

**MASTERCLASS**

# Clinical audit in osteopathic practice: A Masterclass

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**Abstract** Healthcare delivery in the 21st Century is rapidly changing. The combination of political pressures and ensuing infrastructure changes across health delivery models can sometimes make the patient feel a neglected, although vital part of the equation. Putting the patient at the heart of high quality care focuses on the need for patient feedback and clinical evaluation through a variety of different media. Clinical audit is an implicit part of this aim, and it is as applicable to all osteopathic clinicians. The aim is to recognise audit and evaluation as an opportunity rather than a threat to clinical autonomy thereby benefitting both patients and clinicians.

This Masterclass will describe the development of clinical audit, the stages involved in the process, how to identify where changes can be desirable, how to implement those changes, and the often forgotten vital stage of re-audit to identify how those changes have had an effect on the delivery of care.

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**Introduction**

Although clinical audit is not a new process, it has become increasingly an explicit requirement of healthcare delivery since the introduction of clinical governance.<sup>1</sup> Commissioning of osteopathic services by large institutions (such as the National Health Service in the UK) and the clinical governance demands of healthcare insurers have

established clinical audit as a necessary skill for modern clinicians.<sup>2</sup> Internationally, clinical governance has focussed on the importance of quality and safety in healthcare, and has established a series of core principles. The Institute of Medicine in the USA has encapsulated 10 basic rules, the Office of Safety and Quality in Health Care in Western Australia has identified four pillars of clinical governance and encompasses clinical audit, this position is mirrored within healthcare provision in New Zealand also.<sup>3–8</sup>

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Fig. 1 The audit cycle.

The principle of clinical audit was described in the Crimean War following the work of Florence Nightingale; she brought about improvements in survival rates after studying aspects of hygiene and introducing change in contemporary ward practices.<sup>9</sup> In the 20th Century, the work of Codman, Donabedian and Ovretveit advanced the 'science' of audit.<sup>10–12</sup> In UK medical practice, audit was first introduced in a 1989 White Paper; this was the first attempt to standardise audit as part of professional healthcare, and was supported by a national network of Medical Audit Advisory Groups. Clinical audit evolved from medical audit, and was formally introduced into the NHS in 1993.<sup>13</sup> A variety of different organisations have overseen the development of clinical audit on a national basis in both primary and secondary care. The Healthcare Quality and Innovation Programme (HQIP) is the UK national organisation responsible currently for audit practice, and offers a huge range of information for both patients and clinicians concerning practice, involvement, and supportive educational resources.<sup>14</sup> In New Zealand the Director-General of Health designates a number of auditing agencies to carry out audit in various areas of healthcare under the Health and Disability Services (Safety) Act (2001).<sup>15</sup>

The concept of clinical governance is being introduced increasingly into osteopathic practice. It has become an implicit part of the requirements of healthcare insurers, and clinical audit is included within such requirements. Since December, 2012, the concept and requirement of professional revalidation has been introduced for UK medical practitioners as part of their

regulatory process; other countries are also in the process of considering and/or implementing revalidation programmes for clinicians to promote good practice thereby avoiding some of the damaging cases of poor practice exposed in the media.<sup>14</sup> In 2011, the General Osteopathic Council (UK) introduced a pilot process of revalidation for osteopaths, and clinical audit was one of a series of activities offered to participating osteopaths to undertake while involved in this pilot.<sup>16</sup> The support for the use of clinical audit in osteopathic practice is evident in Europe; the Forum for Osteopathic Regulation in Europe (FORE) brings together osteopathic associations, voluntary registers and competent authorities in Europe with the aim to improve standards of osteopathic care.<sup>17</sup> FORE have developed the European Framework for Standards of Osteopathic Practice, within which they stipulate that osteopaths must demonstrate a commitment to undertaking clinical audit to contribute to the maintenance and improvement of their osteopathic practice.<sup>18</sup>

Specific reference to monitoring the quality of care and acting on findings, potentially through the process of audit, is made already in UK Osteopathic Practice Standards.<sup>19</sup> The UK Health and Care Professions Council's Standards of Proficiency for Physiotherapists is more direct in its requirement on audit, and states that registrants must be able to audit, reflect upon and review their practice, and to participate in audit procedures.<sup>20</sup> Internationally, the ability to be able to undertake clinical audit is a required standard or part of training in a range of regulatory

boards, educational establishments, and professional representative groups.<sup>21–23</sup> Different bodies have looked at the usefulness of audit for assessing whether certain proficiencies have been met, e.g. continuing professional development (CPD). The osteopathic regulatory bodies in Australia and New Zealand use audit to monitor adherence to CPD requirements while others include audit capability as part of the process of measuring outcomes of practice and care delivery.<sup>24–28</sup>

## Definition of audit

Research, audit, and service evaluation are terms that are used interchangeably by some clinicians but they have clear differences.<sup>29</sup> Additional differences are described by the UK National Research Ethics Service.<sup>30</sup> Clinical audit has been described as

‘ a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes.’<sup>31</sup>

It is usually represented cyclically, and comprises sections as shown in Fig. 1.<sup>29</sup>

## Why is audit useful?

Clinical audit can have a range of potential benefits for patients, clinicians and practices, including:

- More effective use of clinical time;
- Increased patient satisfaction;
- Efficient use of treatment facilities and resources;
- Increased clinical acumen/improved clinical judgement;
- Identification of training/CPD needs;
- Requests for more appropriate patient investigations;
- Identification of staff training needs.<sup>32</sup>

In addition to the benefits listed above, various studies have reported that clinicians have had some positive personal outcomes from participating in audit through improved communication between professional groups and increased professional satisfaction and knowledge.<sup>33</sup>

## What is the difference between audit, research, and service evaluation?

Research, audit, and service evaluation are often confused; they share some similarities and have some distinct differences. Their differences are summarised by the UK’s National Research Ethics Service.<sup>34</sup>

## Audit in osteopathic practice

Osteopaths who work in small private practice settings, may lack the larger scale support and resources, but undertaking clinical audit as part of continual professional development (CPD) activity can produce quality improvement activities.<sup>35,36</sup> In addition, conducting audits can give practitioners useful information to help them direct their marketing strategies. The National Council for Osteopathic Research (NCOR) has a range of tools available on their website e.g. for measuring patient satisfaction, and effectiveness of treatment.<sup>37</sup> Data from these types of audits can be helpful in promoting osteopathic practices as well as achieving the primary goal of improving the quality of patient care. Internationally, medical clinicians have cited the same difficulties as experienced by single-handed osteopaths, where they lack infrastructure support.<sup>38</sup> Osteopaths have access also to clinical audit guidance through the NCOR’s handbook “An Introduction to Clinical Audit for Practising Osteopaths”.<sup>32,39</sup> A range of other resources are available internationally; these include the audit tool developed by Maire,<sup>40</sup> and items identified in the review by Travaglia and Debono.<sup>41,42</sup>

## What can be audited?

There are various components within the provision of care that can be audited and examined in order to assess quality. Examples of some of these can be found in Table 1.

## The audit environment

There are some criteria that have been established that contribute to a successful audit process or audit culture. Encouraging a sense of ownership at the start of the audit can lead to successful implementation e.g. in the selection of the audit topic, establishing clear roles and responsibilities

**Table 1** Types of audit.

Type	Description
Audits of structure	The structure pertains to the physical attributes of health care, which would include the premises, practice equipment, the service provider team and the patient records. <sup>32</sup>
Audits of process and content of care	The process of care is an amalgamation of the attitudes, skill and knowledge of the practitioner providing care and the sum of their actions and decisions in their professional practice. <sup>32</sup> Patients are generally limited in their underpinning and procedural knowledge of care and are therefore practically unable to assess these aspects of care. However, patients are capable of reliably judging a practitioner's consultations skills so they can still play a valuable part in this area of audit. <sup>32</sup>
Audits of outcome	Outcomes relate to the changes in patients' health status as a result of healthcare so criteria to be measured would typically be responses to an intervention, reported health status, level of knowledge, and satisfaction. <sup>22</sup>
Audits of patient satisfaction	The recommendations of the NHS White Paper of 2010 focus largely on putting patients first and involving them in decision making regarding their care. <sup>33,76</sup> They highlight the importance of using patient feedback to inform future care. Audit is one way of assessing and demonstrating this aspect of care and not only is patient satisfaction an integral part of practice in the NHS, evidence of its existence is also required by many private health insurance companies. <sup>23</sup>
Retrospective and prospective audits	Retrospective audits can be useful for quick acquisition of data relating to care in the immediate past. <sup>77</sup> Emphasis should be placed on the word immediate since best practice is continually changing; historical standards may become out-of-date very quickly, and have little value in informing changes in contemporary practice. <sup>34</sup> Retrospective audit may rely on the completeness of patient records so an accurate representation of care delivery may be lacking. <sup>1</sup> Audits can be carried out prospectively, and this may give a clearer picture of current practice. <sup>1,32</sup> Prospective audits can be planned, staff prepared for involvement, and complete records should be entirely attainable. <sup>1</sup> Prospective audits can, however, influence clinician behaviour. <sup>35</sup>

for different aspects of the audit, holding regular meetings with colleagues, and having readily available support in setting up audit.<sup>33</sup>

## Deciding what to audit

There are various aspects of clinical practice that can be audited. A decision-making table as shown in [Table 2](#) can help this process.<sup>43</sup>

## Selecting a topic

It is important to consider if the proposed topic for audit is a priority for you, your patients, your practice, profession, or nationally. Patients may highlight topics of importance which are different to the priorities of practitioners.<sup>44</sup> The UK Care Quality Commission (CQC), who are responsible for the registration, review and inspection of certain health and social care services, stipulate that the views and

experiences of patients should be sought regularly in the process of assessing quality of care.<sup>45</sup> It may be useful to use the SMART acronym when deciding upon a topic to audit.<sup>46</sup> Is the topic: specific, measurable, achievable, realistic, and timely?

## Reviewing the literature to identify standards and criteria

Identifying best practice can be achieved by searching the literature.<sup>13</sup> Once an audit topic has been agreed by those participating in the audit, appropriate keywords can be used to identify if audits in this area have taken place already, what standards and criteria are appropriate for this topic area, and whether a data collection tool for the audit process exists already.

Explicitly-defined standards in osteopathic care may not be as commonly available as in publicly-funded medicine; in this case it is appropriate to see what is being used in relevant national

**Table 2** Decision-making table for audit topics.<sup>36</sup>

Factor	Consequence
Affects a large number of people in the population/in my practice	Improving the quality of care in commonly reported conditions usually has more impact than for rare conditions
Convincing evidence is available about appropriate types of care to deliver	Otherwise efforts to change current performance are difficult to justify
Good reasons for believing that current performance could be improved	Concentrates effort on optimum elements of care
Lack of information about current care being delivered	Care does not have the opportunity to improve
Need to make better use of practice-based financial resources	Audit can identify where financial changes can be introduced e.g. advertising costs

organisations such as the NHS [UK], Medicare [Australia] or Ministry of Health [New Zealand]. Various sources of standards can be sought, including the National Institute for Health and Clinical Excellence (NICE) and the National Service Framework [UK] the Australian Government Department of Health and Ageing, and the General and Core Health and Disability Services Standard (New Zealand).<sup>47–54</sup> If standards are still not available, it may be necessary for clinicians to discuss this locally (within their practice or regional group) and what they consider appropriate standards to be by consensus agreement.

### Defining criteria and standards

A 'standard' is defined by Samuel et al.,<sup>13</sup> as "A criterion with its expected level of performance".<sup>13</sup> This can encompass a range of performance attainment spanning from a minimum expected level of care to the best care that can be delivered. They can encompass both qualitative and quantitative aspects, and have been described also by Hibble as 'hard standards', which are based on good research data, and 'soft standards', where such data may not be available.<sup>55,56</sup>

Criteria are elements of care that can be defined and measured by clinicians. They are based on agreements relevant to good quality care. Criteria provide clear examples of what aspects of practice are important. Consultation with patients will often provide examples of what are important criteria when assessing good service delivery. Samuel et al.,<sup>13</sup> give the example that it would not suffice to simply ask if patients were happy with an appointment system because it would be difficult to measure any improvements in a follow-up audit. Setting specific criteria for individual elements of the system, such as waiting times and choice of practitioner, would enable better comparison of results in future audit. These

items could be summarised as criteria, when setting criteria and standards, it is important to consider the views of practitioners, and encourage a sense of ownership to ensure a successful and meaningful audit.<sup>13,33</sup>

### Planning the audit

Planning is a vital component in achieving a successful clinical audit. Everyone involved with the audit must be clear about the topic, its purpose, why specific criteria and standards have been set, their role and responsibilities, and where support can be sought if needed.

### Data collection

An integral part of the data collection process is having engaged and motivated clinicians and support staff who want to understand the purpose of collecting data, engage in the process, and see data return.<sup>57</sup>

Existing data collection tools may be available from previously conducted audits, and will be identified during the literature search. However, if a tool is unavailable, a new one can be devised which will need to be piloted to determine its usability, and validity. The data collection tool (DCT) will need to contain key pieces of information relating to the audit. If the audit involves patient care and the ability to track records at follow-up, care must be taken to comply with any legislation such as the UK Data Protection Act, Privacy Acts of Australia and New Zealand and the European Union's Data Protection Directive.<sup>58–62</sup> To preserve patient anonymity, their personal information including name, address, and date of birth should not be recorded on the audit data collection tool. A unique identifier should be added to each DCT and recorded also on the patient's case notes. In a primary or secondary care setting, a patient's



**Table 3** Table to calculate for sample sizes for clinical audits.<sup>34</sup>

Population size	Sample size: 95% confidence; $\pm 5\%$
50	44
100	79
150	108
200	132
500	217
1000	278
2000	322
5000	357

hospital number can be linked to a unique identifier, and retained on a code sheet to link DCT to specific patients. Data can be collected from paper or electronic records. The latter can make routine data collection and audit more manageable, for example, a number of practice management software packages allow the user to produce customised reports.<sup>33,63,64</sup>

### Sample size

The sample size for data collection should be large enough to be representative: unnecessarily large sample sizes merely create burdens of additional time and resources without any tangible benefit.<sup>1,65</sup> In many instances, a 'snapshot' sample of approximately 20–50 will suffice when auditing processes; however in the case of auditing outcomes, calculating a sample size is preferable.<sup>65</sup>

A number of guides exist providing information concerning suitable sample sizes, and assume that standards will be met in 50% of cases. Sample sizes are calculated to ensure a 95% level of confidence that results from the audit population will be within 5% of the results that would have been obtained had data been collected on the whole patient population in a practice. Calculations for different sample sizes are contained in [Table 3](#).<sup>65</sup>

### Sampling

It is important to sample current or recent cases to ensure that standards and criteria for care are relevant. Regardless of sample size, a method for sampling should be decided upon. Different types of sampling exist such as: consecutive sampling (e.g. the last 50 people treated), random sampling (use a random number table and select records numbered according to the table) and stratified sampling (for example choosing equal amounts of males and females despite an unequal sample).<sup>65,66</sup>

### Data analysis

Once all of the audit data have been collected, it should be checked for accuracy since errors in data transfer e.g. from patient case notes, can produce anomalies in the data.<sup>31</sup> The type of data analysis to be used must be established while planning the audit.<sup>31</sup>

Basic analysis of audit data requires the percentage of standards that have been achieved.<sup>31</sup> This can be achieved by using simple statistical functions in widely available software e.g. Microsoft Excel. An Excel spreadsheet can be created and, if desired, a series of macros can be embedded to facilitate the analysis process.

### Implementing changes

Clinical audit is a change process; simply measuring activity will not drive change.<sup>31</sup> Data analysis can identify areas where changes in practice or care are required. Recognising and dealing with barriers to change is paramount if changes are to be successfully implemented. In a practical sense, implementing change should be integrated into existing systems and processes rather than apportioned.<sup>31,67</sup>

The Healthcare Quality Improvement Partnership (HQIP) suggests 6 steps to implementing change. These are shown in [Table 4](#).<sup>57</sup>

### Re-auditing

One of the strengths of audit is its cyclical nature. Those conducting audit should consider when to repeat an audit so that the effects of implemented changes can be established.<sup>55,68</sup> Re-audit is often referred to as the forgotten vital stage. Unless no change was required following an audit, the audit cycle is not complete until follow-up measurements are taken to ascertain whether or not the implemented change has had the desired effect.<sup>31</sup> However, even in circumstances where standards appear to have been met it is worth considering whether or not the performance levels measured in the audit were too low, or if the behaviour of those knowingly being audited changed due to this knowledge.<sup>31</sup>

If the re-audit demonstrates improvement, then some form of monitoring system should be instilled. This can replace the need for full audit but can highlight the need for future audit should there be evidence of deterioration in outcomes.<sup>31</sup>

**Table 4** The Healthcare Quality Improvement Partnership's (HQIP) implementing change.<sup>44</sup>**6 Steps to implementing change<sup>44</sup>**

1. Enlist the support and involvement of key people – involving stakeholders in the change process may help with the momentum of the change;
2. Develop a clear project plan – as with planning the audit itself, it is helpful to establish key role and responsibilities;
3. Support the plan with consistent behaviours – this can involve setting a good example, and reinforcing subjective norms;
4. Develop “enabling structures” – an example would be the active education tools mentioned above;
5. Celebrate milestones – it is important to recognise and celebrate improved performance. The process of re-audit would reveal if there have been positive changes;
6. Communicate relentlessly – keeping the practice team involved and motivated through continuous effective communication can help to maintain changes.

**The audit report**

Audit reports should be tailored in length and content with consideration for who will read the audit report, and what the audience may hope to do with the information.<sup>57,68</sup>

**Barriers to audit**

Audit has not been found to be effective in all instances, and a number of barriers to success have been identified. Insufficient time being made available for healthcare teams to participate in audit activity is commonly cited.<sup>33,44,51,69</sup> A supportive environment appears also to be a key factor in reaping the benefits of the audit process.<sup>1,31,70</sup> Scott et al.,<sup>71</sup> suggest that it seems that healthcare cultures emphasising team work, group affiliation, and coordination result in greater implementation of quality improvement practices, whereas the opposite is true for formal structures, regulations and reporting relationships.<sup>71</sup>

The most recent Cochrane Review found that the effectiveness of audit and feedback on professional practice was small to moderate and varied depending on the design and delivery of the intervention.<sup>72</sup> In addition to the conflicting evidence regarding the effectiveness of audit several studies have documented negative attitudes towards audit including perceived increased workload, restriction of clinical freedom and professional threat and lack of professional rewards.<sup>33,69</sup>

**Summary**

Notwithstanding the above issues and criticisms, clinical audit can play an important part in improving the quality of care in various healthcare settings. It can be carried out by large audit teams or by sole practitioners in private practice. Audit should be practical and made applicable to your particular environment, and implementing change should be performed after thorough consideration for its effects on patients and clinic staff.<sup>73</sup> Although it can be viewed as time consuming, it is possible for sole practitioners to incorporate audit into their continual professional development activities. Increasingly, a range of tools and resources are being made available nationally and internationally to support the audit process. With careful planning, audit need not be an arduous task but an enlightening and engaging activity that can benefit patients, practitioners and relevant professions.<sup>14,32,39,74,75</sup>

**Implications for clinical practice**

- Clinical audit is a valuable process in practice which supports continual service evaluation;
- It provides osteopaths with a means of measuring the effectiveness of their patient management against agreed and proven standards for high quality;
- Clinical audit can support osteopaths who are trying to improve the quality of their care and health outcomes;
- Clinical audit is a valuable means of identifying meaningful continual professional development (CPD) activities.

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