

A short guide to the Research Governance Framework for Practising Osteopaths

This is a summary document to accompany the full version of the revised Research Governance Framework (September 2011/12) available at http://www.ncor.org.uk/wp-content/uploads/2012/11/Research_governance_framework.pdf. This document is being updated currently.

The Research Governance Framework is intended as a guide for all practising osteopaths who wish to undertake practice-based activities including data collection, clinical audit, or research. There are many aspects of the framework that will apply solely to larger organisations including Osteopathic Educational Institutions (OElS), and other Higher Educational Institutions which are not presented here. These organisations are advised to refer to the full document.

What is Research Governance?

Research governance can be described as the broadly agreed framework of regulations, principles, and standards of good practice that exist to achieve and continuously improve research quality across all aspects of healthcare in the United Kingdom and worldwide. The Research Governance Framework is based on European and UK law.

Why do we need a research governance framework?

Research Governance is required for a number of reasons including:

- Provide a clear framework within which to conduct research, data collection, and clinical audit;
- Promote good practice in research;
- Monitor practice and performance;
- Enhance scientific and ethical quality;
- Minimise risk in research;
- Safeguard participants in research;
- Protect researchers and investigators by providing clear guidelines for the conduct of research, and good research practice.

What is the difference between data collection, clinical audit, research, and service evaluation?

The terms research, clinical audit, and data collection are often used interchangeably despite the fact that they are quite distinct. The following definitions are intended to describe the difference between the processes.

Research is concerned with many things including the creation of new knowledge; investigating whether new treatments work and if certain interventions are more effective than others. Research forms the basis of nationally agreed professional clinical guidelines and standards – it determines what best practice is.

Audit of practice is a means of obtaining a profile of patient throughput, characteristics or outcomes. It can also be a means to discover if we are following professional guidelines. Are we following best practice as agreed by the wider health care arena?

Similarities between audit and research:

- Audit and research involve answering a specific question regarding the quality and appropriateness of treatment(s) for patients.
- Audit and research can be carried out either on patients to be recruited in the future (prospectively) or patients who have already experienced treatment (retrospectively).
- Audit and research involve careful sampling, questionnaire design and analysis of findings.
- Both activities should be professionally led.

Service evaluation is frequently commissioned. It assesses the effectiveness of practice(s) within a particular health care setting. Evaluation reports are written so that action can be taken in the same setting, and such reports are intended to influence the work of the evaluator and/or their team. Evaluation tends to inform practice development and may also be discussed with a wider audience.

The differences between these forms of enquiry and service evaluation are described in Table 1.

Table 1. Differences between data collection, clinical audit, research, and service evaluation. *Source: Based on documentation from the UK Health Research Authority¹*

RESEARCH	AUDIT	SERVICE EVALUATION	DATA COLLECTION
<ul style="list-style-type: none"> ▪ May involve experiments based on a hypothesis. 	<ul style="list-style-type: none"> ▪ Never involves experiments and involves measuring against pre-existing standards. 	<ul style="list-style-type: none"> ▪ Designed and conducted to define or judge current care. 	<ul style="list-style-type: none"> ▪ Designed to describe current practice
<ul style="list-style-type: none"> ▪ A systematic investigation. 	<ul style="list-style-type: none"> ▪ A systematic review of practice. 	<ul style="list-style-type: none"> ▪ An investigation of current service without reference to a standard. 	<ul style="list-style-type: none"> ▪ Describes current care delivery
<ul style="list-style-type: none"> ▪ May involve random allocation. 	<ul style="list-style-type: none"> ▪ Never involves random allocation. 	<ul style="list-style-type: none"> ▪ Never involves random allocation. 	<ul style="list-style-type: none"> ▪ Never involves random allocation.

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<ul style="list-style-type: none"> ▪ There may be extra disturbance to patients. 	<ul style="list-style-type: none"> ▪ There is little disturbance to patients. 	<ul style="list-style-type: none"> ▪ There is little disturbance to patients. 	<ul style="list-style-type: none"> ▪ There is little disturbance to patients.
<ul style="list-style-type: none"> ▪ Could investigate a new treatment. 	<ul style="list-style-type: none"> ▪ Never involves a completely new treatment. 	<ul style="list-style-type: none"> ▪ Never involves a completely new treatment. 	<ul style="list-style-type: none"> ▪ Never involves a completely new treatment.
<ul style="list-style-type: none"> ▪ Creates new knowledge about effectiveness of treatment approaches. 	<ul style="list-style-type: none"> ▪ Answers the question "are we following best practice?" 	<ul style="list-style-type: none"> ▪ Answers the question "What standard does the service achieve?" 	<ul style="list-style-type: none"> ▪ Answers the question "What does current service involve?"
<ul style="list-style-type: none"> ▪ May involve experiments on patients. 	<ul style="list-style-type: none"> ▪ Patients continue to experience their normal treatment management. 	<ul style="list-style-type: none"> ▪ Patients continue to experience their normal treatment management. 	<ul style="list-style-type: none"> ▪ Patients continue to experience their normal treatment management.

<ul style="list-style-type: none"> ▪ Often a lengthy process and involves large numbers of patients. 	<ul style="list-style-type: none"> ▪ Usually carried out involving a small number of patients and within a short time span. It may include the administration of a questionnaire or simple interview. 	<ul style="list-style-type: none"> ▪ It is usually carried out involving a small number of patients and within a short time span. It may include the administration of a questionnaire or simple interview. 	<ul style="list-style-type: none"> ▪ It is usually carried out involving a small number of patients over a short period of time. Alternatively, this can be an ongoing process in some practices.
<ul style="list-style-type: none"> ▪ It is based on a scientifically valid sample size (except in the case of some pilot studies). 	<ul style="list-style-type: none"> ▪ It is more likely to be conducted on a pragmatically based sample size. 	<ul style="list-style-type: none"> ▪ It is more likely to be conducted on a pragmatically based sample size. 	<ul style="list-style-type: none"> ▪ The sample size can be pragmatic if data collection is conducted over a short period of time.
<ul style="list-style-type: none"> ▪ Extensive statistical analysis of data is routine. Data 	<ul style="list-style-type: none"> ▪ Some statistics may be useful. 	<ul style="list-style-type: none"> ▪ Some simple statistics may be useful. 	<ul style="list-style-type: none"> ▪ Some simple descriptive statistics may be useful.

<p>analysis can take a number of forms depending on whether qualitative or quantitative research has been carried out.</p>			
<ul style="list-style-type: none"> ▪ Results can be generalisable and hence publishable. Quantitative research tends to be more easily generalisable than qualitative work. Qualitative work, however, can be transferrable. 	<ul style="list-style-type: none"> ▪ Results are only relevant within local practice settings (although the audit process may be of interest to a wider audience and hence audits are publishable). 	<ul style="list-style-type: none"> ▪ Results are only relevant within local practice settings. 	<ul style="list-style-type: none"> ▪ Results are relevant to a local practice setting. Results can be combined across practices to give a pan-professional profile if all data are standardised.

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<ul style="list-style-type: none"> ▪ Responsibility to act on findings is unclear. 	<ul style="list-style-type: none"> ▪ Responsibility to act on findings rests with individual practitioners. 	<ul style="list-style-type: none"> ▪ Responsibility to act on findings rests with individual practitioners. 	<ul style="list-style-type: none"> ▪ Responsibility to act on findings rests with individual practitioners.
<ul style="list-style-type: none"> ▪ Findings influence the activities of clinical practice as a whole. 	<ul style="list-style-type: none"> ▪ Findings influence activities of practitioners within a practice. 	<ul style="list-style-type: none"> ▪ Findings influence activities of practitioners within a practice. 	<ul style="list-style-type: none"> ▪ Findings can influence activities of practitioners within a practice, and profession-wide where data has been amalgamated.
<ul style="list-style-type: none"> ▪ Always requires ethical approval. 	<ul style="list-style-type: none"> ▪ Does not require ethical approval. 	<ul style="list-style-type: none"> ▪ Does not require ethical approval. 	<ul style="list-style-type: none"> ▪ Does not require ethical approval.
<ul style="list-style-type: none"> ▪ Research can identify areas for audit. 	<ul style="list-style-type: none"> ▪ Audit can be a precursor to clinical research by 	<ul style="list-style-type: none"> ▪ Service evaluation can identify areas of practice for audit. 	<ul style="list-style-type: none"> ▪ Data collection can be a precursor to audit. It can

	pinpointing where research evidence is lacking.		help to identify meaningful topics.
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What do I do if I'm considering practice-based research activities?

Reflection on clinical practice can be achieved in a variety of ways. This can be undertaken with case-based discussion involving a colleague, with basic data collection to obtain a profile about various aspects of practice, clinical audit to evaluate whether standards of care in practice are as high as possible; or to test a new management intervention.

Standardised data collection has been undertaken among the osteopathic profession as a whole. This study from 2009 could act as a benchmark for you to compare your practice should you wish^{2,3,4}. The study report contains a standardised data collection tool, and other tools are available on the NCOR website⁵.

Clinical audit is a straightforward and very rewarding process to undertake, and can contribute useful data to clinical practice or the practice environment depending on the topic selected. A range of resources are available to help support osteopaths using clinical audit including a handbook, and audit tools^{6,7}. A summary version can also be found in a Clinical Audit Masterclass⁸.

At the heart of a good research study is asking a good research question. When considering what aspects of care you might want to investigate it is important to consider the PICO format:

Patient/ Population	Intervention	Comparator/ control	Outcome(s)
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There are other key issues to consider prior to undertaking a research study including:

- Research design;
- Research setting;
- Strategy for reviewing the literature;
- The population of interest;
- The intervention being considered;
- Comparator/control;
- Outcome measurement and associated costs;
- Recruitment of participants;
- Ethical review;
- Expertise required for the study design;
- Data collection;
- Data analysis;
- Dissemination of findings.

Further information about each of these items can be found at <http://www.ncor.org.uk/wp-content/uploads/2013/05/RESEARCH-IDEA-CHECKLIST.pdf>.

Research Ethics

Ethical review will have different requirements depending on the type of investigation being undertaken, and the setting. The NHS has its own ethics structure and requirements: further information concerning NHS ethics and the Health Research Authority⁹. Educational institutions have their own internal ethics review processes and they may also refer to NHS ethics committees.

Other forms of investigation don't require formal ethical review but require the permission of a Research and Development department in the NHS, or the permission of the practice principal in a private practice setting. In a private practice setting, it is also good practice to ensure that patients are aware that audit and data collection studies are taking place. This can be achieved by a simple notice in the practice waiting room, and treatment room.

Patients referred from the NHS or treated within an NHS setting

Research and higher education

Individual Osteopathic Educational Institutions (OElS) have their own ethics and governance arrangements for research activity and student research activities. On those occasions when their research involves NHS patients, ethics approval is sought from NHS ethics committees.

What does the Research Governance Framework include?

The research governance framework is an extensive document which includes information relating to:

- Key principles to be considered when conducting high quality research;
- Ethical issues and different factors to be considered when conducting research in an ethical manner;
- The responsibilities of individual researchers involved in the research process;
- Information concerning the manner in which data are collected, processed, and stored. This should be undertaken in accordance with guidance relating to research data, and legal requirements^{10,11,12};
- Advice on how to avoid misconduct on research;
- Signposting to additional sources of information.

The Research Governance Framework currently available on the NCOR site is in the process of being updated by the Health Research Authority. This document is based on the current Research Governance Framework for Health and Social Care (2005)¹³.

References

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