LABORATORY BASED AUDITS

WHY AND HOW?

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Outline

• Introduction
• History
• Step by Step approach to conducting an audit
• Audit versus Research
• Conclusion
AUDIT IS A QUALITY IMPROVEMENT PROCESS
Types of Audit

- Financial Audit
- Internal audit
- Organisational audit – external, independent + voluntary
- Clinical audit – looks in detail at outcomes of specific healthcare intervention
- Laboratory audits
All audits share certain components

- Examine, evaluate and report on findings
- Concerned with ensuring best possible performance
- Examine use of resources
- Involve time, effort and careful planning
- Involve comparing practice with standards/evidence
HISTORY

• 1750 BC, King Hammurabi, sixth king of Babylon instigated audit for clinicians

• Punished for poor performance.
• One of the first clinical audits was undertaken by Florence Nightingale in 1854 during the Crimean War

• She and her team of 38 nurses applied strict sanitary routines and standards of hygiene

• Reduced mortality rates from 40 % to 2%
• Another famous figure who advocated clinical audit was Ernest Codman, an orthopaedic surgeon at HARVARD Medical School.

• Known as the first true medical auditor for his work in 1912 on monitoring evidence of surgical outcomes.

• Codman followed up every patient’s case history after surgery to identify individual surgeon’s errors on specific patients.
Despite the successes of Nightingale and Codman, clinical audit remained dormant for more than a century.

**UK**: Clinical Audit was incorporated within Clinical Governance in **1997**.

Following this, the Royal College of Pathologists established a Professional Standards Unit to advise and help pathology departments and pathologists to meet quality standards in line with 6 pillars of clinical governance.
ISO 15189 & Evidenced Based Laboratory Medicine

• Evidenced based medicine evolves from quality improvement initiatives
• Significant overlap between methodologies of EBM + quality management
• Primary aim of both: improve clinical effectiveness + patient outcome
• Effectiveness of laboratory service is also referred to the new ISO 15189.2012 standard for medical labs
• This refers to the best achievable outcome of service delivery in routine circumstances
Figure 1  Evidence-based laboratory medicine and audit.¹⁷
Place of laboratory based audit in clinical practice

• Comes under clinical governance umbrella and is part of quality management and accreditation

• **Clinical governance**: system in which pathology laboratories are accountable for improving quality of services

• Includes clinical effectiveness, research and development, risk management, education, training and **audit**
What are audits used for in the laboratory?

- Provide evidence on the quality of care and service being provided
- Enables laboratories to use processes to gather evidence that the quality requirements are being met
A laboratory based audit should demonstrate evidence of one of the following:

- Benefit to patient care
- Benefit to health care professionals
- Benefit to the pathology service
- Continuing high quality of pathology service
- Deterioration in pathology service
- Continuing underperforming pathology service
DEFINITION

A laboratory based clinical audit may be defined as ....

"a quality improvement process that seeks to improve patient care and outcomes through systematic review of pathology services that impact on patient care against explicit criteria and the implementation of change”.

Aspects of the structures, 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.
Laboratory Audit: The Process

• Cycle or spiral

• Within the cycle there are stages
  • Establishing best practice
  • Measuring against evidence
  • Taking action to improve quality
  • Monitoring to sustain improvement
The Audit Cycle

Decide on criteria for good practice
Should be evidenced-based.

Set Standards
Should be evidenced-based, realistic taking into account local environmental, social and cultural factors.

Compare
Practice against standard

Compare
Practice against standard

Intervention
Decide and implement any necessary changes.

Fig. 1: The audit cycle
Clinical Audit – the process

Stage 1: Identify problem or issue
Audit Planning and Process

• Ensure that audit design is appropriate to the topic and applicable

• Consult literature

• Sample should be small enough for rapid data acquisition, but large enough to be representative

• Number of cases should reflect commonness of condition and use of tests
How to choose an Audit Topic (1)

• Audits should look at one of the following:

  • **Structure**: resources important for delivery of laboratory tests which have an impact on patient care

  • **Process**: the laboratory investigations itself

  • **Outcome**: what happens to the patient i.e. impact of lab testing (measurable change in health status e.g. mortality and morbidity rates, quality of life indicators.) Measuring outcome is usually complex
How to choose an Audit Topic (2)

- Are there areas where problems have been identified?
- What do our customers think we should look at?
- Where is the clear potential for improving service delivery?
- Where do national standards or guidelines (evidence) exist?
- What high cost areas are there where an audit might identify ways to save money?
- What high risk activities do we undertake where an audit might show up problems and potential for improvement?
Stage 2: Define criteria + standards

- Overall purpose of the audit should be written out as a series of statements or tasks that the audit will focus on.
- Criteria are explicit statements that define what is being measured.
- Standards define the degree to which aspects of laboratory testing should achieve and should always be based on best available evidence.
Stage 3: Data Collection

- Ensure that data collected are precise

- Quantitative data usually collected - audit is about collecting hard facts i.e. how many, how often, to what end + linking it to standards of good practice

- Precise time period

- Data can be collected retrospectively (from computer system or case notes) or prospectively
Stage 4: Compare performance with criteria and standards

- How well the standards were met is determined and reasons for not meeting standards defined

- Theoretically, where standards are not met in 100% of the cases there is potential for improvement
Stage 5: Implementing Change

• Once results have been discussed, agreement must be reached about recommendations for change.

• Action plans need to be developed jointly with other departments without apportioning blame.

• Action plan development may involve refinement of the audit tool particularly if initial measures were incorrectly assessed.
Stage 6: Re-audit: Sustaining Improvements
Similarities between audit and research

• Both aim to answer a specific question relating to quality

• Both can be carried out retrospectively or prospectively

• Both involve careful sampling, questionnaire design + analysis of findings
## Audit versus Research

### Audit

- Are we are achieving the outcomes we have agreed we should be achieving.
- “Are we following agreed best practice?”
- Audit is about quality i.e. if best practice is being followed

### Research

- Is about creating new knowledge.
- “What is best practice?”
- Research is about obtaining new knowledge
Interface between Audit and Research

- Research can identify areas for audit
- Audit may occur as a final step of good laboratory based research program
- Alternatively, research could be viewed as a precursor to the audit process
- Audit can pinpoint areas where research evidence is lacking
- Audit process assists with the dissemination of evidence-based practice
- Audit can look at outcomes e.g. monitor success of treatment which is known to work rather than to find out whether it works
Audits have been used for:

- Developing standardised protocols for specialised investigations
- Establishing therapeutic ranges
- Recommending tests for screening purposes
- Evaluating performance of diagnostic tests
- Establishing and setting turnaround times for tests in various settings
- Investigating methods and their reliability for specific
- Investigating appropriate use of tests in various disease states
- Investigating assay requirements
- Investigating test strategies
- Investigating and introducing uniform methodology
- Investigating laboratory practice
**Box 1 Areas of audit in the laboratory**

**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 (e.g., types of reports, direct communication, computer system)
- Reference ranges
- Interpretation, consultation and comments on reports
- Complaints and corrective action taken
Conclusion

• Audits are essential and in some instances mandatory in pathology for evaluation of the service we provide for patient care

• Audits can form part of a research project in which current practice is identified

• For an audit to be complete, deficiencies need to be rectified and the whole process re-audited / sustained
It is the quality of our work which will please God and not the quantity

Mahatma Gandhi

*Preeminent leader of Indian nationalism*