11483)

4.13.6.4 Headache

Some patients described the onset or increase in intensity of headaches. These patients were either presenting for treatment of headache/migraine or had headache associated with neck pain. In all instances, the increase in symptoms was transient and associated with the initial stages of treatment.

"A couple of hours, it kind of, it started as kind of a headache by the time I was driving home, and I was advised, you know, go home, you're probably going to feel rubbish later, and I did, I felt a bit rubbish at driving home, and it was just a gradual build-up of pain and then nothing would move it for days on end." (10702)

"I used to get pain after I'd had the treatment but now I don't seem to get the migraines after that." (9082)

4.13.7 Patients' understanding of causes of common treatment reactions - Interview data

As part of the interview about common treatment reactions, patients were asked how they made sense of treatment reactions and what sort of language they would use to describe such reactions. Patients described complex conceptualisations of their experience which were to some extent informed by the information given to them by practitioners, but also drawing on their own beliefs and experiences. A number of patients reflected upon the difficulties in ascribing causal links between their experience of additional symptoms and their treatment. This related to temporal factors where symptoms came on at a time distant to the consultation or making a post hoc connection.

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“Well, it happened to me, I might, I don't know, it probably was nothing to do with the treatment was it, but it was about an hour or so afterwards” (11483)

“I might not have even put two and two together and associated the fact that I'd had treatment and I felt tired that night, um, perhaps until it went, I'd had several courses of treatment, or maybe you know the fact that I did read that some people reported this and it put the two and two together in my head really” (13262)

The interview also raised questions in the patients' minds for the first time about experiences that they had not considered anything other than a natural consequence of their condition or treatment: “it just seemed a natural progression for my body to go through” (9640). This was most apparent when patients were talking about what language they would use to describe treatment reactions. Most patients rejected the description of common treatment reactions as “complications” since this was interpreted as a worsening of their condition.

“I suppose it has to be called side-effect, I don't think you could call it a complication, it isn't um, my understanding of a complication would be something that makes things worse” (14344)

Side effects appeared to be more acceptable, when this term was suggested. Patients were more comfortable with describing common treatment reactions as part of a healing or natural process.

“I certainly would not use complications or side effects. Umm I would just say the body was adjusting itself. If something was out of alignment, it was adjusting to being put back in the correct sort of ...”(8736)

“I just think it's all part of the treatment, the way it's healing. It's like when I went in for my injection in my spine, it hurt after, in fact I was numb after, but that's part of the treatment” (9974)

Five broad themes emerged as informing patients' models of causation with respect to reactions after treatment.

4.13.7.1 Theme 1: Structural explanations

Some patients used mechanical or structural models and metaphors to explain how they interpreted their experiences. Postural adaptation of the body's muscles and joints was commonly mentioned in response to treatment.

"I think it's just because she's moved the muscles around in my neck and skull a lot, my muscles don't necessarily want to go where she's telling them to go, they've learnt the wrong things, like sitting badly and that, my muscles have learnt to be in the wrong place, and they're fighting about, against going back" (9173)

One interviewee explained their ideas by using a clock metaphor:

"Well I was just thinking of say winding a spring or winding a clock, it's as if when it no when the clock has wound down, it's not functioning properly, then you start to wind it and it gets a sort of kick start but that doesn't allow the process to run smoothly until its been fully wound and it sort of might have to take stock of that before it actually gets going again." (9640)

Others described a more local relationship between perceived structural adjustment and reactions to treatment:

"I think they're, the headaches I get between treatments are definitely related to the damage that I've done to me, and the headache on the day I think is a reaction to the osteopath trying to put bits back where they should be." (9173)

"Well I mean you'll ache won't you, I mean if somebody's going to be doing it's like doing a workout I suppose really.... If somebody is manipulating you in the way I am manipulated, uhh, you do ache.... You feel sore, especially if it's in an area where say in the spine, something was slightly out, then you're going to feel sore." (10509)

4.13.7.2 Theme 2: Physiological explanations

Physiological ideas about the movement of fluids, the elimination of toxins and sensations related to the release of tension were used by some patients in making sense of how they felt after treatment. Whilst these may be categorised as drawing on physiological ideas, they still tended

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to use the language of mechanics and movement.

“And umm this is obviously as I understand it the toxins being moved round the body.”
(10509)

“... as I understand it, it's pumping up the umm lymph nodes, so therefore you're going to get if, for instance, it gets the circulation going, so you know if your circulation has been a bit sluggish, which possibly it could be at my age anyway, umm, it's just moving all that round.”
(10509)

4.13.7.3 Theme 3: Energetic explanations

The concept of energy was used in two distinct ways by a small number of patients. A metaphysical conceptualisation of energy was used to describe healing power which was seen as sometimes originating from the practitioner and sometimes an inherent property of the body. In response to changes in energy flow the body produced altered sensations or reactions.

“... I'm quite a strong believer in energy and stuff, and I kind of think that there was probably you know, things had been flowing in a set way for so many years, and when it was moved or challenged, so to speak, it kind of, my body was just reacting and to doing something a bit differently, that's kind of my, my take on it....” (13702)

“I think the osteopath's giving you a lot of energy, I suppose, from them, to help you” (11483)

Alternatively energy was framed in a physics context where one type of energy was converted to another as part of the process of treatment.

“Er, that's got to be dissipated in some sort of way, apart from anything else, I would have thought, and I'm thinking sort of as I sit here I'm just thinking this through now, maybe I'm quite wrong, I would have thought that what you're doing every time you manipulate something is you're putting heat into it, because there's energy involved, and that heat has to dissipate and as far as I can see the way it would dissipate normally would be to feel like an ache” (14344)

4.13.7.4 Theme 4: Psychological explanations

Two patients interpreted their responses to treatment in more psychological terms; one focussed on the experience of fear, for which they were having treatment and which was transiently exacerbated by that treatment. This patient drew strongly on the practitioner's interpretation of events, but appeared to accept this as a possible explanation.

“ He said it was like it all coming out of you, the fear..... Which it could have been because I felt really fearful when it all happened, so whether that was taking the fear out of my body, that was how he explained a bit, I don't know.... Well I think that, yes, but when it, yeah, because it was weird because it did make me feel fearful and scared, and that was what we were trying to cure.... So I mean it made sense, but whether it, you know, I'm quite open to believe things” (11483)

The other patient described more global feelings and an increased awareness of self post treatment.

“... having the rub down and having the sort of work on the muscles to ease the stresses and strains does make you, you know initially makes you more conscious of them in a sense, er, and makes you more sensitive to er how fragile everything is....”(13571)

4.13.7.5 Theme 5: Fatigue and healing explanations

Whilst many patients reported feeling tired after treatment, this was often framed in a positive way as an intrinsic part of the healing process. Fatigue and tiredness were not seen as undesirable symptoms, but rather offering the body a necessary opportunity to recover.

“Yeah, because your body's been um put through the mill I suppose in a way, so it's just relaxing and recovering and so you're going tired to help it do that” (11483)

“... it was um as if almost, I mean I do think sleep and healing and all these things go together in some ways, almost as if that was part of the process really..... for example when I've had physiotherapy, that's quite tiring because you're doing exercise etc and I would think of it in those terms, that it's just something's being done to my body that's made it tired.” (13262)

4.13.8 Patients' evaluation of acceptability of common treatment reactions - Interview data

Patients were asked about their views of what makes a treatment reaction acceptable or unacceptable. Responses were categorised accordingly and themes identified for each category. The data suggested that there were a range of constructs used to inform patients' views of acceptability. Four themes were identified as part of the analysis of what patients consider acceptable in terms of treatment reactions. These focussed on the quality of the treatment reaction experienced, belief and understanding about the inherent qualities of the treatment process and healing, the importance of information and the relationship with the practitioner and ideas about the characteristics of the individual. The two themes for the characteristics of unacceptable treatment reactions were the nature of the reaction itself and characteristics of the consultation or treatment.

4.13.8.1 Theme 1: Acceptable - quality of the treatment reaction

The qualities of treatment reactions that contributed to patients viewing them as acceptable included the duration and quality of the reaction. Patients accepted short-term reactions and low-intensity reactions:

“it wasn't an ongoing problem, you know, it wasn't, well it wasn't a problem, it wasn't something that was ongoing either, the next day I felt absolutely fine.” (13262)

“Well it's just uncomfortable, but it's not really hurting, you know, you've had your arm and that pulled about or your back pulled about....but it's not the ooh that sort of hurting.” (14417)

For one individual, the treatment reaction, which was reported as tiredness, was perceived as more than just acceptable but was positively welcome; this accords with the perception of tiredness and fatigue as being a benefit rather than an adverse event:

“I felt like I wanted to go back to bed, I felt that tired and calm and relaxed, it was..oh it was so brilliant.” (9974)

The impact of the reaction was also remarked upon:

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“ Oh, yeah, you know, the whole lot's unpleasant not disabling.” (14344)

“Well I've found them acceptable. They've never bothered me very much, you know certainly hasn't affected your general health, only to improve it” (14415)

4.13.8.2 Theme 2: Acceptable - belief and understanding about inherent qualities of treatment processes and healing

Patients saw treatment as being a process, of which treatment reactions were an intrinsic part, as long as they remained within an acceptable threshold. Seeing treatment reactions as part of a process was the most common way that patients justified their acceptability.

“well for me it's quite acceptable because the osteopath is the only person who has made any difference to my health in general concerning my back and neck and I was really at a bit of a dead end as to you know where to get help, so umm.. for me, it is not a problem getting exhausted, because I know that that is part of how it works.” (9640)

This was sometimes seen as a price to be paid for eventual improvement:

“You don't get something for nothing, do you, um, you can't, if you bring it away from osteopathy, if you bring it to other forms of medical treatment, there is always got to be some sort of a price to pay for um the treatment improving you, now whether that price to pay is acceptable or not is entirely down to the individual I suppose.” (14344)

It was also described as a natural response to a physical intervention, which was often contrasted with perceptions about the nature of medication:

“Yes, your body's reacting in a natural way, instead of being forced to react, isn't it, by medication etc.” (11483)

Patients also used images of connectivity to explain their understanding and acceptance of the interrelationship between treatment and changes in their body, causing a reaction:

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“for me it just shows that actually, there’s no one single, because of the nature of the skeleton and the nature of the human body, you know there’s no one single problem with anything, you know, if you’re going to physically, if you’re going to be a moving, breathing, walking around thing, you’ve got to have all these connectivities.” (13571)

For most patients, acceptability of treatment reactions was a balance of experience of symptoms and anticipated benefit. Patients also gained reassurance from past experience of treatment and from other people’s experience.

“I think they’ve got to be acceptable because you can’t go to a practitioner and not expect anything. I mean you’re bound to have some sort of reaction to treatment because there wouldn’t be umm how can I say this umm if you didn’t have any reaction to the treatment there really wouldn’t be any point in going I don’t think, and you’ve got to its no good going and expecting just whatever you went for to go, and there not to be some sort of side effect or reaction or whatever..... to have any benefit I think you’ve just got to accept that there may be some sort of reaction to it.”(13713)

“...AND WAS THIS REACTION, THIS FEELING A BIT WORSE, WAS THAT A SORT OF SURPRISE TO YOU?

Not really. Other people say the same thing. (12049)

4.13.8.3 Theme 3: Acceptable - the importance of pre-warning information and the relationship with the practitioner

Reactions were regarded as acceptable if the patient had been warned about them in advance, or if they had a trusting relationship with their practitioner, often built up over a number of encounters.

“I was warned that that might happen, so it didn’t alarm me in any way.” (8736)

“I knew that when he did that it was for my longer-term good.” (8736)

“Well, everything to me was quite acceptable, I just...whatever he said to me, I accepted that, yeah, that was ok.” (9974)

4.13.8.4 Theme 4: Acceptable - individual characteristics and experience

Some interviewees expressed the idea that treatment reactions were more acceptable in the context of their own experience of illness, and recognised that treatment reactions, and responses to them, were subjective:

“You know, er, it depends how high your pain threshold is and that sort of thing I suppose.” (14819)

“I mean perhaps everybody doesn't umm...perhaps everybody doesn't get the same symptoms as I do....I mean we're all different after all's said and done aren't we, you know....So maybe some people don't...it doesn't bother them as much as it bothers me, you know.” (10509)

“Because having ME I'm used to being extremely tired and/or exhausted which is something that I just have to accept happens.” (9640)

4.13.8.5 Theme 5: Unacceptable - the nature of the reaction

Patients' views about the unacceptability of treatment reactions in terms of the quality and nature of reactions mirrored their understanding of acceptability. Intensity, duration and impact of the reaction were important, as was the appearance of pain in an apparently unconnected part of the body. Reactions lasting more than a day or two were seen as unacceptable, as were high intensity reactions such as extreme pain. Some used ideas of proportionality, where they considered unacceptable leaving an encounter in more pain than when they arrived or where there was no benefit from treatment or actual harm.

“Well, I think it depends how, I think it depends how serious the problem is that you've got, I mean if you've got a really, you know, if you've got something really, really bad, really, really problematic, and really, really, causing you know major discomfort, the last thing you want if somebody to make it worse, that's, you know that's the, that's your nightmare scenario, isn't it really, so I can understand why some people might come out and think well goodness me, my back's playing up now, and now my leg's playing up as well, you know what I mean, and they

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might think that's a side-effect or whatever of the..." (13571)

"I think increased pain that lasted for longer.... Well I think if you had a lot of increased pain that probably went on for more than 24 hours.... I don't think that would be acceptable.... And possibly if you did suffer with severe headaches or nausea then I think possibly that might be a problem as well." (13713)

4.13.8.6 Theme 5: Unacceptable - characteristics of the consultation or treatment

The nature of the consultation itself and the manner of delivery of treatment was seen as mediating perceptions of unacceptability. The value of the intervention was important in terms of experiencing sufficient benefit; the cost of treatment in proportion to benefit was also mentioned. One patient who had found their osteopathic treatment unacceptable was concerned by not receiving the correct diagnosis and the wrong treatment. Others described the manner of their osteopaths as unacceptable. A few patients identified particular techniques as unacceptable, but these were within the context of having insufficient information to be prepared for the application of a technique.

"Well I think because the particular osteopath I think had an overinflated opinion of his abilities, and sort of gave the impression that he could deal with all manner of things, which I don't really think probably he could, and I found his attitude a little bit umm overbearing perhaps." (12049)

"Well if he just went in and pulled me about and did not tell me what he was doing it for." (14417)

"Well I just didn't like it at all because you know he'd be standing behind me and rolling my head from side to side and then suddenly there'd be a jerk (laughs) something would click and I wouldn't like to have that very often. That's the one kind of treatment that umm I don't like" (8736)

"the actual physical er change I don't think I'd consider it was unacceptable, only if I'd been somewhere and considered I'd been ripped off.... You know, which is er, you know, certain large practices possibly, they try everything, you might have five treatments and the five treatments

4.14 Practitioners' strategies for managing common treatment reactions - interview data

are completely different, and you think well, are they just giving you the five and hoping one will do some good and taking 25 off you each time or whatever...." (14819)

Osteopaths' ability to engage and communicate effectively with patients was also a factor in determining the acceptability of immediate reactions to treatment:

"And if the person didn't listen to me while he's doing the treatment and if I said it was that painful and he wouldn't stop, then there's no way I'd go back again, and I wouldn't go back if I didn't feel comfortable." (9974)

4.14 Practitioners' strategies for managing common treatment reactions - interview data

Osteopaths were asked to describe a recent common treatment reaction that they witnessed in practice and describe the methods that they used to manage such situations effectively. Practitioners' most common strategy for managing common treatment reactions was to forewarn patients of their likely occurrence. In addition to this a number of practitioners made it clear to their patients at the initial consultation that they may contact the practitioner by telephone if they had concerns about how they had responded to treatment. A number of themes focussing on practical strategies were drawn from the practitioner interviews concerning their approaches to managing patients after a treatment reaction. These covered communicating their care and concern to the patient, explaining the nature of the reaction, and modification of their treatment approach. The aims of post hoc practitioner management of common treatment reactions were the same as those evident in the post hoc management of serious treatment reactions, namely the preservation of practitioner and patient wellbeing and the maintenance of a positive therapeutic relationship.

4.14.1 Theme 1: Communicating care and concern to the patient

Practitioners described a range of responses to patients which indicated that they aimed to demonstrate their care and concern for their patients and to maintain or rebuild the therapeutic relationship with their patients. This took the form of enhancing the quality of communications skills used.

4.14 Practitioners' strategies for managing common treatment reactions - interview data

“if we’re looking at 36 hours, two days, then I start to maybe think a bit more, alright, ok, let’s ask a few more questions, let’s be gentle with this person, this person’s now going perhaps to be a little bit more erm I don’t know, I feel I’ve got to sort of up my bedside manner a bit more when that happens, so I’ve got to seem to be more caring and considered about what’s going on here.” (1773)

Reassurance and trust were seen as integral to further progressing of treatment.

“but you know you got the feeling from a er kind of you know sort of practitioner patient sort of relationship point of view, it was sort of on the brink there for a little bit and if you had perhaps handled it a different way, been perhaps dismissive or say oh that’s just one of those things you know she might have you know ultimately reacted quite differently erm, perhaps not taken my subsequent advice on board you know if your judgement has to be has been this treatment will be beneficial it’s not you know if she doesn’t if they don’t have that trust to say well they’ve said to ice pack it and so on and do this that and the next thing, if they don’t take that on board then you know you’re going to struggle certainly to er to get that patient better, you know if they don’t really er trust you you know in the first place, erm why should they listen to anything else you’ve got to say” (1208)

Practitioners also described being attentive in their clinical questioning and in some instances revisiting patient examinations.

“but I reassured her that there wasn’t you know, took her reflexes, did a you know bit of a neurological exam, probably a bit more than was really necessary, but to reassure her that there wasn’t any damage done, there wasn’t any you know long term, it was painful but it was something that was severe without being serious if that makes sense.”(1208)

Two practitioners described sharing regret with their patients and offering apologies as a way of showing their concern and moving forward with treatment.

“....but I think a lot of the time you just have to say, well I’m sorry, I’m really sorry that happened, and often that, I’ve, in my experience that has been what people wanted to hear, and it enabled the treatment to then proceed successfully” (2416)

4.14.2 Theme 2: Explaining the nature of the reaction

Some practitioners described giving their patients detailed explanations of what might have happened to provide their patients with a better understanding of how a treatment reaction had come about, using physical descriptions of processes. This included using physiological and biomechanical explanations.

“I explained to her why she was getting the pain I felt she was getting the pain down into the leg, the the sort of erm proximity of the nerve, erm, relationship to the muscle that we'd been working on, how that working on those muscles ultimately to loosen them off was obviously you know going to transmit some pressure er sort of further afield and that had probably er aggravated the nerve” (1208)

Some practitioners also used the explanation of the causes of a reaction as a route to offering further advice to patients as to how they could manage their condition.

“If they've had an adverse reaction, then I will postulate why that may be, and what it could relate to, whether it relates to the treatment or whether it relates to some activity that they've done or not done, um, so that we have a conversation about the um the problem, and then the patient knows you're taking them seriously” (3256)

4.14.3 Theme 3: Modifications to a treatment approach

In response to a patient experiencing a treatment reaction, practitioners commonly described modifying their treatment, particularly by being more gentle with their application of technique. Practitioners also described selecting different techniques or treating for shorter time periods.

“some patients are very sensitive and don't want any reaction to treatment and so you would try and modify your treatment approach using lighter pressures, for instance, or using more subtle techniques such as BLT or functional, cranial techniques, to minimise um a treatment reaction in somebody who um who, for one reason or another found it undesirable or you felt yourself would not be able to um handle that technique” (2396)

“ I did treat again, er but I modified what I did according to, taking into account the fact that they had been in more pain and doing my best to calm things down by working more

gently” (4711)

Additional approaches such as discussing the use of over-the-counter analgesia and applying hot and cold packs to affected areas of the body were explored with patients.

“if they get inflammation after treatment, you know, to try hot and cold bathing or icepacks or things that they can do for themselves to help themselves as well, which I think is very important, to empower the patient in the process” (3669)

“I mean you can take, if it’s safe for them to take anti-inflammatories and painkillers and they’re happy to do that, then you can say well that will curb it to quite a large degree, you can also try applying cold if it gets really sore, you could try putting a cold pack on it for maybe, at most no more than 20 minutes and describe how to do that, erm and then leave it off for at least half an hour, and then try it again for 20 minutes, if you want to try that, that will also give you some quite good relief often” (1773)

4.15 Serious adverse events

Serious adverse events were defined in the practitioner questionnaire as serious treatment reactions that involved the onset of severe new symptoms or the worsening of existing symptoms after treatment, leading to hospital referral and/or permanent disability and/or incapacity or death. Practitioners were asked whether they had experienced these in the course of their practice since graduation and over the last year. They were also asked to indicate the frequency of these events and to provide a brief description of the last serious treatment reaction that they had encountered.

Some participants gave contradictory or incomplete answers to the different questions. The results are presented followed by a further analysis and adjusted results, which aim to provide the most conservative report of these data. Details of the adjustment criteria are reported in the Statistical Report.

4.15.1 Period prevalence serious treatment reactions - career and over the last year

4.15.1.1 Serious adverse events experienced in osteopaths' career

1,066 practitioners completed both questions about the experience and frequency of serious adverse events over the course of their career. Out of these, 121 practitioners, 11.3% (95% CI 9.6 to 13.4) reported at least one instance of a patient they had treated subsequently having a serious treatment reaction. Table 4.67 shows the frequency of serious treatment reactions reported and illustrates contradictory or incomplete responses.

Table 4.67: Numbers of serious treatment reactions reported

| | occurrence of treatment reaction | | | Total | |
|-----------|----------------------------------|-------------|-------------|-----------|-------|
| | yes | no | missing | | |
| | 0 | 11 | 943 | 12 | 966 |
| | 1 | 73 | 1 | 1 | 75 |
| Number of | 2 | 18 | 1 | 0 | 19 |
| treatment | 3 | 10 | 0 | 0 | 10 |
| reactions | 4 | 4 | 0 | 0 | 4 |
| | 5 | 0 | 0 | 0 | 0 |
| | 6 | 2 | 0 | 0 | 2 |
| | missing | 3 | 0 | 3 | 6 |
| | Total | 121 (11.2%) | 945 (87.3%) | 16 (1.5%) | 1,082 |

Total number of serious adverse events during career: n=171

4.15.1.2 Serious adverse events experienced over the last year of osteopaths' practice

1,074 completed both questions about experience and frequency of serious adverse events during the last year of their practice. Out of these, 43 practitioners, 4.0% (CI 3.0 to 5.3), reported at least one instance of a patient they had treated subsequently having a serious treatment reaction.

1,080 practitioners responded to the question about how many serious treatment reactions their patients had experienced in the past year; 1,045 indicated 0 reactions and 35 practitioners, 3.2% (2.3 to 4.5), indicated having had 1 patient with a serious treatment reaction in the past year. No respondents recorded more than 1 serious adverse event during the last year.

4.15.2 Period prevalence serious treatment reactions - career and over the last year adjusted results

Table 4.68 includes three additional responses representing those who experienced at least 1 serious treatment reaction, but did not report this effectively when completing the question on whether they had had experience of a serious treatment reaction, but completed an other additional item indicating this. Practitioners who indicated that they had experience of a serious treatment reaction but did not provide the number of serious treatment reactions are noted as “missing” in table 4.68.

Table 4.68: Numbers of serious treatment reactions during career adjusted

| | | occurrence of treatment reaction | | | Total |
|-------------------------------------|---------|----------------------------------|-------------|---------|-------|
| | | yes | no | missing | |
| Number of treatment reactions | 0 | 0 | 948 | 0 | 948 |
| | 1 | 82 | 0 | 0 | 82 |
| | 2 | 19 | 0 | 0 | 19 |
| | 3 | 10 | 0 | 0 | 10 |
| | 4 | 4 | 0 | 0 | 4 |
| | 5 | 0 | 0 | 0 | 0 |
| | 6 | 2 | 0 | 0 | 2 |
| | missing | 14 | 0 | 3 | 17 |
| | Total | 131 (12.1%) | 948 (87.6%) | 3(0.3) | 1,082 |

Total number of serious adverse events during career: n=178

Taking these responses into account, 12.1% (131 practitioners) reported having experienced a serious treatment reaction during their clinical practice since graduation. The frequency distribution is shown in table 4.68. Out of these, 44 (4.1%) had such an event during the last twelve months. 35 practitioners experienced 1 serious treatment reaction and 9 practitioners experienced an unknown number of serious treatment reactions during this time.

4.15.3 Practitioners’ descriptions of serious adverse events

Practitioners reported a range of clinical scenarios in response to the question asking about the nature and outcome of the last serious treatment reaction they had experienced which led to hospital referral and /or permanent disability and/or incapacity or death. The nature of the free text responses was varied, with some respondents providing detailed descriptions and some only brief and partial responses. The pilot phase data suggested that some practitioners used

this question as an opportunity to comment on issues not directly related to the question and some reported experiences which were serious to them but did not fit the definition offered in the question. In total, 149 free text comments were received from respondents. We selected the free text comments of those respondents who had indicated that they had experienced a serious treatment reaction and had provided free text ($n = 114$, 77%). These data were categorised as part of the analysis by two independent academic physiotherapists who were not involved in the study.

Of 114 free text responses, 71 (62%) were agreed as consistent with the study definition of a serious treatment reaction, 21 (18%) were considered not to be consistent and 22 (19 %) were allocated to an “unsure” category.

For those that were agreed as fitting our definition, six major categories emerged based on both reported symptoms and the description of the consequent diagnosis or results from tests reported by the practitioners (frequencies are presented in table 4.69):

1. Central neurological symptoms
2. Peripheral neurological symptoms
3. Non-specific musculoskeletal symptoms
4. Symptoms related to underlying pathology
5. Fractures
6. Unallocated

Table 4.69 shows the frequencies of serious treatment reactions within each of the six categories against the period of reporting. The most frequent serious adverse events reported by practitioners related to peripheral neurological symptoms.

4.15.3.1 Central neurological symptoms

This categorisation includes serious adverse events associated with vasovagal symptoms, vertigo, hemi facial paraesthesia and peripheral symptoms associated with cerebro-vascular accident. Of the 14 serious adverse events reported in this category, 3 were reported in the previous year of practice. A range of treatment techniques including soft tissue and examination procedures were associated with these events and 5 practitioners reported the use of high velocity thrusts. Hospital visits were reported in 9 cases and symptomatic resolution in 9 cases. There were 7 reports of stroke and/or symptoms suggestive of transient central ischaemia or vasovagal type

4.15 Serious adverse events

Table 4.69: Categories of serious adverse events

| Cat. | Description | last year | career minus last year | total |
|-------|--------------------------|-----------|------------------------|-------|
| 1 | Central Neurology | 3 | 11 | 14 |
| 2 | Peripheral Neurology | 9 | 19 | 28 |
| 3 | Non spec musculoskeletal | 4 | 13 | 17 |
| 4 | Pathology | 4 | 6 | 10 |
| 5 | Fractures | 1 | 0 | 1 |
| 6 | Unallocated | 0 | 1 | 1 |
| Total | | 21 | 50 | 71 |

SAE's reported here are those independently agreed as fitting the SAE definition.

symptoms, 6 of which occurred directly post treatment and one which was delayed in its onset by several days. Only 1 of these events was reported as following cervical HVT. In 1 case, the practitioner did not include a report of associated techniques; in the remaining 5, occurrence was following examination procedures, soft tissue techniques or articulatory techniques.

Table 4.70 shows data extracted from the free text responses which have been selected as indicative of serious treatment reactions related to the central neurology category.

Table 4.70: Central neurological symptoms

| Practitioner description SAE | Treatment | Post treatment symptoms | Outcomes |
|---|---|--|--|
| Female, under 30 years old, no significant medical history, sedentary occupation presenting with “stiffness between the shoulder blades”. No objective or subjective neurology, previous uneventful treatment for similar episodes. Immediate onset of painless motor paralysis and loss of sensation in XXX arm following “dog technique”. Admitted to XX XX XX where rare form of spinal migraine diagnosed. This proved to be difficult to manage and the patient subsequently suffered severe anxiety which made it difficult for her to hold down a job. | Following “dog technique” | Immediate onset of painless motor paralysis and loss of sensation in XXX arm | Admitted to XX XX XX where rare form of “spinal migraine” diagnosed. This proved to be difficult to manage and the patient subsequently suffered severe anxiety which made it difficult for her to hold down a job. |
| Patient female and between 60 and 70 years old. Traction of CSp with articulation of CSp(gentle) - movement led to spontaneous cavitation of C1/2 left. Patient immediately felt like she was rolling backwards and nauseous. Ended up in hospital - diagnosis vascular compression - irritation of upper CSp. Patient discharged 24-48 hours later - rest resolved symptoms. | Traction of CSp with articulation of CSp (gentle) | Patient immediately felt like she was rolling backwards and nauseous. | Ended up in hospital - diagnosis vascular compression - irritation of upper CSp. Patient discharged 24-48 hours later - rest resolved symptoms. |
| Female patient 80 years old + , heavy smoker. Treatment of soft tissue to trapezeii and C/D articulation gently. She had a stroke a couple of days after treatment and was left confused and disabled/unable to speak. Never sure if it was treatment-related or not, but always very aware since. Never directly linked to treatment. | Treatment of soft tissue to trapezeii and C/D articulation gently. | She had a stroke a couple of days after treatment | was left confused and disabled/unable to speak. Never sure if it was treatment-related or not, but always very aware since. Never directly linked to treatment |
| HVT of CSp on existing patient - male aged between 40 and 50 - which resulted in immediate strokelike symptoms in XXX arm and leg. This resulted in a hospital visit. Patient made gradual recovery. | HVT of CSp | immediate stroke-like symptoms in left arm and leg. | This resulted in a hospital visit. Patient made gradual recovery. |
| During examination of cervical spine for sudden onset neck pain patient reported hemi facial parasthesia and strange sensation of tongue. No treatment performed. Ref to A+E. Spontaneous resolution. Patient female aged between 40 and 50. No smoking, No OCP, no medication, no RTA, no vascular problems, no c-trauma, no clotting disorders. | During examination of cervical spine for sudden onset neck pain. No treatment performed | hemifacial parasthesia and strange sensation of tongue. | Ref to A+E. Spontaneous resolution. |
| Female patient aged between 40 and 50 who had been sent to me by the GP for back pain. Had a history of cerebral infarction following severe road accident between 5 to 10 years earlier. As a result had one sided hemiplegic. Her low back pain improved for treatment. Then she had an acute neck and at her second visit asked me to look at that instead. | neck treatment | After her second neck treatment she felt lightheaded, her pupils dilated. | Assessed in hospital. I spoke to her neurologist. (ten days later she had made a full recovery from the symptoms) and wondered if symptoms were more due to anti epileptic drug she had been given. He thought symptoms were unrelated to osteopathy, he would be happy for me to see her again. |

4.15.3.2 Peripheral neurological symptoms

This categorisation includes serious adverse events associated with vertebral disc damage, radicular symptoms, paraesthesia and motor weakness. There was some initial disagreement between coders with this category which was resolved by discussion. Where participants described discal injury we have elected to infer that these involved peripheral neurological symptoms where subsequent investigation reported prolapsed discs or a surgical intervention on the basis that simple structural damage to the disc was unlikely to involve intervention and imaging in the absence of radicular signs and symptoms. Of the 28 responses, 9 occurred in the previous year of practice. These events were associated with a variety of osteopathic techniques including soft tissue, traction, joint articulation and manipulation. In 9 cases respondents reported the use of High Velocity Thrusts and in 9 cases the use of articulation/traction was reported. Hospital investigations were reported in 15 cases and surgical intervention was reported in 9.

Table 4.71 shows data extracted from the free text responses which have been selected as indicative of serious treatment reactions related to the peripheral neurology category.

Table 4.71: Peripheral Neurological symptoms

| Practitioner description SAE | Treatment | Post treatment symptoms | Outcomes |
|--|--|---|--|
| A few days after treatment for lumbar spine pain and stiffness, a male patient's disc prolapsed after sitting on a low sofa. He was referred to hospital. | treatment for lumbar spine pain and stiffness | disc prolapsed after sitting on a low sofa. | He was referred to hospital. |
| Prolapsed disc L/S leading to sciatic nerve irritation. I originally diagnosed herniation and after MLT L/S there was sciatic nerve pain. Patient took herself to hospital for treatment in 199x. | MLT L/S | sciatic nerve pain. | Patient took herself to hospital for treatment in 199x. |
| Unstable lumbar disc - possibly aggravated by lumbar spine manipulation. Disc operation with favourable outcome. | lumbar spine manipulation. | | Disc operation with favourable outcome. |
| I saw a patient with known degenerative lumbar spine disease, previous disc prolapse and surgery with chronic pain and some nerve root symptoms and made all symptoms much worse with over-enthusiastic soft tissue articulation and traction, not HVT. No immediate hospital admission, but was referred for MRI scanning. Happened at start of my clinical practice. Cannot remember outcome. No complaint against me made. | soft tissue articulation and traction, not HVT. | made all symptoms much worse | No immediate hospital admission, but was referred for MRI scanning. Cannot remember outcome. No complaint against me made. |
| Returning patient, healthcare qualified. History and discussion - no red signs or indications of issue. Clinical exam ROM - no exacerbation or indication of issues. Clinical testing - neuro + compression + orthopaedic tests - no sign. HVT with consent applicable at the time of treatment. Thoracic prolapse became symptomatic. Subsequent MRI confirmed prolapse calcified, indicating longstanding lesion. | HVT | Thoracic prolapse became symptomatic. | Subsequent MRI confirmed prolapse calcified, indicating longstanding lesion. |
| Aggravated disc injury/prolapse which exacerbated nerve root compression. Caused by articulation of the lumbar spine. | articulation of the lumbar spine. | | |
| Male, aged between 40 and 50 with acute low back pain, no radiating pain or signs or symptoms of disc/neurological defect. Following second treatment which included very gentle lumbodorsal lumbar roll he developed leg pain and calf paraesthesia which over the next two weeks developed into weakness of plantar dorsi flex. I referred him to a neuro surgeon who advised urgent surgery. Although the leg symptoms did not immediately follow treatment I cannot honestly state that it was not connected, though I feel would probably have happened anyway. | Following second treatment which included very gentle lumbo-dorsal lumbar roll | he developed leg pain and calf paraesthesia which over the next two weeks developed into weakness of plantar of plantar and dorsi flex. | I referred him to a neuro surgeon who advised urgent surgery. |

4.15.3.3 Non-specific musculoskeletal symptoms

This categorisation includes serious adverse events associated with generalised increases in pain and muscular spasm that sometimes was associated with an inability to move. Of the 17 serious adverse events reported in this category, 4 were reported in the previous year of practice. These events were associated with a variety of osteopathic techniques including soft tissue, joint articulation, springing techniques and manipulation. Hospital visits were reported in 11 cases, where patients underwent further investigation including x-rays and were prescribed medication including analgesics and muscle relaxants. Symptomatic resolution/patient recovery was reported in 7 cases.

Table 4.72 shows data extracted from the free text responses which have been selected as indicative of serious treatment reactions related to non-specific musculoskeletal symptoms.

Table 4.72: Non-specific musculo-skeletal symptoms

| Practitioner description SAE | Treatment | Post treatment symptoms | Outcomes |
|--|--|---|---|
| <p>Patient went into spasm following articular technique. Went immediately to hospital where she received appropriate medication. Released later that day and was fine within three days.</p> | <p>articular technique.</p> | <p>spasm</p> | <p>Went immediately to hospital where she received appropriate medication. Released later that day and was fine within three days.</p> |
| <p>I placed a returning patient in a position for a thoracic lumbar HVT but the patient said it was too uncomfortable. I did not proceed the intervention but the patient went into spasm and the was unable to move and an ambulance had to be called. The patient was taken to A&E and given pain killers, no x-ray was taken. I wrote to the GP explaining I felt this would be advisable seeing as the reaction was so severe and symptoms had not responded. Eventually (after much suffering on the patients side) one was taken and he was diagnosed with cancer.</p> | <p>I placed a returning patient in a position for a thoracic lumbar HVT</p> | <p>patient went into spasm and was unable to move</p> | <p>The patient was taken to a & e and given pain killers, no x-ray was taken. I wrote to the GP explaining I felt this would be advisable seeing as the reaction was so severe and symptoms had not responded. eventually (after much suffering on the patients side) one was taken and he was diagnosed with cancer.</p> |
| <p>Man in 30s with old fracture in XXX shin (some years previous to treatment). I used a cranial technique to restore the midline of the XXX L'ex which resulted in 1 week severe pain and visit to A+E for strong painkillers. Treatment continued and symptoms completely resolved.</p> | <p>cranial technique</p> | <p>1 week severe pain</p> | <p>visit to A+E for strong painkillers. Treatment continued and symptoms completely resolved.</p> |
| <p>Treatment of a biceps tendon/muscle strain which worsened post-treatment which also happened to coincide with a weekend therefore patient presented to A+E in increased pain.</p> | | <p>worsening of presenting symptoms</p> | <p>happened to coincide with a weekend therefore patient presented to A+E in increased pain.</p> |
| <p>Male patient, in thirties, occupational driver with long history of lower back pain, usually seen by colleague. Presented with probable disc related antalgia, worked conservatively to loosen associated muscle spasm and improve comfort and mobility. No HVT. Patient rose quickly from couch - forward bend and twist - instant severe muscle spasm, unable to stand. Ambulance called - A & E - muscle relaxers and pain relief then sent home to rest. 48 hrs to regain mobility. No adverse neurologic outcome.</p> | <p>worked conservatively to loosen associated muscle spasm and improve comfort and mobility. No HVT.</p> | <p>Patient rose quickly from couch - forward bend and twist - instant severe muscle spasm, unable to stand.</p> | <p>Ambulance called - A & E - muscle relaxers and pain relief then sent home to rest. 48 hrs to regain mobility. No adverse neurologic outcome.</p> |
| <p>An acute exacerbation of pain, joint stiffness and hypermobility for no known reason. This followed gentle soft tissue and articulation techniques to the waist and elbow on the same side of the body. Patient was male, in 50's and in good general health with no history of inflammatory joint disorders.</p> | <p>This followed gentle soft tissue and articulation techniques to the waist and elbow on the same side of the body.</p> | <p>an acute exacerbation of pain, joint stiffness and hypermobility</p> | |

4.15.3.4 Symptoms related to underlying pathology

This categorisation includes serious adverse events associated with a variety of previously diagnosed and undiagnosed pathological conditions including cervical spine osteosarcoma, osteoporosis, infective discitis and the diagnosis of a hemi-vertebra. A range of treatment techniques including soft tissue, traction, joint articulation and manipulation were associated with an aggravation of patient symptoms/pain or the post treatment diagnosis of a fracture. One death was reported.

Table 4.73 shows data extracted from the free text responses which have been selected as indicative of serious treatment reactions related to underlying pathology.

Table 4.73: Symptoms related to underlying pathology

| Practitioner description SAE | Treatment | Post treatment symptoms | Outcomes |
|---|--|--|---|
| Female patient, presented with pain from C-D region, XXX shoulder (trapezius and peri-scapular) and XXX arm pain. Tests indicated cervico-thoracic problem. Patient had had lumpectomy of localised cancerous tumour removed from XXX breast more than 10 years ago. Since then had been in good health after normal treatment for that. Symptoms from the current problem did not appear sinister, ie no night pain. Pain induced by positional provocation tests. Ist visit performed HVT gently to upper dorsals D1-4. Patient returned following week with improved symptoms. Performed same HVT procedure - fracture of XXX humerus! To hospital - x-ray diagnosed fracture due to metastases from XXX breast. Patient treated by hospital, improved and had chemo and radiotherapy. | Ist visit performed HVT gently to upper dorsals D1-4. Patient returned following week with improved symptoms. Performed same HVT procedure | fracture of XXX humerus | To hospital - x-ray diagnosed fracture due to metastases from XXX breast. Patient treated by hospital, improved and had chemo and radiotherapy. |
| Elderly female osteoporotic. Old crush fracture @ L1/2 but stable. Previous treatment soft tissue and articulation provided relief. Treatment administered with caution and gentle articulation. Unfortunately aggravated symptoms. | soft tissue and articulation provided relief. Treatment administered with caution | aggravated symptoms. | |
| Middle-aged chap, whiplash injury more than 9 months prior to treatment. Had MRI on neck which was clear several months prior to treatment, came in with neck pain and mild arm symptoms. Treated 4 times - got much better. Treated him 5th time - much worse. 6th time - much better, but noted clawing of a finger. Referred him to neurology. Treated him again - much worse. 2 weeks later died. Massive osteosarcoma in cervical spine. | | Treated 4 times - got much better. Treated him 5th time - much worse. 6th time - much better, but noted clawing of a finger. | Referred him to neurology. Treated him again - much worse. 2 weeks later died. Massive osteosarcoma in cervical spine. |
| Treated an otherwise healthy young man in his 20s who had presented with lower back pain of insidious onset. Was somewhat improved after 1st session which included lumbar spine HVT. Repeated it similarly but this time patient experienced adverse reaction - increase in pain and development of nerve root pain + some urinary disturbance. Was admitted to hospital for further tests. Had 2 MRI scans performed. Second revealed an infective discitis which was treated with IV antibiotics and patient eventually recovered. | included lumbar spine HVT | increase in pain and development of nerve root pain + some urinary disturbance | patient eventually recovered. |
| Fracture of a clavicle due to undiagnosed multiple myeloma. Action: chemotherapy following diagnosis. Prognosis - poor. xxx not yet diagnosed. | | Fracture of a clavicle | Prognosis - poor. not yet diagnosed. |
| I was unhappy with how a patient deteriorated after I treated a shoulder complaint. The second visit showed a hot joint, the patient was sweating and hot and I sent the patient with his wife to A+E. He was admitted with a severe blood infection. | I treated a shoulder complaint. | The second visit showed a hot joint, the patient was sweating and hot | I sent the patient with his wife to A+E. He was admitted with a severe blood infection. |

4.15.3.5 Fractures

This category includes 1 response where the serious adverse event was not associated with a latent or undiagnosed pathological condition. It occurred in the previous year of practice and was associated with a hospital diagnosis of a fractured rib subsequent to an inhibition technique to the thoracic spine.

Table 4.74 shows data extracted from the free text response which has been selected the serious treatment reaction related to a fracture.

Table 4.74: Fractures

| | |
|------------------------------|--|
| Practitioner description SAE | Whilst conducting prone inhibition of TES (iliocoxalis thoracis) unusual cracking sound/sensation. Patient presented at A+E two days later. Attending SHO expressed opinion of fractured rib. No plate or image to confirm. Patient remains in pain as per pre-treatment levels. |
| Treatment | prone inhibition of TES (iliocostalis thoracis) |
| Post treatment symptoms | |
| Outcomes | Patient presented at A+E two days later... Patient remains in pain as per pre-treatment levels. |

4.15.3.6 Unallocated

The one serious adverse event in this category occurred “prior to practising” and concerned a mobilisation technique that was associated with hospitalisation for three days due to a worsening of low back symptoms.

Table 4.75 shows data extracted from the free text responses which were not allocated to a specific category.

4.15.4 Patients’ survey report of worsening of symptoms leading to consultation with another practitioner, temporary incapacity or disability attributed to osteopathic treatment

Of the 1,361 participants who responded to the question, 130 (9.55%) reported having visited the GP, or referred to another medical specialist because of worsening original symptoms, or the appearance of new related symptoms that the patient attributed to their osteopathic treatment.

Of the 1,361 participants who responded to the question about whether they had experienced temporary incapacity or disability that they attributed to their osteopathic treatment, 56

4.15 Serious adverse events

Table 4.75: Unallocated

| | |
|------------------------------|---|
| Practitioner description SAE | Prior to practising and almost exclusively with IVM approach, a mobilisation appeared to contribute to significant worsening (?prolapse) of an apparently xxx low back (disc!) xxx. Acute pain followed by hospitalised for three days fortunately the clinician at the hospital suggested continuing TTT with me once discharged?! However the patient never returned. |
| Treatment | almost exclusively with IVM approach, a mobilisation |
| Post treatment symptoms | Acute pain |
| Outcomes | hospitalised for three days fortunately the clinician at the hospital suggested continuing TTT with me once discharged?! However the patient never returned. |

patients (4.1%) responded positively. Due to the small number of patients it was not possible to test for significant differences between the patients who reported these vs those who did not. However crosstabulation seemed to indicate difference in the following characteristics:

- average baseline pain intensity (had incapacity 6.2 vs did not have incapacity 5.5)
- use of osteoporosis drugs (had incapacity 10.7% vs did not have incapacity 4.3%)
- osteopath used functional technique on upper extremity (had incapacity 7.1% vs did not have incapacity 1.2%)
- osteopath used HVT on shoulder girdle (had incapacity 5.4% vs did not have incapacity 0.9%)
- osteopath used joint articulation on cervical spine/neck (had incapacity 55.4% vs did not have incapacity 43.3%)
- osteopath used joint articulation on shoulder girdle (had incapacity 30.4% vs did not have incapacity 21.0%)
- osteopath used dry needling/accupuncture (had incapacity 8.9% vs did not have incapacity 3.3%)

However it is unclear whether these difference are related to the intervention, the underlying characteristics of the patient or some other confounding factor.

4.15.5 Patients' descriptions of serious treatment reactions - Interview data

Of the nineteen patient interviews that were carried out, 2 patients described events that fitted the definition of a serious treatment reaction. For one of these patients the serious treatment reaction was the focus of the whole interview and caused them to withdraw from osteopathic treatment dissatisfied with the process of care. The other patient mentioned their reaction briefly in passing during the interview and continued to use osteopathy for other symptoms, though they elected to cease treatment with the osteopath to whom they attributed their serious treatment reaction. The first patient's reaction was classified as falling into the "Peripheral neurological symptoms" category with the patient describing severe increase in symptoms and seeking further medical care post treatment. The patient's description of their experience appears below:

"Right, so the very first time I had what I said was this deep um massage more into my buttocks and hip I'd say, and um when, then he said right he'd see me in, at the, that was on a Monday, and he'd see me at the end of the week, which was probably on the Thursday, so I came home and the next morning I couldn't walk.... It had done huge problems, I was in so much pain, I've never had such pain in all my life, erm, and I, as soon as I got out of bed I was absolutely in agony, erm, I kept the second appointment and went and said to him look er whatever happened that day it just made me ten times worse, I really, really can't um manage now with my, I was still calling it my leg was basically the huge problem, and um so he said well that's funny because I didn't really believe that I'd done you know much manipulating, well actually at the time it had hurt a lot, and I didn't know whether I should be saying ooh, don't do that, it's hurting too much.... we made another appointment for the Monday or the following week and I went away and the symptoms just got worse and worse, and I phoned up on the Monday and said I'm sorry, I cannot come, I've now gone down to my GP and I've asked for an MRI scan because this is just, I'm crippled, I literally can't do anything now and the pain, I need painkillers and erm, the severity is too bad, so I then called it a day.... so my experience has not been good." (8175)

This patient cancelled their next appointment.

"I thought that I'd be going there um and that um it would just help my symptoms, I mean um, then what happened was I um I asked for this MRI scan, um when I cancelled my appointment I must say he was very, very professional and he rang me back and said I'm sorry you've cancelled, and I said at the time, don't you think I've got a prolapsed disc, and he said no, um, you haven't got many of the symptoms, well actually the MRI scan showed I had three prolapsed discs" (8175)

They explained during the interview that their concerns related to the lack of adequate diagnostic thinking and testing.

“I think my disappointment with the osteopath was that um I’ve now looked on the internet a lot and one of the things when you um you can test is that you lie flat on the, on a couch and you do a straight leg um test, and it’s how much you can bring your leg up in a straight, well at that particular time if he’d have done that, I could bring it up half an inch only off, you know, a flat surface, and I now have been told well that’s a classic symptom of a prolapse, now he never tested that and he didn’t test my reflexes and my reflexes actually at my GP, when I went for asking for an MRI, was that my reflexes, there were none in my leg” (8175)

Their view was that the osteopath should have realised that their care was outwith his expertise. This was further reinforced by their consultant saying that osteopathic treatment was inappropriate and may have exacerbated their condition. Friends also questioned their decision to seek osteopathic care. Reflecting on the situation, the patient did not entirely blame the osteopath as they had experienced ineffective treatment from a physiotherapist as well. The main concern was the lack of effective diagnosis. When asked about the risks and benefits of seeking treatment in the context of their experience, the patient spoke about inherent risk and the need for having faith in a professional as part of the process of seeking care.

“Um, well there’s always, I’d say there’s always a risk when you go somewhere, you, I mean I’d say that’s the case anyway, whether you’re going to a doctor in a hospital or any of these other um chiropractors or osteopaths, you’re putting your faith in them.... And um I tend to sort of believe them from the outset, um, that they are going to um treat you properly, I mean I don’t think, from my um, now I’m at a neurosurgeon, um, when I asked him about the osteopath, he, he didn’t say, he said that you know whatever he did would have just irritated, so I can accept that he did irritate it, but what I find difficult to accept that he missed the diagnosis” (8175)

The second patient’s reaction was classified into the “Non-specific musculoskeletal symptoms” category. They reported ongoing exacerbation of original pain and symptoms which they felt were permanent and attributable to their osteopathic treatment:

“Where I felt the osteopath was too vigorous and in fact umm did some damage that I mean I discontinued going to see him, but umm that was a bad experience and, after that, I didn’t see an osteopath for a very very long time,....[I] talked to him about what I thought was some early stages of arthritis in my right thumb joint, and he said he thought he could cope with that, and umm he did something which I thought was too vigorous and in fact it’s never been the same again.... I think he actually did damage and its never been good since then. I think

it was sore. I mean it's going back a few years so I can't quite remember.... But it was enough for me to think to myself, right, I'm not going back to him.”(12049)

4.15.6 Rate of serious adverse events

Taking the total number of osteopathic consultations reported per week in table 4.20, we can estimate the volume of patients seen in a year. Using the adjusted annual prevalence of serious treatment reactions an estimate of the number of osteopathic encounters needed to produce 1 serious treatment reaction can be derived:

$$36,079 \text{ consultations} \times 48 \text{ weeks} = 1,731,792 \text{ consultations per year}$$

$$1,731,792 / 44 = 1 \text{ serious treatment reaction per } 39,358.9 \text{ osteopathic consultations.}$$

We observed 4 free text responses from practitioners who had indicated that they had not experienced a serious adverse event in their career but did have content that fitted our SAE definition and were indicative of occurring in the last year. Therefore were able to make a further more conservative adjustment:

$$1,731,792 / 48 = 1 \text{ serious treatment reaction per } 36,079 \text{ treatments.}$$

4.15.7 Practitioners' explanations/causal models for specific serious treatment reactions - Interview data

Practitioners who had experienced a self-defined patient serious treatment reaction were asked to give their interpretation of why it happened. A number of themes emerged from the practitioner interviews suggesting that a range of causal/explanatory models were underpinning their attributions and understanding. These included structural, mechanical and tissue-based physiological interpretations. Characteristically, these explanatory frameworks were congruent with each individual practitioner's model of healthcare, osteopathic treatment and management. Some serious treatment reactions were explained by the presence of a latent pathological condition and some by provocative patient activities outside of the treatment consultation.

Several practitioners emphasised the difficulties of determining a plausible causal pathway linking a particular osteopathic treatment or patient management strategy to the occurrence of a specific serious treatment reaction. These uncertainties, coupled with evident individual patient vulnerability and variability within the osteopathic patient population, led several practitioners to reflect on the role of chance in the experience of serious treatment reactions. These data were congruent with a number of the free text responses from the survey where practitioners

described events that they thought constituted a serious treatment reaction, but did not appear to link clearly to the treatment intervention.

4.15.7.1 Theme 1: Structural explanatory models

Structural explanatory models were largely based on the individual practitioner's understanding of anatomical relationships and the putative effect of the applied osteopathic technique in the generation of the serious adverse treatment reactions whose symptoms were sometimes distant from the site of the treatment intervention.

“he had a locked sacroiliac joint, which was sore, but I hadn't sort of taken into account the length of time it takes for a serious disc um problem to you know, a serious disc protrusion to heal, and either I prolapsed the disc or I shifted a prolapse back onto the nerve” (3669)

“I must have done something to C5, must have, because they left ok, a bit sore, but the following morning I got a phone call saying that they ended up in hospital having to be injected to take the pain down” (2810)

4.15.7.2 Theme 2: Mechanical explanatory models

Mechanical explanatory models were primarily based on an apparent mismatch between the intensity of the applied osteopathic technique and the ability of the patients' tissues to withstand them without structural damage. These models were used to explain serious adverse treatment reactions whose symptoms were often local to the treatment intervention, sometimes involved fractures and were sometimes associated with the presence of an underlying pathology.

“it wasn't a huge force, the reason why it went is because he was um, wasn't flat at the front, there was a sort of higher one side than the other and the force went down one side, it's shearing, and it popped the front” (4275)

“he was a new patient, he looked about late 50s and in fact he was in his 70's, this was in XXXX, he looked far too healthy I think he was a bit osteoporotic and I think it was just too much force for, too much load with his, with the degree of mineralization his ribcage had” (4542)

4.15.7.3 Theme 3: Serious treatment reactions explained by non-specific care factors

Practitioners reported a series of serious adverse treatment reactions apparently that were unrelated to the application of a specific osteopathic technique but were often associated with changes in patient position on the treatment plinth. Typically these reactions were interpreted by practitioners as being severe muscle spasm which frequently resulted in the patient being unable to move from the plinth without outside assistance.

“I rolled him over onto his back to try and mobilise his ribs and as I moved him over he got locked and went into spasm” (1185).

“it was some kind of positional change which set her muscles off into spasm, into what I would call a complete and utter protective spasm that stopped her body moving” (2609)

4.15.7.4 Theme 4: Serious treatment reactions occurring outside of the osteopathic treatment consultation

Some practitioners reported serious treatment reactions that occurred outside of the osteopathic consultation. The practitioners attributed these reactions at least in part to patient activities that were provocative or contributory.

“in my sort of heart of hearts I feel that probably I might have prepared him for something that happening maybe when he was swimming if, because sometimes if you do some kind of annular strain you don't feel the results of it for a few days, and so I feel like in some way I maybe brought that about, maybe speeded that happening” (4652)

“she felt fantastically good after she'd had the treatment, she was out of pain which she hadn't been for a long time there was a very busy road outside the XXX and she couldn't turn her head, and I would imagine that what she did was to sort of go like that with the traffic coming, and that might have produced the cord compression” (1832)

4.15.7.5 Theme 5: The problems of determining a causal pathway

Practitioners frequently commented on the difficulties and uncertainties of determining a plausible causal pathway linking a particular osteopathic treatment or patient management strategy to the occurrence of a specific serious treatment reaction.

“why did it happen? I have no idea; I still can’t think why it should have happened” (1832)

“I couldn’t see a direct connection but the osteopathic treatment was the only thing that could have possibly triggered it.....but I couldn’t give you a physiological pathway.....it was just one of those things that happens, you know there are unforeseen side-effects that can occur with any interference with somebody else’s physiology” (3256)

Some practitioners discussed the role of chance in serious treatment reactions and the inherent unpredictability of rare events:

“I think that sometimes we just cannot predict who will and who won’t have an adverse reaction” (2810)

“the nature of life is every now and then something may happen on your plinth which could be laid down to you doing something when it doesn’t even have to have something with you doing it, so risks of treatment, it’s almost as much for me as risks of someone being in your room when under your care” (2609)

4.15.8 Impact of patient serious adverse events on practitioners - Interview data

Practitioners who had experienced a patient serious treatment reaction were asked how the event had changed their clinical practice. A major theme in the practitioners’ assessment of the personal consequences of a serious treatment reaction was that they were considered to be emotionally charged and highly stressful. They were salient experiences that had a major impact on many of those who experienced them. The experience of a serious treatment reaction caused many clinicians to critically reflect on the general issues around osteopathic treatment and patient care and stimulated many practitioners to change both specific and general aspects of their clinical practice. Some practitioners commented that in retrospect the experience of a serious treatment reaction had a positive effect on their osteopathic work and development as a practitioner.

4.15.8.1 Theme 1: The negative personal impact of serious treatment reactions on some practitioners

The experience of a serious treatment reaction was considered by many clinicians to be a significant event in their professional lives which at the time caused considerable professional anxiety and personal stress.

“it’s the one time it’s happened and it was a nasty experience.....scary is probably a word I could use....it was a horrible moment.... a stressful time, shall we say” (2609)

“it was a bit of a shake-up, you think oh my God, patients come to me and am I hurting them” (2810)

Where the serious treatment reaction was perceived by the practitioner as seemingly disproportionate to the applied technique or where the putative cause of the reaction was unclear, practitioners reflected on the difficulties of managing uncertainties in the context of serious adverse events.

“if I was to take that into consideration every time I treated someone, and avoided doing what I did with her, I would probably be at the point where I wouldn’t actually be able to treat people, that was the hard thing for me to learn from it, was that actually to be completely and utterly safe.... would be to almost not have patients in and not treat them” (2609)

4.15.8.2 Theme 2: Specific and immediate changes to individual clinical practice

In some cases, where the practitioner was convinced that a high velocity thrust was directly implicated in the occurrence of the serious treatment reaction, immediate changes to technique selection were instigated. These included stopping the use of the technique or being more cautious in its application.

“I stopped immediately using an HVT and concentrated on perfecting the other techniques so it wasn’t a gradual situation, it was immediate” (3600)

“It completely changed my clinical practice, the first one did, I think, a couple of years ago, I think yeah I’m more wary, I think with the clause 20 thing coming in, pretty much are wary of that type of thing anyway, and with more and more litigation going around one tends to practise more defensively now, I think, or I do” (2810)

4.15.8.3 Theme 3: General and progressive changes to individual clinical practice

A major theme in the practitioner responses was the impetus given by the experience of serious treatment reactions to critically reflect and change individual clinical practice. These changes included increased vigilance in case history taking, changes in the choice and dosage of appro-

priate osteopathic techniques, the use of “graded” treatment plans, increased participation in professional training and the evolution of more individually tailored “patient-centred” treatment and management strategies.

“patients of a certain age are always treated exceedingly gently and everyone is always told if you don’t feel well, contact me..... I do that by using the absolute minimum of force anywhere, and if a patient says that hurts, I stop.... I never force an issue, if a patient says stop, we stop.... I’m patient-led, I’m not therapy-led” (3256)

“I use a great deal more rhythmic articulation, combined leverage articulation as well which is a halfway house, don’t think it has the same risk because there’s no jerking, no impulse I might move up from moving muscle energy one week to using a thrust the next week, and that would be a graded increase I mentally have a, what I see as a graded erm on the body range of techniques in terms of the physical impact, well physical and mental impact they have” (4711)

4.15.8.4 Theme 4: The positive professional impact of serious treatment reactions

Some practitioners set the experiences of serious treatment reactions in the context of their on-going day-to-day acquisition of clinical experience. In retrospect, some practitioners felt that the experience of a serious treatment reaction had had an overall beneficial effect on their clinical practice by developing a heightened awareness of individual characteristics of patients.

“It was the best thing that ever happened to me.... It just made me much more aware about you know, certainly people who are different age groups than me and I sort of realised that, oh ok, this person is not the same age as me, their body may well be very different to mine, and you know HVT’s something that you have to think very carefully about, before you apply it” (2925)

“I’m more careful on those can look remarkably healthy and young, and you’ve got to keep some awareness of that actually, that’s what I learnt” (4542)

For some their experiences led to them seeking specific professional development.

“I haven’t stopped using the dog technique, I did go on a number of technique courses immediately afterwards just to see that I wasn’t at variance with current practice.... and I took courses on risk assessment and various things that were being run up at the BSO” (3146)

4.15.9 Practitioners' perceptions of serious treatment reactions by practitioners who had not experienced them - Interview data

If practitioners had not experienced a serious treatment reaction in their clinical practice they were asked to identify the essential characteristics that they thought might make up a serious treatment reaction after osteopathic treatment.

Practitioners identified a number of key themes, including the need for medical referral, the exacerbation of presenting symptoms, the appearance of new symptoms, significant functional loss associated with treatment and treatment reactions beyond practitioner expectations and patient tolerance.

4.15.9.1 Theme 1: The need for medical referral

The need for medical treatment and/or management involving referral, the emergency services, hospitalisation and possible surgical intervention were considered to be major characteristics of a serious treatment reaction.

“in my opinion a serious treatment reaction would require medical attention.... or a speedy referral to, you know, emergency GP or A and E, or something like that” (2936)

The necessity for surgical intervention was considered to be indicative of an extreme reaction.

“obviously more extreme end is the need after that for having, well having surgery” (4711)

4.15.9.2 Theme 2: The exacerbation of presenting symptoms

An exacerbation of presenting symptoms associated with osteopathic treatment was considered by practitioners as associated with a serious treatment reaction, particularly if they were prolonged and unresponsive to further treatment.

“much worse pain than they started with for much longer than they anticipated, I would say” (3689)

Increasing levels of pain that were unresponsive to further treatment were thought to be worrying.

“prolonged aggravation of pain, erm, which I mean by that sort of perhaps at least a week erm with still just an increasing level of pain which despite having further treatment doesn't

settle down at all well” (4711)

The exacerbation of symptoms associated with structural damage was a particular concern.

“if somebody has a prolapsed disc and an osteopath went along and tried to manipulate it, and it was just maybe an annular strain before and it becomes a full major prolapse, that wouldn’t be the best thing in the world would it?” (3689)

4.15.9.3 Theme 3: The appearance of new symptoms

The appearance of new neurological symptoms, and particularly the appearance of new central neurological symptoms often linked to vascular damage, were felt to be an important characteristic of serious treatment reactions.

“suppose the thing that we all dread is some sort of vascular accident, due to your treatments, um, that would be very serious, it’s, I suppose if you’ve missed something in terms of pathology and erm you didn’t pick up on it, that would be quite serious” (3489)

The appearance of new peripheral neurological symptoms after treatment was also considered to be serious:

“I would call a serious reaction if they didn’t have any nerve root pain and you’d done a manipulation in the lower back and then they had symptoms of what you think might be nerve root pain” (3689)

4.15.9.4 Theme 4: Significant functional loss

Increased patient disability and functional loss was thought to be significant in the character of a serious adverse reaction.

“Severe pain, but that’s probably not enough in itself, accompanied by disability, which has to be prolonged, neurological damage, effect on the cerebral function, erm, I think that’s probably the main things, I would call that pretty serious” (4542)

“the person walks in and can’t walk out, I think that’s a severe reaction” (3689)

4.15.9.5 Theme 5: Treatment reactions beyond practitioner expectations

Individual practitioner expectations of treatment reactions were mediated by their clinical experience, osteopathic education and further training. Reactions that were unexpectedly more severe or of longer duration than anticipated were considered to be serious.

“Again, something different to what you’d expect in the first place you know from a longer point of view, a much longer course” (3689)

“I would consider to be an adverse reaction to treatment, which would be outside the bounds of what I would expect, and what the patient themselves can tolerate” (2396)

4.15.10 Practitioners’ descriptions of serious treatment reactions by practitioners who had experienced them - Interview data

Practitioners who had experienced what was to them a serious treatment reactions were invited to select a specific event and describe what happened. Practitioners recounted a range of self-defined serious treatment reactions associated with a variety of osteopathic and adjunctive techniques. The serious treatment reactions reported fitted with the categories of serious adverse event derived from the practitioner survey data. They included the exacerbation of, or the appearance of new central and peripheral neurological symptoms, the appearance of non-specific musculoskeletal symptoms, serious reactions associated with latent pathology and structural damage including fractures. Practitioners also described serious reactions apparently not associated with the application of a particular osteopathic technique, but with non-specific care factors such as movement or the patient changing position on the treatment plinth.

4.15.10.1 Theme 1: Serious treatment reactions associated with central neurological symptoms

Practitioners reported the occurrence of a number of serious treatment reactions associated with a range of treatment approaches including cranial and adjunctive techniques.

“I decided to treat her cranially, and she got up off the table and she felt absolutely fantastic.... and I felt very pleased with myself, and I got a telephone call the next morning, she’d been nauseated half an hour after the treatment when she got up the next morning she felt heaviness in the XXX side of the body, pins and needles down her entire XXX side, and when she was walking around her house she kept losing her balance” (1832)

A practitioner using acupuncture/trigger point techniques reported the following reaction:

“I believe that he had needle shock, and I was treating him in a sitting upright position because it was the best position to achieve this point, and he fell flat onto his face..... so we had to call the paramedics, and we went to A and E and I went with him and he stabilised” (1411)

4.15.10.2 Theme 2: Serious treatment reactions associated with peripheral neurological symptoms

The appearance of serious treatment reactions associated with peripheral neurological symptoms was either reported in some cases as immediate or in some instances it was delayed.

“Well one of my more serious patients that I think I mentioned to you was somebody who er, whose arm became completely anaesthetic after I’d dogged the mid-thoracic spine” (1832)

“I didn’t manipulate him, I used some soft tissue, some mobilisation techniques on his sort of lower back, and he basically sort of accused me of er incompetence and negligence er by damaging his nerve.... he phoned back I think it was about three or four days later saying that er he was in incredible pain, leg pain and er would I pay for an MRI scan” (1208)

“about a day and a half later I had a phone call from her saying that she had developed neurological symptoms and that they were strong and frightening.... when I saw her she was in a great deal of pain, very severe radicular pains down her arm and she had pins and needles and was holding her arm in a position because she was finding it uncomfortable.... my interpretation of what had happened was that I had set off nerve root symptoms with my treatment.... the GP, who then asked for an MRI scan pretty immediately” (1719)

4.15.10.3 Theme 3: Serious treatment reactions associated with non-specific musculoskeletal symptoms

The practitioners reported the occurrence of a number of serious treatment reactions associated with non-specific musculoskeletal symptoms that were frequently seemingly disproportionate to the applied technique or associated with changes of patient position on the treatment plinth and immediate in onset.

“I did straightforward soft tissue and articulatory technique, when she turned over on the plinth she felt a bit of a strange twinge in her back.... I felt in her back and just carried on with

the treatment, which I kept very gentle, when she went to get up she couldn't, she couldn't get up, she said the pain was too much when she tried to move... so I was fairly sure that it was, that she'd basically gone into spasm.... so in the end I took the decision and thought actually we need to get some paramedics to give her some gas and air, something to help her get up.... and they just took her down to A and E" (2609)

4.15.10.4 Theme 4: Serious treatment reactions associated with latent pathological conditions

The presence of latent or previously undiagnosed pathological conditions was a characteristic of a number of reported serious treatment reactions that were associated with fractures or systemic symptoms.

"I manipulated her.... I did the treatment as normal, soft tissue, mobilised, prone and supine, did some neck treatment.... went to do another HVT on her, dog,.... but as I went to manipulate her it fractured her XXX humerus, and what it turned out she'd got secondary in that arm, erm, so then I called an ambulance" (1773)

"... it was a middle-aged lady, came in with a relatively simple low back problem, had no history of diabetes, all her normal physiological signs were normal,.... suddenly within six hours of having the osteopathic treatment she collapsed at home, her husband called the ambulance, she was taken to hospital, there they did a full range of blood tests and found that she was massively diabetic and it was a type-2 diabetes.... there was no blame attached to me but I consider the osteopathic treatment precipitated the reaction.... that's the most dramatic that I've ever had...." (3256)

A death was reported subsequent to osteopathic treatment that was attributed to the presence of an aortic aneurysm.

"... I had completely got rid of the back pain, thought it was a successful treatment, didn't do anything to his thoracics, just flexed the lumbar, he had actually been seen by the GP and a cardiologist.... and I said, you know asked him if he was you know had he seen a doctor recently, he said I saw him last week, and he had a thoracic AA, and died in three days, so I'd completely not seen that, his low back pain, release of low back pain was actually referred from the back, from the thoracics....and I was pretty upset with that.... and since that moment I've never ever felt that low back pain can be just um, it can be cardio-vascular, it can be anything really...." (4275)

4.15.10.5 Theme 5: Serious treatment reactions associated with fracture

The occurrence of fracture was associated with the use of high intensity osteopathic techniques, including high velocity thrusts, on older patients.

“Um, the only thing I can really remember is in my very first year of practice, I had an older guy in, [aged between 70 and 80] and I did a lumbar roll on him and I think I fractured one of his TPs.” (2925)

“... it was a cross pisiform thrust somewhere in the mid-thoracic area, and he immediately got a sharp pain somewhere in the right anterior chest wall, and I was immediately concerned.... but it didn't settle for about four weeks, so it was almost certainly a fracture.... I mean he was in quite a lot of pain for a few weeks.... he looked about late 50s and in fact he in his 70's” (4542)

4.15.11 Practitioners' reported information sharing practices for serious treatment reactions - Interview data

Practitioners who had experienced a patient serious treatment reaction were asked to describe the practitioner-patient interactions and information sharing that occurred. Those practitioners who had not experienced a patient serious treatment reaction were invited to give some examples of how they might deal with the situation.

A number of substantive themes emerged from these data. Practitioners expressed the belief that serious treatment reactions were rare. Practitioners reported that they considered that there was a paucity of robust information available to them on these issues and that they were not confident that they had credible or reliable information to impart to patients. Clinicians expressed the view that alerting patients to the seemingly rare possibility of severe treatment reactions could be prejudicial to positive patient outcomes. Practitioners described carrying out patient centered risk/benefit assessments for each individual and that this informed the practitioners' selection of technique and treatment dosage. This was seen as a principal factor mediating the content and form of the practitioner-patient information sharing and consent discourses. There were variations in the way practitioners incorporated the patient requests and responses to information into their clinical decision-making. The data revealed several forms of formal and informal information sharing.

4.15.11.1 Theme 1: The rarity of serious treatment reactions

Practitioners expressed the belief that serious treatment reactions were rare and that this influenced the content and relevance of the information they gave.

“no I don’t, and that I guess is what the big argument is about, is do we advise people of what I see is that probably 1% a career situation happened, do I then advise every single patient and make them nervous about treatment and the effects that may have on them relaxing in treatment or letting me treat, no I probably don’t every time” (2609)

“...I shy away from giving them the worst case scenarios.... it’s extremely rare, so you know it’s unlikely that would happen anyway” (1773)

4.15.11.2 Theme 2: The lack of information about serious treatment reactions

Practitioners reported that they considered that there was a paucity of robust information available to them. This was seen as an obstacle to giving patients clear information about serious adverse events.

“... I tend not to go there I suppose because it’s just not within my experience to, and I haven’t got any information to um, I don’t have enough information, and I don’t know whether that information is available.... I admit if that information is available that is purely my ignorance, that I don’t have that information at hand to er give to patients and inform them.” (2416)

“... do we really know how many people have an adverse reaction from an upper cervical spine manipulation, probably not, and do we know how many people have severe adverse reactions, probably not because it’s under-reported probably, so we can only go on what’s reported....” (2810)

4.15.11.3 Theme 3: The negative impact of advising about serious treatment reactions

Clinicians expressed the view that alerting patients to the seemingly rare possibility of severe treatment reactions was likely to be prejudicial to positive patient outcomes. They were concerned that information would alarm patients and prevent them from deriving the benefit of relaxing during treatment and that negative expectations given by the practitioner would impact on successful outcomes.

“... I think it may affect the way that, for me, patients being relaxed on the plinth enables me to achieve a lot more and I’m worried that if people are sitting there worrying that that’s going to happen to them, that it will affect them....” (2609)

“....I’ll um mention the risk of a serious cardio-vascular event such as a stroke, and I do use the word stroke, and I know that that’s, you know, that’s debatable, it’s debatable whether that’s conducive to them going on and having a successful treatment, but I do use that....” (1719)

Some practitioners expressed the view that an extended consideration of serious treatment reactions may erode their clinical confidence in some techniques and lead to a restriction in the use of high velocity thrusts.

“... so I’m aware that actually to some extent possibly it is totally unpredictable, those are the ones you can’t predict, but because it is so rare I think most times one simply doesn’t think about it, thank God, otherwise you’d never do it....” (4542)

4.15.11.4 Theme 4: The impact of the clinical risk/benefit process on information sharing

The individual practitioners’ clinical evaluation of the risks versus the patient specific benefits in the context of the application of a particular osteopathic or adjunctive technique was a central theme. This risk/benefit analysis determined the scope of practitioner-patient information exchange. However, practitioners did not feel it necessary to gain consent for or inform patients about the risks of treatments that they had, on the basis of their clinical risk management evaluation, considered to be inappropriate.

“... well if I’m manipulating a neck I always talk about the possibility of these things, but maybe sort of couch it slightly, but um I think that what, if I felt that someone was at risk from a serious treatment reaction, I wouldn’t treat them in that way, and um that, yeah that’s how I feel about it....” (4652)

However some techniques were felt to warrant special care.

“I don’t tend to mention the question of stroke unless I’m going to perform a thrust technique.” (4711)

“....with the HVT I will then ask for consent for those specific techniques that I think are probably a little bit more risky....” (3489)

The perception of possible risk influenced the choice of osteopathic technique and this type of decision-making often appeared to take place within the practitioner’s own reasoning process as opposed to being a shared decision with the patient.

“... You know if I thought that, I wouldn’t do it.... I would never take that risk...., so that’s a conversation I have with myself....”(2343)

“...you know if I thought somebody was a bit dodgy I wouldn’t use a sort of lumbar roll, I’d use other techniques....”(1832)

As well as using a case history and standard examination some practitioners emphasised use of palpation as the reason for opting not to use manual techniques.

“...if the condition was such that it was very reactive under my hands.... I mean if I’ve got a raging um torn ligament, pulled ligament, er or acute um inflammatory arthritis, I probably wouldn’t treat them manually, I might suggest they go home and use some icepacks, and that therefore the reaction shouldn’t occur, if you see what I mean.....” (1185)

A minority of practitioners commented on their use of written consent procedures.

“....and I say to them I wouldn’t do that if you were in the risk categories, the high risk categories for any of those I wouldn’t manipulate your neck, but I legally have to verbalise that to you, do I have your consent, and then I’ll write it down, and I think that it needs to be a bit like surgery....”(4415)

There were variations in the way practitioners incorporated the patient requests and understanding into their clinical decision making. Some patients requested to be manipulated and practitioners varied in their response. A small minority of practitioners acquiesced.

“...I will do HVT by and large if the person requests it.”(4275)

However many practitioners resisted patient requests where they felt risks were unacceptable. In such instances, practitioners tended to give more information to patients about the potential harmful consequences of giving a particular intervention in order to explicitly support their decision.

“... if the patient wanted me to do something that I felt was dangerous, then I’d say well I don’t want to do this because there’s a major risk.... he wanted me to manipulate him, and I said an 80 year old, I don’t want to start manipulating, and also I’m going to make you much worse if I do, so it’s just gentle rhythmic traction....” (3689)

“I said are you a betting person, they said no, I said well if you were would you think that 50/50 odds are good, and they said not really no, I said so you’d want the odds to be in your favour, yes, I said well the odds aren’t in my favour if I manipulate you, I have a 50% chance of getting you better or a 50% chance that you will get worse and it might get very much worse, so I don’t want to take the risk and I’m not going to, and most people are, like, wowed by that” (2810)

Some clinicians reported that patients seemed to be happy for practitioners to treat them with techniques that might involve a risk of serious harm where patients appeared not to digest information about risk fully.

“...you have to point out the risks while, before you do it, some patients they’re interested, a lot of patients say oh just get on with it...” (3489)

“...I am very risk-averse but there is a sort of classic thing about high velocity thrust upper cervical spine and I do actually say to people if I’m going to thrust the top erm sort of upper cervical joint I do actually say to them this could give you a stroke or compress your cord or kill you and usually they roar with laughter and they’re quite happy that I go ahead with it...” (1832)

4.15.11.5 Theme 5: The styles of giving information about risks

The data revealed several forms of information giving. These involved the use of metaphors, framing contexts and varying degrees of formality. Few examples were given of practitioners describing risk in absolute numbers. This perhaps reflects their uncertainty about the data available. Some practitioners elected to give written information whilst the majority would use a verbal description of risks if they chose to discuss this with their patients. Some practitioners framed the information by highlighting the benefit and describing the risk in words. Some examples appear below which are indicative of the range of approaches to giving information about serious risk which were described by the interviewed osteopaths.

“..... basically I usually say, you know, this, because we’ve found these restrictions, I feel that the best way to improve the function, the mobility in this area is to use these techniques, this is what they involve, this is what you’ll, you know, you’ll feel, this is what you’ll hear, erm, there has been, you know a link made between, you know, strokes and, you know, these techniques.... but you know, you’re otherwise fit and healthy, I don’t feel there’s any, you know, particular risks, er as I say, and I don’t feel er uncomfortable using these techniques on you, so something along those lines.... I say that’s probably about it, so I’m happy that it’s, you know, clinically safe, you know, to use it on you, so, if you’re happy with that that’s what I’ll do...” (1208)

“.....I would talk someone through a technique like that and explain what’s going on, what I’m trying to achieve as we go along with muscle energy.... before I proceed I have to tell you that there is a potential risk with these kinds of techniques, the risk is extremely small but in very rare cases people have experienced a stroke following this kind of manoeuvre.... I don’t tend to use numbers unless they push me.... I would often say well it’s about as common as having a stroke after having your hair back-washed.... which is, happens once in a blue moon.... but you have to be aware that this is erm a faint possibility, and having told you that, are you happy for me to continue, to proceed?” (4711)

“we talk about having their hair done, them turning to look over their neck in the car, that’s exactly how I explain it, and I do tell them that they are very real risks, yes I do explain to them they are very real risks, but I say to them that the chances are this is the same kind of thing that could happen if you lean backwards at the hairdressers or you look over your shoulder in the car.” (2609)

4.15.12 Practitioners’ management of serious treatment reactions - Interview data

Practitioners who had or had not experienced a patient serious treatment reaction were asked to report the strategies that they used to minimise their occurrence. Specifically they were invited to report anything that they did or did not do to decrease or avoid the possibility of a serious treatment reaction and to describe the circumstances in which they would discuss serious treatment reactions with patients.

Two strong themes emerged from these data. The first of these focussed on prevention strategies aimed at the minimisation or avoidance of risks of harms and serious treatment reactions. The second theme related to management strategies aimed at preservation of patient/practitioner wellbeing and the maintenance of a positive therapeutic relationship prior to, during and after the occurrence of a serious treatment reaction.

4.15.12.1 Theme 1: Serious treatment reaction prevention strategies

Two substantive sub themes emerged from the data on prevention strategies. The first sub theme illustrated that practitioners were performing a form of triage to determine the suitability of the patient for osteopathic treatment. The osteopathic triage included a comprehensive case and medical history and used a variety of physical examinations. The use of careful observation, sensitive palpatory techniques and formal clinical tests were central features of the risk assessment and management of patients to minimise the risk of serious treatment reactions.

“... I mean it’s taking a good history, um, if you’re not sure about things you know asking again and again in a different way but not being too er dogmatic about things.... if their answers have been a bit vague then try and get some further detail from them” (1773)

“Case history taking, clinical testing, as much as possible.... I do reflexes, motor power on everyone that walks through the door, it gives me a base on which to work.... clinical testing, case history taking, thorough case history taking, I think would be probably what we can do primarily to minimise the risk of adverse effects, or creating an adverse effect.... I do what I think I can to make, to satisfy myself that they’re fit to receive treatment” (2416)

The use of palpation was considered to be an important component of a patient specific osteopathic triage.

“... I mean I’ve taken my history, and I’ve examined the patient, and then my third and very important part of my diagnostic skill are my hands” (1185)

Testing tissue and joint integrity were seen as an integral components of the treatment and risk management processes.

“...like you know the test becomes the treatment almost, like you mobilise and feel how far it goes and think well ok, yeah, alright, I was doing that, it’s ok to do it a bit longer....” (1773)

Some practitioners commented that they felt that it was important, as a risk minimisation strategy, that the multi-component osteopathic triage set precise boundaries to the osteopathic treatment process.

“... so you know when it comes to soft tissue approaches I’m, I try to be focal, try to very much to make sure that my treatment approach matches up with my diagnosis and my treatment plan, can we put it that way?” (1719)

“Not to over-treat, to be specific.... find the, what, you know, to spend quite a bit of time finding exactly erm, to your best ability the erm the er correct diagnosis and treat only that....” (4813)

The use of palpatory/proprioceptive sense was reciprocally related to the process of osteopathic treatment, so that triage and testing became part of the treatment and through the clinicians’ sensory feedback treatment became part of the process of testing and triage.

“Well my hands are picking up the tissue reaction all the time, aren’t they, as I’m working on them, so if I go onto an area that doesn’t like me being on it, for whatever reason, I have to work that out in my head as to why, is it related, not related, is it a separate incident, is it something else, what on earth’s going on here, and if it’s telling me to be careful I will be careful, and if it’s telling me that it needs to be released then I’ll carry on doing some more soft tissue to it, it’s the sense of feedback, which is I thought what osteopathy was all about, our patient feedback.” (1185)

“I would be very hesitant to um, to force any joint that doesn’t feel that it’s going to move in any way, shape or form if I was winding the joint up and I felt there was so much resistance I wouldn’t even hesitate, and I wouldn’t never ever try and manipulate that joint in a million years, if I felt there was any risk” (3689)

The second sub-theme in the management of serious treatment reactions concerned practitioners’ adaptation of their treatment approaches based on their triage. Practitioners evaluated the risks versus the patient specific benefits that in his/her opinion were likely to accrue from the application of a particular osteopathic or adjunctive technique. The administration of the technique was adjusted accordingly in terms of intensity, force, duration or frequency.

“... I tend to avoid upper cervical manipulation on people with um strong family history of heart disease or if they are, if they are, have heart disease, um, I always would consider using other techniques first in anybody over the age of 50.... for instance um you know maybe I wouldn’t use manipulative techniques on somebody who was osteoporotic, or I would modify the technique to such a point that it becomes very, very gentle.... I’d say you know there are certain techniques that I would rather not perform because you are taking this medication, or we might have to perform them in a different way” (2639)

“... trying to, you know, manipulate someone who’s, you know, very very immobile,.... in someone who’s generally you know restricted at a sort of spinal level.... I probably would you know as I say use more mobilisation techniques, more muscle energy stuff, get them to do more exercises, before they’re kind of almost built up to perhaps manipulation in more stubborn areas of restriction, so I wouldn’t avoid the techniques, you know I might just be choosy about how much I used them and when I used them....” (1208)

The graduated use of technique intensity and the avoidance of large forces were important elements in risk minimisation.

“... what I tend to do is do other things first to see if I get, much safer things first, to see if I get a reaction from that, and then it’ll give me more confidence to introduce the things I know are relatively more risky, higher risk.... it’s a really hard question, because it’s, I will test it in safe modes first, and then go into the other ones, but do I avoid it, I don’t do HVTs hardly ever...” (4275)

“...I minimise the amount of force that I use and I do not try to do too much at one time. Some people will respond adversely if too much is done, the body’s just not able to accept all the change all at one time, so I try to do it gradually if that’s possible...” (3600)

In contrast to the management of common treatment reactions, these risk-benefit calculations did not appear to form part of the explicit practitioner-patient treatment discourse; they are conducted “privately” by the practitioner as part of their clinical reasoning. These strategies were viewed as a key component of professional clinicianship by practitioners and patients alike. This “private” process has profound implications for the form and content of the information sharing between clinicians and patients. Practitioners did not feel it necessary to gain consent for or inform patients about the risks of treatments that they had, on the basis of their clinical risk management evaluation, considered to be inappropriate for that particular patient at that particular time.

“... if it’s even crossing your mind that there’s a potential risk here of a cerebrovascular accident, then I think you should be already choosing a different technique that doesn’t require high velocity thrust.... so in other words, and if you have to say to somebody, there is a risk here that I could give you, that I could cause you, you shouldn’t be doing it, because it’s not worth it for that level of risk” (4542)

In some cases risk minimisation resulted in the decision not to treat.

“... if I thought it was going to be one of the more serious ones, erm, no because I just wouldn’t do it, I’m trying to think, I just wouldn’t, if I thought it was going to do that I just wouldn’t do the technique, or I wouldn’t treat...” (4415)

4.15.12.2 Theme 2: Serious treatment reaction management strategies

Serious treatment reaction management strategies were employed by practitioners who anticipated serious treatment reactions occurring or once a serious treatment reaction had occurred. These strategies appeared to be aimed at the preservation of patient and practitioner wellbeing and the maintenance of a positive therapeutic relationship, albeit in potentially difficult and

stressful circumstances.

“In osteopathic care” serious treatment reaction management occurred while the patient remained under the direct care of the osteopathic practitioner. This was frequently while the patient was in pain or was incapacitated on the treatment plinth, but also if they were being cared for indirectly by their practitioner, perhaps after they had returned home post treatment. It included preparatory advice about the possibility of serious treatment reactions occurring. If a reaction occurred, practitioners aimed to be calming and reassuring to the patient and ensured that they understood that their wellbeing was of paramount importance to the osteopathic practitioner. They communicated that everything necessary would be done to ensure their recovery and future wellbeing. This included referral and possibly the use of the emergency services.

“Out of osteopathic care” strategies occurred when and if the patient was referred to another healthcare provider, such as to a GP or a hospital, and were used when patients left the care of their osteopath. They included the expression of contrition and apologies by the practitioner, offers of further care without charge, the maintenance of practitioner-patient contact through communication by telephone or practitioner visits to the patients’ home or hospital.

Some practitioners, frequently during treatment, prepared the patient for the possibility of serious treatment reactions. These actions were primarily aimed at the consolidation of the therapeutic relationship. They included advice by the clinician as to the type of possible reactions that might occur, assurances that they would be cared for outside of the osteopathic consultation and suggestions of appropriate methods that could be used by the patient to maintain contact with the practitioner.

“..... I do make absolutely sure that I’ve got the patient on my side so er it doesn’t matter if there are quite dramatic treatment reactions provided that I know that we’re sort of on the same side and that they’re not going to say look, you know hang on, you never told me this was going to happen, or, I mean you can get unexpected treatment reactions but you have to build up a huge erm sense of trust between the practitioner and the patient, especially if the patient is ill, so that when something does happen er there aren’t going to be repercussions....” (1832)

“A very strong relationship with the patient so that they feel confident that they can pick up a telephone..... and what I quite often say to them at the time that I give them the telephone number, I say look, you know, if you’re worried about anything, this may or may not happen, you know, you might have more pain, that’s fine, it might erm, you know various other symptoms that might happen, I give them a list of what is ok, and I say if you’re worried about anything, or the intensity of the pain then let me know, and erm, that seems to do it.....” (2978)

Interviewee 2463 summarised their approach when describing the management of a serious

treatment reaction involving non-specific musculoskeletal symptoms.

“... I just did some very, very gentle sort of calming techniques on her to see if it would start to ease off, then when it was clear it wasn't I did explain to her and said listen, I'm going to try and be rational with you at this point because obviously it's a little bit nervy for you the fact that you can't get up, I said, but remember you have had this at home before, and this is, as I may have explained to you before, and just remember that spasm is something that's controlled by the brain, so you haven't walked in and tripped over or fallen over and caused yourself any major damage, and I haven't done any techniques of any ferocity that would cause you any damage.... and as worrying as it is, just try and stay calm and although this may seem a bit over the top I just want to do the best thing for you to get you out of this situation as quickly as possible, I said I'm sure we'll have you walking again very quickly but I think a bit of gas and air to take away that spasm.... that should help to get you out of this situation.... but in the end, although she was very comfortable, she couldn't get up and she'd been there for 15 minutes, so in the end I took the decision and thought actually we need to get some paramedics to give her some gas and air, something to help her get up, so I got some paramedics along, they gave her some gas and air and she managed to get onto a chair, and they just took her down to A and E, gave her some strong muscle relaxants.... ” (2463)

When patients leave the care of the practitioner, but are in the process of experiencing a serious treatment reaction, practitioners expressed contrition and apologies, and offered further care without charge. They also attempted to maintain practitioner-patient contact through communication by telephone or practitioner visits to hospital or the patient's home.

“... if they came back with an adverse reaction I would be honest with them and I would say I didn't realise you'd react that way, I've never seen that before and I'm surprised, and I'm sorry that that has happened, but this is the reason that I use the technique and I wouldn't have expected that, and I would have I wouldn't have done the technique, that's how I would describe it to them, so they're reassured that I did the best possible for them....”(4415)

“... I had a phone call from her saying that she had developed neurological symptoms and that they were strong and frightening, and that she'd had a lot of pain around her neck, so I asked her to come in and said that I'd see her without charge and we would just assess what had happened and I would do another assessment and find out what was happening.” (1719)

Maintenance of practitioner-patient contact was a frequent strategy used to manage serious treatment reactions. This continued contact enabled some practitioners to continue their care to the point of referral or involvement of other healthcare practitioners.

“... so I went out to visit him at home.... I gave him advice on that and said we’ll either get you back into the practice to have another look at you, just to reassess you, erm or if things aren’t good by the end of the week I’ll come back out.... when I phoned him at the end of the week, he wasn’t any better so I went out to see him again.... I’d contacted his GP erm obviously er because I was quite concerned about him, not that I felt that treatment had caused the, you know could have caused the symptoms....” (1208)

Where patients were admitted to hospital some practitioners considered that it was appropriate to maintain contact and some felt it necessary to visit.

“... the outcome was that I wrote to her, I perhaps shouldn’t have done this, but I did at the time, it was a long time ago now....” (1773)

“... they just took her down to A and E, gave her some strong muscle relaxants which wiped her out a bit, um, she went home later that night and two days later she walked into the clinic to see me just to say don’t worry, it’s all fine, nothing’s wrong, I mean obviously I’d called a hundred times after that.... it was a case of muscle spasm.... thank God it’s only happened the one time in my career.” (1719)

“... I did go and visit her, I was advised, erm, I went to visit her once because I felt that I should.” (1832)

4.16 Adverse events register

Osteopaths were asked whether they thought that the establishment of an adverse events register would be a good idea for osteopathy. Out of the 1,027 osteopaths who responded to the question, 794 practitioners, 77% (CI 74.5 to 79.8), replied affirmatively. A slightly larger number of osteopaths (1,035) replied to a subsidiary question asking whether they would be willing to contribute brief details of any adverse treatment reactions that occurred in their practice. Of the respondents 915 (88.4%, CI 86.3 to 90.2) indicated willingness to contribute to such a register.

An open free text question asking osteopaths to explain their reasons for thinking that a register of adverse events would be good or not was also offered to participants. Of the 937 who completed the free text question, 198 (21.1%) answered no to the question about whether an adverse events questionnaire was a good idea for osteopathy, 702 (74.9%) answered yes and 37 (4.0%) added a comment in the free text question but did not answer the binary question.

4.16.1 Explanations and attitudes towards an adverse events register in osteopathy - Qualitative data from practitioner survey

Free text responses were grouped by their positive or negative answers to the survey question about whether an adverse events register was a good idea for osteopathy. 75% of respondents endorsed the establishment of a register. Some highlighted the potential for it to aid clinical decision making for individuals and for the profession as a whole, as well as help with providing better information to use during consent processes, while others felt it would provide good continuing professional development opportunities and support student learning. Practitioners also cited benefits in terms of professional credibility and the development of research and new knowledge. More detailed analysis focussed on the minority of respondents who indicated that they did not feel that an adverse events register was a good idea for osteopathy, in order to explore the objections and perceived obstacles to the introduction of a register.

4.16.1.1 Explanations of why an adverse events register is not a good idea for osteopathy

Two major themes emerged from the free text data: concerns about the negative impact of a register, and views that there was not sufficient justification that a register would be useful.

The negative impact theme included concerns about blame as a consequence of submitting information to a register. This took the form of concerns about being struck off or held to account, generating a blame culture and fears of information being taken out of context.

“Difficult to standardise and ensure compliance. Practitioners might fear being either stigmatised for being on the register or fear being called to account for such incidents.”

Some respondents felt that the cost of setting up and running such a scheme was not worth the benefits.

“Cost - I don't want to pay any additional money to service this!”

Others were concerned about the potential impact a register would have on the profession's reputation, practice and scope of treatment. Concerns focussed on negative perceptions that a register might create.

“....so I'm not sure what benefit having a register would have, apart from panic the public.”

“I think it would act as negative marketing for osteopathy... it may also lead to misunderstandings about the real risk of treatment, which is minimal.”

Respondents were also concerned that a register might become a tool for reducing the scope of practice.

“I feel it would be the ideal opportunity for GOsC to remove HVT as part of osteopathy treatment.”

“...it could lead to...osteopathic technique being banned.”

Some practitioners considered that an adverse events register could have a negative impact on patients. This was described as provoking fear, putting patients off attending for osteopathic treatment and creating stress in patients.

“This will make patients frightened to have treatment. I appreciate that patients should be informed of potential adverse reactions but this needs to be given in a relaxed and reassured way by the practitioner concerned. To read something on the internet will I fear be very off-putting.”

The second major theme concerned osteopaths' views that there was insufficient justification for the introduction of an adverse events register, in terms of its utility and the likelihood that a register could be implemented and deliver useful information.

There were concerns that such a register was incompatible with the individualised approaches used by osteopaths.

“Because of the diversity of patients and the nature of the individualisation of treatment plans for each patient within osteopathy.”

Some felt that such a register would be not in accord with osteopathic values.

“Osteopathic treatment is about helping the body to regain its normal healing balance. If applied correctly treatment reactions are rare and osteopathic treatment should not be a recipe for conditions so there should not be a recipe of adverse reactions.”

“Medical adverse reactions compare the same drugs prescribed to patients. You cannot compare our treatments in the same way as one patient is very different to another so the reaction is not dependent on a 'technique' we did but on many various factors which is the whole basis of osteopathy.”

A large number of osteopaths raised concerns about the subjective nature of the information and felt that a register was an inappropriate method for recording adverse events, which by their nature were caused by individual osteopaths' treatment and individual patient responses. Respondents felt that a register would not produce useful generalisable information.

“Because each patient is individual, and their responses to treatment are individual and specific to them, the techniques used and the practitioner carrying out the techniques. Also treatment reactions in the same person can vary week to week depending on a multitude of elements.”

“The cases of adverse reaction are individual, eg poor clinical reasoning skills or poor application of technique, for which no lessons could be learnt.”

A few practitioners expressed concerns about who would have access to the information, and whether it could be properly anonymised.

“Would depend greatly on who stored information; why it was stored; who could access it. Nothing can beat good open communication between patient and practitioner on an individual basis.”

Some practitioners mentioned practical concerns about implementing such a register, and suggested that practitioners would be unwilling to submit details.

“Too hard to administer and manage - most treatment reactions can be subjective - would have negative effects for both patients and osteos.”

“Compliance would probably be poor, just as it is with the 'yellow flag' system currently in use by General Practitioners.”

Some also thought that current structures adequately dealt with the issue.

“Not necessary if have examples in clinical guidance material.”

“No real need. If the practitioner has explained the process thoroughly enough and the possibilities the patient will be reassured. Either the GOsC and/or the BoA do have complaints procedure who could advise patients in case of reaction. Another body set up specifically for this would be a little much.”

Practitioners also thought that adverse events were very rare and the effort required to set up a register was disproportionate for such events.

“They are probably so rare as to be statistically invalid.”

“Severe treatment reactions are extremely rare. I personally have not caused permanent disability and nor have other osteopaths I know. No patient has ever reported such an event occurring personally or heard of one. Any patient could have an aneurysm, tumour, deformity. Life is uncertain, nothing can be 100% safe.”

5

Discussion

5.1 Introduction

The discussion adheres to the mixed methods approach by integrating the results from the practitioner cross sectional survey, the observational cohort study of patients from baseline to six weeks and the interview studies of practitioners and patients. For each key area we describe the main findings, outline how they fit with existing literature and highlight the implications for practice and policy. Where an increase or decrease in symptoms/pain is described, we have used a 30% change threshold to summarise results that are likely to have clinical significance to patients. Strengths and limitations of the study are also summarised.

5.2 Characteristics of osteopathic practice

The practitioner survey results are based on 1,082 practitioners with a response rate of 27.8% which is comparable to surveys with professional health care providers⁶³ and osteopaths.⁶⁴ UK osteopaths were reasonably well represented in that there were no differences in age or time since qualification between responders and non-responders, although female practitioners may have been slightly over represented.

Over 80% of patients were reported by osteopaths as seen in dedicated private clinic/practice settings, 15% in home settings and 4.9% in NHS settings. New patients made up between 13% and 21% of osteopaths' weekly patient lists. Higher rates of new patients were found in NHS settings. On average, osteopaths saw 33.3 patients a week and 52% of osteopaths reported that their main setting was in an environment where discussion with other professionals was not available. The average appointment time for new patients was 50 minutes and 30 minutes for follow up appointments. On average, male osteopaths spent less time with new patients than female osteopaths (difference in median of 15 minutes). There were significant predictors of consultation time, but these related to small changes in duration of consultation.

5.2 Characteristics of osteopathic practice

There was considerable variation in the extent of use of different osteopathic techniques. Summaries using averages describe techniques used by osteopaths as a group; however, small numbers of practitioners report performing individual techniques on all of their patients. The most commonly used techniques were joint articulation and soft tissue with an average reported use on 90% of patients. Visceral techniques were the least commonly used, with almost 50% of practitioners reporting not using this approach on any patient in the last month. On average, cranial and visceral techniques were used on 10% of patients and HVT on 50% of patients. HVT was used on 20% of patients when treating the cervical spine, 40% of patients on treating the lumbar spine and 50% on the thoracic spine, but 16% of practitioners did not use HVT in the neck on any patient in the last month. The prediction model for using HVT accounted for only 10% of its variance. The significant predictors associated with increased use of HVT included shorter consultation time, strong beliefs about the predictability and benefits of HVT, lower perception of various risks, being male and being more experienced. Practitioners who reported difficulty discussing treatment reactions with patients were less likely to use HVT. The predictors of increased use of indirect techniques (defined as functional, counterstrain, visceral, cranial approaches) included longer consultation times, being female, perceived importance of headache and migraine as a risk factor when treating the neck and higher perceived risk of HVT for thoracic and lumbar pain.

Adjunctive techniques were used by 44.3% of the sample. The most commonly used approaches were dry needling/ acupuncture, electrotherapy and nutrition therapy, but where used, this was in a low proportion of patients. Our data provided insufficient explanation to predict the characteristics of users of adjunctive techniques.

The baseline patient survey generated 2,039 responses. It contained a short section for practitioners to report the treatment techniques that they had used during the baseline consultation with their patients. It broadly provided corroboration for the estimates that practitioners had made in the practitioner survey. Use of HVT was reported in 43% of encounters. Joint articulation (86%) and soft tissue (91%) were used the most often. However, functional techniques were delivered to 25% in comparison to the 10% estimated in the practitioners' survey. Similarly, 31% reported using cranial techniques and 4% reported using visceral techniques. While the use of soft tissue techniques were distributed across all body areas, the use of HVT was mostly carried out on the thoracic spine (32% of encounters) followed by lumbar spine HVT at 18% and the cervical spine at 14%. All techniques were less prevalent in extremities, reflecting the lower presentation rates of these areas as the primary complaint as well as lower usage of HVT in treating extremities. HVT was used in less than 1.5% of cases for all other areas of the body.

Adjunctive techniques were reported as being used by 19% of practitioners and applied to fewer than 5% of patients. These mostly consisted of dry needling/acupuncture and electrotherapy.

The median age of patients was 56 and 50% of patients were aged between 45 and 64.

5.2 Characteristics of osteopathic practice

Sixty five percent of respondents were females. Fifty seven percent of patients were employed and 29% were retired. Ninety percent of patients were non smokers. Educational levels were spread equally between those leaving school at 16 and those who pursued further education. Common comorbidities were present in 56% of the patients and the highest proportion amongst these were musculoskeletal in nature (43%), followed by digestive or stomach problems (20%), cardiovascular problems (18%) and mental health problems (12%). Twenty seven percent of patients had cold or flu like symptoms in the two weeks preceding the baseline consultation.

Medication use was reported by 62% of patients, the most common medication consumed by patients was related to blood pressure (19%), followed by cholesterol lowering medications (14%), antidepressants (9%) and blood thinning medications (7%). A large proportion (71%) of patients had taken pain killers in the last week before their consultation, of which 38% were anti-inflammatories. Most patients had seen their GP in the last six months prior to consultation (72%), but only 7% were unable to work due to their current symptoms. Health status was generally good with a mean Eq5D score of 0.67. A large majority of patients (90%) reported no problems with self-care, 62% of patients had no problems walking, 70% of patients reported no problems with anxiety or depression. However, approximately half of the patients reported some problems performing usual activities and 77% reported moderate pain or discomfort.

The largest proportion of patients presented with their main complaint being in the low back region (41%), this was followed by the neck area (17%) and shoulders region (13%). Together, these accounted for 71% of the areas where patients' main problems were represented. One third of patients could be described as having acute symptoms of duration of less than one month, 24% sub acute (1-3 months) and the remainder with more chronic conditions.

The majority of patients were in ongoing care (71.9%), and had received a median of five treatment sessions with their osteopath at baseline. The remainder of patients were either new patients or patients presenting with a new episode of symptoms. New patients were similar to ongoing patients in terms of their age, gender and education, but were more likely to be off work, and twice as likely to have taken steroids in the previous week. They also had fewer comorbidities and less widespread pain.

In summary, most patients were seen in dedicated private clinic settings. An average of 33 patients a week were seen, with appointment times of 50 minutes for new patients and 30 minutes for follow up patients. The most common and highly-used techniques were soft tissue and articulation. HVT was used in between 40% and 50% of patients and this varied by location, with the cervical spine being the least frequent spinal site for manipulation. Other osteopathic techniques are used less frequently and low levels of visceral and adjunctive technique use were reported.

A large proportion of patients were female and aged between 45 and 64. About half of the patients seen had a common comorbidity. The largest group of these was musculoskeletal. Spine-related areas of the body were the large majority of primary presentations. Medication related

to common comorbidities was being used by at least 62% of patients and analgesic medication was being used by 71% of patients. Overall health status of patients was good; most difficulties were related to performing usual activities and pain or discomfort. Patients presented mostly with primary complaints in low back and neck regions followed by the shoulder area. There was spread of chronicity of conditions from acute to chronic.

5.2.1 How the results fit with existing literature

In a cross-sectional survey of 171 osteopathic physicians in the USA focussing on the assessment and treatment of spinal and sacro iliac problems, myofascial release techniques were most commonly reported (78%) as used for spinal dysfunction, followed by soft tissue techniques (77%). Similar levels of use for HVT were reported as in our study. Males were found to perform significantly more HVT than females. Cranial techniques were more frequently used than reported by the respondents to our survey.⁶⁵ A similar survey of 520 British osteopaths found results comparable to our own, with articulation (91%) and soft tissue techniques (91%) being most commonly used, followed by HVT and muscle energy techniques. Again, males were more likely to use HVT than females.⁶⁶ Fawkes et al.²⁰ reported on data from 342 osteopaths treating 1,630 patients. Their findings were closely aligned to our results with a similar rank and frequency of techniques used. Similar patterns of treatment are also reported in various single day surveys.²⁸ Slightly lower estimates of use of techniques have been reported amongst 255 Australian osteopaths, but following a similar trend where soft tissue and articulation appear to be the most frequently used technique, followed by HVT and muscle energy technique.⁶⁷ An older UK study of 43 osteopathic practices reviewed 5,310 back pain patient records and reported 69.9% use of soft tissue, 51.9% passive joint movement and 48.0% HVT.²² Our finding that osteopaths use HVT most frequently in the thoracic spine may relate to its use as part of treatment for low back pain and neck pain. There is low quality but increasing evidence that thoracic manipulation is effective in the treatment of neck pain.^{68,69}

There have been few comparative studies which describe chiropractic, physiotherapy, and osteopathy. Evans⁷⁰ reported on a large cross-sectional analysis of the three professions' reported clinical behaviour in response to a vignette of non-specific acute low back pain. Spinal manipulation HVT was highest in chiropractors (90.1%), then osteopaths (60.7%) and lowest in manipulative physiotherapists (6.0%). Soft tissue massage, stretching and spinal mobilisation were most frequently reported by osteopaths and were at similar levels to those found in our study.

Higher levels of HVT manipulation (50% and 85%) and lower levels of soft tissue techniques (29%) have been reported in chiropractic neck treatment than in our study.^{15,71} Mootz et al.⁷² reported on 2,550 chiropractic visits in the USA. HVT spinal manipulation was the most frequent intervention, occurring at nearly 85% of visits. Soft tissue techniques ranged from 12% to 14% of visits. Low back pain was the largest region of complaint (44% to 41%) followed by neck/face

pain or injury (23% to 26%).

Physiotherapy treatment for low back pain in Northern Ireland has been reported as including infrequent use of HVT (8.9%) and moderate levels of articulatory approaches such as Maitland mobilisation (43.8%).⁷³

Chiropractic consultations appear to be shorter than those performed by UK osteopaths. A survey in the Netherlands of 113 chiropractors reported mean duration of first visits at 41 minutes and follow up visits at 15 minutes.⁷⁴ A survey of chiropractic in Europe reported a similar average of 15 minutes for follow up appointments.⁷⁵

In summary, our data concords with other UK studies, suggesting that soft tissue and articulatory techniques are the main manual therapeutic techniques employed by osteopaths. HVT is used by osteopaths fairly frequently, but less so than by chiropractors and more than by physiotherapists. The stronger focus on HVT approaches may partly explain the shorter appointment times reported in consultations by chiropractors.

5.2.2 Implications for practice and policy

The characteristics of osteopathic care in the UK are becoming clearer from the results of this study and others. In the context of risk assessment and management, highly prevalent practice and common characteristics of patients should inform osteopaths' education, continuing professional development and the type of information that is given to patients to inform their expectations of care. For example, a large proportion of patients present with spine-related areas of complaint, and are aged between 45 and 64. Osteopaths should have a good working knowledge of spinal conditions and pathologies which are associated with this age group. Similarly, many patients are presenting whilst using analgesic and other common medicines and a knowledge of the effects and side effects of this type of medication should be expected. There is a tension between the current scope of practice, which does not include prescribing rights, and the need to be alert to potential harms of medication and indeed benefits of medication as an addition or alternative to osteopathic treatment. The question arises as to what extent osteopaths are competent to give direct advice to patients in these areas. The wide range of duration of symptoms reported by patients suggests that there is also scope for osteopaths being required to understand the different needs of patients with chronic and acute episodes of pain.

The core treatment modalities appear to be soft tissue and articulatory techniques with HVT used commonly, but to a lesser extent. Further debate is warranted to consider whether technique modalities that are used infrequently require specific evidence of ongoing competence. This applies to osteopathic techniques that are only occasionally used and to adjunctive techniques which also appear to be infrequently used, but by a significant minority of osteopaths. The argument that competence is related to frequency and familiarity of use of a technique is contrasted by results reported and discussed elsewhere in this report, suggesting that there is low risk of harm generally from osteopathic interventions and that specific groups of interventions do

5.3 Perception of risk and risk management by referral

not appear to be related to the occurrence of minor to moderate adverse events. However, there remains a question particularly relating to adjunctive techniques, as to whether these techniques should be delivered in the context of an osteopathic consultation, where the regulatory structure appears not to have a clear mechanism to determine practitioners' competence.

Patients' expectations may align with "average osteopathy" as access to osteopathy is most commonly through word of mouth. Where individual osteopaths predominantly use techniques that are rarely used by the profession overall, there may be a need for patients to be given specific information about the nature of their practice. An additional consideration relates to the current literature being focussed on US, and Anglo-Asian osteopathy. There may be differences in the prevalence of modalities used by osteopaths in different mainland European countries. This warrants further research to determine whether practitioners educated in different states may require specific advice about the context and practice of osteopathy in the UK.

At least half of the osteopaths in our survey reported that their main practice setting was not in a setting where they could discuss their work with other health professionals. Clinical governance structures for private practice need further consideration where practitioners do not benefit from the structure and support of institutional governance such as in large group settings or in NHS contexts. There are opportunities for peer review and appraisal which are likely to benefit practitioners and their patients, particularly those working alone or in home settings. This would help osteopaths meet Practice Standards³⁵ which include guidance about working with others to secure the most appropriate care for patients and meeting the standard of keeping professional skills and knowledge up to date, which is suggested as including the use of feedback from colleagues.

In summary, there are now opportunities for continuing professional development and pre-registration education to be informed by research that describes the characteristics of UK osteopathy. Further debate about the range of osteopaths' scope and style of practice is warranted, in terms of both patient expectations and the maintenance of competence. Clinical governance issues, particularly pertaining to private practice and practitioners who may be isolated in their work, require further exploration. There are opportunities for structured peer review and appraisal.

5.3 Perception of risk and risk management by referral

Overall osteopaths agreed that it was predictable who would benefit from HVT manipulation, but a significant proportion of osteopaths (28.5%) disagreed. Osteopaths' beliefs about the predictability of minor and major treatment reactions were more variable, with major treatment reactions being seen as the least predictable. Median responses for both were in the middle of the scale, suggesting uncertainty in these areas. Views about the benefits of patients having a treatment reaction such as getting worse before getting better, or the exacerbation of presenting

5.3 Perception of risk and risk management by referral

symptoms being positive, were not generally endorsed; however, between 4.5% and 14.3% of practitioners did hold such views.

All the items associated with risk of vertebro basilar stroke were endorsed as important in the assessment of risk of treatment reactions when treating the cervical spine except gender. Similarly, osteopaths thought that factors relating to referring patients were all important with clinical indicators of undiagnosed pathology or structural deficit being most important (median = 6, IQR 6 to 6, 0-6 scale) and patient satisfaction being least important (median = 4, IQR 3 to 5)

In summary, osteopaths reported some confidence in predicting who would benefit from HVT, but were less certain about predicting the likely occurrence of adverse events relating to HVT. Despite this, they rated as important all the major risk factors associated with vertebro basilar stroke and emphasised undiagnosed pathology and structural deficits as the most important factors in referral.

5.3.1 How the results fit with existing literature

In this study, we focussed on risk factors derived from epidemiological and other data with respect to severe adverse events which have been associated with stroke and treatment of the neck using manual therapy.^{36,76} This list therefore comprises of comorbidities, characteristics of the patient, and medication consumption. Practitioners were not invited to describe their full triage and case history processes and therefore we do not have information about other known screening tests such as those for cranio-vertebral instability. The utility of such screening pre manipulation has not been established and they are rarely used by other musculoskeletal practitioners such as physiotherapists.⁷⁷ Recent recommendations in relation to such tests emphasise the need to develop reliable indexes of physiological risk indicators alongside the use of questionnaires to identify inherent risks.⁷⁸ The causal relationship between manual therapy and stroke remains controversial, with the highest quality study showing a similar increased association between seeing a chiropractor and seeing a family physician and vertebro basilar stroke. The authors of the study conclude that patients present to chiropractors with symptoms associated with vertebro arterial dissection and subsequently develop ischemic stroke.¹³ Research examining risk factors for vertebro arterial dissection is complex and existing research suffers from many methodological weaknesses. Risk factors with some supporting evidence such as vessel size abnormality of the carotid artery are not assessable in osteopathic clinical settings.⁷⁶ Taylor and Kerry⁷⁸ argue that manual therapy theory should encompass a systems based approach which includes knowledge of the whole cervical vascular system and hemodynamic principles in relation to anatomy and biomechanics. Clinicians should be alert to cervical vascular pathology, especially in the context of acute trauma and be aware of neck pain and headache as precursors to posterior circulation ischemia. History and examination should include awareness of vascular risk factors and ability to perform cranial nerve and simple eye examinations.

In summary, risk assessment for the cervical spine in the context of osteopathic treatment remains challenging for practitioners, particularly in the context of rare conditions associated with stroke. Clinical guidance is available to aid practitioners in this area of practice.

5.3.2 Implications for practice and policy

The majority of risk factors reported in systematic reviews are neither necessary nor sufficient for the occurrence of vertebro basilar stroke. It is therefore not surprising that the osteopaths in this study expressed uncertainty about predicting such events, while endorsing the comprehensive list of risk factors they were presented with in our survey. Some risk factors that are necessary or sufficient to produce stroke are beyond the scope of clinical detection in osteopathic settings. Until screening procedures are established that are accurate and practical in the context of osteopathic practice, the detection of such rare events remains problematic for practitioners.

Clinical education and professional development should focus on the history and clinical examination of patients rather than the use of clinical screening tests. Awareness of the function and anatomy of the cervical vascular system and clinical presentation of cervical vascular pathology is recommended to aid in the identification of patients at risk of stroke at presentation for treatment.

5.4 Consent and information exchange

Osteopaths reported high frequencies of gaining consent for examination and treatment related to initial consultations, but lower levels with respect to subsequent treatment and examinations. Consent for specific techniques is more formally recorded and more frequent for the use of HVT where the technique may involve higher perceived risk and stronger application of force. HVT in the context of treating the cervical spine was judged by osteopaths as the most difficult area to talk to patients about possible unpleasant reactions, where 25% of osteopaths found it difficult to talk to patients about this topic. This finding was strongest in the context of new patient consultations. A small proportion of osteopaths reported not gaining consent for examination (11.3%) and treatment (8.6%). Practitioners perceived giving information and receiving consent more than appeared to be perceived by patients. Patients and practitioners considered information giving and consent less of a priority where they have an existing relationship with their osteopath and have experience of osteopathic treatment. Most patients thought it important for osteopaths to ask their permission prior to examination and treatment, however a proportion of patients thought that osteopaths asking permission before examination (30%) and treatment (28.0%) was not important. Again these findings related to the patients' prior experience of osteopathic care; new patients thought that osteopaths gaining permission for examination and treatment was more important than patients who were in ongoing treatment or were presenting with a new episode to an osteopath they were familiar with.

In new patient consultations where most information is being discussed and consent is more prevalent, only 50% of patients reported talking to their osteopath about risks of treatment and 48.4% about likely outcomes of no treatment or alternative treatments. Interview data from patients and practitioners suggested that a range of activities were included in consent processes including the use of written information, discussion at initial and ongoing appointments, and observation of patient behaviour. The salience of information about risks, benefits and alternative treatments and the importance of the consent process was mediated by the experience of care, a positive therapeutic relationship, and the choice to attend for treatment. There was some sharing by practitioners and patients of the concept of consent being implied by choice to attend and compliance with requests by the osteopath. Notable exceptions included a new episode of symptoms, the introduction of a new approach during ongoing treatment, HVT and seeing a new practitioner. Some patients described a need for particular information concerning the intimacy of examination, the extent of undressing required and the need for chaperones between female patients and male osteopaths. Patients valued information about the process of care and saw its provision as relationship building and important in helping them set expectations and to understand their condition and responses to treatment. Risk of treatment was predominantly construed of by patients in terms of a lack of benefit from osteopathy rather than in terms of hazard and harms. Whilst practitioners valued giving information as part of building their therapeutic relationship with patients, some saw giving information about serious risks as an obstacle to this process and considered that information about serious adverse events caused stress in patients and promoted fear. Some of the practitioners interviewed elected not to disclose risks of serious adverse events to their patients. Patients however, did appear to value information about risk, but assumed that there was no or low risk when they had not been given information, or assumed that the osteopath would inform them if there were risk involved with treatment.

Approximately a third of osteopaths replying to the survey felt that they had not received adequate guidance about consent. At interview, practitioners' attitudes to consent as articulated in the 2005 Code of Practice³⁴ included practical concerns about having received insufficient guidance to adhere effectively to the Code and uncertainty about the nature of information that should be given to patients. This was particularly with reference to information about risk.

In summary, we found that most information and consent-related processes occurred where patients were new to the osteopath they were consulting and that new patients rated information as more important than those who were familiar with osteopathy. Osteopaths perceived consent giving taking place more than patients and a small minority of osteopaths reported not engaging in consent-related activity. The focus of information giving was around the nature of osteopathy and its potential benefits, as opposed to risk and alternative and no treatment options. Osteopaths found it most challenging talking to new patients about unpleasant reactions associated with treating the neck. There was uncertainty about the nature of risks and the

extent of information that should be given to patients and some concern from practitioners that giving information about serious risks might cause stress and prevent patients from gaining the best outcomes. A significant number of patients did not recall receiving information about risk and alternative or no treatment options. The importance of the consent process appears to be mediated by experience of care, a positive therapeutic relationship and the choice to attend for treatment. Risk often appears to be understood by patients as lack of benefit rather in terms of hazards and harms. A variety of modes of action were used as part of the consent process. These included verbal, written and behavioural.

5.4.1 How the results fit with existing literature

We found that consenting practices are variable and routine signed consent from patients is rare. These findings appear to be in line with other findings in UK osteopathy²⁰ and appear to fit with expectations of care from osteopathic patients.²¹ Similar findings were reported in a study of 124 chiropractors and their patients in Australia⁷⁹ and in a survey of 83 UK chiropractors.⁸⁰ A qualitative study with 21 Danish physiotherapists found variation between practitioners, with some not perceiving informed consent to be an important part of the consultation.⁸¹ An exploratory qualitative study of nurses in the UK found that consent was seen as preferable but not essential. In contrast, a qualitative study of Canadian physiotherapists, reported that a blanket written consent to treatment, in line with local regulatory guidance, was obtained from all patients on their first visit. This was followed in some cases with further specific modes of consent being used.⁸² It is unclear to what extent the degree of professional and clinical autonomy influences perceptions of the role and importance of consent practice.

The initial consultation was the primary source of consent in our study. Fawkes et al.²⁰ also reported a decrease in reported consent from osteopaths from new patient appointments to follow up appointments.²⁰ Similar findings are reported in Australian chiropractors,⁷⁹ Canadian physiotherapists⁸² and in UK chiropractors.^{83,84} Although initial consent for treatment is reported as high in US chiropractors and UK chiropractors, this is reduced to 10% and 17% respectively in successive visits.⁸³ The decrease in consent-related behaviour after the initial consultation with a patient may be explained by the assumption that information is retained by patients and that consent once received is enduring. There was also evidence from our interviews that some practitioners and patients thought that repeating information was unnecessary.

Osteopaths in our study reported difficulties and omissions discussing risks and major adverse consequences of treatment. Fawkes et al.²⁰ report 79% of osteopathic patients being given information about side effects and 63% about risks. Similar findings are reported in the context of chiropractic care.^{79,80,83,84} About a third of UK-based chiropractors and 44% of US practitioners are reported to never address the nature of risk or major adverse effects to treatment. As in our results, patient anxiety was cited as an important reason for this, together with the remote likelihood and lack of evidence of serious adverse events post treatment.^{80,82,83}

Some of our practitioners and patients regarded seeking and complying with treatment requests as a form of implied consent. Similarly, Canadian physiotherapists regarded the client to be responsible for opting out of treatment and where this did not occur this was seen as implying consent. This was particularly common with techniques perceived as low risk.⁸² Aveyard reports in two qualitative studies that what nurses often construe as implied consent might more accurately be termed compliance, and points out that compliance entails passive acquiescence whilst consent involves active affirmation of a patient's choice.^{85,86}

We also found that patients and practitioners did not see the value of discussing alternative or no treatment options. In the UK and the US chiropractors discussing alternative treatments is reported to be undertaken reluctantly.⁸³ The interview data from our results suggested that to some extent both patients and practitioners saw this as logical in terms of patients electing to attend for a specific osteopathic service and that other treatment options should and would be discussed when osteopathy was not thought to be an option or after treatment had failed to deliver anticipated benefits. Although not voiced by participants, an alternative interpretation is that in a commercial private setting there is a conflict of interest for practitioners to suggest equivalent options for treatment from other providers.¹ Not offering choices to patients was reported in a qualitative study of 17 physiotherapists in Australia, where practitioners emphasised explanations and descriptions of therapy. Practitioners focussed on consent being more informed by beneficence (providing benefit to others⁸⁷, producing good outcomes⁸⁸) than on principles of autonomy (self determination, right to decide what is done^{87,88}).⁸⁹ Similarly, Leach et al.²¹ reported that patients' expectations about explanations about treatment and the benefits of treatment were met more effectively than being given information about risk. Doyal⁹⁰ discussing consent in medical contexts, acknowledges that some patients may not wish to receive a range of information, but nevertheless argues that patients still need to be given information to make reasoned choices. Refusal of information can only be valid when the implications of refusal are understood, including what it will mean in terms of the management of an individual's condition.

There is also evidence that patient recall of risk can be poor, even when risk has been explicitly explained.⁹¹ Psychological factors such as anxiety and the cognitive burden of information have been put forward as possible reasons for patients not understanding or remembering information given in the context of the consent process.⁹² However, it is unlikely that this would wholly account for our findings. It is probable that some osteopaths are not explicitly discussing risk in a way that patients understand. Our finding that patients focus on risk as a lack of benefit, rather than thinking of risk in terms of hazards and potential harms from treatment, may explain an element of the low rates of risk information reported to be received by patients in our study. This finding appears to be in accord with osteopathic patients' expectations, where the most important patient expectations focussed on effective treatment. However, the same study reported that 90.7% of patients expected to be given information on risks and side effects, with

25.6% reporting that they did not receive this information.²¹ Patient expectations to receive information about risk are high and these results taken together with our findings suggest that the information that patients want is probably not being delivered or not being understood and retained by a significant number of patients.

The transmitting and exchange of information between patient and practitioner is a key component of gaining and receiving consent and is explicit in professional codes of practice and standards of proficiency^{34,35,93,94}. Whilst the ethical duty to respect autonomy is clear, the impact of partial or absent consent procedures and information exchange on patients, particularly in the context of low risk interventions, is not clear.⁸¹ Inadequate information giving and consent procedures only explicitly emerge when there is dissatisfaction and a complaint about care. Across healthcare, partnership models have replaced paternalistic decision making and are associated with improved patient outcomes and satisfaction.^{95,96} Current codes of practice reflect this and the forthcoming Osteopathic Practice Standards calls one of its organising themes Communication and Partnership.³⁵ In terms of patient outcomes, in our modelling of variables affecting an increase in current symptoms/pain at six weeks, information and seeking permission were not significant predictors. However, whilst a recent review of complaints in UK osteopathy identified the issue of consent as accounting for only 0.9% of complaints, the authors conceptualised consent as a sub classification of Conduct and Communication which included issues relating to communication, boundaries and conduct and behaviour, which may overlap with consent-related practice. As a group they accounted for 21.1% of complaints.³⁷ Thus it is clear when things do go wrong, consent and issues related to communication are important drivers of dissatisfaction and of the complaints process.

In summary, as in our study, there is some evidence from other health professions that levels and recording of consent vary amongst practitioners. Most information given to patients concerns the nature of treatment and the benefits of treatment. New patients are given more information than returning or ongoing patients and information and consent are perceived as more important by new patients. Patients receiving treatment may not understand or recall risk information and this type of information along with information about alternative or no treatment, is not consistently offered to patients. Risk of having no benefit from treatment is part of the way that patients think about risk, but there is some evidence that patients expect information about risk in terms of hazards and harms. Chiropractors have similar concerns to the osteopaths in our study about giving information about serious adverse events and that there is a need for more information about the nature of risk associated with treatment.

5.4.2 Implications for practice and policy

There are tensions between the standard expected of osteopaths as articulated in the Code of Practice³⁴, current practice and perceptions of both patients and practitioners. The 2011 Osteopathic Practice Standards are unlikely to address these tensions as the underlying stan-

dards remain the same, although in the 2011 version there is a clearer expectation to assess the information needs of the patient.³⁵

Our findings fit closely with other published literature to suggest that the components that make up the consent process and recording of informed consent is under practised by manual therapy practitioners. From a legal and regulatory perspective, this leaves practitioners open to challenge. This study highlights the range of views about the extent of information required for informed consent to be given by a patient. Our practitioners and practitioners in other studies report a reluctance to discuss risk and alternative or no treatment options. It has been argued that this information is essential to fulfil a primary goal of informed consent i.e. enabling patients to make autonomous decisions about their care.⁸⁸ This may have particular relevance to UK osteopathy, where practitioners are themselves autonomous healthcare professionals with open access to their services, and often without clear clinical governance structures associated with healthcare delivery in large organisations. Delivery of risk-related information is complicated for some practitioners by their perception that such information may cause more harm than good in itself and that the primary focus for practitioners and patients is the beneficial outcome of treatment. The apparent differences between the importance of patient autonomy, the duty to treat and beneficence clearly warrants further debate in osteopathy and other manual therapies.

The literature and our findings suggest that at least one reason for not discussing risk is the paucity of pertinent evidence. This may be a legally acceptable argument, because the professional standard is for practitioners to give information that has a logical basis and represents a body of professional opinion⁹⁷ and, arguably, the evidence on risk factors and especially the causal link between treatment and adverse events is poor. Indeed, judicial review in the State of Connecticut in the USA in 2010, delivered a declaratory ruling about chiropractic. The Board found that the evidence was not sufficient to conclude that stroke or cervical artery dissection is a risk or side effect of joint mobilisation, or manipulation of the cervical spine and as such that chiropractors were not required to address these issues as part of informed consent of patients.¹⁴ Even in the absence of a well-established body of evidence, there is still a requirement for osteopaths in the UK to adhere to published standards of practice and thus practitioners need to be aware of what is currently known about the potential positive and negative effects of osteopathic treatments and to be able to communicate these in a manner that is understood by patients. Verbal, visual and written information needs to be expressed in such a way that it is comprehensible to individual patients and this is likely to require some assessment of the patient's existing level of understanding⁹⁸ and their preferences.³⁵

While formal consent practices in the day-to-day provision of care is perceived as cumbersome and at times unnecessary, when things go wrong, it is the gold standard against which practitioners are measured. So the disparity between practice perception and recommended practice needs careful and immediate thought. There is a need to provide further guidance for practitioners and student osteopaths. One way forward would be to enhance understanding of the principle of

autonomy and how it may be used practically to receive informed consent from patients within the context of consultations based on shared decision making and patient/practitioner partnerships. Existing recommendations to enhance shared decision making include the development of decision aids, coaching tips on how to help patients make decisions, recognition of the role of trust and empathy, identification and enhancement of competences needed by practitioners to discuss risk.⁹⁵ Specific guidance for osteopaths about consent and communicating risk has recently been published.³⁸ Further development is required to implement this guidance and to incorporate information from the results of our current study. There are opportunities to update an existing leaflet on consent published by the General Osteopathic Council⁹⁹ and to develop educational resources for practitioners and students. The impact of the delivery and dissemination of such resources could be evaluated with further audit or research using the current study as a reference standard.

In summary, there is a need to develop new guidance and educational materials concerning information giving and consent. These should draw on the results of the current study and related work and include recommendations about process and indicative risks associated with osteopathic treatment. Further audit or research could evaluate the impact of such materials using the methods and results from the current study as a reference standard.

5.5 Patient outcomes

The majority of patients showed improvement across all measures. Fifty five percent of patients achieved at least a 30%, clinically significant, decrease in the current intensity of their main complaint of symptoms/pain. Most of these patients achieved this by day two, post treatment. Sixty nine percent of patients who had made clinically significant decreases in pain in the first 48 hours maintained this at 6 weeks. Of those patients who did not decrease their symptoms/pain intensity within 48 hours, 41.2% were improved at six weeks.

Similar changes were found for patients reporting the average intensity of their symptoms/pain and by day two 52% of patients reported that they were much improved and by six weeks, this increased to 61%.

Improvement levels were higher in new patients and those returning to an osteopath with a new episode or complaint. In these patients, 64.5% and 63.9% respectively made clinically significant improvement in their current symptoms/pain intensity at six weeks.

Using a two point change on the NRS for improvement in intensity of symptoms/pain, those with high intensity symptoms/pain and troublesomeness at baseline and presenting with a new episode increased the chance of a two point reduction on the NRS, and predicted improvement on health status as measured by the EQ5D. Health status improved significantly, showing a medium effect size of 0.52. Patients with widespread pain were less likely to improve their pain intensity and people taking time off work were less likely to improve on the EQ5D. Treatment

techniques used did not predict any of the outcomes.

The proportion of patients who had much improved and very much improved were 46.8% at day one, 52.3% at day two and 61.0% a week six. Overall, at six weeks 86.5% of patients reported some improvement. Satisfaction ratings were globally high. Patients rated these as above 5 out of 7 at all time points and fewer than 2% reported dissatisfaction.

At baseline, 45% had seen another practitioner about their complaint and at six weeks this dropped to 14%. There was also a small decrease in the number of patients taking time off work from 7% to 5%. Analgesic medicine usage fell from 71% of patients to 42% of patients.

The qualitative data corroborated the survey findings with respect to short-term pain relief from osteopathic treatment and global benefit in terms of return to normal life and daily activities. Patients also commented on the beneficial aspects of reassurance, relaxation, and receiving information that increased their sense of control and independence, and some patients commented on the perceived benefits of natural approaches as opposed to drug based therapies. Patients' interpretations of benefits were varied, but the most common attributions were related to physical explanations about treatment such as the restoration of normal movement. Other explanations included valuing their therapeutic relationship, the importance of information and receiving guidance. Some patients expressed uncertainty about how treatment worked, but this was of low importance in the context of their experience of benefit from treatment.

In summary, patients reported improvement in symptoms/pain intensity and this was highest in new patients and those presenting with a new episode. Higher symptoms/pain intensity and troublesomeness levels at baseline were associated with improvement at six weeks in health status and symptoms/pain intensity. The presence of widespread pain was associated with being less likely to improve, and being off work with less improvement in health status. Satisfaction levels were high and there were small decreases in time off work and analgesic medication usage.

5.5.1 How the results fit with existing literature

A broad review of manual therapy concluded effectiveness for interventions commonly given by osteopaths for low back pain, some neck disorders, some types of headaches, and a number of upper and lower extremity conditions. Evidence was inconclusive for mid back pain, sciatica, tension-type headaches, coccydynia, temporomandibular joint disorders, fibromyalgia, premenstrual syndrome, and pneumonia in older adults. Evidence of ineffectiveness vs sham was found for asthma and dysmenorrhea.¹⁰⁰

A systematic review and meta analysis focussing exclusively on osteopathy and restricted to low back pain which included eight RCTs with a variety of active and passive control conditions, found a significant improvement in pain with a small to moderate effect size (0.3).²⁹ In contrast, Posadzki and Ernst¹⁰¹ reviewed sixteen trials of which only five reported efficacy for musculoskeletal conditions. The authors of this latter review conclude that the current evidence is insufficient to suggest that osteopathy is effective. However, this review's conclusion with

respect to back pain has been criticised for not having sufficient focus on the sub-group of back pain evidence, exclusion of relevant studies concerning osteopathic treatment of back pain and the inadequacy of the methods employed, specifically the lack of formal meta-analysis.¹⁰²

Similar to our findings regarding higher benefit to new patients or those presenting with new episodes, Bolton and Newell¹⁰³, in a UK prospective observational study, found that 61% of patients with acute low back pain attending chiropractic treatment improved compared to 28% of chronic low back pain patients. This study used cut points for reliable and clinically significant change. Given the design of the study, differences in improvement rates between acute and chronic patients cannot be attributed to treatment alone. An observational cohort of 619 back pain patients in general practice also found evidence that the longer the duration of the problem the longer it takes to improve.¹⁰⁴ A prospective survey of 500 consecutive patients attending osteopathic practice for new episodes of illness measured outcomes at four months thus giving a reasonable comparison with our 6 week outcomes. Patients with a longer duration of symptoms improved significantly less.²⁶

The patients in our study showed a mean change in intensity of pain from baseline to six weeks of -1.63 on an eleven point scale. In comparison, other studies report a slightly higher decrease in pain. Pringle and Tyreman²⁶ report a change of -2.71 on a ten point scale, and Andersson et al.¹⁰⁵ reported on 83 patients undergoing osteopathic treatment as part of a back pain RCT in the USA showing a change of 3.2 points on a ten point visual analogue scale for pain over a twelve week period. Results from a subgroup of 56 low back pain patients receiving physiotherapy manipulation and exercise, within a randomised controlled trial, reported a mean reduction in pain of 41.6 on a 0-100 scale between baseline and end of treatment and between baseline and six months the difference was 37.9.¹⁰⁶ These greater improvements in pain than those shown in our study may be due to the range of conditions in our sample, the short follow up period and include floor effects of our measure.

Fawkes et al.²⁰ used a seven point global improvement scale in their standardised data collection project examining UK osteopathy. Their results are not directly comparable as their scale used different verbal anchors. However, at final appointment 80.7% of patients fell on the positive side of their scale and this is similar to the proportion of patients in our study that reported some improvement (86.7%). In our study, follow up was obtained at six weeks post baseline; whether the improvement reported above is maintained is unknown. A four-year follow up study of a 150 low back pain patients who received osteopathy found significant improvement in disability at one year but not at four years. However, the loss to follow up was 40%.¹⁰⁷

Rates of time off work and medication consumption have been reported rarely for osteopathic populations. One service evaluation set in an NHS general practice reported that primary care consultations were reduced in the year post osteopathy by 30%, certified time off work was unchanged and ranged between five and eight days and prescription of medication was halved in the group receiving osteopathy.¹⁰⁸ However, as this study was based in primary NHS care it

is not directly comparable to our results, where the large majority of patients were from private practice settings.

Qualitative research in patients with spinal pain receiving osteopathic treatment from a GP who was also an osteopath reported that patients valued osteopathy because of the scope to provide psychological support, to treat without the use of drugs, and to offer sufficient time for comprehensive examinations and explanations.¹⁰⁹ Patients seeking osteopathic care have also been described as expecting to gain control over symptoms and valuing the therapeutic relationship with their osteopath.²¹ Similarly, patients attending a variety of CAM within NHS settings reported valuing a caring and calm attitude from practitioners, and being involved in the process of care, although a proportion of patients reported surprise and lack of understanding about the mechanisms that led to improvement.¹¹⁰ These findings accord with our interview data from patients.

High levels of satisfaction in our study compares with other studies in osteopathy in the USA and UK^{111–113}. Similarly, a survey study of satisfaction of patients with musculoskeletal pain drawn from private physiotherapy practice in Ireland reported that the modal response on a five point satisfaction scale was high.¹¹⁴ Chiropractic surveys have also reported high satisfaction levels from patients.¹¹⁵ However, satisfaction studies in health care tend to be skewed positively. One small UK study comparing satisfaction between patients experiencing care from general practitioners and osteopaths in the same practice found that pain and disability outcomes were unrelated to levels of satisfaction.¹¹²

In summary, there is some evidence available that supports the outcomes reported in our study. There is a paucity of randomised controlled trial evidence specifically concerning osteopathic interventions. Where this exists, it supports the use of osteopathy for non-specific low back pain. Drawing on evidence from manual therapy more generally extends the support for the types of interventions osteopaths commonly use for musculoskeletal conditions. Observational studies suggest that our results concord with other findings that new episodes of symptoms with lower levels of chronicity and more localised pain improve most. High levels of satisfaction have been reported for osteopathy and other areas of manual therapy. Qualitative studies suggest, as in our study, that perceived benefits of care extend beyond relief of pain and include patients gaining a sense of control, reassurance and explanations of their symptoms as well as valuing a therapeutic relationship with their practitioners.

5.5.2 Implications for practice and policy

Arguably, our results demonstrate clinically significant levels of improvement for patients that are in accord with other studies. High levels of satisfaction with care have also been demonstrated. These results should give some confidence to osteopaths, patients and others that for a large majority of patients their experience of osteopathic care will be positive in important ways. However, our design does not enable clear conclusions about the effectiveness of osteo-

5.6 Common treatment reactions and adverse events

pathic treatment. Although practitioners and patients tend to attribute positive (and negative) change to treatment, other factors should be taken into account. The natural history of a condition may in itself lead to resolution of symptoms and be unaffected by treatment. Regression to the mean may also account for some of the improvement recorded. Similarly, high satisfaction ratings may not relate to specific outcomes in terms of pain and disability. There is a need for further research to evaluate the effectiveness of osteopathic treatment using randomised trial methodology. Our study and other recent work in the UK provides a good platform from which to plan for research which further evaluates the effectiveness and cost effectiveness of osteopathic treatment. There is also a need to further explore the mechanisms underlying the apparent effectiveness of osteopathic treatment. Our study failed to identify technique-related predictors of positive outcomes and rather supports a mixed package of osteopathic care which incorporates non-specific aspects of the process of care including the role of communication, explanation and the building of a positive therapeutic alliance.

There is an opportunity to build on these results to establish a reference standard for Short-term outcomes against which osteopaths in practice could audit and benchmark their own work. This would provide a growing body of evidence that evaluates services offered by osteopaths and would enable individual practitioners to initiate quality improvement activities and to provide a focus for continuing professional development.

5.6 Common treatment reactions and adverse events

Increases in symptoms/pain intensity using a 30% threshold for patients' current main complaint affected 18.5% of patients at day one after treatment, 12.2% of patients at day two and 14.2% of patients at six weeks. Out of the patients who had an increase in their current symptoms/pain in the first 48 hours, a third still had an increase in intensity compared with their baseline score at six weeks. Of those patients who did not increase in their symptoms/pain intensity within 48 hours, 8.6% showed an increase at six weeks. Nearly 42% of patients who had an increase in their current symptoms/pain in the first 48 hours had made clinically significant decreases in intensity compared with their baseline score at six weeks. Some patients (10.5%) who initially showed improvement in symptoms/pain within the first 48 hours reported increased intensity of their main symptoms/pain compared with their baseline score at six weeks. Using absolute values of a two point increase on a symptoms/pain intensity scale produces lower proportions of patients that may be categorised as having an increase after treatment.

The large majority of patients having an increase in symptoms/pain had low levels of pain at baseline. Similar results were found when patients reported pain change using average ratings over time. Increasing the number of sites of reported pain by patients, lower baseline pain and consultation with a GP within the last six months predicted increase in pain intensity. Site of complaint and osteopathic treatment variables were not predictive. A lower proportion of

5.6 Common treatment reactions and adverse events

patients (3.0% to 5.6%) reported increases in troublesomeness of their main complaint.

Increases in troublesomeness of other areas of the body ranged from 5.6% to 10.7% of patients and were highest at the six week time point. No particular areas of the body were identified as being vulnerable and decreases in troublesomeness were higher for all areas and two fold for nine out of fourteen areas of the body.

Non-musculoskeletal symptoms increased in the largest proportion of patients at six weeks rather than immediately post treatment. The range was between 2.1% of patients for vomiting to 14.5% for headaches. The proportion of patients with decreases in the intensity of symptoms was larger in all cases than increases at each time point. In the majority of cases this was by a factor of two. At day one post treatment the range of increases in symptoms was between 0.6% for vomiting and 7.8% for fatigue/sleepiness. For the other eleven symptoms measured the reported increases occurred in fewer than 4% of patients.

At interview, practitioners tended to offer higher estimates of the frequency of common treatment reactions than was reported in the survey by patients. Short-term increases in local pain were most commonly described, followed by resolution and improvement in the patient's presenting condition. Practitioners, although expressing uncertainty about the causes of treatment reaction, used physiological, biomechanical and patient factors to interpret reactions. The acceptability of reactions was related to practitioners' familiarity with a reaction, patient views of acceptability and the intensity, duration and nature of reactions. Patient expectations were also considered important by practitioners; forewarning patients of a likely reaction and offering coping strategies and contact with the osteopath emerged as the most common management strategies.

Patients' qualitative data suggested that musculoskeletal pain and fatigue were most commonly experienced. Fatigue was often associated with positive relaxation and light-headedness which were interpreted as part of the natural consequence of treatment. Similarly, patients also reported expectations and acceptance that temporary increases in pain and fatigue were part of the anticipated process of treatment. Patients were largely resistant to viewing these symptoms as complications or side effects. Patients used a variety of frameworks to explain their responses to treatment, including structural/biomechanical, physiological, energetic and psychological models. Patients' views of acceptability were linked to their perceptions about the quality of treatment and their beliefs about treatment processes and healing, but were also linked with their positive perception of the patient-practitioner relationship and the extent to which they had been pre warned of the likelihood of a treatment reaction.

There was some concord between patients' and practitioners' views of acceptability, where intense, long-lasting and high-impact local reactions or responses in other areas of the body were unacceptable. Patients also identified negative characteristics of the consultation as unacceptable, such as lack of rapport, failure to accept patient preferences and perceived inability to listen effectively to the patient.

5.6 Common treatment reactions and adverse events

At interview the most common strategies used by practitioners for managing minor treatment reactions included effective communication of the practitioner's care and concern, providing explanations, and modifying treatment.

In summary, immediate increase in symptoms/pain intensity is the most frequent reaction post treatment, at about 20% at day one after treatment. Other reported increases in symptoms at other areas of the body are less prevalent and increases in non-musculoskeletal symptoms occur in a small proportion of patients. Interview data suggests that treatment reactions are largely expected and accepted by patients and practitioners and appear to be managed well within the context of a patient-centred model of care. Unacceptable reactions to treatment include intense, long-lasting and high-impact local reactions or responses in other areas of the body. Communication and the quality of the patient practitioner relationship appear to mediate the acceptability of treatment reactions.

5.6.1 How the results fit with existing literature

The reporting of minor to moderate treatment reactions in our survey is lower than some other reported values. Four recent systematic reviews of manual therapy and adverse events provide estimates of the incidence of minor to moderate adverse events within the context of manual therapy. Carlesso et al.¹⁷ examined adverse events reported in fourteen RCTs and three observational studies associated with manual therapy in the context of neck pain. The authors reported that minor to moderate, more common adverse events, across studies on average, had an incidence of 16.3%. Carnes et al.¹⁸ reviewed data from eight prospective cohort studies and thirty-one RCTs containing information on adverse events from manual therapy interventions. Pooled estimates of the incidence of minor and moderate adverse events were 41% (95% CI 17-68%) from the prospective cohort studies and 22% (95% CI 11.1-36.2%) from the RCTs. A systematic review examining the safety of chiropractic interventions included one RCT, six prospective cohort studies and twelve retrospective cohorts mostly related to chiropractic populations, but included some results from physiotherapy interventions. The authors conclude that 33% to 60.9% of patients suffer from side effects and that amongst these the most common adverse reactions were local discomfort and radiating pain which tend to occur within 24 to 48 hours and resolve.¹¹⁶ Ernst³ in a much cited and controversial¹¹⁷⁻¹²¹ systematic review of adverse events and spinal manipulation reported that relatively mild adverse effects occur in 30% to 61% of all patients.

Much of the available literature used in these reviews is based on chiropractic and to a lesser extent physiotherapy populations, but there are some relevant recent data from UK osteopathy. In a large survey in the UK of approximately 1,600 osteopathic patients, 65.7% reported symptoms getting worse happening to some extent after treatment and 77.9% of patients feeling some pain or discomfort happening soon after treatment.²¹ The higher level of reporting in this study is likely to be related to the use of a three point response scale and the absence of a true

5.6 Common treatment reactions and adverse events

baseline measure, whereas in our study a threshold of 30% increase from baseline was used to classify those with an increase in intensity of symptoms. As part of a standardised data collection project, UK osteopaths returned data on approximately 1,600 patients' reported experience of complications at their second visit related to the 48 hours post initial consultation. Increased pain was reported in 14.6% of patients. Dizziness (1.5%), nausea (0.7%) and headache (2.3%) and fatigue (6.6%) were reported as occurring in small proportions of patients.²⁰ These results are a little lower than our own and may have been influenced by the single category option to record a complication after treatment and the practitioner report of the patients' experience.¹⁸ A small pilot study of patients which included pre-treatment measures attending an osteopathic teaching clinic found that out of 52 responders all but 4 reported at least one additional response to treatment of which the most common were worsening local pain (24%) and stiffness (18%). These peaked two days post treatment and 96% were rated mild or moderate.¹⁹ One cross-sectional study of 459 patients seeking osteopathic manipulative therapy in the USA reported that 8.6% of patients attributed on or more adverse reactions to their treatment. Pain and soreness made up the largest proportion (6.7%).¹¹¹

In a study of 529 new patients undergoing chiropractic care for non-specific neck pain in the Netherlands 56% indicated experiencing adverse events related to increased pain using a similar scale and threshold to that used in our study and less than 8% reported symptoms such as tiredness, nausea or ringing in the ears.¹⁵ Hurwitz et al.¹²² report adverse symptoms from a RCT of chiropractic treatment of neck pain comparing manipulation with mobilisation. Adverse symptoms were reported by 30.4% of patients, with increased neck pain and stiffness being most common (25%), followed by headache (15.7%), tiredness or fatigue (10%) and radiating pain or discomfort (6.1%). A small UK study of 68 chiropractic patients reported increased pain in 53% of respondents.¹²³ In a large prospective national UK study of adverse events reported by chiropractors from 19,722 patients, Thiel et al.¹⁶ reported increased pain during follow up of 7.3% of patients, however this study failed to measure patients at baseline pre-treatment and practitioners elicited data from patients which may account for the low rates. A cross-sectional survey of 1,058 new patients seen by Norwegian chiropractors found an incidence of 53% reporting local discomfort, 12% headaches, 11% tiredness and 10% radiating discomfort. The reactions were mild or moderate and 74% disappeared within 24 hours.¹²⁴

In a cross-sectional study of 465 patients, drawn from a mixed group of manual therapists using spinal manipulation in Belgium, 61% of patients reported a reaction, 20% of these were headaches, 20% were stiffness, 15% local discomfort, 12% radiating discomfort and 12% fatigue. 64% of these reactions were reported as resolving over 24 hours. The intensity of the reactions was not measured.¹²⁵

Few studies have explored patients' experience of minor adverse events in response to manual therapy. Carlesso et al.¹²⁶ reported findings from 13 patients using semi structured interviews. Patients were drawn from physiotherapy, chiropractic and osteopathic practitioners in Canada.

5.6 Common treatment reactions and adverse events

The authors highlight the importance of receiving education regarding the possibility of experiencing a post treatment response, a belief in “no pain no gain”, weighing benefits vs. harms and the critical component of trust in the practitioner. These findings are closely related to our results. Patient and practitioners in our study expressed some expectation that treatment may of itself include some degree of pain or Short-term increase in symptoms. This expectation was also reported by Leach et al.²¹

In summary, our study is in accord with the literature in terms of the characteristics of common treatment reactions and their resolution. Most of the available literature described patients' experience of chiropractic care. The discrepancy between the relatively low numbers of patients reporting mild to moderate adverse events in our study and those reported in the studies above cannot be explained by the selected measurement, time line, treatment techniques or methodology. One possible explanation could be differences in the characteristics of patient populations attending osteopathy and chiropractic and differences in time spent with patients. There may be differences in the application of techniques and the selection of patients for particular techniques between the osteopathy and chiropractic professions. However, it should be noted that our regression models did not find that the application of any particular group of techniques used by osteopaths increased the risk of patients experiencing a minor to moderate treatment reaction, nor was symptom duration a significant predictor.

5.6.2 Implications for practice and policy

Our study and related literature partially address osteopaths' concerns about the nature of risks of minor to moderate adverse reactions and adds information that osteopaths can use to tell their patients. It is reasonable to tell patients that about 20% of patients will have a Short-term increase in symptoms/pain relating to their presenting complaint and that this is most likely to affect patients with low symptoms/pain intensity on presentation. Practitioners may consider and share with patients that for those with multiple sites of complaint there is a higher chance of having an increase in intensity of their presenting symptoms/pain after treatment. Additionally, practitioners may consider a patient's recent visit to a GP as an indicator that there may be a risk of an increase of symptoms/pain post treatment. Other non-musculoskeletal-type reactions are infrequent the day after osteopathic treatment. Increased fatigue is the most prevalent and this occurs in approximately 8% of patients, however there is some evidence that patients perceive fatigue as a positive part of the therapeutic process. Overall, for non-musculoskeletal symptoms compared with pre-treatment at six weeks, symptoms decrease. The existing literature and osteopaths' perceptions of the frequency of minor to moderate adverse events may over-estimate the prevalence of these events in UK osteopathy.

There is an opportunity of increasing the awareness amongst the osteopathic profession of the value of management strategies that appear to be helpful. These include pre-warning, explaining the nature of reactions and using a therapeutic alliance with patients effectively.

Patients do have specific frameworks in which they construe their reactions to treatment and these are useful for patients in reducing distress and increasing understanding of their treatment. There is an opportunity for practitioners to explore these with patients and to agree a mutually consistent explanation to reduce uncertainty. It is anticipated that increased understanding of the nature and prevalence of adverse events and the implementation of helpful common management strategies would enable practitioners to share information about risk with patients more effectively. This in turn may increase patients' understanding and recall of risk information given by osteopaths.

There is a need for further research to evaluate measures of patient deterioration and their perception of adverse events. Ceiling and floor effects may affect measures used in our study and others.¹⁵ The 30% threshold has been shown as a useful measure of significant clinical improvement,⁶¹ but there may be problems in using the same approach to define increases rather than decreases in pain ratings. Further work is called for to determine the smallest worthwhile effect of treatment that takes into account whether the outcome of an intervention is worth the financial and personal expenditure and risks to patients. A benefit harm trade-off method has been advocated as a more appropriate way of taking account of all the potential outcomes of an intervention.^{127,128}

5.7 Serious treatment reactions and adverse events

Fifty-six patients (4.1%) reported experiencing temporary incapacity or disability that they attributed to their osteopathic treatment. This small number precluded statistical investigation of predictors and treatment effects; however, all these patients were invited to interview and of these, ten agreed and were interviewed. At interview, two patients described experiences that were characteristic of a serious adverse event (In one case peripheral neurological symptoms, failure to diagnose and explain radicular symptoms in the leg and the other was reported aggravated non-specific muscular skeletal symptoms in the hand.) No patients at interview reported life-threatening events or the need for referral to hospital or other permanent disability. All others interviewed, having reported temporary incapacity, described minor to moderate adverse events such as temporary increases in pain and/or fatigue post treatment.

Serious adverse events, including severe new symptoms, the worsening of existing symptoms leading to hospital referral and/or permanent disability or incapacity or death, were reported by 12.1% of practitioners over the span of their career. In the preceding year 4.1% of practitioners reported a serious adverse event. The most conservative estimate of the rate of serious adverse events was 1 in 36,079 treatments.

A taxonomy was developed for serious adverse events as described by practitioners from the survey data. The descriptive categories included: peripheral neurological symptoms, central neurological symptoms, non-specific musculoskeletal symptoms, symptoms related to underlying

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pathology, and fractures. Peripheral neurological symptoms appear the most frequently-reported serious adverse event. Central neurological symptoms included 7 reports of stroke and/or symptoms suggestive of transient central ischaemia or vasovagal-type symptoms, six of which occurred directly post treatment and one of which was delayed in its onset by several days. Only one of these events was reported as following cervical HVT. In one case, the practitioner did not include a report of associated techniques; in the remaining five, occurrence was following examination procedures, soft tissue techniques or articulatory techniques. Similarly other serious adverse events did not have a clear relationship with any specific intervention. In some cases, practitioners' report of the serious adverse events included elements of pre-treatment risk assessment which suggested low risk and subsequent occurrence of a serious adverse event. Our taxonomy aligned with descriptions of serious adverse events from practitioners at interview. Practitioners at interview also considered that such events were defined by the need for medical referral, the exacerbation of presenting symptoms, the appearance of new symptoms, significant functional loss associated with treatment and treatment reactions beyond practitioner expectations and patient tolerance.

At interview, practitioners suggested a range of causal/explanatory models. These included structural, mechanical and tissue-based physiological interpretations. Some serious treatment reactions were explained by the presence of latent pathological conditions and some by provocative patient activities outside of the treatment consultation. Several practitioners identified the difficulties of determining plausible causal pathways to explain serious adverse events. These interview data were congruent with the free text survey data where practitioners also expressed uncertainty about the link between the treatment they had offered and the patient's reaction to treatment.

The occurrence of a serious adverse effect was stressful for practitioners and led to developmental reflection and modification of their practice. Changes to practice included modification of the use of osteopathic techniques and application of graded approaches to the use of techniques, increased vigilance in case history taking, further training, and enhanced patient-centred treatment and management strategies.

Practitioners expressed the belief that serious treatment reactions were rare. Practitioners reported that they considered that there was a paucity of robust information available to them on these issues and that they were not confident that they had credible or reliable information to impart to patients. Some also expressed the view that alerting patients to the seemingly rare possibility of severe treatment reactions could be prejudicial to positive patient outcomes. Practitioners described carrying out patient-centred risk/benefit assessments for each individual and that this informed the practitioners' selection of technique and treatment dosage. This was seen as a principal factor mediating the content and form of the practitioner-patient information sharing about risk.

Practitioners used clinical risk assessment as a prevention strategy to minimise the risk of a

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serious adverse event taking place. These included comprehensive case and medical histories, a variety of physical examinations, observation, palpation, and clinical tests. In contrast to the management of common treatment reactions, some of the osteopaths we interviewed described their formulation of risk as a more internal process that they tended not to share with their patients. This was, in part, used as a rationale for not sharing information with patients, for example, where the practitioner had decided not to use a particular technique this was seen as a reason for not discussing this as an option with a patient. In some instances practitioners described using risk-related information to resist patient requests for manipulation.

Practitioners aimed to preserve patient and practitioner wellbeing as well as attempting to maintain a positive relationship with patients after the experience of a serious adverse event. Short-term strategies included offering calming and reassuring understanding that the patients' wellbeing has paramount importance, and that serious efforts would be made to ensure recovery. This might include referral and/or use of emergency services. In the longer term, practitioners expressed apologies and expressions of contrition, further care free of charge, and maintenance of contact through communication with patients and other health carers as well as visits to hospital or to patients' homes.

5.7.1 How the results fit with existing literature

The majority of studies focus on stroke, as a serious adverse event, related to arterial dissection after cervical manipulation, whereas our study captured practitioners' report of a wider range of adverse events, but also included those associated with treatment of the neck. Few studies have focussed on other areas of the body and non-cerebrovascular events. Primary studies and reviews that have included other adverse events have been based on surveys of manual therapy practitioners and secondary care specialists and case studies. Events described include radiculopathies and cauda equina often attributed to presumed damage of spinal discs, bone fractures, cord compression, dislocations, aortic rupture, myelopathy, and haematoma.^{3,77,129–132} However no reliable estimates of the prevalence of these types of events have been produced.

The most recent reviews cover cervical manipulation and mobilisation¹⁷ and manual therapy in general.³⁹ Carlesso et al.¹⁷ reviewed seventy-six studies and could not reach definite conclusions due to methodological limitations of included studies. Carnes et al.³⁹ reviewed only studies with prospective designs, including eight prospective cohorts and thirty-one RCTs. They concluded that the risk of major adverse events resulting from manual therapy was similar to that of exercise or passive interventions. There were no reports of stroke or death and risk from drug therapy was significantly higher. The rarity of stroke is sufficiently low to explain these findings, as it is unlikely to be captured without using prohibitively high numbers in prospective observational studies. Therefore, other systematic reviews have included case control studies and case series in which patients who had already suffered from a stroke were identified and retrospectively examined the frequency and association with spinal manipulation. Miley¹² found

5.7 Serious treatment reactions and adverse events

a weak to moderate association which was found in young adults, suggesting a five-fold association between manipulation and stroke. Rubinstein et al.⁷⁶ found an association between minor trauma (manipulation therapy of the neck) and arterial dissection with an adjusted odds ratio of 3.8. In contrast, a review in 2007 concluded that the literature suggests that spinal manipulation is associated with serious complications that can lead to permanent disability or death. This review did not attempt to provide quantitative estimates of risk.³ Finally in a review of patients presenting with lumbar disc herniation. The risk of spinal manipulation resulting in severe worsened herniation was calculated to be less than 1 in 3.7 million¹³³ In summary, the majority of the systematic reviews found insufficient evidence to make conclusions about the relationship between manipulation and serious adverse events.

Due to the controversy and high profile of this area, we have included several single studies which explore the relationship between manipulation and adverse events. There are a number of case control studies, most of which focus on a possible link between neck manipulation and stroke. A review of 582 hospital records of vertebro basilar stroke against controls indicated that stroke cases were five times more likely to have visited a chiropractor one week prior to the event and to have had more than three visits with a cervical diagnosis in the month prior to the event.¹⁰ The presence of neck pain is related both to stroke and to the likelihood of seeing a chiropractor, thus no causality can be conferred. A case control study of 151 patients presenting with vertebro arterial dissection and ischaemic stroke or transient ischaemic attack in the USA found similar results, suggesting that there was an association between spinal manipulation within thirty days and the occurrence of stroke, but also preceding neck or head pain. However, in the multivariate analysis the association between manipulation and stroke remained significant after controlling for neck pain.¹¹ A USA study in neurosurgical practice identified 1,712 cases seen during a five year period and of these 172 had received cervical spinal manipulation, the majority by chiropractors. Of these, 22 had serious complications. 21 of these were radiculopathies and 11 were myelopathies, 2 were Brown sequard syndrome and 1 was vertebra artebral occlusion. These were compared to the expected number in the population. The authors calculated that serious complications occurred in 1 out of 850 patients undergoing manipulative treatment in the local region which far exceeds other estimates.¹³⁴ A more recent Canadian case control study identified 818 vertebro basilar strokes and matched them to 3,164 controls. Both cases and controls showed equal rates of visits to chiropractors 30 days prior to hospitalisation and these rates were low at 4%. However, in under 45 year olds, there was a significant association between seeing a chiropractor and having a stroke, where 12.7% of cases saw a chiropractor and only 4.4% of controls had seen a chiropractor. However, 53% of stroke patients had visited their primary care physician compared with 30% of controls and this was significantly associated with an increased risk of stroke. In conclusion, the authors state that it is implausible that visits to a primary care practitioner cause stroke and the association is more likely to be due to risk factors that lead patients to seeking care for symptoms that lead to stroke. They state that there is no

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excess risk of stroke from chiropractic care.

Several survey studies have identified adverse events from surveys of practitioners. A New Zealand-based study surveyed 146 various secondary care specialists (neurosurgeons, neurologists, orthopaedic and vascular surgeons). Forty-two incidents in the previous five years were reported and attributed to spinal manipulative therapy, of these 14 were cerebrovascular incidents.¹³⁰ Although the authors state that chiropractors were responsible for more than half of all the complications, the criteria commonly used to attribute causality are not used in the study's methodology. A survey of 153 South African physiotherapists practitioners reported 52 complications in 29 patients and 93% of these followed cervical manipulation.¹³⁵ A UK based survey of 24 neurologists reported 35 neurological complications of which seven were stroke occurring within 24 hours of cervical spine manipulation over a twelve month period. This study did not include baseline stroke incidence, population size, or information about the delivery or reason for the use of manipulation, nor was information about pre-existing neurological symptoms in patients supplied.¹³⁶ A survey based on 36 German patients with confirmed vertebral arterial dissection within two days of cervical manipulation by chiropractors, reported that neck pain was present in 24 of these prior to manipulation and a variety of other symptoms including tension headaches and other symptoms (tension headaches n = 7, migraine n = 1, vertigo n = 1). Risk factors were present in 22 of the subjects and 10 of which had more than one risk factor, despite this the authors claim that they provided evidence of chiropractic neck manipulation causing VAD in these patients, because a substantial number of patients had an immediate onset of neurological deficits or complaints following manipulation. Despite the authors attribution to chiropractic manipulation 50% of the manipulations were conducted by orthopaedic surgeons.¹³⁷

Prospective studies include a study of 1,058 new patients drawn from 102 Norwegian chiropractors. There were no serious adverse events.¹²⁴ Thiel et al.¹⁶ examined 28,807 treatment consultations and 50,276 cervical spine manipulations and found no reports of serious adverse events.

In summary, there is little available information about adverse events associated with manual therapy treatment to areas of the body other than the cervical spine. While systematic reviews that included prospective designs find little to support the association between manipulation and serious adverse events, the low rate of such events, and in particular VBA related strokes, could account for these results. Retrospective studies have found an association between manipulation and in particular strokes, but the causal link is unclear and the probable confounding variable is the presence of symptoms that lead people to seek treatment and result in a serious event. At least one high quality study has found that a comparative analysis in primary care leads to a similar association which has been explained in terms of patients presenting for treatment with symptoms associated with cervical artery dissection.

5.7.2 Implications for practice and policy

Our study was limited in terms of the objective data relating to serious adverse events, but some of the data from the practitioner survey free text responses and qualitative interviews indicate that these rare, but serious adverse events do indeed occur during or directly after treatment from UK osteopaths. The design of our study did not enable an evaluation of the causes of the serious adverse events that have been identified in our study, but likely explanations include the effect of treatment, the natural history of the presenting condition, patient related factors such as pre-existing pathology and those related to patient actions such as behaviour after treatment or turning over on the treatment couch. Whilst cause can not be clearly established, there is a need for osteopaths to be aware of the range of serious adverse events that have been described in the context of osteopathy. The prevention of serious adverse events where possible is paramount. There has been an argument that the use of manipulation in the cervical spine is unnecessary because of the availability of alternative less forceful techniques.^{138 139} This argument is based on manipulation providing equal or no additional benefit in terms of pain reduction and increased function. Gross et al.⁶⁸ report a systematic review of the effectiveness of manipulation and mobilisation in treating neck pain. They identify low quality evidence supporting the effectiveness of manipulation. Whilst a review of the added benefit of manipulation is beyond the current study, we note that the evidence from systematic review is available for osteopathic treatment of back pain,²⁹ but more limited in other areas.¹⁰⁰ There is a clear need for further research to assess the effectiveness of osteopathy for neck pain and other areas. Further research is also indicated to enable clearer estimates of the frequency and risk of serious adverse events associated with osteopathic treatment.

The findings from our study, as detailed above, do not unequivocally demonstrate increased benefit or satisfaction for any particular technique, and are limited by the design of the current study, as they do not control for natural history, or employ randomisation procedures associated with testing the efficacy or effectiveness of an intervention.

There is a need for debate and the development of further guidance for clinicians and patients that draws on the range of studies funded by the GOsC concerning adverse events. Guidance should include information for patients on the rare inherent risks of post treatment adverse events. These include radicular pain, central nervous system symptoms, and increased non-specific musculoskeletal pain. However such guidance should also consider practitioners' concerns over the possible adverse effects of offering stress inducing information and the impact this may have on the patient practitioner alliance.

5.8 Adverse events register

A majority of osteopaths (77%) thought that the establishment of an adverse events register would be a good idea and 88% of osteopaths indicated that they would be willing to contribute

to such a register. Positive comments about a register included its potential to aid individual and professional decision making, to provide better information to inform the process of consent and to be useful for CPD and student learning.

Osteopaths who were not in favour of establishing an adverse events register were concerned that a register would have a negative impact on the profession. Negative impact was described in terms of blame when submitting information, fears of information being taken out of context, concern that the benefits would not equal the costs and that there would be a negative reputational impact on the profession and its scope of treatment. Some practitioners also voiced concerns that a register could have a negative impact on patients by promoting fear and putting them off attending for treatment.

There were also concerns that a register would not prove to be useful as it could not effectively account for the individualised nature of osteopathic treatment and would not generate scientifically robust information. Osteopaths thought that there would be practical problems setting up a register; that individuals would not contribute information and that existing methods of practice to manage and address adverse events were sufficient.

In summary, a large majority of osteopaths were in favour of establishing a register and would be willing to contribute to a reporting system. Obstacles along with potential benefits to such a system were identified.

5.8.1 How the results fit with existing literature

Monitoring of adverse events relating to medicinal products falls under the auspices of the The Medicines and Healthcare products Regulatory Agency (MHRA) in the UK which takes advice from the Commission on Human Medicines (CHM). A system of reporting of suspected adverse drug reactions is in place nationally. The Yellow Card Scheme enables patients and healthcare professionals to submit information about suspected adverse drug reactions. The scheme recognizes that pre-market testing may not wholly establish the safety of medicines and offers an opportunity for further safety data to be collected and in particular the identification of rare events that may not have come to light in pre-market tests of effectiveness and safety. However, this scheme has been criticized for its inability to provide information on the population of users of a medication, its lack of a comparative control arm and its low methodological level in the hierarchy of evidence. Registries attempting to capture complete data sets have been advocated as a superior method of data collection.¹⁴⁰ Biley¹⁴¹ has advocated the establishment of a register across CAM by making it an operational requirement of the voluntary or statutory professional and regulatory bodies. Ernst and Barnes¹⁴² recommended the use of spontaneous reporting schemes as part of a multifaceted approach to evaluating safety in CAM.

Reporting incident and learning systems have been advocated a part of a wider approach to safety and quality in healthcare. Such systems are commonly in place in hospitals. The characteristics of a successful system include it being non-punitive, confidential, independent, having

access to expert analysis, timely dissemination of information, systems-orientated, having legal protection and to have an easily accessible data submission interface. The system needs to be responsive and have agreement from participating stakeholders that results can be disseminated and acted upon. Such systems need effective resourcing financially and with sufficient expertise to analyse and report on the data.¹⁴³

A consensus building workshop of CAM professional body representatives convened to identify ways forward for collecting and using safety data identified some similar obstacles to those reported by osteopaths in our survey. These included personal responses to treatment and individual variation and practical issues. Additional obstacles were identified and included loss to follow up of those experiencing an adverse event, time issues for practitioners and patients, and the difficulties of funding arrangements. The benefits were summarised as being able to offer CAM practitioners reports, the identification of gaps in education and research, to monitor large data sets, the ability to take prompt action and to enhance education.¹⁴⁴

Thiel and Bolton¹⁴⁵ reported a pilot study of a reporting and learning system in UK chiropractic. Approximately 1,100 chiropractors and 63 final year chiropractic students were sent information about the project. There was good participation by students, leading to the adoption of the system into clinical education, but few reports were submitted by chiropractors in the field. Only eight reports from seven chiropractors over a period of four months were received. The authors suggest that the low uptake was partly explained by concerns about fear of blame and medico-legal consequences, as well as perceived sense of failure and a culture tending to personalise error and emphasise expectations of perfection. Additional factors such as a lack of clarity of the benefits of standardised reporting and the perceived lack of value and time needed to report near misses were also seen as reasons for the low level of participation by chiropractors. A follow up qualitative study of seven chiropractors supported initial concerns that fear of retribution, being too busy and insufficient clarity of what to report were important issues. However, the authors concluded that the system was considered of benefit to the chiropractic profession, but that it is likely to remain under-utilised. Key to further success was seen as involving intensive efforts to educate the profession on the value of the system and the need for personal, local and national initiatives to derive maximum benefits.¹⁴⁶ The chiropractic profession have developed their early UK initiatives into a European system which offers opportunities to extend the benefits of a reporting and learning system across several nations.¹⁴⁷

In summary, safety reporting systems are in use relating to medical interventions. Reporting and learning systems have the potential to enhance safety and practice, but require considerable resourcing and are associated with specific characteristics associated with their success. Pilot work in chiropractic demonstrates successful implementation in an educational setting, but there are considerable obstacles to uptake in professional settings.

5.8.2 Implications for practice and policy

Given the high endorsement of osteopaths for the establishment of a register and the potential contribution it could make to enhancing patient safety, further activity should be undertaken to outline the cost and feasibility of setting up a reporting and learning system in osteopathy. There may be additional opportunities to develop mechanisms to support osteopaths, particularly those working alone, in providing an independent and blame-free forum to discuss safety and patient management with peers. This could provide support to practitioners, many of whom currently work in settings where they do not discuss their clinical work with others.

Establishing such an initiative is likely to need significant stakeholder involvement from professional, statutory and educational organisations in osteopathy. Further information about cost and feasibility should be sought from the chiropractic experience. Should such a system be developed obstacles to implementation and use of such a system identified in our study and relevant literature would need to be carefully addressed, along with a concerted and effective communication strategy to encourage uptake amongst the profession. Given the higher success and use of a system in an educational setting, an alternative scenario might be to develop cross-osteopathic educational institutional systems and then to build on these to develop mechanisms for the profession at large.

5.9 Strengths and limitations

Unlike the majority of previous research, our methodology elicited data from clinicians and patients, utilised quantitative and qualitative approaches and included measurements from patients at several time points. We were able to report on immediate and Short-term reactions to treatment as well as longer patterns of response. Qualitative data provided additional explanations and insights into the survey data and practitioners' and patients' experiences in this area. However further research is required to test the strength of the qualitative findings using survey methods on representative samples.

Our selection of outcome measures covered a range of relevant domains to patients and practitioners and enabled evaluation of primary symptoms as well as other recommended outcomes, including adverse symptoms reported in previous studies. Whilst the prospective survey of patients was sufficiently large to describe a representative picture of treatment responses, it is unlikely to have been sufficiently large to capture rare major adverse events. However, the practitioner survey enables a retrospective report of a sample estimated at 1,728,000 patient contacts in the previous year, thus enabling an estimate of the period prevalence in one year of serious adverse events. We used independent researchers to code the free text descriptions of serious adverse events and took the most conservative analytical approach to reporting the incidence rates. In addition, our definition of serious adverse events enabled us to report on a broad range of events including events seldom reported in previous studies.

The majority of research in this area has focussed either on adverse events or on positive outcomes specific to a single body site or area of treatment, but has seldom been able to address benefits and harms or provided a comprehensive picture of professional practice. This is a particular strength of the current study as the majority of presentations of musculoskeletal type symptoms are not restricted to single sites.¹⁴⁸ In addition, in reference to minor to moderate treatment reactions the qualitative approach used in this study allowed us to investigate patients' and practitioners' explanations and interpretations of these reactions.

The results of the study should nonetheless be interpreted with some caution due to a number of limitations.

This study was based on observational methods which limit our ability to make causal attributions. The interpretation of associations, even in the context of regression modelling, should not be taken as evidence of causation.

There was potential for bias in the recruitment of participants for each stage of the study. The response rates from practitioners, whilst similar to other studies, may include a response bias, although there were few differences between respondents and non-respondents. In addition, there may have been more positive reporting of practice due to the influence of social desirability and there is a risk of under reporting of serious adverse events. The data gathered was retrospective and it is likely that practitioners may have been unaware of additional serious adverse events if these were not attributed to their treatment by patients or where patients elected not to communicate with practitioners after such events. Of more concern was the possibility that the patient survey and those volunteering for interview were unrepresentative of the larger population of osteopathic patients. Patients with the most serious adverse events may not have been able or willing to respond to the six-week follow-up survey or indeed to invitations to be interviewed. In addition, the survey did not explicitly request information on stroke or admission to hospital and patients may not have attributed such events to their osteopathic care. The survey data relied completely on self-report and we did not verify rates of adverse events with medical records. Whilst we requested consecutive recruitment of patients, we did not verify practitioners' recruitment methods.

Whilst some of the measurements used in our study have been proven to be reliable and valid in other settings, some items in the practitioner and patient surveys were constructed by the study team. Despite extensive pilot work the psychometric properties of our instrument have not been formally tested. The items used to assess osteopaths' ratings of the importance of risk factors when treating the cervical spine were extracted from systematic reviews. Therefore no distinction in risk factors was made between predictors, moderators or fixed vs modifiable factors and as outlined above, the items on this list in isolation lacked sufficient and necessary predictive power. In reference to analysis of data, whilst the use of cut point thresholds has been validated for significant reductions in intensity of symptoms, its use for increase in symptoms has been less researched. Floor effects and ceiling effects may have distorted some of our findings. Specifically,

5.9 Strengths and limitations

many of our patients included as having a significant increase in symptoms/pain were those with a low presenting baseline scores where a 30% increase in symptoms/pain may not be clinically meaningful. However, this was explored through sensitivity analyses using absolute changes of two points on the scale. Our analysis did not focus on specific subgroups by primary areas of presentation, although our analyses included both changes in primary presentation and other areas of the body.

A stronger methodology may have been to only recruit new patients, however patient status (new vs returning) was included in regression modelling. Including returning patients in the study provided added insights into issues around both treatment reactions and consent-related practice and the importance of the relationship between practitioners and patients.

6

Conclusions

Part II

Study Instruments and Statistical Report

7

Study Instruments

7.1 Practitioner survey

If you decide to take part in this survey please turn over the page immediately where you will find instructions for filling in the questionnaire.

If you do not want to participate in this survey we would be grateful if you answered the short questions below and return this sheet to us in the Freepost envelope provided.

A). Please indicate why you have decided not to participate in this survey by marking all the items that apply to you:

I do not have enough time

I was given insufficient information

I am not interested in research

I do not think that the research topic is useful to the profession.

B). If you would like to express your views about this project please write them below.

C). How old are you? (years).

D). What sex are you? Male

Female

E). In what year did you qualify as an osteopath?

If you have any further questions then please contact Tom Mars (Research Fellow) at The British School of Osteopathy, 275 Borough High Street, London. SE1 1JE. He can be reached via e-mail at t.mars@bso.ac.uk or on 0207 089 5330.

Thank you for your help.



Thank you for agreeing to participate in this survey.
We would be grateful if you would follow the instructions below.

Instructions for filling out the questionnaire.

1. A blue/black ballpoint pen will give the best results. Please do not use red ink, felt tip pens or pencils.

2. To answer Yes rather than No to a question please mark the response circle Y

A Yes answer looks like this:

N = Yes

3. To change a response please put a cross through the incorrect bubble and complete your preferred selection for example:

Completely
Disagree

Completely
Agree



1

2

3

4

5



4. Please avoid bending or folding the questionnaire.



Professional background

To help us interpret the information that you will be giving us we would like to find out some brief details about yourself and how long you have been practising as an osteopath.

1. What sex are you?

Male M Female F

2. How old are you? (years)

3. In what year did you qualify as an osteopath?

Osteopaths see patients in a variety of different settings. Some practitioners may, in the course of a week, work in more than one clinical location. We would like to find out the number of adult patients treated in these various environments.

4. In your clinical practice over the past month, please indicate how many new and returning patients you saw in the following clinical locations. Please refer to your diary/appointment schedule: if this is impractical please estimate as accurately as you can. Please answer each section or indicate not applicable as appropriate.

4a Within dedicated private clinic/practice:

4a i) Not applicable

4a ii) Average number of new adult patients **per week**

4a iii) Average number of returning adult patients **per week**

4b Within own home/ home of practice principal:

4b i) Not applicable

4b ii) Average number of new adult patients **per week**

4b iii) Average number of returning adult patients **per week**

4c Within GP practice/ hospital/ NHS:

4c i) Not applicable

4c ii) Average number of new adult patients **per week**

4c iii) Average number of returning adult patients **per week**



Osteopaths work in a variety of clinical contexts. Some treat patients as sole practitioners whereas others may have daily contact with fellow osteopaths and/or health professionals.

5. Please indicate where you see most of your patients by choosing one of the options below:

- 5a) Working alone or in a group where you do not discuss patients with others
- 5b) Working with others where you discuss patients

Thank you for answering these general questions. For the rest of this questionnaire we would like you to answer with reference to the working environment in which you see the majority of your patients

6. In your main clinical practice over the past month please indicate the following:

- 6a) The allocated new patient appointment time (mins)
- 6b) The allocated returning patient appointment time (mins)

We appreciate that an osteopathic treatment is tailored to the individual patient and that treatment frequently involves the use of several different techniques. Here we are trying to find out the frequency with which practitioners are using a range of techniques in their overall practice.

7. In your main clinical practice over the past month, please estimate the percentage of your patients rounded up to the nearest 10%, with whom you used each of the following techniques:

Please mark the appropriate circle for every technique (mark each item from a to g)

| | 0% | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% | 100% |
|------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 7a) Cranial/IVM Techniques | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7b) Functional/Counterstrain | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7c) High Velocity Thrust | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7d) Joint Articulation | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7e) Soft Tissue Techniques | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7f) Muscle Energy Techniques | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7g) Visceral | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

8. Please indicate below whether you use other approaches (e.g. acupuncture/electro-therapy) in addition to manual osteopathic techniques?

If Yes, mark here: Y and then please answer Question 9.

If No, mark here: N and then please continue to Question 10.



9. In your main clinical practice over the past month, please estimate the percentage of your patients rounded up to the nearest 25%, with whom you used each of the following approaches:

Please mark the appropriate circle for every technique (mark each item from a to h)

| | 0% | 1-25% | 26-50% | 51-75% | 76-100% |
|-------------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 9a) Electro-Therapy | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9b) Nutrition Therapy | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9c) Dry Needling/ Acupuncture | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9d) Homeopathy | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9e) Herbal Medicine | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9f) Applied or Clinical Kinesiology | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9g) Prescription of Medication | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9h) Injections | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

There has been much debate on the use of high velocity thrust techniques and the appearance of unexpected treatment reactions. Here we are focusing on finding out which spinal areas are manipulated most frequently.

10. In your main clinical practice over the past month, please estimate the percentage of your patients rounded up to the nearest 10%, with whom you used high velocity thrust in the following spinal areas:

| | 0% | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% | 100% |
|---------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 10a) Cervical Spine | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10b) Thoracic Spine | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10c) Lumbar Spine | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

There has been a great deal of debate about the occurrence and types of treatment reactions following osteopathic treatment. We would like to find out osteopaths' views about reactions to treatment.

11. Please rate your level of agreement with the following statements:

11a) An essential response to osteopathic treatment is that patients get worse before they get better:

| | Completely Disagree | | | | | | | Completely Agree |
|------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 11a) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |



Please rate your level of agreement with the following statements:

11b) Patients experiencing an exacerbation of their presenting symptoms after osteopathic treatment is a positive sign:

| | | | | | | | |
|------|------------------------|---|---|---|---|---|---------------------|
| | Completely Disagree | | | | | | Completely Agree |
| 11b) | ① | ② | ③ | ④ | ⑤ | ⑥ | |

11c) Patients experiencing the appearance of unpleasant new symptoms after treatment is a positive sign:

| | | | | | | | |
|------|------------------------|---|---|---|---|---|---------------------|
| | Completely Disagree | | | | | | Completely Agree |
| 11c) | ① | ② | ③ | ④ | ⑤ | ⑥ | |

12. Whether or not you use manipulation/high velocity thrusts as a technique, please rate your level of agreement with the following statement:

It is predictable who will benefit from manipulation/high velocity thrusts:

| | | | | | | | |
|-----|------------------------|---|---|---|---|---|---------------------|
| | Completely Disagree | | | | | | Completely Agree |
| 12) | ① | ② | ③ | ④ | ⑤ | ⑥ | |

A minor or transient treatment reaction may be defined as the onset of new symptoms or the worsening of existing symptoms after treatment that does not cause major distress or incapacity to the patient and is temporary, perhaps lasting less than 24/48 hours.

13. Whether or not you use manipulation/high velocity thrusts as a technique, please rate your level of agreement with the following statement:

It is predictable who will get minor or transient treatment reactions from a manipulation/high velocity thrust:

| | | | | | | | |
|-----|------------------------|---|---|---|---|---|---------------------|
| | Completely Disagree | | | | | | Completely Agree |
| 13) | ① | ② | ③ | ④ | ⑤ | ⑥ | |

A major or adverse treatment reaction leads to hospital referral and/or permanent disability and/or incapacity or death. They may be associated with the onset of new symptoms or the worsening of existing symptoms.

14. Whether or not you use manipulation/high velocity thrusts as a technique, please rate your level of agreement with the following statement:

It is predictable who will get a major or adverse treatment reaction from a manipulation/high velocity thrust:

| | | | | | | | |
|-----|------------------------|---|---|---|---|---|---------------------|
| | Completely Disagree | | | | | | Completely Agree |
| 14) | ① | ② | ③ | ④ | ⑤ | ⑥ | |



In a clinical situation risk may be thought of as the likelihood of harm occurring during or after a therapeutic intervention. We are interested to find out how practitioners assess risk when treating various areas of the spine.

15. In your clinical practice please rate how important you consider the following factors in your assessment of the risk of treatment reactions when treating the cervical spine:

| 15a Patient characteristics | Extremely Unimportant | | | | | | Extremely Important |
|------------------------------------|-----------------------|---|---|---|---|---|---------------------|
| 15a i) Age | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 15a ii) Gender | 0 | 1 | 2 | 3 | 4 | 5 | 6 |

| 15b Recent or current symptoms | Extremely Unimportant | | | | | | Extremely Important |
|---------------------------------------|-----------------------|---|---|---|---|---|---------------------|
| 15b i) Hypertension | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 15b ii) Headaches | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 15b iii) Migraines | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 15b iv) Level of Anxiety | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 15b v) Neck Pain/Stiffness | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 15b vi) Neuro Symptoms in Arm | 0 | 1 | 2 | 3 | 4 | 5 | 6 |

| 15c Recent or current injury | Extremely Unimportant | | | | | | Extremely Important |
|--|-----------------------|---|---|---|---|---|---------------------|
| 15c i) Minor Injury/ Mild Whiplash | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 15c ii) Significant Injury/Moderate or Severe Whiplash | 0 | 1 | 2 | 3 | 4 | 5 | 6 |

| 15d Current medication | Extremely Unimportant | | | | | | Extremely Important |
|-------------------------------------|-----------------------|---|---|---|---|---|---------------------|
| 15d i) Anti-Coagulants | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 15d ii) Oral Contraceptives | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 15d iii) Steroids (Past or Current) | 0 | 1 | 2 | 3 | 4 | 5 | 6 |



In your clinical practice please rate how important you consider the following factors in your assessment of the risk of treatment reactions when treating the cervical spine:

15e Diagnosed medical history

Extremely Unimportant

Extremely Important

- | | | | | | | | | |
|---------|--|---|---|---|---|---|---|---|
| 15e i) | Inflammatory Disease e.g. Rheumatoid Arthritis or Ankylosing Spondylitis | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 15e ii) | Congenital Disorders e.g. Marfans or Hypermobility | 0 | 1 | 2 | 3 | 4 | 5 | 6 |

15f Previous treatment

Extremely Unimportant

Extremely Important

- | | | | | | | | | |
|------|--|---|---|---|---|---|---|---|
| 15f) | Previous treatment given by yourself for similar symptoms leading to a negative reaction | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|------|--|---|---|---|---|---|---|---|

15g Lifestyle

Extremely Unimportant

Extremely Important

- | | | | | | | | | |
|------|--------------------------|---|---|---|---|---|---|---|
| 15g) | Recent or Current Smoker | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|------|--------------------------|---|---|---|---|---|---|---|

16. If there are other significant factors that you feel are important in your assessment of risk when treating the cervical spine please write them below:

We appreciate that in a therapeutic setting osteopaths may feel that it is difficult to talk to patients about the possibility of unpleasant treatment reactions. We anticipate that by exploring these issues we may be able to develop more appropriate guidance to practitioners in this challenging area of practise.

17. When preparing new patients to receive osteopathic treatment using manipulation/high velocity thrusts in the cervical spine, please rate how difficult you find it to talk about unpleasant treatment reactions:

- | | | | | | | | |
|-----|----------------|---|---|---|---|---|---------------------|
| | Extremely Easy | | | | | | Extremely Difficult |
| 17) | 0 | 1 | 2 | 3 | 4 | 5 | 6 |



18. When preparing returning patients to receive osteopathic treatment using manipulation/high velocity thrusts in the cervical spine, please rate how difficult you find it to talk about unpleasant treatment reactions:

Extremely Easy Extremely Difficult

18) (0) (1) (2) (3) (4) (5) (6)

19. When preparing new patients to receive osteopathic treatment in general, please rate how difficult you find it to talk to patients about unpleasant treatment reactions:

Extremely Easy Extremely Difficult

19) (0) (1) (2) (3) (4) (5) (6)

20. When preparing returning patients to receive osteopathic treatment in general, please rate how difficult you find it to talk to patients about unpleasant treatment reactions:

Extremely Easy Extremely Difficult

20) (0) (1) (2) (3) (4) (5) (6)

Osteopaths may use a wide variety of techniques as part of their treatment. We are trying to gain an insight into current osteopathic risk assessment in general. We are interested to learn about practitioner perceptions of the overall risks associated with particular techniques when treating the lumbar and thoracic spine.

21. Most treatment reactions are transient and not severe. Please use the scales below to rate your assessment of the level of risk of these minor reactions when using the following techniques on the lumbar and thoracic spine.

If you do not use a technique listed please indicate not applicable (N/A):

| | | N/A | Extremely Low Risk | | | | | Extremely High Risk | |
|------|---------------------------|-----------------------|--------------------|-----|-----|-----|-----|---------------------|-----|
| 21a) | Cranial/IVM Techniques | <input type="radio"/> | (0) | (1) | (2) | (3) | (4) | (5) | (6) |
| 21b) | Functional/ Counterstrain | <input type="radio"/> | (0) | (1) | (2) | (3) | (4) | (5) | (6) |
| 21c) | High Velocity Thrust | <input type="radio"/> | (0) | (1) | (2) | (3) | (4) | (5) | (6) |
| 21d) | Joint Articulation | <input type="radio"/> | (0) | (1) | (2) | (3) | (4) | (5) | (6) |
| 21e) | Soft Tissue Techniques | <input type="radio"/> | (0) | (1) | (2) | (3) | (4) | (5) | (6) |
| 21f) | Muscle Energy Techniques | <input type="radio"/> | (0) | (1) | (2) | (3) | (4) | (5) | (6) |
| 21g) | Visceral | <input type="radio"/> | (0) | (1) | (2) | (3) | (4) | (5) | (6) |



We appreciate that osteopathic management is dictated by individual patient characteristics. However we are keen to find out about some of the general factors that practitioners consider when they reassess and refer patients.

22. Please rate the importance of the following factors when referring a patient to a GP or others for further care/treatment/investigation:

| | | Extremely Unimportant | | | | | | Extremely Important |
|------|--|-----------------------|---|---|---|---|---|---------------------|
| 22a) | Failure to progress as anticipated | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 22b) | Increase in level of primary symptoms | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 22c) | Increase in level of other pre-existing symptoms | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 22d) | Patient dissatisfaction | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 22e) | Increasing patient depression/anxiety | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 22f) | Indicators of undiagnosed pathology or structural deficit* | 0 | 1 | 2 | 3 | 4 | 5 | 6 |

* such as Carcinoma, Ankylosing Spondylitis or Fracture

The consent process involves the exchange of information between practitioner and patient. The goal of this part of the questionnaire is to explore the practicalities of information exchange and patient consent.

23. In your clinical practice, please indicate how frequently you inform your patients about the following:

| | | Never | | | | | | Always |
|------|--|-------|---|---|---|---|---|--------|
| 23a) | The benefits of your recommended treatment | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 23b) | The risks of your recommended treatment | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 23c) | The outcomes of no treatment or alternative treatments | 0 | 1 | 2 | 3 | 4 | 5 | 6 |

24. Please indicate how frequently you obtain consent for examination and treatment from your new and returning patients:

| Examination | | Never | | | | | | Always |
|--------------------|--|-------|---|---|---|---|---|--------|
| 24a) | Prior to the initial patient examination | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 24b) | Prior to each successive examination in the consultation | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Treatment | | Never | | | | | | Always |
| 24c) | Prior to the initial use of an osteopathic technique | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| 24d) | Prior to each successive osteopathic technique in the consultation | 0 | 1 | 2 | 3 | 4 | 5 | 6 |



25. Please indicate how you record consent when using the following techniques on the cervical spine. If you do not use a technique listed please indicate not applicable (N/A):

| | N/A | Consent not discussed | Verbal but not noted by practitioner | Verbal and noted by practitioner | Written and signed by patient |
|-------------------------------|-----------------------|---------------------------|--------------------------------------|----------------------------------|-------------------------------|
| 25a) Cranial/IVM Techniques | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 25b) Functional/Counterstrain | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 25c) High Velocity Thrust | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 25d) Joint Articulation | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 25e) Soft Tissue Techniques | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 25f) Muscle Energy Techniques | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 25g) Visceral | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 25h) Adjunctive Therapies * | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |

* such as Acupuncture, Electrotherapy etc.

26. Please indicate how you record consent when using the following techniques on the thoracic and lumbar spine. If you do not use a technique listed please indicate not applicable (N/A):

| | N/A | Consent not discussed | Verbal but not noted by practitioner | Verbal and noted by practitioner | Written and signed by patient |
|-------------------------------|-----------------------|---------------------------|--------------------------------------|----------------------------------|-------------------------------|
| 26a) Cranial/IVM Techniques | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 26b) Functional/Counterstrain | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 26c) High Velocity Thrust | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 26d) Joint Articulation | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 26e) Soft Tissue Techniques | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 26f) Muscle Energy Techniques | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 26g) Visceral | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |
| 26h) Adjunctive Therapies* | <input type="radio"/> | <input type="radio"/> (A) | <input type="radio"/> (B) | <input type="radio"/> (C) | <input type="radio"/> (D) |

* such as Acupuncture, Electrotherapy etc.

27. Have you received guidance about consent processes?

If Yes, mark here: (Y) and then please answer Questions 28 and 29.

If No, mark here: (N) and then please continue to Question 30.



**28. From what sources have you received guidance about consent processes?
Please mark all those that are applicable.**

- 28a) Pre Registration Training
- 28b) GOsC
- 28c) BOA
- 28d) CPD
- 28e) Other

29. Please use the scale below to indicate how adequate you feel that this guidance has been:

Completely
Inadequate

Completely
Adequate

- ⓪ ① ② ③ ④ ⑤ ⑥

30. Do you think it is desirable that practitioners receive guidance about consent processes?

If Yes, mark here: Y and then please answer Question 31.

If No, mark here: N and then please continue to Question 32.

**31. Where do you think guidance should come from?
Please mark all those you think are appropriate.**

- 31a) Pre Registration Training
- 31b) GOsC
- 31c) BOA
- 31d) CPD
- 31e) Other

There have been reports of serious treatment reactions related to manual therapy interventions. By this we mean the onset of severe new symptoms or the worsening of existing symptoms after treatment leading to hospital referral and/or permanent disability and/or incapacity or death.

32a) In the course of your clinical practice since your graduation as an osteopath, have any of the patients treated by you experienced a serious treatment reaction leading to hospital referral and/or permanent disability and/or incapacity or death?

- Y N

**32b) If yes:
Please indicate how many:**



33a) Over the last 12 months are you aware that any of the patients that you have treated have experienced an associated serious treatment reaction leading to hospital referral and/or permanent disability and/or incapacity or death?

Y N

33b) If yes:
Please indicate how many:

34. Please can you describe briefly, without compromising patient confidentiality, the nature and outcome of the last serious treatment reaction leading to hospital referral and/or permanent disability and/or incapacity or death:

35a) Some medical professions have a central register of adverse treatment reactions. If such a register was established do you think that this would be a good idea for osteopathy?

Y N

35b) Please explain your reasons.

35c) If a central register was established would you be willing to contribute brief details of any adverse treatment reactions that have occurred in your clinical practice?

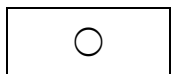
Y N



Intentionally blank

Intentionally blank

Administrative
Purposes Only



Are you willing to help with this research further?

Thank you for completing the questionnaire. It is the first stage of the study which aims to provide information about risk assessment, management and treatment reactions in UK osteopathic practice.

The second stage involves osteopaths distributing questionnaires to all their patients over a two week period. We will collect data on the incidence and the nature of treatment reactions experienced by osteopathic patients, as well as evaluate initial outcomes of treatment. A six week follow up of patients will provide data on short term outcomes.

The third stage of the project involves interviewing practitioners and patients and will be used to help us interpret the survey results.

We hope that osteopaths will be willing to contribute to these further stages of the project. We would be grateful if you completed the questions below in order to enable us to focus our recruitment of participants to complete the project.

34. May we contact you about further stages of this research? Y N

35. I may be willing to hand out patient questionnaires. Y N

36. I may be willing to be interviewed. Y N

If you have answered yes to any of the above we will write to you or e-mail you with more information.

Please provide your e-mail address and telephone number below:

| | |
|---------|---|
| E-mail: | Contact Numbers Daytime: Evening: |
|---------|---|

If you do not want us to use the contact details provided please mark the circle below and complete the table:

I would like to provide new contact details:

Title: Name: Surname:
 <<Title <<FirstName>> <<Professional_Name>>
 >>
 Address:
 <<PracName>>
 <<Addr1>>
 <<Addr2>>
 <<Addr3>>
 Town:
 <<Town>>
 County:
 <<County>>
 Post Code:
 <<PostCode>>

| | | |
|------------|-------|----------|
| Title: | Name: | Surname: |
| Address: | | |
| | | |
| | | |
| Town: | | |
| County: | | |
| Post Code: | | |

Thank you for completing the questionnaire; please check that you have answered all of the questions that apply to you and return it in the Freepost envelope provided.

If you have any further questions then please contact Tom Mars (Research Fellow) at The British School of Osteopathy, 275 Borough High Street, London. SE1 1JE. He can be reached via e-mail at t.mars@bso.ac.uk or on 0207 089 5330.



7.2 Patient survey - baseline

If you decide to take part in this survey please turn to the next page immediately where you will find instructions for filling in the questionnaire.

If you do not want to participate in this survey we would be grateful if you answered the short questions below and return the uncompleted questionnaire to us in the Freepost envelope provided.

A). Please indicate why you have decided not to participate in this survey by marking the items that apply to you:

- I did not have enough time I was given insufficient information
I am not interested Other

B). How old are you? (years). **C). What sex are you?** Male Female

D). Is this the first time that you have visited this osteopath?

If you mislay our Freepost envelope please send any partly filled questionnaires back to us using the Freepost Licence to the address below.

Business Reply Service Licence No SW 1048, The Research Department, The British School of Osteopathy, 275 Borough High Street, London. SE1 1JE.

If you have any questions please contact Tom Mars (Research Fellow) at The British School of Osteopathy. e-mail t.mars@bso.ac.uk or telephone 0207 089 5330.

Thank you for your help

When do I fill out the different sections?

The questionnaire is divided into clearly marked coloured sections that we would like you to fill out before and after your osteopathic appointment.

Section A (White): Today, now, before your osteopathic appointment.

- However if you cannot do this please answer these questions as soon as you can after you have had your appointment.


Section A back page (White): Today, immediately after your osteopathic appointment.

- Please give the white section of the questionnaire to your osteopath so that he/she can fill out the back page.
- It is important that you take this completed section home with you so that you can send it back to us when you have finished the other sections.

Section B (Blue): The first day following your appointment.

Section C (Green): The second day following your appointment.

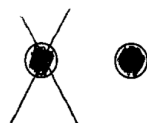
How should I fill out the questionnaire?

1. Please use the pen provided or a blue/black ballpoint pen. Please do not use red ink or felt tip pens.
2. To answer Yes rather than No to a question please mark the response circle 

A Yes answer looks like this:



3. To change a response please put a cross through the incorrect bubble and complete your preferred selection for example:



4. Please avoid bending or folding the questionnaire.

What do I do if I do not finish all the sections of the questionnaire?

We would be very grateful if you would send any partly filled questionnaires back to us in the Freepost envelope.

Section A

**To be completed before today's appointment
(if possible).**

We recognise that your priority at the moment is to see your osteopath. However there is some very important information that we want to collect before you have your consultation. The following section asks questions about why you have come to visit the osteopath and about your health in general. The osteopath may ask you some similar questions as he/she finds out how to help you today.

When completing this questionnaire, please try to be as accurate and honest as you can throughout. There are no 'correct' or 'incorrect' answers. Answer according to your own feelings, rather than how you think most people will answer.

Try not to let your answer to one question influence the answer to other questions.

When you have filled out sections A, B and C please return the questionnaire in the reply envelope provided. **You do not need a stamp.**

If you have any further questions about this questionnaire then please contact Tom Mars (Research Fellow) at The British School of Osteopathy, 275 Borough High Street, London. SE1 1JE. He can be reached via e-mail at t.mars@bso.ac.uk or on 0207 089 5330.

Thank you for your help.

We recognise that patients often have more than one area of symptoms/pain that requires treatment and we will be asking about these later. However for the next question please choose the one main area of symptoms/pain that has caused you to visit the osteopath today.

1). Please indicate the ONE area of your body that is the MAIN focus of symptoms/pain that has caused you to visit the osteopath today.

PLEASE SELECT ONE AREA ONLY.

- | | | | | | |
|----------|-----------------------|------------|-----------------------|-------------------------------|-----------------------|
| Head | <input type="radio"/> | Wrist/hand | <input type="radio"/> | Hip/thigh | <input type="radio"/> |
| Face | <input type="radio"/> | Chest | <input type="radio"/> | Knee | <input type="radio"/> |
| Neck | <input type="radio"/> | Abdomen | <input type="radio"/> | Ankle/Foot | <input type="radio"/> |
| Shoulder | <input type="radio"/> | Upper Back | <input type="radio"/> | Other | <input type="radio"/> |
| Elbow | <input type="radio"/> | Lower Back | <input type="radio"/> | If Other then please specify: | |

If Other then please specify:

Some people tell us that they have distinct bouts/episodes of symptoms/pain with periods in between when they have no symptoms/pain. For the next two questions we would like you to think about your most recent bout/episode. You do not need to be exact, please mark the circle nearest to your answer.

2). Please indicate how long you have had the CURRENT bout/episode of the MAIN area of symptoms/pain that has caused you to visit the osteopath today.

PLEASE SELECT ONE ONLY

- | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Less than one month | 1 to 3 months | 4 to 6 months | 7 months to 3 years | More than 3 years |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

3). How long is it since you have had a whole month WITHOUT any symptoms/pain in the MAIN area that has caused you to visit the osteopath today?

PLEASE SELECT ONE ONLY

- | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Less than one month | 1 to 3 months | 4 to 6 months | 7 months to 3 years | More than 3 years |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

4). Concerning your MAIN area of symptoms/pain: In the last month, that is in the last four weeks, on average, how INTENSE were your symptoms/pain rated on a 0 to 10 scale where 0 is "no symptoms/pain" and 10 is "worst possible symptoms/pain?"

No Symptoms/Pain

Worst Possible Symptoms/Pain

- 0 1 2 3 4 5 6 7 8 9 10

5). Concerning your MAIN area of symptoms/pain: How would you rate your symptoms/pain on a 0 to 10 scale at the present time, that is right now; where 0 is “no symptoms/pain” and 10 is “worst possible symptoms/pain?”

No Symptoms/Pain

Worst Possible
Symptoms/Pain

- 0
 1
 2
 3
 4
 5
 6
 7
 8
 9
 10

6). Concerning your MAIN area of symptoms/pain: In the last month, that is in the last four weeks, on average, how TROUBLESOME have your symptoms/pain been?

No symptoms/
pain
experienced

Not at all
troublesome

Slightly
troublesome

Moderately
troublesome

Very
troublesome

Extremely
troublesome

-

7). At the present time, that is right now, please indicate how TROUBLESOME each of the following areas of symptoms/pain are.

**PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY AREA
(Mark each item from a to n)**

| Area of symptoms/ pain | No symptoms/ pain experienced | Not at all troublesome | Slightly troublesome | Moderately troublesome | Very troublesome | Extremely troublesome |
|---------------------------|-------------------------------------|---------------------------|-------------------------|---------------------------|-----------------------|--------------------------|
| a) Head | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b) Face | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| c) Neck | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| d) Shoulder | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| e) Elbow | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| f) Wrist/Hand | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| g) Chest | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| h) Abdomen | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| i) Upper back | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| j) Lower back | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| k) Hip/thigh | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| l) Knee | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| m) Ankle/foot | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| n) Other | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

We would like to find out to what extent and how frequently you have suffered from a number of other symptoms over the last two weeks, that is the last 14 days prior to your osteopathic appointment today.

8). In the last two weeks, that is in the last 14 days, on average, how INTENSE were ALL of the symptoms listed below on a 0 to 10 scale where 0 is “no symptoms” and 10 is “worst possible symptoms.”

**PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY SYMPTOM
(Mark each item from a to m)**

| | No symptoms | | | | | | | | | | Worst possible symptoms |
|-------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|--------------------------|
| a) Fatigue/ sleepiness | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| b) Dizziness/light headedness | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| c) Nausea | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| d) Vomiting | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| e) Headaches | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| f) Ringing in the ears | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| g) Confusion/ disorientation | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| h) Fear/Anxiety | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| i) Depression | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| j) Bruising | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| k) Skin rash | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| l) Numbness/tingling: arms/hands | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| m) Numbness/ tingling: legs/feet | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |

9). In the last two weeks, that is in the last 14 days, how OFTEN have you had ALL the symptoms listed below on a 0 to 10 scale, where 0 is “not at all” and 10 is “every day. ”

PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY SYMPTOM
(Mark each item from a to m)

| | Not at all | | | | | | | | | | Every Day |
|-------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|--------------------------|
| a) Fatigue/ sleepiness | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| b) Dizziness/light headedness | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| <hr/> | | | | | | | | | | | |
| c) Nausea | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| d) Vomiting | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| <hr/> | | | | | | | | | | | |
| e) Headaches | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| f) Ringing in the ears | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| <hr/> | | | | | | | | | | | |
| g) Confusion/ disorientation | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| h) Fear/Anxiety | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| <hr/> | | | | | | | | | | | |
| i) Depression | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| j) Bruising | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| <hr/> | | | | | | | | | | | |
| k) Skin rash | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| l) Numbness/tingling: arms/hands | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| <hr/> | | | | | | | | | | | |
| m) Numbness/ tingling: legs/feet | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |

10). Have you had the symptoms of flu or a cold in the last two weeks?

Y N

11). In the last week, that is in the last 7 days, have you been taking any painkillers?

IF YES, MARK HERE: Y AND INDICATE THE MEDICATIONS YOU HAVE USED BELOW.

Anti-inflammatory tablets

For example (Diclofenac, Naproxen, Celecoxib, Ibuprofen, Ketoprofen, Neurofen)

Mild pain killers

Paracetamol

Moderate pain killers

For example (Codeine, Co-Codamol, Co-Dydramol, Co-Proxamol, Dihydrocodeine, Tramadol)

Strong pain killers

For example Morphine, Diamorphine, Fentanyl, Buprenorphine, Oxycodone

IF NO, MARK HERE: N AND THEN PLEASE GO ON TO QUESTION 12.

12). By marking one circle in each group below please indicate which statements best describe your own health state today.

Mobility

I have no problems with walking around

I have some problems with walking around

I am confined to bed

Self-care

I have no problems with self-care

I have some problems washing or dressing myself

I am unable to wash or dress myself

Usual activities

(e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities

I have some problems with performing my usual activities

I am unable to perform my usual activities

Pain / Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety / Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

13). We would like to know when you filled out this section of the questionnaire.

PLEASE SELECT ONE ONLY

- On the same day as my appointment with the osteopath and before my consultation.
- On the same day as my appointment with the osteopath but after my consultation.
- After the day of my consultation

Thank you for answering our questions. Please give this to your osteopath so that he/she may complete the back page which will record your treatment today.

Please ensure that your osteopath gives this part back to you so that you can return it after you have completed Section B and Section C

TO BE COMPLETED BY YOUR OSTEOPATH AT THE END OF YOUR APPOINTMENT TODAY.

We would like to know what osteopathic techniques you used to treat your patient today.

1). Please indicate the body areas/osteopathic techniques that you used to treat your patient today.

IF YOU DID NOT USE A TECHNIQUE PLEASE INDICATE NOT APPLICABLE (N/A).

| | N/A | Cervical spine/ neck | Thoracic spine/ mid back | Lumbar spine/ low back | Shoulder girdle | Upper extremity | Pelvic girdle | Lower extremity |
|---------------------------|-----------------------|-----------------------|--------------------------|------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Functional/ counterstrain | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| High velocity thrust | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Joint articulation | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Soft tissue techniques | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Muscle energy techniques | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

2). Please indicate if you used the following techniques to treat your patient today:

Cranial osteopathic/IVM Techniques Y N

Visceral Y N

3). Did you use other therapeutic approaches listed below to treat your patient today?

IF YES, MARK HERE: Y AND INDICATE THE OTHER APPROACHES THAT YOU USED.

| | | | | | |
|---------------------------|-----------------------|---------------------------------|-----------------------|----------------------------|-----------------------|
| Electro-therapy | <input type="radio"/> | Homeopathy | <input type="radio"/> | Prescription of medication | <input type="radio"/> |
| Nutrition therapy | <input type="radio"/> | Herbal medicine | <input type="radio"/> | Injections | <input type="radio"/> |
| Dry needling/ Acupuncture | <input type="radio"/> | Applied or clinical Kinesiology | <input type="radio"/> | Other (please specify): | <input type="radio"/> |

IF NO, MARK HERE: N

Thank you for answering our questions. Please give the questionnaire back to your patient so that they can finish the other sections at home. They will return the completed questionnaire to us in a Freepost envelope.

7.3 Patient survey - day one

Section B

To be completed on the first day following your appointment.

When completing this questionnaire, please try to be as accurate and honest as you can throughout. There are no 'correct' or 'incorrect' answers. Answer according to your own feelings, rather than how you think most people will answer.

Try not to let your answer to one question influence the answer to other questions.

When you have filled out sections A, B and C please return all the completed sections of the questionnaire in the reply envelope provided. **You do not need a stamp.**

If you have any further questions about this questionnaire then please contact Tom Mars (Research Fellow) at The British School of Osteopathy, 275 Borough High Street, London. SE1 1JE. He can be reached via e-mail at t.mars@bso.ac.uk or on 0207 089 5330.

Thank you for your help.

Now that you have a little more time to help us we would like some more background information about you and your health. This information will help us describe the range of people seeking osteopathic care. We are also interested to find out how you are feeling since seeing your osteopath yesterday.

1). How old are you? (years)

2. What sex are you?

Male M Female F

3). What was the date of the appointment with your osteopath? (dd mm yyyy).

4). How old were you when you left full time education?

PLEASE SELECT ONE ONLY.

16 years old or less

17 to 18 years old

19 years or older

Still in full time education

5). Which of the following best describes you?

PLEASE SELECT ONE ONLY.

Employed (Full or part time, including self-employed).

Unemployed and looking for work.

At school or in full time education.

Unable to work due to long term sickness.

Looking after your home/family.

Retired from paid work.

Other (please describe)

6). Are you a current smoker?

 Y N

The next series of questions are about what treatment and advice you are receiving for your general health and wellbeing.

7). Are you currently suffering from any of the health problems listed below?

IF YES, MARK HERE: AND INDICATE THE PROBLEMS YOU ARE SUFFERING FROM.

Painful Joints:

Rheumatoid Arthritis

Ankylosing-Spondylitis

Osteo-Arthritis

Other

Bone Problems:

Osteoporosis

Other

Difficulties with your breathing:

Chronic Obstructive Pulmonary Disease (COPD), Chronic Bronchitis, Emphysema.

Other

Heart problems:

Heart Disease, Congestive Heart Failure, Hypertension (High Blood Pressure)

Angina

Other

Digestive or stomach problems:

Hiatus Hernia, acid Reflux/Heartburn, Recurrent Indigestion, Ulcers

Other

Diabetes

Mental health problems:

Depression, Anxiety

Other

IF NO, MARK HERE: AND GO ON TO QUESTION 8.

8). In the last week, that is in the last seven days, have you been taking any of the medications listed below?

IF YES, MARK HERE: Y AND INDICATE THE MEDICATIONS YOU HAVE BEEN TAKING BELOW.

Anti-depressant drugs

For example: Amitriptyline, Dosulepin, Lofepamine, Nortriptyline, Imipramine, Trimipramine, Luoxetine (Prozac), Citalopram (Cipramil), Escitalopram (Cipralext), Paroxetine, (Sertraline).

Anti-coagulant drugs

For example: Warfarin.

Blood thinning drugs

For example: Clopidogrel, Aspirin, Dipyridamole.

Blood pressure lowering drugs

For example: Lisinopril, Perindopril, Ramipril, Nifedipine, Candesartan, Losartan, Enalapril, Doxazosin, Bisoprolol, Propranolol, Co-Tenidone, Amlodipine (Istin), Diltiazem.

Anti-angina drugs

For example: Carvedilol, Atenolol, Bisoprolol, Labetalol, Isosorbide Mononitrate, Propranolol, Diltiazem, Nifedipine, Verapamil, Nicorandil, Glyceryl Trinitrate .

Cholesterol lowering drugs/statins

For example: Simvastatin, Atorvastatin, Pravastatin, Rosuvastatin.

Steroids

For example: Prednisolone.

Osteoporosis drugs

For example: Calcichew (D3 or Forte), Adcal (D3), Fosamax (Alendronate Sodium), Risedronate Sodium.

IF NO, MARK HERE: N AND GO ON TO QUESTION 9.

9). Is this the first time that you have visited this osteopath?

IF YES, MARK HERE: Y AND GO ON TO QUESTION 12.

IF NO, MARK HERE: N AND GO ON TO QUESTION 10.

10). Is this the first time that you have visited this osteopath for your current symptoms/pain?

IF YES, MARK HERE: Y AND GO ON TO QUESTION 12.

IF NO, MARK HERE: N AND GO ON TO QUESTION 11.

11). Please indicate the number of previous visits you have had to this osteopath for your current symptoms/pain:

12). Have you visited another healthcare professional (eg chiropractor, physiotherapist, homeopath, GP) about the symptoms/pain that caused you to visit the osteopath yesterday?

Y N

13). Have you been to see your GP within the last 6 months?

Y N

14). Are you currently unable to work because of your symptoms/pain?

IF YES, MARK HERE: Y AND GO ON TO QUESTION 15.

IF NO, MARK HERE: N AND GO ON TO QUESTION 16.

IF NOT APPLICABLE, MARK HERE: AND GO ON TO QUESTION 17.

15). How many days have you been off work on this occasion?

16). How many days have you had off work due to your symptoms/pain in the last year, that is the last 12 months?

Osteopaths use a range of treatment methods; these may include “hands on” treatment and sometimes other approaches. We would like to know about some of the treatment you may have received in your consultation yesterday.

17). Did your osteopath put your neck/back into a position and perform a quick movement during which you may have heard a “click”?

IF YES, MARK HERE: Y AND ANSWER FOR EACH OF THE THREE AREAS BELOW.

Neck

Mid back

Low back

Y N

Y N

Y N

IF NO, MARK HERE: N AND GO ON TO QUESTION 18.

IF NOT SURE, MARK HERE: AND GO ON TO QUESTION 18.

18). Did your osteopath treat you using any of the approaches below?

IF YES, MARK HERE: **AND INDICATE THE APPROACHES THAT HE/SHE USED.**

- | | | | | | |
|------------------------------|-----------------------|--|-----------------------|--|-----------------------|
| Dry needling/ Acupuncture | <input type="radio"/> | Prescription of medication | <input type="radio"/> | Use of herbal and other supplements | <input type="radio"/> |
| Injections | <input type="radio"/> | Electro-therapy e.g. Ultrasound, TENS machines, Laser therapy. | <input type="radio"/> | Specific advice about diet | <input type="radio"/> |
| Homeopathy | <input type="radio"/> | | | | |

IF NO, MARK HERE: **AND GO ON TO QUESTION 19.**

IF NOT SURE, MARK HERE: **AND GO ON TO QUESTION 19.**

19). During your visit to the osteopath did he/she talk to you about the following?

PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY ITEM

(Mark each item from a to d)

- | | | |
|---|-----------------------|-----------------------|
| a. The reasons why your osteopath needed to examine you. | <input type="radio"/> | <input type="radio"/> |
| b. The likely benefits of your recommended treatment. | <input type="radio"/> | <input type="radio"/> |
| c. The likely risks of your recommended treatment. | <input type="radio"/> | <input type="radio"/> |
| d. The likely outcomes of no treatment or different treatment approaches. | <input type="radio"/> | <input type="radio"/> |

Please rate your level of agreement with the following statements.

20). I think that it is extremely important that my osteopath asks my permission before I am examined.

Completely Disagree

Completely Agree

21). I think that it is extremely important that my osteopath asks my permission before I am treated.

Completely Disagree

Completely Agree

22). At your visit to the osteopath yesterday please indicate if he/she asked your permission to proceed prior to the following:

PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY ITEM

(Mark each item from a to d)

- | | | |
|---|-----------------------|-----------------------|
| a. Your first examination. | <input type="radio"/> | <input type="radio"/> |
| b. Each successive examination in the consultation. | <input type="radio"/> | <input type="radio"/> |
| c. Your treatment. | <input type="radio"/> | <input type="radio"/> |
| d. Each successive technique in the consultation. | <input type="radio"/> | <input type="radio"/> |

We would like to know how your treatment has affected how you are feeling since you visited the osteopath yesterday.

23). At the present time, that is right now, please indicate how TROUBLESOME each of the following areas of symptoms/pain are.

**PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY AREA
(Mark each item from a to n)**

| Area of symptoms/pain | No symptoms/pain experienced | Not at all troublesome | Slightly troublesome | Moderately troublesome | Very troublesome | Extremely troublesome |
|-----------------------|------------------------------|------------------------|-----------------------|------------------------|-----------------------|-----------------------|
| a) Head | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b) Face | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| c) Neck | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| d) Shoulder | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| e) Elbow | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| f) Wrist/Hand | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| g) Chest | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| h) Abdomen | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| i) Upper back | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| j) Lower back | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| k) Hip/thigh | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| l) Knee | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| m) Ankle/foot | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| n) Other | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

24). Concerning your MAIN area of symptoms/pain: Since your osteopathic treatment yesterday, on average, how INTENSE were your symptoms/pain rated on a 0 to 10 scale where 0 is “no symptoms/pain” and 10 is “worst possible symptoms/pain?”

No Symptoms/Pain

Worst Possible Symptoms/Pain

⓪ Ⓛ Ⓜ Ⓝ Ⓞ Ⓟ Ⓠ Ⓡ Ⓢ Ⓣ Ⓤ

25). Concerning your MAIN area of symptoms/pain: How would you rate your symptoms/pain on a 0 to 10 scale at the present time, that is right now; where 0 is “no symptoms/pain” and 10 is “worst possible symptoms/pain?”

No Symptoms/Pain

Worst Possible Symptoms/Pain

⓪ Ⓛ Ⓜ Ⓝ Ⓞ Ⓟ Ⓠ Ⓡ Ⓢ Ⓣ Ⓤ

26). Concerning your MAIN area of symptoms/pain: Since your osteopathic treatment yesterday, on average, how TROUBLESOME have your symptoms/pain been?

| | | | | | |
|-------------------------------------|---------------------------|-------------------------|---------------------------|-----------------------|--------------------------|
| No symptoms/ pain experienced | Not at all troublesome | Slightly troublesome | Moderately troublesome | Very troublesome | Extremely troublesome |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

We are interested to find out if you have suffered from any of the following symptoms since your last osteopathic appointment yesterday.

27). Since your osteopathic treatment yesterday, on average, how INTENSE were ALL the symptoms listed below on a 0 to 10 scale where 0 is “no symptoms” and 10 is “worst possible symptoms.”

**PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY SYMPTOM
(Mark each item from a to m)**

| | No symptoms | | | | | | | | | | Worst possible symptoms | | | | | | | | | | |
|-------------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| a) Fatigue/ sleepiness | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b) Dizziness/light headedness | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| c) Nausea | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| d) Vomiting | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| e) Headaches | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| f) Ringing in the ears | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| g) Confusion/ disorientation | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| h) Fear/Anxiety | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| i) Depression | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| j) Bruising | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| k) Skin rash | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| l) Numbness/tingling: arms/hands | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| m) Numbness/ tingling: legs/feet | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

28). Please indicate how you think your overall symptoms/pain have changed since your osteopathic treatment yesterday.

| | | | | | | |
|-----------------|------------|-----------------|-----------|--------------------|---------------|--------------------|
| Very much worse | Much worse | Minimally worse | No change | Minimally improved | Much improved | Very much improved |
| ① | ② | ③ | ④ | ⑤ | ⑥ | ⑦ |

29). Have you visited your GP or been referred to hospital or another medical specialist/practitioner because of a worsening of your original symptoms or the appearance of new related symptoms that you attribute to your osteopathic treatment yesterday?

Y N

30). Please indicate how satisfied you were with the treatment by your osteopath yesterday.

| | | | | | | |
|-------------------|---|---|---|---|---|----------------|
| Very Dissatisfied | | | | | | Very Satisfied |
| ① | ② | ③ | ④ | ⑤ | ⑥ | |

31). Would you recommend the osteopathic treatment that you had yesterday to others with similar symptoms/pain?

Y N

32). We would like to know when you filled out this section of the questionnaire.

On the same day as my consultation with the osteopath but after my appointment.

The day following my appointment.

Two days following my appointment.

More than two days following my appointment.

Thank you for your help in answering our questions so far. Please complete the final short questions in Section C tomorrow. These last questions will give us very valuable further information. However, if for any reason you find that you are unable to complete Section C we would be very grateful if you could check that you have answered all the questions that apply to you and return the questionnaire in the Freepost envelope

Thank you for your help.

7.4 Patient survey - day two

Section C

To be completed on the second day following your appointment.

When completing this questionnaire, please try to be as accurate and honest as you can throughout. There are no 'correct' or 'incorrect' answers. Answer according to your own feelings, rather than how you think most people will answer.

Try not to let your answer to one question influence the answer to other questions.

When you have filled out sections A, B and C please return the questionnaire in the reply envelope provided. **You do not need a stamp.**

If you have any further questions about this questionnaire then please contact Tom Mars (Research Fellow) at The British School of Osteopathy, 275 Borough High Street, London. SE1 1JE. He can be reached via e-mail at t.mars@bso.ac.uk or on 0207 089 5330.

Thank you for your help.



We would like to know how your treatment has affected how you are feeling since your last osteopathic appointment 2 days ago.

1). Concerning your MAIN area of symptoms/pain: Since your osteopathic treatment 2 days ago, on average, how INTENSE were your symptoms/pain rated on a 0 to 10 scale where 0 is “no symptoms/pain” and 10 is “worst possible symptoms/pain?”

No Symptoms/Pain

Worst Possible
Symptoms/Pain

0 1 2 3 4 5 6 7 8 9 10

2). Concerning your MAIN area of symptoms/pain: How would you rate your symptoms/pain on a 0 to 10 scale at the present time, that is right now; where 0 is “no symptoms/pain” and 10 is “worst possible symptoms/pain?”

No Symptoms/Pain

Worst Possible
Symptoms/Pain

0 1 2 3 4 5 6 7 8 9 10

3). Concerning your MAIN area of symptoms/pain: Since your osteopathic treatment 2 days ago, on average, how TROUBLESOME have your symptoms/pain been?

No symptoms/
pain
experienced

Not at all
troublesome

Slightly
troublesome

Moderately
troublesome

Very
troublesome

Extremely
troublesome

Please continue to page 3

4). At the present time, that is right now, please indicate how TROUBLESOME each of the following areas of symptoms/pain are.

**PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY AREA
(Mark each item from a to n)**

| Area of symptoms/ pain | No symptoms/ pain experienced | Not at all troublesome | Slightly troublesome | Moderately troublesome | Very troublesome | Extremely troublesome |
|---------------------------|-------------------------------------|---------------------------|-------------------------|---------------------------|-----------------------|--------------------------|
| a) Head | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b) Face | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| c) Neck | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| d) Shoulder | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| e) Elbow | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| f) Wrist/Hand | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| g) Chest | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| h) Abdomen | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| i) Upper back | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| j) Lower back | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| k) Hip/thigh | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| l) Knee | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| m) Ankle/foot | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| n) Other | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

5). Since your osteopathic treatment 2 days ago, on average, how INTENSE were ALL the symptoms listed below on a 0 to 10 scale where 0 is “no symptoms” and 10 is “worst possible symptoms.”

**PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY SYMPTOM
(Mark each item from a to m)**

| | No symptoms | | | | | | | | | | Worst possible symptoms |
|-------------------------------------|-------------|---|---|---|---|---|---|---|---|---|-------------------------|
| a) Fatigue/ sleepiness | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| b) Dizziness/light headedness | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| <hr/> | | | | | | | | | | | |
| c) Nausea | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| d) Vomiting | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| <hr/> | | | | | | | | | | | |
| e) Headaches | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| f) Ringing in the ears | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| <hr/> | | | | | | | | | | | |
| g) Confusion/ disorientation | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| h) Fear/Anxiety | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| <hr/> | | | | | | | | | | | |
| i) Depression | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| j) Bruising | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| <hr/> | | | | | | | | | | | |
| k) Skin rash | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| l) Numbness/tingling: arms/hands | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| <hr/> | | | | | | | | | | | |
| m) Numbness/ tingling: legs/feet | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

6). Please indicate how you think your overall symptoms/pain have changed since your osteopathic treatment 2 days ago.

| | | | | | | |
|-----------------|------------|-----------------|-----------|--------------------|---------------|--------------------|
| Very much worse | Much worse | Minimally worse | No change | Minimally improved | Much improved | Very much improved |
| ① | ② | ③ | ④ | ⑤ | ⑥ | ⑦ |

7). Have you visited your GP or been referred to hospital or another medical specialist/practitioner because of a worsening of your original symptoms or the appearance of new related symptoms that you attribute to your osteopathic treatment?

Y N

8). Please indicate how satisfied you were with the treatment by your osteopath.

| | | | | | | |
|-------------------|---|---|---|---|---|----------------|
| Very Dissatisfied | | | | | | Very Satisfied |
| ① | ② | ③ | ④ | ⑤ | ⑥ | |

9). Would you recommend the osteopathic treatment that you have had to others with similar symptoms/pain?

Y N

10). We would like to know when you have filled out this section of the questionnaire.

PLEASE SELECT ONE ONLY.

- Two days following my appointment.
- Three days following my appointment.
- More than three days following my appointment.

The next stages of the study

Thank you for completing the questionnaire. It is part of a larger study which aims to provide information about risk assessment, management and treatment reactions in osteopathic practice in the UK.

The next stage involves completing a questionnaire in 6 weeks time which will be a much shorter version of the questionnaire that you have just completed. For this reason we would like you to provide us with your name and address so that we can send you the final questionnaire and pre-paid return envelope.

We will also be inviting up to thirty people to be interviewed either by telephone or in person. The interviews will add important additional information and help us interpret the responses to the questionnaires.

We hope that you will be willing to contribute to these further stages of the project and would be grateful if you completed the questions overleaf.

PTO

Please provide your contact details.

Please use block capitals

Title Mr/Mrs/Ms/Other.....

Family Name..... Forename(s).....

Address.....

.....

.....

.....

Postcode.....

Telephone (including STD code)

Daytime..... Evening.....

Email.....

10. I am willing to be contacted about being involved in further stages of this research.

Y N

11. I may be willing to be interviewed (those invited will be sent further information).

Y N

Thank you for completing the questionnaire; please check that you have answered all of the questions that apply to you and return all the sections in the Freepost envelope provided.

If you mislay our Freepost envelope please send any partly filled questionnaires back to us using the Freepost Licence to the address below.

Business Reply Service Licence No SW 1048, The Research Department, The British School of Osteopathy, 275 Borough High Street, London. SE1 1JE.

If you have any questions please contact Tom Mars (Research Fellow) at The British School of Osteopathy. e-mail t.mars@bso.ac.uk or telephone 0207 089 5330.

7.5 Patient survey - six weeks

Six week questionnaire

Thank you for agreeing to help us further by providing us with information about your experiences since your osteopathic appointment 6 weeks ago. The answers that you have already given are now being analysed and will give us valuable information on the immediate effects of osteopathic treatment. By helping us with this questionnaire you will be giving us information that we can use to examine the short term effects of osteopathic treatment.

When completing this questionnaire, please try to be as accurate and honest as you can throughout. There are no 'correct' or 'incorrect' answers. Answer according to your own feelings, rather than how you think most people will answer.

Try not to let your answer to one question influence the answer to other questions.

When you have filled out this questionnaire please return the questionnaire in the reply envelope provided. **You do not need a stamp.**

If you have any further questions about this questionnaire then please contact Tom Mars (Research Fellow) at The British School of Osteopathy, 275 Borough High Street, London. SE1 1JE. He can be reached via e-mail at t.mars@bso.ac.uk or on 0207 089 5330.

Thank you for your help.



*



B A R C O D E



*

How should I fill out the questionnaire?

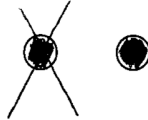
1. Please use a blue/black ballpoint pen. Please do not use red ink or felt tips.

2. To answer Yes rather than No to a question please mark the response circle

A Yes answer looks like this:

= Yes

3. To change a response please put a cross through the incorrect bubble and complete your preferred selection for example:



4. Please avoid bending or folding the questionnaire.

We would like to know if you have had any further treatment for the symptoms/pain that originally caused you to visit your osteopath six weeks ago. In addition we would like to know how you have been feeling since your osteopathic appointment and what advice and further treatment you have received for your health and well being.

1. What is today's date? (dd mm yyyy).

2. How many osteopathic appointments have you had for your main symptoms/pain since your visit to your osteopath six weeks ago?

3). How many times have you visited your GP or another healthcare practitioner about your main symptoms/pain since your visit to your osteopath six weeks ago?

4). Are you currently unable to work because of your symptoms/pain?

IF YES, MARK HERE: Y AND GO ON TO QUESTION 5.

IF NO, MARK HERE: N AND GO ON TO QUESTION 6.

IF NOT APPLICABLE, MARK HERE: AND GO ON TO QUESTION 6.

5). How many days have you been off work since your appointment six weeks ago?

6). In the last week, that is in the last 7 days, have you been taking any painkillers?

IF YES, MARK HERE: Y AND INDICATE THE ONES YOU HAVE BEEN TAKING BELOW.

Anti-inflammatory tablets

For example (Diclofenac, Naproxen, Celecoxib, Ibuprofen, Ketoprofen, Neurofen)

Mild pain killers

For example Paracetamol

Moderate pain killers

For example (Codeine, Co-Codamol, Co-Dydramol, Co-Proxamol, Dydrocodeine, Tramadol)

Strong pain killers

For example Morphine, Diamorphine, Fentanyl, Buprenorphine, Oxycodone

IF NO, MARK HERE: N AND GO ON TO QUESTION 7.

7). Have you had the symptoms of flu or a cold in the last two weeks?

Y N

8). By marking one circle in each group below please indicate which statements best describe your own health state today.

Mobility

- I have no problems with walking around
- I have some problems with walking around
- I am confined to bed

Self-care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual activities

(e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain / Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety / Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

9). At the present time, that is right now, please indicate how TROUBLESOME each of the following areas of symptoms/pain are.

**PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY AREA
(Mark each item from a to n)**

| Area of symptoms/ pain | No symptoms/ pain experienced | Not at all troublesome | Slightly troublesome | Moderately troublesome | Very troublesome | Extremely troublesome |
|---------------------------|-------------------------------------|---------------------------|-------------------------|---------------------------|-----------------------|--------------------------|
| a) Head | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b) Face | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| c) Neck | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| d) Shoulder | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| e) Elbow | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| f) Wrist/Hand | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| g) Chest | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| h) Abdomen | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| i) Upper back | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| j) Lower back | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| k) Hip/thigh | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| l) Knee | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| m) Ankle/foot | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| n) Other | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

10). Concerning your MAIN area of symptoms/pain: In the last month, that is in the last four weeks, on average, how INTENSE were your symptoms/pain rated on a 0 to 10 scale where 0 is “no symptoms/pain” and 10 is “worst possible symptoms/pain?”

No Symptoms/Pain

Worst Possible
Symptoms/Pain

⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩

11). Concerning your MAIN area of symptoms/pain: How would you rate your symptoms/pain on a 0 to 10 scale at the present, time that is right now; where 0 is “no symptoms/pain” and 10 is “worst possible symptoms/pain”?

No Symptoms/Pain

Worst Possible
Symptoms/Pain

⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩

12). Concerning your MAIN area of symptoms/pain: In the last month, that is in the last four weeks, on average, how TROUBLESOME have your symptoms/pain been?

| | | | | | |
|-------------------------------------|---------------------------|-------------------------|---------------------------|-----------------------|--------------------------|
| No symptoms/ pain experienced | Not at all troublesome | Slightly troublesome | Moderately troublesome | Very troublesome | Extremely troublesome |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

13). In the last two weeks, that is in the last 14 days, on average, how INTENSE were the ALL of the symptoms listed below on a 0 to 10 scale where 0 is “no symptoms” and 10 is “worst possible symptoms.”

**PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY SYMPTOM
(Mark each item from a to m)**

| | No symptoms | | | | | | | | | | Worst possible symptoms |
|-------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|--------------------------|
| a) Fatigue/ sleepiness | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| b) Dizziness/light headedness | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| c) Nausea | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| d) Vomiting | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| e) Headaches | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| f) Ringing in the ears | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| g) Confusion/ disorientation | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| h) Fear/Anxiety | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| i) Depression | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| j) Bruising | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| k) Skin rash | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| l) Numbness/tingling: arms/hands | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |
| m) Numbness/ tingling: legs/feet | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 |

14). In the last two weeks, that is in the 14 days, how OFTEN have you had ALL of the symptoms listed below on a 0 to 6 scale where 0 is “not at all” and 6 is “every day?”

**PLEASE MARK THE APPROPRIATE CIRCLE FOR EVERY SYMPTOM
(Mark each item from a to m)**

| | Not at all | | | | | | Every Day | | | | | |
|-------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|--------------------------|--|
| a) Fatigue/ sleepiness | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| b) Dizziness/light headedness | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| <hr/> | | | | | | | | | | | | |
| c) Nausea | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| d) Vomiting | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| <hr/> | | | | | | | | | | | | |
| e) Headaches | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| f) Ringing in the ears | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| <hr/> | | | | | | | | | | | | |
| g) Confusion/ disorientation | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| h) Fear/Anxiety | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| <hr/> | | | | | | | | | | | | |
| i) Depression | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| j) Bruising | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| <hr/> | | | | | | | | | | | | |
| k) Skin rash | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| l) Numbness/tingling: arms/hands | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |
| <hr/> | | | | | | | | | | | | |
| m) Numbness/ tingling: legs/feet | <input type="radio"/> 0 | <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 | <input type="radio"/> 8 | <input type="radio"/> 9 | <input type="radio"/> 10 | |

15). Please indicate below how you think your overall symptoms/pain have changed since your osteopathic treatment, six weeks ago.

| | | | | | | |
|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Very much worse | Much worse | Minimally worse | No change | Minimally improved | Much improved | Very much improved |
| <input type="radio"/> 1 | <input type="radio"/> 2 | <input type="radio"/> 3 | <input type="radio"/> 4 | <input type="radio"/> 5 | <input type="radio"/> 6 | <input type="radio"/> 7 |

16). Have you visited your GP or been referred to hospital or another medical specialist/practitioner because of a worsening of your original symptoms or the appearance of new related symptoms that you attribute to your osteopathic treatment?

Y N

17). Have you suffered any temporary incapacity or disability that you attribute to your osteopathic treatment?

Y N

18). Please indicate how satisfied you are with the treatment by your osteopath.

Very Dissatisfied

Very Satisfied

0

1

2

3

4

5

6

19). Would you recommend the osteopathic treatment that you have had to others with similar pain/symptoms?

Y N

Thank you for participating in the final phase of this project. The important information that you have given us about your experiences will be used to help shape future osteopathic practice in the UK. Please check that you have answered all of the questions that apply to you and return it in the Freepost envelope.

If you mislay our Freepost envelope please send any partly filled questionnaires back to us using the Freepost Licence to the address below.

Business Reply Service Licence No SW 1048, The Research Department, The British School of Osteopathy, 275 Borough High Street, London. SE1 1JE.

If you have any questions please contact Tom Mars (Research Fellow) at The British School of Osteopathy. e-mail t.mars@bso.ac.uk or telephone 0207 089 5330.

7.6 Practitioner interview guide

**Study Title: Clinical Risk, Osteopathy and Management Study (CROaM)
Practitioner Interview Guide field version.**

Introduction:

My name is XXXXXX and I am from the British School of Osteopathy and one of the research team on the CROaM study. (I'm phoning to speak to XXXX to carry out an interview that we have arranged for this time.)

Thank you very much for participating in the CROaM study and agreeing to be interviewed. Before we start I'm just going to go through one or two points with you to make sure that you are happy and understand the context and purpose of the interview. If I sound a bit mechanical at times its because I need to use my script at times to make sure that interview questions are broadly similar across different people.

Just to introduce myself a little - I am an osteopath by background but here today in the role of research interviewer. I am very interested in your views and experiences from practice.

May we start by checking whether you have any questions about the study and that you are happy with the consent form that you have signed and returned to us.

I have a copy of your consent form in front of me is there anything you would like to clarify.

Our primary purpose in this interview is to gain insight into your personal views and opinions that have been formed through your individual experience in clinical practice. We are interested in building our understanding from the survey that you kindly completed.

Some of the questions will be about treatment and reactions to treatment that you have encountered. In order to keep the identity of individual patients anonymous, it would help me if you avoided using the personal names or identifying features of any case that you might mention. However if these are mentioned we will change any such features when transcribing the interview.

If there are any questions you are uncomfortable with, or would rather not answer, simply say so, and I will go on to the next question. If you decide you no longer wish to be interviewed, please tell me so, and I will simply end the interview and stop recording. You do not have to give an explanation for this decision.

Do you have any further questions before we begin the recorded interview?

Just give me a few seconds to start the recording equipment

**Study Title: Clinical Risk, Osteopathy and Management Study (CROaM)
Practitioner Interview Guide field version.**

1. To start with a few questions about you and your practice:
 - i. How long have you been practicing?
 - ii. If I may ask how old are you?
 - iii. What sort of environment do you see most of your patients?
 - iv. Roughly speaking how many patient do you see in an average week?
 - v. Please tell me about the types of patients you see?
 - vi. What kind of approaches do you favour?
 1. Are there any other approaches you use?

Great that gives me the background. Thinking about your recent clinical work, we are particularly interested in patient's responses to treatment.

2. Tell me about the types of common reactions to treatment that you see on a regular basis.
 - a. Considering one of these reactions, please would you tell about a particular case which was an example of this.
 - i. What happened?
 - ii. Why did it happen?
 - b. I'm interested in understanding what makes reactions acceptable or not acceptable – what are your views
 - c. Please tell me briefly about some of clinical examples of this from your own practice.
- What did you say, what did you do, what did the patient say and how did they react?
 - d. Can you summarise for me what makes these kinds of events acceptable or unacceptable?
 - e. Continuing to think about these common treatment reactions - What are your views around the issue of patient consent in this area? (anchored to common treatment reactions)
 - f. Please give me an example of a typical way in which you might approach this with a patient?
 - g. *Follow up probe: you mentioned XXXX what about benefits of treatment, what about alternative treatments?*
 - h. What are your views about the code of practice and its expectations in this area?
3. I'd like to move onto serious treatment reactions.
 - a. Have any of your patients ever experienced a serious treatment reaction?

If no go to 4.

**Study Title: Clinical Risk, Osteopathy and Management Study (CROaM)
Practitioner Interview Guide field version.**

If yes: (select one if many)

- b. How long ago was this?
 - c. What happened?
 - d. Why did it happen?
 - e. How did your patient make sense of the situation?
 - i. Were there differences between your understanding and the patients understanding? Can you tell me about these?
 - f. Can you tell me about any ways in which this experience has changed your clinical practice?
 - g. Is there anything that you avoid doing to minimize the risk of these things happening?
 - h. Can I turn the question around now please tell me the types of things you DO to minimize the risk of these kinds of things happening to patients?
 - i. What are the circumstances that you might mention these serious reactions to patients?
 - ii. So that I can really get a clear understanding please give me an example of the words or phrases that you might say to a patient in these circumstances.
 - 1. Alternative: Imagine that I was sitting in with you what would be the types of things I'd hear you say to a patient?
4. Please tell me the characteristics that you think might make up a serious treatment reaction after osteopathy?
- a. Is there anything that you avoid doing to minimize the risk of these things happening?
 - b. Can I turn the question around now please tell me the types of things you DO to minimize the risk of these kinds of things happening to patients?
 - i. What are the circumstances that you might mention these serious reactions to patients?
 - ii. So that I can really get a clear understanding please give me an example of the words or phrases that you might say to a patient in these circumstances.
 - 1. Alternative: Imagine that I was sitting in with you what would be the types of things I'd hear you say to a patient?

Thank you very much indeed for your time today and for sharing your experiences. Do you feel that our discussion has covered the important issues in this area?

Have we missed anything? Do you have any advice for us, as we do this research?

The next stage for us is to transcribe and analyse the interviews and to draw out themes from the information you and others have given us. These sort of interviews give us richer more detailed information than we can capture with a questionnaire.

Would you like us to send you the transcript of this interview?

How would you prefer this - As a paper copy or by e-mail? (interviewer notes e-mail address)

Thanks again for your time - this concludes the interview.

End

7.7 Patient Interview guide

**Study Title: Clinical Risk, Osteopathy and Management Study (CROaM)
Patient Interview Guide field version.**

Introduction:

My name is XXXXXX and I am from the British School of Osteopathy and one of the research team on the CROaM study. (I'm phoning to speak to XXXX to carry out an interview that we have arranged for this time.) IF NOT CONVENIENT – RECALL or REARRANGE.

Thank you very much for participating in the CROaM study and agreeing to be interviewed. We plan to record the interview, before we turn on the recording equipment. I'm just going to go through one or two points with you to make sure that you are happy and understand the context and purpose of the interview. If I sound a bit mechanical at times its because I need to use my script at times to make sure that interview questions are broadly similar across different people.

Just to introduce myself a little - I am an osteopath by background but here today in the role of research interviewer. I am very interested in your views and experiences of osteopathic treatment, but as a researcher, I am unable to offer any specific advice about your treatment or future care.

May we start by checking whether you have any questions about the study and that you are happy with the consent form that you have signed and returned to us.

Some of the questions will be about treatment you have experienced. I do not know the identity of the practice or the osteopath, who treated you and it would help me if you avoided using the personal names or identifying features of the practice you attended. However if these are mentioned we will change any such features when transcribing the interview.

We are interested in your personal experiences as a patient and in particular to learn how you felt after your treatment and how your osteopath communicated with you about the treatment they were offering. We are interested in building our understanding from the survey that you kindly completed.

If there are any questions you are uncomfortable with, or would rather not answer, simply say so, and I will go on to the next question. If you decide you no longer wish to be interviewed, please tell me so, and I will simply end the interview. You do not have to give an explanation for this decision. At this stage do you have any questions?

I will begin recording.

Study Title: Clinical Risk, Osteopathy and Management Study (CROaM)
Patient Interview Guide field version.

1. 'In order to find out a little more about you and to provide some background, I'd like to start with a few questions about you and find out about how you came to visit an osteopath so

 - a. May I ask how old you are
 - b. What is your work situation – what do you do for a living?
 - c. How often have you used osteopathy in the past?
 - d.and over what time period?
 - e. Tell me about some of the things your osteopath does whilst treating you.
 - f. Please describe to me the reasons why you have visited an osteopath in the last 6 months.

2. Great that gives me a background. We are particularly interested to find out about what people have experienced after they have been treated both good and not so good things.
 - a. Please would you describe to me in general concerning the treatments that you have had over the last six months how your main symptoms or pain have responded to osteopathic treatment?
 - b. Can you give me more detail by thinking of a specific example – think about a consultation when you had a specific reaction and talk me through your experience of what happened?
 - i. How do you feel straight after treatment,
 - ii. Over the next couple of days
 - c.
 1. Follow up probe to explore negative experience:
 - iii. Was your reaction a surprise?
 - iv. Tell me about that – a. why wasn't it a surprise b. what was surprising?

IF NO NEGATIVE REPONSES TO TREATMENT GO TO D

- c. Why do you think that happened.... What do you think is going on when things like this happen? How did you make sense of what happened?
 - i. What we are interested in how people make sense of what they experienced and felt after treatment.
- d. Thank you for telling me about the main problem. I'd like to move on to other things that you might have felt after treatment.
 - i. Did you have any other responses to your treatment/can you tell me about anything else you felt after treatment

Study Title: Clinical Risk, Osteopathy and Management Study (CROaM)
Patient Interview Guide field version.

1. IF NO: Just to check some people have said that they have felt tired or maybe had a headache after treatment have you had anything like this or other responses?
2. IF YES: Please tell me about what happened
 - a. Why do you think that happened.... What do you think is going on when things like this happen? How did you make sense of what happened?

IF NO RESPONSE IN TERMS OF REACTION TO TREATMENT GO TO 4.

3. I'm trying to figure out how people consider these types of reactions. Some people use words like side effects, or complications.. Some people don't think about these things in those terms
 - a. What sort of words would you use to describe these things?
 - b. I'm interested in understanding what makes reactions to osteopathic treatment acceptable or not acceptable – what are your views
 - i. NEED TO PROBE IF ONE IS MISSING
 - c. How do you weigh up the risks and benefits of treatment?
4. Thank you for telling me about your views and experiences of treatment. I'd like to move onto to the types of information that your osteopath gave you and what information you think is important.
Note alternative probes for those in longer term treatment – what about if you were visiting a new osteopath, what about if osteopath wanted to use a new technique?
 - i. What do you remember being told by your osteopath about the outcome or benefits of your treatment?
 1. Is it important that your osteopath tells you about outcomes and benefits of treatment?
 2. Please tell me why?
 - ii. What do you remember being told by your osteopath about other possible treatments or having no treatment? I.e. other treatment options or alternatives?
 1. Is it important that your osteopath tells you about other possible treatments or having no treatment?
 2. Please tell me why?
 - iii. What do you remember being told by your osteopath about the potential risks of treatment?
 1. Is it important that your osteopath tells you about the potential risks of treatment?
 2. Please tell me why?
 - iv. What do you remember being told by your osteopath about their reasons for examining you?
 1. Is it important that your osteopath tells you about their reasons for examining you?

**Study Title: Clinical Risk, Osteopathy and Management Study (CROaM)
Patient Interview Guide field version.**

2. Please tell me why?

We had a range of comments about osteopaths asking their patients permission to treat. Some people said that it was important whilst others it wasn't needed.

b. What are your views in this area?

c. In what ways should this be done – when, at what stage? (PROMPT check out issue with ongoing treatment)

We also had a range of comments about osteopaths asking their patients permission to carry out an examination. Some people said that it was important whilst others it wasn't needed.

d. What are your views in this area?

e. In what ways should this be done – when, at what stage? (PROMPT check out issue with ongoing treatment)

Thank you very much indeed for your time today and for sharing your experiences.

Do you feel that our discussion has covered the issues which are important to you?

Have we missed anything?

TURN OFF RECORDING

Thank you. Do you have any questions at this stage? This interview will now be transcribed. Would you like us to send a transcript of this to you, so you may get a chance to see what you said and comment on it. IF yes, How would you prefer this - As a paper copy or by e-mail? (interviewer notes e-mail address). It might take a few weeks for us to get it transcribed. When we send it to you I think the cover letter says that if we don't hear from you in two weeks we will assume that you are happy with the transcription. Is that OK?

End

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