Lesson 1.
An introduction to clinical audit

The word audit comes from the Latin word *audire* which means ‘to hear’. Through the audit process, you discover or more literally ‘hear’ what is happening in a specific area of patient care by comparing it to accepted guidelines and standards. It is only when you know exactly what is happening in that area (and what should be happening) that you can work out what is going wrong and how you can improve it (Box 1).

Box 1. The aims of audit
- To improve patient outcomes
- To promote the cost effective use of resources
- To provide education
- To empower health care staff
- To encourage reflection on one’s own practice

It is easy to be misled into thinking that you already know why there are shortfalls in patient care. However, it is only when you have properly investigated a problem through performing an audit that you can really understand the barriers to good patient care and how to overcome them.

A formal definition of clinical audit is as follows: ‘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’. The definition goes on to say: ‘aspects of the structure, process and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented to an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery’.  

The process of audit is typically described as an ‘audit cycle’ (Figure 1) and each part of the process will be described in a lesson in this book. The first
step is to identify the problem to be audited (lesson 2). Standards or criteria must then be set which describe the ideal practice (lesson 3). Once these have been identified, the cycle is entered. Information is gathered about what is currently done (lesson 4) and the data are analysed and compared with the standards originally set (lesson 5). If there are any deficits, methods of improvement should be decided upon. These changes should then be implemented and the process re-audited to assess whether the changes made have led to any improvements in care (lesson 6). Ideally, the cycle should go on and on, with a continuous process of re-evaluating the situation as time goes by. Each of these steps will be discussed in greater detail in the book. In the appendix at the back of the book, a number of worked examples are provided.
Common types of clinical audit

Critical incident or adverse event audit

Critical incident or adverse event audit involves the identification of patients where an adverse (bad) event or outcome, such as severe morbidity or death, has occurred. The management of these identified cases is reviewed by a panel of healthcare professionals to identify substandard care and to learn lessons for the future management of similar cases. It helps by identifying the avoidable factors in that particular case.

The best example of a critical event audit is the Confidential Enquiry into Maternal Deaths which was introduced in the UK as early as 1952. As maternal deaths are now rare in the developed world, cases of severe morbidity or ‘near misses’ are often audited instead.

Case notes review

The case notes review involves regular presentation of cases within units for analysis and discussion. It includes checking that all the necessary admission procedures were performed and how the current management was initiated. It often involves the presentation of rare or interesting cases – but the detailed review of a selection of regular patients is often just as revealing.

Criterion-based audit

Criterion-based audit is the most commonly used type of audit. It follows the steps of the classic audit cycle. The quality of care is assessed objectively against previously agreed criteria. The criteria are developed by a multi-disciplinary team using a systematic review of literature or evidence-based guidelines. This book focuses purely on this type of audit.

Classification of criterion-based clinical audit

Criterion-based audit can be classified into:

- **audit of structure** – examining the organisation or resources (what is available)
- **audit of process** – examining the activities themselves (what you do)
- **audit of outcome** – examining the effectiveness of activities on individuals and communities (what are the results).
Audit of structure

The term ‘structure’ relates to the actual facilities provided in a healthcare setting, such as buildings, theatres, staff or equipment. It may mean different things at different levels of the healthcare system. For example, at a district level you may ask whether there are enough health centres for the population while, within a hospital, you may want to know whether there are enough trained staff to run each ward or enough theatre beds to cope with the volume of work.

Audit of structure is sometimes regarded as an administrative area but it is just as important as that of process and outcome. Problems uncovered in the other audit types (process and outcome) commonly have their origin in a faulty structure.

Audit of process

Audit of process is the most frequently conducted type of clinical audit. It looks at the actual process of clinical care, examining whether there is ‘good practice’. Process audits can be divided into a number of specific areas:

- **Administrative**, such as delays in appointments, waiting times, cancelled clinics
- **Notes and correspondence**, such as completion and legibility of clinical notes, whether entries are signed, dated and timed, and whether appropriate information was provided on discharge
- **Resource usage**, such as the indications for use of a test such as ultrasound or of a particular antibiotic
- **Criteria used for diagnosis**, such as making a diagnosis of a urinary tract infection
- **Management of a clinical condition**, such as postpartum haemorrhage or pre-eclampsia – are they being managed in accordance with local guidelines?

Audit of outcome

An audit of outcome examines the final impact or results of the clinical care process. The result may be seen in its effect on an individual patient, on a group or on a whole community. For example, you might audit satisfaction rates among clinic attendees, the complication rates of surgery or the number of children who have been vaccinated against measles in your community.
This is indisputably the most important area to audit but it is often the most difficult to perform. As with all audits, the outcome measures have to be set against generally accepted standards. This is sometimes called ‘bench mark up’.

**Do we know that audit works?**

Clinical audit is a widely accepted process in Western clinical health care. Indeed, doctors in many developed countries are expected to complete audit as part of their routine duties. Clinical audit was studied extensively in the 1990s and is reviewed in a useful book called *Principles for Best Practice in Clinical Audit*, produced by the UK National Institute for Clinical Excellence.

There are many examples of audit working well to improve quality. Over 100 randomised clinical trials have now been conducted examining the effectiveness of audits of practice with feedback of the results to the staff. Disappointingly, they show only a ‘small to moderate benefit’ from this process. The review suggests, however, that the effect may be much larger when the baseline quality is low and when feedback is provided more intensively. This is supported by a large randomised trial in Argentina which has shown major benefits of a ‘multifaceted approach’ to behaviour change in labour ward practice. The intervention included selection of opinion leaders, interactive workshops, training of manual skills, one-on-one academic visits with hospital birth attendants, reminders and feedback. The effects were dramatic: the rate of prophylactic oxytocin use increased from 2% to 84% and the episiotomy rate decreased from 41% to 30% at hospitals receiving the intervention. The rates of both remained stable at control hospitals. These effects were still seen 12 months later.

In obstetrics, high-quality care is a key requirement for reducing maternal mortality and morbidity. Critical event audit was first introduced in the UK in the 1950s. This audit may have been partially responsible for the remarkable reductions in maternal mortality at this time. Since then, health care in the UK has advanced and the focus of audit has moved to improving morbidity rates, cost effectiveness and patient satisfaction.

There have been fewer audits conducted in low-resource settings, even though the evidence above suggests that this is where they may have the most effect. Indeed, there have been dramatic improvements in the quality of care demonstrated in some settings. In Uganda, the authors conducted a criterion-based audit into pre-eclampsia care and found impressive improvements in process indicators with few associated costs. Similar improvements have been reported in Tanzania, Mozambique and Ghana. The audit project in Ghana
first coined the phrase ‘holding up a mirror’ because the very process of clearly seeing your own practice made you want to improve.

The experience of those conducting audit in low-resource settings is that, as well as being effective, the process can be both low cost and empowering for the health workers. In the Ugandan Audit in Maternity Care project, the project from which this book stems, the empowerment of health workers involved was clearly evident:

‘Staff at all levels found that problems that they thought required large amounts of money and the work of powerful politicians to solve can often be tackled from below. Often an apparently insurmountable problem can be improved by surprisingly simple acts – a guideline posted on the labour suite wall, the repair of a broken machine, allowing women to keep their placentas after delivery as an incentive for institutional delivery, making accessible the equipment from the ward sister’s cupboard and regularly checking stocks. Because these small improvements can be made cheaply and by many members of staff, the combined effect can be impressive.’

Graham points out that, although sometimes substandard care is caused by the need for additional drugs and equipment, improving it is not inherently expensive in a setting where basic amenities are available. Rather, it is usually caused by delays in starting appropriate care: drugs must be located or purchased or unlocked, operating rooms must be cleaned, doctors and other key staff must be found.

Who should do audit?

Everyone! Audits can range from very simple and small to massive and complicated. They can be performed by those inside an organisation or by an external group. They can be carried out by anybody: not just doctors, nurses and midwives but also students, allied health professionals, support staff and clerical workers. Anyone involved in patient care can and should be involved in the audit process.

The audit process is adaptable to all situations, as it does not give standard answers but enables those performing it to develop local solutions to local problems. It is therefore relevant to all healthcare providers within all parts of the system, from nursing and midwifery assistants to teaching hospital con-
What is the difference between audit and research?

Research is the systematic and rigorous process of enquiry that aims to describe processes and develop explanatory concepts and theories to contribute to a scientific body of knowledge. Research aims to discover something new or to find out whether an untested technique actually works. Audit is about maintaining and achieving quality, through review, monitoring and evaluation against agreed standards. Put simply, research discovers what we should be doing while audit checks to see whether we are doing it. An outline of the differences between research, audit and service evaluation are shown in Table 1.

Clinical audit is not…

Blame

Every occurrence of substandard care is multifactorial, without exception. Blame is a concept that should not enter the discussion within audit. It is not useful, as it focuses all the attention on one person rather than analysing the processes and people that allowed the deficit to occur. When this happens, the system which allowed for the error will not be improved and the error is sure to repeat itself. When a serious error occurs resulting in a bad outcome, there are inevitably many people and processes involved and all could have stopped the bad outcome from occurring. But the same is true for even simple human error like prescribing the wrong medication: even simple drug errors should be preventable.

Let’s examine the reasons why a patient might be given the wrong drug. One doctor may have prescribed the wrong drug and it may be tempting to simply blame this doctor. But human errors will always occur and there should have been a variety of back-up systems in place to prevent accidents occurring as a result of human error. Human error should be minimised by the doctors being alert and fresh – this is unlikely after a long weekend on call with little sleep. There should be guidelines easily available to check drug doses and senior doctors available in case of uncertainty. There should be two nurses to check the drug, both of whom should have spotted the error and
alerted the doctor. The pharmacist should also check the drug. The patient also has some responsibility to ask what the drug is for and why they need it. So there should be a variety of checks in place.

Table 1. The differences between research, audit and service evaluation (derived from the UK National Research Ethics Service leaflet, *Defining Research*)

<table>
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<tr>
<th>Research study</th>
<th>Audit</th>
<th>Service evaluation</th>
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<tr>
<td>The attempt to obtain new knowledge. Includes studies that aim to generate hypotheses, as well as studies that aim to test them.</td>
<td>Designed and conducted to produce information to inform delivery of best care.</td>
<td>Designed and conducted solely to define or judge current care.</td>
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<td>Quantitative research: designed to test a hypothesis. Qualitative research: identifies and explores themes following established methodology.</td>
<td>Designed to answer the question: ‘Does this service reach a predetermined standard?’</td>
<td>Designed to answer the question: ‘What standard does this service achieve?’</td>
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<tr>
<td>Addresses clearly defined questions, aims and objectives.</td>
<td>Measures against a standard.</td>
<td>Measures current service without reference to a standard.</td>
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<td>Quantitative research: may involve evaluating or comparing interventions, particularly new ones. Qualitative research: usually involves studying how interventions and relationships are experienced.</td>
<td>Involves an intervention already in use chosen by the healthcare professional and patient.</td>
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<td>Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.</td>
<td>Usually involves analysis of existing data but may include administration of simple interview or questionnaire.</td>
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<td>Quantitative research: study design may involve allocating patients to intervention groups. Uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.</td>
<td>No allocation to intervention groups: the healthcare professional and patient have already chosen the intervention.</td>
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<tr>
<td>May involve randomisation.</td>
<td>No randomisation.</td>
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<tr>
<td>Usually requires ethical review.</td>
<td>Does not normally require ethical review.</td>
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Human errors will always occur but a good healthcare system will have enough checks in place to prevent them leading to disaster. Even if it seems obvious that one person is to blame for a mistake, pointing the finger at them will probably not improve the situation. Another practitioner may well make the same error when put into the same situation. It is very easy to think ‘I would never do that’ but, if the process is flawed, it may be that you would. Audit should therefore always focus on the process rather than the individual.

**Inspection from authorities**

Audit should empower those working day to day to see an element of practice that could be improved and work out how best to improve it. This is most successfully performed ‘in house’ where local solutions to local problems can be found. External inspections decrease morale, detract attention from clinical care and make staff defensive. If they cannot be avoided, then best to make them unannounced and supportive. The best audits however come from within the local organisation.
Exercises

Exercise 1: The meaning of audit

1. Discuss the meaning of audit.
2. What is the definition of audit?
3. Look at the definition of audit on page 1 carefully and discuss the meaning of each of the following:
   - ‘critically’
   - ‘systematically’
   - ‘own professional activities’
   - ‘commitment to improving performance’
   - ‘quality of care’
   - ‘cost-effectiveness of care’.
4. What other types of audit have you heard of? In what ways are they the same as clinical audit?

Exercise 2: The audit diagram

1. Complete the audit diagram on the next page:
2. Discuss each box in turn:
   - What does each step mean?
   - How can each step be completed?
   - How can you organise your organisation so that a continuous cycle is set up?
3. Discuss each box in turn:
   - What problems could you have with an audit?
   - How could each step produce conflict, errors or bad feeling?
   - How can these be avoided?