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## Clinical audit in orthopaedics

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*What is clinical audit?*

"A systematic approach to quality improvement that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change". This was introduced formally in the NHS (National Health Service) in the United Kingdom in 1993 [1],[2],[3],[4],[5] .

In other words - Clinical audit monitors the use of particular interventions, or of the care received by the patients against agreed standards. Any departures from the best practice can then be examined in order to understand and act upon the causes.

Effective clinical audit is helpful for health professionals, health service managers, patients and the public. It supports health professionals in making sure their patients receive the best possible care. It can inform the health service managers about the need for organisational change or new investment to support health professionals in their practice [6],[7],[8] .

It helps to ensure the patients are given the best possible care and provides the public with confidence in the quality of the service as a whole.

*History of clinical audit*

During Crimean War Florence Nightingale and her team of 38 nurses applied strict sanitary routines

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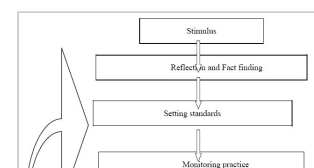
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and standards of cleanliness to the hospital and equipment, and with Florence's gift, kept meticulous records of the mortality rates among the hospital patients. The mortality rates fell from 40% to 2% after the changes were made. They were instrumental in overcoming the resistance of the British doctors and officers to Florence's procedures. Her methodical approach, as well as the emphasis on uniformity and comparability of the results of health care, is recognised as one of the earliest programs of outcomes management <sup>[2]</sup> .

Ernest Codman became known as the first true medical auditor following his work in 1912 on monitoring surgical outcomes. Codman's "end result idea" was to follow every patient's case history after surgery to identify individual surgeon's errors on specific patients. Although his work is often neglected in the history of health care assessment, Codman's work anticipated contemporary approaches to quality monitoring and assurance, establishing accountability, and allocating and managing resources efficiently <sup>[2]</sup> .

### *Contemporary medicine*

Despite the successes of Nightingale in the Crimea and Codman in Massachusetts, clinical audit was slow to catch on. This situation was to remain for the next 130 or so years, with only a minority of healthcare staff embracing the process as a means of evaluating the quality of care delivered to patients.

The National Institute of Clinical Excellence(NICE) in UK,has described the various aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery <sup>[2]</sup> .

### *What is the difference between clinical audit and research?*

Audit and research are two different entities. As both share some common features there is a tendency to use them in conjunction. Clinical audit compares current practice to the standard practice. Research determines what constitutes the best practice.

The purpose of the audit is to assess one's performance. Audit tells us whether we are doing the things in the right way. An audit runs in a cycle. The steps in the cycle are setting standards, assessing the current performance, finding out the deficits, implementing the change and reassessing whether the standard is achieved. The statistics and methods are usually simple.

Research generates new idea and tells us about right thing to do. This is peer reviewed. It can be complex, needing full ethical standards and approval. The information generated from the research helps to set the standards of practice.

### *Clinical audit - a domain of clinical governance*

Clinical governance is a framework through which medical organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. A duty of quality was placed on NHS organisations in the 1999 NHS Act. This introduced corporate accountability for clinical quality and performance. Clinical Governance is a 'whole system' process which has a number of features <sup>[9],[10],[11],[12]</sup> .

- Patient centred care needs which mean that patients are kept well informed and are given the opportunity to participate in their care.
- Good information about the quality of services is available to those providing the services as

well as to patients and the public.

- Variations in the process, outcomes and in access to health care are greatly reduced.
- NHS organisations and partners work together to provide quality assured services and drive forward continuous improvement.
- Doctors, nurses and other health professionals work in teams to a consistently high standard and identify ways to provide safer and even better care for their patients.
- Risks and hazards to patients are reduced to as low a level as possible, creating a safety culture throughout the NHS.
- Good practice and research evidence is systematically adopted.

The importance of the philosophy - patient centred, safety conscious, multi-disciplinary in delivery, is emphasised along with the methods to be used such as continuous improvement at a number of organisational levels tackling variation and using evidence.

Doctors in each speciality must take the lead in setting evidence based, achievable standards that can be monitored in their respective speciality. Ideally the monitoring should be performed by an independent clinician and during normal clinical activity. Once the standard of the service is identified, one needs to implement the change required to correct the deficiency in the service. One must be obliged to demonstrate that existing resources are being used as effective as possible. The solutions for the deficiencies must be innovative, cost effective and bring out improved care of the patients <sup>[13]</sup> .

*To cite an example:*

How to audit a poorly performing doctor?

It is the duty of a doctor in his clinical practice to demonstrate seven principles for being a good clinician. Good medical practice, good clinical care, teaching and training, maintaining good relationship with patients, treating colleagues fairly, probity, keeping oneself healthy <sup>[14]</sup> .

To ensure these, a doctor needs to have appropriate attitude, knowledge and skills <sup>[15]</sup> . To enable them to meet their responsibilities for clinical governance they

1. Need to work in teams
2. Be constantly constructively self critical
3. Be committed to continuous professional development
4. Know how to avail themselves of and apply relevant best evidence
5. Meet the responsibility set out in good medical practice.

What are the barriers to clinical governance <sup>[10],[16],[17]</sup> :

1. Poor fabric of building in which to deliver in patient service
2. Too few alternatives to admission of patient
3. Too few treatment options
4. Too little of integration of multidisciplinary follow up

Conditions which can lead to errors happening include high work load, too much complacency or exhaustion, inadequate knowledge, poor design, inadequate supervision, ability or experience to

manage conditions, stressful environments among others, overestimating ones own skills etc.

### *Types of clinical audit* <sup>[18]</sup>

**Standards-based audit** - A cycle which involves defining standards, collecting data to measure current practice against those standards, and implementing any changes deemed necessary.

**Adverse occurrence screening and critical incident monitoring** - This is often used to peer-review cases which have caused concern or from which there was an unexpected outcome. The multidisciplinary team discusses individual, anonymous cases to reflect upon the way the team functioned and to learn for the future. In the primary care setting, this is described as a 'significant event audit'.

**Peer review** - An assessment of the quality of care provided by a clinical team with a view to improving clinical care. Individual cases are discussed by peers to determine, with the benefit of hindsight, whether the best care was given. This is similar to the method described above, but might include 'interesting' or 'unusual' cases rather than problematic ones. Unfortunately, recommendations made from these reviews are often not pursued as there is no systematic method to follow.

**Patient surveys and focus groups** - These are methods used to obtain users' views about the quality of care they have received. Surveys carried out for their own sake are often meaningless, but when they are undertaken to collect data they can be extremely productive.

### Perspective of clinical audit in orthopaedic practice

In the last 30 years clinical orthopaedics has seen major advancement in every field. This has come through refinements and improvements in skills, knowledge as well as technology. Because of these changes, we are facing an ocean of change in our training and education.

The true essence of surgical innovation and improvement has come through because of individual surgical experiences and new techniques with little evidence of clinical trials. The orthopaedic surgeon relies on multidisciplinary approach for developing a new technique or method of the treatment. These refinements need to be evidence based and accountable. The surgical learning curve and technical difficulty associated with a new technique is variable from individual to individual and also to country to country. The enormous amount of funding spent in developing new technology in the western world brings inequality in the orthopaedic community especially between the developed and developing world. Thus, the perspective of the clinical audit changes according to the economy or the healthcare budget of the country.

The surgical trials are often expensive and difficult to run <sup>[19]</sup>. Surgical trials present important challenges in design, including the difficulty of blinding, comparing operative and non-operative treatments, the ethical concerns related to surgical placebos, and the effect of learning curves and surgical expertise<sup>[20]</sup>.

Without sponsorship and financial support surgical trials are simply impractical. Ethical approval for patient interventions becoming a well established hurdle towards scientific research in current orthopaedic practice <sup>[19]</sup>. To develop a meaningful audit one should be able to get access to literature evidence and then set a standard in the practise for improving patient care.

### Role of evidence based orthopaedics in clinical audit

Orthopaedic surgeons want what is best for their patients. Determining best practice, however, is not always straightforward. Clinicians use many sources of information to determine treatment options for

their patients. Surgeons rely in large part on their training. As surgeons progress through their careers, practice learned through training is influenced by their own experience, the advice of colleagues, and their personal learning, including continuing medical education and the use of texts or the surgical literature. One of the more powerful forces in shaping best practice is, and should be, the surgical literature. The literature, however, is often contradictory <sup>[21].[22],[23]</sup> .

Evidence based practice has given direction and magnitude for understanding the solution for a specific question whether in diagnosis, therapeutic or surgical interventions and outcome determination. Most peer reviewed indexed journals in orthopaedics requires an article to be based on the level of evidence. By using best scientific evidence, resources could be freed from what is deemed to be ineffective treatment in order to ensure a more effective service for all on the basis of principles of distributive justice <sup>[24]</sup> . The practical implications of such a framework may result in the determinations overtly based on evidence, but covertly used as mechanism of rationing rather than rationalising the health care. The translating best research evidence to treatment for an individual patient continues to remain a challenge. Patient specific evidence is not always clear, and research evidence needs to be integrated with attitudes and values of clinical decision making process <sup>[25]</sup> .

The levels of evidences are as follows in descending order

Level 1a - Systematic review and meta-analysis

Level 1b - Randomised Controlled Trials (RCTs)

Level 2 - Cohort study

Level 3 - Case control study

Level 4 - Cross sectional study

Level 5 - Case reports

It is highly desirable to have high quality RCTs for providing an evidence towards changing practice and existing practice. But it is clearly undesirable to undervalue anything that does not come in the form of a RCT <sup>[22]</sup> . In truth, lesser forms of evidence provide many insights, hail many breakthroughs and warn of impending disasters in ways which would be simply impossible with RCTs. Lower levels of evidence play an important part in generating hypothesis for RCTs.

*Examples of Evidence based orthopaedics:*

Example 1:

*"Weekly Pin- Site care was as effective as a daily care in patients with external fixation" - Dahl et al (2004).*

This study was designed as randomised unblinded controlled trial with outcome measures relating to infection rate and its severity. They found no difference between weekly or daily pin site care groups with an external fixator. The pin site infections are the most common feared complication associated with the use of external fixator. However because there is lack of evidence to guide the management of local skin wound at the pin site, the techniques of pin care remain anecdotal and of personal preference (Temple, 2004 - Cochrane database). This study which compares two different time intervals for pin care provides valuable information regarding no easily measurable differences between daily and weekly pin site care <sup>[26]</sup> .

### Example 2

"The Sliding hip screw is better than short femoral nails for extracapsular femoral fracture"- Parker MJ (2004).

This is a meta-analysis of 28 trials with operative details and fracture fixation complications as the outcome measures. In patients with extracapsular proximal femoral fractures, the sliding hip screw performs better than the short gamma nail. No advantage is seen with the intramedullary hip screw or the proximal femoral nail compared with the sliding hip screw. Limited evidence supports the use of the short intramedullary nails compared with the blade plate or condylar screw. On the basis of this review, the sliding hip screw remains as the "gold standard" for fixation of intertrochanteric hip fractures [27] .

The above cited examples does relate to the best practice as evidenced in the literature. Surgeons involved in individual practices in the community has less time to attend to various learning facilities, and thus may resort to the few standard journals which may influence the decision making in different areas of Orthopaedics. A critical appraisal of the available literature is the first step towards developing a clinical audit procedure. One must assess the merit of the study and apply the changes implemented elsewhere in their own practice for improving the quality of patient care [28] .

### How to conduct an audit? [5]

Audit can be conducted essentially in stages as described below:

- Selection of a topic
- Specification of desired performance
- First data collection
- Comparison of performance against standards
- Implementation of the change
- Second data collection

### Deciding a topic for the audit:

The topic is decided mainly according to the practice in unit. A corrective action is mandatory when unacceptable levels of performance have been identified or suspected which may define the process of clinical audit. A clinical audit question can range for a variety of diagnostic, therapeutic, and management issues. Having established that an audit can be justified, an additional question must be addressed, i.e. what is the aim of this particular audit?

The clinical issues can be the performance of a particular procedure in terms of outcome, or an existing disease situation. The following few examples could give some directions [29],[30],[31],[32],[33],[34] .

### Examples:

1. Increased post-operative infections
2. Open tibial fractures - acute management
3. Use of thrombo-prophylaxis in lower limb arthroplasty
4. Interval between admission and operation of a hip fracture
5. Adequacy of fracture fixation
6. Timing of fixation of acute ankle fracture dislocations
7. Mortality and Morbidity audits

The non clinical issues can range from diagnostic protocol to management issues.

*Examples:*

1. Out patient follow up (Loss of patients attendance and the reason)
2. Data maintenance in the wards (like fluid maintenance chart, accuracy of medical documentations)
3. General hospital medical records and database
4. Balance of patient volume and minimum time spent in physical examination
5. Risk assessment for tumours
6. Time of Residents training
7. Lead protection in operation theatres

*Specification of the desired performance*

Once aim has been established, we have to define clearly the level of desired performance. Performance is described in terms of criteria and associated standards. The criteria are defined as systematically developed statements that can be used to assess the appropriateness of specific health care decisions, services and outcome <sup>[16]</sup>. It is essential that the criteria are based on good quality research evidence.

The standard has been defined as the percentage of the events that should comply with the criterion <sup>[35]</sup>. When standards are set they can be used as targets, which trigger action to improve performance. There may be particular local constraints that make the attainment of high standards difficult, eg. Limited resources or patients who are poorly compliant. Daniels and Sabin developed a framework for the "accountability for reasonableness" in the decision making process. The model would apply to all healthcare decision makers, particularly those who are faced with financial constraints pitched against an exponentially increasing demand <sup>[36]</sup>. Sometimes a standard can be set just above current performance in order to serve as a stimulus to improvement.

*First data collection*

An assessment tool has to be designed in the form of questionnaire. It is desirable to have a questionnaire that is reliable and valid. These assessment can be made either for a specified number for patients or for a particular duration. After completing the list of patients, one must ensure they are representative sample of the population in question. Also, one must ensure that this data is reproducible and extracted by an independent observer. By tabulating the results a reasonable conclusion can be derived about the current performance.

*Comparison of performance against standards*

An answer to the following sets of questions has to be determined

1. Is there a deviation of the current performance from the available best evidence in the literature?
2. If there is a shortfall, what are the specific issues that need addressing?
3. Single or multiple issues to be addressed?
4. What steps need to be taken to address these issues?
5. Will implementation of the required issues improve the standard of care?

## *Implementation of changes*

Once the audit has made clear why changes in performance are needed, one has to make practical plans to implement the change. The practical issues are related to the following questions

1. Who is responsible for implementing the change?
2. What is the precise change required?
3. How to develop the method to ensure a change does occur ?
4. When is the time to collect a second set of data after the agreed changes have been implemented?

Different strategies can be adopted to implement the change according to the needs of the target population. A wide range of strategies are available - eg. Feedback, educational strategies etc <sup>[5]</sup> .

## *Collection of second data*

Once the changes are implemented in the new practice, the performance has to be re evaluated by performing another audit at a stipulated time interval. If the desired improvement has been achieved then it technically completes an audit cycle. This is known as closing the audit loop. Sometimes a re-evaluation may provide information and identify the areas that can be improved further to meet the standards.

## **Flow chart of audit cycle**[\[Figure - 1\]](#)

## *Characteristics of a good audit*

A good audit constitutes good planning, systematic and adequate collection of the data, participation of all people in the audit process in the unit, and coordination between the individuals involved in the audit and presenting the conclusions of the work to the audit board. An audit board consists of the surgeon, practitioners, nurses, social services and local health authorities and managers. They all should be collectively responsible for delivery of good quality of care to the population in question by reducing health inequalities.

## **Uses of audit**

- Sets a best practice in the hospital
- Improves patient confidence
- Helps patients to change the clinical performance of health professionals
- Formulates guideline or protocol
- Audit acts as link between learning and education
- An opportunity for the doctors to update the literature
- It can reduce unnecessary expenses - eg. Investigations not appropriate to the clinical diagnosis
- Enhances the dignity and respect of a doctor as well as gives self satisfaction
- Can generate a research study
- In the event of legal claims - - result of an audit can be supportive
- When applying for a funding allocation - - an audit can be stepping stone



Conducting audit is a tedious process, needing manpower, funding and time. A busy surgeon has less time to devote towards well managed audit. They sometimes feel threatened by the prospects.

Audit may have methodological weaknesses such as poor criterion, inadequate sampling and failure to complete the cycle. Objective evidence of current performance is also required. Data extraction could be standardised and follow explicit rules, lest biased misinterpretation of the results may lead to implementation of a substandard practice.

### *Clinical audit in the Indian perspective*

There is non uniformity of the standards of the care of patients from state to state, city to city and hospital to hospital. The governmental institutions run low in health budget annually. Only the premier institutes in the country which has autonomous organization and managers to run the health care activities have access to large funds. In the rural hospitals, the state of the art in orthopaedics and trauma surgery is virtually absent. Implementation of modern equipments in the metropolitan cities and their hospitals has led to the difference in public opinion.

Thus, a large pool of patients with financial capabilities looks towards the private sector for better health care.

There are differences between different institutes in the residency training in orthopaedic surgery. There are instances when one assumes that qualification means fully competent for a surgical skill, which is realised by many younger surgeons. A large volume of the young generation of training doctors migrates to the metropolitan cities in search of more experience or they migrate to the west for greener pastures.

Thus, in an environment where the surgeons have the last say on setting the standard of care, we are probably creating a more non-uniform environment where standards of care may be in question.

There is lack of training and education of guidelines and management protocols for most disease situations. Even if there are guidelines set by the hospitals, there is lack of communication amongst members to do continuous teaching and training for improving the standards in the respective hospital, thus raising hope for the common people who run the democracy. Education and training of the allied medical professionals are inadequate and not everyone in the system takes equal interest in the quality of care. This makes a great divide between the skilled and non skilled personnel.

There is also lack of communication between the rural and urban areas which leads to ignorance in the rural community regarding the standard of practice for different clinical conditions. There is gulf of difference in providing funding between the centrally run and state run institutions.

Above all we have major issues in political and economic agendas which results negative attitudes and a resistance to change amongst the care providers and patients.

### *How to perform clinical audits against all odds?*

Each institution and their respective departments should form a working committee under the able guidance of a motivated surgeon.

In larger institutions where record keeping is adequate, the head of the department or the orthopaedic surgeon concerned should be responsible for the audits pursued in the unit. One should employ a clinical audit coordinator who would be delegated for completing the audits under the supervision of the

surgeon. The audit coordinator should be able to liaise with all staffs in the unit for successful completion of the projects. Once the change is implemented one has to meticulously collect the second set of data to show the change and complete the audit cycle.

In the smaller hospitals, one should be able to employ a clinical auditor who is employed by the state to maintain a database for the department and perform regular audit as required even on simple aspects of treatment e.g. fracture management protocols. One could complete an audit cycle with help of the surgeon and the superintendent of the hospital.

#### *Link between audit, learning and education*

Audit is a mode of learning. It holds a key part in continuing professional development (CPD). Continuing education is a narrow concept based on lectures, seminars, courses and conferences outside of work place. Nowadays, CPD encompasses continuing education and acquisition of new knowledge and skills in the clinical setting. One has enhanced management and communication skills. One improves in their learning skills, assessment skills and teaching skills. One should be able to effectively use information technology (which India is very advanced in) and attend more intensely to the social, cultural, ethical and psychological influences in a work place. This is not only because work place learning is less expensive, because of less loss of staff time, but primarily because it is probably a more effective way of bringing together research findings and practice, improving professional practice and promoting team development. [5],[20],[37]

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 **Figures**


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