



Clinical audit in the laboratory

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ABSTRACT

Audits are part of the continuous quality improvement process and one of the key elements of clinical governance. Laboratory-based clinical audits are concerned primarily with the everyday aspects of laboratory services and are a means of providing feedback to the users of the laboratory and its staff. They involve measuring the performance of laboratory services against established standards. These standards have ideally been established using the principles of evidence-based medicine. If necessary, changes are implemented and then a re-audit is performed after a certain time period to ensure that the changes have been implemented and maintained. Areas of audit in the laboratory include the preanalytical, analytical and postanalytical phases. This review article examines the basis of clinical audits in the laboratory and then proceeds to describe in detail how a laboratory-based clinical audit should be performed and monitored, with special reference to the chemical pathology laboratory.

Healthcare delivery organisations globally are utilising various quality indicators to measure the efficacy of specific interventions as well as to identify healthcare improvement opportunities. These quality indicators are further being used for performance and outcome measurements as a means to measure, monitor and improve the quality of care and services. Laboratory data are important in the medical decision making process and influence 70% of medical diagnoses.¹ "Audit" means to evaluate, and in the context of the pathology laboratory would mean a systematic and critical analysis of pathology services. An audit is a quality improvement process and is an essential part of the quality assurance programme of a laboratory. The standard definition of clinical audit is "a quality improvement process that seeks to improve the patient care and outcomes through systematic review of care against explicit criteria and the implementation of change".²

Five distinct activities can be considered under the broad umbrella of audit:

- ▶ Solving problems associated with process or outcome
- ▶ Monitoring workload in the context of controlling demand
- ▶ Monitoring introduction of new tests and/or changes in practice
- ▶ Monitoring adherence with best practice (eg, with guidelines)³
- ▶ Monitoring of analytical quality.

HISTORY

Audit is not a new process.⁴ As early as 1750 BC, King Hammurabi, the 6th king of Babylon, instigated audit for clinicians.⁵ In modern medicine, one

of the first clinical audits was undertaken by Florence Nightingale during the Crimean War of 1853–1855; she applied strict sanitary routines and hygiene standards that decreased the mortality rates from 40% to 2%. Another famous figure who advocated clinical audit was Ernest Codman (1869–1940), an orthopaedic surgeon at Harvard Medical School. He became known as the first true medical auditor following his work in 1912 on monitoring surgical outcomes. Despite the early work of these pioneers, clinical audit is relatively new to modern medical practices.

CLINICAL GOVERNANCE AND AUDITS

Clinical audit is one of the key elements of clinical governance, the latter being a system through which healthcare organisations are accountable for continuously improving the quality of services. It is described as "a framework through which organisations are accountable to continue to improve the quality of the service and safeguard high standards of care by creating an environment in which excellence in clinical care would flourish".⁵ In 1989, the White Paper *Working for Patients* saw the first move in the UK to standardise clinical audit as part of professional healthcare,⁶ and later it was stipulated that time was to be allocated for audit work within each consultant's job.⁷ In an attempt to assess clinical performance, medical audit was introduced as part of the 1997 white paper health reforms of the NHS in the UK.⁸ In 1997, the Royal College of Pathologists published guidelines entitled *Clinical Audit in Pathology*⁹ and established *The Professional Standards Unit* for providing guidance to pathologists to produce evidence on the quality of service they provide.¹⁰ In 2005, the Royal College of Pathologists published a code of practice for clinical biochemists and clinical biochemistry services in which clinical biochemists were required to participate in clinical audits to assess the quality and appropriateness of the services provided.¹¹

Benchmarking schemes, which share similarities with clinical audits, have been in existence in the USA for many years. Benchmarking is the process of measuring products, services and practices against leaders in a field, allowing the identification of best practices that lead to sustained and improved performance.

AUDIT AND EVIDENCED-BASED MEDICINE

Evidence-based medicine (EBM) is at the core of continuous quality improvement programmes and audits are very much part of the continuous process to implement and maintain best practice in the laboratory. Audits use EBM to set the standard. All of the audit activities are found in the practice of evidence-based laboratory medicine

(EBLM), namely that there is a clinical question for which the test result should provide an answer and that the answer will lead to a decision being made and an action taken, leading to an improved health outcome. EBM and EBLM are essential tools in the assessment of clinical effectiveness, as high quality systematic clinical research is necessary for investigating the impact of any intervention on clinical outcome.¹² Fig 1 shows how EBLM and audit are linked.¹³

AUDIT VERSUS RESEARCH?

According to the Research Governance Framework for Health and Social Care, research can be defined as “the attempt to derive new knowledge by addressing clearly defined questions with systematic and rigorous methods”.¹⁴ In general, research generates evidence to support, refute or develop a hypothesis. It aims to study the effect of change on clinical or service practice. Clinical audit, on the other hand, aims to improve patient outcomes by improving professional practice and the general quality of services rendered. It compares current practice against a standard that has already been set and examines whether this practice meets required standards, follows published guidelines and applies the knowledge that has been gained through research. In some instances there might be no standard practices that have to be developed. An important distinguishing difference between the two is that standard of practices are the basis of measurement in clinical audits and not hypotheses (table 1). Research may direct audit, which may lead to the development of hypotheses that can be tested by research.² Research increases overall knowledge and discovers best practice.

Research can identify areas for audit that are critically important for patient care. As resources are limited in the laboratory, research can identify areas that need to be prioritised and monitored. Audits may occur as a final step for a good laboratory-based research programme, and they can pinpoint areas where the research evidence is lacking.

In a systematic review of studies that have examined inappropriate laboratory use, it was found that many of these studies did not use implicit or explicit criteria, thus not meeting methodological standards, and suggesting that research is needed to develop evidence-based standards for measuring inappropriateness of laboratory test use. This may be a challenging task, as there can be differing views on the appropriateness of a test request. When inappropriate laboratory

utilisation is identified, methods to rectify the problem must be developed, tested and implemented.

STEP-BY-STEP APPROACH TO PERFORMING AN AUDIT OF LABORATORY SERVICES

Ideally, clinical audits should be conducted within a structured programme, with effective leadership, involving all staff, and with emphasis on team work and support. Appropriate funding should be made available, as clinical audits may involve substantial costs, 80% of which are related to the use of staff resources.¹⁵ Time is allocated for personnel to participate in clinical audits, as they can be time consuming, and funding is discussed. Given the significant levels of resource input, research is needed into the value of clinical audit, and the cost implications of clinical governance need to be explicitly recognised. Some institutions recommend that all audits should be registered and approved by the institutional committee. Often, audit results in criticism of other departments or individuals without their knowledge or involvement, thus joint audit is desirable and should be encouraged.

The audit cycle

Clinical audit is a cyclical process (fig 2).¹⁶ Coles suggested combining the learning cycle and the audit cycle to produce a double-looped cycle starting with observing practice, reflection on practice, setting new standards and, after further observation and reflection, implementing change followed by monitoring and re-audit.¹⁷

The stages of a clinical audit

There are five stages of a clinical audit.¹⁶

Stage 1

This involves preparation for the audit, including choosing a team, co-ordinator and a topic. Ideally, the topic should be relevant with potential benefit to patient care or the organisation. Three areas can be addressed: preanalytical, analytical and postanalytical (box 1).

A quantity impact analysis may be performed to choose and prioritise ideas for a clinical audit.¹⁹ This produces a list of topics which can be prioritised. Another approach is to examine the number of points on “test request pathways” for specific clinical conditions. At each point there are aspects of the testing process that can be audited.

Stage 2

This involves defining and selecting the criteria and standards to which the performance will be compared. A criterion is a specific statement of what should be happening, is used to assess quality of care and is preferably evidence based; therefore a literature search is essential.²⁰ Criteria are often also called guidelines or benchmarks and are based on biomedical research and health technology assessment. They are outcome orientated and usually developed by a multidisciplinary team.²¹ Unfortunately, the quality of published guidelines is variable, many not being explicit or evidence based.¹⁸ If no acceptable guidelines are available, the organisation needs to develop their own best practice guidelines before the clinical audit is commenced. The All Wales Clinical Biochemistry Audit Group has published 25 guidelines for various investigations in clinical biochemistry.²² Their group recently evaluated the impact of these guidelines on laboratory services in their area of practice

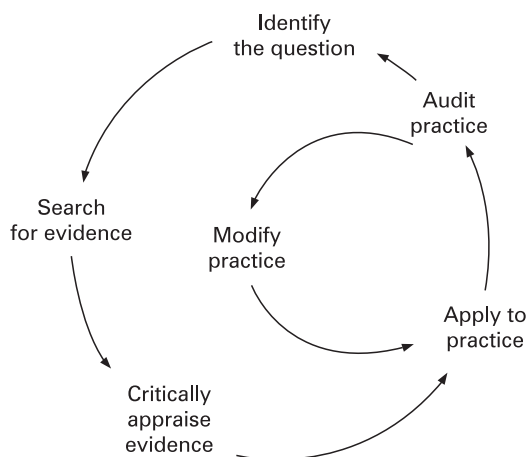


Figure 1 Evidence-based laboratory medicine and audit.¹⁷

Box 1 Areas of audit in the laboratory¹⁸

Preanalytical

- ▶ Request forms; are they easy to use? Are all relevant details provided by the user?
- ▶ Specimens: is the right specimen received at the right time? Are the appropriate investigations selected by the laboratory staff
- ▶ Phlebotomy services and transport of samples to laboratory

Analytical

- ▶ Is the range of investigations available appropriate? The number of requests for a specific test and the positivity rate should be audited. Those tests for which requests which are rare and/or have a low positivity rate should be withdrawn
- ▶ Are the test methods being carried out according to standard operating procedures?
- ▶ Safety policies and procedures. Every laboratory should have a comprehensive safety policy. Every single accident in the laboratory should be recorded and improvements made if necessary. The use of dangerous substances should be audited
- ▶ Efficient use of staff. The training of all staff may be audited.
- ▶ Purchasing of equipment, reagents, stationary and other items
- ▶ Laboratory reports: are they precise and clear?
- ▶ Storage of reagents and specimens
- ▶ Internal and external quality assessment
- ▶ Test utilisation

Postanalytical

- ▶ Turn-around times for each request. Attempts should be made to monitor the turn-around time in each department and see whether improvements can be made
- ▶ Reporting methods (eg, types of reports, direct communication, computer system)
- ▶ Reference ranges
- ▶ Interpretation, consultation and comments on reports
- ▶ Complaints and corrective action taken

(Wales) and found that they had led to a more efficient and effective use of laboratory services.²³

Stage 3

This involves data collection and measuring the performance. The data should be precise and relevant, and collected over a specified time period. Patient registers may be used to identify patients, and clinical records are often used as data sources. Audit staff needs to be careful about the accuracy, timeliness and completeness of clinical records. The data collected must be adequate (sample size) and relevant to enable making valid conclusions.²⁴ If a questionnaire is used, it should be clear, concise and unambiguous, avoiding double-barrelled and leading questions. Data are generally collected retrospectively and most audits only require the use of basic descriptive statistics.²⁵ Where possible, the results should be compared with audits performed by peer groups or national standards.²⁶

Stage 4

This involves analysing the results obtained and making improvements, identifying barriers and obstacles to change. An integrated plan is developed for the delivery and monitoring of interventions. Implementation methods that are most

Table 1 Some differences between audit and research

Audit	Research
Determines whether the laboratory is following agreed practice	Creates new knowledge and provides foundations for national and/or local agreement about what kind of clinical care and treatment we <i>should</i> be providing
Measures against accepted standards	Based on a hypothesis
Reviews current practice and compares it with best practice	Improves overall knowledge and discovers best practice

suitable are discussed and may involve education of laboratory staff and users of pathology services using outreach programmes, presentations and group discussions.

Stage 5

This involves a re-audit after an agreed time period to ensure that improvement is sustained. A single data collection does not constitute an audit,³⁶ as the first data collection establishes the laboratory's current position and the second one establishes if improvements have been made.²⁶ A timescale for a reaudit is decided upon using the original design.²⁷ Any changes that have improved service delivery are monitored, evaluated, sustained and reinforced in a supportive environment. This stage is critical to the successful outcome of the audit process, as it determines if changes implemented have resulted in an improvement of the laboratory services.

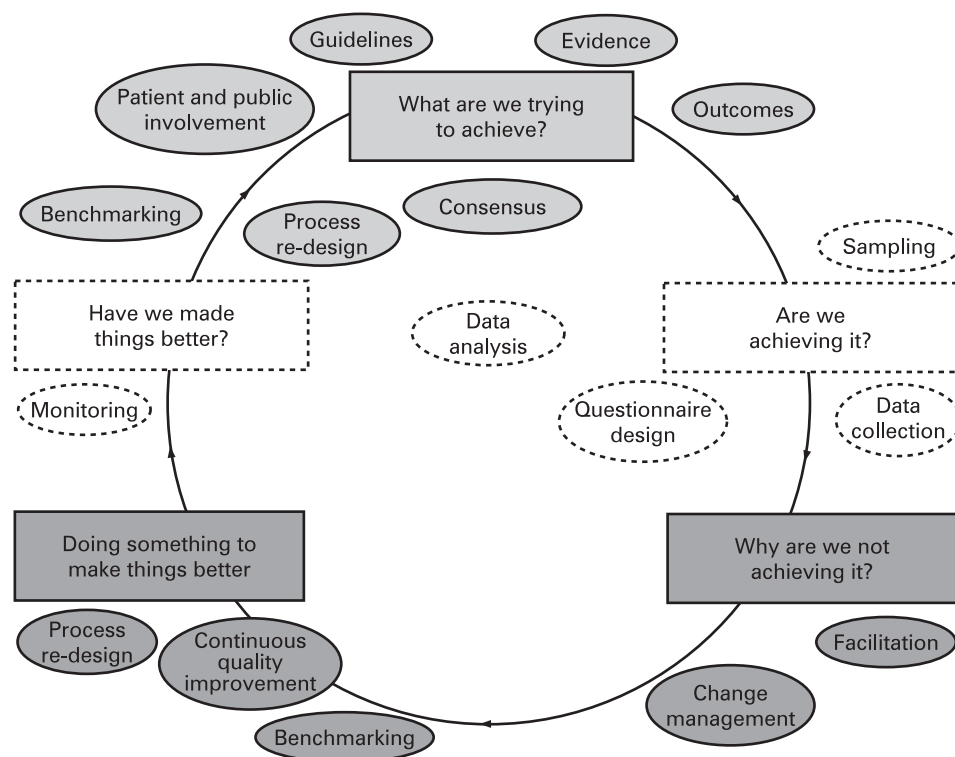
Finally, the audit report is written in a structured way with a title and background to the study. Aims and objectives should be clearly stated, defining the criteria and standards used and ending the report with a conclusion and recommendation for improvement and reaudit.²⁷ Results of a good audit should be disseminated locally via the local health authorities and nationally through professional organisations and meetings. The Royal College of Pathologists has published examples of high quality laboratory-based clinical audits under the title *Writing your audit report*.²⁷

IMPACT OF AUDIT ON LABORATORY SERVICES

As pathologists, our obligation to clinical medicine is to monitor test usage and to evaluate their usefulness. Clinical audits in the laboratory are concerned primarily with the daily aspects of laboratory services and are useful for providing feedback to the users of the laboratory and its staff. They have been beneficial in assessing and modifying laboratory and clinical practice ranging from the use of services to the clinical effectiveness of laboratory tests as well as their impact on clinical outcomes.²⁸

Clinical care

Clinical guidelines of a high quality may help clinicians to change the ordering pattern of tests to one that is more rational with a better cost/benefit ratio, the ultimate goal being to improve the quality of care of patients.²⁹ Van der Weiden *et al* studied the appropriateness of cholesterol testing in their setting and found that cholesterol testing was not being performed according to national guideline recommendations.³⁰ Audits can be used to improve the quality of laboratory service by decreasing turnaround time by improving various processes involved in the testing process, such as sample registration time, test result validation and result delivery time. In a survey that examined incompletely filled in laboratory request forms and their impact on the phoning out of critical results in our laboratory, we determined that they are detrimental to patient

Figure 2 The audit cycle.²⁵

care and this is an example of how preanalytical errors may influence the clinical course of a patient.³¹

Quality assurance programmes

Clinical audits can highlight areas where better use of resources can be implemented.³² They may also be used to assess whether quality assurance methods in the laboratory are adequate and conform to accepted standards. Housley *et al* recently described an audit of the use of internal quality control procedures in 54 laboratories and highlighted significant variability in internal quality control practice. They consequently proposed a set of regional standards that were developed and disseminated and a reaudit at a future date has been proposed.³³ Audits can be used to provide evidence of poorly managed external quality assessment schemes or programmes that are too analytically focussed.

Test utilisation

In an effort to cut costs, healthcare organisations are studying test utilisation and its impact on clinical outcomes. Clinical audit has been used to examine the requesting patterns and identify problem areas. Mainwaring *et al* performed an audit of coagulation screen requests of patients admitted to the medical assessment unit and found that numerous tests were performed unnecessarily leading to an unnecessarily high workload and unnecessary costs.³⁴ An audit by the North Thames Clinical Chemistry Audit and QA Group in 2004 highlighted several problem areas in test requests for aldosterone and renin. These ranged from improper processing and storage to inadequate preparation of patients and inappropriate use of reference ranges.³⁵ In our laboratory we observed that although phosphate is an important indicator of mortality in especially the seriously ill patient, it is not a regularly performed test.³⁶

Similarly, Kwok and Jones carried out an audit on unnecessary repeat testing in an immunology laboratory and found that

this contributed to high cost and a waste in technician time and reagents. During a 12 month period, they found that repeat requests for tumour markers and autoantibodies made up 16.8% of the workload leading to waste of resources.³⁷ Audits have been reported to improve communication among colleagues leading to improved patient care, increased professional satisfaction and better administration, as illustrated by an extensive review of 93 publications by Johnston *et al*.³⁸

Ultimately it is the pathologist's duty to help clinicians order the appropriate tests, at the correct time, in the correct order. Combination of practice guidelines, modification to the laboratory requisition form and funding policy changes have been found to significantly decrease the use of several tests.³⁹

MONITORING FOR A SUCCESSFUL CLINICAL AUDIT

Ideally, there should be an audit committee in the organisation in charge of all clinical audits. This committee should have a clear strategy with specified programmes and associated activities. They form a support group, organise funds and meet regularly to monitor the progress of. An up to date database of audits in progress should be readily available. All staff should partake and receive adequate training. The conclusions and criteria of the audits should be standard based according to EBM principles. There must be evidence of appropriate action plans that have been implemented according to the results found.

CONCLUSION

Systematic improvement of health services requires the objective measurement of people, practices and organisations against valid and explicit standards in order to identify and implement appropriate change.⁴⁰ Laboratory-based clinical audits are an essential part of total quality management. They are important for good clinical governance. In the laboratory they have been found useful in developing guidelines for testing, assessing test utilisation and various aspects of quality assurance programmes.

Interactive multiple choice questions

This JCP review article has an accompanying set of multiple choice questions (MCQs).

To access the questions, click on BMJ Learning: take this module on BMJ Learning from the content box at the top right and bottom left of the online article. For more information please go to: <http://jcp.bmj.com/education> Please note: the MCQs are hosted on BMJ Learning – the best available learning website for medical professionals from the BMJ Group.

If prompted, subscribers must sign into JCP with their journal's username and password. All users must also complete a one-time registration on BMJ Learning and subsequently log in (with a BMJ Learning username and password) on every visit.

Take-home messages

- Audits are part of continuous quality improvement in the laboratory and one of the key elements of clinical governance.
- Audits compare current practice against an accepted standard that has been set and examine whether this practice meets the standard.
- Audit is a cyclical process: it compares practice to standards, measures performance, makes improvements and, importantly, involves a re-audit after a time period to ensure that the improvement is *sustained*.
- There are ample areas for audit in the laboratory, ranging from the preanalytical to the postanalytical phases.

Additionally, they forge important liaisons between clinical and laboratory staff, leading to improved communication. They ultimately lead to improved patient care and cost containment.

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