



Surgery without audit is like cricket without keeping the score.

—Hugh Brendon Devlin, *British Surgeon (1932–1998)*

46.1 What is a Clinical Audit?

Audit literally means ‘official inspection of an organization’s data or finances, typically by an independent body’. While most audits relate to financial matters, medical audits are used by health care professionals to evaluate, estimate, and improve the care of their patients in an organized way. These can be internal or external. Medical audit provides a systemic feedback to health authorities about the quality of medical care that was being given. With the help of audits, doctors learn about what they have been practicing, comparing their results with other benchmarks, and thus changing their practice to improve its effectiveness [1].

In audits, a comparison is made between the patient care being given and standard protocols. An audit encourages the use of the best clinical practices to provide important feedback to doctors and policymakers from previous experience [2].

46.2 Is Medical Audit a New Concept?

The first documented audit was conducted by Florence Nightingale in 1853 who measured the death rate in a hospital during the Crimean war. This was reduced from 40% to 2% by applying simple hygienic measures [3]. Medical audit is now compulsory in most western countries but its practice is rare in developing nations largely due to a lack of awareness, lack of commitment, and also due to the absence of adequate medical records. The other reason for its absence are that it is perceived as a threat to clinical freedom.

Clinical audits have existed in some form or another for over 100 years in developed countries. In these countries, there are specific laws for health care units, doctors, and paramedics. The focus of clinical audits in the developed world is on patient outcome measures. There are deliberate efforts to improve patient care and many Quality Improvement programmes are used for this. In the UK, the National Health Service has a special audit system called ‘The National Clinical Audit and Patient Outcomes Programme’ and in America, the ‘American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP)’ is a validated, risk-adjusted, outcomes-based programme to measure and improve the quality of surgical care.

46.3 What are the Types of Audit?

An audit can be based on different determinants of the quality of care [4]. They include:

- The infrastructure of the institution—Beds available in the wards or intensive care units, number of operation theatres, nurse–patient ratio, qualified personnel etc.
- Patient-related activities—Quality control of check-in or checkout procedures, checklists for surgical procedures, records and note keeping, audit on infection control guidelines, prescription, pharmacy, sentinel events etc.
- Patient outcome audit—Recovery parameters and complication rates, mortality audits etc.

46.4 What is the Difference between Audit and Research? Does Audit Help in Research?

Research and clinical audit both have many similarities in terms of starting with a question and ending with answers. The answer in research is to a hypothesis whereas in audit it is to change clinical practice. Both require collection of data on patients and both depend on methodology to reach meaningful conclusions and both improve patient care [5]. The standard of data collection is important in both. If audit findings are published most people would ask for ethics appraisal. However, despite many similarities there are differences between the two activities (Table 46.1).

46.5 What is the Debate around Clinical Audit?

Any audit checks the line of treatment provided by a health care unit against standard lines of management within and outside an institution [6]. The basic requirement for such an audit to happen is to have internal reference points to say that this is the norm. The concerns over clinical audit are [7, 8]:

Table 46.1 Audit versus research

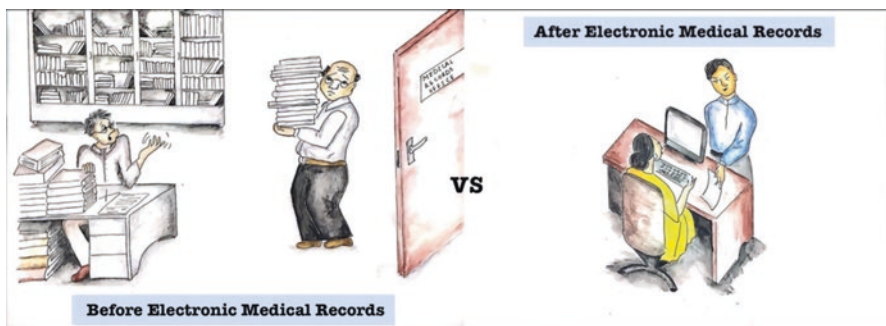
Medical audit	Health outcomes research
Audit is a systematic review of the medical care given to patients to identify whether we can improve patient outcomes	Research is a systematic investigation that aims at increasing knowledge
In audit no experiment is done	In research experiments are done on patients or healthy volunteers
No new drugs or procedures are tested	New drugs or procedures may be tested on suitable subjects
Does not involve patients travelling to a health care unit except for regular follow up	Patients may be required to travel to the health Centre according to a fixed protocol
In case there is more than one treatment available for a disease the patient has the choice	Strict criteria are used for treatment allocation and usually patients do not have a choice
The aim is improvement of the existing system by comparing audit results with accepted standards	The aim is to test a hypothesis and add new knowledge

There may be a number of different factors which influence a patient’s admission to a hospital which may not entirely depend on the quality of care available but also health insurance and affordability. In addition, medical practice is often faced with challenging or life-threatening cases and in them, it may not always be possible to follow ‘standard’ protocols for treatment. Thus, audit should not be a fault-finding exercise and is, therefore, best done by agencies who understand the complexities of patient care.

46.6 What are the Advantages and Disadvantages of Audit?

Many clinicians who practice audit feel that it helps them improve professionally, improves communication among various disciplines and various levels of personnel involved and encourages good data keeping and research. Good audit improves patient care and provides professional validation for the health care provider.

However, many think it to be a waste of time and that it detracts from patient care. Most physicians are unwilling to criticize their colleagues and may also refuse to accept externally imposed standards of care, and perceive audit to be a professional threat. A further serious objection, especially in developing countries where the resources are so limited, is that a strict audit may curb professional creative freedom, restricting practice to a prescribed policy and discourage innovation [9].



46.7 What is the Audit Cycle?

The audit cycle has three major components of planning, audit, and action. These components can be studied by five basic steps:

1. *Preparation*: For this, we need to think of a topic that has a high priority for the hospital. For instance, in the Department of Internal Medicine, we can choose to do an audit on the demographic data of patients we admit with HINI infection, the treatment we offered to those with accidental poisoning, complications occurring during community-acquired pneumonia or to study the mortality of patients admitted with acute pancreatitis.
2. *Selection criteria*: We need to define the criteria for inclusion in the audit report. The mortality data may be of inpatients or the 30- or 90-day post-operative mortality. We can record and grade according to the widely used classification of post-operative complications described by Clavien and Dindo [10], which makes comparisons between different centres easier.
3. *Measuring the level of performance*: The data collected is analyzed and also compared with set standards. In case the accepted standards of care have not been met we should explain why this was so.
4. *Making improvements*: This involves presenting the results and discussing them with colleagues in our institution and elsewhere. We should use the results to develop an action plan, specifying what needs to be done, how it will be done, who is going to do it, and by when.
5. *Maintaining improvements*: This follows the preceding stages of the audit, to determine whether the schedules have been effective, or whether further improvements are needed. The audit/re-audit process goes on till there is improvement and thus it is called the 'audit cycle' or 'audit spiral'. This cycle is the most important step in the whole process to progress and show efficacy in the area of interest. For example, if the mortality of COVID patients admitted to the intensive care unit was found to be 15% against the internationally accepted figure of 5% we need to find why this was so and rectify the same.

The audit cycle is diagrammatically depicted in Fig. 46.1.

46.8 What is the Status of Clinical Audit in India?

In a recent paper published in Current Medicine Research and Practice the authors mention about the dismal status of medical audit in our country [11]. They also state that the pressure to conduct an audit is absent here. In one of the nation's premier super-specialty hospitals in Hyderabad, it was found in a survey although 86% of doctors thought that conducting audits was important not a single department was doing it.

In 1962, a committee headed by Dr. A. Lakshmanaswami Mudaliar submitted its report which emphasized the importance of medical audit [12]. In 2005 the NABH, which restructures the functions of hospitals at all levels, imposed audit processes to measure the improvement in the quality of care they provided. However, the

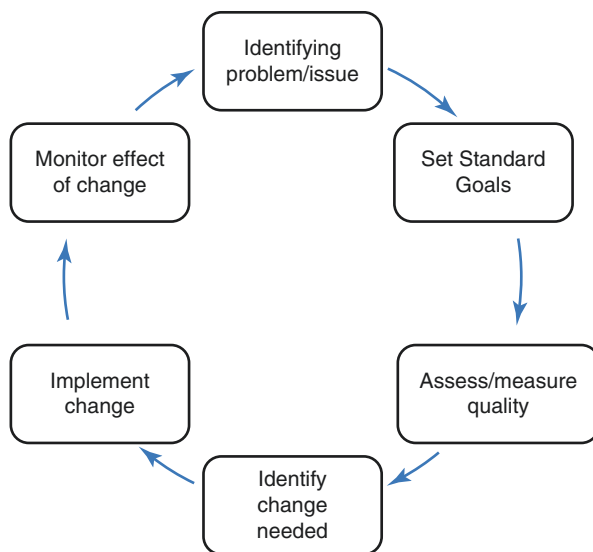


Fig. 46.1 Audit cycle

problem with the NABH is that only 600 facilities are under its supervision and it has been able to popularize the concept of clinical audit in very few of them.

Presently Ayushman Bharat, funded by the Government of India accounts for almost one-third of all health insurance expenditure in India. A number of states such as Andhra Pradesh, Tamil Nadu, Karnataka, Maharashtra, and Gujarat have instituted programmes where treatment is available in the private sector [13]. While this has led to an influx of funds into health care, there has been no increase in clinical audits or the use of accreditation mechanisms. Most state governments are focusing on the structural indicators of patient care like the availability of well-equipped operation theatres, qualified staff etc. Such indicators are concrete; easy to understand and evaluate. What is problematic is that there is no clear established relationship between good infrastructure and good clinical outcomes. As this data is lacking even in the best institutes it is difficult to say that these private hospitals are offering better patient outcomes than public hospitals.

There is, however, one exception to the above and that is the state of Maharashtra which has partnered with a public sector insurance company, the National Insurance Company. In 2013, they launched an appraisal tool for empanelment of hospitals using all three indicators—structure, process, and outcome. This tool included 85 standards to evaluate health care facilities. These indicators were grouped into nine separate chapters, namely: (1) Human resources, (2) Infrastructure, and Facilities (3) Infection Control, (4) Medication Monitoring, (5) Patient Medical Records, (6) Standard Operating Protocols, (7) Quality of Patient Care, (8) Transparency in Pricing, and (9) Patient Satisfaction Indices. The appraisal tool is being used till today in running the scheme.

The audit report of each hospital in the state should also be available.

46.9 Conclusions

- A health care unit that integrates regular audits with clinical work in its curriculum can lead to continuous improvement. An audit has a positive impact on patient outcomes.
- The simple exercise of comparing practice with protocol-based standard therapy, encourages practitioners to comply with protocols. The recording of a patient's history and the examination seems to be a simple exercise but if done properly can lead to improvements in patient care.
- Conducting a clinical audit, builds up a large database that is available for corrective action.
- Establishing whether the protocols have been followed in all conditions, can provide protection to healthcare providers against negligence.
- Collection of data helps in creating transparency which bonds a trust relationship between a patient and a doctor.
- All these factors will help in building a future universal health care system.

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