Clinical Risk Osteopathy and Management Summary Report

S. Vogel[1], T. Mars[1], S. Keeping[1], T. Barton[1], N. Marlin[2], R. Froud[2], S. Eldridge[2], M. Underwood[3], T. Pincus[4]

The Research Centre

The British School of Osteopathy[1] in collaboration with Barts and the London[2], Warwick Medical School[3], Royal Holloway[4]

This report summarises the CROaM study and has been amended post peer review. The scientific report is currently being amended to address reviewers comments.

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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.

Executive Summary

0.1 Background and aims

The Clinical Risk Osteopathy and Management (CROaM) study is one of four pieces of research commissioned by the General Osteopathic Council exploring adverse events, treatment reactions and related topics. The overall purpose of the study was to document reported treatment reactions and adverse events; to provide a description of UK osteopaths' risk assessment and risk management; to describe and model osteopaths' and patients' perceptions and beliefs about adverse events and treatment reactions. In addition, using short-term follow-up of patient outcomes, to provide a narrative evaluation of the comparative risks and benefits of osteopathic treatment.

The value and need for this information arose from recent debate in the medical, scientific, lay and osteopathic press, specifically concerning the cost benefit and risk profile within osteopathy. More importantly, there was little existing information about adverse events associated with osteopathic treatment. Osteopaths also expressed concerns about adherence to elements of their Code of Practice in this area; these largely related to their ability to manage risk and give patients accurate and relevant information for the purposes of receiving consent from patients.

The aims of the research were to:

- determine the frequency and impact of treatment reactions and adverse events;
- provide information about risk management and assessment from patients' and osteopaths' perspectives;
- provide a framework to interpret adverse events from the perspective of patients and osteopaths;
- provide a baseline for guidance in this area, grounded in the available evidence, and provide a risk versus benefit context for osteopathic practice.

0.2 Methods

A mixed methods approach was used. 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. The design employed does not allow conclusions to be made about causal relationships between osteopathic treatment, positive patient outcomes and adverse events.

0.3 Findings

1,082 (27.8%) osteopaths completed the practitioner survey. Interviews took place with 24 osteopaths. 2,057 patients, recruited from 212 osteopaths, completed baseline questionnaires. 1,387 (77%) patients returned six week follow up questionnaires. Interviews took place with 19 patients.

- The majority of osteopathic patients are seen in private dedicated clinical settings. On average osteopaths see 33 patients a week. Patients have mostly back, neck and shoulder problems, with variable duration from acute to chronic.
- The most commonly used techniques are soft tissue and joint articulation. Near to 43% of patients received HVT, most commonly to the thoracic spine (32%) and lumbar spine (18%) and less frequently to the neck (13%). Visceral techniques are not commonly used. Adjunctive techniques are used by nearly 50% of osteopaths, but only on a small proportion of patients.
- Fifty percent of osteopaths describe their main practice setting as being where they are not able to discuss patients with other professionals.
- On average patients' health status is good, although complaints of pain are common. Just over half of patients report common comorbidities. The majority of which are musculoskeletal.
- Medication usage is high and analgesic medication usage was reported by over 70% of patients at baseline.

- Osteopaths express uncertainty about predicting the likely occurrence of adverse events related to HVT, although they are more confident about predicting the benefits. All the major risk factors associated with vertebro basilar stroke were rated as important by osteopaths in the context of treating neck pain.

- Osteopaths report high levels of receiving consent for new patients and the introduction of new techniques. However, receiving consent from returning patients and for repeated techniques is low in over a third of osteopaths. Osteopaths expressed concern over discussions involving adverse events particularly with new patients regarding treating the cervical spine. There were also differences between the reported frequency that osteopaths described gaining consent with the patients reported experience of being asked permission/consent for examinations and treatments. Patients reported lower levels of consent than did osteopaths. Overall, a small proportion of patients reported that they had received information about risks (36%) and alternative or no treatment options from their osteopaths (38%). The Code of Practice concerning consent for all patients throughout the process of care is at odds with some current practice and to some extent with what patients expect. For patients, consent was perceived to be mediated by the experience of care and their choice to attend treatment. Patients tended to understand risk as a lack of benefit rather than in terms of hazards and harms.

- Improvement of pain/symptoms was reported by the majority of patients, with around half of patients achieving at least a 30% decrease in pain/symptoms by day two post treatment. Those with widespread troublesome pain/symptoms were least likely to improve. New patients and those returning with a new episode of pain/symptoms improved most. Patients rated their global improvement and satisfaction highly.

- Immediate increase in pain/symptom intensity was the most frequent reaction post treatment and occurred in around 20% of patients. These treatment reactions were perceived by patients at interview as acceptable and appeared to be well managed. Osteopaths and patients perceived forewarning of likely increases in pain as helpful in their management.

- To reduce the possible bias due to osteopaths selecting patients known to have good outcomes we carried out a sensitivity analysis on new patients versus returning patients. Only 6 out of 19 comparisons showed significant differences between the two groups. These differences were small in magnitude and involved small numbers of patients and conclude that the threat of bias is small.

- Comparisons between those that received HVT and those that did not showed that for most outcomes there was no link between HVT and outcome.
- Four percent of patients reported temporary incapacity or disability that they attributed to their osteopathic treatment. But only 2 of 10 of these patients described experiences characteristic of a major adverse event at interview. There were no reports of life-threatening events, referral to hospital or other permanent disability in our patient sample.
- Around 12% of osteopaths reported patients experiencing a major adverse event over the span of their career. Four percent of osteopaths reported such events within the past twelve months. The most conservative estimate of the rate of major adverse events derived from this data was 1 in 36,000. However the margins of error around this estimate are unknown. It may be more useful to consider the evidence from this study as suggesting that major events are rare, but do occur and that osteopathy can be considered a low risk intervention.
- The majority of osteopaths favoured the establishment of an adverse events register.

0.4 Implications for practice and policy

- There are opportunities for continuing educational development and pre-registration education to be informed by research that describes the characteristics of UK osteopathic practice and the nature of the patients presenting to osteopaths in the UK. For example, there may be opportunities to enhance levels of knowledge with respect to common co-morbidities and pathologies associated with the age range of patients that frequently use osteopathic services.
- 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 with respect to techniques used infrequently. Clinical governance issues, particularly pertaining to private practice and osteopaths who may be isolated in their work, require further exploration. There are opportunities for structured peer review and appraisal.
- Some risk factors that are necessary or sufficient to produce stroke related to the neck 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 osteopaths.

- Clinical education and professional development should focus on the history and clinical examination of patients to assess suitability for treatment 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 when presenting for treatment. Osteopaths should be aware, that whilst serious events are rare, that they do occur.

- There is a need to develop new guidance and educational materials for osteopaths concerning information giving and consent. These should draw on the results of the current study and related work and include recommendations about consent related processes 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.

- 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 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, the design of the current study does not enable clear conclusions about the effectiveness of osteopathic treatment. There is a need for further research to evaluate the effectiveness of osteopathic treatment using randomised trial methodology and to explore further the mechanisms underlying the apparent effectiveness of osteopathic treatment. Our study failed to identify technique-related predictors of positive outcomes, but instead supports a mixed package of osteopathic care, which values 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 the results of the current study to establish a reference standard for short-term outcomes against which osteopaths in practice could audit and benchmark their own work and provide a focus for continuing professional development.

- Several management strategies have been identified that appear to be helpful in managing temporary increases in symptoms/pain following treatment. These include pre-warning, explaining the nature of reactions and using practitioners' therapeutic alliance with patients effectively. This information should be given to all patients regardless of the site of the main complaint or the nature of the intervention planned by the osteopath. 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 osteopaths to explore these with patients and to agree a mutually consistent explanation to reduce uncertainty. It is anticipated that a wider understanding of the nature and prevalence of adverse events in osteopathy and implementation of common positive management strategies would enable osteopaths 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. 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.

- Low-quality evidence supporting the effectiveness of manipulation has been reported for the treatment of neck pain. Good quality evidence including a systematic review is available for osteopathic treatment of back pain, but more limited in other areas. 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.

- 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 further information for patients on the rare risks of post or during treatment adverse events. These include radicular pain, central nervous system symptoms and increased non specific musculoskeletal pain.

- 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 osteopaths, many of whom currently work in settings where they do not discuss their clinical work with others.

- Should a reporting and learning 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. A concerted and effective communication strategy to encourage up

take amongst osteopaths in practice would need to accompany implementation. Given the higher success and use of a such systems in a chiropractic 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 osteopathic profession at large.

Final Summary Report

0.1 Introduction

This report summarises the methods, key findings, implications and limitations of a research study commissioned by the General Osteopathic Council (GOsC). By necessity, this short report abstracts only key points from the main scientific report, where the findings and implications are described in full.

The overall purpose of the study was to document reported treatment reactions and adverse events; to provide a description of UK osteopaths' risk assessment and risk management; to describe and model osteopaths' and patients' perceptions and beliefs about adverse events and treatment reactions. In addition, using short-term follow-up of patient outcomes, to provide a narrative evaluation of the comparative risks and benefits of osteopathic treatment.

The value and need for this information arose from recent debate in the medical, scientific, lay and osteopathic press, specifically concerning the benefit and risk profile of osteopathic treatment. Whilst much of this debate has focussed on the association between manipulation of the neck and stroke, 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. Importantly, there was little existing information about adverse events and treatment reactions associated with osteopathic treatment. Osteopaths have expressed concerns about adherence to elements of their Code of Practice in this area. These largely related to their ability to manage risk and give patients accurate and relevant information for the purposes of receiving consent from patients. The wider context for the study includes the further development of evidence informed osteopathy and the need to demonstrate effective treatment, which appropriately recognises the limits and risks of osteopathic care.

Our aims were to:

- determine the frequency and impact of treatment reactions and adverse events;

- provide information about risk management and assessment from patients' and osteopaths' perspectives;
- provide a framework to interpret adverse events from the perspective of patients and osteopaths;
- provide a baseline for guidance in this area, grounded in the available evidence, and provide a risk versus benefit context for osteopathic practice.

Adverse events were conceptualised throughout the study as untoward occurances that occured in the context of osteopathic care, but not necessarily having a causal relationhip with treatment.

0.2 Methods

A mixed methods approach was used that included both quantitative and qualitative methods. Specifically, it included a cross-sectional survey to all UK practising osteopaths, followed by in depth interviews with a selected number of respondents. Patients seeking osteopathic treatment were recruited for an observational cohort survey study which was also followed by in-depth patient interviews with selected respondents. These patients were recruited from osteopaths responding to our initial survey. The patient survey included measures pre-treatment, one day post-treatment, two days post-treatment and at six weeks. This approach was adopted to enable investigation of a large numbers of patients and osteopaths. The inclusion of follow-up data from patients provided information that enabled analysis of patient outcomes. The in depth interviews allowed an exploration of issues covered superficially in the survey and facilitated triangulation of the survey data to confirm, refute or provide additional insights. Using quantitative and qualitative approaches enabled an informed purposive selection and recruitment of subjects for interview.

Survey instruments and interview schedules were developed by the research team and drew on existing measures and relevant literature where possible. All instruments were developed with the use of user consultations and pilot phases for both the patient and osteopath surveys and enabled data collection and entry processes to be tested.

A wide range of analytic methods were used to summarise and model the data. These included descriptive statistics and multiple regression modelling of quantitative data and content and thematic analyses of qualitative data.

0.3 Findings

Response rates and key findings are summarised by topic area followed by implications for practice and policy which are identified by bullet point notation.

0.3.1 Response rates

The total number of osteopaths available for the postal sample was 3,896. Table 1 shows the numbers of questionnaires sent out in the pilot and main phase of the osteopath survey and their associated response rates.

Table 1: Response rates to the osteopath survey

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

The osteopath survey results are based on responses from 1,082 osteopaths (response rate = 28%). UK osteopaths were well represented in the sample. There were no differences in age or time since qualification between responders and non responders, although female osteopaths may have been slightly over represented. Figure 1 summarises the recruitment and response rates in the patient survey.

A total of 63 osteopaths were invited for interview. A range of characteristics were used to select osteopaths for interview, including osteopaths who had reported that they had experience of a major adverse event occurring in their practice. Thirty osteopaths agreed to be interviewed and 24 interviews took place.

Seventy-four patients who reported an increase in their pain/symptoms or reported some temporary disability of incapacity that they attributed to their osteopathic treatment were invited for interview. Nineteen patients agreed and were interviewed.

0.3.2 Characteristics of osteopathic practice

The majority of patients are seen in dedicated private clinic settings (80%) and returning patients constitute the majority of osteopaths' patient lists (87%). On average, osteopaths see around 33 patients per week and the average appointment time was reported as 50 minutes for new patients and 30 minutes for follow-up appointments. Around half of osteopaths (52%) reported

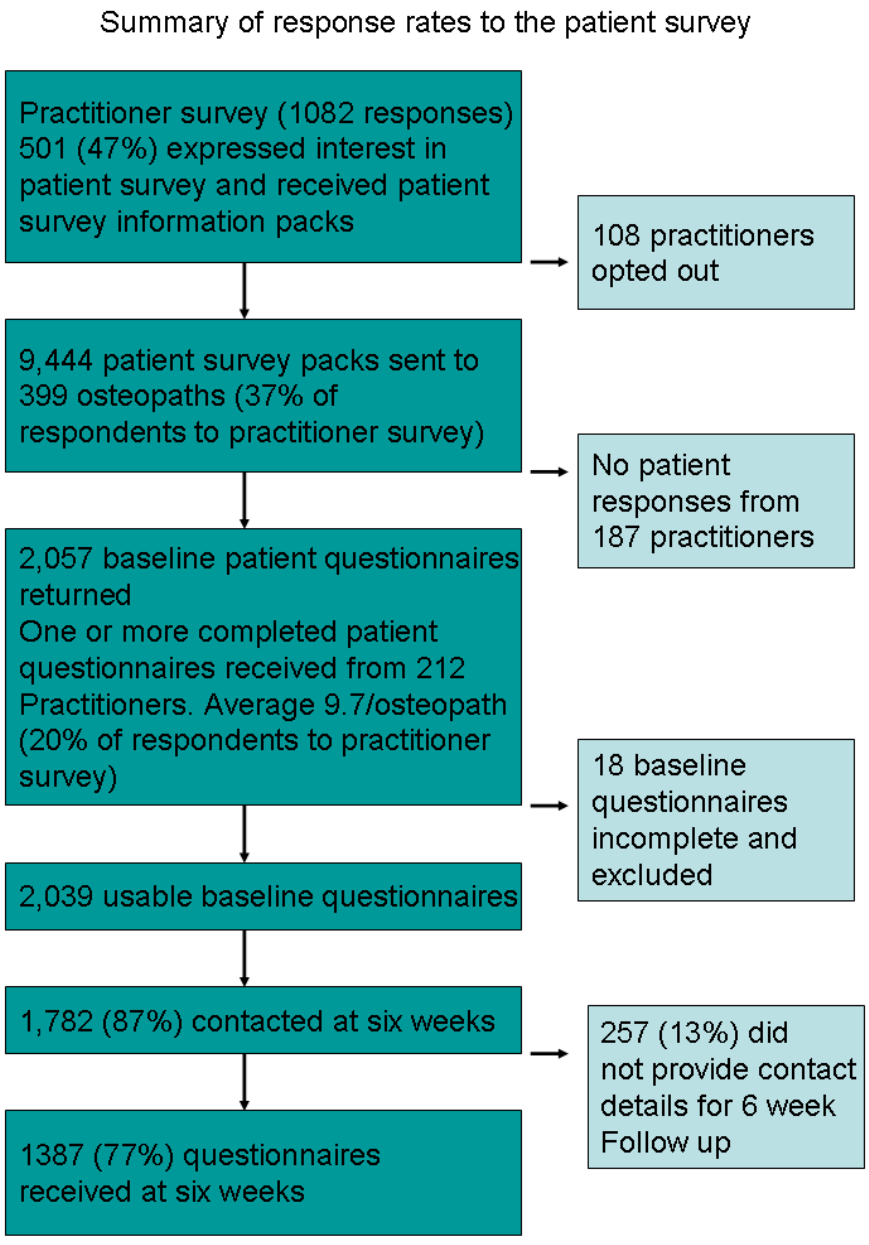

Figure 1: Summary of recruitment and response rates for the patient survey -

that their main practice setting was in an environment where discussion with other professionals was not available.

There is considerable variation in the extent of use of various osteopathic techniques. While soft tissue and joint articulation were reported to be used on 90% of patients, on average cranial and visceral techniques were only used on 10% of patients. HVT was most often used on the thoracic spine (50%) and considerably less when treating the cervical spine (20%). The patient survey broadly corroborated these estimates in reference to articulatory techniques of joints, soft tissue massage and HVT, but functional and cranial techniques were more highly reported (25% and 31% respectively). It also corroborated the use of HVT on thoracic spine being the most frequently manipulated area, while lumbar and cervical spine manipulation was considerably lower (18% and 14% respectively). Significant predictors of the use of HVT indicated that it was more often used by experienced male osteopaths, those who held strong beliefs about the predictability and benefit of HVT, lower perception of various risks and shorter consultation times. However, although significant, the combination of these factors only explained 10% of the use of HVT. Adjunctive techniques were commonly reported as used by 44% of osteopaths, but mostly only on a small proportion of their patients. These were most often dry needling acupuncture, electrotherapy and nutrition therapy.

The patient survey generated 2,039 responses, of which 1,387 (77%) returned follow-up questionnaires at six weeks. The mean age of patients was 56 years old and 65% of respondents were female. The majority of patients were employed (65%) and education levels were equally spread between those who stopped education at 16 years of age and those who continued their education. Common comorbidities were prevalent (56%) and 43% were musculoskeletal, while 27% of respondents reported experiencing cold or flu like symptoms in the two weeks prior to consultation. Medication usage relating to common comorbidities was also high (62%). The use of analgesia in the week prior to consultation was reported by 71% of patients, and 38% reported the use of anti-inflammatory medication. Health status was generally good and only 7% were unable to work due to current symptoms. Despite this, half the patients reported problems performing usual activities and 77% reported moderate pain or discomfort. The most common area of patients' main complaint was the low back region (41%) followed by the neck region (17%) and the shoulders (13%). Duration of pain was distributed fairly evenly between acute, subacute and chronic durations. The majority of patients were in ongoing care (72%) and for these the average number of treatment was 5 at baseline.

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.

- These findings provide opportunities for continuing educational development and pre-registration education to be further informed by the results that describe the characteristics of UK osteopathic practice and the nature of the patients presenting to osteopaths in the UK. For example, there may be opportunities to enhance levels of knowledge with respect to common comorbidities and pathologies associated with the age range of patients that frequently use osteopathic services.

- 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 in the context of infrequently used osteopathic techniques and adjunctive approaches. Clinical governance issues, particularly pertaining to private practice and osteopaths who may be isolated in their work, require further exploration. There are opportunities for structured peer review and appraisal.

0.3.3 Perception of risk and risk management

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. However, osteopaths were responding to a list comprised of comorbidities, characteristics of patients and medication consumption. There is an emerging literature arguing that manual therapy should apply more whole systems approaches in relation to anatomy and biomechanics to improve awareness of vascular risk factors, but this argument has not been implemented or tested in manual therapists. Risk assessment for the cervical spine in the context of osteopathic treatment remains challenging for osteopaths, particularly in the context of rare conditions associated with stroke. Clinical guidance is available to aid osteopaths in this area of practice.

- 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 osteopaths.

- Clinical education and professional development should focus on the history and clinical examination of patients when assessing risk of treating the neck 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 when presenting for treatment.

0.3.4 Consent and information exchange

There are discrepancies between the expectations of osteopaths' Code of Practice and the reported behaviour of osteopaths. Osteopaths report high levels of obtaining consent for new patients and the introduction of new techniques. However, obtaining consent from returning patients and for repeated techniques is low in over a third of osteopaths. There were also differences between the reported frequency that osteopaths described gaining consent with the patients reported experience of being asked permission/consent for examinations and treatments. A small minority of osteopaths report not engaging in consent-related activity. Patients reported lower levels of consent than did osteopaths. The Standards of Practice concerning consent for all patients throughout the process of care is not reflected in some current practice and to some extent with what patients expect.

The focus of information-giving is around the nature of osteopathy and its potential benefits, as opposed to risk and alternative and no treatment options. Osteopaths find it most challenging talking to new patients about unpleasant reactions associated with treating the neck and there is uncertainty about the nature of risks and the extent of information that should be given to patients. Some osteopaths expressed concern that giving information about serious risks may cause stress and prevent patients from gaining the best outcomes. A significant number of patients do 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 than 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. Chiropractors have similar concerns to the osteopaths in our study about giving information about serious adverse events. Osteopaths report a need for more information about the nature of risk associated with treatment.

There are tensions between the standard expected of osteopaths as articulated in the Code of Practice, current practice and perceptions of both patients and osteopaths. This study highlights the range of views about the extent of information required for informed consent to be given by a patient. Our osteopaths 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. This may have particular relevance to UK osteopathy, where osteopaths 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 osteopaths by their perception that such information may cause more harm than good in itself and that the primary focus for osteopaths 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 Osteopathic Practice Standards are unlikely to address these tensions although there is a clearer expectation to assess the information needs of the patient.

- There is a need to develop new guidance and educational materials for osteopaths concerning information-giving and consent. These should draw on the results of the current study and related work and include recommendations about consent-related processes 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.

0.3.5 Patient outcomes

Patients reported improvement in pain/symptom intensity and this was highest in new patients and those presenting with a new episode. Fifty five percent of all patients achieved at least a 30% clinically significant decrease in the current intensity of their main complaint by day two. Higher pain/symptom intensity and troublesomeness levels at baseline were associated with improvement at six weeks in health status and pain/symptom 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. 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.

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 however, 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 some other musculoskeletal conditions.

Other observational studies concord with the findings, suggesting that new episodes of symptoms with lower levels of chronicity and more localised pain improve most. As in the current study, high levels of satisfaction have been reported for osteopathy and other fields of manual therapy. Similar to the results of the current study, other qualitative studies suggest 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 osteopaths.

- 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 osteopathic treatment. 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 explore further 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 values 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 osteopaths to initiate quality improvement activities and to provide a focus for continuing professional development.

0.3.6 Common treatment reactions and adverse events

Immediate increase in pain/symptom intensity is the most frequent reaction post-treatment, with between 10% and 20% of patients experiencing this at day one after treatment. Nearly 42% of those reporting an initial increase in pain/symptoms went on to make clinically significant reductions at six week compared to their base line status. A large majority of patients who experience an increase in their pain/symptom intensity after treatment had low baseline scores. Low baseline pain/symptom intensity and increasing number of sites of pain at baseline are associated with increased pain/symptom intensity after treatment. Reported increases in pain/symptom troublesomeness at other areas of the body are less prevalent and increases in non-musculoskeletal symptoms occur in a small proportion of patients. Our sensitivity analysis comparing new patients with returning patients showed few significant differences between the groups based on small numbers of patients. This suggests that the threat of osteopaths selecting patients for inclusion in the study that they knew to have good outcomes was small. Comparisons between patients who received HVT and those that did not suggest that increased intensity of symptoms/pain and the appearance of new symptoms was not related to HVT.

Interview data suggests that minor adverse events and treatment reactions are largely expected and accepted by patients and osteopaths. 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. Treatment reactions appear to be managed well within the context of a patient-centred model of care. Unacceptable reactions and adverse events 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 minor adverse events and treatment reactions.

Our study is in accord with the literature in terms of the characteristics of minor adverse events and their resolution. Most of the available literature described patients' experience of chiropractic care. The discrepancy between the relatively low numbers of patients reporting adverse events in our study and those reported in the other studies 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 the length of 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.

- There is an opportunity of increasing the awareness amongst the osteopathic profession of the value of management strategies that appear to be helpful in managing treatment reactions and minor adverse events. These include pre-warning, explaining the nature of reactions and using their therapeutic alliance with patients effectively. This information should be given to all patients regardless of the site of the main complaint or the nature of the intervention planned by the osteopath. 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 osteopaths 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 osteopaths 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. 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 risk to patients.

0.3.7 Serious treatment reactions and adverse events

Fifty-six patients (4%) reported experiencing temporary incapacity or disability that they attributed to their osteopathic treatment, of which 10 were interviewed. At interview 2 patients described experiences that were characteristic of a serious adverse event. (One patient reported developing peripheral neurological symptoms post-treatment and a failure to diagnose and explain these radicular symptoms and the other reported a permanent aggravation of non-specific musculoskeletal symptoms). 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% of osteopaths over the span of their career. In the preceding year 4% of osteopaths reported a serious adverse event. The most conservative estimate of the rate of serious adverse events was 1 in 36,079 treatments. However the margins of error around this estimate are unknown. It may be more useful to consider the evidence from this study as suggesting that major events are rare, but do occur and that osteopathy can be considered a low risk intervention. A taxonomy was developed for major adverse events as described by osteopaths from the survey data. The descriptive categories included: peripheral neurological symptoms, central neurological symptoms, non-specific musculoskeletal symptoms, symptoms related to underlying pathology, and fractures. Peripheral neurological symptoms appear the most frequently reported serious adverse event.

The occurrence of a serious adverse event was stressful for osteopaths 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.

Osteopaths expressed the belief that serious treatment reactions were rare. Osteopaths reported that they considered that there was a paucity of robust information available to them about 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. Osteopaths described carrying out patient-centred risk/benefit assessments for each individual and that this informed the osteopaths' selection of technique and treatment dosage. This was seen as a principal factor mediating the content and form of the osteopath-patient information sharing about risk.

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 vertebro-arterial 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 they explain in terms of patients presenting for treatment with symptoms associated with cervical artery dissection. The limitations of our study prohibit establishing causal factors that are implicated in serious adverse events in relation to osteopathic treatment. However, the data suggests that whilst adverse events do occur, these are rare.

- 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. This argument is based on manipulation providing equal or no additional benefit in terms of pain reduction and increased function. Low-quality evidence supporting the effectiveness of manipulation has been reported. 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.

- 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 further information for patients on the rare 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 osteopaths' concerns over the possible adverse effects of offering stress inducing information and the impact this may have on the patient-practitioner alliance.

0.3.8 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 higher quality information to use in the process of consent, to be useful for CPD purposes and to enhance 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 osteopaths 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. Some 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.

- 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 evaluate 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 osteopaths, many of whom currently work in settings where they do not discuss their clinical work with others.

- Establishing an adverse events register/reporting and learning system 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 in chiropractic, 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.

0.4 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 osteopaths' 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 osteopaths 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 osteopath 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 1 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 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. In addition, in reference to minor to moderate treatment reactions the qualitative approach used in this study allowed us to investigate patients' and osteopaths' 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 survey methods without the use of another group of patients for comparison. This limits 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 osteopaths, whilst similar to other studies, may have represented 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 osteopaths 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 osteopaths 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. Whilst our sensitivity analysis comparing new patients with returning patients gives us some confidence, recruitment bias is still a potential source of bias. 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 osteopaths' 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 osteopaths 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, many of our patients included as having a significant increase in pain/symptom intensity were those with low presenting baseline scores where a 30% increase in pain/symptoms may not be clinically meaningful. However, this was explored through sensitivity analyses using absolute changes of two points on the scale and using improved stayed the same and deteriorated categories. 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.