

Complaints and claims against osteopaths: a baseline study of the frequency of complaints 2004–2008 and a qualitative exploration of patients' complaints

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ABSTRACT

Introduction

The primary objective of this study was to investigate the frequency and character of complaints made by patients about osteopathic care, and to whom those complaints had been made. The second objective was to gain a greater understanding of the nature of the complaint and the circumstances leading to complaints. The study is one of four pieces of work commissioned by the National Council for Osteopathic Research to provide evidence of risk associated with osteopathic care. The project was funded by the statutory regulator, the General Osteopathic Council (GOsC); the right of patients to be made as fully aware as possible of any known risks associated with the intervention, before consenting to care, is reflected in their Code of Practice for Osteopaths.

Methods

The project comprised a literature review followed by primary research, in collaboration with the organisations that record or advise on the majority of complaints from osteopathic patients: the regulator, the GOsC; the providers of professional indemnity insurance; and the professional body, the British Osteopathic Association (BOA).

The three stages of the project aimed (1) to create a classification scheme suitable for categorising and coding the types of complaint made by osteopathic patients, developed using consensus panel methods; (2) to conduct a quantitative analysis of anonymised complaints records supplied by the participating organisations; (3) to use qualitative methods to gain understanding of the nature of complaints through a series of interviews with purposively selected individuals in the participating organisations. A thematic analysis of the transcripts of these interviews was used to generate a conceptual framework about how complaints arise, and why they become formalised.

Results

The literature review established that no previous studies had quantified complaints about osteopathy, nor examined patterns in the types of complaints within manual therapy professions. Complaints statistics from the respective regulators show that rates of complaint vary somewhat between professions, with osteopathy being somewhat low compared to chiropractic (at 211) and high compared to physiotherapy (rates being 68, 211 and 20 per 10,000 p.a. respectively). The research literature on adverse events suggested that serious effects after osteopathic treatment are extremely rare (1 in 500,000 or less frequent) while mild effects are common (up to 8 out of 10 patients).

Anonymised records for 351 complaints from osteopathic patients in the five-year period 2004-2008 were supplied by the participating organisations, of which only 97 were formal complaints to the regulator. With a mean population of 3,731 osteopaths on the GOsC Register, this represented a mean rate of 187 per 10,000 registrants p.a.. A classification system was developed in order to code complaints by type. The pattern of complaints by type showed that the most frequent complaints were related to clinical care (68%), of which a large proportion were adverse events. The second most frequent type of complaint was about conduct and communications (21%). However, there were statistically significant differences (p<0.0001) between organisations in the distribution of complaints by type. Between 2004 and 2008 there was no statistical evidence of an upward trend, nor any change in the patterns of complaints by type.

The thematic analysis of the five narrative interviews generated a hypothesis that complaints are a complex chain of events: the event that **triggers** a complaint – most often pain or reaction to treatment or the conduct of the osteopath – is the explicit reason for the complaint, but this will be preceded by **underpinning factors**, such as unmet or unmanaged expectations. Patients have a **desired outcome** in mind when they complain. The progress of the initial complaint – whether it is formalised or **resolved** – depends on the osteopath's understanding of the patient, their reaction to the discord, and their ability to communicate empathetically.

Conclusions

The report provides recommendations for future monitoring of complaints and identifies priorities for future research: these include developing and testing the new classification system; improving on the quality and accuracy of the routinely collected data to assist in evaluation of outcomes; and utilising further sources of quantitative and qualitative data.

Important messages emerged – especially from the interview data – for the osteopathic profession, for the osteopathic organisations and Insurance Providers, and for policy development. Explicitly listening to users' complaints is likely to build patients' confidence in the osteopathic profession. The reports and dissemination strategy should inform the profession, educators, insurers and the public of the findings.

EXECUTIVE SUMMARY

This summarises the findings of each chapter. Note that references to the statements made below can be found within the relevant chapter.

1. Introduction

- ➤ The primary aim of this project was to investigate the frequency and character of complaints made by patients about osteopathic care, and to whom those complaints had been made.
- ➤ The secondary aim of this project was to gain a greater understanding of the nature of the complaint and the circumstances leading to complaints.
- ➤ The overall methodological approach was Action Research, which aims to improve a service or professional practice.
- ➤ Both formal and informal complaints were included; also complaints that resulted in claims.
- There are two main pathways for complaints: via the Regulator or via the osteopath and their provider of Indemnity Insurance.
- ➤ All information on complaints and claims (apart from those that go to Court or Regulator hearings) is confidential and not in the public domain. Statistics are routinely published only for complaints heard by General Osteopathic Council (GOsC) Professional Conduct Committees.

2. A review of evidence on complaints in manual therapies

- ➤ The scientific literature on complaints and claims within healthcare is limited, mostly concerned with adverse events and complaints against medical doctors. The grey literature yielded contextual information relevant to osteopathy.
- The search for published data revealed no papers on malpractice trends in manual therapy professions. The search was hampered by the lack of an indexing term

- within the research databases for patient complaints, reflecting the novelty of this area of research.
- All types of complaints *by patients* against osteopaths were included. The scope was extended to chiropractic, physiotherapy and other health professions due to the paucity of research evidence overall.
- ➤ Complaints statistics were published by a number of regulatory bodies in the UK. The number of complaints by patients to the osteopathic regulator, GOsC, between 2001–2007 was 68 per 10,000 registrants per annum, on average. The comparable rates for chiropractors, dentists and physiotherapists were 211, 45 and 20, respectively.
- ➤ The number of local complaints about the service was not published for osteopaths or chiropractors. The rate of local complaints against dentists, logged by the Dental Complaints service, was eleven times greater than the rate of complaints to the regulator; for NHS-employed professions, local complaints were some fifteen times higher than those to the regulator (the HPC).
- An upward trend in litigation, as observed within orthodox medicine, does not appear to have occurred in osteopathy.
- Although there is an extensive literature on complaints against doctors, few studies were located which aimed to identify factors causing patients to complain, or to gain understanding of why patients complain. In medicine, physician characteristics such as low patient satisfaction scores, surgical specialty, and a history of complaints increase the likelihood of complaints. The physician who is able to establish rapport, to be accessible to patients for queries, to meet care expectations and communicate effectively is less likely to receive a complaint. Patient characteristics appear less important, although emergency presentation and living in an urban area may be risk factors.
- ➤ There was no routine adverse event reporting system within osteopathy; the literature suggested that serious adverse events were very rare (less than 1 in 500,000); mild effects were more frequent. Data collection piloted by a UK training clinic showed mild "additional effects of treatment" were experienced by over 50% of patients 1-7 days after treatment. Education of practitioners in

- dealing with complaints appropriately, and coping with anger expressed by patients, may be helpful in avoiding conflict and for speedy resolution of complaints.
- Adverse events and complaints can provide a learning tool for practitioner education. A pilot system of routine incident reporting has been tested within chiropractic as a learning system.
- ➤ Key publications about the legal and ethical aspects of handling complaints showed a shift since 1996 towards speedy local resolution of complaints; these principles have been implemented within the NHS over time.
- ➤ This literature review confirmed that the present study, designed to quantify the frequency of complaints within osteopathy, and to gain understanding of why patients complain, is the first of its kind, providing novel information applicable to all the manual therapy professions.

3. Access to the data

- The research critically depended on access to the data on complaints; the research team was fortunate to receive support from all five organisations: the GOsC and the four providers of professional indemnity insurance to osteopaths: Balens, Howden, Three Counties and Towergate-MIA.
- ➤ Three of the four insurers Balens, Howden, and Three Counties viewed the study as a positive step towards risk management and agreed to participate fully. We hope that the study outputs will demonstrate that collaboration is costeffective by helping to reduce the frequency of complaints.
- ➤ The anonymised Events Log Files provided by the participating organisations contained sufficient detail to attempt a quantitative analysis of frequencies and trends, and permitted the complaints to be coded by type.
- The study protocol had four stages: a literature review; development of a classification system for type of complaint; statistical analysis of the collated complaints data; and a qualitative interview study of key individuals in the participating organisations, to gain understanding about why complaints are made.

- ➤ The General Osteopathic Council, the British Osteopathic Association and the providers of professional indemnity insurance to osteopaths, all supplied data and/or made staff time available for interviews or discussion.
- An expert Steering Group was a huge asset to this research. It provided representation of all the stakeholders, including users, and not only facilitated collaboration but also provided legal, ethical, academic and user expertise at all stages of the study.

4. Creation of a new system for classification of types of complaint

- ➤ A new "NCOR3" system for classification and coding has been developed specifically for osteopathic complaints.
- ➤ The new classification is meaningful to the participating organisations, relates to the professional Code of Practice for Osteopaths produced by the GOsC, and is patient-centred.
- The new classification system will enable common standardised recording of complaints within all the participating organisations, in the future.
- ➤ The use of a common classification in future would facilitate regular monitoring of complaints, making it simpler to combine datasets, to compute frequencies, and to speedily identify those areas within the Code of Practice that generate most complaints. This will mean that information can be fed back promptly to the profession so that remedial action, such as targeted training and education, can take place.
- ➤ The classification system seemed robust under test when used to code complaints data from several different sources within the study. It has yet to be put to the critical test of routine use by the organisations that deal with complaints.

5. Trends in complaints against osteopaths

➤ 1,058 complaint records were received, of which 684 (65%) were related to the five-year period 2004–08.

- ➤ GOsC formal complaints were excluded from the analysis as there was overlap with records in the Insurer's files, and more detail was contained within the Insurers' files; this left 561 complaints in the period 2004–08.
- ➤ The majority of complaints were made by patients (351, 69%) in the study period 2004–08. These patient-initiated complaints were entered into the subsequent analysis.
- The most frequent types of patient complaint fell into the broad categories of Clinical Care (68%) and Conduct/communication issues (21%). There were statistically significant differences (p<0.0001) between the regulator and the insurers in the types of complaint received, with more conduct/communications complaints going to the regulator and more clinical care issues being reported to the insurers, but no clear separation into two distinct groups of complaints reflecting fitness to practise and malpractice claims respectively.
- There was no statistical evidence of a temporal trend in overall complaints, in any type of complaint, or in any organisation, over the five-year period.
- The number of patient complaints identified in 2004-08 was 351, of which about one third (97) became formal complaints from patients to the regulator. Collation of data from the various sources is essential to obtain a full picture of the complaints and problems that patients encounter during osteopathic care.

6. Gaining understanding of why patients complain

- ➤ This part of the project aimed to gain understanding of the nature of complaints and why they arise.
- ➤ The methodology chosen was qualitative, using narrative interviews with those key individuals in the regulatory body (the GOsC), the professional association (the BOA) and the Insurers, who deal directly with the patient and/or osteopath involved in complaints.
- These interviews provided rich data, from which emerged a clear and consistent framework of understanding of complaints, reflecting the depth of understanding of the interviewees based on their long years of experience.

- The thematic analysis of the five narrative interviews generated a conceptual framework describing the factors involved in patients' complaints in terms of four concepts: underpinning factors; triggers; desired outcomes; and resolution factors. Two strong cross-cutting themes emerged as affecting all stages of a complaint. These were communication/therapeutic relationship and conflict resolution.
- ➤ The relationship of the four key themes describes why complaints arise and become formalised. The event that triggers a complaint most often pain or reaction to treatment or the conduct of the osteopath is the explicit reason for the complaint, but this will be preceded by underpinning factors, such as unmet or unmanaged expectations. Patients have a desired outcome in mind when they complain. The progress of the initial complaint whether it is formalised or resolved depends on the osteopath's understanding of the patient, their reaction to the discord, and their ability to communicate empathetically.
- The analysis was validated by the participants as fitting their view of the factors giving rise to complaints.
- ➤ Complaints are complex, only rarely involving a single event; they are much more likely to arise from a complex chain of circumstances.
- The results highlight that the role each of the organisations, and the osteopaths, play in preventing and resolving complaints.

7. Discussion

- Regular monitoring and audit of patient complaints is desirable for the future. It critically depends on the collaboration of all providers of osteopathic professional indemnity insurance.
- ➤ Discussions need to be held between the GOsC and the Insurers with a view to facilitating future monitoring by collecting and coding a number of key data items in a standard way: using and testing the new classification system for type of complaint, and exploring the potential for record linkage.

- ➤ The results have a number of implications for osteopathic practice.

 Recommendations have been made to improve recognition of potential high-risk events within a consultation.
- ➤ Several implications for policy have emerged. The proposed recommendations are for national joint working to develop approved specific information leaflets; targeted training of all osteopaths to prevent and handle complaints more effectively; and collecting formal patient feedback as a continuing professional development (CPD) requirement.
- Questions were raised about the current system for handling complaints, including whether a review of the system may be justified.

8. Conclusions

- ➤ The project has provided rich data about osteopathic complaints.
- ➤ The results provide a baseline for future monitoring of trends.
- ➤ The project was labour-intensive due to the very large amount of data processing required to analyse the trends.
- > To facilitate future monitoring, further development of national standards for coding for selected data items is needed.
- Further testing is required of the new classification for osteopathic complaints.
- Further qualitative research is needed to test the hypothesis generated within this study about why patients complain.
- > The results and the implications of the results now need to be widely disseminated and discussed.

GLOSSARY

BOA British Osteopathic Association

CPD Continuing Professional Development

HC Health Committee of the GOsC

HPC Health Professions Council

GCC General Chiropractic Council

GMC General Medical Council

GOsC General Osteopathic Council

IC Investigating Committee of the GOsC

NCOR National Council for Osteopathic Research

NHS National Health Service of the UK

OEI Osteopathic Educational Institution

PCC Professional Conduct Committee of the GOsC; the results of hearings

are published in annual 'Fitness to Practise' reports

PI Professional Incompetence: an allegation used by the GOsC

Professional Conduct Committee

UPC Unacceptable Professional Conduct: an allegation used by the GOsC

Professional Conduct Committee

CHAPTER 1 INTRODUCTION

1.1 Aims of the project

The primary aim was to investigate the frequency and character of complaints made by patients about osteopathic care, and to whom those complaints had been made. The second aim was to gain a greater understanding of the nature of the complaint and the circumstances leading to complaints.

The longer term aim of this research project was to provide baseline information about complaints as a basis for future monitoring of trends, and to identify priorities and barriers to future research on this topic, with a view to gaining robust evidence on how to reduce complaints in future.

This project is one of four "NCOR Adverse Events Projects" relating to a number of areas associated with risks, benefits and informed consent, which were commissioned by the General Osteopathic Council (GOsC), through the National Council for Osteopathic Research (NCOR), in 2007. Information about adverse events in osteopathic practice is valuable in order that patients can be appropriately informed of risks associated with treatment. The need for osteopaths to inform patients of risks was re-emphasised by the Regulator in the Code of Practice for Osteopaths issued in 2005 (General Osteopathic Council 2005), in which Clause 20 stated:

"You should not only explain the usual inherent risks associated with the particular treatment but also any low risks of seriously debilitating outcomes".

Prior to this project, information on complaints from patients against osteopaths had not been documented in a systematic way in the UK. The objectives of the project were as follows:

- 1. To document the evidence that existed about complaints against osteopaths;
- 2. To assess the feasibility of accessing data about complaints;
- 3. To collate available data and arrive at a common system of classifying complaints by type;

- 4. To evaluate the frequency of complaints and trends in the data;
- 5. To gain understanding of why complaints occur from documentary sources or through new data collected in interviews;
- 6. To develop theory about why complaints occur using qualitative methods;
- 7. To disseminate results in order to influence and improve practice.

1.2 Methodology

The overall methodological approach was Action Research (Holloway and Wheeler 1997) as the research is embedded in, and aims to improve, a service or professional practice. Both quantitative and qualitative data were collected and synthesised in order to be able to:

- adequately describe complaints and claims according to frequency, type,
 nature and legal and financial outcome;
- evaluate any temporal trends in complaints;
- gain understanding of the circumstances leading to complaints, particularly those alleging adverse reactions to treatment;
- provide reports to feed back to the participants and the professions with implications for practice, policy and training.

1.3 Study Organisation

The study took place between May 2008 and April 2009. The members of the Research Team are listed in Appendix 1. The project was directed by a Steering Group (Appendix 2), which met with the Research Team and Co-applicants five times face to face and provided much further email input. The Steering Group actively assisted in designing appropriate methodology, developing the classification, and advising on execution of the study. The research team reported to the NCOR Grants Governance Committee.

1.4 Defining complaints and claims

A complaint may be defined as a communication of dissatisfaction from a complainant which requires a response (Citizens Charter Complaints Task Force 1998).

A claim is usually initiated by a formal communication from the solicitor representing the complainant, alleging harm of some kind, for which the claimant feels some compensation is justified. Most complaints and claims start as an initial communication made in writing, or by telephone or in person. Such initial communications were termed "informal complaints" for the purposes of this project. Many informal complaints are not pursued beyond the initial communication. If the complainant proceeds with further action, the informal complaint may become a claim or a complaint made to the governing organisation (formal complaint) or a complaint made to the police.

This study includes all three of the above categories together with all the **informal complaints** that were not pursued beyond the initial contact.

1.5 To whom can patients complain?

Complaints and claims about osteopathic care can be made through a variety of possible routes (see Figure 1.1). In order to collect data for this study, systematic and accessible records of complaints and claims were needed, hence we focussed on the osteopathic route on the left of the figure, in which patients complain either to their osteopath directly (whether the osteopath is working in private practice, for the NHS, or in an OEI training clinic); or to the regulator (GOsC), the statutory body established under the Osteopaths Act 1993.

Complaints may also be directed along non-osteopathic routes. Another healthcare professional, such as a GP or a chiropractor, may be the first port of call. Other agents include the police, Citizens Advice Bureaux, firms of litigation solicitors (Life 2005), or patient support charities, such as WITNESS.

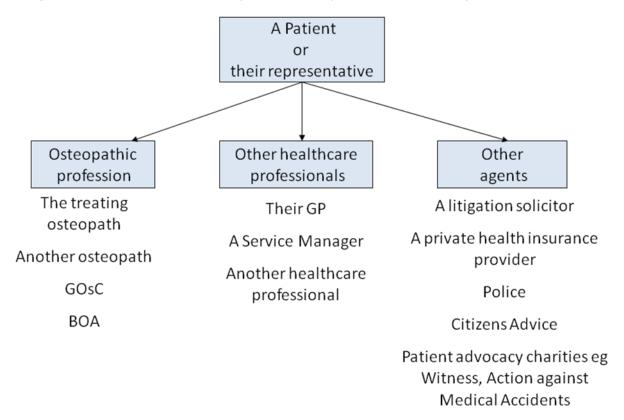


Figure 1.1 To whom can a patient complain about osteopathic treatment?

It was considered that any complaints made initially to non-osteopathic agents would be notified to either the osteopath concerned or to the General Osteopathic Council, in due course, in order for the complaint or claim to proceed. However, investigation of these routes was outside the scope of this pilot study.

1.6 The osteopathic profession route for complaints and claims

The focus of this project was complaints and claims made by osteopathic patients via the osteopathic profession route: either to the regulator (GOsC) or directly to an osteopath and hence to the BOA and the insurer. It was important for this project to have an understanding in some detail of the process and procedures of these two different pathways, shown diagrammatically in Figure 1.2.

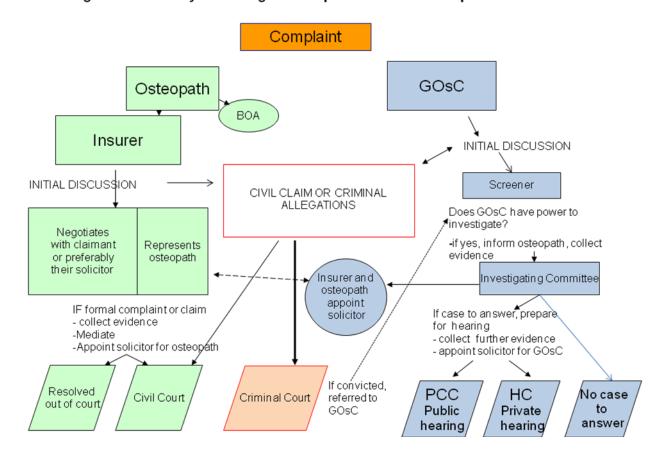


Figure 1.2 Pathways in dealing with complaints made via osteopathic routes

1.6.1 Complaints or claims made directly to the osteopath

The process for complaints made directly to the practitioner is shown on the left side of Figure 1.2. The osteopath ought to inform the insurance broker that provides his/her indemnity insurance, immediately upon receiving a complaint, and the broker will notify the Insurance Company under-writing the relevant part of the policy. Osteopaths may also seek help from their professional body, the British Osteopathic Association (BOA). The insurance provider will negotiate with the complainant or their representative, on behalf of the osteopath. At the time of the study, there were four approved professional indemnity insurance providers for osteopaths: Balens (who provided the BOA scheme), Howden, Three Counties, and Towergate-MIA. These four companies are brokers that facilitate the contracts through insurance companies such as Royal Sun Alliance.

If the patient appoints a solicitor to pursue a claim, then the insurer will act for the osteopath and, if appropriate, attempt to resolve the claim using mediation. If the claim proceeds to court, then the insurer will appoint a solicitor to act for the osteopath. The parties will attempt to resolve the claim before it reaches court – if no agreement is reached, the claim will be decided in the Civil Court.

The outcomes of complaints and claims range from a sizeable financial compensation award to the patient, down to resolution achieved swiftly by the osteopath speaking to the patient. It should be noted that the legal pathways in Scotland and Northern Ireland may differ from those described here for England and Wales.

1.6.2 Complaints made to the GOsC

The process followed for complaints made to the General Osteopathic Council (GOsC) is described more fully in Appendix 3. In brief, complaints made to the GOsC follow the path on the right side of Figure 1.2. Initial contact from patients or other agents who are considering whether to make a formal complaint about an osteopath are recorded by the GOsC, provided the osteopath is identified by the complainant. These records are termed 'informal complaints' within this project. A member of the GOsC Regulation team will speak with the complainant and provide information on the formal complaints process; a Making a Complaint Form will be provided should they wish to pursue the complaint formally.

Formal complaints received by the GOsC are first considered by a Screener (an osteopathic member of the Investigating Committee (IC)), who determines whether the GOsC has the power to consider the allegations. The Screener will dismiss the complaint if it falls outside of the GOsC's legal remit. If it is within the GOsC's power to deal with the complaint, the case is referred to the IC and the osteopath will be notified of the complaint. The allegations are investigated and all relevant evidence is gathered and put before the IC. The IC will then consider the complaint and decide whether there is a case to answer. Unless the IC decides there is no case to answer, it will refer the complaint to either the Professional Conduct Committee (PCC) or the Health Committee (HC) and the case is prepared for hearing.

If the allegations made by the patient involve criminal conduct that has been reported to the police, the GOsC will be notified of this by the police. If there are police investigations, the GOsC will generally delay its own investigations until the conclusion of the criminal proceedings. If the allegations raise immediate concerns for the protection of the public, the IC may convene a hearing to decide whether to suspend the osteopath's registration on an interim basis whilst the police and the GOsC investigations are carried out. Criminal proceedings (central box in Figure 1.2) involve the police at an early stage; they gather evidence; the evidence is then passed on to the Crown Prosecution Service to decide whether there is sufficient evidence for the case to go to the Criminal Courts.

1.7 Confidential and Public Complaints

Some information about complaints is in the public domain:

- all formal complaints to the GOsC that are found proven at a GOsC PCC hearing are reported in the GOsC annual Fitness to Practise Reports, which reveal the identity of the osteopath but not that of the patient;
- formal complaints that are considered at an HC hearing are publicised only if the case is proven and there has been a restriction imposed on the osteopath's practice of osteopathy that patients should be informed about e.g. conditions are attached to the osteopath's practice or in the case that the osteopath is suspended;
- all cases that go to court are public and reveal the identity of the osteopath; the
 identity of the complainant is also made public except in the case of sexual
 allegations.

There are many complaints that do <u>not</u> become public, including:

- informal complaints made to the GOsC that are not pursued and formal complaints that are dismissed by the Screener: no-one but the patient may be aware of the complaint;
- formal complaints made to GOsC that go to the Investigating Committee (IC) and where it is found that there is no case to answer: only the osteopath, their insurer and the complainant may be aware of the complaint;

- formal complaints that go to a GOsC PCC hearing but are not found proven are
 <u>not</u> reported unless the osteopath requests that the GOsC publicises the decision.
 PCC hearings are, however, held in public and so information about the case will have entered the public domain;
- formal complaints that are considered at an Health Committee (HC) hearing will be not reported unless restrictions are placed on the osteopath's practice of osteopathy that patients should be informed about;
- complaints made to an osteopath and notified to the insurer: only the insurer, the osteopath and patient may be aware, unless the case goes to court.

Many complaints of the above types may have extensive documentation held by the GOsC or the insurer. These case files are likely to contain highly sensitive personal data including copies of medical records. Access by researchers to such data would, for ethical reasons, require permission from both parties involved – the osteopath and the patient.

Statistics are routinely published only for complaints heard by the GOsC conduct committees.

The purpose of this research was to focus on complaints brought by patients against osteopaths, but it should be remembered that complaints against osteopaths may be brought by other agents, including individuals who are not patients, by organisations, or by the Registrar.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction and Methods

The purpose of the literature review was to:

- 1. Set the context for this study;
- 2. Collect and summarise evidence relevant to complaints against osteopaths;
- 3. Estimate the trends in complaints within healthcare, from published data.

2.1.1 Scope of the review

This research was patient-oriented. It was concerned with complaints made by **patients** against osteopaths. Complaints against osteopaths made by other health professionals or agencies such as the police were excluded. All types of complaint were considered, reflecting the osteopathic Code of Practice (General Osteopathic Council 2005) which covers the conduct of the osteopath in relation to:

Duty of care

Personal standards

Contract with the patient

Personal relationships with the patient

Access to records

Fees

What the law requires

The work environment

Examining and treating intimate areas

Financial and commercial activity

Problems with the health of the osteopath

What to do if trust breaks down

Data protection

Legal limitations on what an osteopath can do

Practice information

Confidentiality

For the purposes of the literature review, it was useful to distinguish between complaints and claims and *adverse events* (such as side effects, damage or harm, which a patient may or may not complain about), simply because the published literature on adverse events is extensive. In contrast, the relevant literature on complaints and claims in manual therapies is scant, and found mainly in grey literature, such as the annual reports of professional regulatory bodies. As this study was the first to investigate this topic within osteopathy, the literature review attempted to cover all relevant published information, which fell broadly into three areas: statistics on frequencies of complaints, claims and adverse events; evidence on why patients complain; and published information about the principles of effective procedures for considering/investigating patient complaints.

2.1.2 Search Strategy

A wide ranging search for published evidence about complaints against health professionals was conducted on research databases (PubMed, Science Direct, Medline, EMBASE, CINAHL and Psychinfo), as well as using the internet search engine, Google, and professional websites. A variety of search terms were used including synonyms for osteopaths, chiropractors, physiotherapy, patient complaints, malpractice, adverse events, conduct and patient safety. A systematic search proved difficult, because "patient complaint" is an ambiguous term that yielded mostly presenting symptoms, rather than dissatisfaction. "Malpractice", which is the Mesh term for medical negligence, produced thousands of papers but none within manual therapies. "Patient safety" yielded mainly papers about surgical risk or acquired infection. "Adverse events" papers were mainly about iatrogenic risk estimation or reporting/ detecting systems, rather than patient complaints. However, a number of relevant, recent papers were found; and leads from their bibliographies and related articles were followed up, yielding the literature reviewed here.

2.2 Frequency and trends in complaints in manual therapies

In order to set osteopathy within the context of other UK health professions, statistics on the rates of complaints were extracted for both osteopathy and selected comparable professions, from data published by their regulators. All the statistics presented below

relate to complaints made *by patients*. Complaints made by other agencies such as health professionals, employers or other organisations were excluded as far as possible. Rates have all been standardised to numbers of complaints per 10,000 practitioners per annum to facilitate comparisons.

The frequency of patient complaints concerning osteopathy was found within the reports from the **General Osteopathic Council** (GOsC): GOsC annual Fitness to Practise reports from 2001 to 2005-06, and the Annual Reports for 2006–07 and 2007–08, available on the GOsC website.

The GOsC reported 18-35 <u>formal complaints</u> each year, with no clear trend since 2001 (Table 2.1). In recent years about half of complaints were found to have "no case to answer". The total number of registrants (i.e. registered osteopaths) was extracted from the published Registers in order to compute the rate of formal complaints which ranged from 47 to 100 (mean=68) per10,000 registrants per annum. These figures mean that each year, a formal complaint is made against up to 1% of the profession, half of which will go to formal Committee hearings.

The Osteopaths Act 1993 classified the type of complaint under one of four categories: Unacceptable Professional Conduct, Professional Incompetence, Criminal Conviction or Health. The reports from the GOsC Fitness to Practise Committee report on complaints in these categories, as well as reporting how the allegations relate to the profession's Code of Practice (General Osteopathic Council 2005). In 2005–06, the GOsC reported 35 complaints; most included several problem areas within the Code of Practice, the most common areas being duty of care (28, 80 %), communicating with patients (24, 69%), relationships with patients (19, 54%), complaints procedures (17, 49%), and consent (11, 31%).

Table 2.1 General Osteopathic Council statistics on formal complaints

	2001	2002	2003	2004-05	2005-	2006-	2007-
					06	07	08
Formal	21	33	22	27	35	18	23
complaints							
Found to have a	4	16	6	12	15	11	14
Case to answer							
% with case to	19%	48%	27%	44%	43%	61%	61%
answer							
Total	3089	3300	3452	3610	3731	3845	4016
Registrants*							
Rate of	68	100	64	75	94	47	57
complaints**							

^{*} GOsC Statutory Register of Osteopaths – annual data;

The figures from the **General Chiropractic Council** (GCC) annual reports (Table 2.2) suggest that the rate of formal complaints to the GCC range from 173 to 324 (mean of 211) per 10,000 per annum, about three times higher than that to the GOsC in the same period. A somewhat lower proportion of complaints had "no case to answer".

Table 2.2. General Chiropractic Council statistics from Annual Reports

	2003-04	2004-05	2006	2007	2008
Number of complaints	22	76	64	46	43
No case to answer (%)	11 (50%)	21 (28%)	29 (45%)	16 (35%)	16 (37%)
Total Registrants	-	2349	2340	2437	2489
Rate of complaints**	-	324	274	189	173

^{**} Rate per 10,000 registrants

^{**} Rate per 10,000 registrants

The chiropractic profession has also conducted some research on claims arising from complaints. A review of 204 malpractice claims to one indemnity insurer (MIA) over a five year period between 1997–2001 (Norman and Thiel 2003) showed that the vast majority were related to treatment rather than conduct. Some 32.8% involved adverse effects of treatment, 28.5% involved negligent/ inappropriate treatment, 21.6% involved ineffective treatment and 6.4% involved wrong diagnosis. While the numbers of claims per year suggested only a slight year-on-year increase, there was a steep upward trend in the proportion of adverse effect claims from 12% in 1997 to 43.5% in 2001.

The **Health Professions Council** (HPC) is the statutory "umbrella" regulator for a number of allied health professions. The HPC covers currently 15 professions including physiotherapy, the largest of the health professions and the most closely comparable to osteopathy. Complaints about the 15 professions are reported in the HPC Fitness to Practise Reports (Health Professions Council 2007). Note that the HPC reports allegations received in a given year, whereas the GOsC reports on cases considered by the IC, PCC and HC committees in a given year. A second difference is that only about one quarter of allegations to the HPC comes directly from members of the public; many come from employers, for example 39% for the period 2002-05. These employer complaints were excluded, even though some represent complaints made by patients to the employer; even if they were included, the rate of overall complaints to the HPC (Table 2.3) appears somewhat lower than the rate to the GOsC. By profession, the rate of allegations between April 2005 and March 2008, per 10,000 registrants per annum, was 16 for occupational therapists, 20 for physiotherapists, and 31 for podiatrists. The highest rate in the HPC was for paramedics at 69. The physiotherapy rates were considerably lower than those for osteopathy and chiropractic (20, 68 and 211 respectively per 10,000 per annum).

The difference may in part arise because most physiotherapists are employed by the NHS; or because HPC statistics were affected by organisational factors. It is a relatively new regulatory body and the increase in complaints it received over time may have been in part due to increasing public awareness of its existence, and in part due to the steadily increasing number of professions it regulates. There was also an increase over time in the proportion of allegations found to have a "case to answer", which was 44% in 2004-05, 58% in 2005-06 and 62% in 2007-08.

Table 2.3 Health Professions Council statistics from Fitness to Practise Reports, for all the professions on the register (white) and for physiotherapists (blue)

	2002-03	2003- 04	2004- 05	2005-06	2006- 07	2007-08
Allegations received	70	134	172	316	322	424
% allegations from the Public	-	21%	17%	22%	24%	25%
Number of Registrants	144141	144834	160513	169366	177230	178289
Rate of complaints	5	9	11	19	18	24
Physiotherapy allegations	-	-	35	79	52	85
% from the public	-	-	-	20%	46%	39%
Number of physiotherapists	-	-	35620	40037	40670	42676
Rate of complaints	-	-	10	20	13	36

Dentists are comparable in some ways to osteopaths – most practitioners work within private practice. The statutory regulator, the General Dental Council (GDC), registers over 36,000 dentists (almost ten times the number of osteopaths) and handles complaints about dentists' fitness to practise.

In 2008, the dental regulator (GDC) reported on 898 complaints, 52% from patients, of which 164 (18%) were referred for formal public hearings. The rate of complaints of (898/36281) or 248 per 10,000 per annum was similar to the GCC (chiropractic) figures above. However, there are differences between the fitness to practise procedures of the regulators, which may affect the statistics; the GDC operates a two-stage process, with the Investigating Committee able to apply mild sanctions, dismiss or refer for a committee hearing. A rate based on their 164 public hearings (45 per 10,000 p.a.) may offer a more valid comparison with the rates of other regulators. The hearings of the Professional Conduct Committee resulted in serious sanctions for

most: erased (23%), suspended (23%), conditions of practice (23%), admonishment (13%), the remaining few percent being concluded or postponed.

2.2.1 Complaints made locally about health care services

The rates published by the various regulators represent only one part of the picture. Many complaints are made locally within the services. These data were not available for osteopathy, but were available for some other professions.

The majority of the allied health professions (under the HPC) are employed within the NHS, where the complaints procedures encourage patients to make their complaints locally to the manager/ employer. The statistics for such NHS complaints were sought; data that were directly comparable to those from the HPC were not found, but the numbers of written complaints, by profession, within the NHS in 2008-09 were published (The Health and Social Care Information Centre 2009). There were 4,056 complaints within the NHS for professions allied to medicine, and 2541 for ambulance crews, a total of 6,597, some fifteen times the number (424) lodged with the HPC in the same period. These "service" complaints were mainly resolved locally, 73% within the time limit of 25 days. The nature of the complaints made locally within the "service" may well differ from the complaints made to the regulator. The topics of complaints were not published by profession; but for all NHS complaints in total, the main topics were aspects of clinical treatment (41%), attitude of staff (13%), appointment delays (11%), and communication / information for patients (written or oral) (10%). Not surprisingly, these figures are dominated by complaints against the largest professional groups, doctors and nurses, who had 45% and 22% of all local complaints, respectively.

In 2006, the GDC established an independent Dental Complaints Service (DCS) to handle "local" complaints about service and care within private practices. In 2008–09 the Dental Complaints Service handled 11,485 calls on their hotline, of which 1,870 (11%) were lodged as complaints. The rate of local "service" complaints was thus about 1,870/36,281, about 515 per 10,000 registrants per annum, some eleven times higher than the regulator's public hearings, above. A proportion of the dental profession works within the NHS, and the NHS complaints statistics (The Health and Social Care Information Centre 2009) showed 908 written complaints against dentists,

increasing the number of service complaints to 2778, some 17 times higher than the "regulator" complaints.

The speed of resolution of local complaints tends to be much faster. For example, over two-thirds of the "service" dental complaints were resolved within a week, either within the practice or with the help of a member of the DCS staff. Only 8 required a hearing before the DCS panel. The speed of the fitness to practise processes of the regulators is typically much slower, for example the average wait for a GDC hearing was over one year, at 75 weeks.

The outcome for the majority of local dental complaints was a refund of fees (57.6%) or an explanation (28%), while a small number of complainants receiving an apology (6.4%) or a contribution towards treatment costs (7.9%).

2.2.2 The effect of the complaints procedures on the published statistics

The intention of complaints procedures within health services is that most complaints should be handled and resolved locally. As the CHRE makes clear (http://www.chre.org.uk/policyandresearch/), the regulatory bodies are not complaints-handling bodies. The regulatory body's systems are intended to assess **fitness to practise** of practitioners who may harm patients, in order to protect the public, not to resolve the complaint on behalf of the patient. Two types of complaints systems exist, fulfilling different roles. However, there is overlap between the two systems when registrants are self-employed: the CHRE recognises that the regulator may then handle less serious cases as well as those where there is a threat to public safety. Where the majority of registrants are employed by the NHS, for example the professions regulated by the HPC, there is a clear framework for dealing locally with complaints about the service. The effect of these organisational differences on the rates of complaint, and the routes of complaint, may be substantial.

The introduction of the 2009 report "Listening, responding, improving" (Department of Health 2009) aimed to provide patients with a clear and simple route for complaints. The impact of this policy may mean even more complaints are elicited and, because of the new structures for independent local resolution of complaints, possibly fewer complaints made to the regulator. In fact, the General Medical Council (GMC) website (November 2009) specifically states that complaints should

be resolved locally, except where the patient thinks that the doctor is unfit to practise or is a risk to patients. For professions such as osteopathy, working predominantly in small private practices, local resolution is more challenging, which may mean that a higher proportion of non-serious complaints go to the regulator.

2.3 Frequency of adverse events in manual therapies

Adverse events are only sometimes reported by patients, either as a complaint or as feedback to the practitioner; they may also be reported by other healthcare providers via the medical "yellow card" system – for example, when a doctor assesses the possible causes of a stroke or cerebrovascular accident, or they may emerge in a systematic retrospective case-note review. Most of the literature on adverse events attempts to ascertain them as completely as possible.

Adverse events in healthcare are undoubtedly under-reported. Sari et al. (Sari, Sheldon et al. 2007) found that in a case-note review of 1006 admissions to a large NHS hospital, 110 (11%) of the case notes revealed incidents involving patient harm. Only 5% of these incidents were detected by the routine incident reporting system. Vincent et al. (Vincent, Neale et al. 2001) found a similar rate of 11.7% of patients experiencing adverse events in two acute NHS hospitals, through a case-note review. Half of the events were judged to be preventable, and one-third were moderate or serious events, including death.

The evidence about adverse effects related to osteopathy is currently limited to the effects of spinal manipulation, with the exception of one study on cranial approaches to treatment (Greenman and McPartland 1995; McPartland 1996). The evidence is based on studies in which the manipulation has been carried out by any one of a variety of healthcare professionals (e.g. chiropractors, medical doctors and physiotherapists) and the methodologies are weak, being mainly surveys, case reports and case series (Gibbons and Tehan 2006; Leach 2006; Snelling 2006; Ernst 2007; Lucas and Moran 2009). Papers by Gibbons and Tehan (Gibbons and Tehan 2006) and Carnes et al. (Carnes, Mars et al. 2010) provide a good overview of the current evidence on risks. Several strong messages emerge. The risks are extremely low. High velocity low amplitude (HVLA) thrust techniques are considered more dangerous than non-impulse techniques. The two most serious complications are

stroke/vertebrobasilar accidents (VBA) following neck manipulation and cauda equina after lumbar manipulation. The risk of stroke appears to be about 1 in 500,000 (or 0.00002%) and may be even lower. This can be compared with the risk of serious gastric complications from prolonged use of non-steroidal anti-inflammatory drugs (NSAIDS), which may be as high as 1 in 1,000 (Stevinson and Ernst 2002).

Mild adverse events such as pain and stiffness after manual therapy are common: in a teaching clinic (Rajendran, Mullinger et al. 2009) 93% of participants reported an "additional effect of treatment" at some point in the first 7 days after treatment; 96% of these were rated as mild or moderate. The most common were transient pain (83%); stiffness (47%), headache, tiredness and light-headedness, most commonly at 2 days after treatment. 15% reported their effects as severe at some point during the week. Mild effects such as headache, stiffness, local discomfort, radiating discomfort and fatigue occur in between 30% and 61% of all patients (Ernst 2007; Carnes, Mars et al. 2010).

Mild adverse effects of chiropractic care were included in an investigation of outcomes of treatment for neck pain (Rubinstein, Leboeuf-Yde et al. 2007) in a cohort of 529 patients experiencing 4891 consultations. Fifty-six percent of patients recorded an adverse event of some kind, of which 13% were severe. About three-quarters of such after-effects were musculoskeletal or pain-related.

The Australian manipulative physiotherapists conducted a survey about risk and adverse effects in treatment of the cervical spine (Magarey, Rebbeck et al. 2004). The results of the survey showed wide use of cervical thrusts (84.5%) and passive mobilisation (99.8%). Mild adverse effects such as dizziness occurred at a rate of about 1 per 50,000 thrust procedures and, surprisingly, were equally frequent with passive techniques.

Comparisons between the above studies are hampered by the lack of standard definitions for mild, moderate and serious adverse effects within manual therapies. Using a Delphi study, (Carnes, Mullinger et al. 2010) attempted to develop a standardised terminology using a panel of experts from various healthcare professions. Classification as minor, moderate or major depended on the severity of the effects (mild, moderate, severe), the duration of the effects (short to long term) and the nature of the effects. The consensus taxonomy, once validated by users, will

be useful for classifying adverse events as minor/not adverse, moderate or major in the future.

2.4 Trends in complaints in the NHS

There has been a steep increase in medical negligence litigation since the mid 1980s. One commentator (Harpwood 2001) reported that the number of claims in England doubled between 1983 and 1987; the costs quadrupled between 1976 and 1985; there was a 36% increase in the cost of negligence claims in 2000; and the general rise in the number of claims and the level of damages awarded may represent the growth of a "compensation culture". Another factor may be the high risk of iatrogenic effects of modern medicine (Vincent, Neale et al. 2001): an estimated 1 in every 14 NHS inpatients suffers an adverse event (Harpwood 2001).

Harpwood (Harpwood 2001) proposed that the hidden agenda behind clinical governance, with its drive to promote clinical audit and clinical risk management, was to manage the rise in healthcare claims and costs. Increasingly, clinical protocols and practice guidance set out more clearly the standards for medical care, so that negligence hearings have becoming better defined.

2.5 Why do patients complain?

There is a small amount of published research exploring why complaints occur, most from recent years. None relates to osteopathy. A small number of clinicians generate a disproportionate share of malpractice complaints (Hickson, Federspiel et al. 2002; Stelfox, Gandhi et al. 2005). Low patient satisfaction almost doubled the risk of malpractice lawsuits against physicians in one large teaching hospital in the USA (Stelfox, Gandhi et al. 2005). Rates of complaints were highest for surgeons and seemed to be correlated with the number of prior complaints (Hickson, Federspiel et al. 2002); this review suggested that the risk of complaints was not correlated with patient characteristics, illness complexity, or even physician technical skills. Rather, it was related to the physician's ability to establish rapport, to be accessible to patients for queries, to administer care consistent with expectations, and to communicate effectively. A recent paper reported that certain patient characteristics were predictive of complaints (Wu, Lai et al. 2009); in a well conducted case-control study in

Taiwan, the occurrence of an in-patient complaint was higher for admissions as an emergency, and for patients living in urban rather than rural areas. Compensation (money paid after mediation) was more likely the greater the severity of medical injury.

2.6 Legal and ethical aspects of complaints handling

The legal and ethical principles governing the handling of patients' complaints have shifted over the past three decades. The changes in the legal and ethical principles have had profound effects not only on attitudes of health care professionals and patients, but also on the systems and processes for handling complaints – and hence on the complaints statistics.

The key milestone in this shift in attitude (Heywood 2010) was laid by Lord Woolf, as the Lord Chief Justice, who introduced the "Access to Justice" report in 1996 (Lord Woolf 1996; Mayberry 2003). This landmark report was designed to revolutionise the civil justice system. It recommended that patients, their advisers and their healthcare providers, should work together more closely to try to resolve disputes cooperatively rather than proceed to litigation. He specifically recommended a pre-action protocol for medical negligence cases, as a way to reduce costs and delays. The protocol encouraged openness and information, timeliness and making both sides aware of their options, with the aim of restoring the patient—healthcare provider relationship. The Woolf reforms have been criticised (Genn 2010; Heywood 2010), as the costs of litigation remain high, yet they have had far-reaching effects.

Complaints within the NHS are now viewed as an active component of the culture of improving healthcare (Department of Health 2009; Parliamentary and Health Service Ombudsman 2009). The emphasis in the NHS (NHS Choices 2009) has shifted towards a more open system which is less threatening to clinicians and encourages local reporting and resolutions of complaints. A responsible healthcare provider has a duty to assist patients in making a complaint if they have a grievance. Similarly, in 2006 the regulator for the dental profession, as noted above, set up an independent Dental Complaints Service to facilitate local resolution of all complaints except those about fitness to practise (Dental Complaints Service 2009).

Practitioners need support and training in order to deal effectively with complaints, whatever the size of their organisation. Local resolution is challenging, requiring skills to support patients in making their grievances known, or to deal effectively with angry or emotional patients. A Californian team (Virshup, Oppenberg et al. 1999) has designed a tool to train clinicians in how to cope with the anger that a patient may express in complaints. This comprises tools for self-evaluation and for strategic risk management. Practitioners need education in order to understand patients' expectations, to ensure they communicate well with patients and improve patient satisfaction, possibly as part of ongoing professional development (BOA British Osteopathic Association 2009).

Safety and quality of health care has an increasingly high profile. Routine incident (adverse event) reporting systems have become the cornerstone of patient safety improvement and quality of care programmes (Meyer, Battles et al. 2003), with occasional case-note review as a useful addition.

Adverse events and complaints can be used as a learning tool for practitioner education. The UK chiropractic profession developed and piloted in 2005 a "reporting and learning system" for reporting patient safety incidents (Thiel and Bolton 2006). Unfortunately, despite intensive communication with the profession, the rate of returns from the 1100 practitioners invited to participate was disappointing, with only seven practitioners sending in reports of incidents in a 4-month period. The reporting system was subsequently christened "PIRLS" and adopted for routine, voluntary use by the College of Chiropractors, an academic organisation; however, the relationship with the professional association is unclear. At present there is no routine reporting system for adverse events in osteopathy, and complaints against practitioners are not fed back to them routinely for reflection. A prospective self-reporting system for osteopathic patients has recently been piloted in the European School of Osteopathy's training clinic (Rajendran, Mullinger et al. 2009).

CHAPTER 3 ACCESS TO DATA ABOUT COMPLAINTS

3.1 Cooperation

The research critically depended on access to the data on complaints that were held by five organisations closely involved with the osteopathic profession – the GOsC and the four providers of professional indemnity insurance – that all provided data; and on the same five organisations together with the professional association, the BOA, that made staff time available for interviews and discussion. The research team was fortunate to receive support from all six organisations. The insurers viewed the study as a positive step towards risk management.

3.2 Types of complaints data held within the organisations

The GOsC and the providers of indemnity insurance all held two types of data on complaints against osteopaths:

- The **Events Log File** was a record of all complaints and "incidents" that might initiate a complaint. The file contained a few items of information such as the date of the initial complaining letter or phone call, name of insured osteopath, nature of complaint or claim and financial or other outcome. These files were mainly paper records, but the GOsC and Balens (which covered the largest number of osteopaths; they operated the BOA scheme during this period) had electronic records for recent years.
- 2 The **Case Files** were highly confidential, paper-based files associated with those complaints that progressed: each Case File contained all the documents for the case, including correspondence, any legal, court, or hearing documents, and other information such as copies of medical records.

The Events Log Files could readily be anonymised, and did not reveal sufficient detail of the complaint to permit identification of the complainant or the osteopath. These files provided sufficient detail to permit a quantitative analysis of frequencies and trends.

However, access to samples of text from the Case Files (our original proposal in order to gain understanding about why patients complain) posed ethical problems. Even if the documentary data provided for the study were totally anonymised, the narrative could potentially reveal the identities. Even if an interpretive analytical approach were used, access to the documents would require informed consent from the patient and osteopath; because of the risk that the subjects or others could recognise the narrative as their own story (see Appendix 5 for more details). In order to obtain ethical approval, access to the Case Files would need to be justified in relation to the Data Protection Act and Human Rights legislation.

Documentary analysis of a small sample of the case files was therefore not possible within the timescale of the project, particularly as we considered that it could be intrusive to request consent from patients for retrospective events. We therefore amended our initial plan for gaining insight into why patients complain, and proposed a series of interviews with staff who had experience of dealing with complaints within the participating organisations. We felt that this methodology was more suitable for the pilot nature of this project, as the interviews would provide a broader perspective and overview than the documentary analysis, and this approach was approved by the Steering Group.

3.3 Protocol for the study

The protocol comprised four stages as outlined here:

Stage I: Literature Review on complaints and claims within manual therapies, and reasons why patients complain. Further details are given in Chapter 2.

Stage II: Development of a Classification Scheme to describe the type of osteopathic complaints. Further details are given in Chapter 4.

Stage III: A quantitative analysis of the collated complaints data from the participating organisations' Events Log Files, to obtain statistics on frequencies of complaints by type, year and organisation from each supplier. Further details are given in Chapter 5.

Stage IV: A qualitative interview study to gain understanding of the nature of complaints; a series of interviews was conducted with purposively selected key individuals in the regulatory body, the indemnity insurers, and the professional body (BOA). Further details are given in Chapter 6.

A Gantt chart showing the timescale for the different stages during the 12 months of the project is shown in Appendix 4.

3.4 Ethics approval

Ethics Approval and Research Governance Approval were granted by the University of Brighton, Faculty of Health and Social Science, Faculty Research Ethics and Governance Committee. Further details are included in Appendix 5.

3.5 Access to the data

Five organisations – the regulator (GOsC), and four providers of indemnity insurance to osteopaths: Balens, Howden, Towergate-MIA, and Three Counties – were approached formally (see Appendix 8 for copies of the letters used within the study) with a request to release anonymous data on all complaints or incidents over the past 5-10 years for Stage II and III of the study. Further details of the organisations and the data held in their Events Log Files are given in Appendix 6.

Balens converted all of its paper records on initial complaints in 2004-2008 to electronic format specifically for this study and was able to supply most of the data items required for the study. Howden and Three Counties supplied records of each event on paper. Towergate MIA had continued concerns over confidentiality and supplied minimal details.

The organisations were also approached formally to request the collaboration of key individuals in interviews with a researcher for Stage IV of the study. The British Osteopathic Association (BOA) was also approached, because of its role in advising osteopaths about how to respond to complaints.

CHAPTER 4 DEVELOPING A CLASSIFICATION SYSTEM FOR CODING TYPES OF COMPLAINT

4.1 Aim

No common standard of classification for osteopathic complaints existed at the start of this study. Complaints were categorised differently within the various organisations, making collation of the data very difficult. In order to conduct quantitative analysis to observe patterns, changes and trends over time and over type of complaint, a common system for classification and coding was required. As guiding principles, we considered that it was important to develop a classification that:

- was reasonably detailed;
- created clearly defined categories that were usable by all the participating organisations;
- distinguished complaints according to their basis in law;
- related to the words patients use when they complain;
- related to the professional code of practice for osteopaths.

4.2 Methods

The development of the classification system used a form of Focus Group methodology, with the Steering Group acting as a Consensus Panel and Nominal Group during repeated rounds of drafting, review, testing and re-drafting (Ritchie and Lewis 2003). The Steering Group was a multi-disciplinary expert panel with legal, professional, academic, and patient stakeholder expertise.

The Research Team developed the initial draft classification, drawing on the literature review and the data within the Events Log Files from the insurers and the GOsC. The GOsC's Professional Conduct Committee's disciplinary hearings reports, and the Code of Practice which sets out the standards of conduct and practice expected of an osteopath, were also sources of data. The researchers used a bottom-up approach, using the wording of actual complaints as a starting point, so that the classification

arose as far as possible from the words used by patients. For each proposed category of complaint, sample illustrative quotes were taken from the Events Log Files.

Each version of the proposed classification was presented to the Steering Group for discussion. The categories were amended and then reviewed again in an iterative process through several drafts until a final form of the classification was agreed.

The final classification was tested by the researchers: it was used to classify all the (anonymous) complaints data which the organisations provided as mainly free text extracts from their Events Log Files. A small number of final modifications and refinements to the classification were made in liaison with the Steering Group.

4. 3 Results

The final "NCOR3" classification system is shown in Table 4.1a, which shows complaints related to Conduct and Communication, Table 4.1b, which shows complaints related to Clinical Care, and Table 4.1c, which shows complaints related to other issues. In each table, the first column is the new proposed standard for Complaint Type; the terms are related closely to the GOsC's 'Code of Practice'. The second column (Incidents) contains the main issues or incidents cited by patients as causes of complaint. The third column, Potential Legal Action, shows the most likely legal action that might be pursued following a severe complaint in each group. The fourth column provides some illustrative quotes from the anonymised Events Log File from the GOsC.

In each category, there is a spectrum of severity. If any complaint is severe, then it may be referred to the police with a view to a criminal case, as appropriate, and subject to their further investigation.

 Table 4.1 Final "NCOR3" Classification system for complaint type

Table 4.1a. Conduct a	Table 4.1a. Conduct and Communication										
COMPLAINT TYPE	COMPLAINT TYPE INCIDENTS		Quotes from text in GOsC log file of informal complaints								
Professional relationships	Inappropriate or disparaging comments about another practitioner or therapeutic discipline	LIBEL/SLANDER									
Consent	Failure to obtain or to record consent	BATTERY (CIVIL) NEGLIGENCE	"The Osteopath performed acupuncture on her without consent"								
Communication	Lack of information about care or diagnosis, treatment or management	NEGLIGENCE	"The Osteopath kept increasing the number of treatments that would be needed. Would not allow open dialogue about this".								
Boundaries	Inappropriate comments or touch, lack of privacy, feeling	BATTERY (CIVIL) / SEXUAL OFFENCES	"The Osteopath discussed her condition when she bumped into him at the supermarket"								
	exploited financially		"The Osteopath removed Complainant's boxer shorts and massaged his bottom"								
			"Like a salesman. Charged £700 when website said up to £400"								
Conduct/Behaviour	Relationship issue, respect, libel or slander, breach of	LIBEL/SLANDER / BREACH OF CONFIDENTIALITY	"Found the Osteopath to be rude, impatient and short tempered."								
	confidentiality	CONTIDENTIALITY	"When she called the Osteopath's practice, a woman answered She could hear that the Osteopath was watching the racing on Channel 4"								

Table 4.1b Clinical Care	Table 4.1b Clinical Care									
COMPLAINT TYPE	INCIDENTS	POTENTIAL LEGAL ACTION	Quotes from text in GOsC log file of informal complaints							
Ineffective treatment	Failed to improve symptoms	NEGLIGENCE	"Decided to stop consulting osteopath as not responding to treatment - seen another osteopath who after one visit has managed to sort out my knee complaint"							
Substandard practice	Treatment careless, lacks proper skills, disregards established rules, delay in diagnosis causing damage, inconsistent diagnosis, exceeding limits of competence, hygiene	NEGLIGENCE	"Under private health care scheme, but the Osteopath hasn't filled out form so insurers aren't paying up" "The Osteopath is ripping patients off as charges £23 for only 10 mins"							
Inappropriate diagnosis	Failed to diagnose, failed to refer, lack of examination or tests	NEGLIGENCE	"Had not recognised meningitis and as a result his son is severely disabled" "The Osteopath said (patient) was fit to work although 2 independent doctors have said he is not fit to work"							
Adverse event	Treatment caused injury or pain, or more pain or other health effects	NEGLIGENCE	"Cranial treatment left her dizzy and nauseous" "He performed a particular manipulation on her hip which has left her with back pain she never had before"							

Table 4.1c Other types							
COMPLAINT TYPE	COMPLAINT TYPE INCIDENTS		Quotes from text in GOsC log file of informal complaints				
Business practice	Inadequate/lost records; advertising standards; Employment; fails to provide medical report; financial practice	EMPLOYMENT LAW/ DATA PROTECTION/ MIS- REPRESENTATION	"The Osteopath used an obituary of a fellow osteopath to advertise her own services" "He saw Osteopath's husband twice and has now discovered that he is not registered."				
Accidental damage	Trips, falls, spills, hazards	OCCUPIER'S LIABILITY					
Fitness to practise impaired by health	Fitness to practise impaired due to mental or physical health, including addiction issues	NEGLIGENCE/ DIMINISHED RESPONSIBILITY					

When put to the test, assigning a code to every complaint, the two independent coders (JL, AF) showed a high degree of consistency. The few disagreements were resolved by adding additional examples under existing headings in the Incidents column of the Table. Some clarification was required in relation to complaints of a financial nature. If the patient's complaint suggested they felt exploited by the charges made by the osteopath, then this was coded as a Boundary issue. If the complaint was related to lack of a fee scale, for example, then this was coded as Business practice.

4.4 Discussion

The final classification system appeared reliable. Its utility will be evaluated in future investigations of this type, and through use within the organisations recording osteopathic complaints.

It is similar but in places very different from the General Medical Council's recently developed "Seibel Allegations: Category, Type and Subtype". These are presented in summarised form in Appendix 7. The GMC categories of Clinical Care, Probity, Health and Relationship with Patients are similar to our categories of Clinical Care, Health and Conduct and Communication. The GMC system has some extra categories: failure to comply with GMC investigation, Maintaining GMP (equivalent of the GOsC's Code of Practice), teaching/ supervision, and working with colleagues. The differences may reflect the difference in professional roles and the context of the services provided by osteopaths and medical doctors.

As the Code of Practice for Osteopaths is constantly being updated, the classification will almost certainly need to develop over time. Experience with the use of the classification will also highlight areas that need improvement in the future.

CHAPTER 5 TRENDS IN COMPLAINTS AGAINST OSTEOPATHS BETWEEN 2004 AND 2008

5.1 Introduction

The aim of this part of the project was to investigate the frequency and character of complaints made by patients about osteopathic care, and to whom those complaints had been made. The focus was on complaints made to the two types of organisations dealing with most complaints against osteopaths, the regulator (GOsC) and the providers of indemnity insurance.

5.2 Methods

The process for obtaining ethics approval and requesting access to the anonymised data extracts from the Events Log Files of the participating organisations was described in Chapter 3. The dataset that we requested from suppliers is shown in the Appendix 8.4. The actual datasets provided by the participating organisations were more limited, and are shown in Appendix 6.

The study period was determined by the period for which electronic data were available from the larger sources: the GOsC was able to supply electronic data for 2000-08 as two files comprising Informal and Formal complaints. Balens was able to supply electronic data for 2004-08. The study period was therefore the five years from 2004-08 inclusive.

The files of "raw" data from the GOsC and the insurers were saved in 'Read only' format for safe-keeping. All processing and analysis was performed on versions held in Microsoft EXCEL spreadsheets.

5.2.1 Data Processing

The data files required a very large amount of data processing. Each individual complaint record was given a unique Study Number, which identified the source organisation and the complaint record. We retained the organisation's reference number to permit record linkage back to the source material if required. The sequence of the data items was re-arranged to conform to a standard sequence, retaining only

the data items required for analysis. The files were processed to check for duplicates, to determine the year when the complaint was initiated, to exclude those outside the study period 2004-08, to exclude complaints that were not made by patients, and to classify the complaint type using the NCOR3 classification system.

The main data items required for analysis were organisation, year of complaint, complainant, type of complaint and outcome of complaint. Most of this information was supplied as free text. The researchers derived two new data items – complainant and complaint type – by visual inspection of the free text within every record, and hand coding. The complainant (originator of the complaint) was categorised as one of four codes: the patient, an osteopath, a third party or other (not related to a patient complaint or origin not known). It should be noted that some incidents are notified to the insurer by the osteopath even though the patient has not made a complaint. These potential complaints were considered as patient's complaints even though in some cases no further action occurred.

All complaints were manually assigned a Complaint type code, using the "NCOR3" classification described in Chapter 4. The categories and terms used for the types of complaint varied widely between suppliers, and manual coding of all records was required. The manual assignment of type code was performed independently by two researchers (AF, JL). Differences in coding were resolved by joint review. The Steering Committee also scrutinised problematic complaints. Where a complaint was multi-component (i.e. including a number of categories), one code was assigned where possible. We prioritised certain complaint types (e.g. Boundary issues and Medical Negligence issues) and referred some back to the person in the organisation who dealt directly with the complainant to decide, with access to more data than the researchers possessed, what was the main concern expressed by the patient.

In order to avoid double-counting of complaints, we attempted to identify complaints recorded in more than one file and to exclude duplicate records.

5.2.2 Statistical Analysis

The collated data were used to generate summary descriptive statistics, including patterns in the data by year and type of complaint. The number of complaints per year was too small to permit meaningful breakdown by sub-groups (for example

geographical area). Non-parametric Spearman's correlation was used to test for trend year on year for each organisation. Chi-squared tests were used to test for differences in the distribution of complaint type between organisations.

5.3 Results

5.3.1 Data Processing

All suppliers were able to provide data for the study period 2004-08. Note that the files were supplied in the last quarter of 2008; hence counts for 2008 may be about 25% incomplete.

The number of complaints records sent by each organisation is shown in Table 5.1 and Figure 5.1. A total of 1,058 complaint records were received for the study. The two largest suppliers provided electronic records, with the GOsC providing 712 (67%) and Balens providing 315 records (30%) of the total available data. The three smaller organisations provided 31 records on paper representing 3% of claims. Towergate-MIA provided minimal information permitting counts only. Over 30% of the records were dated before 2004, the start of the study period, and 5% were undated.

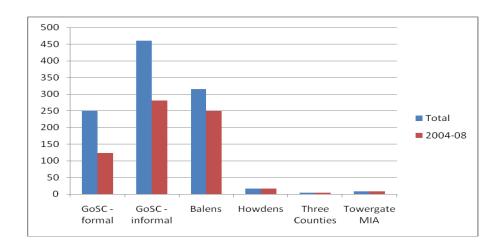


Figure 5.1 Complaints records received, by organisation, for 2004-08

Table 5.1 Number of complaints records received, by organisation and by year*

	GOsC				Insurers							TOTAL		
	formal		inform	nal	Bal		How		3Co		MIA			
											n			
YEAR	n	%	N	%	n	%	n	%	n	%	%		n	%
Pre 2004	126	50.2	150	33	48	15	0	0	0	0	0	0	324	30.6
2004	29	11.6	52	11	39	12	7	41	0	0	9	100	136	12.9
2005	34	13.5	72	16	57	18	7	41	1	<i>20</i>	0	0	171	16.2
2006	20	7.97	77	17	59	19	0	0	1	20	0	0	159	15
2007	22	8.76	53	11	61	19	2	12	2	40	0	0	140	13.2
2008	18	7.17	27	5.9	33	10	1	5.9	1	20	0	0	80	7.56
Year n/k	2	0.8	30	6.5	18	5.7	0	0	0	0	0	0	50	4.73
All years	251		461		315		17		5		9		1058	
2004-08 n	123		281		249		17		5		9		684	
2004-08 %	49.004		60.95		79.05		100		100		100		64.65	

Bal =Balens

How =Howden

3Co =Three Counties

MIA =Towergate-MIA

Duplication within files from the insurers did not occur, only one record was held for each complaint. Duplication between files from the different insurers was not possible, since an osteopath would have only one provider of indemnity insurance in any given year. Duplication between the two sets of GOsC data was removed so that they did not overlap: the Log file of GOsC informal complaints contained a field to identify progression to a Formal complaint. All complaints progressing to GOsC formal complaints were excluded from the GOsC informal complaints data set.

Duplication between the GOsC and insurers' files was more difficult to identify. Formal complaints at the GOsC that reach the Investigating Committee will be notified to the osteopath and the insurer. These were found within the Howden file by visual scanning: 2 of 17 (12%) Howden records were GOsC formal cases. Attempts were made to identify the GOsC formal complaints systematically in the Balens' file, by examining the Insurance Company recorded against the case, and the classification of complaint type assigned at Balens. Appendix 9 shows the results for this investigation; it did not appear possible to systematically identify the records within the Balens' file that were formal complaints to the GOsC. Visual inspection of the free text was considered too time-consuming and unreliable. We therefore made the assumption that all GOsC formal complaints, which were quite small in number at 18-34 per annum, had a corresponding record in an insurers file and, to avoid doublecounting, excluded the GOsC formal complaints from the subsequent analysis. It is unclear if a small amount of duplication may remain, for cases that became formal but were dropped by the Investigation Committee. The loss of data from this action was small, because the GOsC formal complaint records contained no detail with which to categorise the source of the complaint and very little about the nature of the allegation.

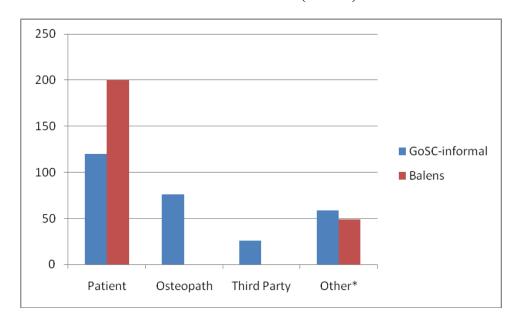
The 123 excluded GOsC formal complaints records comprised 55 (45%) allegations of Unacceptable Professional Conduct, 36 (29%) of Professional Incompetence, and 23 (19%) combined UPC/PI allegations; there were also 2 health issues, 2 criminal offences, and 5 convictions. No further information about the complaint type was available in these records. Additional information from the GOsC (K Green, personal communication) established that the final end-of-year total for 2004-2008 was 131 formal complaints, and that the complainant was the patient in the majority of cases (97, 74%).

The remaining 561 records of complaints for the years 2004-08 inclusive were processed: the complainant was ascertained and coded. Table 5.2 and Figure 5.2 show that of the 561 records for 2004-2008, there were 351 (63%) complaints made by patients. Some 80% of the 249 Balens records and 43% of the 281 GOsC informal records were patients' complaints. The total of 351 patient-initiated complaints in 2004-08 was included in the subsequent analyses. Of these, 200 (57%) were recorded by Balens, 120 (34%) were GOsC informal complaints and the remaining 31 (9%) were from the other three insurers.

Table 5.2 Complaints 2004-08 by complainant and organisation (excluding GOsC formal complaints)

	GOsC		Insurers			Total	
Complainant	informal	Bal	How	3Co	MIA	N	%
Patient	120	200	17	5	9	351	63
Osteopath	76	0	0	0	0	76	14
Third party	26	0	0	0	0	26	4.6
Other*	59	49	0	0	0	108	19
Total	281	249	17	5	9	561	100
% patient complaints	42.7	80.3	100.0	100.0	100.0	62.6	

Figure 5.2 Complaints 2004-2008, by complainant, from Balens (n= 249) and GOsC informal records (n= 281)



5.3.1 Complaints by type

All 351 complaints were assigned a type classification, according to the classification system developed for the study described in Chapter 4. The quality of the data permitted classification of all but a small number which could not be classified as the information was unclear.

Table 5.3 and Figure 5.3 show the complaints by complaint type, grouped into the higher-level categories of Conduct and Communications, Clinical Care and Other. The majority of complaints (n=240, 68%) related to Clinical Care, notably including 141 adverse events, mainly from the Balens data. The second largest group was Conduct and Communications, with 74 (21%) complaints. There were just 37 (10%) Other types of complaint, including only 1 complaint related to Health, 1 Accidental Damage, 12 mentioning multiple issues and 23 that contained too little information to be coded.

Table 5.3 Number of patient complaints 2004-08, by organisation and type

	GOSC		All sources	% of			
Type of complaint	informal	Bal	How	3Co	MIA		total
Conduct and communication							
Professional Relationships	0	0	0	0	0	0	0.0
Consent	2	1	0	0	0	3	0.9
Communication	4	4	0	0	0	8	2.3
Boundaries	14	19	1	0	0	34	9.7
Conduct	16	11	2	0	0	29	8.3
Total conduct issues	36	35	3	0	0	74	21.1
% by source	48.6	47.3	4.1	0.0	0.0	100.0	
Clinical Care							
Substandard Practice	16	6	2	0	0	24	6.8
Inappropriate Diagnosis	3	28	2	0	0	33	9.4
Ineffective treatment	2	18	3	0	0	23	6.6
Business Practice	8	3	0	0	0	11	3.1
Dissatisafaction	8	0	0	0	0	8	2.3
Adverse event	29	103	6	3	0	141	40.2
Total clincal care issues	66	158	13	3	0	240	68.4
% by source	27.5	65.8	5.4	1.3	0.0	100.0	
Other complaints							
Health	1	0	0	0	0	1	0.3
Criminal offence	0	0	0	0	0	0	0.0
Conviction	0	0	0	0	0	0	0.0
Multiple issues	11	1	0	0	0	12	3.4
Unclear	6	5	1	2	9	23	6.6
Accidental damage	0	1	0	0	0	1	0.3
Total other complaints	18	7	1	2	9	37	10.5
% by source	48.6	18.9	2.7	5.4	24.3	100.0	
Total- all complaint types	120	200	17	5	9	351	100.0
% by source	34.2	57.0	4.8	1.4	2.6	100.0	

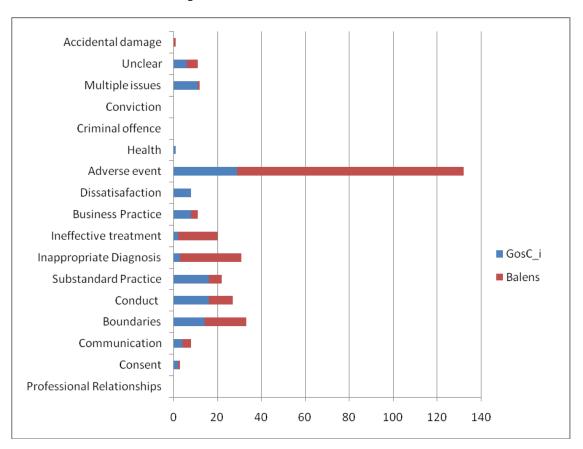


Figure 5.3 Distribution of complaints by type comparing Balens and GOsC informal complaints

It is clear in Figure 5.3 that while both the GOsC and Balens received complaints on a wide variety of issues, Balens received more complaints related to clinical care, especially adverse events and inappropriate diagnosis, while the GOsC received more diverse complaints and tended to have more of the complaints around conduct, dissatisfaction with care and substandard practice. These differences between Balens' data and GOsC informal data were statistically significant (chi-squared 24.1, p= <0.0001). Patients appear to direct complaints about conduct and communications to the GOsC and complaints about adverse events to the osteopath, who refers the case to his/her insurer.

5.3.2 Outcome of complaints

The "Outcome of complaint" was a field requested by the researchers. However, this data item was blank in most of the files received. Recent discussions (L Lambert, Balens; personal communication) suggest that Balens does have a coded electronic

record of outcome and it may be possible to obtain this in subsequent studies. However within the current study, limited outcomes data were available within the Balens file: scanning of the text showed that 29 (15%) complaints were recorded as being resolved by "financial concession in good faith" such as refund of fees by the osteopath, and 5 (2.5%) complaints showed financial settlements made in response to a legal claim.

In contrast, high quality data on outcomes were available for the GOsC formal complaints, and these are reported here because they illustrate how useful high quality outcome data are for the profession and the public. Table 5.4 reports on the outcome of the 123 GOsC formal complaints between 2004 and 2008. Some 34 (28%) of the 123 complaints were still in process at the time of transfer of data to the research team, one third having been in process for more than two years. Of the 123 complaints, 27 (22%) have been upheld and 62 (50%) have been dismissed, mostly with no case to answer. Of the cases that have been processed, 30% were upheld.

Table 5.4 Outcome of GOsC formal complaints by year

							% of
OUTCOME	2004	2005	2006	2007	2008	Total	total
In process							
Referred to IC	4	0	0	0	7	11	8.9
With Screener	0	1	0	0	2	3	2.4
Referred to PCC	2	2	2	10	4	20	16.3
Total in process	6	3	2	10	13	34	27.6
Dismissed							
No case to answer	14	15	7	7	5	48	39.0
Dismissed	3	2	3	1	0	9	7.3
Withdrawn	0	0	1	1	0	2	1.6
Cancelled	0	1	0	0	0	1	0.8
Dismissed by screener	0	1	0	0	0	1	0.8
Case closed	1	0	0	0	0	1	0.8
Total dismissed	18	19	11	9	5	62	50.4
Upheld							
Upheld	5	8	4	2	0	19	15.4
Upheld-conditions	0	4	2	1	0	7	5.7
Upheld-appeal	0	0	1	0	0	1	0.8
Total Upheld	5	12	7	3	0	27	22.0
Total complaints	29	34	20	22	18	123	100.0

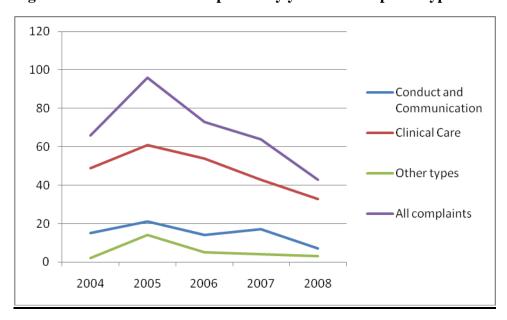
5.3.3 *Trends*

The Towergate-MIA data have been excluded in this section because the precise year was unknown, hence the total complaints analysed in this section was 342. Because of the small numbers, detailed sub-division by year, organisation and by complaint type was not meaningful. The trends have therefore been examined by aggregated complaint types, and by organisation. Table 5.5 and Figure 5.4 show trends by complaint type. The graph allows visual inspection of trends.

Table 5.5 Trends by complaint type

Complaint group	2004	2005	2006	2007	2008	2004-08
Conduct and Communication	15	21	14	17	7	74
Clinical Care	49	61	54	43	33	240
Other types	2	14	5	4	3	28
All complaints	66	96	73	64	43	342

Figure 5.4 Number of complaints by year and complaint type



Even allowing for numbers in 2008 being low, by up to 25%, because of the timing of our data collection, there is no suggestion of an upwards trend in the number of

complaints year on year. Clinical Care complaints appeared to peak in 2005, other types of complaint have been fairly level.

The following Table 5.6 and Figure 5.5 show complaints by organisation. Again, there is no evidence of an upward trend in any of the organisations; rather there was a peak in 2005 in all organisations, even after allowing for the estimated 25% of missing data in 2008.

Table 5.6 Trends in numbers of complaints, by organisation, excluding

Towergate-MIA

Towergate-MIA						
Organisation	2004	2005	2006	2007	2008	2004- 08
GOsC informal	22	39	26	19	14	120
Balens	37	49	46	41	27	200
Howden	7	7	0	2	1	17
Three Counties	0	1	1	2	1	5
Total	66	96	73	64	43	342

120 100 80 GOsC informal total Balens total 60 Howden total 40 Three Counties total Total 20 2004 2005 2006 2007 2008

Figure 5.5 Number of complaints by year, by organisation

Statistical tests were conducted to test for a significant trend across the five years, in the Balens and GOsC informal data. The Spearman's correlation coefficient by year was not significant for Balens (p=0.505) or for GOsC informal complaints (p=0.188). There was significant similarity in the shape of curves for the two organisations however (p=0.037).

5.4 Discussion

We were fortunate in the level of cooperation of the organisations providing data. Hopefully, the information gained will prove useful to the source organisations as a valuable and cost-effective exercise assisting them in reducing the frequency of complaints.

Monitoring for trends has proved to be possible, although labour-intensive due to the lack of standardisation in the way in which incidents are recorded. An improved and streamlined system could be devised and implemented utilising a common classification, and ideally incorporating record linkage.

Double-counting within the data was minimised by excluding the GOsC formal complaints from the analysis, since they will certainly be recorded by the insurers. However, there is a possibility that some complainants initiate complaints both with the GOsC (creating an informal record) and with their osteopath (creating an insurers' record). There is currently no way to check if this is the case. We consider it very unlikely that complaints were omitted from the analysis due to exclusion of GOsC formal complaints.

The 2008 counts were estimated as being up to 25% incomplete, due to submission of the data before the end of year. Subsequent data provided by the GOsC (K Green, personal communication) for formal complaints in 2008 showed that our analysis included 123 (94%) of the 131 formal complaints in 2008. In future studies, the transfer of data could be timed to obtain data for complete years, but when this pilot was planned, there was limited information. The project revealed which years were available, the timing for completion of a year's data within each organisation, how long it took to arrange the extraction and to process the data received. In fact the project placed considerable demands on the two main suppliers (GOsC and Balens) to conduct the extraction; the analysis suffered some delay because of the long waits for the GOsC dataset; and the researchers needed time to carry out considerable manual processing on the data once received. It was not feasible within the timescale of the project to request updated datasets. Delaying the project end-data beyond the funding period would have caused problems with staffing and funding.

The total number of complaints (n= 351) made by patients over 5 years in a mean population of 3731 osteopaths represents a total rate of 187 per 10,000 registrants p.a., some 3 times higher than the rate based on published data from GOsC hearings. This emphasises the need to collate all complaints data to obtain a full picture. It is also instructive to identify the "regulator" and "service" complaints (see Chapter 2) for comparison with data from other professions: the 123 formal "regulator" complaints were embedded within the insurers' data. The remainder of the complaints (n=228), including the informal GOsC complaints, could probably be considered as "service" complaints. The ratio of service to regulator complaints is only around 2:1, compared with over 10:1 in allied health and dentistry. The rate of informal complaints to the GOsC and the insurers is also very small compared with the huge numbers received by the Dental Complaints Service (32% pa).

Overall, the largest groups of complaints related to Clinical Care (68%), particularly adverse events, and Conduct and Communications (21%). However, the prominent issues differed between organisations. The numbers of complaints regarding Boundary Issues and Conduct issues were similar in the GOsC informal and Balens' data. Within Clinical Care, the adverse events category was the most prominent, and the most common of all complaints to insurers. The high number of adverse events in the insurers' data was unsurprising as it was a condition of the policy to report any incident.

Between 2004 and 2008 there was no evidence of an upward trend, suggesting that the increase in litigation seen in the NHS is not present in osteopathic services. However, it would be advisable to continue to monitor trends both in order to gain adequate statistics to be able to detect subsequent changes in trends, especially in the sensitive areas of boundaries issues and adverse events, as well as detecting any up-turn in the future.

The outcome of complaints was not systematically recorded in the files, except for the GOsC formal complaints. It would be very valuable for the future to obtain more information about outcome of complaints, and to be able to link GOsC formal records to the corresponding record in the insurer's files.

CHAPTER 6 UNDERSTANDING WHY PATIENTS COMPLAIN

6.1 Aim

The aim of this part of the study was to gain understanding of the causes and situations that give rise to patients' complaints, through interviews with key personnel within the organisations that handle complaints.

6.2 Methods

The methodology chosen was to undertake face-to-face, individual interviews with those key individuals in the regulatory body and the insurers who deal directly with the patient and/or osteopath involved in a complaint. These individuals communicate directly with and advise the parties to a complaint, record the details of the case, and take appropriate action. Their direct involvement, in an intermediary role, over a number of years means that they have observed the narrative, the emotions, and the course of many complaints, and have synthesised in their own minds an understanding of how and why complaints come about.

The relevant intermediary person(s) in each organisation were identified and invited to participate in an interview. In addition, we invited the member of staff at the professional association (British Osteopathic Association) who often provides first line advice to osteopaths. They were sent the letter of invitation, Information Sheet, and Consent Form as attached in Appendix 8.

Semi-structured interviews were conducted using the interview Question Schedule in Appendix 8. They were conducted in a quiet room within the interviewee's workplace. The interviewer asked the Intermediary in turn about the typical course of types of complaints, grouped as shown in the left hand column of Table 3.1 in Chapter 3, and covered complaints at all levels of severity, from those that do not progress, to those that involve court proceedings and claims for compensation. Questions explored views, events and emotions around what causes the patient to instigate that type of complaint, how the osteopath typically reacts at each stage, and what actions or reactions cause escalation or resolution. The question schedule was piloted with a member of staff prior to use. Interviews were digitally recorded.

In order to minimise the risk of identities of individual parties to a complaint being identified, interviewees were asked not to mention individual cases or identities but to try to give an overview of the course of different types of complaint.

For the analysis, the recordings of the interviews were transcribed verbatim, in full, by an independent transcriber. The results were not reported as narrative, in order to minimise this risk that the narrative might suggest to any patient that the story was their own. A thematic analysis was conducted, interpreting the text and seeking to summarise, generalise and draw out themes (Braun and Clarke 2006). The analysis was conducted mainly by AF, with independent validation from JL on one interview and an experienced researcher within the research centre (Dr V. Cross) on another. An iterative approach was adopted, developing a conceptual framework from reading and re-reading the transcripts. Each script was then coded individually using the themes identified, and the main themes from each transcript identified so that differences could be highlighted. Reflexive notes by the interviewer were used to add insight to the interviewee stand-points and to make interviewer bias explicit. Participant feedback was used to validate the trustworthiness of the results.

6.3 Results

Face-to face interviews were conducted with participants from GOsC, BOA, and three staff from the providers of indemnity insurance. These personnel were highly experienced, all having dealt with complaints for seven years or more. The interviewees are identified in the text and tables of verbatim quotes using codes to show whether they came from the staff at GOsC (R1), BOA (P1), or the professional indemnity insurers (coded as I1, I2, and I3 respectively). All interviews were conducted by the same interviewer (AF). The researchers interpreted and summarised the participants' views as objectively as possible. The researchers' views and biases were recorded, and are described in the Discussion section later in the chapter.

Most of the themes that emerged in the analysis were common across all interviewees and we considered that saturation was reached in identification of themes. There were some differences in viewpoint between the interviewees, discussed in a later section. The themes that emerged are shown in the small boxes in Figure 6.1; these were grouped into larger concepts, shown in the larger boxes. The full conceptual

framework that emerged from the data is shown in Figure 6.1, and represents the interviewees' combined views of how complaints arise. The four large boxes represent the highest level concepts in our framework, and the smaller boxes show the themes that contribute to each concept. The four concepts also convey the narrative of the complaint over time. The event that is voiced by the patient as a complaint – called here the **Trigger** – is actually the second point on the time-line of the complaint. Prior to the trigger event, there will have been one or more **Underpinning Factors**, antecedents to the complaint that may be present from the outset of the therapeutic encounter. Once the Trigger event has occurred, there are two sets of factors that determine the manner in which the complaint progresses. The patient will explicitly or implicitly have in mind a **Desired Outcome** they want to achieve. Then there are a number of **Resolution Factors** that determine the likelihood of complaints being formalised and progressed or alternatively coming to a speedy or satisfactory resolution.

In the following pages, the conceptual model is presented graphically in Figure 6.1, and then a textual commentary is given for each of the concepts and the themes within them, together with illustrative verbatim quotes. The text attempts to faithfully describe the participants' views that emerged at interview, and not the researchers' opinions on these views.

Communication Protecting others **Business Practice** Eg Boundaries Need to be heard Compensation/refund Adverse event Accidental damage Apology Recognition **DESIRED** TRIGGERS Practice eg **OUTCOMES** Ineffective treatment Financial External pressures Patient complaints Relationship **RESOLUTION UNDERPINNING FACTORS FACTORS** Knowledge Communication Expectations Third parties Personality

Figure 6.1 The thematic framework emerging from the interviews

Concept 1: Underpinning factors

These are predisposing factors that make a complaint more likely, and they may be established some time before the event that triggers the complaint occurs, in some instances before the first appointment. These underpinning factors concerned themes of expectations, communication, and the patient-practitioner relationship within the clinic, as well as external pressures on the patient from their daily lives. These issues may be expressed explicitly by the patient when they complain, or they may be apparent from the story, or they may be elicited on further investigation. Verbatim quotes to illustrate each theme are included in italic script.

Theme 1.1: Expectations

Patients come for their consultation with expectations. Interviewees suggested that expectations were based on previous treatment experiences and input from third parties such as family and friends. We may assume that the media also play a part. Patients also appear to have expectations (often unvoiced) regarding the amount of treatments that they will require, the costs involved and the nature of examination and treatment. The first appointment is a critical time.

'certainly the danger area for a lot of stuff is the first appointment'

'You've got to manage the expectations by giving stuff up front.'

'the underlying reason I think on most things that, you know, that um ... they're not told ... they're not told or given enough information when they first phone up to make an appointment. They're not told that they're going to have to undress. They're not told that if they want to they can bring somebody with them if they're uncomfortable about doing that. They're not told ... they're not always told, necessarily told how much it's going to cost, or they're not told that, you know, that the first treatment will be more because it's an assessment.'

Initial expectations of treatment may be unrealistic. Patients may anticipate a lot more treatment than is possible at the first treatment and may also expect a vast or total symptomatic improvement (P1). Osteopaths are often visited by patients in acute pain, expecting emergency treatment and symptom resolution. There may be

disappointment and potential for complaint if these expectations are not managed (I3). It was suggested that osteopaths may agree to treat a patient when referral might have been more appropriate, motivated either by concern for the patient or by confidence in their own abilities (I2, I3). There may be issues when follow-up appointments are shorter than expected: patients appear to judge a treatment session in terms of duration in a way that they would not with a GP or dentist. Unexpected treatment techniques, whether it is an unexpected manipulation, a treatment focusing upon the involuntary mechanism (or 'cranial osteopathy') or the uses of adjuncts such as dry needling, may not deliver what a patient was expecting (R1).

'a lot of the public do not realise how long an assessment will take, so they don't actually get much in the way of treatment possibly on the first appointment'

'I don't doubt that most of the complaints are genuinely done, but they're done from a point of misunderstanding where they don't ... you know, they either expected a miracle cure or they, you know, because the person ... you know, they've invested quite a lot of money in these treatments.'

'You'll find that there are some people that are going to see an osteopath that think they're going in there, they're going to get a quick fix, they're going to have one treatment, it's going to be a miracle treatment, and they're going to walk out the door and everything's going to be absolutely fine.'

Undressing is another critical area, when the patient does not expect to be asked to undress for examination and treatment. Whilst the need for undressing may be clear and obvious to an osteopath, it will often not be so to a patient. They will often come to an osteopath after years of experience of seeing GPs where undressing for treatment is the exception rather than the rule (P1). There is a clear change in dynamics once a patient is in a state of undress that a practitioner must be aware of. The patient will most probably feel vulnerable and uncomfortable. They may feel shocked by the request. It is possible that any information imparted at this stage will not be absorbed by the patient (I1).

'the surprise for them is the intimacy of it and the level of undress required for it'

'there is nowhere else from my own experience as a patient and for most other patients' experience where you are in your underwear, bending over and touching your toes, bending from side to side, being watched, being asked to walk, you know, they can report how they've had to walk up and down the room in their underwear and while the practitioner has watched them do that, you know, and but again, you know, a clinical investigation, but the patient doesn't know, they just ... all they know is that they were standing there in their bra and pants and they had to walk backwards and forwards while the osteopath watched them'

Adverse reactions are the final important area where mismatch between expectation and outcome can create complaints. Patients will not expect to feel worse after treatment unless they are informed of the possibility and the nature of treatment reactions (P1). Emotion also colours expectation. If a person is in pain, they will be hypersensitive and this may affect their perception of events (I2).

'when you are in pain and you are used to going to the GP, getting painkillers, which is the alternative in most cases, and there is some sort of temporary relief without much, if any, cost involved, then you go to an osteopath and pay your thirty to fifty pounds, go back home and find that it's worse, it's an immediate need to say that this is a waste of money'

Underlying these specific expectations may be an underlying misunderstanding of the perceived purpose and place of osteopathy. Patients may view osteopathy as symptom-driven; to treat and resolve certain types of pain quickly. The practitioner's longer-term model of osteopathy and its position as a natural healthcare system concerned with wellbeing may not be well understood (I2).

Theme 1.2: Communication

Running through all complaints irrespective of the triggering event is the issue of communications. Communication is needed in order to manage expectations; there must be a clear agreed treatment plan – a framework within which the osteopath and patient can work (I3). There is a need for clear, well considered and timely communication in order to reduce the chances of problems arising. The style and the content of this communication are important and must be delivered in a style appropriate to the individual patient. Imparting information alone is not enough; it is

vital to check that the patient understands the information that has been given. The need to inform patients to come prepared to undress for examination and treatment before they attend the first appointment was consistently expressed; informing them after they arrive is too late. The patient needs to be in a position of equal partnership – not undressed and lying on a bench – in order to fully participate in discussion of their options for treatment, and about benefits and risks.

'90% of the problems come down to communication'

'the communication skills required to deal with emergency treatments are sometimes a little bit different to those required for patients with er ... um ... a more sort of ingrained problem and the patients'

'if someone comes in pain, they're unlikely, generally speaking, they're unlikely to remember everything the osteopath said

'you have so many varying personalities that you're dealing with, so many varying people that you're dealing with, it's hitting on that right level of information for that right person, and getting to their level of communication really that ... that makes them understand the process.'

'communication is the most important part of the treatment really, when it comes to claims ... informed consent all the way through ... basically building on the communication level with the patient all the way through and making sure that that patient knows exactly what they're paying for ... exactly what they're getting and exactly what ... what they're looking to achieve throughout the treatment plan, all the time'

'If a patient feels informed, you know, if they can understand why they might be reacting in the way they're reacting, then you're probably half way there,' 'the inappropriate touching sort of cases that we get, ... many of them are not established in that way, but there will be failures to communicate established and consent not being obtained ... But there are some clinical justifications for what's being done, you know, and the patient just didn't understand'

How can you stop it? The only person that can stop it is the osteopath. The osteopath remaining within that column of what is right and secondly, giving the patient the complete sort of reassurance that if you're unhappy, just pick the phone up and talk to me

'I think gone are the days when patients went to healthcare practitioners and sat there and just accepted what was said. I think patients now want ... they want an explanation, they want to be part of the process, they want to give consent, they want to understand what they're agreeing to'

Theme 1.3: Relationship

The nature of the patient-practitioner relationship was considered to be of great importance. If a trusting and open relationship is established, there will be good channels of communication and the patient will feel they have a degree of control of, and involvement in, their treatment plan. If any problems do then occur, these are likely to be viewed in a more magnanimous manner. Conversely, a poor relationship may underpin the complaint and reduce the likelihood of an effective resolution (I2). The importance of the therapeutic relationship reflects many patients' growing desire to be a part of the process: they want information, to understand and to be able to consent (I3). There was a feeling expressed that the communication skills demanded by this need were being well met among more recent graduates (I3).

'we know there are practitioners out there who don't really feel that a full history is that relevant or that ... or that the patient needs to know what it is that needs to be done to them, you know. The patient must just accept what is done to them.'

'People don't sue so easily people they like.'

'if something goes wrong they [may] trust the relationship enough to say OK we need to work with this'

"... I think more than even communication, it's relationship, not just professional relationships, but relationship"

Within this sphere of relationships, two interviewees (R1, I1) proposed that some patients feel a need to achieve closure in the patient – practitioner relationship when they complain. The patient may blame the practitioner's perceived errors rather than blame their own decisions and actions. In this way they achieve an explanation and closure in a way without having to blame themselves for their decision in seeking a treatment that has caused them pain.

Theme 1.4: External pressures

Pressures on the patient may also predispose them to complain. For example, stressful life events such as marital breakdown can lead people to behave or react emotionally in more extreme ways. These are factors over which the osteopath has no control, but careful history-taking and listening may well alert the osteopath to take special care in communicating.

'they've got um ... stressful situations, they've got, you know, problems in their life with other partners ... and they find that an osteopath actually spends much more time with them listening to them, you know, it's gentle treatment, they feel comfortable, they, you know, they're feeling benefit from it, and they get quite dependent on that practitioner, and I think that can get the practitioner into some trouble sometimes because it'

'lonely people whose um ... mental health is a contributory factor to their ... their physical problems'

Concept 2: Triggers

Triggers were the explicit cause(s) expressed by complainants as the reason for their complaint. These causes are many, covering all the types of complaint (see the classification system developed in Chapter 4). Certain types of triggering event featured more strongly in the interviews: firstly, practice-related events such as adverse events, ineffective treatment that does not meet expectations and leads to a questioning of the osteopath's competence, or the lack of a proper examination before treatment. Secondly, communication issues such as inappropriate comments or conduct, and other boundary issues. Events such as accidental damage and business practice were described by interviewees as extremely rare and therefore not discussed in depth. Health complaints were similarly rare but were described as normally being generated by concerned colleagues rather than from patients.

Theme 2.1: Ineffective treatment

Several interviewees described the scenario that occurs when treatment appears ineffective: patients have an expectation of the practitioner addressing the plan of treatment and of cost-benefit. They hold, or develop over time, an idea of how many appointments they may need and how much they expect to spend as a maximum before they want to cut off treatment. If the osteopath fails to recognise lack of effect, the patient may feel they are not achieving what they expected and not getting value for money.

'I think the early patients are very much financially motivated ... If it happens later on, then in my ... my sort of experience on a lot of these cases is that the treatment doesn't perform as well as expected, so they've usually gone to seek a second opinion'

'at the other end of the scale, the patient who's been for the tenth appointment, and it's just been a series of promises that they're getting there, they're getting there, but still no relief, is another area.'

Theme 2.2: Adverse events

An adverse event (reaction to treatment) is one of the most common triggers for complaints and claims. Common adverse events included persistent pain or neurological symptoms caused by manipulation or pain caused in another area of the body by treatment. Patients may accept an initial discomfort but may not when the problems persist for any length of time. They will often express their complaint in terms of 'not feeling right' or not being back to 'how they used to be' with consequent effects on life and work. Complaints of this sort will often be seen some time after the initial cause, sometimes as long as two years. Interviewees were clear that patients do not expect side effects from osteopathy in the same way as they might with other treatments such as a GP's prescription.

'it will be a ... a significant pain caused by a manipulation, that doesn't go away, um ... it will be soreness to a degree that was probably more than they anticipated it would be, so that concerns them. Um ... numbness, and loss of sensation, pins and needles and things like that having had a manipulation.'

'They feel as if they've paid for something and it hasn't worked or that it's made them worse. Um ... especially if they feel there's been a misdiagnosis made'

'they're usually quite upset about the fact that obviously they've come for treatment, the treatment hasn't worked and they're actually in more pain now than they were before they went to see the osteopath'

'the actual trigger points are various. I mean, one of the key ones is somebody who suffers the same amount or possibly a greater element of pain within a limited space of time'

Theme 2.3: Communication

Communication issues are also a common trigger, often when the osteopath's words or attitude appear unprofessional, or when the osteopath fails to achieve a rapport with the patient.

'flippant remarks are something that crops up as well ... the use of language is very important and clearly they've developed their own patter and their language, particularly the ones that have been going a long time'

'So all we get to hear of is when that hasn't quite ... the consent hasn't quite sunk in at the client's end or maybe the osteo didn't even really ... go into the depths of consent taking, rather than just the general kind of implied consent, the kind of very general approach. That's fine ... if nothing happens in the relationship, if the treatment sort of goes OK and people sort of feel alright, well it's not an issue. These only start to go clang when ...'

'obvious communication issues where what they said or how they said it made the client feel uncomfortable. Maybe the treatment was fine, but the person was creepy. Or I didn't like the innuendoes or I felt they were being sexist. Or I was just told gruffly to strip off, you know, no um ... robe was offered, no screen, da,da,da,da, they appeared insensitive.'

'there will be comments about underwear, or comments about other patients and some funny story about a level of undress of another patient or a particular medical, you know, an embarrassing medical condition'

'The patient ... doesn't know why the osteopath's massaging there when their pain is somewhere else.'

'the osteopath was telling me all about this that they were doing or their family or that and the other, and you can see quite clearly that this is, you know, this has been... building up a relationship, putting somebody at their ease ... but ... if something goes wrong, that becomes a negative rather than a positive which is quite sad.'

Complaints about boundary issues are triggered where patients feel exploited in some way: they may feel shock, upset, relief at leaving the clinic, anger. This often happens after they leave the treatment room. The patient may describe feelings of violation where, for the osteopath, all procedures were normal. Emotion can colour the patient's perceptions of events. The osteopath's and patient's interpretations of what has happened may be poles apart. It can occur after an adverse event where a patient may feel that they have been injured or hurt. An ineffective treatment could

also lead to an emotional response due to the hope and trust invested in treatment. These feelings will clearly affect the manner of the patient's complaint.

'people come in pain and they're, you know, their antenna are out like stalks, but they're hypersensitive, sometimes I think, the imagination takes over'

'I think what you see when you get consent or boundary issues is very much where the osteo thought they'd communicated it but the patient didn't hear it that way'

'treatments that are considered intimate by the patient, I think um ... can be quite a source of complaint for us, and ... they come to us on the basis that the patient feels as though they've been assaulted in some way, and what's made them feel that way is the level of intimacy that there was in the touching, and the conversations and the level of uncovered-ness'

Concept 3: Desired outcomes

This concept represents patients' motivations for making complaints.

Theme 3.1: Protecting others

Interviewees reported that patients often express the desire to protect future patients from the same experience.

'there may be an element of, you know, sort of philanthropy in it that they don't want it to happen to anyone else. But more than that I think it's just that, you know, you've done this to me, you need to pay for it effectively'

'they want to avoid a repetition on somebody else having to go through this traumatic problem, and lastly they are looking for compensation'

Theme 3.2: Apology

They may also want an apology for or recognition of the alleged wrongdoing by the osteopath. (I1) This is particularly true where the allegation is one of inappropriate conduct. (R1)

'They want the apology, they want the... the admission of liability. Um... they want to... someone to stand up and say yes it was my fault because they want to be able to point that finger and say it was that person that did it to me'

Theme 3.3: Being heard

There was also a perception among the interviewees that patients often need to feel someone has listened to them and understood their complaint (I1).

'the NHS did a survey some years back and they found that, you know, a lot of the patients that had sued for malpractice had said all I wanted to do was be heard and I didn't get the feeling the nurse/doctor really heard my concerns, was prepared to listen to me'

Theme 3.4: Compensation

Compensation may be a relatively low priority for the complainant. One interviewee advised that a recent NHS survey had ranked patients' motivations in order of frequency as: the need for an explanation, to prevent a similar event in the future, and desire for compensation (I3).

'it comes down to the person because um ... the mindset of some people is, to be fair, once they've got the money they don't care two hoots, you know, they've got their money back, they're quite happy to walk away. Um ... other people see it as their duty to actually do something about it and make it known that this person has done what they're alleging'

When establishing what the complainant's motivation may be, the knowledge or insight of the osteopath may be invaluable. As well as knowledge of the details of the events that triggered a complaint, they will have an understanding of the patient's personality and any psychosocial issues that may underpin a complaint. (I1, P1)

Concept 4: Resolution factors

These are additional factors that determine the likelihood of an initial complaint being made formal and pursued by the patient. Four major areas were identified by the interviewees.

Theme 4.1: Finance

Financially motivated complaints were considered more likely to be made formal.

This was particularly true with regard to adverse events, where although the motivation might be expressed in terms of protecting others, the financial demand for a refund or compensation may be the patients' way to seek justice for harm they

perceive. This compensation may be for pain or injury caused, for effects on lifestyle or for the cost of treatments sought elsewhere to resolve the effects of an adverse event. Many of these complaints will tend to occur early on in the treatment plan and the complainant will tend be proactive in their actions often taking advice to inform and further their complaint (II).

'...because they're paying for your knowledge, they're paying for that private treatment, so they're paying for you to tell them what's wrong ... so the expectation I think is slightly higher when you actually pay for a treatment than if you turn up at the doctor's surgery'

'if they approach the osteopath and... some agreement could be reached over fees, then there's a chance it wouldn't be made into a formal complaint.'

'sometimes I think patients think they are going to be able to get some um ... financial payout with GOsC, or even by getting a complaint found that that will give them some clout in getting a claim. Because some people will go down both routes.'

There was consensus that osteopathy is viewed by patients as a service or as a commodity (I2, I1). Patients will expect value for money especially in the context of the growth of consumer rights and information. This gives an interesting perspective into the resolution of complaints. If a patient feels that the treatment was not appropriate for them, has not been effective or that they should have been referred, then as with other commodities or services, a refund will often resolve the complaint. This was deemed to be particularly relevant to complaints regarding ineffective treatment (P1). When money is the primary motivation, the complainant will often approach the osteopath first with their complaint (R1).

Theme 4.2: Personality

The second factor was the role of the complainant's personality. Many patients were seen as level-headed, reasonable and fair; they tend to be open to mediation when a problem does occur. Even in the case of serious injury, a patient may judge the osteopath not to be at fault. In contrast, some patients will have a more emotional response, and are more liable to experience feelings of violation, victimisation, anger, greed or a desire for revenge. Others tend to be guided by advice from friends and family, who may encourage a compensation claim. Unfortunately, there will be patients who are potential complainants from the outset, perhaps due to psychological issues or stresses in their lives, or even on occasionally greed or bitterness: 'serial

complainers' were described by one interviewee, 'chancers' by another (P1, I1). The osteopath's insight and the case history may be invaluable in identifying patients with psychological issues in the early stages, for example such patients may exhibit emotional dependence upon the practitioner (P1). One interviewee claimed that there would always be clues in the case history that would indicate potential psychosocial issues that an osteopath should be aware of (I1). The personality may also influence how long it may take to complain: some people will be liable to complain immediately, others will be more stoic and patient with the treatment process. Personality and the level of emotional tension affect patient-practitioner communication, both before and subsequent to the event, and affect the chances of achieving a satisfactory resolution.

'in effect you've got three groups really. You've got the ones that are looking for the compensation to an insurance company, the ones that simply want their money back ... the third group is the ones that go to the Council and um ... you know, their motivation I am sure is entirely different'

'The people that are more extrovert will get all stroppy straight away virtually and they're not afraid of telling you exactly what they think. ... they've come into the clinic, read the riot act. Then you've got, you know, the kind of more introverted type ... it sort of, it twitters away in the background so it niggles them and it niggles them and they keep thinking about it and it builds into something'

'if somebody's aggressive to start with ... it's probably quite unlikely that you're going to be able to placate them in any case'

Theme 4.3: Knowledge

The level of knowledge that a complainant has about their rights and legal processes can affect both the route of the complaint, the likelihood of making the complaint formal, and how responsive the individual is to mediation.

There will be more potential for a complaint if the patient is sceptical of complementary medicine, is not fully engaged in the therapy process, or is attending as a last resort. Some patients may not take in much of the information given by the osteopath, for a variety of reasons: important information such as possible treatment reaction will need to be reinforced with some people whereas others will assimilate it straight away.

'Now, what they will either do is go straight to the therapist themselves concerned, or they'll bypass the therapist and they will go and see a solicitor, or they will go straight to the GOsC and make a complaint about the osteopath. I think, where they make their complaint depends on the level of knowledge they have about the industry in a lot of cases.'

'... and I think that the culture has changed dramatically, the availability of information of what your rights are, what you should expect from a healthcare professional. The internet is full of advice. There are solicitors out there who'll give you one hour for free, telling you what you should have had. There is so much information, there's consumer programmes on TV, especially with the type of patients the osteopath's dealing with'

The **osteopath's knowledge** of the patient and of the complaints procedures is also important. Their knowledge of the patient may provide valuable insight into avenues for mediation. Where an osteopath is slow in responding to a complaint, does not recognise why a patient is unhappy, or is aggressive in their response, they may drive the patient to make the complaint formal. Examples were given where there was no response to a complaint or a limited or defensive response, and the complaint had subsequently been formalised. It was suggested that there was uncertainty in the profession regarding how best to respond and some osteopaths were reluctant to admit any liability (R1). Several interviewees report regrettable emotional reactions such as anger and arguments with the patient.

'I think speaking directly to the patient is important, because that ... that seems to um ... that re-establishes the um ... the relationship'

'if it doesn't get sorted quickly or if they sense that the therapist is a bit reticent or dragging their heels in responding ... I think that triggers the kind of going for the jugular mentality which can result in a GOsC or malpractice claim'

'there's been a lot of aggression, a lot of things said, there's a lot of heat and emotion in the situation, and it's not going to happen ... because they're very upset and very angry.'

'I think the osteopath's attitude I think um ... occasionally, not always um ... but occasionally um ... an osteopath can be quite defensive in that ... in that scenario um ... and doesn't know, or seem to know, how to respond in a constructive way to a patient's complaint when it's made directly to them, and so that can escalate'

'The reason that it becomes so formal a complaint is the failure of the practitioner to handle or reach into the patient's need for a response, the patient's need for an explanation, the patient's need for somebody to deal with it immediately'

Theme 4.4: Third Parties

There was consensus among interviewees that third parties can be instrumental in encouraging a patient to formalise a complaint. These third parties may be friends, family, other practitioners that treatment or advice is sought from or the patient's GP. For example, another practitioner who criticises previous treatments, or a GP who is sceptical of osteopathy, will tend to fuel a complaint. Friends may on the one hand, tend to damp down a complaint if they have favourable experience of osteopathy after a similar treatment reaction; on the other hand, friends may amplify discontent or recommend "no win, no fee" solicitors.

A diagnosis that is in apparent conflict with the treating osteopath's diagnosis, whether as a result of a scan or blood test through a GP or consultant, or from another osteopath or chiropractor, may drive a complaint. Not only might it undermine the osteopath's diagnosis but also, more seriously, the results can be interpreted as the confirming an adverse effect of treatment (R1).

'people go away and they talk to other people, they talk to their family or they talk to ... and they say ooh you really ought to do something about that, you know, that's terrible, and you can get your money back or you can put some sort of claim in to get some money'

'another fruitful area of problems, is where you get a conflict of diagnosis between what the osteopath said, what maybe a rival osteopath may have said, what a chiropractor or physio might have said, not to mention the doctor or the hospital, you know'

'The patient who swaps practitioners, either goes to a chiropractor, another osteopath, or back to conventional side and somebody says well actually, I think that what was done to you by the osteopath is the core cause of the aggravation'

'they might go to a different practitioner, like a chiropractor or physiotherapist, or back to their doctor and then like get a response from them, that they've been wasting their money or time with an osteopath, which might spark a complaint'

The GOsC as regulator plays a specific third party role. The GOsC role was considered positively as a body that a complainant feels more comfortable approaching regarding a complaint (rather than directly to the osteopath). Their role was felt to be particularly important if there was a need to establish what had happened, whether the patient's account of their experience was correct, and to protect other patients if there were recurrent problems with a particular osteopath (P1,

R1). The role of GOsC was also viewed negatively, as sometimes detrimental, in that complaints can escalate or formalise beyond that which the complainant intended (I1). The GOsC may sometimes be approached by patients who just want to discuss things or to have their complaint acknowledged or logged but, as the regulator, the GOsC may be obliged to investigate further. Several interviewees voiced their view of the desirability of more rigorous screening of complaints or of establishing a neutral mediating process to allow the discussions of patients' complaints without the need for an official complaint to the GOsC, when the patient is not concerned about fitness to practise (I1, I2, I3).

'I really think they (GOsC) should stop making it so easy for people to complain by saying to them do you want to make a complaint, you know, er ... and to try and put the onus back on the patient to really explore every avenue with the osteopath before making a complaint'

Another osteopath can also act as a third party, sometimes inadvertently. The variability between osteopaths was seen as both a strength and a weakness of the profession. If a patient sees two osteopaths, at different times, who differ markedly in their approach to the case history, examination and treatment or in terms of outcome, then one osteopath may be seen as falling short of accepted or expected standards. A complaint may ensue, about the osteopath who appears less competent or acceptable (R1).

'the patient will come and say that they've ... now gone to another osteopath who's worked wonders ...'

... they'll go to another osteopath and quickly have seen results, from the different treatment approach, so they think that the first treatment approach ... obviously there was something wrong with it.'

Cross-cutting themes

Cross-cutting theme 1: Communication/Therapeutic relationship

Two strong cross-cutting themes emerged as affecting all stages of a complaint. The first was Communication issues/Therapeutic relationship. The second was Conflict Resolution.

The communication skills of an osteopath were seen as key by all interviewees in terms of the likelihood of complaints arising and being formalised. Good listening skills are required and the use of language is important. If good communication is established from an early stage and clear information given, a patient will feel informed, involved and more able to ask questions than when they are unsure or unhappy with something. They are also less likely to complain when something goes wrong, as they will not perceive that something has been done to them but that the process that they understood and were happy with has gone awry.

The value of maintaining good levels of communication regarding treatment is vital. Even with acute patients where full explanations may be difficult due to pain levels, or with patients who have been treated over many years, it is important to maintain high levels of communication particularly regarding consent and risk. Interviewees described how easy it seemed for osteopaths to fall into bad habits and not communicate fully with patients whom they had seen over a long period of time. This has implications for CPD.

Complaints involving boundaries are often actually problems of communication where a patient has not been informed as to why a procedure is warranted. Without this communication, the requisite consent is also lacking (R1).

Adverse events will always happen, but communication is a variable that can be worked on to prevent them resulting in a formal complaint (I3, I1). This has implications for prevention of complaints.

A timely, well-considered response to a complaint may make for a swift resolution. Yet osteopaths were described as being reluctant to admit liability when things went wrong as they mistakenly considered this the 'correct' approach in the context of their insurance policy. This has implications for training in the profession.

Complaints are resolved effectively when there is good communication after the event. Patients want an explanation of what had gone wrong. They want time, reassurance and options regarding how the problem can be resolved. Where appropriate an acknowledgement of the osteopath's or clinic's role in a problem and any changes instigated in response will facilitate resolution. The osteopath is in a unique position to meet these needs and the patient will often approach the osteopath

directly because of his/her knowledge and skills. Patients may respond well if given responsibility in a shared decision or plan to put matters right.

'Sometimes if there is a good understanding between the patient and the practitioner then you will find that they will manage to get it back on track ...it does depend on the person that you're dealing with and again it comes down to the level of communication between the patient and the practitioner.'

Cross-cutting theme 2: Conflict resolution

The second cross-cutting theme, conflict resolution, represents the need for appropriate action at every stage to resolve conflict. The osteopath needs the skills to respond in a sensitive way to the patient's concerns, and the flexibility to react according to the range of patient personalities and to fairly extreme emotional states. Such skills would help to avoid the factors that underpin, trigger and formalise complaints.

6.4 Discussion

Qualitative findings are unique, specific and non-generalisable: they derive from the views of the specific participants in the study as interpreted by the specific researchers. The findings are highly applicable to the context that generated them, provided the study was designed and conducted rigorously. Data saturation was reached. The results of the analysis were validated through participant feedback. The extent to which the results can be generalised depends on the openness and consistency of the views expressed, and judgements from the wider world about the truthfulness and plausibility of the results.

There are some obvious sources of bias in this study: the interviewees spoke from apparently very different stand-points; and the main researchers were osteopaths. The likely effects, and ways in which we minimised them, are discussed here.

6.4.1 Interviewee bias: differences between interviewee views

The interviewees had a wealth of experience. However, their views were affected by the fact that they deal with the problems rather than the successes within the profession. In addition, their interpretation of events was inevitably subjective and idiosyncratic because of their own personality, attitudes and world view, and also by

the role of the organisation that they represent. The insurers sit on a different "side of the fence" from the regulator. The regulator represents the interests of patients; the insurers and the professional body represent the interests of the osteopaths.

A second source of bias was the intermediary role itself. None of the interviewees were directly involved in any dispute, they heard the details "second hand" from one side, sometimes two sides, without the opportunity to question both sides in the dispute (apart from in formal hearings). For example, one of the insurer interviewees had the view that "all therapists give the full information before treatment" (I1). It would be useful to authenticate the model developed here, by using first-hand data (documents or interviews) from the osteopaths and patients themselves. Such documents (written records of patient complaints) are limited, in that they will tend to provide a partial and more superficial understanding, in the sense that they only give what the patient expresses explicitly as the cause and motivation of the complaint. First-hand interviews would be limited because the sample size would be resource-limited. In comparison, the experience of these particular interviewees synthesised a large number of complaints.

Despite the differences of stand-point, the same main themes emerged from the interviews very consistently and with little variation. Communication issues and the therapeutic relationship were considered as key at each stage for preventing, handling and resolving complaints. Both insurers and the regulator spoke about the response of the osteopath as a potential escalating factor. However, there were some differences. The regulator, being more in touch with the patient viewpoint, gave a stronger message about the importance of patient involvement and control in clinical decision making, and the need some patients feel for closure on a bad experience. The insurers and professional body interviewees, being more in touch with the osteopaths, spoke a great deal about communication failures, ranging from lack of prior information about what to expect in terms of undressing and treatment, lack of consent at first visit, through to poor communication when a complaint has been made. Several interviewees spoke about the patient personalities that can escalate complaints, the value of the insight of the osteopath for resolution; the need for an apology as part of the outcome; and the role of patients' knowledge of "the system" for complaints. One interviewee also spoke of the loss of power experienced by patients when lying undressed on a couch in relation to validity of consent.

There was a difference in view about whether complaints made several years after an event reflected a point where a patient has become disillusioned enough to make a complaint or whether it reflected the rise of 'no win, no fee' lawyers. Further observation and monitoring of claims is needed to resolve this question. There was some variance in opinion between the interviewees regarding whether there had been a growth in litigation and the emergence of a compensation culture. Where some felt that there were 'chancers' that were seeking to claim, others felt that the particular relationship between patient and practitioner meant that people were generally loathe to complain about an individual that they knew and that the growth of a compensatory culture was perhaps more a problem for corporations.

6.4.2 Reflexivity of the researchers

The interviewer was an osteopath in private practice. This gave the advantages of depth of understanding of the clinical situations that can arise. The possible disadvantage is a possible tendency to focus on the role of the osteopath, and on the implications for practice, rather than for patients or for educators or regulators. Bias within the qualitative analysis was minimised by using several independent analysts. All were manual therapist-researchers (two osteopaths and one physiotherapist). The coding framework was a consensus view of the data. The analysis has also been validated by the participant feedback: all the interviewees confirmed the model as fitting their view of the factors giving rise to complaints.

6.4.3 Implications of the results

The analysis provided rich insights into why patients complain, with many specific implications for the organisations involved in the study and for professional regulation and training. The insurers have a key role in advising osteopaths: further training for osteopaths on how to manage complaints made directly to them would be valuable in achieving local resolution of complaints. Osteopaths need skills in responding promptly, using suitable forms of words, and interacting appropriately with the patient. Osteopaths also need to be aware of actions which can cause complaints against fellow professionals: they need to avoid criticism of competence or contradiction of a previous diagnosis. Providing a different approach to care than a colleague is an unavoidable trigger for some complaints, and need not imply a difference in standards. The regulator may also play a role in determining whether a

formal complaint is made, and via which route, depending on the advice given to patients by the staff member who handles the initial call. While the advice that the GOsC gives to complainants is recorded, and quality assured by the inspection processes of the Council for Healthcare Regulatory Excellence (CHRE), the GOsC policy on giving advice is not explicit or public.

The introduction of a mediation process would appear to be a step that the profession might consider; the advantages and disadvantages of such a step are explored a little further in the following Discussion Chapter.

CHAPTER 7 DISCUSSION

This chapter reflects on the findings of each of the above chapters, the obstacles and the limitations of the results from the study as a whole, and considers the implications for the profession.

7.1 The evidence-base on patients' complaints in manual therapies

The literature review presented in Chapter 2 highlighted the lack of both quantitative and qualitative research in this area. The literature review was hampered by the lack of indexing terms for complaints within the thesaurus/dictionaries of the research databases.

The review confirmed that this was the first study of its kind within osteopathy and manual therapies. Only a few studies in all the health literature have explored why patients complain. The current very limited evidence, from hospital medicine in the USA and Taiwan, suggests that complaints are less likely if patient satisfaction is high, and the practitioner is able to establish rapport, administer care consistent with expectations, and communicate effectively.

Information from grey literature from professional organisations and regulators highlighted the distinction between "regulator" complaints – about fitness to practise – and local "service" complaints, which appear to be 11-16 times more numerous within the NHS allied health professions and dentistry. This report presents the first statistics on the rates of local "service" complaints with osteopathy. Such service statistics are essential in order to obtain a full picture of complaints within a profession.

7.2 Establishing a basis for future collaboration

Research of this type relies on cooperation in order to access, collect and interpret the data held within the different organisations that receive complaints. One of the four insurers was reluctant to release data which was detailed enough for in-depth analysis. Fortunately their data was a small component of the study, since they were providers of insurance to only a small number of osteopaths. Their cooperation in the future would be advantageous. We would hope that the study outputs would demonstrate to

all the insurers that collaboration is cost-effective, and that current collaborators will support future studies of this type.

7.3 The "NCOR3" system for classification and coding of types of complaint

The formal approach which was adopted for the development of an osteopathyspecific system for classification and coding of the type of complaint means that the proposed new classification has validity and meaning from a legal, professional and patient viewpoint.

The classification system is essentially a beta-test version. It is likely to evolve with use, and also when revisions are made to the Code of Practice for Osteopaths or to the relevant laws. It would be extremely helpful for monitoring of complaints in the future if the organisations could agree to use the new system for classifying complaints by type. It would make it simpler to combine datasets, to compute frequencies, and to speedily identify those areas within the Code of Practice that generate most complaints.

The difficulty that the researchers encountered when trying to classify the complaints records retrospectively would not apply when and if the system were used real-time within the GOsC and the insurers: "unclear" complaints would be unlikely, and "multiple issues" would be fewer.

7.4 Trends in complaints against osteopaths

The combined data on all initial complaints logged by the insurers and the regulator suggested that the rates of complaints were low and that there was no upward trend. The mean rate in the study period was 187 per 10,000 registrants per annum, after combining the insurers' and the regulators' data, of which about one third had become formal complaints to the regulator. The outcomes in terms of claims via the insurers could not be estimated reliably from the data provided.

The low rates appear reassuring but could be deceptive. The NHS health professions and the dental professions had some 10-15 times more local "service" complaints than complaints to the regulator. The low rates in osteopathy could reflect high patient satisfaction – but could equally reflect poor advertising of the complaints procedures

that inform patients how and where to make a complaint about an osteopath; or they could reflect confusion about the options available to patients (i.e. making a complaint to the regulator or taking civil action), or that the options are not patient-friendly.

The evidence collected within the study showed that patients tended to channel different types of complaint to the GOsC compared with the insurers, but there was a considerable spread of complaint types received by both types of organisation, suggesting a possible lack of clarity about where to direct complaints against osteopaths, and that less serious complaints may be made to the regulator, as the CHRE would anticipate within a profession which is largely self-employed (http://www.chre.org.uk/policyandresearch/).

The GOsC received a total of 217 informal complaints from patients in the study period, of which 97 (45%) became formal complaints (these were excluded due to overlap with insurers' data); the remaining 120 informal complaints were included. The text notes on the informal complaints suggested that some of the concerns that remained may have been quite serious. The patient may well have been directed to approach the osteopath/the insurers to make a claim; as we were unable to link records, this could not be ascertained. There are also, inevitably, patients who do not wish to pursue their initial complaint, and an unquantifiable number of patients who never voice their complaints or dissatisfaction to any formal organisation. The osteopathic complaints statistics therefore cannot reflect fully the extent of dissatisfaction.

7.5 Implications for future monitoring of complaints

The accuracy of the quantitative analysis of complaints and claims was limited by inadequacies in the raw data, which is unsurprising, as the organisations had not been asked to supply such data before.

In order to facilitate future monitoring of complaints, there needs to be discussion and implementation of changes in the way data are recorded within the organisations that receive complaints from the public: whether to adopt the new classification system, and whether some additional data items could be collected routinely in the Log Files. The free text in the Log Files giving a "potted history" of the patients' concerns was helpful not only for developing the classification, but also for checking the quality and

consistency of coding, and gaining additional insight into the less common types of complaint. It represents valuable data in its own right and we recommend it should be retained and used further.

One of the most surprising features of the data is that the outcome of complaints seems in many cases to be unrecorded. There is often no formal record of whether or not an osteopath or the insurer has come to a satisfactory agreement with the patient who has complained.

The GOsC formal complaints records were not used within the analysis, because the same complaints were recorded within the insurers' files. The exclusion and lack of data about them, made it difficult to fully describe "regulator" and "service" complaints. Further discussion is needed about if and how these formal complaints should be utilised.

Difficulties with the data extracted for the research from the Log Files arose for a number of reasons, including the data not being recorded, not sent in the form requested, or sent in a form that the researchers could not use. There were specific problems in the data that need to be remedied for the future, in order to enable key variables such as complainant or year to be derived, to improve **accuracy of the reported frequencies:**

- **The complainant** was not always specified clearly whether this was the <u>patient</u> or another party (e.g. osteopath, police, member of the public, health professional, or other).
- **Potential (rather than actual) complaints** these are events notified by the osteopath to the insurer, where it was unclear whether the patient had made a complaint or not; these need to be able to be identified and possibly excluded.
- Lack of record-linkage data between the GOsC and the insurer's files, to identify any complaints recorded by both, in order to avoid inflating the counts. The degree of overlap is thought likely to be quite small but is difficult to quantify. The ethical case for doing this linkage will need to be argued, balancing the public interest against human rights concerns.

- **Incomplete annual data** for 2008, as the data were transferred at the end of the third quarter of the year, depressing our estimates for 2008 by about 25%.
- Incomplete ascertainment of complaints there may be other organisations holding additional complaints which do not get notified to the insurers or the GOsC, such as firms of litigation solicitors, private healthcare insurers, trade unions and charities aiming to support patients against abuse. These need to be ascertained in future. Complaints made within clinics attached to osteopathic educational institutions should always be notified to insurers and are thought to be included within the insurers' data.

Secondly, there were problems within the data that made classification of type of complaint difficult or uncertain, thus affecting the **distribution of complaints by type:**

- Unclear information held on Log File;
- **Multiple complaints** were mentioned and patient's primary concern not identified.

Thirdly, analysis of **other complaint characteristics** was hampered by lack of systematic recording of:

- **Outcomes** of the complaint, how far it proceeded, and what response the patient received;
- Claims and legal proceedings need to be identified;
- Patient characteristics such as age and gender, and whether the complaining patient was 'treatment-naïve' or 'treatment-experienced';
- Osteopath characteristics (age, gender, years in practice, type of practice).

7.6 Understanding why patients complain

The qualitative interview study undertaken within this project was the first study to try to develop a model of how complaints arise in manual therapies, and the results have many implications for practice and policy. The methodology of narrative interviews with key individuals (intermediaries) in the regulatory body, the insurers, and the professional body (BOA) had both advantages and disadvantages as explained in Chapter 3, but was considered the optimum approach for this pilot study.

The resulting model proposed the factors that act as antecedents, the events that trigger complaints, and the factors determining the consequences. The framework of concepts that were derived represents a hypothesis for future testing. The fact that it was approved by all participants adds validity. No particular obstacles were encountered with the qualitative interview study data collection or analysis, data saturation was reached, and the findings were validated by participant feedback. These findings should be viewed in the context that:

- Qualitative studies are not generalisable, they are unique to the setting and participants;
- The conceptual framework is only one of many possible ways of framing the data;
- The interviewees were intermediaries, one step removed from the complaint itself;
- All the key intermediaries have now been interviewed.

7.7 Implications for practice

The data from the interviews were immensely rich and provided many insights about the problem areas in practices, and where targeted training is needed to reduce complaints and improve patient satisfaction. The data pinpointed high-risk events where practitioners need to take special care in order to avoid complaints.

Information <u>before</u> the first appointment is critical. Patients expectations need to be managed before they arrive at the practice: the need to know what kind of osteopathic or allied techniques may be given, the need to get undressed, and for touch and physical examination. The information should cover all the areas that may be potential sources of contention or surprise, e.g. extent of treatment at first appointment, costs, suitable clothing and undressing, the option of bringing a chaperone, and treatment effects and reactions. Patients need to know what they are "buying" at the first appointment: costs, duration, how much treatment time compared with history taking. High quality information before the first appointment should become part of the profession's culture.

There is potentially more risk associated with a first appointment. Establishing empathy with the patient is important so that the patient can voice any concerns or fears openly. Explanation of what is happening and why, particularly when touching the patient's body, helps the patient to understand the treatment and avoids feelings of violation and abuse. The osteopath also needs to give the patient information about what their problem is, what the treatment will aim to do, and what to expect after treatment such a transient stiffness and soreness.

Osteopathic consultation involves procedures which are taboo in normal life — undressing in front of stranger, touch, holding. As one interviewee stated, "they (*patients*) don't expect the degree of intimacy". It is vital that osteopaths do not forget how strange the experience can be for patients who are new to it.

Discussions involving consent for treatment, the management plan and sensitive topics need to be respectful of the patient's views. Osteopaths need to be more aware of the sense of vulnerability and loss of personal power created by being undressed and lying down (physically lower than the practitioner), undermining their ability to take in information. At critical points in the consultation where partnership in the discussion and decision-making are required, the practitioner needs to be sensitive to these issues.

Practitioners need to be especially aware of body language, behaviour and case history suggestive of emotional crisis, psychological problems and dependence, as patients who are vulnerable due to pain or external pressure in their lives will not only feel pain more acutely, but can react in unpredictable ways and are more likely to complain.

Lack of consistency between practitioners may alarm patients. A new patient who has received previous treatment from another practitioner for the same complaint represents a risk for complaints. Patients expect consistency in quality of service, treatment and diagnosis within osteopathy and dislike poor service or conflicting diagnoses. Inconsistency between osteopathy and other health professions particularly with regard to diagnosis, can lead to accusations of wrong diagnosis.

Adverse reactions (unexpected or worse pain) often trigger a complaint. Patients may understand when the event was unavoidable. However, practitioners need to ensure that they take a good case history and perform tests to identify risk factors. Reduction of adverse event rates is desirable. Could risk factors be identified more effectively in practice?

Lack of improvement of symptoms is another warning signal. A patient can easily feel exploited if a course of treatment continues indefinitely. Patient and practitioner need to have a common, clear, agreed understanding of the purpose of continuing treatment. The practitioner's recommendation has to be in the best interests of the patient. If symptoms do not improve, the patient may still wish to continue as a means to prevent deterioration. Or they may feel the treatment is not working, and referral or advice on other types of treatment may be appropriate.

Prolonged courses of treatment (or "maintenance") are a potential area for complaint, even if there has been agreement on this as the treatment plan. Regular review is still needed and regular communication with the patient about what the treatment is aiming to achieve and what the physical findings are. It is easy for a practitioner to slip into a known treatment routine without explanation, and for social conversation to replace the professional dynamic of the consultation.

Communication is a key area of complaint. However, empathy, listening skills, appropriate conversation topics for putting the patient at their ease, and awareness of personal boundaries, are all skills that practitioners can learn.

The way the osteopath reacts to a complaint is crucial. A prompt, polite and appropriate response is likely to lead to a rapid resolution. An angry or delayed response is likely to escalate the complaint. Skills training in handling complaints and conflict within the profession would improve the outcome of individual complaints and enable the whole profession to be more confident about receiving complaints, suggestions, and dissatisfaction.

7.8 Implications for policy

There are three areas where policy on development could be used to improve professional practice:

- Measures to reduce the frequency of complaints;
- Measures to ensure patients feel supported when they complain;
- Consideration of a review of procedures for handling osteopathic complaints.

Each of these is described in more detail below.

7.8.1 Measures to reduce the frequency of complaints

Improved patient information in two areas specifically, may assist osteopaths in communication of key information. Nationally agreed, patient-centred information that complies with the GOsC Code of Practice for Osteopaths is needed on at least two topics:

- Approved information for practices to provide to patients before their first visit;
- Approved information for patients about the likely after-effects of treatment and on the balance between risk and benefit.

Such information needs to have practitioner buy-in and acceptability; hence it will be essential that it is developed through joint working between the regulatory and professional organisations (GOsC and BOA).

Complaints could be used more fully to provide learning opportunities for practice. Practitioners need to welcome complaints or feedback about their service. UK health service policy emphasises that complaints are useful, they provide free feedback on the service, and are the best form of market research (Citizens Charter Complaints Task Force 1998). It is proposed that the GOsC considers informing the profession about the volume and nature of informal complaints so that the profession can use this information as a learning opportunity.

There seem to be two areas where approved, targeted training to all members of the profession would be beneficial – again this could well be developed through joint working at national level by the relevant organisations:

- Training aimed at reduction of the frequency of adverse treatment effects,
 which form a large proportion of complaints;
- Training aimed at equipping practitioners to handle a complaint well; to provide a timely, considered response; to deal with conflict and aggression

from patients (Virshup, Oppenberg et al. 1999); and towards viewing complaints and suggestions as a way to improve practice.

7.8.2 Ensuring patients feel supported when they complain

The interview data suggested that patients may be poorly informed or confused about osteopathic complaints procedures, which is contrary to the ethos behind the new NHS (Department of Health 2009) complaints system. This actively encourages patient complaints, suggestions and comments at local-level; national and regional organisations such as the GMC and the Health Service Ombudsman have a limited role, as a safety-net if patients are not satisfied with the local response. Dealing with complaints better not only makes service-users feel more valued, it also makes services more effective, personal and safe. Osteopaths need to be encouraged to elicit feedback from patients. The effectiveness of the newly-formed BOA Complaints Resolution Service, initiated in August 2010, will be watched with interest as a way of providing patients with access to a telephone hot-line for local complaints about services. This may provide some of the features recommended by the Department of Health guidance.

7.8.3 Consideration of a review of procedures for handling osteopathic complaints This section is not intended as a criticism of the GOsC processes, or the insurers' processes, but a reflective look at the system as a whole, attempting to see it from the viewpoint of a patient at grass roots level, faced with the choice of complaining to a practitioner they may have found unpleasant, or to the GOSC who are very helpful but whose role is not complaints handling, and who may direct them back to the osteopath.

Several of the interviewees raised concerns about the current complaints system, including the slowness of the processing of some complaints, lack of clarity and simplicity for patients, and the sometimes disproportionate damage to an osteopath's practice when the fitness to practise investigation finds no case to answer. These concerns suggested that, in the interests of all concerned, a buffer should exist between the "run of the mill" problems that can be adequately remedied at local level and the cases that need to be referred to the regulator. The quantitative data also supported the view that there was no clear delineation between fitness to practise

complaints (which should go to the regulator) and other complaints which should be handled locally through the osteopath and their insurer. It is important to distinguish between the two processes under discussion here: the regulator's processes are designed to establish whether a practitioner is fit to practise; the osteopath/ insurer's processes are designed for handling complaints.

The first question, therefore, is whether complaints are routed appropriately, whichever organisation – the regulator or the osteopath/insurer – initially receives the complaint? Are all complaints recorded and classified according to type and severity, and then are they routed appropriately? Ideally, all serious complaints about fitness to practise would be directed to the regulator and all less serious complaints would be directed to the complaints handling route.

A Government task force (Citizens Charter Complaints Task Force 1998) identified the principles of an effective complaints system. These included: easy to access and well publicised; speedy; confidential; informative; simple to use; fair; effective; and regularly monitored and audited. These principles raise a second question, which is to consider whether the current system for osteopathic complaints needs review in the light of these ethical principles?

Any review, if undertaken would need to take account of the fact that complaints systems are still evolving: different models have been implemented by different UK regulators, and their experiences could be useful. Any new system would also need to be consistent with the legislative framework governing the regulator. Any new system should always retain the option for the patient to complain directly to the GOsC at any point if they had concerns relating to fitness to practise.

Any review could need to consider the implications of a change to the current system, including whether the osteopathic profession is ready to encourage complaints. This may be considered in the wider context of obtaining feedback from users, a valuable exercise for any service provider that can cover both positive and negative satisfaction and suggestions. The potential drawbacks of eliciting feedback are the possible financial costs of making changes, more administration and, if there were more complaints to be dealt with, possible refunds of fees.

Any review would also need to consider the legal and ethical issues: whether focussing on local systems and improving speed of resolution might put justice in jeopardy. Mediation has been strongly promoted by the Courts since the Woolf Reforms of 1996 (Lord Woolf 1996); the professional indemnity insurers keenly support mediation as a means of settling cases, but mediation has its critics. Speedy local resolution is likely to mean that more complaints are resolved by refund of fees. Would this be unfair to the osteopath, who may have done their job competently? Would it be unfair to the public, as "unfit" practitioners may not be reported to the GOsC? Would it encourage patients to make claims for compensation from osteopaths? Is it possible to devise a system that delivers on the principles above, but safeguards the public from practitioners who have repeated complaints or who have harmed their patients?

Considerable discussion is clearly needed in the profession to see if a revised system is required, and if so, whether it could be designed to make these aims achievable without detriment to patients and the public.

Chapter 8 Conclusions

Complaints research has proved to be a rich source of information, yielding insights that are relevant to improving the standards of osteopathic care. The project achieved its objectives: new knowledge has been gained about the sources of the data on complaints, and about how complaints are classified, the patterns and trends in complaints, and why complaints occur. Important messages emerged – especially from the interview data – for the osteopathic profession, for the organisations, and for policy development.

An expert Steering Group was a huge asset to this research. It provided representation of all the stakeholders, including users, and not only facilitated collaboration, but also provided legal, ethical, academic and user expertise at all stages of the study.

The data on complaints over a five-year period in the UK have been obtained, collated, coded and analysed. The results provide baseline data on frequencies and patterns of complaints. The results are reassuring in that there is no evidence of an upward trend and rates are relatively low. The study forms a basis for monitoring trends in complaints against osteopaths in the future.

A number of recommendations have been made to facilitate the future monitoring of complaints: these include developing and testing the system for classification and coding of complaints, improving on the consistency of the data recorded within the organisations, recording outcomes of complaints more systematically, and utilising further sources of quantitative and qualitative data.

Further qualitative research is proposed to gain further understanding and to verify and validate the trustworthiness of the conceptual framework. This will need to access new forms of data, such as (i) directly gathered data from the complainants and their osteopaths, subject to ethical approval, and/ or (ii) the free text within the Log Files (which was more informative than we had anticipated). Direct contact with the osteopath and the patient involved in a complaint is ethically quite difficult as both can be considered vulnerable. If means can be devised for minimising the distress caused by interviewing the parties to a complaint, further such research may be possible.

A greater insight and understanding of the circumstances leading to complaints has been gained, yielding learning opportunities for the profession about improving the way complaints are dealt with, and recommendations for a review of the national framework for handling osteopathic complaints.

The reports and dissemination strategy will inform the profession, educators, insurers and the public of the findings and promote respect for the osteopathic profession.

The information within this report will be disseminated in numerous ways, in collaboration with the funder (the General Osteopathic Council) and the National Council for Osteopathic Research (NCOR):

- A lay report, summarising the main messages in language accessible to a lay audience.
- A report for practising osteopaths, which will include discussion of prevention of complaints.
- A scientific publication for an osteopathic research journal.
- Articles for the professional journals, The Osteopath (GOsC) and Osteopathy Today (BOA).
- Presentation at scientific and professional conferences.
- Web-based dissemination via the NCOR, GOsC and other appropriate channels.

References

- BOA British Osteopathic Association. (2009). "Members section http://www.osteopathy.org/."
- Braun, V. and V. Clarke (2006). "Using Thematic analysis in psychology." Qualitative research in psychology **3**: 77-101.
- Carnes, D., T. S. Mars, et al. (2010). "Adverse events and manual therapy: A systematic review." Man Ther Jan21 epub ahead of print.
- Carnes, D., B. Mullinger, et al. (2010). "Defining adverse events in manual therapies: A modified Delphi consensus study." Man Ther **15**(1): 2-6.
- Citizens Charter Complaints Task Force (1998). <u>How to deal with complaints</u>. London, Cabinet Office Archive

 http://archive.cabinetoffice.gov.uk/servicefirst/1998/complaint/b5intro.htm, HM Government.
- Dental Complaints Service (2009). Annual review 2008-09, http://www.dentalcomplaints.org.uk/images/pics/Annual_Review_2008-2009_1.pdf.
- Department of Health (2009). <u>Listening, responding, improving: a guide to better customer care</u>. London, <a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPublicat
- Ernst, E. (2007). "Adverse effects of spinal manipulation: a systematic review." <u>J Roy</u> Soc Med **100**: 330-338.
- General Osteopathic Council (2005). <u>Code of Practice</u>, <u>http://www.osteopathy.org.uk/about_gosc/about_standards.php</u>.
- Genn, H. (2010). <u>Judging Civil Justice: The Hamlyn Lectures 2008</u>. Cambridge, Cambridge University Press.
- Gibbons, P. and P. Tehan (2006). "HVLA thrust techniques: what are the risks? ." International Journal of Osteopathic Medicine **9:pp**.
- Greenman, P. E. and J. M. McPartland (1995). "Cranial findings and iatrogenesis from craniosacral manipulation in patients with traumatic brain syndrome." <u>J Am Osteopath Assoc</u> **95**: 182-188.
- Harpwood, V. (2001). "Clinical governance, litigation and human rights." <u>J</u> Management in Medicine **15**: 227-241.
- Health Professions Council (2007). Fitness to practise: Annual Report 2006. London.
- Heywood, R. (2010). "Saving costs in clinical negligence: the Jackson Report recommendations." <u>Professional Negligence</u> **26** (3): 124-139.
- Hickson, G. B., C. F. Federspiel, et al. (2002). "Patient complaints and malpractice risk." JAMA **287**(22): 2951-2957.
- Holloway, I. and S. Wheeler (1997). <u>Qualitative Research for nurses</u>. London, Blackwell.
- Leach, J. (2006). "Risk and negligence: A minefield or an opportunity?" <u>International</u> Journal of Osteopathic Medicine **9**(1): 1-3.
- Life, R. (2005). <u>A survey of complaints filed with solicitors. Undergraduate Research</u>
 Thesis
- Lord Woolf (1996). Access to Justice. London, TSO The Stationery Office.
- Lucas, N. P. and R. Moran (2009). "Clinical guidelines, adverse events and SQUID." Int J Osteopathic Med 12: 47-48.
- Magarey, M. E., T. Rebbeck, et al. (2004). "Pre-manipulative testing of the cervical spine review, revision and new clinical guidelines." Man Ther **9**: 95-108.

- Mayberry, M. K. (2003). "Effects of the civil procedure rules on clinical negligence claims." <u>Postgrad Med J</u> **79**: 74-77.
- McPartland, J. (1996). "Craniosacral iatrogenesis, side-effects from cranio-sacral treatment: case reports and commentary " <u>J Bodywork Mov Ther</u> 1: 2-5.
- Meyer, G. S., J. Battles, et al. (2003). "The Us Agency for Healthcare Research and Quality's activities in patient safety research." <u>Int J Quality Health Care</u> **15 Supplement 1**: i25-i30.
- NHS Choices. (2009). "How to complain (accessed 09/11/2009)."
- Norman, R. and H. Thiel (2003). <u>Retrospective analysis of medical malpractice data</u> for members of the British Chiropractic Association. WFC 7th Biennial Congress, Orlando, Florida, USA.
- Parliamentary and Health Service Ombudsman (2009). <u>Every complaint matters:</u> <u>annual report 2008-9</u>. London, TSO (The Stationery Office).
- Rajendran, D., B. Mullinger, et al. (2009). "Monitoring self-reported adverse events: A prospective, pilot study in a UK osteopathic teaching clinic." <u>International Journal of Osteopathic Medicine</u> **12**(2): 49-55.
- Ritchie, J. and J. Lewis (2003). <u>Qualitative research practice</u>. London, Sage Publications Ltd.
- Rubinstein, S. M., C. Leboeuf-Yde, et al. (2007). "The Benefits Outweigh the Risks for Patients Undergoing Chiropractic Care for Neck Pain: A Prospective, Multicenter, Cohort Study." <u>Journal of Manipulative and Physiological Therapeutics</u> **30**(6): 408-418.
- Sari, A. B., T. A. Sheldon, et al. (2007). "Sensitivity of routine system for reporting patient saftey incidents in an NHS hospital: retrospective case note review." BMJ **334**: 79.
- Snelling, N. (2006). "Spinal manipulation in patients with disc herniation: a critical review of the risk and benefit." <u>Int J Osteopathic Med</u> **9**: 4-12.
- Stelfox, H. T., T. K. Gandhi, et al. (2005). "The relation of patient satisfaction with complaints against physicians and malpractice lawsuits." <u>The American</u> Journal of Medicine **118**(10): 1126-1133.
- Stevinson, C. and E. Ernst (2002). "Risks associated with spinal manipulation." <u>Am J Med 112</u>: 566-571.
- The Health and Social Care Information Centre (2009). Data on written complaints in the NHS 2008-09, http://www.ic.nhs.uk/webfiles/publications/complaints/Data_on_written_complaints_in_the_NHS_2008_09_Report.pdf.
- Thiel, H. and J. Bolton (2006). "The reporting of patient safety incidents--first experiences with the chiropractic reporting and learning system (CRLS): A pilot study." <u>Clinical Chiropractic</u> **9**(3): 139-149.
- Vincent, C., G. Neale, et al. (2001). "Adverse events in British hospitals: preliminary retrospective record review " <u>BMJ</u> **322**: 517-519, doi:510.1136/bmj.1322.7285.1517
- Virshup, B. B., A. A. Oppenberg, et al. (1999). "Strategic risk management: reducing malpractice claims through more effective patient-doctor communication." <u>Am J Med Qual</u> **14**(4): 153-159.
- Wu, C.-Y., H.-J. Lai, et al. (2009). "Patient Characteristics Predict Occurrence and Outcome of Complaints Against Physicians: A Study From a Medical Center in Central Taiwan." <u>Journal of the Formosan Medical Association</u> **108**(2): 126-134.

APPENDICES

Complaints and claims against osteopaths: a baseline study of the frequency of complaints 2004-2008 and a qualitative exploration of patients' complaints

NCOR Adverse Events Project No. 3

APPENDICES

- 1. Research Team
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APPENDIX 1 THE RESEARCH TEAM

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Dr Anne Mandy, Principal Research Fellow, Clinical Research Centre, University of Brighton

Prof Elizabeth West, Director of Research, School of Health and Social Care, University of Greenwich

Brenda Mullinger, Postgraduate Research Development Officer, European School of Osteopathy, Maidstone, Kent

Rachel Ives, Curriculum Manager, College of Osteopaths, Borehamwood, Herts

APPENDIX 2 STEERING GROUP

The Steering Group comprised 7 individuals who met with the research team at the required intervals (at 0, 3, 6 and 12 months) to advise, steer, and monitor progress. They ensured that the project kept to the required timescale and delivered the outcomes specified in the brief in an appropriate way. The members were:

- **Tim McClune**, NCOR member, Osteopath, former member of GOsC Professional Conduct Committee.
- **Bernadette Ranger**, Service User Representative and Admissions Officer at the European School of Osteopathy.
- David Balen, Director of Balens Specialist Insurance Brokers (a provider of professional indemnity cover for osteopaths) and lecturer on risk management at two osteopathic colleges.
- **Paul Grant**, legal advisor to this project, Solicitor, Osteopath, Chairman of Board of Governors of the College of Osteopaths.
- **Professor Julie Stone** MA LLB, Barrister (non-practising), Consultant on regulatory, legal and ethical services to the healthcare sector.
- Catherine Goodyear, representing the British Osteopathic Association (BOA).
- **Asgar Hassanali,** Executive Director, Lockton Affinity (a provider of professional indemnity cover for osteopaths) (from September 2008).

Steering Group Meetings took place on 14th January, 12th May, 21st July, 13th October 2008 and 19th January 2009.

APPENDIX 3 THE GOSC FITNESS TO PRACTISE PROCESS

Initial contact

If a patient is concerned about the conduct or treatment they have received from an osteopath, they may contact the GOsC. This initial contact is usually made in writing or by telephone. A member of the GOsC fitness to practise staff (GOsC staff) will respond to the patient, outlining the options available to them if they wish to make a formal complaint about the osteopath. A record will be made of the patient's concerns and this event is termed an 'informal complaint' for the purposes of this research. The information provided by GOsC staff may include:

- information about the process of making a formal complaint about an osteopath to the GOsC, and about the GOsC's fitness to practise procedures
- Information about other options for pursuing the concern, such as seeking further advice from the osteopath, or from another healthcare professional or from the Citizens Advice Bureau
- Advice to contact the police if the allegation is criminal in nature.

The outcome of this stage is **the patient's decision to make a formal complaint or not**. If the patient wishes to make a formal complaint to the GOsC, they will be asked to put their complaint in writing. They may do this by completing the GOsC "Making a Complaint" form, or GOsC staff will assist by taking a formal statement of complaint from the patient.

Screening

When the GOsC receives a **formal complaint** from a patient (a signed statement or completed Complaint form), GOsC staff will arrange for that complaint to be considered by a Screener.

The Screener is an osteopathic member of the Investigating Committee whose role is to establish whether power is given by the Osteopaths Act 1993 for the GOsC to deal with the allegation if it proves to be well founded (see section 20(6) of the Osteopaths Act 1993). This means that the allegation has to be:

- that the osteopath has been guilty of unacceptable professional conduct (UPC)
- that the osteopath has been guilty of professional incompetence (PI)
- that the osteopath has been convicted of a criminal offence within the UK
- that the osteopath's ability to practise is seriously impaired because of his physical or mental condition.

The outcome of this stage is the Screener's decision as to whether there is **power for GOsC to investigate the complaint or not**. If there is power, s/he will refer the case to the Investigating Committee for investigation.

The GOsC may not have the power to investigate the complaint if, for example: the practitioner is not registered with the GOsC; the complaint is not serious enough; the

complaint is not related to an osteopath's practice; there is unlikely to be sufficient evidence to support the complaint (see GOsC "Making a Complaint" factsheet, 2009); the complaint is one of negligence (see GOsC Fitness to Practise Report 2005-06).

Investigating Committee (IC)

The IC's role is to investigate allegations (complaints) that are referred to it by the Screener and, in light of the information it has been able to obtain, to consider whether there is a case to answer. (See section 20(9), The Osteopaths Act 1993)

The IC will notify the osteopath that a complaint has been made and that it is being investigated. The osteopath will be provided with a copy of the complaint and is invited to make his/her comments on it (see section 20(9) of the Osteopaths Act 1993). The osteopath will be advised to inform their professional indemnity insurer that a complaint has been made to the regulator and is being investigated.

Over a period of weeks, GOsC staff, on behalf of the IC, will gather any other information that may be relevant to the complaint, e.g. the patient's medical records, MRI scan/x-ray results etc, as well as the osteopath's response. In some cases, the patient will be asked to comment on the osteopath's response. The Screener's report and all supporting information that has been gathered will then be presented to the IC. The IC will consider all the evidence available and decide whether or not there is a case for the osteopath to answer.

The IC will provide reasons for its decision, and these are communicated to both the osteopath and patient.

If the IC decides that there is no case for the osteopath to answer, the case is closed. The IC may, however, notify the osteopath that this case may be considered again if a subsequent complaint is received about the osteopath. (See Rule 24 of the GOsC (Investigation of Complaints) (Procedure) Rules Order of Council 1999).

If it is the IC's decision that there is a case to answer, it will refer the case:

- to the Professional Conduct Committee, if the allegation is one of unacceptable professional conduct, professional incompetence, or where the osteopath has been convicted of a criminal offence in the UK and the offence may have material relevance to the osteopath's fitness to practise osteopathy. (See section 20(11) of the Osteopaths Act 1993)
- to the Health Committee, if the allegation is that the osteopath's ability to practise is seriously impaired because of his/her physical or mental condition. (See section 20(12) of the Osteopaths Act 1993).

Professional Conduct Committee (PCC)

If the case is referred to the PCC, solicitors acting for the GOsC will prepare the case for a public hearing. This preparation will include the formulation of allegations against the osteopath and may include the gathering of further reports or statements from the patient or a third party.

Both the GOsC and the osteopath will usually attend the hearing and be legally represented. Both parties present their case, after which the PCC retires to consider in private whether or not the **allegation has been proven**. If it is proven, the PCC will apply one of the following sanctions:

- an admonishment of the osteopath
- make an order imposing conditions with which the osteopath must comply whilst practising as an osteopath (a Conditions of Practice Order)
- order the Registrar to suspend the osteopath's registration for a period of time (a Suspension Order)
- order the Registrar to remove the osteopath's name from the Register.

(See section 22(4) of the Osteopaths Act 1993).

Health Committee (HC)

If the case is referred to the HC, the HC may consider the case without the need for a hearing or it may consider the case in a private hearing. Either way, both the GOsC and the osteopath, or their legal representatives, are able to make representations to the HC before it makes its decision as to whether or not the **allegation has been proven**. If it is proved that the osteopath's physical or mental condition does seriously impair his/her ability to practise osteopathy, then the HC will take one of the following steps:

- make an order imposing conditions with which the osteopath must comply whilst practising as an osteopath (a Conditions of Practice Order)
- order the Registrar to suspend the osteopath's registration for a period of time (a Suspension Order).

Interim Suspension Order

The IC, PCC and HC all have powers to suspend an osteopath's registration on an interim basis. They will do this if they consider this necessary in order to protect the public whilst a case is being investigated or is awaiting a hearing. The PCC and H C may also impose an interim suspension, having found the case proved and having imposed a sanction. A sanction will not take effect until a period of time has passed (28 days), sufficient to allow the osteopath to decide whether to appeal the Committee's decision. If an appeal is made, the sanction would not take effect until the appeal has been heard. The purpose of this interim suspension order would be to protect members of the public during the appeal period.

Appeals

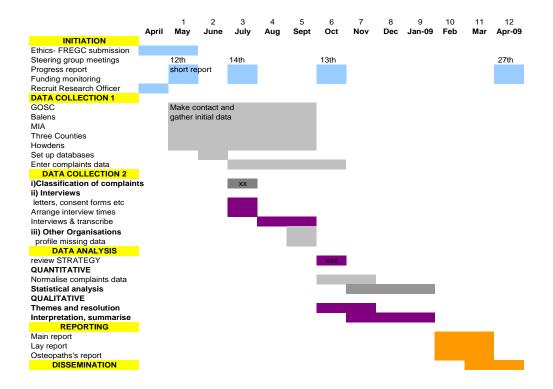
It is possible for the osteopath to appeal the decision of the PCC and HC.

Patient complains to GOsC FTP department Doespatient No, informal make complaint complaint only formal? Formal complaint to Screener Does GOsC Νo, have power in complaint this case? dismissed Evidence to IC Is there a case No case to to answer? answer PCC or HC hearing Is case proven? Not proven PCC or HC apply sanctions

Figure A 3.1 The GOsC fitness to practise process

APPENDIX 4 GANTT CHART

Project timescale



APPENDIX 5 ETHICS APPROVAL

Ethics approval was granted by the University of Brighton on 3 July 2008. In order to obtain approval, the original proposal had to be substantially modified, and information on our strategy to minimise risk of breaching confidentiality was provided by the researchers.

Modification of the study design

The original study design was a document analysis of a sample of the case files held by the participating organisations. These case files contained the full documentation in relation to the formal complaints and subsequent investigations. The data was confidential and equivalent to medical records in terms of Data Protection. Informed consent from the research subjects (patient and osteopath) would have been required. Compliance with informed consent was thought likely to be low, in view of the painful or stressful nature of the event and the time that had passed since the conclusion of some cases. The Steering Committee advised the researchers to adopt a revised study design.

Minimising the risk of breaching confidentiality

The primary aim of the study was to provide descriptive statistics on complaints. The organisations holding the data were all keen to collaborate in the study and be represented on the Steering Committee for the project. The organisations each held an "Events Log File" of potential complaints, including brief details of each case and (possibly) the financial settlements awarded. The data required for the study were stripped of all identifiers of the subjects (patient and osteopath) and posed no risk of breach of confidentiality. In fact, the largest Professional Indemnity Insurer has for several years provided a spreadsheet in anonymised form to the osteopathic professional body (BOA) as an indicator of risk management. This analysis could be viewed as an audit of risk management or a service evaluation, to inform both practice and the public. A comparable study was done by the chiropractic profession and has been presented at scientific conferences.(Norman and Thiel 2003)

APPENDIX 6 PARTICIPATING ORGANISATIONS AND DATA

The data for this project were supplied by means of the kind cooperation of the providers of indemnity insurance for osteopaths:

- Balens (who operated the BOA scheme at that time)
- Howden
- Three Counties
- Towergate MIA

And the Regulator of the osteopathic profession:

• The General Osteopathic Council (GOsC)

Data items supplied

The following data items were supplied to the research project in anonymized form for the analysis of trends:

GOsC formal complaints data

Region of UK

Date complaint received

Type of complaint (4 categories only)

Outcome of complaint

Date of outcome

GOsC informal complaints data

Region of UK

Date complaint received

Nature of complaint (in-house notes)

Progression to formal complaint

Balens complaints data

Organisation Code

Organisation Reference

Region of UK where complaint occurred

Date first event occurred

Nature or type of complaint

Complaint type code

Final outcome

Financial outcome

Legal outcome

Unique complaint ID

Howden, Three Counties and Towergate MIA data

(supplied on paper, the following data items were derived by researchers)

Date of complaint

Notes about complaint ("negligence" only in MIA file)

Date ended

Outcome

APPENDIX 7 SEIBEL CLASSIFICATION OF COMPLAINTS USED BY THE GENERAL MEDICAL COUNCIL

This is a summarised table of the 2006 version of the classification

ТҮРЕ				
Failure or refusal of 2nd opinion				
Practice accessibility				
Fail to report adverse drugs reactions				
Fail to promote health of children				
Consulting colleagues				
Discrimination or delay in access to care				
-				
Not informing colleagues				
Investigations or treatment inadequate or substandard				
Non optimal pain relief				
Inadequate patient assessment				
Patient examination inappropriate/lacking care or respect,				
no chaperone				
Not recognising own limits				
Poor record-keeping				
Failure to refer				
Not reporting risk (environmental)/health and safety				
Treating family/friends Fail to help in emergencies				
Inefficient use of resources				
memcient use of resources				
Failure to comply – Health or Performance Assessment				
Not adapting practice when ill				
Mental and behavioural illness				
Physical illness				
Fail to protection colleagues and patients against				
communicable disease				
Not seeking independent medical care for self, family,				
Keeping up-to-date knowledge base				
Maintaining/improving via training, QA, audit				
Maintaining/improving via reflective practice, evidence				
Conduct- dishonesty, indecency, pornography, supply of				
medicines, breach of regulations				
Conflict of interest, inducements				
Criminality caution				
Criminality conditional discharge				
Criminality conviction				
Financial/commercial dealings- encouraging gifts, exploiting				
patients, forgery, maladministration				
Failure to cooperate with enquiries, giving poor evidence				
Failure to reveal suspension/restriction to employer				
Fail to reveal suspension/restriction to patients				
Providing misleading , false or unjustified information on				
services				
Research governance and research ethics				
Tell GMC of charge/offence				
Writing false CVs/applications				
Delay, inaccurate or incorrect reports or documents				
Communication- failure in explanation, listening, language				
Communication with young people				
Confidentiality breach				

CATEGORY	ТҮРЕ
Polationships With Patients	Ending relationships with patients – handover of records,
Relationships With Patients	on-going care, explanation, justice
Relationships With Patients	Maintaining trust in profession
Relationships With Patients	Patients' family/friends information needs
Relationships With Patients	Respect for patients
Relationships With Patients	Safeguard patients' interests –indemnity insurance
Teaching/Supervision	Assessment/appraisal
Teaching/Supervision	Audit and peer review
Teaching/Supervision	Personal commitment
Teaching/Supervision	Practical skill
Teaching/Supervision	References/reports
Teaching/Supervision	Responsiveness to individual. needs
Teaching/Supervision	Supervision
Teaching/Supervision	Understanding educational principles
Working with colleagues	Arranging cover
Working with colleagues	Delegation and referral
Working with colleagues	Enabling reporting of risk
Working with colleagues	Reporting risk (colleagues)
Working with colleagues	Respect for colleagues
Working with colleagues	Sharing info. with colleagues
Working with colleagues	Taking up appointments
Working with colleagues	Working in teams

APPENDIX 8 STUDY DOCUMENTS AND LETTERS

Appendix 8.1	Letter to organisations holding data
Appendix 8.2	Information Sheet for organisations
Appendix 8.3	Consent Form for Organisations
Appendix 8.4	Core Dataset requested for all complaints and claims
Appendix 8.5	Letter to intermediary
Appendix 8.6	Information Sheet for intermediaries
Appendix 8.7	Consent Form for intermediaries
Appendix 8.8	Ouestion schedule for interviews of intermediaries

Appendix 8.1. Letter to organisations holding data

(University headed paper)

Dear ..

Re Research on trends in patient complaints against osteopaths

I am writing to formally request the collaboration of your organisation in this research, which is being conducted by the CONDOR collaboration over 12 months May 2008 to April 2009. The funds for the project were made available by the General Osteopathic Council, and as grant-holders we are accountable to the National Council for Osteopathic Research.

The project commenced formally on 1st May when osteopath Adam Fiske took up the post of Research Officer for the project, based at Eastbourne. We have received ethical approval from the Faculty of Health Research Governance and Ethics Committee; and the project plan was discussed with the Project Steering Group and our advisor Professor Julie Stone on 12th May.

The primary aim of the project is to create a complete picture of all complaints and claims over the past 5-10 years, including complaints that were logged by you but not pursued. At this stage, the dataset that we are proposing to collect is in draft form, pending discussions with all the organisations involved (the four insurers and the General Osteopathic Council). The proposed dataset contains no identifiers of the osteopath or patient in the case. The data items we would like to obtain are in Annex 1. The second aim of the study is to gain understanding of the nature of complaints and the circumstances that lead to complaints of different types. This information will be obtained through interview with the person(s) within your organisation who deal directly with complainants or osteopaths, subject to consent by your organisation and the interviewee.

Further details of the study are given in the attached Information Sheet. If you have any further queries, please do not hesitate to contact us. If you agree to collaborate in the study, I would be most grateful if you could return the attached Consent Form. Many thanks.

I look forward to hearing from you,

Yours sincerely

Dr Janine Leach

Enc: Information Sheet, Consent Form

Appendix 1

Appendix 8.2. Information Sheet for participating organisations

NCOR Project 3: Trends in insurance claims and patient complaints to the regulator

The National Council for Osteopathic Research (NCOR) has awarded funding to the CONDOR collaboration to conduct this research study. CONDOR combines two universities and two osteopathic training schools: the University of Brighton, the University of Greenwich, the European School of Osteopathy, and the College of Osteopaths.

Aims and purpose of research

The aim of the research is to collect information about the number of complaints and claims concerning osteopaths that have occurred over the past 10 years, and investigate trends. The research will also try to understand the circumstances leading to complaints, particularly those alleging adverse reactions to treatment, with a view to reduction of complaints in future.

The study will collate existing data held by the regulator GOsC and the four indemnity Insurers (Balens, MIA, Three Counties and Howden). Preliminary information about other possible sources such as osteopathic college clinics, firms of litigation solicitors, private healthcare insurers, trade union Amicus and the professional body, British Osteopathic Association (BOA) will also be collected to assess the full extent of potential data on complaints over the past 10 years or more.

Your participation

We would like to invite your organisation to participate in the study. Participation is entirely voluntary and you are free to withdraw at any time. If you agree to participate, please sign and return the enclosed Consent Form.

What will I be asked to do?

The Principal Investigator for the project, Dr Janine Leach, or the Research Officer for the project, Adam Fiske, will contact you for initial discussions to establish what data you hold, the period it covers, and how much and in what form you may be able to provide it for the research. All the data we require will be anonymous with respect to the osteopath and the patients' identity.

The first data required for the study is a log of all complaints and claims, including formal complaints, informal complaints, and incidents which do not progress at all. We would like to identify each one by a unique ID code, and create a spreadsheet which categorises them by type, data, and outcome. After discussions with you, the dataset (Appendix 1) will be piloted to ensure it provides the information required.

Secondly, in order to gain as much understanding as possible of the circumstances leading to the complaint occurring and progressing, we would like to interview the person(s) in your organisation who deal directly with the people involved in a case.

We have called this member of your staff an Intermediary. The interview will take about one hour and will be tape-recorded. The interview will be exploratory and gather facts and typical stories of how different types of complaint progress.

Dissemination of results

The main outputs from the study will be three reports. The Final Report of the project will be a formal report of the full results of the project. A Lay Report will summarise the main messages in language accessible to a lay audience. A Report for practising osteopaths will include discussion of prevention of complaints. The reports will be disseminated widely, and the results of the study presented to scientific, professional and lay audiences orally, electronically and in print.

We anticipate that the reports and dissemination strategy will inform the profession, educators, insurers and the public of the findings and promote respect for the osteopathic profession.

Possible risks to your organisation

We are confident that the data requested will not reveal the identity of any subject. The results disseminated from the study will be fully anonymised with respect to the patients, the osteopaths and the organisations providing the data. All data and records of interview will be securely stored at the University of Brighton, will only be seen by the researchers, and will be destroyed when the research is completed.

The only identifier within the "spreadsheet" dataset is the first 2 digits of postcode. The stories which may be told at interview will be anonymised and will not be reported verbatim. An interpretive approach will be used to summarise and generalise the interview data and the final reports will not contain any individual patients' stories.

Conduct of the research

The research funding has been made available by the General Osteopathic Council. The conduct of the research is being overseen by a Steering Group comprising representatives of the General Osteopathic Council, the NCOR Grants Governance Committee, the Insurers and a User representative. We also have a legal advisor, Paul Grant, and an ethics advisor, Professor Julie Stone. The protocol for the research has been scrutinised and approved by the University of Brighton Faculty of Health and Social Science Research Ethics and Governance Committee.

If you have concerns regarding the conduct of the research, you can contact one of the following people:

Principal Investigator, Dr Janine Leach, Senior Research Fellow in Osteopathy, University of Brighton

Tel 01273 643457

Professor Ann Moore, Clinical Research Centre for Health Professions, University of Brighton, 49 Darley Road, Eastbourne BN20 7UR
Tel 01273 643944

Appendix 8.3. Consent Form for release of data by organisation

Consent form

NCOR Project 3: Trends in insurance claims and patient complaints to the regulator

- ♦ I agree to take part in this research to collect information about the number of complaints and claims that have occurred over the past 10 years, and investigate trends. The research will also try to understand the circumstances leading to complaints, particularly those alleging adverse reactions to treatment, with a view to reduction of complaints in future.
- ♦ The researcher has explained to my satisfaction the purpose of the study and the possible risks involved.
- ♦ I have had the procedure explained to me and I have also read the Information Sheet. I understand the procedures fully.
- ♦ I am aware that I will be asked to provide anonymised records of every complaint or claim made by patients against osteopaths in the past 10 years.
- ♦ I am aware that one or more members of my staff may be interviewed for the study, subject to their consent.
- ♦ I understand that any confidential information will be seen only by the researchers and will not be revealed to anyone else.
- ♦ I understand that this organisation is free to withdraw from the investigation at any time.

On behalf of	(Organisation)
Name (please print)	
Signed	Date

Appendix 8.4. Core Dataset for Complaints

REQUIRED FOR EACH INCIDENT, COMPLAINT OR CLAIM ON RECORD AT ORGANISATION'S (INSURER OR REGULATOR) OFFICES*

Study number :	
4 digit organisation code 4 digit case code	
Organisation's Reference number for complaint (up to 12 characters)	
Region of UK where complaint occurred (2 digits of postcode)	
Date first event occurred in this complaint DDMMYYYY	
Nature or type of complaint as recorded in-house (free text)	
Complaint type coded (classification code) **	
Did complaint progress? (yes or no)	
Final outcome of complaint (free text)	
Date of final outcome DDMMYYYY	
Financial outcome (if any) (free text)	
Legal outcome (if relevant) (free text or code)	
Name any other organisations involved (free text)	
Other information (free text)	

Notes

^{*} This is the dataset required for this research. The participating organisations will supply as many of the items as they have available. Each participating organisation holds data on a spreadsheet for monitoring purposes, but there is variation in the data items held and the way complaints and outcomes are classified. The researchers will request the data in electronic format as a spreadsheet.

^{**} Classification to be developed with participants with reference to prior research in chiropractic and physiotherapy

Appendix 8.5. Letter to Intermediary

(University headed paper)

Dear ..

Re Research on trends in patient complaints against osteopaths

I am writing to invite you to be interviewed by a member of the research team for this study. Your employer is collaborating in the study by providing data for the research. We understand that you are involved with the handling of complaints in your organisation and have experience of dealing directly with the osteopath and complainant or their representatives.

The data we have collected from your employer has allowed us to create a picture of all complaints and claims over the past 5-10 years, including complaints that were logged by you but not pursued. We have classified the complaints into different types. If you consent to be interviewed, we would make the necessary arrangements, and in the interview we would ask you to share your experience of the nature of such complaints and the circumstances that lead to complaints of different types, subject to your consent.

Further details of what is involved are given in the attached Information Sheet. If you have any further queries, please do not hesitate to contact us. You are entirely free to accept or decline this invitation to be interviewed. Whatever your decision, I would be most grateful if you could complete and return the attached Consent Form. Many thanks.

I look forward to hearing from you,

Yours sincerely

Adam Fiske Research Officer

Enc Information Sheet, Consent Form

Appendix 8.6. Information Sheet for intermediaries

NCOR Project 3: Trends in insurance claims and patient complaints to the regulator

The National Council for Osteopathic Research (NCOR) has awarded funding to the CONDOR collaboration to conduct this research study. CONDOR combines two universities and two osteopathic training schools: the University of Brighton, the University of Greenwich, the European School of Osteopathy, and the College of Osteopaths.

Aims and purpose of research

The aim of the research is to collect information about the number of complaints and claims concerning osteopaths that have occurred over the past 10 years, and investigate trends. The research will also try to understand the circumstances leading to complaints, particularly those alleging adverse reactions to treatment, with a view to reduction of complaints in future.

The study will collate existing data held by the regulator GOsC and the four indemnity Insurers (Balens, MIA, Three Counties and Howden. The Principal Investigator for the project, Dr Janine Leach, or the Research Officer for the project, Adam Fiske, will have already visited your organisation and collected anonymised information about complaints against osteopaths.

Your participation

In order to gain as much understanding as possible of the circumstances leading to the complaint occurring and progressing, we would like to interview the person(s) in each organisation who deal directly with the people involved in a case. We have called this person the Intermediary.

We would like to invite you to participate in an interview. Participation is entirely voluntary and you are free to withdraw at any time. If you agree to participate, please sign and return the enclosed Consent Form.

What will I be asked to do?

The Research Officer Adam Fiske will contact you to arrange to interview you at a time and place convenient to you. The interview will take about one hour and will be tape-recorded. The interview will be exploratory and gather some facts about complaints as well as your experience of complaints against osteopaths, and typical stories of how different types of complaint progress.

Dissemination of results

The main outputs from the study will be three reports. The Final Report of the project will be a formal report of the full results of the project. A Lay Report will summarise the main messages in language accessible to a lay audience. A Report for practising

osteopaths which will include discussion of prevention of complaints. The reports will be disseminated widely, and the results of the study presented to scientific, professional and lay audiences orally, electronically and in print.

We anticipate that the reports and dissemination strategy will inform the profession, educators, insurers and the public of the findings and promote respect for the osteopathic profession.

Possible risks to you

We are confident that the data requested will not reveal the identity of any subject. The results disseminated from the study will be fully anonymised with respect to the patients, the osteopaths and the organisations providing the data. All data and records of interview will be securely stored at the University of Brighton, will only be seen by the researchers, and will be destroyed when the research is completed.

The stories which you recount at interview will be anonymised and they will not be reported verbatim. The data from all the interviewees will be summarised and generalised and the final report will not contain any individual patients' stories.

Conduct of the research

The research funding has been made available by the General Osteopathic Council. The conduct of the research is being overseen by a Steering Group comprising representatives of the General Osteopathic Council, the NCOR Grants Governance Committee, the Insurers and a User representative. We also have a legal advisor, Paul Grant, and an ethics advisor, Professor Julie Stone. The protocol for the research has been scrutinised and approved by the University of Brighton Faculty of Health and Social Science Research Ethics and Governance Committee.

If you have concerns regarding the conduct of the research, you can contact one of the following people:

Principal Investigator, Dr Janine Leach, Senior Research Fellow in Osteopathy, University of Brighton

Tel 01273 643457

Professor Ann Moore, Clinical Research Centre for Health Professions, University of Brighton, 49 Darley Road, Eastbourne BN20 7UR

Tel 01273 643944

Appendix 8.7. Consent Form for Intermediaries

Consent form for Intermediaries

NCOR Project 3: Trends in insurance claims and patient complaints to the regulator

- ♦ I agree to take part in this research which will collect information about complaints and claims that have occurred over the past 10 years, and try to understand the circumstances leading to complaints, with a view to reduction of complaints in future.
- ♦ The researcher has explained to my satisfaction the purpose of the study and the possible risks involved.
- ♦ I have had the procedure explained to me and I have also read the Information Sheet. I understand the procedures fully.
- I am aware that I will be interviewed about the different types of complaints.
- ♦ I understand that any confidential information will be seen only by the researchers and will not be revealed to anyone else.
- I understand that I am free to withdraw from the investigation at any time.

Name (please print)	
Signed	Date

One copy to be kept by the subject, one by the researcher

Appendix 8.8. Question schedule for interviews of intermediaries

Date of interviewe Name of interviewee Name of interviewer

Introduction by Interviewer

"You know already that we have collected statistical data on complaints against osteopaths from your organisation, and you have been collaborating with us in trying to develop a robust typology for complaints.

Because of your experience of dealing first hand with osteopaths or patient in relation to complaints, from first incident to final outcome, we want to ask some questions to explore your perception of the events and emotions around complaints of different types."

A. INITIAL QUESTIONS

What is your role in relation to complaints coming into your organisation? How many years have you been dealing with complaints first-hand?

B. QUESTIONS ON EACH TYPE OF COMPLAINT

The interviewer has a series of cards with the name of each complaint type. The type cards are displayed one at a time in the same sequence in order to ensure clarity about which type of complaint is being discussed.

Typically, with this type of complaint.....

How would the complaint start?

Is there a typical background to this type of complaint?

Will the patient and osteopath been in contact before they contact you?

What is the typical sequence of events following first contact with you?

How does the osteopath react?

Does the way that the osteopath reacts affect the complaint in any way?

How does the patient react?

What actions make it more likely that the complaint is resolved?

What tends to escalate the complaint?

What are the most likely outcomes?

Are there any other points about this type of complaint?

C. END OF INTERVIEW

Are there any other points which you have observed in relation to osteopathic complaints?

In your opinion, is there a key point that leads to a complaint being formally lodged?

Are some complaints more easily resolved than others?

Thank you very much for taking part.

If you are agreeable, could I contact you to check any points that I am not clear about from this interview?

APPENDIX 9. Identifying GOsC formal complaints in Balens data

Attempts were made to formally link records which were present in both GOsC and the insurer's files, in order to avoid double-counting. In the files from the insurers with small numbers of complaints, this could be performed by reading the data on individual records. However, Balens' file contained a large number of records, so attempts were made to identify the GOsC formal complaints systematically and electronically, either logically or by scanning for certain terms within the records.

The Balens' file contained a single record for each complaint; each record contained a large free text field with notes showing the course of the complaint, with relevant dates; another field recorded the insurance company to which the complaint had been notified; a third field contained the code assigned at Balens for the type of complaint. These are shown in

Table 5.2, for all the data received from Balens for the study.

Table 5.2. The complaint type assigned by Balens, according to the insurer to whom the complaint was referred.

	Insurer								
Balens primary classification	DAS	Eagle Star	Insurance & Risk Solutions Ltd	Marketform	Medical Protection	Royal & Sun Alliance	Towergate	Zurich Insurance Co Ltd	Grand Total
Criminal defence	2					1			3
Disciplinary	35	0	0	2	1	17	0	1	56
Medical Malpractice	4	1	7	13	2	182	2	0	211
Other Legal	5	0	0	0	0	2	0	0	7
Products caused injury Professional	0	0	0	1	0	4.4	0	0	1
Indemnity	0	0	0	1	0	11	0	0	12
Public liability	0	0	0	0	0	3	0	0	3
Sexual impropriety	1	0	0	0	0	2	0	0	3
Uncoded	1		1	1	1	14			18
Total	48	1	8	18	4	232	2	1	314

When the osteopath notifies Balens that they have received a formal complaint through GOsC, then Balens will use an Insurer called DAS to cover the costs of supporting the osteopath through the fitness to practise process. As the table above shows, the main insurer for Disciplinary type complaints was DAS, but some were recorded with other insurers. Summing the complaints coded as Disciplinary, Criminal, and Other Legal, gives a total of 66 complaints. However, GOsC had supplied the researchers with 123 formal GOsC complaints in 2004-2008, meaning that more than half could not be identified in Balens' file. Hence we concluded that it was not possible to electronically identify GOsC formal complaints individually within Balens' data.

The "NCOR3" classification of complaint type for the same 21 DAS cases, coded independently for the analysis, using the text information provided in the file, is shown below. It is clear that the "NCOR3" classification cannot be used to predict which cases were also GOsC fitness to practise cases.

Table showing complaint	DAS
g 1	complaint
type used in the analysis	complaint

type used in the undrysis				Grand
NCOR3 classification	DAS		Other insurer	Total
accidental damage			1	1
adverse event		5	98	103
boundaries		7	12	19
boundaries/substandard				
practice			1	1
business practice		2	1	3
communication			4	4
conduct/behaviour		3	8	11
consent			1	1
inappropriate diagnosis		1	27	28
ineffective treatment		2	16	18
substandard practice			6	6
unclear		1	4	5
(blank)				
Grand Total		21	179	200







