10 Auditing research and planning for the future

10.1. What is audit?

Audit is a process used to assess the performance of a function or service by comparing it with set criteria. Most people are familiar with financial audit but clinical audit is an essential element of modern healthcare.

A short definition of clinical audit: is 'improving the quality of patient care by looking at current practice and modifying it where necessary'. A more comprehensive definition comes from the UK National Institute for Health and Clinical Excellence:

- 'Clinical audit is 'a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. 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.'

Clinical audit can take many forms in modern healthcare. Examples include:

- Assessing facilities for patients compared to guidelines
- Comparing clinical outcomes against national standards
- Comparing patient treatment times against local targets
- Assessing performance against local quality management standards

In laboratory medicine audit is central to quality management. Laboratory accreditation against the international standard ISO 15189:2012 requires laboratory management to define standard operating procedures and performance standards for all laboratory functions. Evidence of compliance with those procedures and standards is obtained by a planned series of audits undertaken by individuals not directly involved in the specific procedure or standard.

The components of audit are:

- Identifying the topic to be audited
- Defining the standards against which the audit will be performed
- Collecting data
- Data analysis to compare performance with standards
- Applying change
- Review impact of change

To be of value the audit cycle should be closed, which means reviewing the audit once change has been implemented to confirm that it has addressed the original topic. Therefore, audit may be considered as a continuous rather than a 'one-off' process.

Together these components constitute the well-known audit cycle, depicted in Figure 10.1.

10.2. Auditing research

New researchers may often be confused by the difference between research and audit. As a result it is fairly common for a medical student to think that he/she is doing research when he/she is performing a clinical audit. This is because the process involved in research and audit is similar. However, the fundamentals of research and audit differ as may be seen from the statement that: 'Research is concerned with discovering the right thing to do; audit with ensuring that it is done right'. The main differences between research and audit are recorded in Table 10.1.

Figure 10.1. | The audit cycle

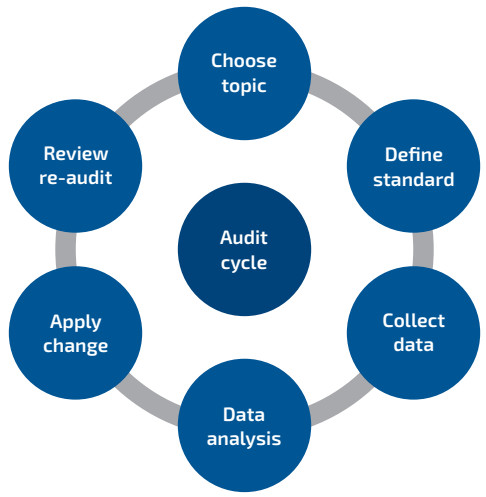

Table 10.1. | Fundamental differences between research and clinical audit

Research	Clinical audit
Based on hypotheses; creates new knowledge	Based on facts, which form the standards for the audit
Involves novel approaches to problem solving	Involves the application of standard techniques to data
Must comply with research governance, including research ethics	Should be registered with the local clinical audit committee

This section deals with the application of audit techniques to a research project.
The application of audit to research is a logical and helpful way to assess the effectiveness of a research project. Auditing research facilitates the optimal use of precious resources and allows for modifications in the project that will help to improve outcomes within the parameters of the original aims and objectives. It is the aims and objectives that form the criteria against which the audit is performed.

To be of value audit of a research project should not be left until the end of the project. At that stage it is too late to realise that one or more aims and objectives have not been met by the investigations performed. There are no hard and fast rules for the timing of audit in a research project but it is logical to perform an audit of performance against an objective when the investigations performed in support of that objective are complete or at an advanced stage. With this approach the general audit cycle may be modified to apply to research audit as depicted in Figure 10.2.

Another consideration to add value to audit of a research project is the involvement of someone other than the primary researcher. For a new researcher it is appropriate for the research supervisor to lead the audit. For a more experienced researcher this is a role for the research mentor.

Figure 10.2. | Auditing research

10.3. Recording and analysing audit findings

The use of a template is recommended for recording and analysing the findings of audit of a research project. A completed template serves as a record of the audit, which can be held both by the researcher and the person who led the audit. The template can also be used to reassure the employing authority and/or the grant awarding body that the research project is being conducted under good standards of research governance.

There are many variations of template available and researchers may be advised to adopt the template that is preferred locally. Table 10.2 sets out a simple template that can be adapted for any research project. One benefit of the template in Table 10.2 is that it allows for updating following review and re-audit, effectively closing the link. Some research institutions may like to see completed audit templates signed to indicate acceptance of the findings.

Table 10.2. | Simple template for recording audit of a research project

Title of research project:
Date of audit:
Who was involved in the audit? (List of people including designation)
Research objective being audited: (This should include a brief description of the reason for selecting the topic)
Criteria: (This section identifies the aspects which you are going to measure and should be clearly defined)
Analysis and findings: (This section should outline the level of compliance achieved against the objective and if full compliance not achieved an explanation of why. What was learnt from the data collection?)
Conclusions and reflections from the audit: (What changes are needed? How will changes be implemented; who will do this and when?
Re-audit date: (Suggest appropriate time period for evaluating impact of any change)
Re-audit findings: (The re-audit report should include the date of second data collection, the Standard achieved and whether further action is required)

10.4. Planning for the future

The appeal and excitement of research to most scientists lies partly in the satisfaction of proving a hypothesis that may help improve patient care, and partly in the unpredictable nature of research. Even the most tightly designed and controlled research projects are capable of throwing up unexpected results, which stimulate further research questions. It is rare for a research project to finish without the researcher being stimulated to consider 'what happens next?'
Examples of how a successful research outcome in laboratory medicine may stimulate further research questions include:

- A basic research finding that opens up a pathway or mechanism that influences understanding of pathophysiology
- The application of basic research findings to a clinical research project
- Evidence from a clinical research project that can be translated into routine clinical practice
- The opportunity to introduce a new method into the Laboratory Medicine repertoire
- Evidence from an epidemiological research project that prompts a hypothesis to explain a particular association

If the research project matches any of these examples then the researcher may wish to plan for one or more follow-up research projects. Such follow-up projects will involve new research questions and may involve new research collaborators.

Researchers should consider a systematic approach to planning for future research. One way to do this is to modify the cycle and the template adopted for auditing research so that they are applied to review of the original research question. Examples of how this may be achieved are recorded in Figure 10.3 and Table 10.3.

Planning future follow-on research takes the researcher back to earlier in this booklet (Figure 1.1) as he/she will be involved in:

- Reading and evaluating the scientific literature (Chapter 4)
- Formulating a research plan (Chapter 5)
- Submitting a research proposal for external approval and funding (Chapter 6)
- Conducting research investigations and analysing findings (Chapter 7)
- Writing research papers for publication (Chapter 8)
- Delivering research findings as posters or oral communications (Chapter 9)
- Auditing research and planning for the future (Chapter 10)

Figure 10.3. | Planning future research

Table 10.3. | Simple template for identifying follow-up research

Title of research project:
Date of final review:
Who was involved in the final review? (List of people including designation)
Research question being reviewed: (This should include a brief description of the reason for selecting the topic)
Criteria for review: (This section identifies the aspects which you are going to measure and should be clearly defined)
Analysis and findings: (This section should outline the level of compliance achieved against the research question. What was learnt from the data collection?)
Conclusions and reflections from the review: (What has been achieved? What unanswered questions remain?)
Suggested areas for follow-up research: (Suggest preparation required)

10.5. The final report

Many research funding bodies require a formal report at the end of the project. This report is evaluated to determine the outcomes for the project and whether they delivered value for money. The structure and format of this final report will vary according to the funding body and the researcher should ensure strict compliance. Writing the final report will be easier if the project has been audited as suggested in this Chapter.

10.6. References

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