

The Standardised Data Collection Project

Standardised data collection within osteopathic practice in the UK: development and first use of a tool to profile osteopathic care in 2009

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June, 2010



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Acknowledgements

We are grateful to the General Osteopathic Council for funding the National Council for Osteopathic Research to undertake this project.

We are grateful to the many osteopaths who gave their time to participate in the development of the standardised data collection tool and the collection of data for this project, and to the NCOR members who have fed into this proposal at various stages of its development. We are grateful to them for their time and comments. We are indebted to the members of the Steering Group including Michael Watson, Bryan McIlwraith, Jorge Esteves and Kelston Chorley for their time and expertise in ensuring the project was valid and fit for purpose.

Finally, we are grateful to those patients who agreed to their anonymised data being collected for this project.

EXECUTIVE SUMMARY

INTRODUCTION

This report describes the development of a Standardised Data Collection (SDC) tool for use in osteopathic practice. As part of the project development, the SDC tool was piloted in United Kingdom (UK) osteopathic practices for three months between April and July, 2009; the project report presents also the data collected through this piloting exercise. Finally, the report offers recommendations for further use and development of the tool, future data collection topics, and areas of osteopathic practise likely to benefit from future investigation.

It should be emphasised that the data collected is **pilot data**. This information will provide background information concerning osteopathic activity in clinical practice. However, it is <u>not</u> appropriate to be used in isolation to support advertising claims advocating efficacy of treatment approaches.

BACKGROUND TO THE STUDY

Quality initiatives linked to clinical governance have been introduced by a number of healthcare professions; the creation of national datasets has been linked to such initiatives. Datasets help to identify key information concerning those patients being managed including their symptoms, what treatment is offered and what supporting advice and information is provided. Osteopathy is a developing and maturing profession, and the development of a means to collect anonymised osteopathic practice data on a national scale was viewed as timely to promote further professional development and promote the maintenance of high standards of practice.

AIMS OF THE PROJECT

- The primary aim of this project was the development of a standardised data collection tool to enable osteopaths to collect patient data, and to pilot the data collection tool at a national level.
- A secondary aim of this project was to promote the involvement of UK osteopaths in participatory data collection. Data collection will be mandatory in the NHS from 2012. The project established a network of regional research hubs to engage and train osteopaths in clinical data collection.

SDC TOOL DEVELOPMENT PROCESS

i. Searching the literature

A search of the literature was carried out to identify initiatives undertaken by other professions, nationally and internationally, to develop standardised data collection tools.

The literature search included PubMed, subscription healthcare databases (including AMED, CINAHL, Index to Theses, and PsycInfo), specific manual therapy databases (OSTMED, PEDro and MANTIS), and hard copy print media. Author searches were conducted and personal contacts were utilised. All searches were taken from the inception of the database to May, 2010 and no limits were applied.

The literature showed the primary motivations for development of standardised data collection tools included:

- Profiling professional activities including clinical practice
- Protecting the scope of practise in the face of increasing regulation
- Increasing professional visibility
- Raising standards of care through focussing on management practices and outcomes

ii. SDC tool development process

A nominal group technique was used to develop the standardised data collection tool to generate ownership and to produce a national consensus. The network of research hubs acted as the nominal group to identify topics for inclusion in the SDC tool.

Examples of existing standardised data collection tools were examined but were regarded as unsuitable for osteopathic practice. Hub members focussed on a number of key topics areas for data collection. These included:

- Patient demographics
- Symptom profiles
- Osteopathic patient management including techniques and other management strategies
- Outcomes of treatment
- Financial implications of care

A three stage testing process was undertaken. This involved:

- Two separate content validity testing stages involving members of the research hubs. This
 was to identify any omissions or superfluous criteria or topic areas.
- A third pilot involving non-hub members to identify any regional differences
- Obtaining feedback to address the practical issues associated with data collection in practice

The final version of the tool prepared for a national pilot was comprised of 5 sections. These included:

- A patient-completed section
- The initial presentation of symptoms
- The management of the patient at their first appointment
- Management of the patient at their second and subsequent treatment(s)
- Final outcome(s) of care

iii. Piloting the SDC tool

Recruitment for the national pilot was voluntary and undertaken though advertisement in print journals and via the email networks of the professional association and regulator. A total of 342 practitioners (9.4% of the UK profession) participated, contributing 1630 completed patient datasets.

Limitations of the project and pilot data

The primary aim of the project was to create and test a standardised data collection tool for osteopathy. A small number of issues were highlighted during the project

- Analysis of the data collected from the national pilot exercise highlighted areas where the
 tool performed well, but identified others where questions used in the tool need refinement
 to improve clarity and reduce the potential for ambiguity.
- Participants in the national pilot were volunteers. It would be preferable, in the future, to generate a dataset through random sampling of the osteopathic profession.
- The use of a validated and nationally recognised outcome measure (depending on the physical or clinical area being assessed) to accompany the SDC would be beneficial.
- In the future, outcome data must be patient completed, and a mechanism to allow this to be undertaken away from osteopathic practices would ensure that the risk of bias is minimised. The practicalities of achieving this and the associated costs will need careful consideration.

KEY FINDINGS FROM THE NATIONAL PILOT

Notwithstanding the limitations outlined above, piloting the SDC in practice produced a set of pilot data that could represent a useful first step to developing a profile of UK osteopathic practice.

Key findings about the SDC tool included:

- The SDC tool developed with and by the profession performed extremely well.
- The tool was clear and easy to complete and generated meaningful data.
- Practitioner compliance was high with 86% of those volunteering actually collecting data,
 and data collection forms were completed thoroughly and validly.
- Practical issues for completion were cited including that some patients were in considerable pain and, understandably, did not want the added burden of having to complete a form prior to their consultation. Other reports included that patients were simply short of time either attending in their lunch time or on the way to other appointments.
- The data collection form has been amended to reduce the burden on patients.
- A few questions were reported to have ambiguous wording and these have been re-worded to make the meaning clearer.

Key findings from the SDC pilot data included:

Patient demographics

- 56% of patients were female and 43% were male
- 93.9% of patients were white
- The age range of patients was from 5 days old to 93 years old
- Occupational data showed that 47.9% were in full time employment, and 10.9% selfemployed full time; 19% were retired, and 14.2% worked part time as either employed or selfemployed, and 6.3% were not currently employed
- GP referral was reported by 6.3% of patients
- A total of 48.1% of patients reported between 1 and 4 visits to their GP concerning their current symptoms, and 29% had undergone previous NHS treatment or investigation
- Access to treatment was rapid. A total of 16.8% of patients were offered an appointment on the same day; a further 54.2% were offered appointments within the next 72 hours.

Symptom profiles

Space was provided to record up to three symptom areas.

- Lumbar symptoms were the most common (36%), followed by cervical spine (15%), sacroiliac/pelvic/groin (7.9%), head/facial area (7%), shoulder (6.8%), and thoracic spine (6%)
- Additional symptoms were recorded in 2.9% of patients
- Symptom duration for the current episode was categorised and included acute (<6 weeks) in 51%; subacute (7-12 weeks) in 15%, and chronic (13 weeks or more) in 32%. A total of 2% of patients did not respond</p>
- A total of 797 patients reported the presence of comorbidities, as diagnosed by their medical practitioner. The most common of these was hypertension (11.7%), followed by asthma (6.6%), and arthritis (5.7%)

Osteopathic patient management

- Practitioners recorded that 97% of patients were suitable for osteopathic treatment
- Treatments given to patients were varied and complex. Soft tissue treatment was the most common (78%), followed by articulation (72.7%), and HVLA thrust/manipulation techniques (37.7%). These were followed in frequency by cranial osteopathy (25.8%), muscle energy (18.3%), and functional technique (13.7%)
- Additional interventions in patient management included education (35.8%), and exercise
 (22.6%). A variety of self-management strategies were discussed with 88% of patients

Outcomes of treatment

- Simple patient-reported outcomes were recorded on the data collection sheet. These were
 drawn from the literature but are not validated measures and their findings should be treated
 with caution.
- After the first appointment, the majority of patients (59.4%) reported no complications of treatment. The most common complications within the first 24-48 hours after treatment were increased stiffness (18%), increased pain (14%), and fatigue (6.6%). After the second and subsequent appointments, 77.3% of patients reported no complications of treatment.
- Only a small number of patients (10.4%) were off work at first presentation; of these 5.3% were able to return to work after one treatment, and 3.1% after two treatments.
- In cases where patients underwent onward referral, 88% were to their GP for further investigation, and 13% were to a hospital consultant.

Financial implications of care

- The responsibility for payment for treatment was met by individual patients in 90% of cases;
 only 8% of osteopathic care was funded by outside sources
- The cost of investigations or treatment undergone by patients through the NHS prior to treatment is hard to quantify but 29% had received NHS care or investigations by their first osteopathic appointment

RECOMMENDATIONS FOR FUTURE WORK

Issues raised

- Gaining consent is now a statutory requirement for osteopaths but it is clear that this remains an area of considerable confusion as it does for other professions. There is a need for clarification based on sound and informed legal opinion concerning the need for verbal and/or written consent information.
- The role of manipulative techniques in older age groups has been documented in general terms but no information is available concerning which area of the body is being manipulated. Safety information on the use of HVLA techniques on this age group is notably lacking.
- The provision of osteopathic care to infants and young children has been documented in the data collection process; 8.6% were under 20 years of age and 5.6% were aged 0-9 years. This is an area of therapeutic provision that requires more work to identify research priorities within this subset of patients.
- The lack of access by patients belonging to different ethnic minorities has been documented. Greater exploration concerning why this has occurred would ensure that equal access to treatment is possible for all ethnic groups, and that appropriate education is given to osteopaths to raise awareness of cultural sensitivities.
- A high proportion of osteopaths have documented that they are recommending exercise to patients. Little work has been undertaken in this area which is not formally taught in all osteopathic educational institutions.
- Osteopaths have documented that they refer to a large number of other healthcare professionals to try and enhance their patients' recovery.
- The small sample produced significant and positive patient feedback; the profession needs to confirm the findings with a further data collection exercise involving a larger number of participants from a random sample of the profession.

Further use and development of the standardised data collection tool

- The development of an electronic format for use by individual practitioners in their practices to enhance their own data collection.
- Use of the tool for research purposes to ensure that data is being collected in a standardised format.
- Use of the tool for periodic snapshot surveys with a larger randomly sampled group to identify if the significant and positive patient feedback can be replicated.
- The development of a short form of the tool for use in practice on a day-to-day basis.

1. INTRODUCTION

Very little has been recorded from a national perspective of the day-to-day practice of osteopaths in the private sector, the profile of patients who consult osteopaths or the outcomes of their care.

1.1 Aims of the project

- The overall aim of this project was to develop and pilot a "Standardised Data Collection" tool (SDC) for the collection of patient-based data within osteopathic private practice in the UK. The primary aim of the project was to generate good-quality information of high relevance to the stakeholders of the osteopathic profession in the UK.
- The project's second aim was research and development; the active involvement of practitioners in practice-based data collection has been effective as a means of building research capacity within other professions.
- The process and methodology of developing and implementing standardised data collection offered the opportunity to involve practitioners in the process of developing new knowledge concerning the practice of osteopathy, whilst being rooted in participatory research.
- The data emanating from standardised data collection can be used nationally to characterise practice, set standards for audit activities and provide information relevant to all stakeholders in NCOR as well as the profession at large, which may be used as a basis for further valid audit activities and to develop meaningful research questions. Developing meaningful research questions is particularly important to the osteopathic profession, so that it can focus and prioritise the limited funding resources available for research.

1.2 The stakeholders for this project included

- the General Osteopathic Council¹ (the profession's regulatory body) and the general public, who were interested in aspects such as safety and adverse reactions, informed consent, insurance, and clinical governance;
- the British Osteopathic Association² (the professional body) and practitioners who are interested in information on aspects such as marketing, cross-professional dialogue, treatments and outcomes:
- NCOR and the research community, who are interested in research development,
 evidence, priority setting for research and audit, evidence-based practice and assessment

- of quality of care³; and the NHS which is interested in efficient use of resources particularly in the treatment of back pain^{4,5,6,7,8,9,10}
- the government which is interested in safety, regulation, quality and integrative care ¹¹.

1.3 Project phases

The project had three distinct phases:

Phase 1: Building Research capacity in regional hubs

- Initiation and development of the practitioner research hubs and hub activities
- Search of literature for existing data collection tools
- Development of draft SDC tools in all individual hubs
- Creation of draft unified SDC tool, based on feedback from all hubs and the Steering Group
- Pilot testing of the draft SDC tool, involving two rounds of testing and updating by hub members
- Third pilot testing by non-hub members in each hub region

Phase 2: The osteopathic SDC tool

- Final refinements and design of the SDC tool by the steering group in readiness for a national pilot
- Development of guidance notes to accompany the tool for users.

Phase 3: National pilot using the SDC tool

- National pilot of SDC tool by volunteers from the profession on up to 10 new patients over
 a 3 month period (1 month recruitment and 2 months for follow up)
- Analysis of data
- Report preparation

The overall project was a form of cooperative enquiry between practitioners and NCOR stakeholders. The three phases are reported in subsequent chapters of this report.

1.4 Ethical Issues

Advice was sought from a number of NHS Trusts and the University of Brighton Research Ethics Committee and we were informed that ethical approval was not required for this type of development work. All patient data and practice data were anonymised within the Clinical Research Centre.

2. BACKGROUND TO THE PROJECT

The general public, NHS and government have been documented as showing increasing interest in the provision of complementary and alternative medicine (CAM)^{12,13}. Clinical recommendations focusing on the management of spinal pain have examined both allopathic and non-allopathic approaches; the latter includes osteopathy^{4,5,8,9} Although the evidence base for osteopathy and the use of manual therapies in the management of low back pain continues to grow, there is still debate over their benefits¹⁴.

Complementary and alternative medicine is currently used by some 13% of the population in the United Kingdom¹⁵. Access to osteopathic treatment is through a variety of locations: private practices, NHS hospital outpatient departments, GP's Practices and clinics attached to osteopathic education institutions. The vast majority of patients access treatment through private practices¹⁶.

Limited survey work has been undertaken to describe daily osteopathic practice; where it exists, this has shown that back pain represents approximately 50% of presentations in clinical practice¹⁷. Existing data is based on a variety of settings and methodologies including retrospective data collection, data gathered from single practices, data from clinics in osteopathic educational institutions, or single snapshot surveys of one day in practice^{18, 19, 20, 21, 22}. Such data must be treated with caution and a amore systematic and all-encompassing means of collecting practice-based data was proposed.

2.1 Quality of practice initiatives

Quality initiatives were launched by the Royal College of General Practitioners in 1983^{23,24,25} The Royal College of Nursing²⁶ and the Allied Health Professions in the 1980s and 90s^{27,28,29}. Given the progress of these initiatives, it seemed timely for osteopathy to initiate significant work in this area.

Clinical governance now demands standards in clinical audit, patient record keeping, use of suitable outcome measures, patient satisfaction measurement, demonstration of continuing professional development (CPD) and awareness and implementation of evidence as the basis for treatment strategies^{30,31}. Several professions have issued new guidelines to respond to the

demands of clinical governance including osteopathy with the General Osteopathic Council's "Code of Practice" issued in May, 2005^{32,33,34,35}.

The introduction of clinical governance into the healthcare arena has affected not only NHS practitioners but those in complementary healthcare professions such as osteopathy^{36,37}. Clinical governance has modified the focus from quality assurance to demand standards in patient record keeping, monitoring outcomes by the use of suitable outcome measures, clinical audit, patient satisfaction measurement, patient safety, the implementation of evidence as the basis for treatment and management strategies, and demonstration of clinically beneficial continuing professional development (CPD)^{38,11}. These demands reflect some of the requirements outlined in the recent "Code of Practice" issued by the General Osteopathic Council³⁵. Osteopathy currently lacks a dataset to fulfil the information requirements in many of these areas.

The development of a standardised data collection tool developed by osteopaths for osteopaths was identified as a constructive and timely initiative to address this omission. A formal proposal was submitted for consideration of funding to the GOsC Council by the National Council for Osteopathic Research (NCOR) in March 2005.

2.2 The role of NCOR

The impetus for forming the National Council for Osteopathic Research (NCOR) in 2003 was the recognition that research activity and capacity in the osteopathic profession in the UK was very low. NCOR is an independent "think tank" for research, with multiple stakeholders including the General Osteopathic Council (the regulator of the profession), the British Osteopathic Association (the professional association) and all the osteopathic educational institutions (OEIs) within the United Kingdom, with an independent Chairperson³⁹. The aim of NCOR was to address the need for a research strategy for osteopathy, informed by a set of research priorities identified in collaboration with the profession. The development of the SDC and the information gained from it is a key part of addressing this need. Many professions have found themselves in this situation historically and have addressed their needs in a variety of ways^{40, 41,42}.

The mission of NCOR is the development of a profession-wide research culture which is inclusive, robust, and credible, has national and increasingly international impact and benefits for

osteopathic teaching, learning and patient care. A number of strategies were identified to achieve this mission, the two foremost being:

- (i) to establish and develop a comprehensive information resource for osteopathic research in order to promote a mutual research dialogue within the osteopathic profession and with other related professions
- (ii) to create a forum that would develop and nurture a pan-professional osteopathic research culture, facilitate linkage of research to practice and identify national research priorities.

The SDC project was developed as part of the research capacity-building, culture changing work within the profession. The development of the SDC project took place progressively within the network of osteopathic research hubs in order to maximise the cultural shift of the profession through wide involvement of practitioners, participation, ownership and education. The SDC tool development followed specific stages, all reported in subsequent chapters.

3. BUILDING RESEARCH CAPACITY IN REGIONAL HUBS

NCOR chose the strategy of developing the standardised data collection tool through a regional network of practitioner "research hubs". While this approach is complex and takes time, compared to methods such as the use of an expert panel, there is evidence that the use of a network (a complex intervention) has the advantages of educational outreach, active involvement, feedback and ownership have been shown to be very valuable in achieving the difficult task of changing clinical practice towards evidence-based practice. In contrast, passive dissemination of materials has been shown to be largely ineffective ^{43,44}. This approach has been used within specialties in the physiotherapy profession for neuro-musculoskeletal dysfunction and whiplash-associated disorders and has proved to be an effective means of identifying audit and research priorities, for highlighting patient and practice profiles, and outcomes of care ^{45,46,47,48}. The developed tool had a variety of other potential uses by encouraging dialogue with other practitioners, setting levels of standards of care, setting audit standards and wide involvement of the profession.

The use of an "audit" based approach to improving quality of care and promoting evidence-based practice has been used extensively within the NHS ⁴². The NCOR strategy for capacity building was very similar to that developed by the Department of Health's National Coordinating Centre for Research Capacity Development for building research infrastructure⁴⁹. One of the four prongs of their strategy was the development of networks such as the Primary Care Research Networks. The Chartered Society of Physiotherapists also recognised the importance of research networks, investing in its own high profile national network (the National Physiotherapy Research Network)⁵⁰.

3.1 Developing the hubs

Since most osteopaths work in private practice, without a research infrastructure, NCOR initiated the development of a research network for osteopaths, based on small regional groups or hubs, to involve practising osteopaths in research activity, including protocol development, data collection, analysis and interpretation of data. They were seen as integral to the creation of a research culture embracing research awareness, research capacity growth, research capability and a firm culture of

evidence based practice. In order to initiate a cultural shift within the osteopathic profession towards service delivery which is evidence-based, high quality and safe, and to promote a culture which stimulates practitioners to undertake research and to implement research evidence in daily practice, practitioners needed more involvement in and experience of basic research skills such as developing research questions and systematic collection of data.

A network of nine osteopathic research hubs were created across the country, based on a model used by other comparable professions in the UK, USA and Australia^{51,52,53,54}. The regional research hubs were intended to be practitioner-driven. They were created at the request of the profession, where a critical mass of research-interested osteopaths existed. Hubs were established in London, Sussex (Haywards Heath), West Yorkshire (Leeds), Oxfordshire (Oxford), Devon (Exeter), Avon (Bristol), South Wales (Cardiff), Perthshire (Perth) and Glasgow.

The regional research hubs comprised both experienced and less experienced researchers. Most members of the profession who trained prior to 1990 had little research training. Hub meetings were facilitated by the NCOR research officer, who provided expertise, education on research resources, and support for developing the hub and the SDC project. The hubs were not self–facilitating at the start of the project and required considerable support. This network required further development in order to capitalise on its potential and to fulfil the aims and objectives of the SDC plan and capacity building for the profession.

3.2 Hub research activities 2007-2009

The hubs were initiated by asking for expressions of interest concerned with being involved in the collection of data and involvement in a research hub, issued at the General Osteopathic Council series of regional conferences held between March, and July, 2005 in a variety of locations throughout the UK and the Republic of Ireland. A series of introductory workshops were then organised to explain the objectives of a research hub and how it could be run, and those of a standardised data collection tool and its potential benefits for osteopaths and osteopathy. The working model of a hub was also discussed during the workshops to allow bottom-up development and allow the hub to meet the needs of practitioners. Workshops were held between May and July, 2006.

A range of activities were offered by the NCOR facilitator or requested by hub participants, which supported the research capacity building aims. In addition to considering what clinical questions needed to be answered for the SDC project, activities included critical appraisal of published papers, literature searching, clinical audit, and specific research projects undertaken in each hub which varied according to the interests of the hub members.

The results of some of the research activities were presented as posters at the 2008 research conference in London, "Osteopathy – Art and Science", as shown in Figure 1.

Figure 1. Posters from the research hubs

Identifying the minimum requirements in a patient record card for osteopaths

Fawkes CA, Chorley K, Esteves J, Herson D, Leaman J, Morriss C, Phillips K, Power C, Relf M, Scott R.

Identifying referral patterns among osteopaths

Fawkes CA, Brice C, Enel A, Ford Z, Howard C, Thompson J, Vickers H.

The creation of an informed consent form for osteopathy by consensus.

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

A case series examining the osteopathic management of patients during pregnancy

Fawkes CA, Baillie S, Brooks J, Gosset N, Keefe V, Lamb S, Mitchell N, Peters T, Sawell P, Wahba T.

The SDC project was initiated in the hubs through attendance of the NCOR Chair and research officer at hub meetings. They gave presentations on the SDC project aims, and discussed participants' information needs and ideas for relevant data items.

4. A REVIEW OF THE LITERATURE

A search of the literature was conducted to identify existing data collection tools nationally, internationally, and across disciplines. The search utilised online research databases, hand searching of non-electronic osteopathic journals and contact with osteopathic institutions internationally. Search terms were developed from discussion within the project team, existing experience and from consultation with colleagues who had worked on similar projects. Terms were categorised using the PICO format devised by Glasziou *et al.*, 2003⁵⁵.

A bibliographic framework was plotted to facilitate the research strategy⁵⁶. Full information concerning the search strategy and terms used is contained in Appendix 1.

4.1 Data collection in osteopathy

The importance of profiling clinical practice has been recognised by many professions within both allopathic and complementary and alternative medicine professions^{57,58}. The use of standardised data collection has been demonstrated to be one of the most effective ways to achieve such profiling. As long ago as 1975, American osteopaths Kelso and Townsend recognised the need for a record system that could potentially aid research⁵⁹. This was supported by Seffinger *et al.*, 1995, and Friedman *et al.*, 1996^{60,61}. This expression of need resulted in the creation of the standardised medical record developed by Sleszynski *et al.*,1999, known as the subjective, objective, assessment, plan (SOAP) form^{62,63}.

US osteopathy, in common with US midwifery, recognised the need for standardised data collection but has focussed very strongly on clinical data and patient records. A goal for the Louisa Burns Osteopathic Research Committee has been to establish a central data repository that will permit osteopathic physicians to submit daily clinical data for use in national osteopathic outcomes research.

Outcomes have become a feature of the modern lexicon of healthcare professionals and can encompass a variety of different factors. These can include physical data, psychological data, evaluation of patient function and quality of life, patient satisfaction measures, healthcare costs, or a combination of these⁶⁴. Other researchers have proposed that outcomes can be stratified into three groups: input (subject to stratification by diagnosis), intervention, and outcomes⁶⁵. This results-focussed research places emphasis on the procedures of care affecting patients, but places

no concern on the mechanisms of care. The use of standardised data collection can assist in the recording of some of these areas of data.

Early attempts at standardised data collection began with the work of Seffinger *et al.*, 1995 who collected data on musculoskeletal findings of structural examination, and areas of somatic dysfunction⁶⁰. This work was further developed by Friedman *et al.*, 1996⁶¹. The new SOAP outpatient form was published finally in 1999 to accurately record examinations performed and treatments provided⁶². An evolution of Sleszynski's work into the musculoskeletal examination form arrived in 2004 with the addition of information on gait and station, anterior, posterior and lateral spinal curves, leg lengths, levelness of bony landmarks, and the clinical methods used during the examination. American osteopaths have also used extensively the ICD-9-CM codes^{66,67,68,69,70}.

Although osteopathic care in the UK shares many features of American osteopaths, the focus on musculoskeletal conditions alone in data collection would not reflect anecdotal views of current practice. Earlier attempts were made to profile osteopathic practice in the UK. Burton, 1981 undertook the retrospective examination of a large sample of case notes but this included varying criteria based on subjective information including osteopathic diagnosis¹⁸. Other attempts at data collection by individual osteopaths were limited with published information focusing solely on age and postcodes of attending patients^{71,72}. The most comprehensive attempt at data collection has been undertaken by McIlwraith, 2003 but this focuses solely on his own practice and makes it difficult to draw generalisable conclusions about the profession¹⁷. Routine data collection takes place within the OEIs e.g. the British College of Osteopathic Medicine currently using the DataEase computer programme^{19,73}. The provision of a standardised data collection tool for use by the entire osteopathic profession that could potentially capture a picture of the entire scope of practice had been lacking.

Once the criteria for topics to be included within a standardised data collection tool have been agreed, another hurdle that must be addressed is the lack of common nomenclature. Commonality of nomenclature has been emphasised in a range of studies where standardised electronic and paper-based data capture systems have been introduced, thereby allowing compatibility of data between existing platforms e.g. Electronic Privacy Information Centre (EPIC), Systematised Nomenclature of Medicine – Clinical Terms (SNOMED CT), North American Nursing Diagnosis Association (NANDA), and Nursing Interventions Classification Nursing Outcomes

Classification (NIC NOC)^{74,75,76,77}. The problem of varying terminology and nomenclature has been discussed in osteopathy (Kirk, 2003), but unless this is addressed uniformly at undergraduate level it is unlikely to become embedded within practice⁷⁸.

4.2 Data collection across disciplines

All professions undergo change within their practice as they mature and are subject to increasing regulation. Concerns about the need to protect the scope of practise have been voiced within osteopathy and other healthcare professions and have been one of the motivators in developing data collection tools. This has been evident in the case of midwifery in the United States where collecting clinical data was regarded as necessary for the survival of midwifery practice ⁷⁹. Lack of profiling of practice was viewed as rendering such care increasingly invisible, liable to decreased access by patients, and professional marginalisation. Increasing professional visibility is only one outcome for data collection. Raising the standards of clinical care through focussed attention on management practices and outcomes has been identified as important in the reduction of errors where routine data collection takes place ⁸⁰.

In the United Kingdom, standardised data collection has been utilised with notable effect within the physiotherapy profession. The development of standardised data collection tools has focussed on neuro-musculoskeletal dysfunction and whiplash-associated disorders; the tools have been used within NHS practice and in private practice⁴⁵⁻⁴⁸. From 2012 routine data collection related to waiting times and referral sources will be mandatory within the NHS. As osteopaths become increasingly integrated within the NHS, the need to be able to use data collection systems with ease will become even more important. This need is being addressed already by many United Kingdom (UK) osteopathic educational institutions (OEIs) as they prepare the next generation of osteopaths.

Some professions have focussed very specifically on data collection of a single area of clinical practice or area of injuries. This was demonstrated by Hauret *et al.*, 2010 in their attempt to describe musculoskeletal injuries among US military personnel⁸¹. The size of the problem within US military personnel was regarded as being underestimated and an objective means to examine this was sought. During the period 2001 and 2002, three groups within the US Department of Defence worked independently to develop a comprehensive list of injury-related diagnostic codes that could be used for injury surveillance. The groups combined their effort and the products of

their consensus groups to produce a broader definition of injury definition for use in future injury surveillance activities^{82,83}. The three nominal groups utilised ICD-9-CM codes within medical records to arrive at a consensus list⁸⁴.

Midwives in the United States undertook a variety of methods to create their own standardised data collection forms. The American College of Nursing and Midwifery (ACNM) developed an Intrapartum Minimum Data Set based on an adaptation of Donabedian's work ^{85,86}. This dataset attempted to characterise midwifery care by recording work requirements, resources, the physical and organisational practice settings, and the process of care. Greener described the process of midwifery care as being the activities that go on between midwives and their patients. These processes were inevitably influenced by the philosophy or perspective of the care giver. Midwives were invited to participate in web-based data collection, using the minimum data set, through advertisement in their professional newsletter. A large proportion expressed a preference for data collection using a personal digital assistant (PDA).

Further research by the midwifery profession identified that midwives were using their own versions of data collection tools, most frequently paper-based. Views were sought on the factors that would influence participation in data collection and these included a standardised format which was portable, a web-based tool, the ability to be able to compare personal practice to a national standard, easy to use, and be able to produce reports, having a designated entry person, being concise, and able to complete quickly.

In addition to the minimum data set, further tools were developed to focus on specific areas of midwifery practice or national regions including perinatal processes and outcomes (Optimality Index-US), and the Midwives Alliance of North America (MANA) statistic project using a 150-item data collection tool⁸⁷. Walker *et al.*, 2008 report that the profession recognises the need to join together its resources and develop a national midwifery database with a web-based data collection tool interface that could be aggregated to capture a national snapshot for policy makers as well as midwives⁷⁹.

4.3 The benefits of standardised data collection

The potential benefits of standardised data collection have been described within a range of different professions. This has also been discussed in the work by Saranto and Kinnunen, 2009 in

their systematic review⁸⁸. Early studies by Moloney and Maggs, 1999 identified the poor standard of nursing documentation; other authors also found this had an impact on nursing outcomes^{89,90}. This can also be found in the medical profession and osteopathic profession and is a common finding in disciplinary hearings^{91,92}. Improvements in documentation, the process of care and the outcomes for patients were identified in nine out of 14 studies reviewed by Saranto and Kinunnen, 2009^{93,94,95,96,97,98,99,8100,101}. Currell and Urquhart, 2003 found in their review of nursing studies that there was no evidence that standardised data collection and standardised nomenclature leads to changes in practice¹⁰². However, it is notable that they regarded standardised data collection solely as a note keeping system and, in contrast to other reviewers, not necessarily having the capacity to instil reflection about the care planning process. This particular perspective on the part of the research team may not be shared with the nursing practitioners they studied.

In summary, the literature indicates that although the use of standardised data collection tools can be time-consuming, their benefits outweigh their barriers. They have been shown to assist with:

- Profiling professional activities including clinical practice
- Protecting scope of practise in the face of increasing regulation
- Increasing professional visibility
- Raising standards of care through focussing on management practices and outcomes

5. DEVELOPMENT OF A PILOT STANDARDISED DATA COLLECTION TOOL

The road to development of standardised data collection (SDC) tools has varied across disciplines. Standardised data collection tools have been developed most commonly using a nominal group technique to obtain consensus on the type of information that should be included.

5.1 Nominal group technique

This is a structured and focussed interview approach that encourages the generation of ideas around a specific topic of interest¹⁰³. It has been described as a potentially powerful learning and development tool which has a particular role in analysing issues within healthcare^{104,105}. It is also a favoured technique in attempting to bridge the gap between healthcare professionals and researchers and their differing priorities; this has been demonstrated in the work of Moore and Klingborg, 2007, and Kristofco *et al.*, 2005 in their work on identifying practitioners' needs for continual education^{106,107}; Tomlinson *et al.*, 2009 in the development of a clinical assessment instrument¹⁰⁸; and Sarre and Cooke, 2009 in developing indicators for measuring research capacity development¹⁰⁹.

Nominal group technique has been used in the development of clinical guidelines where the approach was modified to reflect the concepts of Charles *et al.*, 1999; Fardy and Jeffs, 1994, and Gallagher *et al.*, 1993 who specifically focussed on general practice ^{110,111,112,113}. Nominal group technique has been used more commonly to identify patients' and healthcare professionals' priorities in primary care. Osteopaths can be considered in a similar manner to primary care professionals as they have become increasingly first contact healthcare professionals for patients who more frequently bypass primary care professionals particularly for musculoskeletal conditions². It was for this reason that the nominal group technique was employed in the development of the data collection tool. Some initial scepticism concerning the usefulness of the process and the end product was aired and this has also been noted among other professional groups starting such an initiative ¹¹². Increasing participation in the process and subsequent ownership largely rebuts this scepticism over time. When questioned about the barriers to data collection, a consistent comment is the time involved and the feeling that data collection is itself becoming another intervention in the care process and potentially burdensome ^{114,115,116,117,118,79}.

Public, or user, involvement is increasingly promoted by government policy; there is no widely accepted method for doing this although groups like INVOLVE produce guidance for both researchers and users to make this as productive an experience as possible for both parties¹¹⁹. Difficulties have been cited in this endeavour by Drennan *et al.*, 2007, and Ryan *et al.*, 2001 where users can drift into providing information on personal health journeys to the exclusion of the specific discussion required^{120,121}. As the SDC tool was intended as a clinical tool, providing information to clinicians, user input was not included in the initial tool development. This follows a precedent set by other tool development processes across disciplines.

5.2 Development of a draft Osteopathic SDC Tool

In the development of the osteopathic SDC tool, an iterative approach was used to develop the dataset and the data collection form, refined through several rounds of feedback and discussion within the network of research hubs. The creation of research networks and their helpfulness in the research process has been documented by many different professions ^{50-53,122-129}. Meetings of nominal groups were held in each of the nine hubs. The regional hubs members acted as participants in the Nominal Group, and the NCOR research officer as facilitator. The participants across the network represented a purposive sample of osteopaths from across the UK. Field notes were recorded to collect the views expressed of osteopaths participating in the groups.

5.3 Initial group discussions

The group discussions were initiated by using the physiotherapy data collection tools as examples Discussion aimed at identifying the participants' priorities, goals, and perceived obstacles in profiling and evaluating practice. One initial difficulty encountered was the lack of clear understanding concerning the nature of a standardised data collection tool. The developed tools were discussed initially to identify their suitability for minor amendment or the need for a completely fresh approach to create a tool suitable for osteopathic practice. It soon became clear that, because the practitioners had little experience in use of such data collection tools, ownership of the final tool would only be achieved by working through the process of development from the beginning with the creation of a data collection tool to specifically reflect the osteopathic approach to patient care.

5.4 Key topic areas for the draft SDC tool

Draft osteopathic data collection tools were developed independently within each of the nine hubs; and the needs of participants determined the identification of data items to be collected. Initial hub meetings focussed on identifying a broad range of questions suitable to be included in a data collection tool. This included demographic and clinical questions, sharing much in common with the type of information habitually gathered during the case history- taking process. Patient consultations create a huge volume of information from the initial visit through the provision of ongoing care; it is necessary to be quite strict on limiting the number of different topic areas for data collection. Key themes emerged for all hubs and are summarised in the following list:

- 1. Patient profiles including
 - ♦ age
 - ♦ sex
 - ♦ ethnicity
 - registered disability status
 - ♦ occupation
- 2. Symptom profiles including
 - site of symptoms
 - duration of symptoms
 - intensity of pain
 - recording of pain/disability score (e.g. on a visual analogue scale)
 - ♦ mode of onset of symptoms
 - general health status (including medication)
 - presence of any co-morbidities
- 3. Therapeutic history including
 - previous consultations
 - previous investigation(s)
 - outcome(s) of previous treatment
- 4. Osteopathic management including
 - diagnosis made
 - ♦ treatment delivered
 - use of any adjunctive treatment or other additional management strategies
- 5. Outcomes of treatment, for example
 - response (both beneficial and adverse) to treatment
 - ♦ change in visual analogue scores
- 6. Financial information concerning
 - cost of treatment
 - further investigations requested

The hub members produced considerable numbers of questions initially, based frequently on "what it would be nice to know". Initial numbers of suggested questions ranged between 28 and 73. Two rounds of discussion took place before a draft version of the tool was created for each hub. The hub members became more focussed progressively on priority information and its useful application to individual practices and practitioners in addition to how the profession en masse could use the information. Attention was paid specifically to the language used in the patient completed section to avoid jargon which may be confusing to some patients.

A composite tool was formed from all draft tools developed individually in the hubs. This composite version of the tool was then presented to the hub members and the steering group for further discussion and refinement. The composite tool contained 57 separate questions.

5.5 The role of the steering group

The role of the Steering Group (see Appendix 2) was to act as an expert panel to examine the draft composite SDC tool and the comments that had been contributed from hub members who had provided feedback on the draft composite tool. The first version of the merged data collection tool was presented to the steering group in February, 2008.

The Steering Group evaluated each question in turn in the merged composite tool and revisions to the tool were recorded directly onto the tool. Face- and content- validity of the tool was assured by involvement of the practitioners together with input from the expert review panel. The steering group focussed on addressing potential areas of ambiguity of some of the questions and ensuring that the content of the questions was appropriate. Comments relating to the layout of the tool, font size and consideration of osteopaths who may have disabilities were also considered. Additional comments raised concerns about the practicalities of getting patients to complete their part of the tool prior to their appointment. This was one of the main reasons that a paper-based format was retained since patients may be unfamiliar with or simply unwilling to complete an electronic version of the data collection tool.

A revised version of the tool was created following the Steering Group meeting and this was fed back to the hubs for comment and further discussion. A further two rounds of discussion took place with the input of the steering group to examine hub member feedback. Careful attention was paid to formatting and a version of the tool was created ready for use in the first pilot with hub members.

5.6 Testing the Pilot SDC Tool

A three stage testing process was used. The purpose of the two initial stages was to gain information from the participants about the SDC tool, any omissions in criteria or topic areas and any difficulty with the terminology, and to enable the researchers to detect any difficulties and inaccuracies in completion of the tool. The third pilot evaluated any regional differences that might cause problems.

The initial pilot test involved use of the SDC form for 2 weeks in volunteer practices, four practitioners from each hub using it for new and existing patients. Following extensive feedback from this first pilot test, the SDC tool was revised.

The second pilot was conducted using the revised tool from the first pilot. All hub participants were invited to trial the SDC tool for all new and existing patients for 1 month and asked to provide feedback at hub meetings concerning the piloting process. The tool was revised further by the steering group based on feedback from the second pilot stage. Feedback from hub members included comments that they found the revised format more user-friendly and quicker to use with familiarity. One osteopath contacted the research team to state that one patient had refused to be involved since he was very suspicious concerning the purpose of the data and "wasn't sure where it was leading to". Many hub members expressed the view that as many categories as possible should be used which could be related to existing and published sources of literature 130. This would allow comparison of the results of the data collection process with national standards existing for previous data collection exercises e.g. Census data. Methods of collecting data used by other health professions were examined to identify where they could be utilised also e.g. READ code groupings 131.

The use of categories for collecting information relating to a patient's profession was also cited as being difficult and it was suggested that postcodes could be used instead. Work has been carried out in this area by Carstairs to create an index of deprivation for the UK^{132,133, 134,135}. The inclusion of identifying data in the form of date of birth and full postcode could lead to anonymity being compromised. Following discussion with the steering group, it was agreed that age alone would be used and the first part of the postcode alone was included to provide some geographic information but without the potential for compromising anonymity.

Other comments focussed on practical issues e.g. allowing the tool to be distributed in a format compatible for Mac computer users, and the need to provide a means of easily converting Imperial height and weight measures into metric. A question relating to ethnicity generated considerable comment relating to its inclusion, its potential offensiveness to all patients, the fact that it was so large and perhaps the number of options could be shortened. The ethnicity categories used were those produced from the Equality and Human Rights Commission (formerly the Commission for Racial Equality)^{136,137}. It was stressed to participants that not including a question relating to ethnicity would be seen as a surprising omission for a healthcare profession but in future versions of the tool it could be labelled as optional.

Other more specific comments related to a perceived need to collect more specific data concerning the reactions to treatment both minor and serious, and to capture any variation between first and subsequent treatments. The need to separate treatments into first, second and subsequent visits as practitioners add different dimensions to treatment at various stages of the care process; and the need to add more recommendations for self-management including advice was stressed to reflect that treatment can change between visits.

The use of language was questioned by some osteopaths; the term "maintenance" had been used initially and this caused considerable debate. Advocates stated that it was beneficial for the profession to be seen to be offering long term care and support to patients where it might be absent through other agencies. Other osteopaths voiced their disquiet stating that funders from the NHS and health insurers are not interested in financing long term care for chronic conditions and potentially this could be a drawback for osteopathy. A compromise was reached using the term "episodic care".

The third pilot stage took place using practitioner representatives who were non-hub members from different areas of the UK; four representatives in each region used the tool for one month to assess the tool for regional differences in use and terminology. Feedback from participants in the third pilot was considered by the steering group. This included comments that the SDC was very comprehensive and quite daunting at first sight but was easy to follow, flowed well and was quite quick to use in practice. The possibility of having versions in two font sizes was raised, and the fact that the layout could be improved to make a better use of the space rendering the tool shorter. The option of an electronic or web-based version of the tool was raised and this may indicate the

need for further consideration in the future. This view has been echoed by other professional groups who have developed data collection tools⁶⁶. The range of options within the questions was viewed largely as being helpful, especially in the patient-completed section. Additional suggestions for options to be included within questions were contributed. Further comments suggested the need for qualifying statements attached to some of the questions to ensure absolute clarity of response.

Additional input was also received from NCOR members concerning the potential use of measurement scales within the tool. It was suggested that co-morbidity indices could include those used by Groll *et al.*, 2005; post-treatment reaction(s) categories could utilise those recorded by Cagnie *et al.*, 2004; and outcome scales could be based on those used by Kemler *et al.*, 2003^{138,139,140}.

Further amendment of the SDC tool took place: the design and layout of the final draft version of the SDC tool was then refined to facilitate readability, ease of completion and user-friendliness. After a final review by the hubs, the SDC tool was finalised in readiness for a three month national pilot. The detailed feedback from all pilot stages has been included in the minutes of the Steering Group meetings which have been submitted to the GOsC education committee. The SDC tool prepared for piloting is described in Chapter 6.

6 THE SDC TOOL

The standardised data collection tool that underwent national piloting contained 65 separate pieces of information (SDC version 1, see Appendix 3). The SDC form was separated into two distinct sections to allow patients to complete their own socio-demographic information, leaving the practitioner to complete the second section on the presenting symptoms and treatment and outcome. The identity of each patient was kept anonymous; the forms were identified by a practitioner code followed by a 3 digit number allocated in the practice.

The form was designed to follow the flow of a consultation and contained five parts:

- Part 1 Patient data
- Part 2 Presenting symptoms
- Part 3 Management and treatment at first appointment
- Part 4 Second and Subsequent appointments
- Part 5 Final outcome(s) of care.

Part 1 comprised data supplied by the patient, and all subsequent sections were completed by the practitioners with the exception of questions relating to outcomes of care.

6.1 Patient-completed section

The patient-completed form requested demographic information including age, sex, ethnicity, height, weight, occupation, work status, and levels of physical demand in both work settings and leisure time. The structure of the ethnicity question followed NHS guidance for collecting this information within healthcare settings. The patient-completed section also included information relating to whether the patient was registered as disabled, the duration of their current problem to provide information concerning the number of patients presenting to osteopaths who can be described as acute, sub-acute or chronic, and the time off work with the problem to provide an indication of cost to the state sector. The referral route to the practice was recorded. Information connected to the NHS was collected including the number of previous visits to the general practitioner (GP); the nature of previous investigations with specific reference to medication, inpatient treatment, outpatient treatment, and medication in order to identify the cost to the NHS incurred before osteopathic intervention. Additional information was recorded concerning the waiting times experienced by patients referred for NHS appointments for their current symptoms.

Marketing information for practitioners was included which concerned why patients chose osteopathy and how they heard about a particular practice.

The need to collect accurate data from patients, by completion of their own section of the data collection tool was a key consideration when deciding whether to make the data collection form paper-based or electronic, or a version of both. The practicalities of asking patients of varying ages to complete an electronic system was seen as unrealisable in most practices.

6.2 Practitioner-completed section

Part 2 of the form was for practitioner completion only. This section was sub-divided into three sections which recorded initial presenting symptoms; the management and treatment applied at the first appointment, and the management and treatment applied at second and subsequent treatments.

The intention of collecting a wide range of information was to document the different aspects of osteopathic care commonly employed in day-to-day practice. Osteopaths are increasingly being placed in the role of first contact health practitioners and the importance of being able to recognise when patients are suitable for treatment and when they need to be referred for different investigation(s) or management is implicit in all competent healthcare practitioners, in addition to being part of the GOsC Code of Practice.

Information was collected about symptom areas, the nature of onset of symptoms, and the full extent of investigations that had taken place for the presenting set of symptoms. Presenting symptoms were chosen in place of diagnostic categories. This caused some discussion amongst practitioners who felt that categories similar to those used by groups like Health Response could be used and it would be an objective way of documenting those particular pathological states could be legitimately used in practice promotion¹⁴¹. The lack of objectivity about diagnosis and an inability to capture information concerning the clinical reasoning processes inherent in arriving at that diagnosis made recording of symptom areas a more reliable choice of data item.

The range of co-morbidities, as diagnosed by a medical practitioner, was recorded to try and document the general health status of patients attending osteopathic practice. The range of management strategies were recorded including active intervention using a range of techniques and supporting information e.g. exercise. A significant body of research relates to the use of

spinal manipulation in the management of a variety of symptoms, most notably, back pain. The range of techniques used by osteopaths in managing patients of varying age groups is often overlooked and it is with some frustration that the profession is labelled frequently by one technique. The use of a range of osteopathic techniques has been described in the literature and osteopathic care contains over 100 different techniques or procedures ^{142,143,144,145,146}. The most commonly used structural approaches are broadly grouped into seven major types:

- High velocity low amplitude (also called thrust or manipulation techniques). This involves a quick movement within a joint's normal range of movement and does not exceed the anatomical barrier of the joint. Movement can be targeted to specific spinal segments and, with appropriate positioning of the patient, requires very little force. The goal of the technique is to restore joint play^{147,148}. The technique is frequently characterised by a clicking sound whose source has been investigated by a number of researchers^{149,150,151}. This technique most closely resembles chiropractic manipulation and is subject to most contraindications;
- Soft tissue/massage techniques¹⁵²;
- Articulation involving gentle repetitive movement of a joint to try and increase the range of movement;
- Muscle energy. This involves repeated isometric contractions with passive joint movement to increase joint mobilisation and lengthen contracted muscles ^{143,144};
- Counterstrain. This involves the symptomatic joint being placed in a position of least discomfort while at the same time monitoring the degree of tenderness at a nearby tender point until the tenderness reduces^{143,144,153}. The only contraindication is patient unwillingness or inability to cooperate;
- Myofascial release techniques. These techniques are similar to deep massage techniques and are designed to stretch muscle and reduce tension¹⁴⁴;
- Lymphatic pump techniques. These techniques attempt to mechanically assist lymphatic drainage. There are a small number of contraindications to this technique ¹⁵⁴;

However, there is a paucity of evidence that records all of the technical approaches and supporting information used in everyday patient care by UK osteopaths.

Information concerning the gathering of informed consent was recorded. The issue of consent has vexed the profession considerably and it was felt that this information should be documented to try and identify in what manner most osteopaths are gaining consent information. Additionally, some summary information was collected about selected outcomes of care, including the number of treatments, referral, and risk-benefit information such as "reactions to treatment" and improvement of symptoms.

7. A NATIONAL PILOT OF THE SDC TOOL

These results represent the first broadly-based national picture of UK osteopathic practise based on individual patient data from a large number of practices. It must not be forgotten that this data is **pilot data** and represents the final stage of the SDC tool development process.

7.1 Methods

Recruitment

Recruitment of practices to participate in the national data collection project was voluntary. All members of the profession practising within UK private practice were eligible and were invited to participate in the trial of the SDC to collect data on up to 10 new patients presenting over a 3 month period (1 month of recruitment and 2 months for follow up) in 2009.

In order to maximise participation in the national data collection, NCOR conducted a well-publicised launch of the SDC tool, promoting the aims and benefits of participating in the survey, at a series of national meetings and in the osteopathic press. Invitations to participate were distributed by email using existing contacts as well as the BOA and GOsC distribution lists. Recruitment was conducted personally at regional conferences and participation in the project was advertised to practitioners in the *The Osteopath* and *Osteopathy Today*.

The number of eligible registered osteopaths that volunteered during the recruitment period was 394, approximately 10% of the profession.

Data collection

Each of these 394 practitioners was sent 10 SDC forms and guidance notes (Appendices 3 and 4) in April 2009 by email or post depending on personal preference. Participants were emailed, or contacted by letter also, to emphasise the duration of the study and other supporting information including email and telephone contact details for the research team, in the event of any queries regarding completion of the data collection tool.

Participants were asked to undertake data collection between April 20 and July 17, 2009, and to complete a form for 10 new patients or 10 former patients who were starting a new episode of care during the first month of the study period. Practitioners were asked to follow up patients until the end of their course, or for two further months until 17th July 2009, whichever arrived sooner, and then complete the final (outcome) part of the form. The completed data collection

forms were given an identification (ID) code to ensure patient anonymity was preserved at all times. The patients were informed about the data collection by the osteopath, during their first routine consultation for their episode, and asked to complete the demographic section of the form (Part 1).

Osteopaths who participated were asked for their comments on the use of the tool within their practices at the end of the three month period. Any questions that arose from participants during the initial stages of the national pilot were recorded and reported to the steering group.

Input and processing of data

All completed standardised data collection forms were returned to the Clinical Research Centre at the University of Brighton. The forms were numbered for anonymity and referred to by their numbers only in future discussion. The data was entered into an EXCEL spreadsheet by the project administrator, Mrs Shirly Mathias, and subsequently checked and analysed by the research team.

Quality was assessed in terms of invalid, free text or missing data. Some variables required conversion to standardise the data where different units were applied, such as days/weeks/months. Free text data was grouped and coded if possible into existing or new categories.

Data Analysis Methods

Descriptive statistics were used to summarise the data in terms of frequencies, means and standard deviations within EXCEL; statistical tests were applied to selected items using Graphpad software¹⁵⁵. Data analysis was undertaken by Dr Janine Leach.

Late forms continued to arrive in small numbers and a cut-off of 31st December, 2009 was applied; by this point 1630 forms had been received. The forms were completed very thoroughly, with few unanswered questions; after analysis less than 1% missing data was found for most questions. No questionnaires had to be excluded due to poor quality of data.

Completed forms were received from 342 (86.8%) of the 394 osteopaths originally recruited; This represented a mean of 5 (4.7) patients contributed to the study per practitioner. A very small number of patients (33, 2%) were still continuing their initial course of treatment at completion of the data collection period.

8. ANALYSIS OF FINDINGS FROM NATIONAL SDC PILOT

Initial analysis of the pilot data has been undertaken using descriptive statistics. This has allowed the data to be summarised in terms of frequencies, means and standard deviations. Further areas for the use of inferential statistics will be identified on completion of the project and following discussion with members of NCOR. Analysis of findings of each section of the standardised data collection form will be presented in turn as they were asked on the SDC tool (shown in Appendix 3).

PART I – PATIENT DATA

These socio-demographic data were completed by patients. There were 5 forms (0.3%) with all patient data missing; presumably these patients did not wish to complete a form.

1.1 Sex

There were slightly more female (56%) than male patients (43%).

Table 1. Sex of patient in the dataset

Sex	Number	Percentage
Female	912	56
Male	703	43
No response	15	1
Total	1630	100

1.2 Ethnicity of patients

This question used the NHS ethnicity categories. 83.5% of the patients described themselves as white British, with a further 8.6% in other white categories. 3.1% were Asian or Asian British. This item was well completed with only 1% of patients not responding.

Figure 2. Ethnicity of patients

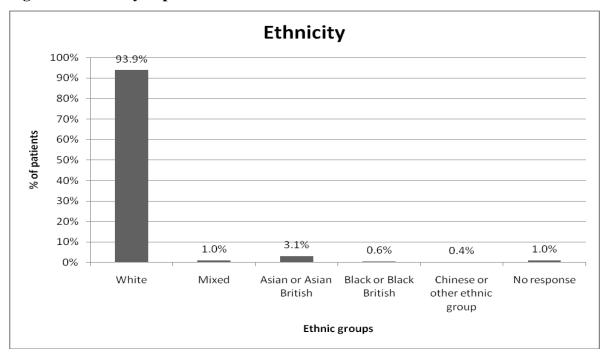


Table 2. Ethnicity - all categories

Ethnicity*	Number	Percentage
White British	1390	85.3
White Irish	75	4.6
Any other white background	65	4.0
White		93.9
Mixed White and Black Caribbean	6	0.4
Mixed White and Black African	0	0.0
Mixed white and Asian	6	0.4
Any other mixed background	4	0.2
Mixed		1.0
Asian or Asian British Indian	34	2.1
Asian or Asian British Pakistani	16	1.0
Asian or Asian British Bangladeshi	0	0.0
Any other Asian Background	1	0.1
All Asian or Asian British		3.2
Caribbean	5	0.3
African	5	0.3
Any other black background	0	0.0

All Black or Black British		0.6
Chinese	2	0.1
Other ethnic groups	4	0.2
All minority ethnic groups		5.1
No response	17	1.0
Total	1630	100

^{*} Descriptors used are based on those of the Office for National Statistics

1.3 Age of patients

Patients were asked for their age: this information was missing for quite a large number 2.6% of patients. Ages, where given, ranged from new-born (5 days old) to 93 years old (Figure 3). The majority of osteopathic patients were between 30 and 59 years of age; the average age was 44.76 (SD= +/- 19.08) years. A small peak in the youngest age group is noticeable in Figure 3, and the second graph (Figure 4) shows that this peak is due to the relatively large number of babies, especially in the 0-12 month age group.

A total of 140 (8.6%) patients were aged less than 20 years, and if these are excluded the mean age of adult patients rises to 48.42 (SD 15.51) years.



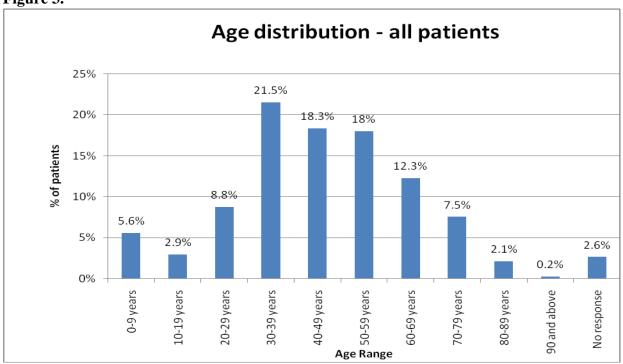
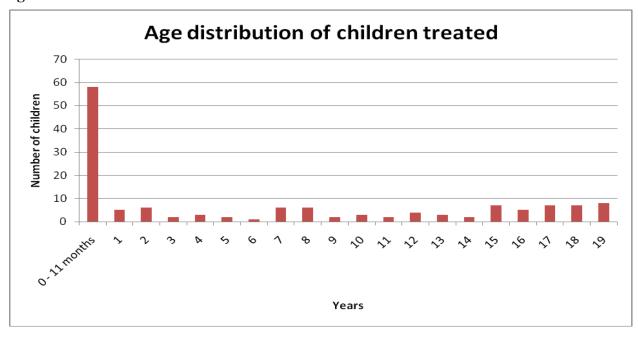


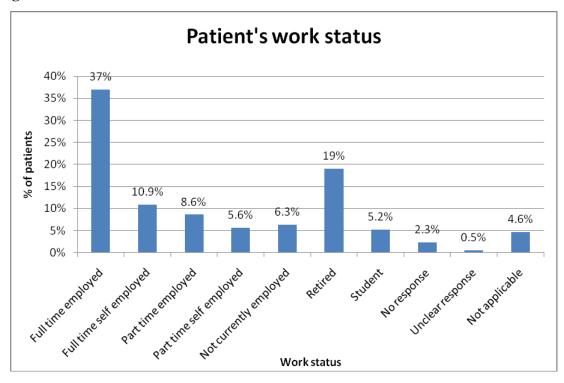
Figure 4.



1.4 Patients' work status

The majority of patients (62.1%) were employed, and most of these were in full-time employment. Retired patients comprised almost one-fifth of the sample. The category labelled "Unclear" included responses such as "full time, part time, carer"; "not applicable" included "baby" and "toddler".

Figure 5.



1.5 Patients' occupation

Data concerning occupations were described in free text and indicated a huge variety of working roles. Patients were also asked how physically demanding their occupation was, and answers were distributed across the whole range from sedentary to strenuous.

Table 3.

Physical Activities	Number	Percentage
Sedentary	322	20
Light	232	14
Moderate	374	23
Strenuous	227	14
Not appropriate	442	27
No response	33	2
Total	1630	100

1.6 Physical demands of leisure time activities

Similarly, the physical demands of patients' leisure activities were evenly distributed across the categories.

Table 4.

Leisure time activities	Number	Percentage
Sedentary	257	16
Light	416	26
Moderate	673	41
Strenuous	203	12
Not applicable	67	4
No response	14	1
Total	1630	100

1.7 Disability status

Some 2% of patients reported that they were receiving disability allowance.

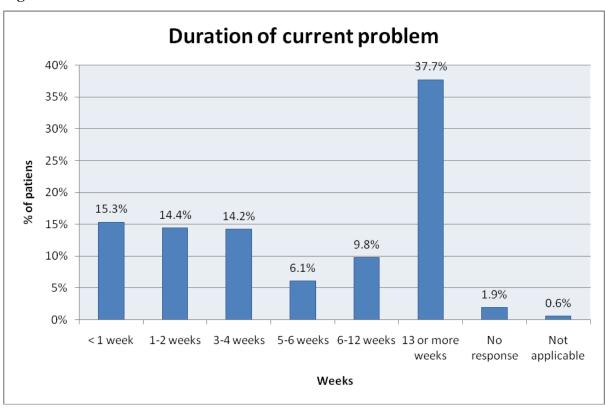
Table 5.

Disability allowance	Number	Percentage
Yes	27	1.7
No	1455	89.3
No response	148	9.1
Total	1630	100

1.8 Duration of the current problem

This graph represents the patients' responses when asked how long, in weeks, they had experienced their current problem. More than one-third thought their episode had lasted 13 weeks or more.

Figure 6.



1.9 Sickness absence

The vast majority of patients were not off work with their current problem. Some 13% were off work at their first appointment, most for less than 1 week. Chronic sickness absence was rare in this sample of patients with only 1% on longer term sickness absence of 5 weeks or more.

Time off work for the current problem 85.5% 90% 80% 70% 60% % of patients 50% 40% 30% 20% 8.2% 10% 1.8% 1.5% 1.2% 1.0% 0.6% 0.2% 0% 2 weeks < 1 week 1 week 3 weeks 4 weeks 5 or more Not No applicable weeks response Weeks

Figure 7.

1.10 Source of referral to the practice

Most patients referred themselves to the practice, but significant numbers were referred by other healthcare professionals e.g. the GP or another healthcare practitioner. Small numbers were referred by other sources such as family and friends, employers or an insurance company.

Table 6.

Referral Source	Number	Percentage
Self	1302	79.9
GP	103	6.3
NHS Consultant	4	0.2
Employer	16	1.0
Another healthcare practitioner	89	5.5
Insurance company	27	1.7
Solicitor	5	0.3
Family and friends	39	2.4
Other	14	0.9
No response	31	1.9
Total	1630	100

1.11 Number of prior visits to the GP about this condition

Almost half of the patients (48.2%) had visited their GP prior to visiting the osteopath, with 28.9% having 2, 3, 4 or more visits. One patient claimed to have visited their GP 54 times. Responses labelled "Unclear" include "lots", "many", "several", "visited consultant", and "seen GP".

Figure 8.

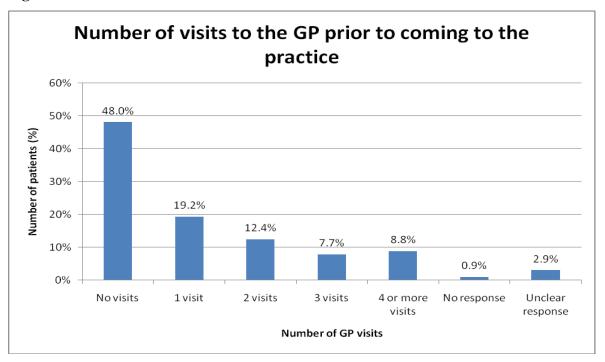


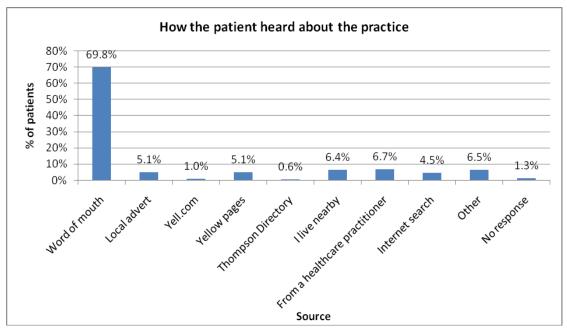
Table 7.

Prior number of GP visits	Number	Percentage
No visits	783	48.0
1 visit	313	19.2
2 visits	202	12.4
3 visits	126	7.7
4 or more visits	144	8.8
No response	14	0.9
Unclear response	48	2.9
Tota	al 1630	100

1.12 How the patient heard about the practice

Most patients heard about the practice by word of mouth. Advertising represents a relatively small source of patients.

Figure 9.



This question permitted multiple answers, but only 7.1% of patients reported using multiple types of information.

Table 8.

Source	Number	Percentage
Word of mouth	1137	69.8
Local advert	83	5.1
Yell.com	17	1.0
Yellow pages	83	5.1
Thompson Directory	9	0.6
I live nearby	104	6.4
From a healthcare practitioner	110	6.7
Internet search	74	4.5
Other	106	6.5
No response	22	1.3
Total	1745	107.1

1.13 Reasons why patients chose to use osteopathy

Patients were asked why they decided to have osteopathic treatment. The question was multichoice, permitting several factors to be ticked; 42% of patients reported several motivating factors. Table 9 shows that the most common reasons for choosing osteopathy were personal recommendation (65%) and previous experience of osteopathy (20%). The desire to have a drugfree (9.1%) or hands-on therapy (9.1%) together with desire to have osteopathy (9.6%) suggest a considerable proportion of patients actively choosing this type of touch therapy. Personal research and failure of other treatment(s) also feature as reasons.

Table 9.

Reasons for choosing osteopathy	Number	Percentage
Personal recommendation or referral	1058	64.9
Personal research	128	7.9
Waiting for NHS physiotherapy appointment	31	1.9
Failure of previous treatment	169	10.4
Previous experience of osteopathic treatment	323	19.8
Desire to have osteopathic treatment	157	9.6
Wanted a form of manual or hands-on treatment	148	9.1
Did not want treatment through the NHS	40	2.5
Wanted to have drug-free treatment	149	9.1
Other	50	3.1
No response	57	3.5
Total	2310	141.7

1.14 Prior osteopathic treatment

More than half of the sample of the patients (59%) had never visited an osteopath before.

Table 10.

Prior osteopathic treatment	Numbers	Percentage
Yes	649	40
No	967	59
No response	14	1
Total	1630	100

1.15 Waiting times for first appointment

Patients were asked how long they had to wait for the first appointment (for this condition) to be offered after contacting the practice.

Osteopathic care was available to patients very promptly; the waiting time for the first appointment was less than a week for 84.3%, and 16% of patients were seen on the same day as their request for an appointment.

A small number of patients (0.6%) waited for longer than one month, with 2 patients waiting 60 days. No information is available concerning the reasons for the longer waiting times.

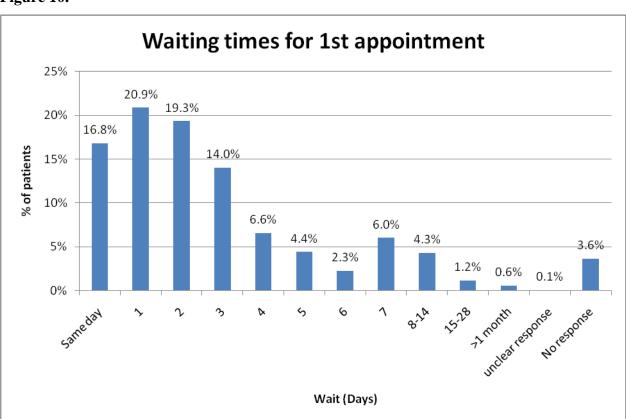


Figure 10.

These results are presented in tabulated format overleaf.

Table 11. Waiting times for first appointment

Length of wait for 1 st appointment (Days)	Number	Percentage
Same day	274	16.8
1	340	20.9
2	315	19.3
3	229	14.0
4	107	6.6
5	72	4.4
6	37	2.3
7	98	6.0
8	8	0.5
9	5	0.3
10	31	1.9
11	0	0.0
12	1	0.1
13	0	0.0
14	25	1.5
15	5	0.3
16	1	0.1
17	0	0.0
18	0	0.0
19	0	0.0
20	3	0.2
21	8	0.5
28	2	0.1
> 1 month	9	0.6
unclear response	1	0.1
No response	59	3.6
Total	1630	100

1.16 Patients waiting for NHS care

Only 101 patients (6%) in the sample were on an NHS waiting list for the same condition as they sought osteopathic treatment.

Table 12.

NHS Waiting List	Number	Percentage
No	1518	93
Yes	101	6
No response	11	1
Total	1630	100

1.17 Waiting time for NHS care

Patients were asked how long they had been waiting for NHS treatment for this condition. Among the 6% of patients on an NHS waiting list, 23% had been waiting more than 2 months.

Table 13.

NHS waiting time	Number	Percentage
Up to 4 weeks	40	40
5 to 8 weeks	19	19
9 to 12 weeks	9	9
13 to 24 weeks	11	11
More than a year	3	3
unclear response	2	2
Not applicable	17	17
Total	101	100

1.18 Prior NHS treatment or investigation for this episode

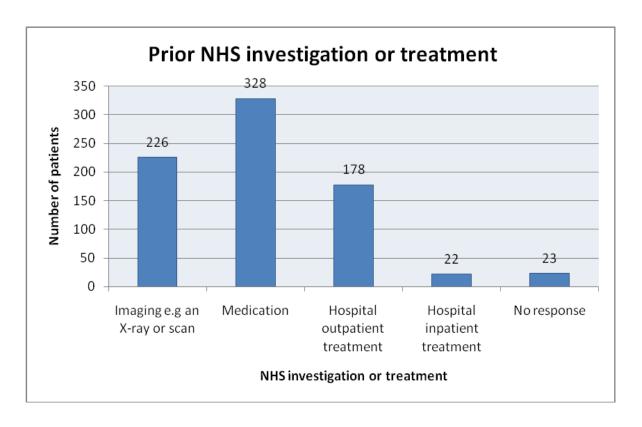
Almost one-third of patients (29%) had received NHS treatment or investigations prior to attending the osteopath for this episode.

Table 14.

Prior NHS treatment or investigation	Number	Percentage
Yes	479	29
No	1135	70
No response	16	1
Total	1630	100

The type of NHS treatment received usually was either imaging investigations or treatment in the form of medication or out-patient treatment. A small number (1.3%) had received hospital inpatient treatment prior to attending an osteopath.

Figure 11.

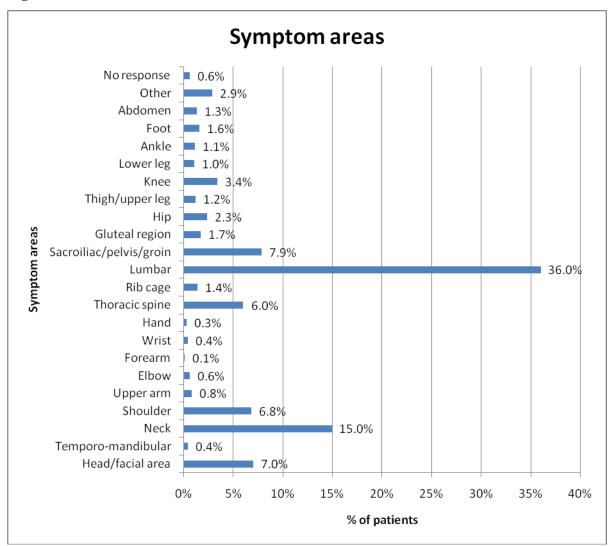


PART 2: PRESENTING SYMPTOMS

2.1 Symptom Areas

Space was provided on the standardised data collection form to record up to three symptom areas in total for each patient. This graph shows the distribution for the first symptom area. The most common first symptom was the lumbar spine (36%), followed by cervical spine (15%), sacroiliac/pelvis, head/ face (7%), shoulder (6.8%), and thoracic spine (6%). Head pain is thought to comprise mainly headache symptoms.

Figure 12.



Symptom areas described in the category "other" include a wide range of symptoms reflecting the age of the patient. In children, these included feeding disorders, sleep disturbance, colic symptoms, and continuous crying. In adults, the range of symptoms included generalised muscle pain, dizziness, balance disorders, and ear, nose and throat conditions.

Table 15.

First symptom areas	Number	Percentage
Head/facial area	114	7.0
Temporo-mandibular	7	0.4
Neck	244	15.0
Shoulder	111	6.8
Upper arm	13	0.8
Elbow	10	0.6
Forearm	2	0.1
Wrist	7	0.4
Hand	5	0.3
Thoracic spine	98	6.0
Rib cage	23	1.4
Lumbar	587	36.0
Sacroiliac/pelvis/groin	128	7.9
Gluteal region	28	1.7
Hip	38	2.3
Thigh/upper leg	20	1.2
Knee	55	3.4
Lower leg	17	1.0
Ankle	18	1.1
Foot	26	1.6
Abdomen	22	1.3
Other	47	2.9
No response	10	0.6
Total	1630	100

In addition to profiling the symptom areas for the total sample of patients, the profile for babies (0-12 months) and for children (1-14 years) was extracted and analysed separately. This analysis is presented in Appendix 5.

2.2 Duration of current symptoms for this episode

The duration of symptoms at presentaion was recorded. In 51% of patients, their symptoms had been present for 6 weeks or less (acute symptoms); 15% of patients were sub-acute with symptoms lasting for 7-12 weeks duration, and 32% had chronic symptoms of 13 weeks or more. When compared to the patient-reported duration of symptoms, the practitioners were tending to record slightly longer duration than the patients.

Table 16.

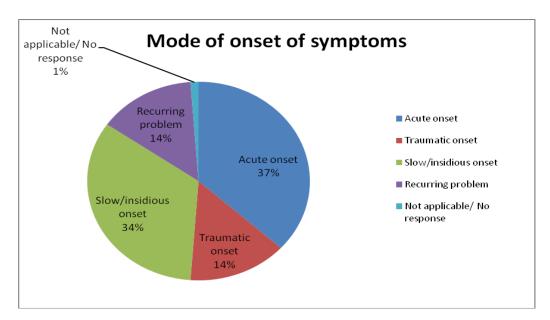
Duration of current symptoms	Numbers	Percentage
Acute(< 6 weeks)	834	51
Subacute (7-12 weeks)	236	15
Chronic (13 weeks or more)	529	32
Check up only	1	0
No response	30	2
Total	1630	100

2.3 Mode of onset of symptoms

The mode of onset of symptoms ranged from acute to slow and insidious, with acute onset accounting for 37% of cases.

When acute onset is taken together with traumatic onset, these account for 51% of patients in the sample which is consistent with the figures in Table 16.

Figure 13.



2.4 Number of previous episodes

Almost half the patients were experiencing a first episode of a problem. These data are consistent with that in Table 10 where 649 patients reported they were new to osteopathy.

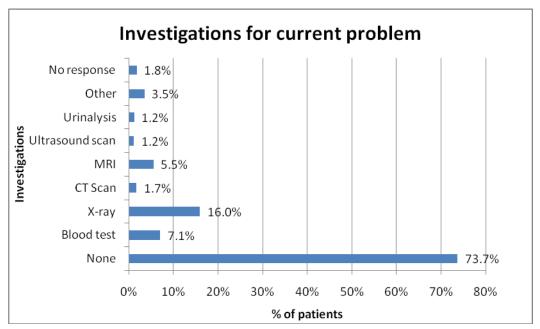
Table 17.

Number of previous episodes	Number	Percentage
Yes, first time onset	701	43.0
Second episode	235	14.4
Third episode	152	9.3
Fourth or more episodes	512	31.4
No response	22	1.3
Not applicable	6	0.4
Unclear response*	2	0.1
Total	1630	100

2.5 Investigations undertaken for this current problem

This question was intended to refer to investigations undertaken by the osteopath either within the practice or ordered from other agencies, but caution is needed as the wording did not specify this. The figures may therefore include referrals back to the GP for investigation to be carried out, because the question did not specify that these were private investigations.

Figure 14.



Such investigations were fairly unusual, reported for 24.5% of patients in total. The use of X- Rays were the most common investigation, recorded for 16% of the sample; some patients had multiple investigations recorded.

Table 18.

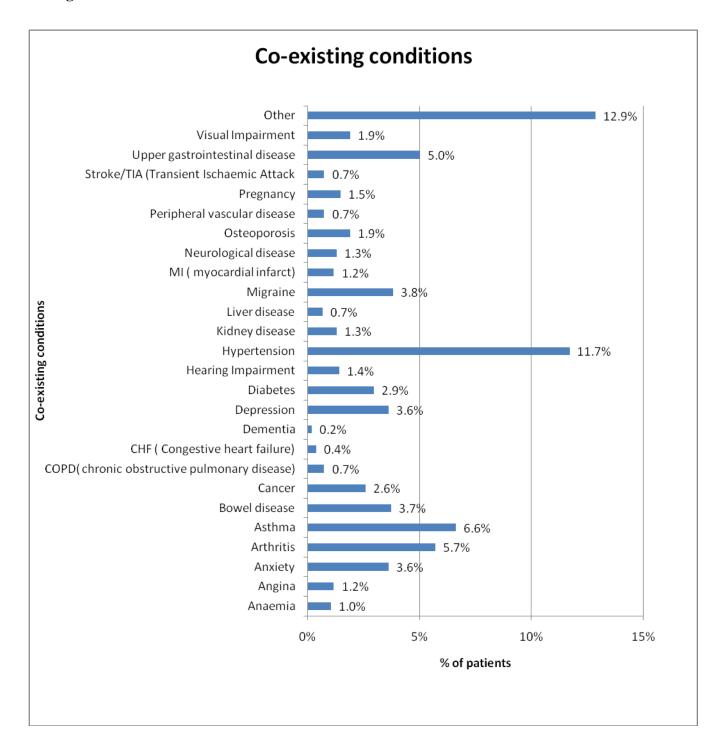
Investigations for current problem	Number	Percentage
None	1202	73.7
Blood test	115	7.1
X-ray	260	16.0
CT Scan	28	1.7
MRI	90	5.5
Ultrasound scan	19	1.2
Urinalysis	20	1.2
Other	57	3.5
No response	29	1.8
Total	1820	111.7

2.6 Current co-existing conditions diagnosed by a medical practitioner

The osteopaths were asked to report co-morbidities, that is, co-existing conditions that had been diagnosed by a medical practitioner. The total number of co-morbid conditions recorded was 1277. For 357 patients, the practitioner recorded "none", and for 476 patients the questions was unanswered, hence the status is uncertain. As this is important data, modification of the question is indicated.

The most common co-morbidity was hypertension, followed by asthma, arthritis, upper gastrointestinal (GI) disease, migraine, bowel disease, anxiety and depression. If anxiety and depression are considered together as mental health problems, these are almost as common as hypertension. Comorbities included under "other" contained 41 separate conditions ranging from musculoskeletal (spinal stenosis, fibromyalgia, ankylosing spondylitis, and restless leg syndrome), endocrine (hypothyroidism and hypopituitarism), connective tissue disorders (Ehlers-Danlos syndrome), and immune disorders (arteritis, discoid lupus and polymyalgia rheumatica).

Figure 15.



PART 3: PATIENT MANAGEMENT AND TREATMENT

3.1 Patient suitability for osteopathic treatment

Practitioners recorded that 97 % of patients in the sample were suitable for osteopathic treatment and 2% of the patients were unsuitable for osteopathic treatment. A total of 99% of practitioners responded to this question. However the wording of this question appeared to confuse a few percent of practitioners who recorded treatments given to patients they had coded as unsuitable, or vice versa.

Table 19.

Patient suitability for osteopathic treatment	Number	Percentage
Yes	1577	97
No	39	2
Yes but not for HVLA thrust	1	0.001
No response	13	0.8
Total	1630	100

3.2 Treatment given to the patient at first appointment

The types of treatments given were varied and complex. Figure 16 shows the total number of types of treatment given to the 1630 patients. This was a multi-choice question and the total number of treatments recorded was large, as shown by the table overleaf, representing a mean value of combinations of 3.5 types of treatment per patient.

The most common types of treatment were soft tissue and articulation given to 78% and 73% patients respectively; high velocity low amplitude (HVLA) thrust/spinal manipulation, education, cranial osteopathy, and exercises were also common interventions. It should be noted that 38 patients (2.3%) received no treatment.

The use of HVLA thrust/spinal manipulation techniques varied considerably by age as shown in the Figure 17. The use of HVLA in the older patients was surprising. It may be that the terminology was being used rather loosely by the participants to embrace a wide range of techniques employing directed forces even if of low velocity and low force. Further research would be needed to elucidate this.

Figure 16.

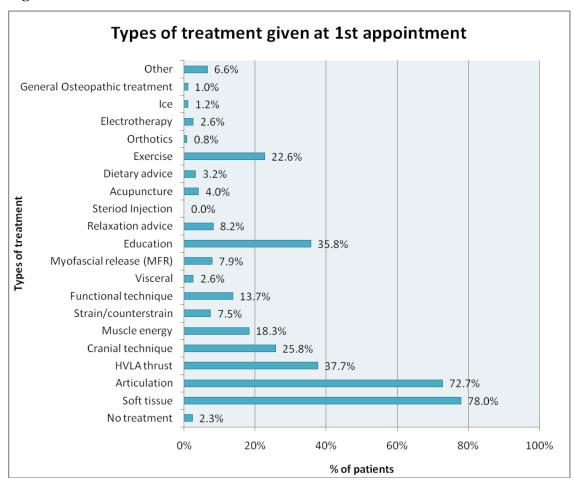


Figure 17.

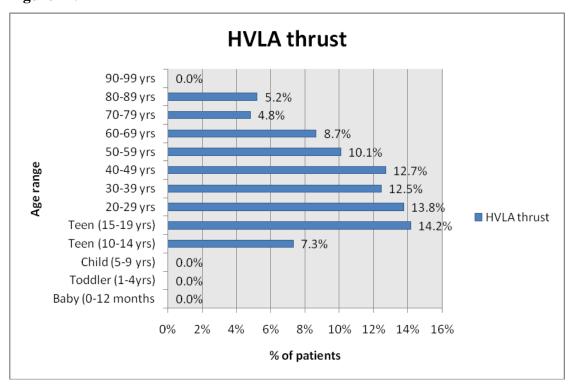


Table 20.

Types of treatment given at 1st appointment`	Number	Percentage
No treatment	38	2.3
Soft tissue	1272	78.0
Articulation	1185	72.7
HVLA thrust/spinal manipulation	615	37.7
Cranial osteopathy	420	25.8
Muscle energy	299	18.3
Strain/counterstrain	122	7.5
Functional technique	224	13.7
Visceral	42	2.6
Myofascial release (MFR)	128	7.9
Education	583	35.8
Relaxation advice	133	8.2
Steroid injection	0	0.0
Acupuncture	65	4.0
Dietary advice	52	3.2
Exercise	369	22.6
Orthotics	13	0.8
Electrotherapy	42	2.6
Ice	19	1.2
"General Osteopathic Treatment"	17	1.0
Other	107	6.6
Total	5745	352

A total of 41 additional interventions were recorded in free text in the "other" category. These included applied kinesiology, harmonics, cryotherapy, "dry needling", pandiculation, lymphatic drainage, Spencer technique, traction, balanced ligamentous tension technique, inhibition, and strapping.

3.3 Informed consent obtained for particular techniques

Informed consent was obtained from 57% of patients, and a wide variety of specific techniques were recorded by the practitioners.

Table 21.

Informed Consent	Number	Percentage
Yes	933	57
No	436	27
Not applicable	206	13
No response	55	3
Total	1630	100

3.4 Pre-consent information about examination and treatment

Pre-consent information usually was given orally (70.8%); written information was provided by 20.3% of practitioners, and 10.9% of practitioners used both forms of information. There was a high non- response rate of 19.2% to this question.

Table 22.

Pre-consent information	Number	Percentage
Orally	1154	70.8
Written form	331	20.3
Other	10	0.6
No response	313	19.2
Total	1808	110.9

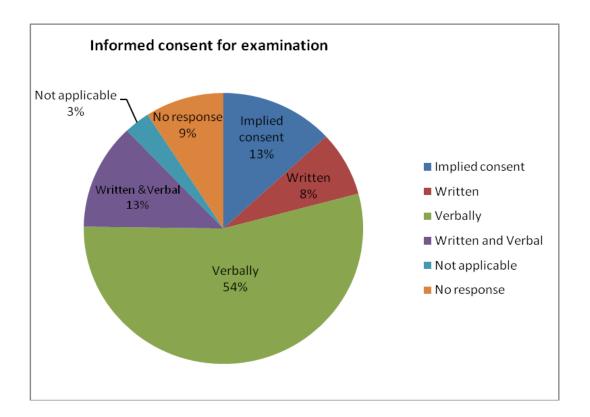
3.5 Informed consent for examination

Informed consent for examination usually was gained verbally or implied. A total of 20.3% of osteopaths used written consent for this part of the consultation, with most gaining verbal consent too. The non-response rate to this question was 9.1%.

Table 23.

Informed consent for examination	Number	Percentage
Implied consent	214	13.1
Written	126	7.7
Verbally	886	54.4
Written and Verbal	206	12.6
Not applicable	49	3.0
No response	149	9.1
Total	1630	100

Figure 18.



3.6 Specific areas of education and advice to inform patients about their condition

The majority of patients received all of the following types of information described in Table 24, particularly anatomical information, advice concerning physical activity and anticipated response to treatment.

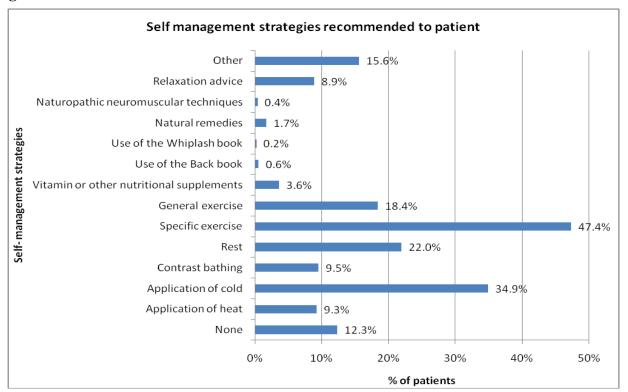
Table 24.

Education and advice given to patients	Numbers	Percentage
Anatomical information	1196	73
Possible risk factors associated with a recurrence		
of symptoms	743	46
Anticipated response to treatment	1375	84
Anticipated number of treatments	930	57
Advice concerning physical activity	1147	70
Total	5391	330

3.7 Recommended self-management strategies

Self management strategies were suggested to most patients, with only 12.3% receiving no advice in this respect.

Figure 19.



As a multi-choice question, Table 25 shows that the mean number of strategies suggested to patients for self-management was 1.85.

A variety of self-management strategies were included also in the category of "other". These included advice on posture; moving and handling; the use of complementary medication e.g. analgesia, non-steroidal anti-inflammatory drugs or topical applications; the need for orthotic assessment, the use of postural supports, and breathing exercises.

Table 25.

Self management strategies	Number	Percentage
None	201	12.3
Application of heat	151	9.3
Application of cold	569	34.9
Contrast bathing	155	9.5
Rest	358	22.0
Specific exercise	772	47.4
General exercise	300	18.4
Vitamin or other nutritional supplements	59	3.6
Use of the Back book	9	0.6
Use of the Whiplash book	4	0.2
Natural remedies	28	1.7
Naturopathic neuromuscular techniques	7	0.4
Relaxation advice	145	8.9
Other	254	15.6
Total	3012	185

3.8 Discussion of the possible causes of the symptoms

A total of 97% of patients were included in discussions relating to the possible cause of their presenting symptoms.

Table 26.

Discussion of possible causes of symptoms	Number	Percentage
Yes	1588	97.4
No	14	0.85
No response	28	1.7
Total	1630	100

3.9 Information discussed concerning possible risks and side-effects

The majority of patients received this type of information, particularly for side-effects (79%), with somewhat fewer receiving information concerning risks (63%).

Information concerning possible risks and side-effects 90% 79% 80% 70% 63% 60% % of patients 50% ■ Possible Risks 40% 28% ■ Possible Side-effects 30% 20% 14% 9% 7% 10% 0% Yes No No Response

Figure 20.

3.10 Responsibility for payment

A total of 89% of patients reported they were self-funded. The remaining responses to the question indicate that only 9% of osteopathic patients are funded by outside sources.

Table 27.

Responsibility for payment for treatment	Number	Percentage
Self	1453	89
Insurance company	107	6.6
Employer/own company	9	0.6
Referral by NHS	9	0.6
Other	20	1.2
No response	32	2.0
Total	1630	100

3.11 Pending insurance claim or litigation

Only 2% of patients reported that they had an insurance case or litigation claim pending. A total of 95% did not have any insurance case or litigation claim pending.

3.12 Time allocated for first appointment

The duration of the first consultation ranged from 10 minutes to 90 minutes, but was not continuously distributed. The three most popular times were 30 minutes, 40-45minutes, or 60 minutes. A graph comparing the distributions for the lengths of the first and second consultations is presented in Figure 24.

3.13 Complications of treatment within 24 – 48 hours after 1st appointment

The data collection form recorded several simple patient-reported outcomes. The first was the side-effects of the first treatment. The majority (59.4%) of patients reported no side-effects, but increased stiffness or pain was relatively common (18% and 14.6% respectively). A few experienced fatigue (6.6%), while headache (2.3%), dizziness (1.5%), or nausea (0.7%) were uncommon.

One serious adverse event was recorded by a practitioner who added free text describing this as an "Emotional Response"; this was considered unlikely to represent an event which meets the usual definition of a serious adverse event. Table 28 shows that 12.6% of patients had more than one reaction to treatment.

Table 28.

Complications after 1 st treatment	Number	Percentage
None	969	59.4
Increased pain	238	14.6
Increased stiffness	293	18.0
Dizziness	24	1.5
Nausea	12	0.7
Headache	38	2.3

Fatigue		107	6.6
Serious adverse event		1	0.1
No response		121	7.4
Other		8	0.5
Complications not known		7	0.4
Not applicable		17	1.0
	Total	1835	112.6

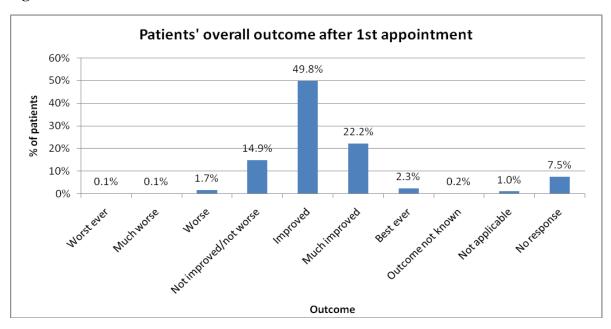
The additional complications of treatment described as "other" were reported in five individual patients who recorded increased crying, bruising, slight discomfort, soreness, and the development of flu-type symptoms.

3.14 Patients' overall outcome after the first appointment

At the end of the course of initial treatment for this episode, the overall outcome for each patient was reported. The simple measure used is not a validated outcome measure and further work, based on significantly larger numbers of presentations, is required to validate this data.

The most common outcome reported was "improved" (50%); 22% were "much improved", and 2.3% were best ever. A total of 74.3% improved after their first treatment. A small proportion (15%) was "not improved but not worse", and 1.7% was worse. Four patients (0.2%) reported being much worse or worst ever, after the first treatment.

Figure 21.



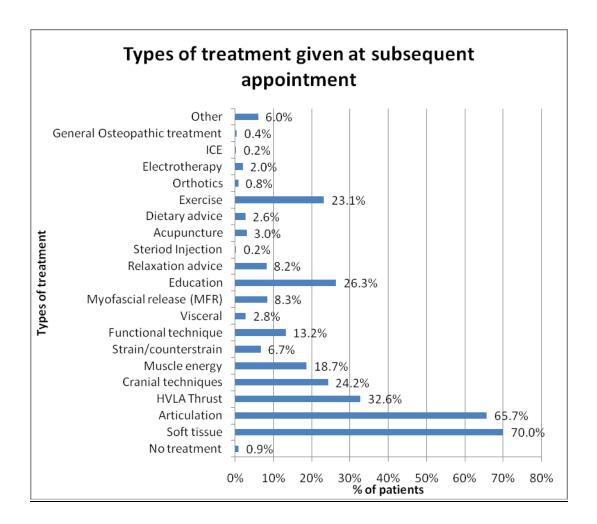
PART 4: SECOND AND SUBSEQUENT APPOINTMENTS

The intention of this part of the data collection form was to summarise the osteopathic care provided during both second and subsequent treatments. However, in practice it may be a record of the second treatment rather than a summary of all subsequent treatments in the course. An amendment to the wording of the definitive standardised data collection tool is indicated.

4.1 Types of treatments given at subsequent appointments

The types of treatments provided at the second and subsequent appointments continued to be varied and complex. They are shown in Figure 22.

Figure 22.



4.2 Informed consent obtained for specific techniques at subsequent appointments

Informed consent was obtained from 42% of patients for second and subsequent appointments.

Table 29.

Informed consent	Number	Percentage
Yes	677	42
No	588	36
Not applicable	39	2
No response	326	20
Total	1630	100

4.3 Type of pre-consent information given about examination and treatment at subsequent appointments

Pre-consent information about examination and treatment continues to be provided orally at second and subsequent treatments (59.8%) compared with other forms of information.

Table 30.

Pre-consent information	Number	Percentage
Orally	975	59.8
Written form	166	10.2
Other	13	0.8
No response	563	34.5
Total	1717	105.3

4.4 How informed consent was obtained for examination at subsequent appointments

Informed consent for examination was gained verbally at second and subsequent treatments in 45% of cases, and with implied consent in 20% of cases. The non-response for this question (22%) was higher than for the first treatment (9.1%)

Table 31.

Informed consent	Number	Percentage
Implied consent	320	20
Written	40	2
Verbally	731	45
Written and verbally	106	6
N/A	80	5
No response	353	22
Total	1630	100

4.5 Specific education and advice to inform patients about their condition given at the second and subsequent appointments

Table 32.

Education and advice given to patients during		
second and subsequent treatments	Number	Percentage
Anatomical Information	806	49
Possible risk factors	603	37
Anticipated response to treatment	973	60
Anticipated number of treatments	734	45
Advice concerning physical activity	1002	61
Total	4118	253

4.6 Self-management strategies recommended to the patient at subsequent appointments

A range of self-management strategies were recommended at second and subsequent treatments. They are described in Table 33 overleaf.

Table 33.

Self-management strategies	Number	Percentage
None	152	9.3
Application of heat	129	7.9
Application of cold	411	25.2
Contrast bathing	122	7.5
Rest	234	14.4
Specific exercise	830	50.9
General exercise	304	18.7
Vitamin or other nutritional		
supplements	63	3.9
Use of the Back book	6	0.4
Use of the whiplash book	2	0.1
Natural remedies	24	1.5
Naturopathic neuromuscular		
techniques	3	0.2
Relaxation advice	143	8.8
Other	155	9.5
Total	2578	158

4.7 Discussion of possible causes of symptoms at subsequent appointments

Practitioners were asked to record whether they discussed possible causes of symptoms at second and subsequent appointments.

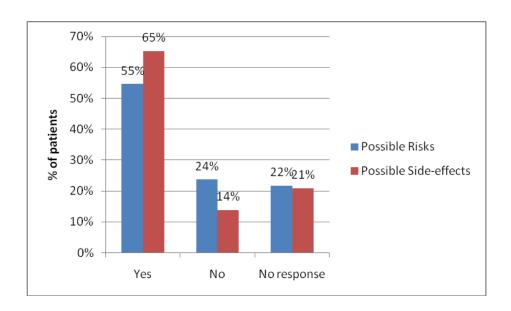
Table 34.

Discussion of possible causes	Number	Percentage
Yes	1329	82
No	48	3
No response	253	15
Total	1630	100

4.8 Information discussed concerning the possible risks and side effects at subsequent appointments

Information concerning risks and side-effects of treatment was provided at subsequent appointments. Once again, as for the first appointment, more patients receive information on side-effects (65%) than for risks (55%).

Figure 23.



4.9 Responsibility for payment for subsequent treatment(s)

A total of 76.6% of patients were self-funding for second and subsequent treatments. The remaining 8.1% of respondents were funded by other sources.

Table 35.

Responsibility for payment	Numbers	Percentage
Self	1249	76.6
Insurance company	101	6.2
Employer/own company	11	0.7
Referral by NHS	10	0.6
Other	10	0.6
No response	249	15.3
Total	1630	100

4.10 Pending insurance or litigation claims at subsequent appointments

Only 2% of patients reported they had an insurance claim or litigation ongoing at their subsequent appointments.

Table 36.

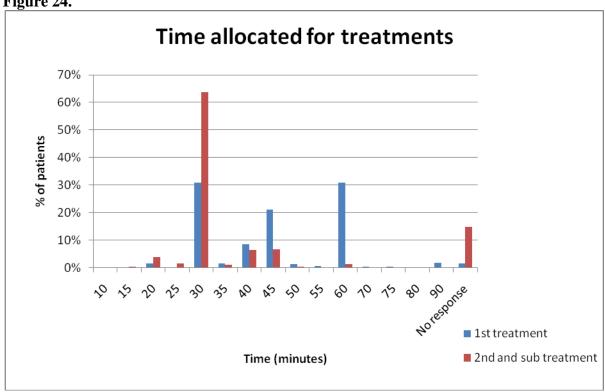
Insurance case pending	Number	Percentage
Yes	36	2
No	1339	82
No response	255	16
Total	1630	100

4.11 Time allocated for follow up appointments

The time allocated for the second and subsequent treatments ranged from 10 minutes to 60 minutes, with 30 minutes allocated for 64% of patients.

Figure 24 compares the time allocated for the first and subsequent appointments.

Figure 24.



PART 5: FINAL OUTCOME(S) OF CARE

5.1 Total number of treatments for this episode

There were 49 patients with no treatment data. For the remainder, the number of treatments ranged from 1 to 17 with a mean of 3.45 (SD +/- 2.04). There was a slight but non-significant difference in the number of treatments given to the 631 patients discharged after the course of treatment (mean =3.03 treatments) compared to the 631 patients recommended to return for episodic care after their initial course of treatment (mean =3.96 treatments).

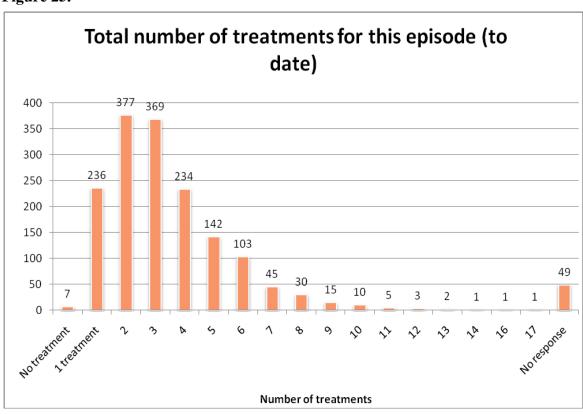


Figure 25.

5.2 Complications after further treatment

The wording of this question was a little ambiguous, and could have been interpreted as either continuation of initial reactions, or reactions present at last treatment, or reactions to subsequent treatments. Hence the response cannot be considered to be as accurate as the first report of complications in Part 3.

Table 37.

Complications after further treatment	Numbers	Percentage
None	1260	77.3
Increased pain	61	3.7
Increased stiffness	71	4.4
Dizziness	5	0.3
Nausea	4	0.2
Headache	12	0.7
Fatigue	44	2.7
Serious adverse event	0	0
No response	68	4.2
Other	4	0.2
Complications not known	12	0.7
Not applicable	130	8.0
Total	1617	103

Complications included within the "other" category included tearfulness, fatigue followed by increased energy, and soreness for two days after treatment. From the free text responses recorded, these responses indicate reactions after the second treatment and not lasting complications from the first appointment.

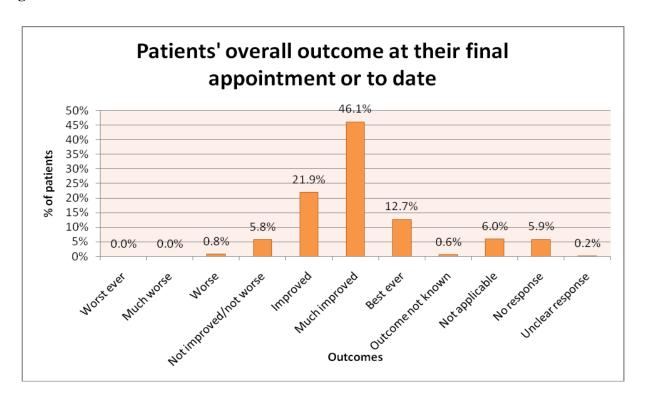
5.3 Patients' overall outcome at their final appointment

At the end of the course of initial treatment for the episode (or the last treatment before submitting the form), the overall outcome was reported. All but 33 patients completed their initial course by the end of follow-up.

The outcomes below represent reported improvement compared with the outcomes of the first treatment; the most common outcome was "much improved" (46%), and 13% were "best ever". When taken together with the 22% of patients reporting "improved", a total of 80.7% of the patients in this sample considered they gained some degree of improvement following their course of treatment.

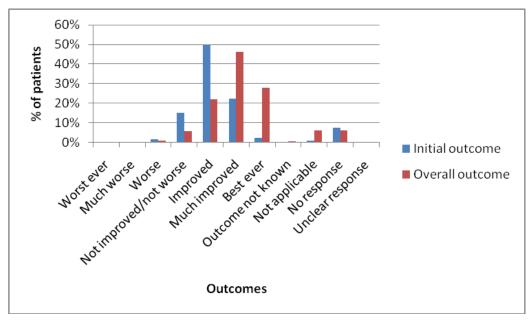
A small proportion, 6%, was not improved but not worse, and 1% was worse. No patients reported being much worse or worst ever at the end of their treatment period.

Figure 26.



The outcomes were thought likely to vary according to the duration of symptoms at presentation.

Figure 27.



The graph in Figure 28 shows the final outcomes in patients grouped as acute, sub-acute or chronic at presentation (as given in section 2.2 of this chapter). While a higher percentage of the acute patients are much improved, the percentage in the three positive outcome categories

(improved, much improved, best ever) was 84% for both acute and sub-acute; for chronic patients it was 76%. While those patients with unknown duration of symptoms appear to do worse at 53% improved, almost 40% of this small group had unknown outcome or not applicable, suggesting they were non-standard presentations.

60 50 40 % of patients 30 acute 20 ■ sub-acute 10 ■ chronic 0 ■ Duration not known Not improved hot worse Muchimproved MOTKROWN Improved best ever Treatment outcomes

Figure 28.

5.4 Contact with a patient's GP during the course of treatment

GP contact was made for a total of 10.1% of patients, for a variety of reasons as described in Table 38.

Table 38.

Contact with a patient's GP during the course of		
treatment	Number	Percentage
Yes since patient was referred to practice by GP	57	3.5
Yes since GP had requested information	4	0.2
Yes to request further information or investigation	63	3.9
Yes for referral for other treatment	40	2.5
No the patient's GP was not contacted	1307	80.2
Other	6	0.4
No response	153	9.4
Total	1630	100

5.5 The number of treatments before the patient was able to return to work

Only a small number of patients (10.4%) were off work at their first presentation. The small number of patients who were absent from work due to their symptoms were able to return to work after one treatment in 5.3% of cases or two treatment in 3.1% of cases.

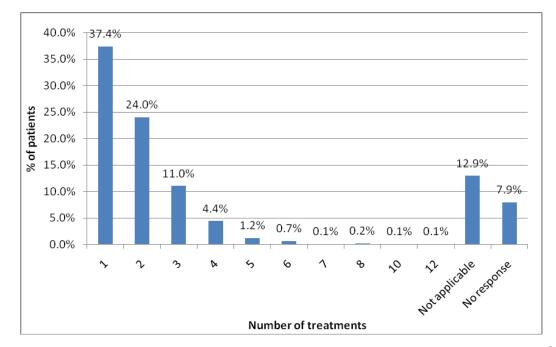
Table 39.

Number of Treatments	Number	Percentage
1	86	5.3
2	51	3.1
3	18	1.1
4	11	0.7
5	2	0.1
10	1	0.1
11	1	0.1
Not applicable	1345	82.5
No response	115	7.1
Total	1630	100

5.6 Number of treatments before the patient achieved relief of immediate symptoms

While the results look impressive, "immediate relief" of symptoms is somewhat ambiguous, as it can be interpreted as total or partial relief, which may explain the high non-response rate. This question will require more precise wording for future use.

Figure 29.



5.7 The end result of the consultation period

At the end of the follow- up period, all but 33 patients (2%) had completed their first course of treatment for their new episode of symptoms. Practitioners were asked to report what the end result of the consultation period was. The two most common results were that the patient was discharged (39%) or recommended to return for episodic care (39%). Episodic care is an option that patients may choose, particularly if they have recurrent problems, because it provides ongoing contact for advice and support. A total of 8% of patients were referred on to another practitioner, or in 2% of cases were referred for investigation while remaining under the care of the practice.

This question was not well completed with a 9.2% non-response rate. Further dialogue with practitioners may be needed to improve completion of this important item.

Figure 30.

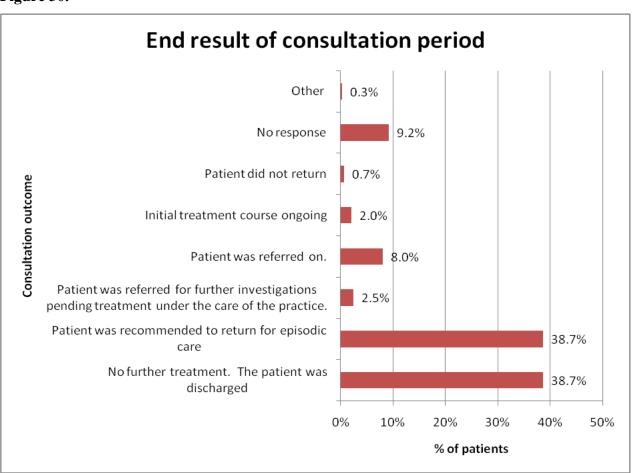


Table 40.

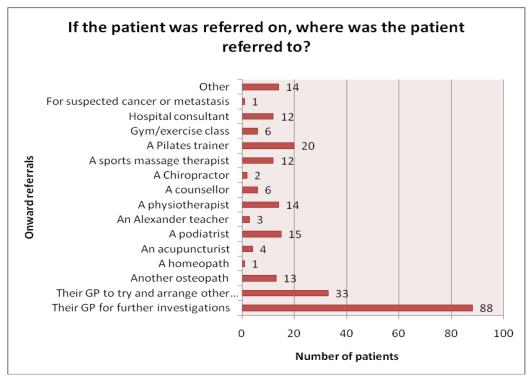
End result of the consultation period	Number	Percentage
No further treatment. The patient was discharged	630	38.7
The patient was recommended to return for episodic care	630	38.7
The patient was referred for further investigations		
pending treatment under the care of the practice.	40	2.5
The patient was referred on	131	8.0
Initial course of treatment is ongoing	33	2.0%
The patient did not return	11	0.7%
No response	150	9.2%
Other	5	0.3%
Total	1630	100%

5.8 Onward referral from the practice

Participants were asked to record where they referred patients. A total of 244 patients were recorded as being referred on by their practitioner to other support or care. This represents onward referral at the end of the treatment course together with referral for adjuvant or parallel treatment with another practitioner. The wide range of other practitioners that osteopaths refer to may reflect tailoring of recommendations to the individual patient's needs and preferences.

The majority of onward referrals are to a patient's GP for further investigation, reflecting the role of the osteopaths integrated within the wider healthcare system. One further patient was recorded as being referred on with suspected cancer, an important role that osteopaths have reported anecdotally in the past. The entire range of referral destinations is shown in Figure 31.

Figure 31.



PERFORMANCE OF THE SDC TOOL

The data collection project using the SDC tool generated a substantial amount of high quality data which met the objectives of characterising practice, setting standards for audit activities, and providing information relevant to all stakeholders in NCOR and to the profession at large.

The quality of the data was a credit to the participating osteopaths and their patients. The SDC tool developed with and by the profession performed extremely well: it was clear and easy to complete and generated meaningful data. In the project, not only was practitioner compliance high with 86% of those volunteering actually collecting data, but also they completed their forms thoroughly and validly. The number of patients per practitioner was 4.7, somewhat lower than hoped for. This may be due to insufficient eligible patients with new episodes, the fairly short time window for recruitment, or the additional workload of participating, within a busy schedule.

It is possible that recruitment was biased in terms of patient selection. A very undesirable bias would be one in favour of patients with good outcomes: it is not impossible that a practitioner could select patients more likely to respond well to treatment, or omit to submit patients that did not respond well. Some form of checking may be needed in future data collection projects. Some osteopaths have reported that practical difficulties arose in patient recruitment since some patients were in considerable pain and, understandably, did not want the added burden of having to complete a form prior to their consultation. Other reports included that patients were simply short of time either attending in their lunch time or on the way to other appointments. This interrupted the consecutive flow of data collection.

There were a few questions where the wording was reported to be ambiguous or unclear to some practitioners. These questions will be re-worded on version 2.0 of the data collection form, aiming to streamline the form and make the meaning clearer.

In the following chapters, an indication is given concerning how the analysed data could be utilised to inform the profession, to develop further valid audit activities, and to develop meaningful research questions.

9. **DISCUSSION**

9.1 Introduction

In this chapter, the outcomes of the project as a whole are discussed in terms of building research capacity, the profile of osteopathic care, and implications for the profession. The messages for the profession that emerged from the data are threaded through the sequence of the information presented in Chapter 8, and will now be drawn together. The Figures and Tables mentioned refer to those presented in the Chapter 8.

9.2 Building research capacity in osteopathy

Research capacity within osteopathy has been developed through this project in a number of ways. The development of nine regional NCOR research hubs has drawn research-interested practitioners into training, discussion and active participation in the design and conduct of projects at regional level, and the SDC project at national level. The design and development of the SDC has also involved a Steering Group of other individuals and organisations - the British Osteopathic Association, the General Osteopathic Council, and practitioners with involved in the training and education within the profession. They have had experience of working together, involvement in the development of research capacity through networks and of developing a dataset for the SDC tool through a nominal group methodology.

The concept of a research network as a way of developing research capacity has proved fruitful; considerable valuable experience has been gained, and lessons have been learnt about sustaining a research network within a profession as small as osteopathy – this remains challenging, and is still evolving.

This data collection project has provided the most detailed cross-sectional profile of osteopathic care in the UK to date. The earlier snapshot survey in 2001 by the GOsC collected sociodemographic details of osteopaths and the patients they saw on a single day. In contrast, the patients described by this survey were homogeneous; they were all commencing treatment for a new episode- and the data about care is much more detailed, with additional follow-up of patients providing some outcome data.

The involvement of the profession in the design of the dataset clearly paid dividends: a total of 9.4% of the 4198 osteopaths registered with the GOsC in 2009 volunteered to participate in the project¹. A total of 87% of these osteopaths actively collected data. High quality data were collected for 1630 patient episodes, a sufficient sample size for statistical analysis.

The quality of the data collected in the project was good because the dataset was developed and thoroughly piloted by the osteopaths in the hubs, prior to the national pilot data collection period. The final SDC tool functioned well, with high response rates to most questions, few additional comments, and little evidence of misinterpretation.

Feedback from participating osteopaths, and from the analysis of the data, has lead to further review and slight modification of the form as shown in Appendix 6. The SDC was not well suited for use with infants and small children, due to the difference in children's presenting symptoms compared with adults: many of the questions were not applicable. However, the data gathered in this project will inform the development of a special version of the SDC tool for infants and children in the future.

9.3 Profile of osteopathic care

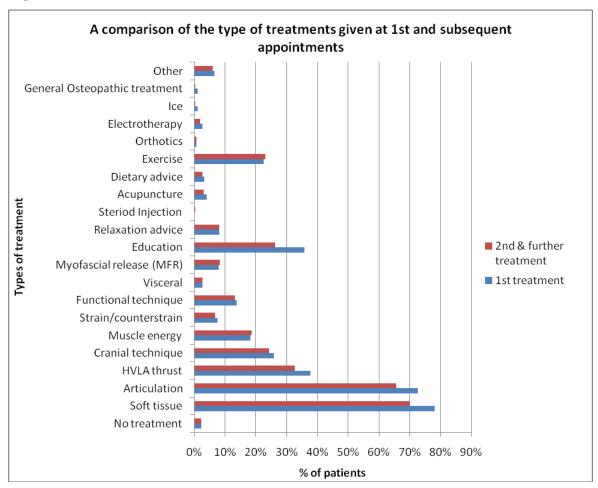
The results of this project supported the view that osteopaths predominantly treat musculoskeletal conditions. Low back problems (lumbar spine and pelvic problems) comprised over 40% of presenting symptoms, with cervical spine, shoulder and thoracic spine comprising a further 28% of the conditions treated by osteopaths.

The evidence base for osteopathic care remains strongest for musculoskeletal conditions. However, the range of presenting symptoms is diverse, including headache (7%), conditions suffered by infants and children (8.5%), with considerable clinically diagnosed co-morbidity (13%), and differing modes of onset including trauma. Although the dataset includes a significant number of presentations from infants and children, the evidence base for this area of practice remains small although anecdotal evidence for this area of practice is stronger.

The wide range in the types of treatment delivered (Figures 16 and 22) shows the diversity and flexibility of osteopathy. This diversity of care has the advantage of offering patients choice, but can also be an unwelcome source of confusion for members of the public.

However, almost all patients received soft tissue treatment and joint articulation. The use of high velocity low amplitude (HVLA/spinal manipulation) techniques, education, cranial osteopathy and exercises was also common. The treatment approaches appear to vary only slightly between first and subsequent visits as shown in Figure 32 below.





The wide scope of osteopathic practice involves dealing with an extensive range of presenting problems and using a variety of techniques for treatment, patient education and self-management. This demonstrates why it is essential that osteopaths continue to receive a high level of training including anatomy, physiology and pathology to underpin their knowledge of such presenting problems and the rationale and evidence for using appropriate management interventions.

The data provided evidence that osteopaths were providing a patient-centred service. The waiting times for treatment were short; 17% were seen on the same day, and 38% within 48 hours. A total of 84% of patients were seen within a week of their first contact with the practice (Figure 10). The patients received long consultations, normally 30-60 minutes for the first appointment, and 30-45

minutes at subsequent appointments. The majority of consultations included education (73%), information-giving (84%) (Tables 24 and 26; Figure 20) including advice on self-management strategies (88%), with many patients being given more than one strategy to try.

Co-morbidities, diagnosed by a medical practitioner, were recorded in 13% of patients. The most common conditions reported were hypertension (11.7%), mental health problems (anxiety [3.6%] and depression [3.6%]), asthma (6.6%), arthritis (5.7%), upper gastrointestinal disease (5%), migraine (3.8%), and bowel disease (3.7%). It seems that some targeted training of osteopaths in the recognition and appropriate advice/referral for hypertension and mental health problems could be priority areas for improving the quality of care.

9.4 Outcomes of osteopathic care

A total of 39% of patients had a satisfactory resolution of their symptoms and were discharged (Figure 30). A similar proportion (39%) of patients took the opportunity to return for "episodic care" - treatment delivered at intervals and often called maintenance care. The number of treatments until discharge or the end of the initial course of treatment represents a measure of outcome and is useful for evaluating cost-benefit: the number of treatments ranged from 1 to 17 with a mean of 3.45 treatments to discharge (Figure 25). There is scant data on the cost per consultation in the UK, but in most geographical areas is thought to be in the range £25-£50, making a course of treatment on average £86-£172. The mean of 3.45 treatments per course was unexpectedly low, and may be an artefact due to the follow-up period being 2 months - which only allowed for 4-5 fortnightly appointments. However the fact that relief of symptoms was rapid (Figure 29) supports the validity of the data.

The simple patient-reported outcome scale recorded 74.3% as being improved, much improved or "best ever" after the first treatment (Figure 21), rising to 80.7% after the final treatment (Figure 26). The results suggest that most patients experience some degree of relief following the first treatment, and further improvement after a short course of treatment. However, these figures do have to be *interpreted with some caution* because there was potential for under-reporting of unsuccessful patient-episodes, and output from the project is pilot data. The project will have to be replicated using a larger randomly selected sample using the SDC tool in combination with a validated and nationally recognised outcome measure to confirm the findings of the project.

The fact that outcomes among those with sub-acute and chronic symptoms were almost as good as those with acute symptoms supports the recommendations of osteopathic care as a first line option in the NICE guidelines for early chronic low back pain¹⁰.

9.5 Patient Safety

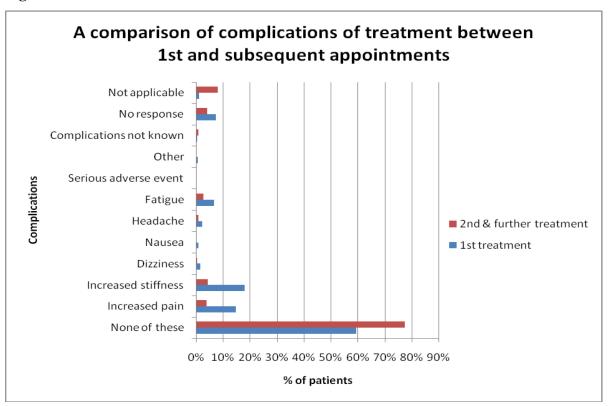
Little information has been documented concerning the short term response to osteopathic treatment. The only published work addressing short term effects and involving only eight osteopaths was undertaken by Cagnie *et al.*, 2004 in Belgium¹³⁹. The data collection tool has provided some information in an area where data are notably lacking.

Reported side-effects were quite common immediately after treatment. A total of 18% of patients reported stiffness, and 14.6% reported increased pain for the first 24 to 48 hours after treatment. A total of 7.4% did not respond; for a further 0.4% the response was not known, and for 1%, the question was not applicable (e.g. patients attending for a consultation only). In 0.5% of patients, additional responses included comments about bruising, slight discomfort and the development of short term flu-like symptoms.

After the second and subsequent treatments, 4.4% of patients reported stiffness and 3.7% reported increased pain (Table 37). Additional side-effects that were reported were minor and transient including fatigue (2.7%), dizziness (0.3%), and nausea (0.2%).

A comparison of the reactions after the first treatment and after second and subsequent treatments showed that increased pain, increased stiffness and fatigue were the most frequently reported side effects after treatment but these reduced after the second and subsequent treatments.

Figure 33.



These figures are comparable to those reported in the literature ^{139,156,157}. No serious adverse events, as described in the literature, were reported ^{158,159}.

9.6 Equality and diversity in access to care

The patient profile information (Table 1) showed that osteopathy was accessed by slightly more women (56%) than men (43%). While the age distribution of patients (Figure 3) showed that people of all ages from birth to octogenarians used osteopathy. It also showed that users were concentrated in those of working age; the peak in the distribution spanning ages 30-59 years, with a mean age of 45 years. In addition, the data showed evidence of the popularity of osteopathic care for infants: of the 91children aged 0-9 years included in the sample of 1630 patients, 64% were infants of 0-12 months old.

The fact that 89% of patients paid for treatment privately and less than 10% of treatments were funded by agencies other than the patient themselves (Table 27), may represent a potential barrier to treatment for those on low incomes. The information about occupation and work status (Figure 5) confirmed that osteopathy was used by people from all backgrounds and types of occupation, but 81% were employed people or retired. Only 6.3% of patients were registered as unemployed currently, suggesting that there may be inequity of access to osteopathic care due to low income.

Parents who do not have discretionary income may be unlikely to be able to access osteopathic care for their infants and children. Where there is a mismatch between the osteopathic patient profile and the profile of the general population, there may be either inequity of access or a lack of appropriate marketing in the under-represented sector of the patient population. For example, the age profile of patients does not resemble the frequency of musculoskeletal problems within the population, and suggests that the elderly may be particularly disadvantaged in accessing osteopathic care.

The ethnic profile of osteopathic patients showed that the vast majority (94%) of patients were white British or white European, and a lower proportion of ethnic minorities compared to the UK population as a whole. A comparison of the ethnic background from the 1630 patients in the pilot sample is compared with data from the 2001 Census¹⁶⁰ in Table 41. It should be stressed that there is a 9 year difference between the Census data and the SDC dataset and this has coincided with a period of recorded immigration into the UK which may change the population percentages to some degree¹⁶¹. Government statistics do, however, show a decline of 9% (52,000) in Long Term International Migration (LTIM) for the period 2008 to 2009¹⁶².

Table 41.

Ethnic group*	Percentage of total	Percentage from
	population	SDC pilot dataset
White	92.1	93.9
Mixed	1.2	1.0
All Asian or Asian British	4.0	3.2
All Black or Black British	2.0	0.6
Chinese	0.4	0.1
Other ethnic groups	0.4	0.2
All minority ethnic groups	7.9	5.1

^{*} Descriptors used are based on those of the Office for National Statistics

The data raises questions about whether patients from ethnic minorities use osteopathy so little because it is funded by the state sector. Lack of use of osteopathic care by ethnic groups may be related to the site of osteopaths' practices, or the health preferences of different groups. Investigation of the reasons for the lack of ethnic diversity would be helpful.

The data on comorbidity confirmed that the general health of the patient sample was good, with recorded co-morbidity in only 13% of the sample (Figure 15). However, this may suggest that the long-term sick are disadvanataged in access to osteopathy.

In summary, the data suggest probable inequity of access to osteopathic care in the very young, the elderly, among ethnic minorities, those on low incomes, and the long-term sick. This evidence is of concern and is likely to be related at least in part to the lack of funding of care from the state sector.

Further work is required to investigate the reasons for an apparent inequity of access; whether this relates to reasons cited earlier, or are practices simply positioned in areas where patients do not represent a national picture in terms of age, ethnicity and disability. Further work is also required concerning the nature of disabilities experienced by patients. The SDC form was intended to provide a snapshot of patients and detailed information about each aspect of healthcare was not possible within the confines of the SDC tool

9.7 Osteopathy in the wider healthcare setting

The data showed that osteopaths interact with orthodox medical and diagnostic services, as well as with other health care providers. Contact with GPs occurred for 10.1% of patients, and diagnostic investigations were recorded for 24% of patients.

A total of 13% of patients were referred by their osteopath to another practitioner. The majority were referred for further investigation(s) or treatment from orthodox medicine, but also to other complementary practitioners or exercise specialists. This showed the degree to which the osteopaths were working as integrated healthcare practitioners, within a wider healthcare arena, and also conforming to the osteopathic Code of Practice which requires osteopaths to work with other healthcare practitioners and refer patients where appropriate. The variety in the routes of referral (Fig 5.8) suggested that patients were offered choice. The data also confirmed anecdotal reports of osteopaths detecting suspected malignancy and referring patients appropriately for further investigation or treatment.

9.8 Cost-effectiveness and NHS resources

A total of 48% of patients had visited their GP prior to visiting the osteopath (Figure 11). In contrast, only 6% had been referred to the osteopath by their GP (Table 6), and only 0.6% of patients were paid for by the NHS (Table 27). The GP was contacted during the course of treatment for 10.1% of patients; in 6.4% of cases this was due to a request for further information or investigation, or a referral requesting other treatment (Table 38).

While the NHS was paying for osteopathic treatment for only 0.6% of patients in the sample, patients reported considerable use of other NHS resources prior to attending the osteopath for their current episode (Figure 11), with 29% of patients having received NHS treatment or undergone investigations, a few of these being hospital in-patient treatments. A total of 48% of patients had visited their GP, with a substantial number having 2, 3, 4 or more visits to their GP.

A small number (6%) of the sample were on an NHS waiting list for treatment (Table 12) and 23% of these had been waiting for NHS treatment for 2 months or longer (Table 13). The pilot data indicate that favourable outcomes were reported by patients, even those with chronic symptoms. This highlights the need for a more systematic enquiry to identify if early referral to an osteopath could contribute to savings to the NHS if patients were treated successfully preventing transition into chronic pain states with its attendant costs to the state. Published audit data from the Plymouth acute service has specifically investigated costs by delivery of successful osteopathic treatment, and savings from prevention of unnecessary consultant referrals and investigations ¹⁶³.

9.9 Sickness absence and return to work

Most people using osteopathic treatment (86%) were able to remain at work whilst under-going their course of treatment. Some 13% of patients were off work at their first appointment, most for less than 1 week. It appears that patients opt to go to their osteopath promptly if they are off work with their problem. Those that were off work were able to return to work within 1-3 treatments (Table 39).

Chronic sickness-absence was rare in this sample of patients (Figure 7) and only 1% of the patients were referred by their employer (Table 6). In view of the good outcomes suggested by

the data for chronic symptoms, it appears there may be an opportunity for marketing by the profession among employers.

9.10 Practice management issues

The results showed that 59% of the new episodes described were for patients who were new to osteopathy (Table 10), which may suggest that practices are flourishing, and that members of the public are aware of osteopathy and use it when they need it (finances permitting).

The desire to have a drug-free (9.1%) or hands-on therapy (9.1%) was a common reason for choosing osteopathy. The patient-centred care, with short waiting times and choice in treatment and after-care are other aspects which osteopaths can utilise in their marketing. These findings echo factors identified in the work by Chown *et al.*, 2008 when investigating the provision of osteopathic care vs a hospital-based intervention¹⁶⁴.

Advertising represented a relatively small source of patients. Most patients had heard about the practice they attended by word of mouth (Table 8) and chose osteopathy because of personal recommendation (Table 9). However there were clearly large sectors of the population not being reached by osteopathy. There appeared to be potential for osteopathy to offer services to employers to reduce sickness absence due to musculoskeletal conditions and to target services to the sectors of the population mentioned in the equality and diversity section above.

9.11 Consent issues

The questions on this topic were carefully worded in order to be non-threatening to practitioners, in order to minimise non-response. Despite this, non-response was much higher than for the other data items, between 9% and 19%. The wording was kept deliberately rather general, although this had the disadvantage of making responses harder to interpret. Obtaining accurate information around this issue requires specific and sensitive questioning within a separate piece of research.

The current evidence from the data was slightly inconsistent, but suggested that informed consent for examination was obtained from 80-90% of patients, for treatment using specific techniques from 57% of patients at first treatment (Table 21), and 42% at second and subsequent treatments (Table 29). Information about the risks and side effects of treatment was reportedly given to 63%

and 79% of patients respectively (Figure 20) but again the wording of this question was rather general and hence imprecise.

It is important to note that at the time the data collection project, the systematic review of adverse events associated with manual therapies, commissioned by the General Osteopathic Council, had not been published. There was little robust information for osteopaths to base their consent procedures on and, anecdotally, a degree of confusion remains concerning the exact information that should be provided and the appropriate manner to avoid unduly alarming patients while allowing them to make an informed choice about their care. This is an area which is important to all osteopathic stakeholders, but especially patients and would benefit from further work.

A series of issues can be identified from the findings of the SDC project, and areas of future work have been highlighted. These are discussed in greater depth in Chapter 10.

10. CONCLUSIONS

The research activities of developing and using the SDC tool involved nine NCOR research hubs, the national professional organisations (GOsC and BOA) and a total of 9.4% of practitioners who documented that they utilised a wide variety of approaches to practice. The results will be disseminated to participants in the tool development and in the SDC national pilot by a variety of means, providing further education in the research process.

It is hoped that the SDC tool will continue to be used by practitioners to collect and analyse their own data to evaluate their own practices, and to provide useful discussion material for groups of practitioners, who often work in isolation.

10.1 The SDC tool

The fact that the SDC tool was developed by and with osteopaths, and underwent substantial pilot-testing with osteopaths, meant that it was immediately meaningful, clearly relevant and easily applied in participating practices. National scales and classifications were used, where appropriate, making the data comparable to other studies.

10.2 Implications of the results

The pilot data from the standardised data collection project provides evidence about current osteopathic care in the UK. Important messages emerge from the data about inequity of access to osteopathic care, the quality of osteopathic care, the outcomes of care, the active role of osteopaths in the wider healthcare arena, the possible potential for osteopathy to offer savings of NHS resources, and to aid employers with long term sickness absence.

10.3 Limitations of the project

All research activity requires a degree of self-reflection and evaluation to identify how a project could be improved. This project is no different and a selection of limitations has been identified.

• The study was intended primarily to create and test a standardised data collection tool for osteopathy. The findings from the national pilot highlight areas where the questions in the

- tool performed well, but others where the questions need re-examination to increase clarity and reduce any danger of ambiguity.
- Participants in the national pilot were volunteers; it would be preferable to produce a future dataset with a random sample of the osteopathic profession.
- The use of a validated and nationally recognised outcome measure (depending on the physical or clinical area being assessed) in combination with the tool would be beneficial.
- All outcome data must be patient completed, and a mechanism to allow this to be undertaken away from practices would ensure that the risk of bias is minimised. The practicalities of such an endeavour and the cost associated would need careful reflection.

10.4 Issues raised

Analysis of the findings identified a number of issues raised by the data. These may direct the profession to areas of future research, or it may highlight areas of activity to be addressed by osteopathic stakeholders.

- Gaining consent is now a statutory requirement but it is clear that this remains an area of considerable confusion for osteopaths as it appears to for other professions. There is a need for clarification based on sound and informed legal opinion concerning the need for verbal and/or written consent information.
- The role of manipulative techniques in older age groups has been documented in general terms but no information is available concerning which area of the body is being manipulated. Safety information on the use of HVLA techniques on this and other age groups is notably lacking.
- The provision of osteopathic care to infants and young children has been documented in the data collection process; 8.6% were under 20 years of age and 5.6% were aged 0-9 years. This is an area of therapeutic provision that requires more work to identify research priorities within this subset of patients.
- The lack of access by patients belonging to different ethnic minorities has been documented. Greater exploration concerning why this has occurred would ensure that equal access to treatment is possible for all ethnic groups, and that appropriate education is given to osteopaths to raise awareness of cultural sensitivities.
- A high proportion of osteopaths have documented that they are recommending exercise to patients. Little work has been undertaken in this area which is not formally taught in all osteopathic educational institutions.

 Osteopaths have documented that they refer to a large number of other healthcare professionals to try and enhance their patients' recovery.

10.5 Further use and development of the standardised data collection tool

This project has provided baseline pilot data for comparison with future snapshot surveys. It may be possible also to revisit the format of the existing tool for future projects. Future development could occur in the following manner:

- The development of an electronic format for use by individual practitioners in their practices to enhance their own data collection;
- Use of the tool for research purposes to ensure that data is being collected in a standardised format;
- Use of the tool for periodic snapshot surveys with a wider volunteer group;
- The development of a short form of the tool for use in practice;
- The development of a version of the SDC tool for infants and children is proposed, in collaboration with the osteopathic organisations specialising in this area of practice e.g. the Foundation for Paediatric Osteopathy, the Sutherland Cranial College, and representatives from the children's clinics within OEIs.

At the end of the project, the SDC tool was considered to have worked well both for data collection and for data analysis, and has needed only limited modifications for future use. A revised version of SDC tool (Version 2.0, Appendix 6) has been produced for use by all members of the profession, with guidance notes (Appendix 7). There is national and international interest in the use of the SDC tool, with enquiries from osteopathic groups in New Zealand, Australia, Canada and mainland Europe.

The SDC can be adapted for a range of uses for collecting practice-based data of various types. Guidance notes for practices on how to use the data have been produced (Appendix 8), in order to provide positive benefits for the UK profession by enabling practices to create their own individual profile.

10.6 Use of the pilot SDC data

The information derived from the national pilot of the SDC has provided information about a number of important issues relevant to professional practice, policy, regulation, and future

research. The pilot evidence presented here may be used by practitioners and professional organisations to provide information about osteopathy and osteopathic care to the general public, commissioners and government organisations. It should be stressed, however, that the data should not be used in isolation to support claims relating to advertising for individual practitioners.

10.7 Future research

The results have raised a number of important questions about practice that can only be answered fully through further research which will facilitate better understanding and/or better statistics. A few of these questions are drawn out here.

- The data suggested that the profession is unsure about how best to gain informed consent for treatment. These very sensitive questions may be answered best by further in-depth interviews, to gain understanding of the difficulties and scenarios that cause problems. Research into best practice within and outside the profession will enable sensible and useful guidance to be drawn up for practice.
- Systematic investigation of osteopathic treatment for the cervical spine and head/facial symptoms involving the use of a nationally recognised and validated outcome measure. The addition of an outcome measure to gather cost effectiveness and safety data would help to address the gap in the literature in these common areas for treatment (15% and 7% of consultations respectively).
- Shoulder symptoms have been documented in 6.8% of patients. This is an area of marked paucity of literature and further investigation with the use of appropriate outcome measurement would be beneficial.
- More information concerning trends in treatment responses and any complications in older age groups would be helpful. The population has a greater percentage in older age groups and more could decide to seek treatment in the future. There is a need to identify what evidence is available for identification of contraindications to manipulative treatment in older age groups in addition to where demineralising conditions are present e.g. in patients with osteoporosis, on long term steroid medication, or with spinal malignancies present.
- A means of generating data on complications of treatment which is solely patient-completed could be investigated. A system that reflects the yellow card system available to medical practitioners could be investigated; information concerning the initiatives being undertaken by other professions could also be identified.

- There were substantial number of patients who were infants and children, but too few to permit adequate statistical analysis. Further specific research is needed to establish the presenting symptoms, treatments given and outcomes in this age group. Data collection involving infants and children will help to identify the key research priorities for this patient group.
- Investigation of the exercise regimes/advice being offered by osteopaths would be a helpful area of investigation. The inclusion of exercise in the management of patients is notably present in many clinical guidelines. It is important that the advice and recommendations by osteopaths are not only evidence based but appropriate and effective for patients ^{165,166}.
- The need for care among older patients with chronic conditions is rising due to changing population demographics. Many elderly patients report anecdotal benefit from osteopathic care but no data exists concerning what the benefits are and if this is reflected in reduction in the use of other services.
- The data on osteopathy within the wider healthcare arena showed that referrals were quite common, but further research would be useful to gain understanding of the relationship of osteopaths with other health professionals, both the medical profession and other complementary practitioners. A more systematic investigation for referral to other healthcare professionals, the reasons for this, and the outcome(s) of such referrals would be beneficial.
- Research identifying why patients of working age are in the majority in consultations should be clarified. Is lack of funding the prime barriers to osteopathic care for other groups, or are other factors involved?
- Research identifying the health choices of ethnic groups in terms of complementary care should be clarified. Exploring the reasons why more patients from ethnic minorities do not attend for osteopathic treatment would be helpful.
- Research focussing on what information and advice needs patients expect from osteopaths would be valuable. The provision of advice and education has been documented but other areas may be lacking?
- Little robust information was available for osteopaths on which to base their consent procedures at the time the data collection period was undertaken. Further work to look at the consent procedure and providing balanced information describing the risks, benefits, and alternative treatment options would be helpful to allow patients to make an informed choice about their care. Further information concerning adverse events will be available

as all of the work commissioned by the GOsC reaches its conclusion. The final piece of work, the Clinical Risk Osteopathy and Management (CROaM) study, will build on the outcome data concerning complications of treatment identified during the national pilot data collection project¹⁶⁷.

A total of 39% of patients were recommended by their osteopaths to return for "episodic care" (also referred to as "maintenance treatment" by some osteopaths). Some osteopaths advocate long term management of patients as a positive aspect for the profession, while others felt this would be a barrier to the inclusion of osteopaths in the NHS and promoting their activities to insurers and other health commissioners who do not advocate the use of long term care ^{168,169}. Research in this area would be helpful to identify what benefits patients with recurrent symptoms, especially within an older age group, report from long term care.

10.8 Dissemination strategy

An abstract for the first intended paper for the *International Journal of Osteopathic Medicine* (IJOM) has been produced and is available in Appendix 9; this describes the development process of the SDC tool. This paper was presented at the 8th International Conference on Advances in Osteopathic Research (ICAOR) in Milan in May, 2010. A full paper is currently being finalised in preparation for submission for publication. A second paper is planned presenting the results of the national pilot phase of the data collection project.

A subset of the results has been used for the report for practitioners (Appendix 10), and this will be utilised as the basis for wider dissemination through shorter articles prepared by the research team in both *The Osteopath* and *Osteopathy Today*, and as a poster presentation for the BOA conference in November 2010.

10.9 Future use of the data

This report contains the full set of results from the project, for presentation to the GOsC as funder of the project. The dataset will be available as a resource for future research, with appropriate permission from the sponsors. Individuals or organisations will be able to apply to NCOR and the University of Brighton, the research sponsor, if they wish to use the data or the results for any specific purpose.

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Appendices

Appendix 1	Search strategy for literature review
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Appendix 1 Search strategy for literature review for development of SDC data collection tool

Search terms were developed from discussion within the project team, existing experience and from consultation with colleagues who had worked on similar projects. Terms were categorised using the PICO format devised by Glasziou *et al*, 2003⁵⁵.

P (Patient or population)

I (Intervention or indicator)

C (Comparator or control)

O (Outcome)

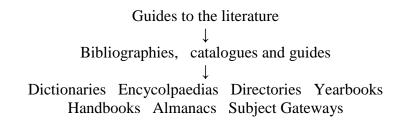
Search terms included:

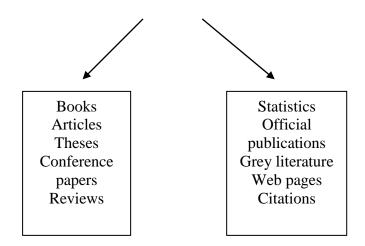
- Population: Osteopath*, physiotherap*, manual therap*, chiropract*, physical therap*, primary care, family care, family pract*, general pract*, nurs*, osteopathic medicine (MeSH)
- Intervention or Indicator: data collect*, standardi\$*, instrument*, tool*, medical record*, case record*, clinical record*, record keeping, physician progress note*, clinical evaluation, examin* form*, outpatient form*, short note form*, case history, patient notes, handover, morning report, electronic medical handover, electronic health record*, electronic patient record*, standardi\$ed operating protocol, patient assessment*, single organ system, standard* operating system, MSEF, musculoskeletal examination form, proforma*, web?based data collection, on?line data collection, medical records/standards (MeSH), continuity of patient care/standards (MeSH), forms and records control (MeSH), musculoskeletal diseases/diagnosis* (MeSH), osteopathic medicine/standards*(MeSH), physical examination (MeSH).
- Outcome: quality framework, pain, mobility, quality of life, practice profile, demographics, outcome* of care, statistics and numerical data (MeSH),

Terms limiting hits to those with abstracts were not included. No limits were applied for language and date limits included literature from inception of the database to present. The search was repeated during the life of the project to detect newer literature within this topic area. Boolean

operators were used where appropriate (depending on the database) to produce focussed and manageable search strings.

A bibliographic framework was plotted to facilitate the research strategy. The framework is described below.





Both methodological and topic literature were searched; a brief indicative search was carried out initially and followed by a more comprehensive search. The library online public access catalogue (OPAC) was also used to identify authors who have produced books within the topic area. (OPAC via BUBL Link online public access catalogues: http://link.bubl.ac.uk/libraryopacs/).

Disciplines to search

Health care Education Social science Psychology Information Science

Tools to search subject areas

Library catalogues	Print sources	CD ROMs	Databases	Websites
\downarrow	\downarrow	\downarrow	\downarrow	\downarrow
General search OPACs	specific sp	pecific s	subject specific abstracts	subject based organisa- tions

Source: Hart, 2001⁵⁶.

Citation indices were also used to locate publications which cited a particular author. Information on citation indices was accessed via the Institute for Scientific Information (ISI) www.isinet.com/
. Web sources were accessed using a second generation search engine (Google: www.google.co.uk) and a meta-search engine (metacrawler: www.metacrawler.com). The webcrawler strategy used the terms (data+collection+tool + health?care +assessment).

Medical matrix and pages of institutions and sites known to have an interest in data collection were also accessed. Conference proceeding were examined and reference lists of retrieved papers were searched to identify other sources of information.

Key words to facilitate the search were identified by examining literature sources and textbooks. A hard copy thesaurus was consulted to identify a wide variety of additional free text search terms. Medical subject headings (MeSH) were also identified and used.

BOOLEAN operators and truncation tools were used for the search. The search terms were entered into a variety of databases including PubMed, AMED, CINAHL, PsycLit, British Nursing Index, Index to Theses, Science Direct, PEDro, Ingenta Connect, OSTMED, Cochrane Library, HTA and ISI Web of Science. Limits were not applied at the end of the search due to the limited

amount of relevant material available. Pearl citation searching was utilised and hand searching of old osteopathic journals was also undertaken.

Author searches were carried out and reference lists were examined to identify any additional sources of evidence.

Appendix 2 Members of SDC Project Steering Group

The Steering Group was composed of representatives from various stakeholders:

Mr Jorge Esteves representing NCOR

Mr Michael Watson (Chair) representing the professional association BOA

Mr Bryan McIlwraith representing the GOsC 2007-2008 and as a practitioner with long-

term experience of data collection in his own practice

Mr Kelston Chorley representing hub members and practitioners with experience of data

collection for NHS commissioning

Mr Greg Sharp*

The SDC Project Team also attended Steering Group meetings:

Professor Ann Moore Principal Investigator

Carol Fawkes Project Officer

Dr Janine Leach Data Analysis

Mrs Shirly Mathias Research Administrator

^{*} Mr Greg Sharp, a practising osteopath with experience of working in the NHS, was originally part of the steering group but resigned due to work commitments.

Appendix 3 The data collection form used in the project -Version 1.0 of the SDC

	Part 1: PATIENT CO Please complete all sections: this information will he				
Prac	ctitioner code:	Date of first appointment:			
	which ethnic group do you belong? (Tick one) this rmation will help us to serve all ethnic groups equally)	Gender: Male □ Female □			
A	White ☐ British ☐ Irish	Postcode: Please state first part only e.g. SE11, BN20			
	☐ Any other White background, please record	What is your age? Years			
В	Mixed ☐ White and Black Caribbean ☐ White and Black African ☐ White and Asian	What is your height? metres* cms*			
	☐ Any other Mixed background, please record	What is your weight?			
С	Asian or Asian British Indian Pakistani Bangladeshi	kilograms* grams* *if needed, refer to the imperial to metric conversion chart at the back of this form			
	☐ Any other Asian background, please record	What is your main occupation?			
D	Black or Black British ☐ Caribbean ☐ African	How would you describe your current work status? (tick as appropriate)			
	□ Any other Black background, please record	 ☐ Working full time (employed) ☐ Working full time (self-employed) ☐ Working part time (employed) 			
Е	Chinese or other ethnic group ☐ Chinese ☐ Any other, please record	 □ Working part time (self-employed) □ Not currently employed □ Retired □ Student 			
	v physically demanding is your upation?	How strenuous are your leisure time activities? (see examples overleaf)			
\square n	edentary light noderate not appropriate trenuous	□ sedentary □ light □ moderate □ strenuous			
EXAMPLE LEISURE ACTIVITIES Sedentary: handicrafts, cinema Light: badminton, bowling, light gardening, walking (including to and from shops) Moderate: jogging, swimming, moderate gardening Strenuous: basketball, competitive cycling, competitive swimming, football, squash, heavy gardening					

Do you receive disability allowance? Yes □ No □						
How many weeks have you had this current problem?	How many weeks have you been off work with this current problem?					
☐ less than 1 week ☐ 1-2 weeks ☐ 3-4 weeks ☐ 5-6 weeks ☐ 7-12 weeks ☐ 13 or more weeks	☐ less than 1 week ☐ 1 week ☐ 2 weeks ☐ 3 weeks ☐ 4 weeks ☐ 5 or more ☐ not applicable					
Who referred you to this practice?						
□ self □ my GP □ NHS Consultant □ my employer □ another healthcare practitioner □ insurance company □ solicitor						
How many times have you visited your GP about this condition prior	r to coming to here?times					
How did you hear about this practice? (tick all that apply)	Why did you decide to have osteopathy? (tick all that apply)					
 □ Word of mouth/recommendation □ Local advert □ Yell.com □ Yellow pages □ Thompson Directory □ I live nearby □ From a healthcare practitioner □ Internet search □ Other, please specify 	 □ Personal recommendation or referral □ Personal research □ Waiting for NHS physio appointment □ Failure of previous treatment □ Previous experience of osteopathic treatment □ Desire to have osteopathic treatment □ Wanted a form of manual or hands on treatment □ Did not want treatment through the NHS □ Wanted to have drug-free treatment □ Other, please specify 					
Have you ever had any osteopathic treatment before? ☐ yes ☐ no	How long did you have to wait for the first appointment (for this condition) to be offered to you after contacting the practice?Days					
Are you on an NHS waiting list for treatment for this condition? ☐ yes ☐ no	How long have you been waiting for NHS treatment for this condition?Weeks Not applicable					
Have you had previous NHS treatment for this episode of this condition? Yes □ No □ If yes, has this included: <i>Tick all that apply</i> □ Imaging e.g. an X-Ray or scan □ Medication □ Hospital outpatient treatment □ Hospital inpatient treatment						
I agree to the information recorded on this form being used for audit and/or research purposes. All information will be anonymous and treated with the strictest confidence. <i>Please tick</i> \square yes \square no Date:						

Part 2: FORM for PRACTITIONER COMPLETION						
1. Practitioner code	2. Date of first appointment					
3. Symptom areas: Please record up to three areas in order of priority						
1 = Head/facial area 2 = Temporo-mandibular 3 = Neck 4 = Shoulder 5 = Upper arm 6 = Elbow 7 = Forearm 8 = Wrist 9 = Hand 10 = Thoracic spine 11 = Rib cage	12 = Lumbar 13 = Sacroiliac/pelvis/groin 14 = Gluteal region 15 = Hip 16 = Thigh/upper leg 17 = Knee 18 = Lower leg 19 = Ankle 20 = Foot 21 = Abdomen 22 = Other					
4. How long has the patient had their current symptoms with this episode? weeks	5. Type of onset of symptoms? <i>Tick one option</i> □ Acute onset □ Traumatic onset □ Slow/insidious onset □ Recurring problem					
6. Is this the first episode? <i>Please tick</i> ☐ Yes, first time onset ☐ Second episode ☐ Third episode ☐ Fourth or more episodes	7. What investigations have taken place for this current problem? Tick all that apply None Blood test X-Ray CT Scan MRI Ultrasound scan Urinalysis Other (please state)					
8. What current co-existing conditions (diagnosed by a	medical practitioner) does the patient have? Tick all that apply					
 □ Anaemia □ Anxiety □ Arthritis □ Asthma □ Bowel disease □ Cancer □ COPD (chronic obstructive pulmonary disease) □ CHF (Congestive heart failure) □ Dementia □ Depression □ Diabetes □ Hearing impairment 	 ☐ Hypertension ☐ Kidney disease ☐ Liver disease ☐ Migraine ☐ Mi (myocardial infarct) ☐ Neurological disease ☐ Osteoporosis ☐ Peripheral vascular disease ☐ Pregnancy ☐ Stroke/TIA (Transient Ischaemic Attack) ☐ Upper gastrointestinal disease ☐ Visual impairment ☐ Other (please state) 					

MANAGEMENT and TREATMENT					
First appointment					
9. Was this patient suitable for osteopathic treatment?	□ Yes □ No				
10. What treatment has been given to the patient today?					
 □ No treatment □ Soft tissue □ Articulation □ HVLA thrust □ Cranial techniques □ Muscle energy □ Strain/counterstrain □ Functional technique □ Visceral □ Myofascial release (MFR) 	 □ Education □ Relaxation advice □ Steroid Injection □ Acupuncture □ Dietary advice □ Exercise □ Orthotics □ Other (please name) 				
11. Was informed consent obtained for any particular technique (Please state)					
12. How was this pre-consent information given to the patient about osteopathic examination and treatment? Tick all that apply □ Orally □ Written form (e.g. information leaflet) □ Other	13. How was informed consent for examination gained? <i>Tick one option</i> ☐ Implied consent ☐ Written ☐ Verbally ☐ Written and verbal ☐ Not applicable				
 What other education and advice have been given to all that apply □ Anatomical information □ Possible risk factors associated with a recurrence of symptoms 	the patient to inform them about their condition? <i>Please record</i> Anticipated response to treatment Anticipated number of treatments Advice concerning physical activity				
15. What self-management strategies have been recomm Please tick all that apply None Application of heat Application of cold Contrast bathing Rest Specific exercise General exercise	ended for the patient to use? Vitamin or other nutritional supplements Use of the Back book Use of the Whiplash book Natural remedies Naturopathic neuromuscular techniques Relaxation advice Other (please state)				
16. Have the possible causes of the symptoms been discussed with the patient?Yes □ No □	17. Has information concerning the following potential factors been discussed with the patient? Possible risks Yes □ No □ Possible side-effects Yes □ No □				

18. Who is responsible for payment for treatment □ Self □ Insurance company □ Employer/own company □ Referral by NHS □ Other (please state)	19. Is an insurance case or litigation claim pending? Yes □ No □				
20. Time allocated for first appointment mi	nutes				
21. After the first appointment, did the patient report any of the known complications of treatment described below within the first 24-48 hours? (Please ask the patient to record all that apply)	22. What was the patient's overall outcome after the first appointment? Please ask the patient to record				
 None of these Increased pain Increased stiffness Dizziness Nausea Headache Fatigue Serious adverse event, if known, please describe below 	 □ Worst ever □ Much worse □ Worse □ Not improved/not worse □ Improved □ Much improved □ Best ever 				
SECOND AND SUBSEQUENT TREATMENTS	S				
23. What types of treatment have been given to the patient? <i>H</i>	Please tick all that apply				
 No treatment Soft tissue Articulation HVLA thrust Cranial techniques Muscle energy Strain/counterstrain Functional technique Visceral Myofascial release (MFR) 	□ Relaxation advice □ Steroid Injection □ Acupuncture □ Dietary advice □ Exercise □ Orthotics □ Other (please name) □ Education				
24. Was informed consent obtained for any particular technique used? Yes □ Technique (<i>Please state</i>)					
25. How was this pre-consent information given to the patient about osteopathic examination and treatment? Please tick all that apply □ Orally □ Written form (e.g. information leaflet) □ Other	26. How was informed consent for examination gained? <i>Please tick one option</i> ☐ Implied consent ☐ Written ☐ Verbally ☐ Written and verbal ☐ Not applicable				

27. What other education and advice have been given to all that apply □ Anatomical information □ Possible risk factors associated with a recurrence □ Anticipated response to treatment □ Anticipated number of treatments □ Advice concerning physical activity	the patient to inform them about their condition? <i>Please record</i> of symptoms
28. What self-management strategies have been recomm □ None □ Application of heat □ Application of cold □ Contrast bathing □ Rest □ Specific exercise □ General exercise	ended for the patient to use? Please tick all that apply Vitamin or other nutritional supplements Use of the Back book Use of the Whiplash book Natural remedies Naturopathic neuromuscular techniques Relaxation advice Other (please state)
29. Have the possible causes of the symptoms been discussed with the patient? Yes □ No □	30. Has information concerning the following potential factors been discussed with the patient? Possible risks Yes □ No □ Possible side-effects Yes □ No □
31. Responsibility for payment for treatment □ Self □ Insurance company □ Employer/own company □ Referral by NHS □ Other (please state)	32. Insurance case or litigation claim pending Yes □ No □
33. Time allocated for follow up appointments	minutes
The state of the s	COME REPORT
Date of final visit:	Total number of treatments for this episode (to date). Please state:
34. Did the patient continue to report any of the known complications of treatment described below within the first 24-48 hours? (<i>Please ask the patient to record all that apply</i>) □ None of these □ Increased pain □ Increased stiffness □ Dizziness □ Nausea □ Headache □ Fatigue □ Serious adverse event, if known, please describe below	35. What was the patient's overall outcome at their final appointment or to date. <i>Please ask the patient to record</i> \[\textstyle \text{Worst ever} \\ \textstyle \text{Much worse} \\ \textstyle \text{Not improved/not worse} \\ \textstyle \text{Improved} \\ \textstyle \text{Much improved} \\ \textstyle \text{Best ever} \\ \end{array}

36. Did you contact the patient's GP during this course of treatment? <i>Tick one option</i> □ Yes since patient was referred to practice by GP □ Yes since GP had requested information □ Yes to request further information or investigation □ Yes for referral for other treatment □ No, the patient's GP was not contacted	37. How many treatments did the patient have before being able to return to work (if applicable? ☐ Treatments ☐ Not applicable
38. How many treatments did the patient have before they achieved relief of immediate symptoms? ☐ Treatments ☐ Not applicable	39. What was the end result of the consultation period? □ No further treatment. The patient was discharged. □ Patient was recommended to return for episodic care. □ Patient was referred for further investigations pending treatment under the care of the practice. □ Patient was referred on.
40. Was the patient referred on from the practice? Yes If yes, where was the patient referred to? Tick one option. Their GP for further investigations Their GP to try and arrange other treatment Another osteopath A homeopath An acupuncturist A podiatrist An Alexander teacher A physiotherapist A counsellor A chiropractor A sports massage therapist A Pilates trainer Other (please state)	□ No □

HEIGHT CONVERSION CHART for adults			WEIGHT CONVERSION CHART for adults								
ft* in*	ft in			st*		st lb	kg	st lb	kg	st lb	kg
4`06" 4 6½	m* 1.4 1.4	6 0 6 ½	m 1.8 1.8	lb* 6 stone	kg* 38.1 38.6	9 11 9 12	62.1 62.6	13 08 13 09	86.2 86.6	17 05 17 06	110.2 110.7
4 7 4 7½ 4 8 4 8½	1.4 1.4 1.4 1.4	6 1 6 1½ 6 2	1.9 1.9 1.9 1.9	6 1 6 2 6 3	39.0 39.5 39.9 40.4	9 13 10 stone 10 01	63.1 63.5 64.0 64.4	13 10 13 11 13 12 13 13	87.1 87.5 88.0 88.5	17 07 17 08 17 09 17 10	111.1 111.6 112.0 112.5
4 9 4 9 4 9 4 10	1.5 1.5 1.5	6 21/2 6 3	1.9 1.9 1.9 1.9	6 4 6 5 6 6 6 7	40.8 41.3 41.7	10 01 10 02 10 03 10 04	64.9 65.3 65.8	14 01 14 02	88.9 89.4 89.8	17 10 17 11 17 12 17 13	113.0 113.4 113.9
4 10½ 4 11 4 11½	1.5 1.5 1.5	6 3½ 6 4	1.9 2.0 2.0	6 8 6 9 6 10	42.2 42.6 43.1	10 05 10 06 10 07	66.2 66.7 67.1	14 03 14 04 14 05	90.3 90.7 91.1	18stone 18 01 18 02	114.3 114.8 115.2
5 0 5 ½ 5 1 5 1½	1.5 1.5 1.6 1.6	6 4½ 6 5 6	2.0 2.0 2.0 2.0	6 11 6 12 6 13 7	43.6 44.0 44.5 44.9	10 08 10 09 10 10 10 11	67.6 68.0 68.5 69.0	14 06 14 07 14 08 14 09	91.6 92.1 92.5 93.0	18 03 18 04 18 05 18 06	115.7 116.1 116.6 117.0
5 2 5 2½ 5 3 5 3½	1.6 1.6 1.6 1.6	5½ 6 6 6 6½	2.0 2.1 2.1 2.1	stone 7 01 7 02 7 03	45.3 45.8 46.3 46.7	10 12 10 13 11stone 11 01	69.4 69.9 70.3 70.8	14 10 14 11 14 12 14 13	93.4 93.9 94.4 94.8	18 07 18 08 18 09 18 10	117.5 117.9 118.4 118.8
5 4 5 4½ 5 5	1.6 1.6 1.7	6 7 6 7½	2.1 2.1 2.1	7 04 7 05 7 06	47.2 47.6 48.1	11 02 11 03 11 04	71.2 71.7 72.1	15stone 15 01 15 02	95.3 95.7 96.2	18 11 18 12 18 13	119.3 119.8 120.2
5 5½ 5 6 5 6½ 5 7	1.7 1.7 1.7 1.7	6 8 6 8½ 6 9	2.1 2.1	7 07 7 08 7 09 7 10	48.5 49.0 49.4 50.0	11 05 11 06 11 07 11 08	72.6 73.0 73.4 73.9	15 03 15 04 15 05 15 06	96.6 97.1 97.5 98.0	19 stone 19 01 19 02 19 03	120.7 121.1 121.6 122.0
5 7½ 5 8 5 8½	1.7 1.7 1.7	6 9½ 6 10		7 11 7 12 7 13	50.4 50.8 51.3	11 09 11 10 11 11	74.3 74.8 75.3	15 07 15 08 15 09	98.4 98.9 99.3	19 04 19 05 19 06	122.5 122.9 123.4
5 9 5 9½ 5 10 5 10½	1.8 1.8 1.8 1.8	6 10½ 6 11 6		8 stone 8 01 8 02	51.7 52.2 52.6 53.1	11 12 11 13 12 stone	75.8 76.2 76.7 77.1	15 10 15 11 15 12 15 13	99.8 100.2 100.7 101.2	19 07 19 08 19 09 19 10	123.8 124.3 124.7 125.2
5 11 5 11½ 6 0	1.8 1.8 1.8	11½ 7 0		8 03 8 04 8 05 8 06	53.5 54.0 54.4 54.9	12 01 12 02 12 03 12 04	77.6 78.0 78.5 78.9	16 01 16 02 16 03	101.6 102.1 102.5 103.0	19 11 19 12 19 13 20stone	125.7 126.1 126.6 127.3
				8 07 8 08 8 09 8 10	55.3 55.8 56.3 56.7	12 05 12 06 12 07 12 08	79.4 79.8 80.3 80.7	16 04 16 05 16 06 16 07	103.4 103.9 104.3 104.8	20 07 21stone 21 07 22stone	130.5 133.6 136.8 140.0
				8 11 8 12 8 13 9 stone	57.1 57.6 58.1 58.5 59.0	12 09 12 10 12 11 12 12 12 13	81.2 81.7 82.1 82.6 83.0	16 08 16 09 16 10 16 11 16 12	105.2 105.7 106.1 106.6 107.0	22 07 23stone 23 07 24stone 24 07	143.2 146.4 149.6 152.7 155.9
				9 01 9 02 9 03 9 04	59.0 59.4 59.9 60.3 60.8	12 13 13 stone 13 01 13 02	83.5 84.0 84.4 84.8	16 12 16 13 17stone 17 01 17 02	107.5 108.0 108.4 108.9	Z4 U/	133.7
				9 05 9 06 9 07 9 08 9 09	61.2 61.7 61.7	13 02 13 03 13 04 13 05 13 06 13 07	85.3 85.7	17 02 17 03 17 04	109.3 109.8		
				9 10		13 07					

HEIGHT CONVERSION CHART for children									CONVERSION for children
ft in	n m	ft in	m	ft in	m	ft in	m	st lb	kg
0 1/2			0.5	2 91/2	0.9	3 10	1.2	1	0.5
0 1/2			0.5	2 93/4	0.9	3 101/4	1.2	2	0.9
0 3/4			0.6	2 10	0.9	3 101/2	1.2	3	1.4
0 1			0.6	2 101/4	0.9	3 103/4	1.2	4	1.8
0 91/			0.6	2 101/2	0.9	3 11	1.2	5	2.3
0 93/			0.6	2 103/4	0.9	3 111/4	1.2	6	2.7
0 10			0.6	2 11	0.9	3 11½	1.2	7	3.2
0 10			0.6	2 111/4	0.9	3 113/4	1.2	8	3.6
0 101			0.6	2 11½	0.9	4 0	1.2	9	4.1
0 103		1 1111/4	0.6	2 113/4	0.9	4 ½	1.2	10	4.5
0 11			0.6	3 0	0.9	4 1	1.2	11	5.0
0 11			0.6	3 1/4	0.9	4 1½	1.2	12	5.4
0 11			0.6	3 ½	0.9	4 2	1.2	13	5.9
0 11			0.6	3 3/4	0.9	4 21/2	1.2	1 stone	6.4
1	0.3		0.6	3 1	0.9	4 3	1.2	1 07	9.5
1 1/4			0.6	3 11/4	1.0	4 3½	1.3	2 stone	12.7
1 1/2			0.6	3 11/2	1.0	4 4	1.3	3 stone	19.1
1 3/4			0.6	3 13/4	1.0	4 41/2	1.3	3 07	22.2
1 1	0.3	2 11/2	0.7	3 2	1.0	4 5	1.3	4 stone	25.4
1 11/	4 0.3	2 13/4	0.7	3 21/4	1.0	4 51/2	1.3	4 01	25.9
1 11/2	/2 0.3	2 2	0.7	3 21/2	1.0			4 02	26.3
1 13	3/4 0.4	2 21/4	0.7	3 23/4	1.0			4 03	26.8
1 2	0.4	2 21/2	0.7	3 3	1.0			4 04	27.2
1 21/2	4 0.4	2 23/4	0.7	3 31/4	1.0			4 05	27.7
1 21/2	2 0.4	2 3	0.7	3 31/2	1.0			4 06	28.1
1 23/4	4 0.4	2 31/4	0.7	3 33/4	1.0			4 07	28.6
1 3	0.4	2 3½	0.7	3 4	1.0			4 08	29.0
1 31/4	4 0.4	2 33/4	0.7	3 41/4	1.0			4 09	29.5
1 31/2	2 0.4	2 4	0.7	3 41/2	1.0			4 10	29.9
1 33/4	4 0.4		0.7	3 43/4	1.0			4 11	30.4
1 4	0.4	2 4½	0.7	3 5	1.0			4 12	30.8
1 41/4			0.7	3 51/4	1.0			4 13	31.3
1 41/2			0.7	3 51/2	1.0			5 stone	31.8
1 43/2			0.7	3 53/4	1.0			5 01	32.2
1 5	0.4		0.8	3 6	1.0			5 02	32.7
1 51/4			0.8	3 61/4	1.0			5 03	33.1
1 51/2			0.8	3 61/2	1.0			5 04	33.5
1 53/4			0.8	3 63/4 3	1.0			5 05	34.0
1 6			0.8	7	1.1			5 06	34.5
	1/4 0.5		0.8	3 71/4	1.1			5 07	34.9
1 61/2			0.8	3 7½	1.1			5 08	35.4
1 63/4			0.8	3 73/4	1.1			5 09	35.8
1 7	0.5		0.8	3 8	1.1			5 10	36.3
1 71/2			0.8	3 81/4	1.1			5 11	36.7
1 71/2			0.8	3 8½	1.1			5 12	37.2
1 73/4			0.8	3 83/4	1.1			5 13	37.7
1 8	0.5		0.8	3 9	1.1			6 stone	38.1
1 81/4			0.8	3 91/4	1.1				
1 81/2			0.8	3 9½	1.2				
1 83/4	4 0.5	2 91/4	0.9	3 93/4	1.2				

Source:

http://www.hantspt.nhs.uk/sys_upl/templates/AssetBrowser/AssetBrowser_disp.asp?ItemID=3069&basketPage=&basketItem=&pgid=7132&tid=146&page=1

Abbreviations: ft = feet; in = inches; m = metres; st = stone; lb = pounds; kg = kilograms

Appendix 4 Guidance notes for the SDC form, version 1.0



Osteopathic Standardised Data Collection (SDC) Project

Guidance on completing the SDC form Background to the questions being asked on the SDC form

April 2009. V 1.0

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Guidance on completing the Standardised Data Collection (SDC) form

These forms are being used in osteopathic practices across the United Kingdom to provide information about the patients and treatments at each individual practice and in the UK as a whole. The information will help in improving services and assessing whether treatments are effective.

Each osteopath is asked to complete the SDC form for <u>10 patients consulting with a NEW EPISODE</u>.

The questions are intended to be self- explanatory and unambiguous. Please let us know if they are not.

FOR PATIENTS

Please answer the questions by ticking the boxes or using your own words. For your height and weight, there is a conversion chart at the back of the forms if you only know your height in feet and inches or your weight in pounds. If you are not sure about any question, please ask your osteopath.

Thank you for completing the form!

FOR OSTEOPATHS

Length of data collection

The data collection process will begin on Monday 20th April and finish on Friday 17th July, 2009. Each practitioner is requested to post their completed forms back to the Clinical Research Centre as quickly as possible after that date.

You should have been assigned a practitioner code to enter at the top of the form.

Completing the form

The SDC is intended to allow easy recording of information as an initial consultation progresses on to a second visit and subsequent follow up of a patient in clinical practice.

The data collection form is divided into two parts: <u>Part 1 is for patient completion</u> before their first appointment, for example in the reception area. Osteopaths who do not have reception support may prefer to complete Part 1 in the clinic with the patient.

<u>Part 2 is for practitioner completion</u>. The exception is that, preferably, the <u>patient</u> should complete the questions recording outcomes of care: these are questions 21, 22, 34, and 35. Patient completion will provide a more objective response, less prone to bias.

Please let us know if any of the questions are unclear to you; it is easier to respond to initial queries by email.

At the end of the data collection period

When you have completed your data collection forms, please post them back to Carol Fawkes, the project officer, at the Clinical Research Centre, University of Brighton. The full postal address is at the front of this document. Please send the forms back at the most economical postage rate available and enclose a receipt; your postal costs will then be reimbursed.

Thank you for taking part.

Background to the questions being asked on the SDC form

Introduction

The standardised data collection tool (SDC) has been developed by osteopaths in private practice in collaboration with NCOR, to allow the collection of information which will help to profile both patients and approaches to practice. The SDC has been developed in the knowledge that osteopaths treat patients from a wide range of age groups and with an extensive array of symptoms.

The information collected by the SDC will be helpful for individual clinicians, but also the profession as a whole as it deals with the demands of healthcare in the 21st century.

Ethics

Ethical advice was sought early in the development of the SDC. Data collection does not involve the introduction of new treatments and formal ethical review is not required. The data collection process is more comparable to audit than research in the strict definition of the term. All data collected will be anonymised and treated confidentially by the research team analysing the data. Patients will be asked for their permission for the data to be used for analysis and they are asked to tick the box at the end of the patient completed form. If they have any concerns about the data collection exercise, please refer them to the research officer.

Scales and classifications used in the SDC

Scales have been chosen, where available, which are documented in published literature and have been validated. National scales have also been used e.g. those contained in Census reports; this will allow comparison of findings from the data gathered in the osteopathic data collection exercise with national findings.

Part 1: Patient completed form

Patient's self reported ethnicity

Ethnicity classifications have been taken from those recommended by the Equality and Human Rights Commission http://www.equalityhumanrights.com/en/Pages/default.aspx

Patient Height and weight

Metric data will be collected about height and weight; a conversion form can be found at the back of the SDC for anyone who commonly uses imperial measures and is unfamiliar with their metric equivalents. A conversion chart has been used from http://www.hantspt.nhs.uk/sys_upl/templates/AssetBrowser/AssetBrowser_disp.asp?ItemID=3069@basketPage=&basketItem=&pgid=7132&tid=146&page=1.

Duration of current problems

The duration of current problems will allow coding of information into "acute", "sub-acute" and "chronic" classifications, as recommended by the International Association for the Study of Pain http://www.iasp-pain.org//AM/Template.cfm?Section=Home.

Part 2: Practitioner completed form

Question 3: Symptom areas

It is important that the three main areas of symptoms are recorded. It is recognised that patients can consult for treatment with many more areas of pain or other symptoms.

The categories have been modelled on those that appeared in two papers:

Parsons S, Carnes D, Pincus T, et al. Measuring troublesomeness of chronic pain by location. BMC Musculoskeletal Disorders. 2006;7:34.

Carnes D, Parsons S, Ashby D *et al.* Chronic musculoskeletal pain rarely presents in a single body site: results from a UK population study. *Rheumatology*. 2007;46:1168.

Question 8: Co-existing Conditions

Categories have been used that were published in Groll DL, To T, Bombardier C, et al. The development of a comorbidity index with physical function as the outcome. *Journal of Clinical Epidemiology*. 2005;58:595-602.

Question 21: Complications of treatment

This question relates to findings documented in research studies including the work by Cagnie, Vinck, *et al.* looking at common side effects of manual treatments.

Cagnie B, Vinck E, Beernaert A, et al. How common are side effects of spinal manipulation and can these side effects be predicted? *Manual Therapy*. 2004;9:151-6.

Question 22: Outcome

A number of rating scales exist, but many focus exclusively on pain. A generalised and validated global perceived effect scale, developed by Kemler *et al.* has been used in the SDC.

Kemler MA, De Vet HCW, Barendse H, *et al.* The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow up of the randomised controlled trial. *Annals of Neurology.* 2003;55(1):13-18.

What happens at the end of the data collection period?

The last day for data collection is 17th July. If a patient is only part of the way through their treatment, the form would be completed up to this point and a note can be added to this effect at the end of the data collection form.

All of your 10 data collection forms can then be returned to the Clinical Research Centre for Health Professions* where the data will be anonymised and analysed. A final report concerning the data will be produced for the profession to use.

What happens if I need help?

If you have any problems while trying to complete the data collection tool, <u>please</u> contact the research officer, Carol Fawkes by telephone or email. Contact details are given below.

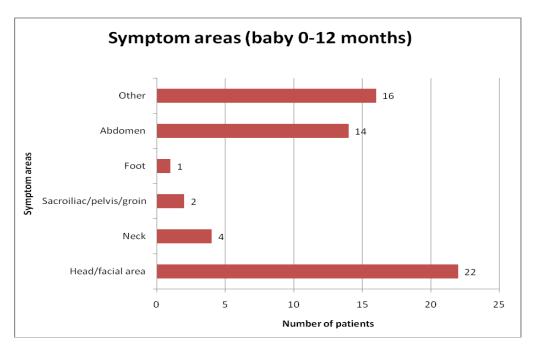
*Clinical Research Centre for Health Professions Aldro Building, University of Brighton 49, Darley Road Eastbourne East Sussex BN20 7UR

Telephone: 01273 643457 (Mobile: 07732 178 308)

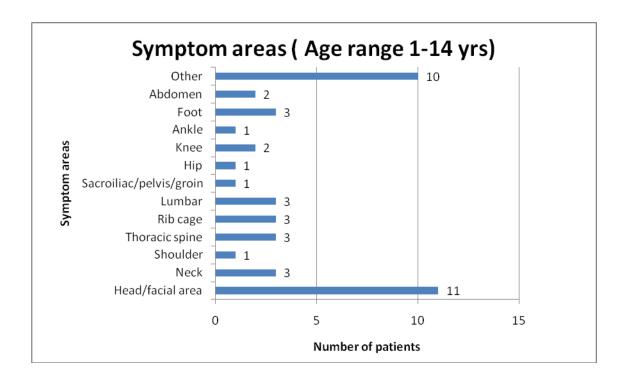
Email: c.a.fawkes@brighton.ac.uk

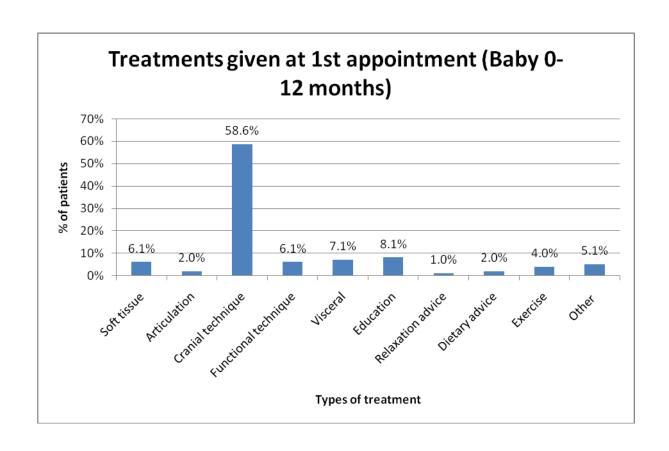
Appendix 5 Symptoms and treatments of babies and children

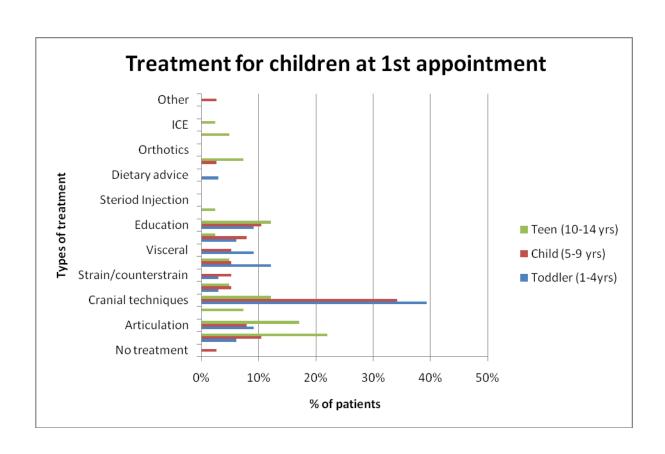
The profile of symptoms and treatment for babies and for children was extracted separately. The numbers are small and do not distort the overall picture. The graphs show numbers of patients rather than percentages.



The children included below were between 12 months and 14 years. The older teenagers 15-19 had a more adult profile of symptoms so were not included.







Appendix 6 – Modified SDC tool after 3 month pilot – Version 2.0 of the SDC

Part 1: Initial consultation for new episode To be completed by the osteopath						
Practitioner ID code 1. Date of first appointment	2. Sex: Male □ Female □					
3. Postcode: Please state first part only e.g. SE11, BN20	4. Patient's age (years)					
5. Patient's height Metres and cms* Feet and inches*	6. Patient's weight Kg and g* Stone and lbs*					
7. What is the patient's main occupation?	8. How would you describe the patient's current work status? (tick as appropriate)					
Not applicable □	☐ Working full time (employed) ☐ Working full time (self-employed) ☐ Working part time (employed)					
9. Does the patient receive disability allowance? Yes □ No □ Not applicable □	☐ Working part time (employed) ☐ Working part time (self-employed) ☐ Not currently employed ☐ Retired ☐ Student ☐ Pre-school					
10. How physically demanding is the patient's occupation?	11. How strenuous are the patient's leisure time activities? (see examples below)					
□ strenuous □ sedentary □ not applicable □ light	☐ strenuous ☐ sedentary ☐ moderate ☐ not applicable ☐ light					
EXAMPLE LEISURE ACTIVITIES Sedentary: handicrafts, cinema Light: badminton, bowling, light gardening, walkin Moderate: jogging, swimming, moderate gardening Strenuous: basketball, competitive cycling, competitive	g (including to and from shops)					
12. Who referred the patient to this practice? □ patient □ GP □ insurance company □ employer □ NHS Consultant □ solicitor □ another healthcare practitioner	13. Has the patient ever had any osteopathic treatment before? ☐ yes ☐ no					
14. How did the patient hear about this practice? (tick all that apply)	15. Why did the patient decide to have osteopathy? (tick all that apply)					
 □ Word of mouth/recommendation □ Local advert □ Yell.com □ Yellow pages □ Thompson Directory □ I live nearby □ From a healthcare practitioner □ Internet search □ Other, please specify 	□ Personal recommendation or referral □ Personal research □ Waiting for NHS physio appointment □ Failure of previous treatment □ Previous experience of osteopathic treatment □ Desire to have osteopathic treatment □ Wanted a form of manual or hands on treatment □ Did not want treatment through the NHS □ Wanted to have drug-free treatment □ Other please specify					

16. How long did the patient have to wait for the <u>first appointment</u> to be offered? ☐ Same day ☐ 2-3 days ☐ 4-7 days ☐ 8 days or more					
17. Is the patient on an NHS waiting list for treatment for this condition? ☐ yes ☐ no	18. How long has the patient been waiting for NHS treatment for this condition? Weeks Not applicable □				
19. How many times has the patient visited their GP about this condition prior to coming to here? times					
20. How many weeks has the patient had this current problem? ☐ less than 1 week ☐ 1-2 weeks ☐ 3-4 weeks ☐ 5-6 weeks ☐ 7-12 weeks ☐ 13-51 weeks ☐ 1 year or more	21. How many weeks has the patient been off work with this current problem? ☐ less than 1 week ☐ 1 week ☐ 2 weeks ☐ 3 weeks ☐ 4 weeks ☐ 5 weeks or more ☐ not applicable				
22. Has the patient had previous treatment or investigation. Yes □ No □ If yes, has this included: <i>Tick all that ap</i> Imaging e.g. an X-Ray or scan Blood test Medication Urinalysis Hospital outpatient treatment Hospital inpatient treatment Other (please state)					
23. Type of onset of symptoms? <i>Tick all that apply</i> □ Acute/sudden onset (of unknown origin) □ Traumatic onset (of known origin) □ Slow/insidious onset □ Recurring problem	24. Is this the first episode? <i>Please tick</i> ☐ Yes, first time onset ☐ Second episode ☐ Third episode ☐ Fourth or more episodes				
25. Severity of main symptoms on first visit – for patient completion Best					

26. Symptom areas: Please record up to four predominant symptom areas in order of priority for the patient									
	1 st \square	2nd □	3	3rd □	4th				
2 Te 3 No 4 Sh 5 U ₁ 6 El 7 Fe	ead/facial area emporo-mandibular eck noulder pper arm bow orearm 'rist		11 12 13 14 15	Hand Thoracic Rib cage Lumbar Sacroiliac Gluteal re Hip Thigh/upp	c/pelvis	s/gro	in	18 19 20 21	Knee Lower leg Ankle Foot Abdomen Other
27. What current co-existing conditions (diagnosed by a medical practitioner) does the patient have (tick all that apply)									
☐ Hypertensic ☐ MI (myocar ☐ Peripheral v	rdial infarct) vascular disease (Transient Ischaen al disease				Cance Diabe Hearin Visual Kidne Liver Pregna Bowel Upper	o (cher tes ng ir l imp y dis dise ancy l dise	mpairment pairment sease ase		pulmonary disease)
Part 2: Management and treatment									
28. What treatment plan was agreed with the patient?									
	nic management opathic treatment						onsultation on eferred on	ıly	
	of treatment approa	ent	een	used with t			Education Relaxation a Steroid Inject Acupuncture Dietary advice Exercise Orthotics Lifestyle adv Other (please	ction c ce	

Part 3: Information and Consent (this information will be treated in strict confidence)							
30. I	How was consent gained for examination?	31. H	low was cons		ed for tr	eatment?	
	Implied consent Verbally Written Written and verbal Not applicable Other		Implied con Verbally Written Written and Not applica Other	verbal			
32. V	Vere any of the following procedures conducted and	l was sp Condu Yes		nt obtaine	ed? Conse Yes	nted No	N/A
Pe Or Ce Lu	er rectal er vaginal ral ervical HVT Imbar HVT noracic HVT						
33. I	Did you discuss with the patient			Yes	No	N/A	
	Treatment options for their problem? Possible risks and side effects of treatment The anticipated response to treatment The anticipated number of treatments Ways to avoid recurrences in the future? An explanation of the presenting problem?						
34. V	What self-management strategies have been recomm	ended t	for the patient	t to use?			
	application of heat application of cold Contrast bathing	 □ Us □ Us □ Na □ Re 	tamins or oth the of Back Bo the of Whiplas attural remedic atturopathic ne claxation advi	ook h Book es euromusc ce	cular tec	chniques	S
35. V	5. Who is responsible for payment for treatment		an insurance	case or l	itigatio	n claim p	ending?
 □ Self □ Insurance company □ Employer/own company □ Referral by NHS □ Other (please state) 		Yes		No 🗆			
	Referral by NHS	37. Ti	me allocated		appoint	ment	

Part 4. Second appointment					
38. After the <u>first</u> appointment, did the patient report any complications of treatment within the first 48 hours?	39. What was the patient's overall outcome after the <u>first</u> appointment?				
 □ None of these □ Increased pain □ Increased stiffness □ Dizziness □ Nausea □ Headache □ Fatigue □ Serious adverse event, if known, please describe below 	 □ Worst ever □ Much worse □ Worse □ Not improved/not worse □ Improved □ Much improved □ Best ever 				
40. What types of treatment approaches have been used with the patient? Please tick all that apply					
 □ No hands on treatment □ Soft tissue □ Articulation □ HVLA thrust □ Cranial □ Muscle energy □ Strain/counterstrain □ Functional □ Visceral 	□ Education □ Relaxation advice □ Steroid Injection □ Acupuncture □ Dietary advice □ Exercise □ Orthotics □ Myofascial release (MFR) □ Other (please name)				
41. What self-management strategies have been record None Application of heat Application of cold Contrast bathing Rest Specific exercise General exercise Other (please state)	mmended for the patient to use? Please tick all that apply Vitamin or other nutritional supplements Use of the Back book Use of the Whiplash book Natural remedies Naturopathic neuromuscular techniques Relaxation advice Advice concerning physical activity				
42. Time allocated for follow up appointments	minutes				
Part 5: Last visit of initial course of treatment for this episode					
43. Date of final visit: 44. Total number of treatments for this episor					
45. Has the patient completed the initial course of treatment for this episode?					
☐ Yes ☐ No, treatment is ongoing ☐ Patient did not return (reason unknown) ☐ Treatment terminated due to illness ☐ Treatment terminated due to finance ☐ Treatment terminated for other reason (please state)					
46. Severity of main symptoms on last visit – for patient completion 0 1 2 3 4 5 6 7 8 9 10 Best ———					

Į.	-					
47. Is the patient continuing to report any complication of treatment ☐ None of these ☐ Increased pain ☐ Increased stiffness ☐ Dizziness ☐ Nausea ☐ Headache ☐ Fatigue ☐ Serious adverse event, if known, please describe	final appointment or to date? ☐ Worst ever ☐ Much worse ☐ Worse ☐ Not improved/not worse ☐ Improved ☐ Much improved					
49. How many treatments did the patient have before						
☐ Not applicable (retired) ☐ Not applicable (not off	work) in Not applicable (not able to return to work)					
50. Did you contact the patient's GP during this course ☐ Yes ☐ No If yes, reasons for contact ☐ Patient was referred by the practice ☐ To request further information or investigation ☐ Other (please specify)	☐ GP had requested information ☐ To request referral for other treatment ☐ To provide the GP with information					
51. At the last treatment, what was agreed for the patient's future care?	52. If the patient was referred on from your practice, where were they referred to?					
 □ None planned. Patient was discharged □ Patient opted to return for episodic care 	☐ Their GP ☐ Other medical consultant ☐ Other practitioner (please state)					
I attent opted to return for episodic care	Other practitioner (prease state)					
 □ Patient awaiting results of investigation □ Patient was referred on for investigation/treatment 	53. If the patient was referred for other treatment while still having osteopathic treatment, where were they					
I then was referred on for investigation teatment	referred to?					
☐ Still continuing initial course of treatment ☐ Patient planning to return for further treatment	 □ Their GP □ Other medical consultant □ Other complementary practitioner 					
☐ Other (please state)	 ☐ Physiotherapist or podiatrist ☐ A counsellor ☐ Exercise trainer or class ☐ Other (please state) 					
and serve all groups equally) White Asian □ British □ □ Irish □ □ Any other White □ background, please record □	his question is optional: the information is intended to try or Asian British Chinese or other ethnic group Indian Pakistani Pakistani Chinese Bangladeshi Any other, Any other Asian ckground, please record					
□ White and Black Caribbean Black □ White and Black African □ □ White and Asian □ □ Any other Mixed background, □	ck or Black British Caribbean African Any other Black ckground, please record					

Thank you for completing this form

Statement of accreditation

"This standardised data collection tool has been produced by the National Council for Osteopathic Research (NCOR), and funded by the General Osteopathic Council (GOsC), the UK regulator of osteopaths. The intellectual property rights in the standardised data collection tool are jointly owned by the NCOR and the GOsC. The tool should be referenced in published work as: Fawkes CA, Leach CMJ, Mathias S, Moore AP. Standardised data collection tool for osteopathic practice. National Council for Osteopathic Research (UK) and General Osteopathic Council UK, 2009".

Appendix 7 – Modified guidance notes for SDC tool version 2.0



Osteopathic Standardised Data Collection (SDC) Project

Guidance on completing the SDC form Background to the questions being asked on the SDC form

April 2010. V 2.0

Contact
Project Officer
Clinical Research Centre for Health Professions
Aldro Building
University of Brighton
49, Darley Road
Eastbourne
East Sussex
BN20 7UR

Telephone: 01273 643457

Email: insert name

[©] The National Council for Osteopathic Research, 2010

Guidance on completing the Standardised Data Collection (SDC) form

These forms are being used in osteopathic practices across the United Kingdom to provide information about the patients and treatments at each individual practice and in the UK as a whole. The information will help in improving services and assessing whether treatments are effective.

Each osteopath is asked to complete the SDC form for <u>10 consecutive patients</u> <u>consulting with a NEW EPISODE.</u>

The questions are intended to be self- explanatory and unambiguous. Please let us know if they are not.

A form will be forwarded to you to be placed on display in your practice to alert patients that data collection is ongoing in your practice as part of a quality assurance process.

Please display this explicitly so that patients are aware that data is being collected and shared. It is also important that patients are <u>explicitly</u> asked that they agree to their confidential data being shared.

If any patients indicate that they are not willing to be involved in the data collection process, it would be helpful to make a note of the reason(s) for this and where this patient is positioned within the consecutive patients consulting you for treatment. Any patients who refuse to have their data shared should not be regarded as one of the 10 consecutive patients.

Length of data collection

The data collection process will begin on date to be inserted and finish on date to be inserted. Each practitioner is requested to post their completed forms back to the Clinical Research Centre as quickly as possible after the completion date for the data collection.

Completing the form

The SDC is intended to allow easy recording of information as an initial consultation progresses on to a second visit and subsequent follow up of a patient in clinical practice.

The data collection form is divided into five parts:

Part 1 contains patient data relating to the initial consultation. It is preferable for the patient to complete Question 25 to gain an unbiased picture of their symptoms.

Part 2 deals with issues relating to the management and treatment of patients including the treatment approaches used and supporting advice given.

Part 3 deals with issues relating to the gathering of consent. This information will be treated in strict confidence.

Parts 1,2 and 3 relate to the first appointment only.

Part 4 relates to the second appointment. This section gathers information relating to the response to treatment after the patient's first appointment, and all of the treatments

and advice concerning self-management given to the patient at their second appointment. It is preferable that the <u>patient</u> should complete the questions recording outcomes of care: these are questions 38 and 39. Patient completion will provide a more objective response, less prone to bias.

Part 5 relates to the last visit of the initial course of treatment provided for this episode of symptoms. Once again, to minimise bias, it is preferable if the patient completes Questions 46, 47 and 48.

Please let us know if any of the questions are unclear to you; it is easier to respond to initial queries by email.

At the end of the data collection period

When you have completed your data collection forms, please post them back to the project officer at the Clinical Research Centre, University of Brighton. The full postal address is at the front of this document. Please send the forms back at the most economical postage rate available and enclose a receipt; your postal costs will then be reimbursed. No reimbursement can be made for photocopying or for the use of ink jet cartridges.

Thank you for taking part.

Background to the questions being asked on the SDC form

Introduction.

The standardised data collection tool (SDC) has been developed by osteopaths in private practice in collaboration with NCOR, to allow the collection of information which will help to profile both patients and approaches to practice. The SDC has been developed in the knowledge that osteopaths treat patients from a wide range of age groups and with an extensive array of symptoms.

The information collected by the SDC will be helpful for individual clinicians, but also the profession as a whole as it deals with the demands of healthcare in the 21st century.

Ethics

Ethical advice was sought early in the development of the SDC. Data collection does not involve the introduction of new treatments and formal ethical review is not required. The data collection process is more comparable to audit than research in the strict definition of the term. All data collected will be anonymised and treated confidentially by the research team analysing the data. Patients will be asked for their permission for the data to be used for analysis. If they have any concerns about the data collection exercise, please refer them to the project officer, insert name.

Scales and classifications used in the SDC

Scales have been chosen, where available, which are documented in published literature and have been validated. National scales have also been used e.g. those contained in Census reports; this will allow comparison of findings from the data gathered in the osteopathic data collection exercise with national findings.

Part 1: Initial consultation details for a new episode

Patient height and weight (Questions 5 and 6)

Data will be collected about height and weight in a manner with which you and the patient are familiar. A conversion form will be used at the Clinical Research Centre to convert all data into metric form. The conversion chart to be used can be found at http://www.hantspt.nhs.uk/sys_upl/templates/AssetBrowser/AssetBrowser_disp.asp?ItemID=3069@basketPage=&basketItem=&pgid=7132&tid=146&page=1.

Qu. 16. How long did the patient have to wait for the first appointment to be offered?

This question requires information explicitly on the first appointment <u>offered</u>. Some patients may only come at a certain time of day or request to see a certain practitioner: this extends the waiting time. The time until the first available appointment offered is what is required.

Qu. 20. Duration of current problems

The duration of current problems will allow coding of information into "acute", "subacute" and "chronic" classifications, as recommended by the International Association for the Study of Pain http://www.iasp-pain.org//AM/Template.cfm?Section=Home.

Qu. 24. How long has the patient had their current symptoms with this episode? It is noticeable in practice that patients may have a problem for several weeks but their symptoms may develop and that is the impetus for seeking treatment. This question relates to the duration of time that the symptoms have been noticeably worse so that they have to seek treatment.

Qu. 25. Severity of the main symptoms present at the first visit (or visit with new episode of symptoms). This is a visual analogue scale that attempts to measure the severity of the symptoms the patient is experiencing; this may include many symptoms including e.g. pain, stiffness, and soreness.

Qu. 26. Symptom areas

It is important that the three main areas of symptoms are recorded. It is recognised that patients can consult for treatment with many more areas of pain or other symptoms. The categories have been modelled on those that appeared in two papers:

Parsons S, Carnes D, Pincus T, et al. Measuring troublesomeness of chronic pain by location. *BMC Musculoskeletal Disorders*. 2006;7:34.

Carnes D, Parsons S, Ashby D, *et al.* Chronic musculoskeletal pain rarely presents in a single body site: results from a UK population study. *Rheumatology*. 2007;46:1168.

Qu. 27. Co-existing Conditions

Categories have been used that were published in Groll DL, To T, Bombardier C, et al. The development of a comorbidity index with physical function as the outcome. *Journal of Clinical Epidemiology*. 2005;58:595-602.

Part 4: This section relates to information gathered at the patient's second appointment.

Qu. 38. Complications of treatment

This question relates to findings documented in research studies including the work by Cagnie, Vinck, *et al.* looking at common side effects of manual treatments.

Cagnie B, Vinck E, Beernaert A, *et al.* How common are side effects of spinal manipulation and can these side effects be predicted? *Manual Therapy.* 2004;9:151-6. This question specifically deals with any complications to treatment the patient experienced in the first 48 hours following the first treatment.

Qu. 39. Outcome of treatment

A number of rating scales exist, but many focus exclusively on pain. A generalised and validated global perceived effect scale, developed by Kemler *et al.* has been used in the SDC.

Kemler MA, De Vet HCW, Barendse H, *et al.* The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow up of the randomised controlled trial. *Annals of Neurology.* 2003;55(1):13-18. This question specifically deals with the patient's overall outcome after their first treatment.

Part 5: Last visit of the initial course of treatment for this episode

Qu. 46. Severity of the main symptoms.

This question attempts to identify the severity of the symptoms present at the patient's last visit. It is preferable if the patient completes this scale to avoid potential bias.

Qu. 47. Complications of treatment.

This question wants to know specifically if the patient is **continuing to experience** any lasting complications of treatment from the list provided. It is preferable if the patient completes this scale to avoid potential bias.

Qu. 48. Outcome of treatment

This question tries to identify specifically the patient's outcome of care at their final appointment or at their last appointment within the data collection period. It is preferable if the patient completes this scale to avoid potential bias.

Qu. 54. Patient's ethnic group

Ethnicity classifications have been taken from those recommended by the Equality and Human Rights Commission http://www.equalityhumanrights.com/en/Pages/default.aspx. This is a sensitive question for some patients and is optional if the patient feels uncomfortable providing this information.

What happens at the end of the data collection period?

The last day for data collection is date to be inserted. If a patient is only part of the way through their treatment, the data collection form would be completed up to this point and a note can be added to this effect at the end of the form.

All of your 10 data collection forms can then be returned to the Clinical Research Centre for Health Professions* where the data will be anonymised and analysed. A final report concerning the data will be produced for the profession to use.

What happens if I need help?

If you have any problems while trying to complete the data collection tool, <u>please</u> contact the project officer, <u>insert name</u> by telephone or email. Contact details are given below.

*Clinical Research Centre for Health Professions Aldro Building, University of Brighton 49, Darley Road Eastbourne East Sussex BN20 7UR

Telephone: 01273 643457 Email: insert email address

Appendix 8 Dissemination strategy

Dissemination of this study is planned in a series of stages.

Tool development process

- i. An abstract of the standardised data collection (SDC) tool development process was presented at the 8th International Conference on Advances in Osteopathic Research held in Milan in May, 2010. A copy of the abstract will appear in a future edition of the *International Journal of Osteopathic Medicine* (IJOM).
- ii. A full paper will be submitted to IJOM and a copy of the modified SDC tool (Version 2.0) will be published with this paper.

Findings of the national pilot

- i. An article will be published in *The Osteopath* highlighting the fact that the project has now finished and alerting osteopaths to the fact that the full report and a practitioners' report is available on the NCOR web site (www.ncor.org.uk).
- ii. An article will be published in *Osteopathy Today* focussing on how the results of the study can be used to promote practice and reflective practice. This will be written by the research team and submitted to the BOA.
- iii. A poster presentation will be made at the BOA conference in November, 2010.
- iv. A paper describing the results of the study will be submitted to IJOM.
- v. A paper describing the benefits of the use of standardised data collection and comparing it with the initiatives from other professions will be submitted to another academic journal.

Appendix 9 Abstract of the SDC tool development process

Development of a standardised data collection (SDC) tool to profile osteopathic practice in the United Kingdom

Fawkes CA¹, Leach CMJ¹, Mathias S¹, Moore AP¹. 1. University of Brighton

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Introduction: There is increasing interest in the provision of osteopathy from the public at large, the NHS and from government. Osteopathy is among a number of therapeutic approaches featuring in clinical recommendations, notably for back pain. Access to osteopathic treatment is through a variety of locations: private practices, National Health Service (NHS) hospital outpatient departments, General Practices (GPs) and clinics attached to osteopathic education institutions. The vast majority of patients access treatment privately.

Aim: Existing survey work suggests that back pain accounts for approximately 50% of an osteopaths' workload and that musculoskeletal type presentations form the majority of the remainder of the case load. However, these data have been produced by teaching clinics, single practices, or single day surveys, and need to be treated with some caution. In 2007 the National Council for Osteopathic Research (NCOR) began development of a standardised data collection (SDC) tool which fostered ownership for osteopaths. This would allow the profession to collect data concerning patients' profiles, their route to treatment, and outcomes of care. The data will also attempt to inform future research priorities for the profession.

Methods: The SDC tool was developed through a consensus process which has been successfully employed in other healthcare disciplines. A nominal group technique was employed. A series of meetings were held within the network of NCOR research hubs created in different locations throughout the United Kingdom (UK); the hubs acted as the nominal groups. A consensus version of the tool underwent two pilot phases by hub members, and one with non-hub members. The pilot data collection tool was used between April and July, 2009. This was comprised of two sections; one for patient completion, and the second part for completion by the practitioner, with the exception of questions involving the severity of symptoms and outcome information.

Results: A total of 1630 completed SDC forms were returned for analysis. Descriptive analysis of the data has provided information concerning basic demographics of patients presenting for osteopathic treatment. Information has also been gathered on presenting symptoms, the route to osteopathic care, time for access to treatment and the use of resources within the NHS. Data concerning management strategies employed in osteopathic care have been recorded, and information concerning the outcomes of care has been produced.

Considerable feedback was received from osteopaths involved in the project and this, in combination with the data analysis, has indicated where some further changes could be made to the standardised data collection tool for future use in snapshot surveys. A definitive version of the tool has been created since the completion of the final pilot phase of the project.

Conclusions: Early analysis has provided interesting pilot data concerning the profile of UK osteopathy. This data will be used to assist the continued development of the profession by indicating future research priorities, and support osteopaths who wish to learn more about their practices and are aiming to expand their practices into other healthcare arenas e.g. the NHS. This project was made possible through funding by the General Osteopathic Council.

Appendix 10 Report for the profession and guidance on how to use the data

The Standardised Data Collection (SDC) project 2009

Report for the osteopathic profession

Authors: Carol Fawkes, Janine Leach, Shirly Mathias, Ann P. Moore

University of Brighton

Acknowledgements

We are grateful to the General Osteopathic Council for funding the National Council for Osteopathic Research to conduct this project.

We are grateful to the many osteopaths who gave their time to participate in the development of the standardised data collection tool and the collection of data for this project, and to NCOR members who have fed into this proposal at various stages of its development. We are indebted to the members of the Steering Group including Michael Watson, Bryan McIlwraith, Jorge Esteves and Kelston Chorley for their time and expertise in ensuring the project was valid and fit for purpose and the results were exploited in full.

Finally, we are grateful to those patients who allowed their anonymised data to be included in the data collection project.

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Abstract

- 1. Introduction
- 2. Development of the osteopathic SDC tool
- 3. National data collection using the SDC tool
- 4. Profile of osteopathic care
- 5. Outcomes of osteopathic treatment
- 6. Patient Safety
- 7. Equality and Diversity in access to care
- 8. Osteopathy in the wider healthcare setting
- 9. Cost effectiveness and NHS resources
- 10. Sickness absence and return to work
- 11. Practice management issues
- 12. Consent issues
- 13. Discussion of the results
- 14. Future use of the results
- 15. Implications for research and use of the current dataset
- 16. Dissemination of the results
- 17. Future use of the SDC tool

Abstract

The overall aim of this project was to develop and pilot a "Standardised Data Collection" (SDC) tool for the collection of patient-based data within osteopathic practice in the UK. The primary aim of the project was to generate good-quality information of high relevance to the stakeholders of the osteopathic profession in the UK. Very little was known from a national perspective of the day-to-day practice of osteopaths in the private sector, the profile of patients who consult osteopaths or the outcomes of their care. The project's second aim was the active involvement of practitioners in research as a means of building research capacity within the profession.

The project arose from the need to develop research capacity in the osteopathic profession, in the context of increasing use of complementary therapies by the general public, the national emphasis on quality assurance, audit within clinical governance, and on patient-centred care.

Methods

The project as a whole was framed as a form of cooperative enquiry between practitioners and NCOR. To allow maximum involvement and ownership, a Nominal Group Technique was used with practitioners in the nine NCOR regional research hubs generating the topics of interest. The project Steering Group acted as an expert panel, and the tool evolved through three iterative rounds of development, feedback and refinement until a draft SDC tool emerged. A three-stage testing process was conducted before the final SDC tool was ready for a large scale national pilot. An opportunity to participate in a 3-month data collection of all new patient-episodes was advertised to all osteopaths registered currently with the General Osteopathic Council (GOsC).

Results

A total of 9.4% of the profession volunteered to participate and data were collected on 1630 new patient episodes in 2009. The data were input and descriptive statistical analysis was carried out providing a profile of osteopathic care. Important messages emerged from the data about possible inequity of access to osteopathic care, the quality of osteopathic care, outcomes of care, the active role of osteopaths in the wider healthcare arena, the possible potential for osteopathy to offer savings of NHS resources, and to aid employers with long term sickness absence.

The project has provided baseline pilot data for comparison with future snapshot surveys, as well as providing robust information about a number of important issues relevant to professional practice, policy, regulation, and future research. The evidence presented here may be used by practitioners and professional organisations to provide information about osteopathy and osteopathic care to the general public, commissioners and government organisations. The pilot data should not be used in isolation to support advertising claims made by individual practitioners.

1 Introduction

The aim of this report is to provide positive benefits for the UK profession from the SDC project, by providing information for practices about the project's results, and to show the variety of uses of that data, including

- enabling practices to create their own individual profile;
- providing a resource for presentations to the public, the media and to NHS commissioners.

The stakeholders for this project included

- the General Osteopathic Council¹
- the general public, who were interested in aspects such as safety and adverse reactions, informed consent, insurance, and clinical governance
- the British Osteopathic Association (the professional body)²
- ❖ practitioners who are interested in information on aspects such as marketing, crossprofessional dialogue, treatments and outcomes; NCOR and the research community, who are interested in research development, evidence, priority setting for research and audit, evidence-based practice and assessment of quality of care³
- ❖ the NHS which is interested in efficient use of resources particularly in the treatment of back pain^{4,5,6,7,8,9,10}
- the government which is interested in safety, regulation, quality and integrative care¹¹.

2 Development of the osteopathic SDC tool

The standardised data collection tool was developed by and with many practising osteopaths in the nine regional NCOR research hubs, and was designed to specifically reflect the osteopathic approach to patient care.

The SDC tool underwent a three-stage testing process prior to the launch of the final SDC tool version 1.0, for a national pilot data collection project in 2009. The final version of the SDC tool contained 65 data items in five sections. As far as possible, national classifications were used for comparability, and structured questions or tick-boxes were used to make the form easily completed.

The form was designed to follow the flow of a consultation and contained five sections: Part 1: Patient data; Part 2: Presenting symptoms; Part 3: Management and treatment at first appointment; Part 4: Second and subsequent appointments; Part 5: Final outcome(s) of care. The first section was patient-completed, the remaining sections were practitioner-completed. Patients were required to complete questions concerning their duration of symptoms and their outcomes of care at the first, second and final treatment.

3 National data collection using the SDC tool

Recruitment of practices to participate in the national data collection was voluntary. All UK practising osteopaths were invited to participate in the trial of the SDC. Participation involved collecting data on up to 10 new patients presenting over a 3 month period (1 month of recruitment and 2 months for follow up) in 2009.

In order to maximise participation in the national data collection, NCOR conducted a well-publicised launch of the SDC tool, to promote the aims and benefits of participating in the survey, at a series of national meetings and in the osteopathic press. Invitations to participate were distributed by email using existing contacts as well as the BOA and GOsC lists; recruitment was conducted personally at regional conferences and participation in the project was advertised to practitioners in *The Osteopath* and *Osteopathy Today*.

The number of eligible, registered osteopaths that volunteered during the recruitment period was 394 representing 9.4% of the profession. Each of these 394 practitioners was sent 10 SDC forms and guidance notes in April 2009. The data collection tools were given an identification (ID) code which preserved patient anonymity. The data collection period was between April 20th and July 17th, 2009. The completed data collection tools were returned to the Clinical Research Centre over the next 5 months and were anonymised and entered into an EXCEL database as they arrived.

A total of 1630 completed forms were received from 342 (86.8%) of the 394 osteopaths originally recruited. The forms were completed very thoroughly, with few unanswered questions. The results are presented fully in the final report to the General Osteopathic Council. The results which hold important implications for practice have been drawn together below.

4 Profile of osteopathic care

The results supported the view that osteopaths predominantly treat musculoskeletal conditions. As shown in Figure 1, low back problems (lumbar spine and pelvic problems) comprised over 40% of presenting symptoms, with cervical spine, shoulder and thoracic spine problems comprising a further 28% of the conditions treated by osteopaths. However, the range of presenting symptoms is diverse, including headache (7%), conditions suffered by infants and children (8.5%), with considerable (13%) clinically diagnosed co-morbidity, and differing modes of onset including trauma.

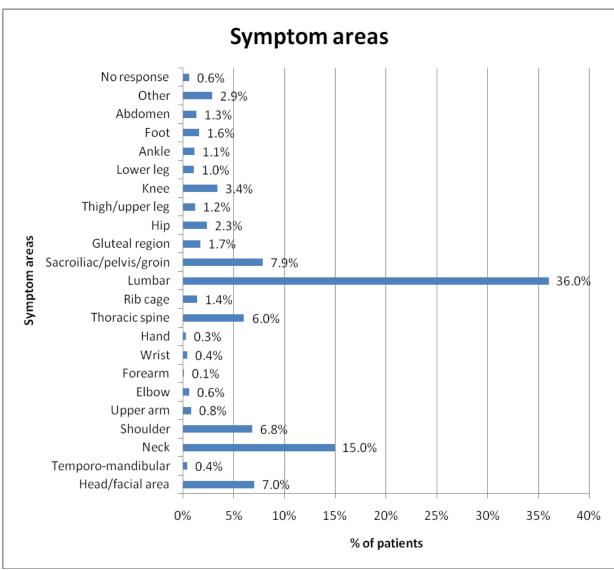
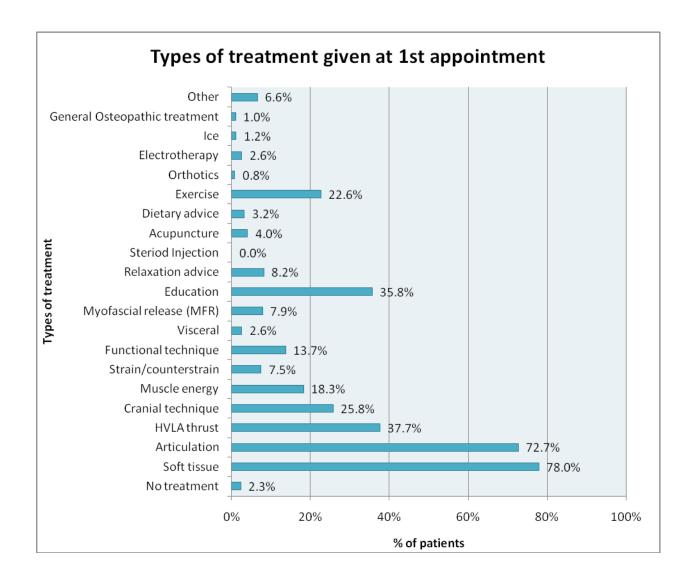


Figure 1. Site of first symptom at presentation

The wide range in the types of treatment given (Figure 2) shows the diversity and flexibility of osteopathy; this diversity of care has the advantage of offering patients choice, but can also be an

unwelcome source of confusion for members of the public. However, almost all patients received soft tissue treatment and joint articulation. The use of HVLA (high velocity low amplitude/thrust techniques), education, cranial osteopathy and exercises were also common.

Figure 2.



The type of treatment given at second and subsequent appointments showed a similar distribution.

The wide scope of osteopathic practice – dealing with a wide range of presenting problems and using the wide range of techniques for treatment, patient education and self-management – demonstrates why it is essential that osteopaths continue to receive a high level of training including anatomy, physiology and pathology.

The data provided evidence that osteopaths were providing a patient-centred service. The waiting times for treatment were short, with 84% patients seen within one week (Figure 3). The patients received long consultations, normally 30-60 minutes for the first appointment and 30-45 minutes at subsequent appointments.

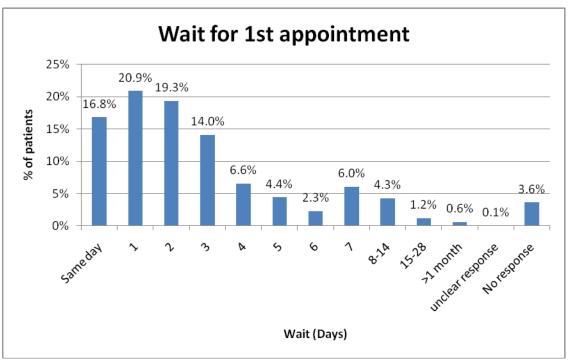


Figure 3. Waiting time for first appointment offered

The majority of consultations included education (73%) and information-giving (84%) (Figure 4) as well as advice on self- management strategies (88%), with many patients being given more than one strategy to try (Figure 5).

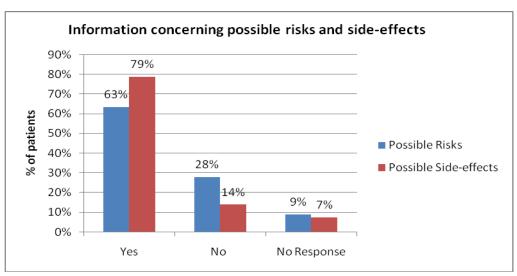


Figure 4. Information-giving about possible risks and side effects

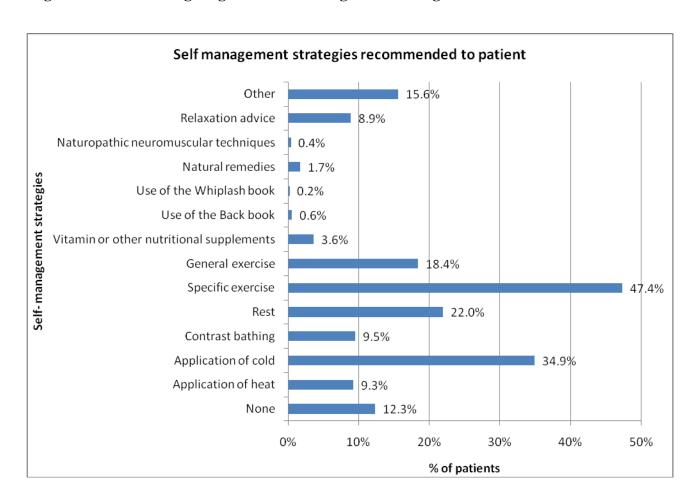


Figure 5. Information-giving about self-management strategies

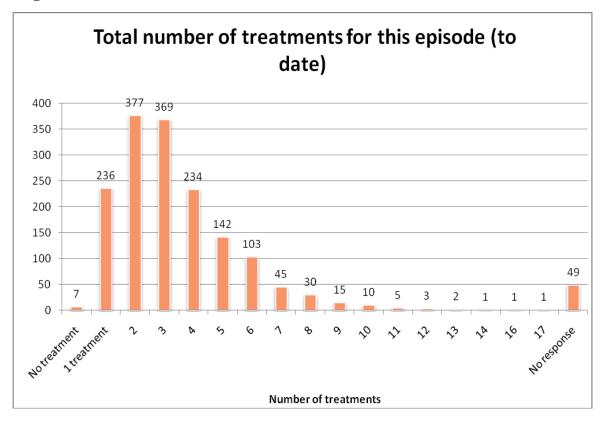
Co-morbidity diagnosed by a medical practitioner was recorded in 13% of the sample, the most common conditions were hypertension (11.7%), mental health problems (anxiety [3.6%] and depression [3.6%]), asthma (6.6%), arthritis (5.7%), upper gastrointestinal (GI) disease (5%), migraine (3.8%), and bowel disease (3.7%). There is clearly scope for osteopaths with suitable additional training to assist in the recognition of hypertension and mental health problems, with appropriate advice and referral to appropriate specialist care.

5 Outcomes of osteopathic treatment

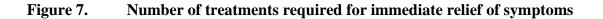
More than one-third (39%) of patients had a satisfactory resolution of symptoms and were discharged after their course of treatment. A further one third (39%) of patients took the opportunity to return for "episodic care" - preventive treatment at intervals, also called maintenance care. A total of 10% of patients were referred on for investigation(s) or treatment. Less than 1% of patients had not completed their course.

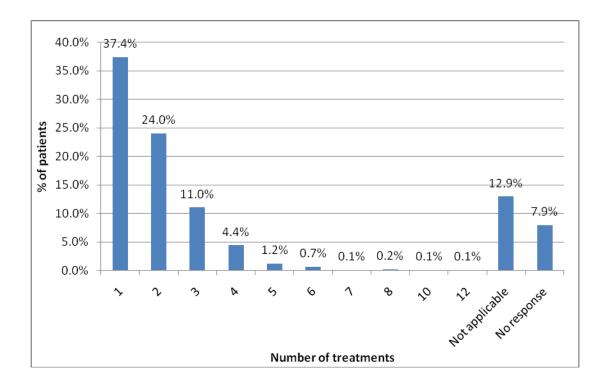
The number of treatments until discharge or the end of the initial course represents a measure of outcome and is useful for evaluating cost-benefit: the number of treatments ranged (Figure 6) from 1 to 17 with a mean of 3.45 (SD=2.04) treatments to discharge.

Figure 6.



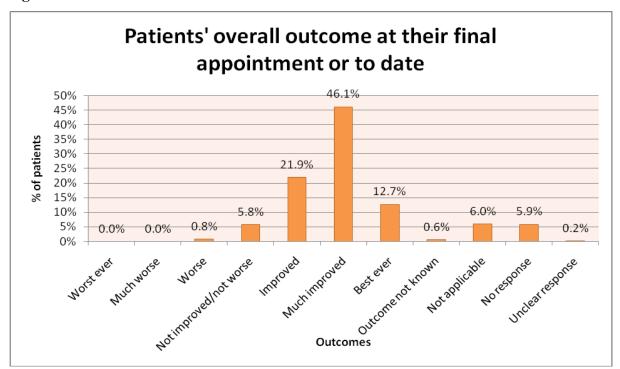
There is scant data on the cost per consultation in the UK, but in most geographical areas it is thought to be in the range £25-£50, making the cost of the course on average £86-£172. The mean of 3.45 treatments per course was unexpectedly low, and may be an artefact due to the follow-up period being 2 months - which only allowed for 4-5 fortnightly appointments. However the fact that relief of symptoms was rapid (Figure 7) supports the validity of the data.





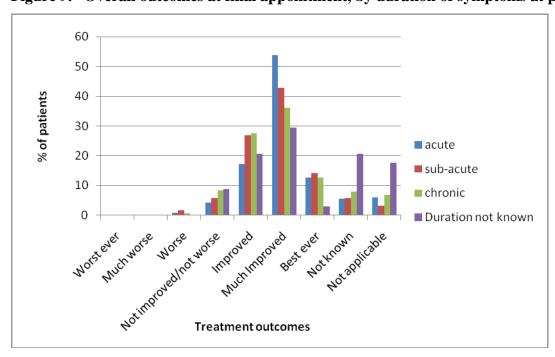
A simple patient-reported outcome scale was used which asked patients to tick whichever box best described their overall outcome at that date. The data provided useful statistics, with 74.3% of patients reporting to be improved, much improved or "best ever" after the first treatment, rising to 80.7% after the final treatment (Figure 8) and less than 1% in the "worse" category. The results suggested that most patients experience relief following the first treatment, and considerable improvement after a short course of treatment. These results do have to be <u>interpreted with some</u> <u>caution</u> because there was potential for under-reporting of unsuccessful patient episodes, and the outcome measure was not a validated scale for patient-reported outcomes.

Figure 8.



Outcomes were compared, after sub-dividing the patients according to duration of symptoms at presentation. As shown in Figure 9, outcomes among those with sub-acute and chronic symptoms were almost as good as those with acute symptoms. This result supports the recommendations of osteopathic care as a first line option in the guidelines published by the National Institute for Health and Clinical Excellence (NICE) for the early management of chronic non-specific low back pain ¹⁰.

Figure 9. Overall outcomes at final appointment, by duration of symptoms at presentation



6 Patient Safety

Reactions to treatment were reported more frequently by patients after the first treatment than after the second and subsequent treatments (Table 1). The reactions that were reported were minor and transient after the first treatment and included stiffness (18%), pain (14.6%), fatigue (6.6%), headache (2.3%), dizziness (1.5%), or nausea (0.7%. These figures are comparable to those reported in the literature ^{12,13}. No serious effects were reported.

Table 1

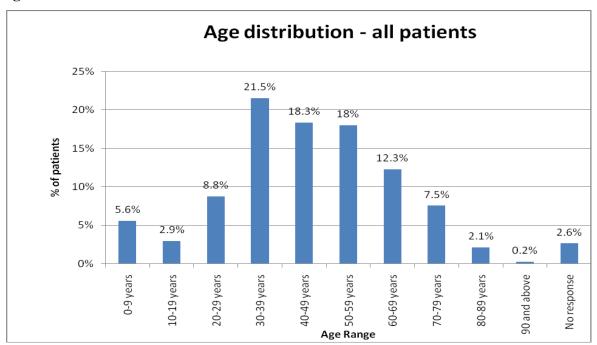
Complications reported after	Percentage after 1 st	Percentage after 2 nd and
Treatment	treatment	subsequent treatments
None	59.4	77.3
Increased pain	14.6	3.7
Increased stiffness	18.0	4.4
Dizziness	1.5	0.3
Nausea	0.7	0.2
Headache	2.3	0.7
Fatigue	6.6	2.7
Serious adverse event	0.1*	0
No response	7.4	4.2
Other	0.5	0.2
Complications not known	0.4	0.7
Not applicable	1.0	8.0
Total	112.6	103

^{*}This was recorded in free text as an "emotional response": this was considered unlikely to represent an adverse event as defined commonly in the literature.

7 Equality and diversity in access to care

The gender profiles showed that osteopathy was accessed equally by men and women. While the age distribution of patients (Figure 10) showed that people of all ages from birth to octogenarians used osteopathy, it also showed that users were concentrated in those of working age, the peak in the distribution spanning ages 30-59 years, with the mean at age 45 years. In addition, the data showed evidence of the popularity of osteopathic care for infants: of the 91children aged 0-9 years, 58 (64%) were babies of 0-12 months old.

Figure 10



The fact that 89% of patients paid for treatment privately and less than 10% treatments were funded by agencies other than the patient themselves (Table 2), represents a potential barrier to those on low incomes. The information about occupation and work status confirmed that osteopathy was used by people from all backgrounds and types of occupation, but 81% were employed people or retired. Only 6-8% of patients were unemployed or disabled, suggesting that there may be inequity of access to osteopathic care due to low income.

Table 2.

Responsibility for payment	Number	Percentage
Self	1453	89.1%
Insurance company	107	6.6%
Employer/own company	9	0.6%
Referral by NHS	9	0.6%
Other	20	1.2%
No response	32	2.0%
Total	1630	100%

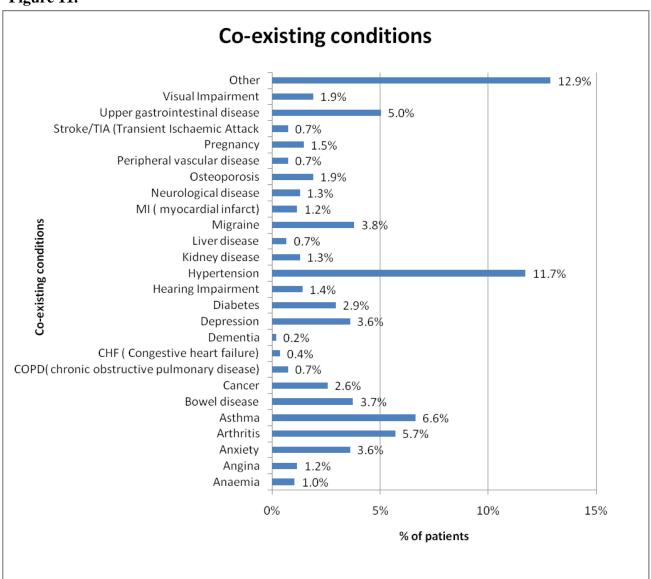
Parents who do not have discretionary income are potentially unlikely to be able to access osteopathic care for their babies and children. Where there is a mismatch between the osteopathic patient profile and the profile of the general population, there may be also either inequity of access or a lack of appropriate marketing in the under-represented sector of the patient population.

For example, the age profile of patients does not resemble the frequency of musculoskeletal problems within the population, and suggests that the elderly may be particularly disadvantaged in accessing osteopathic care.

The ethnic profile of osteopathic patients showed that the vast majority (94%) of patients were white British or white European, and a slightly lower proportion of ethnic minorities compared to the UK population as a whole. The data raises questions about whether under-representation of ethnic minorities is because so little osteopathic care is paid for from the public purse. Investigation of the reasons for the lack of ethnic diversity would be helpful.

The data on co-morbidity confirmed that the general health of the patient sample was good, with recorded co-morbidity in only 13% of the sample (Figure 11).

Figure 11.



In summary, the data suggest possible inequity of access to osteopathic care in the very young, the elderly, in ethnic minorities, those on low incomes and the long-term sick. This evidence is of concern and is likely to be related at least in part to the lack of funding of care from the state sector.

8 Osteopathy in the wider healthcare setting

Osteopaths interact with orthodox medical and diagnostic services, as well as with other healthcare providers. Contact with a patient's GP occurred for at least 10.1% of patients, and diagnostic investigations were recorded for 29% of patients.

A total of 244 patients were referred by their osteopath to another practitioner; the majority for further investigation(s) or treatment from orthodox medicine, but also to other complementary practitioners or for lifestyle interventions such as exercise specialists (Figure 12).

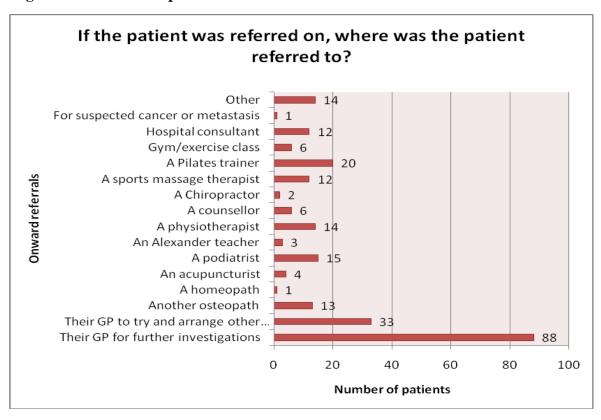


Figure 12. Referral of patients

The data showed the degree to which the osteopaths were working as integrated healthcare practitioners, within a wider healthcare arena, and also conforming to the osteopathic Code of

Practice which requires osteopaths to work with other healthcare practitioners and refer patients on if appropriate. The variety in the routes of onward referral (Figure 12) suggested that patients were offered choice. The data also confirmed anecdotal reports of osteopaths detecting suspected malignancy and referring patients appropriately for further investigation or treatment.

Almost half of the patients (48.1%) had visited their GP prior to visiting the osteopath (Figure 13). In contrast, only 6% had been referred to the osteopath by their GP and only 0.6% of patients were paid for by the NHS. The patients' GP was contacted during the course of treatment for 10.1% of patients; for 6.4% this represented a request for further information or investigation, or a referral requesting other treatment.

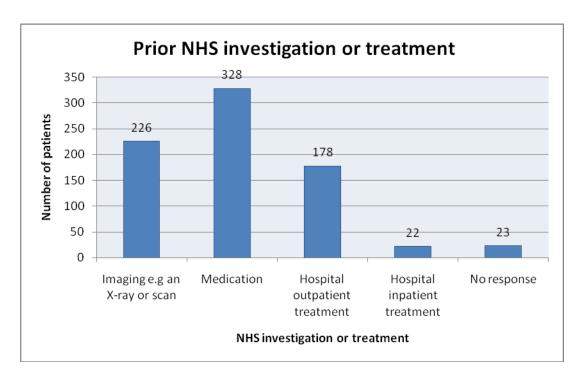
Number of visits to the GP prior to coming to the practice 60% 48.0% 50% Number of patients (%) 40% 30% 19.2% 20% 12.4% 8.8% 7.7% 10% 2.9% 0.9% 0% No visits 1 visit 2 visits 3 visits 4 or more No response Unclear visits response Number of GP visits

Figure 13

9 Cost-effectiveness and NHS resources

While the NHS was paying for the osteopathic treatment of only 0.6% of patients in the sample, the patients reported considerable use of other NHS resources prior to attending the osteopath for their symptomatic episode (Figure 14), with 29% of patients having received NHS treatment or investigations, a few of these being for hospital in-patient treatments.

Figure 14. Use of NHS resources



A small number (6%) of patients were on an NHS waiting list for treatment, and 23% of these had been waiting for NHS treatment for more than 2 months. In view of the favourable outcomes reported by even those with chronic symptoms, these data raise significant questions about whether early referral to an osteopath could potentially lead to significant savings to the NHS. A targeted research study investing this specific question would be required to support this.

10 Sickness absence and return to work

Most people using osteopathic treatment (86%) were able to remain at work whilst under-going their course of treatment (Figure 15). Some 13% were off work at their first appointment, most for less than 1 week. Those patients that were off work were able to return to work within 1-3 treatments (Table 3).

Figure 15. Sickness absence

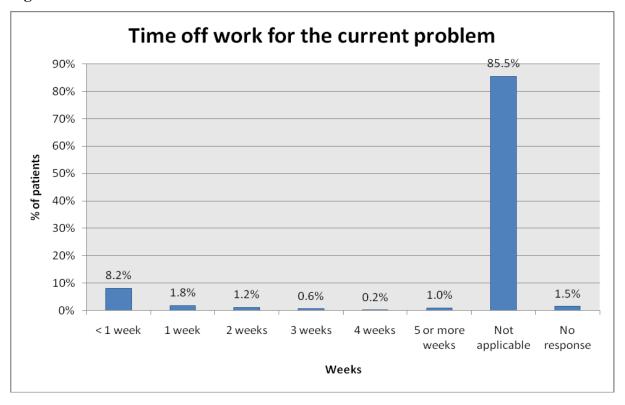


Table 3. The number of treatments before the patient was able to return to work

Number of Treatments	Number	Percentage
1	86	5.3
2	51	3.1
3	18	1.1
4	11	0.7
5	2	0.1
10	1	0.1
11	1	0.1
Not applicable	1345	82.5
No response	115	7.1
Total	1630	100

Chronic sickness-absence was rare in this sample of patients; only 1% of patients were referred by their employer. In view of the favourable outcomes suggested by the data for chronic symptoms,

there would appear to be a potential opportunity for marketing by the profession among employers.

11 Practice management issues

The results showed that 59% of the new episodes described were for patients who were new to osteopathy, which may suggest that practices were flourishing, and that members of the public were aware of osteopathy and used it when they needed it, finances permitting.

The desire to have a drug-free (9.1%) or hands-on therapy (9.1%) was a common reason for choosing osteopathy. The results have also demonstrated patient-centred care, with short waiting times and choice in treatment and after-care are other aspects which osteopaths can utilise in their marketing.

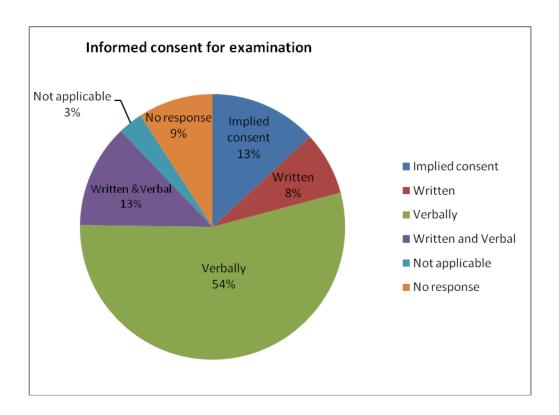
Advertising was a relatively small source of patients. Most (70%) patients had heard about the practice they attended by word of mouth and 65% stated that they chose osteopathy because of personal recommendation. However, there were clearly large sectors of the population not being reached by osteopathy: there appeared to be potential for osteopathy to offer services to employers to reduce sickness absence due to musculoskeletal conditions and to target services to the sectors of the population mentioned in the equality and diversity section above.

12 Consent issues

The questions on this topic were carefully worded in order to be non-threatening to practitioners, in order to minimise non-response. Despite this, non-response was much higher than for the other data items, between 9% and 19%. The wording was kept deliberately rather general, although this had the disadvantage of making responses harder to interpret. Obtaining accurate information around this issue requires specific and sensitive questioning within a separate piece of research.

The current evidence from the data was slightly inconsistent, but suggested that informed consent for examination was obtained from 80-90% of patients (Figure 16)

Figure 16. Informed consent for examination



Consent for treatment using specific techniques was obtained from 57% of patients at first treatment (Table 4) and 42% at subsequent treatment.

Table 4. Informed consent for treatment using specific techniques

Informed Consent	Number	Percentage
Yes	933	57
No	436	27
Not applicable	206	13
No response	55	3.1
Total	1630	100

Information about the risks and side effects were reportedly given to 63% and 79% of patients respectively as shown in Figure 4, but again the wording of this question was rather general and hence imprecise. Considerable further investigation is needed on the issues around informed consent.

12 Discussion of the results

This data collection project has provided the most detailed cross-sectional profile of osteopathic care in the UK to date. The earlier snapshot survey in 2001 by GOsC collected socio-demographic details of osteopaths and the patients they saw on a single day¹⁴. In contrast, the patients described in this project were homogeneous - they were all commencing treatment for a new episode – making the data about care much more detailed, and the additional follow-up of patients has provided some outcome data.

The involvement of the profession in the design of the dataset clearly paid dividends: not only did 9.4% of the 4198 osteopaths registered with the GOsC in 2009 (source: GOsC web site) volunteer to take part in the project, but also 87% of these osteopaths actively collected data and were thus involved in systematic research activity¹. High quality data were collected concerning 1630 patient episodes, a sufficient sample size for statistical analysis.

Feedback from participating osteopaths, and from the analysis of the data, has lead to further review and slight modification of the standardised data collection tool. The tool was not well suited for use with small children, due to children's presenting symptoms being different from adults, and many of the questions being not applicable. However, the data gathered in this project will inform the development of a special version of the questionnaire for infants and children for the future.

We hope that the SDC tool will continue to be used by practitioners to collect and analyse their own data to evaluate their own practices, and to provide useful discussion material for groups of practitioners, who often work in isolation.

13 Making use of the results

This project has provided baseline data for comparison with future snapshot surveys, as well as providing information about a number of important issues relevant to professional practice, policy, regulation, and future research. The evidence presented here may be used by practitioners and professional organisations to provide information about osteopathy and osteopathic care to the general public, commissioners and government organisations.

The data from the standardised data collection provided evidence about current osteopathic care in the UK. Important messages emerged from the data about possible inequity of access to osteopathic care, the quality of osteopathic care, favourable outcomes, the active role of osteopaths in the wider healthcare arena, and the possible potential for osteopathy to offer savings of NHS resources, and to aid employers with long term sickness absence.

14 Implications for research and future use of the current dataset

The dataset will be available as a resource for future research, with appropriate permission from the sponsors. Individuals or organisations will be able to apply to NCOR and the University of Brighton, the research sponsor, if they wish to use the data or the results for any specific purpose.

The results have raised a number of important questions about practice that can only be fully answered through further research, to gain understanding and/or better statistics. These include for example:

- ❖ Is there lack of equity of access for the elderly and for ethnic minorities?
- What are the obstacles and difficulties for osteopaths in gaining informed consent for treatment?
- ❖ In what circumstances are HVLA techniques used in the treatment of the elderly?
- ❖ What is meant by "specific exercise"?
- ❖ What is the profile of presenting symptoms, treatments given and outcomes of babies and children presenting for osteopathic treatment?
- ❖ What are the patterns of referral to the medical profession and other complementary practitioners?

15 Dissemination of the results

The full report of the project has been submitted to the GOsC and will be uploaded onto the GOsC's and NCOR's web sites. The first paper for the *International Journal of Osteopathic Medicine* has been drafted, describing the development of the SDC tool. A second paper is planned presenting the results of the national pilot data collection.

This report represents dissemination to practitioners, and this will be utilised as the basis for wider dissemination through shorter articles in *The Osteopath* and *Osteopathy Today*, and as a poster for the BOA conference in November 2010.

16 Future use of the SDC tool

The SDC tool also has many possible future uses for research, and snapshot surveys. At the end of the project, the SDC tool was considered to have worked well both for both data collection and data analysis, and has needed only limited modifications for future use. A revised version of the SDC tool (Version 2.0,) has been produced for use by all members of the profession, with accompanying guidance notes. There is national and international interest in the use of the SDC tool, with enquiries from osteopathic groups in New Zealand, Australia, Canada and mainland Europe.

The SDC tool can be adapted for a range of uses for collecting practice-based data of various types. The SDC tool may also be used in association with validated and reliable outcome measures e.g. the SF-36 or SF-12; alternatively the EuroQol-5D could be used which may produce some cost effectiveness data.

The SDC tool can be adapted also for specific purposes, such as specific symptom sites (a version for cervical spine symptoms is currently being used); a short version of the form to gather information on a daily basis is also being developed. The development of an electronic version for possible ongoing use within the profession is also proposed.

The development of a version of the SDC tool for infants and children is proposed, in collaboration with the osteopathic organisations specialising in this area of practice e.g. the Foundation for Paediatric Osteopathy, the Sutherland Cranial College, and representatives from the children's clinics within Osteopathic Educational Institutions.

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