Royal College of Obstetricians and Gynaecologists

Setting standards to improve women's health

Clinical Governance Advice
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# UNDERSTANDING AUDIT

## 1. Background

Clinical governance provides a framework for accountability and quality improvement. While research is concerned with discovering the right thing to do, audit is concerned with ensuring that the right thing is done.[1] *A First class service*[2] outlined structures within the National Health Service (NHS) for setting standards: the National Institute of Clinical Excellence (NICE) and the National Service Frameworks (NSF); and monitoring performance: the Commission for Health Improvement (CHI) and the Performance Assessment Framework (PAF). Analogous mechanisms have been established in Scotland.[2] Modifications have been under way in response to the Kennedy report,[3] which recommended bringing together national audit and assessment activity within a single independent organisation, the Commission for Healthcare Audit and Inspection (CHAI) in April 2004.[4] This organisation will provide external audit and quality assurance mechanisms for the NHS.

National clinical audit funding will cover central costs (e.g. database design, tools for data collection, transmission and feedback), data analysis, 'benchmarking', project management and administration. This funding will not cover local data collection or resource implications of change. However, as good medical practice, individual doctors are required to undertake clinical audit.[5] NHS trusts are required to ensure that hospital doctors take part in national clinical audits, confidential enquiries and audit programmes endorsed by the CHI. Obstetricians and gynaecologists therefore need to understand the principles of clinical audit. In this document, the issues surrounding audit methodology, organisation and implementation of change are discussed.

## 2. Definition

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.[6]

## 3. Evidence

A review of the evidence by NICE concluded that audit is an effective method for improving the quality of care. The same review also described the audit methods associated with successful audit projects.[6] These findings are drawn upon in this document to give practical advice for undertaking audit.

## 4. What can be audited?

Audit may evaluate the structure (organisation or provision) of services, the process of care or the outcome of care against an agreed standard.

### *4.1 Measure of structure or service provision*

Audit can provide an overview of service provision. For example, research evidence shows that the outcome for patients with ovarian cancer is better if they are operated on by an appropriately trained gynaecologist and managed within the framework of a multidisciplinary team.[7–9] An audit of the referral and management of patients with ovarian cancer can provide an overview of service provision in this area. Good quality healthcare services need to be patient-centred and acceptable to those who use them. Measuring the views of those who use services enables healthcare providers to assess the service delivered from the patient's perspective.

### *4.2 Process measure*

Process measures are clinical practices that have been evaluated in research and shown to have an influence on outcome. For example, research evidence shows that the use of antenatal steroids has improved perinatal outcome. Evaluation of this process of care would entail measuring the proportion of appropriate women who received antenatal steroids. Process measures may be used to assess the quality of care and have some advantages over outcome measures:

- they provide a more direct measure of the quality of care provided
- they occur more frequently, so smaller samples are needed
- the findings are easier to interpret
- as smaller audits are needed, they cost less to achieve.

### *4.3 Outcome measure*

Outcome measure is the physical or behavioural response to an intervention; for example, the health status (dead or alive), cure following surgery for stress incontinence, level of knowledge or satisfaction (e.g. users' views on the care they have received). Outcomes can be desirable; for example, improvement in the patient's condition or quality of life, or undesirable, e.g. adverse effects of a treatment. The assessment of outcomes such as cancer survival rates is fundamental to measuring quality of care but the use of outcomes alone in assessing quality of care has limitations:

- outcomes are not a direct measure of the care provided; ascribing causal factors to variation in care may be problematic, e.g. social and health inequalities may contribute to variation in mortality rates
- not all patients who experience substandard care will have a poor outcome
- many factors contribute to eventual outcome (e.g. disease severity, health status and social and health inequalities); therefore, mechanisms to account for these differences are required (e.g. case-mix adjustment for co-morbidity)
- outcomes may be delayed
- research evidence about the impact of some care processes on outcome is limited
- adverse outcomes occur less frequently so larger samples will be needed.

Despite all the difficulties associated with the interpretation of outcome measures, mortality and morbidity measures are important and this is a major justification for regular monitoring. 'Critical incident' or 'adverse event' reporting involves the identification of patients where an adverse event has occurred, such as the Confidential Enquiries into Maternal Deaths (CEMD), the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) and the

National Confidential Enquiry into Perioperative Deaths (NCEPOD).[10] These are examples of outcome reporting. However, only adverse events are reported.

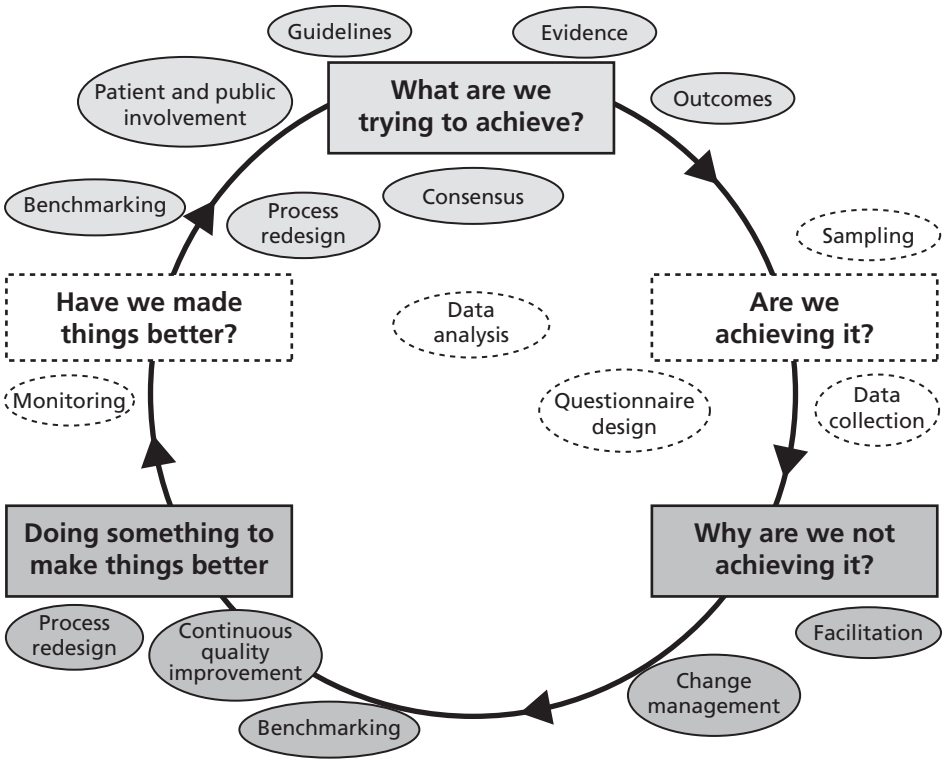


**Figure 1.** The Clinical audit cycle

## 5. The audit cycle

Audit can be considered to have five principal steps, commonly referred to as the audit cycle (Figure 1):

- selection of a topic
- identification of an appropriate standard
- data collection to assess performance against the prespecified standard
- implementation of changes to improve care if necessary
- data collection for a second, or subsequent, time to determine whether care has improved.

Audit projects require a multidisciplinary approach with the involvement of stakeholders (including consumers or users of the service provided) and the local audit department at the planning stage. Good planning and resources are also necessary to ensure its success.

### *5.1 Selection of a topic*

It is essential to establish clear aims and objectives at this stage so that the audit is focused and addresses specific issues within the selected topic. A key consideration is 'how will we use the results of this audit to change or improve practice?'.

In selecting a topic for audit, priority should be given to common health concerns, areas associated with high rates of mortality, morbidity or disability, and those where good research evidence is available to inform practice or aspects of care that use considerable resources. It is important to involve those who will be implementing change at this stage of the audit process.

## 5.2 *Identification of an appropriate standard*

### 5.2.1 Review criteria

These are defined as 'systematically developed statements that can be used to assess specific healthcare decisions, services and outcomes'. In audit, review criteria are generally used for assessing care; this approach is sometimes referred to as criterion-based audit. The criterion is the reference point against which current practice is measured. High-quality evidence-based guidelines can be used as the starting point for developing criteria. Where this is not possible, criteria should be agreed by a multidisciplinary group including those involved in providing care and those who use the service. Where criteria are based on the views of professionals or other groups, formal consensus methods are preferable. Review criteria should be explicit rather than implicit and need to:[6]

- lead to valid judgements about the quality of care, and therefore should be based on research evidence about the importance of those aspects of care
- relate to aspects of care that are important either to patients or in terms of clinical outcome
- be measurable.

Examples of audit topics and review criteria are given in Table 1.

**Table 1** *Examples of audit and review criteria*

| Audit topic | Review criteria |
|---|---|
| Induced abortion | Screening for lower genital tract organisms and treatment of positive cases among women undergoing induced abortion should be carried out to reduce post-abortion infective morbidity |
| Caesarean section | A thromboprophylaxis strategy should be part of the management of women delivered by caesarean section |
| Hysterectomy | Transcervical resection of the endometrium or endometrial ablation should be available and offered to women with dysfunctional uterine bleeding as an alternative to hysterectomy |

### 5.2.2 Standard and target level of performance

This is defined as 'the percentage of events that should comply with the criterion' (e.g. the proportion of women undergoing induced abortion who were screened for lower genital tract organisms, the proportion of women delivered by caesarean section who received thromboprophylaxis, the proportion of women with dysfunctional uterine bleeding who were offered transcervical resection of the endometrium or endometrial ablation). Information about the levels of performance that can be achieved may be helpful when making plans for improvement. Target levels of performance should be examined periodically. The most common approach for setting target levels of performance is informal agreement among the group leading the audit or among health professionals. In some settings, external standards can be useful. However, in many audits no explicit targets are set and the aim is to improve upon current performance.

Target levels of performance have been most used in screening programmes. For example, in screening for cervical cancer there are quality criteria to be met, such as the proportion of cervical smears that have endocervical cells.

The term 'standard' has been used to refer to different concepts, sometimes as an alternative word for 'clinical guidelines' and 'review criteria', either with or without a stated target level of performance and, somewhat confusingly, also to refer to the observed or desired level of performance. However, it has been defined as 'the percentage of events that should comply with the criterion' in the interests of clarity.

### 5.2.3 Benchmarking

This is the 'process of defining a level of care set as a goal to be attained'. There is insufficient evidence to determine whether it is necessary to set target levels of performance in audit. However, in some audits, benchmarking techniques could help participants in audit to avoid setting unnecessarily low or unrealistically high target levels of performance. Reference to the levels achieved in audits undertaken by other professionals is useful. National audits may provide data for benchmarking. For example, the National Sentinel Caesarean Section Audit Report[11] gives regional and national data for comparison on topics such as the use of regional anaesthesia in women having caesarean section.

## *5.3 Data collection to assess performance against the pre-specified standard*

Data collection in criterion-based audit is generally undertaken to determine the proportion of cases where care is in accordance with the criteria. In practice, the following points need to be considered.

### 5.3.1 What data items to collect?

Consideration needs to be given to which data items are needed in order to answer the audit question. For example, if undertaking an audit on caesarean section rates, collecting information on the number of caesarean sections alone will not give sufficient information to measure the caesarean section rate. Data on the number of other births that took place is also required. In general, for audit projects with clear aims, objectives and well-defined review criteria, it is easier to identify those data items that require collection. Definitions need to be clear so that there is no confusion about what is being collected. The definitions will depend upon the review criterion that is being assessed. For example, if collecting data on rupture of membranes, it may need to be specified whether this is spontaneous or artificial.

Data collectors should always be aware of their responsibilities to the Data Protection Act[12] and any locally agreed guidelines. There are also nationally agreed guidelines, known as the Caldicott Principles, a key part of clinical and information governance. The six Caldicott Principles are:

1. Justify the purpose(s). Every proposed use or transfer of patient-identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed by an appropriate guardian.
2. Do not use patient-identifiable information unless it is absolutely necessary.
3. Use the minimum necessary patient-identifiable information. Where use of patient-identifiable information is considered to be essential, each individual item of information should be justified with the aim of reducing identifiability.
4. Access to patient-identifiable information should be on a strict need-to-know basis. Only those individuals who need access to patient-identifiable information should have access to it, and they should only have access to the information items that they need to see.
5. Everyone should be aware of their responsibilities. Both clinical and nonclinical staff should be aware of their responsibilities and obligations to respect patient confidentiality.
6. Understand and comply with the law. Someone in each organisation should be responsible for ensuring that the organisation complies with legal requirements.

Under the Data Protection Act 1998, it is an offence to collect personal details of patients such as name, address, or other items that are potentially identifiable for the individual without consent. There seems to be consensus that clinical audit is part of direct patient care and therefore consent to use of data for audit can be implied through consent to treatment,

provided that information is given to patients that their data may be used in this way. It is rarely acceptable to use patient identifiers, such as names and addresses, but some form of pseudo-anonymised identifiers may be used. Audit project protocols should be submitted to the local research and development committee and ethics committees to seek approval if necessary. Guidance on how to do this is can be obtained from the respective bodies.

### 5.3.2 How to collect the data

Sources of data include:

- routinely collected data if available (e.g. birth registers); this enables repeated data collections with the minimum of extra effort
- clinical records
- data collection through direct observation or from questionnaire surveys of staff or patients.

Routinely collected data can be used if all the data items required are available. It will be necessary to check the definitions for data items that are used within the routine database to ensure its usefulness for the aims of the audit. Also, the completeness and coverage of the routine source needs to be known.

Where the data source is clinical records, training of data abstractors and use of a standard pro forma can improve accuracy and reliability of data collection. The use of multiple sources of data may also be helpful. However, this can also be problematic, as it will require linking of data from different sources with common unique identifiers.

Questionnaire surveys of staff or patients are often used for data collection. There are several validated questionnaires on a wide range of topics that may be adapted to a specific audit project. There is also literature on developing these (see Appendix).

### 5.3.3 Who will collect the data?

Thought needs to be given to who will collect the data, as well as the time and resources that will be involved. In small audit projects it may be feasible for the principal investigators to go through clinical notes for data abstraction. However, for larger projects, e.g. a prospective audit on induction of labour practices within a maternity unit, it may be more appropriate for those involved in the care of the woman giving birth (e.g. midwives or obstetricians) to fill in standard data collection sheets. Where available, audit support staff should be involved.

### 5.3.4 Data management

Data that are collected on paper forms are usually entered on to electronic databases or spreadsheets such as Microsoft Access®, Epi Info® or Microsoft Excel® for cleaning and analysis. Data entry may be done by optical character recognition (OCR) software, optical mark readers (OMR) or manually. OCR is most accurate for questionnaire data using tick boxes but less accurate for free text responses. The method of data entry needs to be taken into account when designing the questionnaire or data collection sheet. For manual data entry, accuracy is improved if double data entry is used. However, this can be a time consuming exercise. If the facilities and resources are available, electronic collection of data can be considered. In this case, data are entered immediately, at source, into a computer and saved to disk. While this is quick and requires minimal storage space, it can be difficult to handle unexpected responses. As information is entered directly into a computer it cannot be verified or double-entered.[13]

Consideration also needs to be given to the coding of responses on the database. For ease of analysis of closed questions it is generally better to have numeric codes for responses. For example, yes/no responses can be coded to take the value 0 for no and 1 for yes. Missing data

will also need to be coded; for example, with the number 9. The code assigned for missing data should be distinguished from those where the response is 'not known' (if this was an option on the questionnaire).

It is advisable to incorporate consistency checks as data are being entered, in order to minimise errors. For example, if there are two questions:

(a) How many previous pregnancies of at least 24 weeks of gestation has this woman had?
(b) How many previous caesarean sections has she had?

A consistency check will highlight entries with responses other than 0 to question (b) if the response to question (a) is 0.

### 5.3.5 Data analysis

Simple statistics are often all that is required. Statistical methods are used to summarise data for presentation in the form of summary statistics (means, medians or percentages) and graphs.[14] Statistical tests are used to find out the likelihood that the data obtained has arisen by chance and how likely it is that a real difference exists between two groups. Before data collection has started it is essential to know what data items will be collected, whether comparisons will be made, and the statistical methods that will be used to make these comparisons.

Data items that have categorical responses (e.g. yes/no or A/B/C/D) can be expressed as percentages. Some data items are collected as continuous variables; for example, mother's age, height and weight. These can either be categorised into relevant categories and then expressed as percentages or, if they are normally distributed, the mean and standard deviations can be reported. These summary statistics (percentages and means) are useful for describing the process, outcome or service provision that was measured.

Comparisons of percentages between different groups can be made using a chi-square test; t tests can be used to compare means between two groups, assuming that these are normally distributed. Nonparametric statistical methods can be used for data that are not normally distributed. These comparisons are useful in order to determine whether there are any real differences in the observed findings; for example, when comparing audit results obtained at different time points or in different settings. In some situations a sample-size calculation may be necessary to ensure that the audit is large enough to detect a clinically significant difference between groups, if one exists. In this situation, it is important to consult a statistician during the planning stages of the audit project.

These simple statistics can be easily done using Microsoft Excel spreadsheets and Microsoft Access databases. Other useful statistical software packages include Epi Info, SAS, SPSS, STATA and Minitab.

## *5.4 Implementation of changes to improve care if necessary*

Data analysis and interpretation will lead to the identification of clinical areas that should be addressed. There are many methods by which this can be done. The feedback of audit findings is most commonly used; for example, presentation at regular audit meetings will stimulate discussions and solutions may be agreed. The NICE review[6] identified several audits in which change in care had occurred. Simple methods were occasionally effective, for example:

- feedback of data collected
- provision of clear data, perhaps using modern information systems, supported by active teamwork
- support from the organisation for teamwork
- use of several methods together within the context of an implementation plan.

Change does not always occur in audit and consideration of the reasons for failure may take place after the second data collection. Resistance to change among local professionals or in the organisational environment or team should be considered. Patients themselves may have preferences for care that make change difficult.

The significance of teamwork, culture and resistance to change has led several authors to propose frameworks for planning implementation. These usually include analysis of the barriers to change and use of theories of individual, team or organisational behaviour to select strategies to address the barriers. For some topics, such as adverse incidents, systems for continuous data collection may be justified.

## 6. Organisation of audit

The NICE review[6] found that some methods of organising audit programmes were better than others. The following features are associated with successful audit:

- structured programmes with realistic aims and objectives
- leadership and attitude of senior management
- nondirective, hands-on approach
- support of staff, strategy groups and regular discussions
- emphasis on teamworking and support
- environment conducive to conducting audit.

### *6.1 Common reasons why audits fail*

- Failure to participate and attitudes to audit.
  Involving all stakeholders (including service users) in the project can encourage participation. It is important to recognise the attitudes of those whose behaviour is being audited, and to modify the audit process to accommodate these views.

- Failure to continue and complete the audit cycle.
  This makes it impossible to determine whether the audit has led to any improvements in care.

- Failure to provide a supportive environment for audit.
  Perceived lack of support at all stages, together with a range of structural and organisational problems, is associated with poor progress in conducting audit. Research has pointed to a theory–practice gap for clinicians carrying out audit, one solution being to change the organisational culture to one in which clinical audit is supported and actively encouraged.

- Lack of resources, especially time.
  This includes lack of protected time to investigate the audit topic, collect and analyse data, and the time to complete an audit cycle. It follows that audit should be recognised as an important part of clinical practice and those directly involved in audit need to be allocated protected time.

- Lack of training in audit methodology and evidence-based skills.
  Health professionals and audit support staff require adequate knowledge and skills for undertaking audit, and they should be keen to learn. Barriers identified in the literature include a lack of training in evidence-based audit skills and the failure to apply what has already been established.

- Cost.
  It must be recognised that audit requires appropriate funding and that improvements in care resulting from clinical audit can increase costs.

## Developing questionnaires

There is a large amount of literature on how to develop questionnaires.[15,16] Some of the general principles involved are presented here.

Questionnaires are often used as a tool for data collection. Questions may be open or closed. Generally, questionnaire design using open questions; e.g., "What was the indication for caesarean section?" (followed by space for free text response) is easier. However, analysis of these data is difficult, as there will be a range of responses and interpretation can be problematic. Open questions may be more difficult and time consuming to answer and can lead to non-reponse, which results in loss of data.

Questionnaires can be composed entirely of closed questions (i.e. with all possible answers predetermined). More time is needed to develop this type of questionnaire but the analysis is generally easier. An example of this type of questionnaire is:

Which of the following statements most accurately describes the urgency of this caesarean section?

A. Immediate threat to the life of the fetus and the mother.
B. Maternal or fetal compromise that is not immediately life threatening.
C. No maternal or fetal compromise but needs early delivery.
D. Delivery timed to suit the woman and staff.

Closed questions assume that all possible answers to the question are known but not the distribution of responses. Time and consideration needs to be given to the options available for response as, if a desired response is not available, the question may just be missed out and it may put people off completing the rest of the questionnaire. For some questions, the 'other' category can be used with the option 'please specify', which gives an opportunity for the respondent to write in a response. However, if this is used, thought must be given *a priori* as to how these free-text responses will be coded and analysed. In some situations, not having a category of 'other' may lead to the question not being answered at all, which means that data will be lost.

If questionnaires are developed for a specific project, they need to be piloted and refined to ensure their validity and reliability before use as a tool for data collection. While those who developed the questionnaire understand the questions being asked, the aim of piloting is to check that those who have to fill in the questionnaire are able to understand and respond with ease. Questionnaires that are not user friendly are associated with lower response rates, the quality of data collected will be poor and hence results will be of little value.

## References

1. Smith R. Audit and research. [see comments]. *BMJ* 1992;**305**:905–6.
2. Department of Health. *A First Class Service; Quality in the New NHS*. London: Department of Health; 1998.
3. Department of Health. Learning From Bristol: *The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary* 1984–95. London: Department of Health; 2001.
4. Commission for Health Improvement. Commission for Health Improvement response to Alan Milburn statement today. Media statement 18 April 2002. [www.chi.nhs.uk/eng/news/2002/apr/07.shtml] Accessed 11 September 2003.
5. General Medical Council. *Good Medical Practice*. London: General Medical Council; 2001.

6. NHS, National Institute for Clinical Excellence, Commission for Health Improvement, Royal College of Nursing, University of Leicester. *Principles for Best Practice in Clinical Audit*. Oxford: Radcliffe Medical Press; 2002. [www.nelh.nhs.uk/BestPracticeClinicalAudit.pdf] Accessed 11 September 2003.
7. Junor EJ, Hole DJ, Gillis CR. Management of ovarian cancer: referral to a multidisciplinary team matters. *Br J Cancer* 1994;**70**:363–70.
8. Woodman C, Baghdady A, Collins S, Clyma JA. What changes in the organisation of cancer services will improve the outcome for women with ovarian cancer? *Br J Obstet Gynaecol* 1997;**104**:135–9.
9. Department of Health. *The NHS Cancer Plan*. London: Department of Health; 2000.
10. Penney GC. Audit. In: O'Brien PMS, Broughton Pipkin F, editors. *Introduction to Research Methodology for Specialists and Trainees*. London: RCOG Press; 1999. p. 95–106.
11. Royal College of Obstetricians and Gynaecologists, Clinical Effectiveness Support Unit. *The National Sentinel Caesarean Section Audit Report*. London: RCOG Press; 2001.
12. Department of Health. *Data Protection Act 1998. Protection and Use of Patient Information*. London: Department of Health; 1998.
13. McKenzie-McHarg K, Ayres S. Data management. In: O'Brien PMS, Broughton Pipkin F, editors. *Introduction to Research Methodology for Specialists and Trainees*. London: RCOG Press; 1999. p. 140–6.
14. Brocklehurst P, Gates S. Statistics. In: O'Brien PMS, Broughton Pipkin F, editors. *Introduction to Research Methodology for Specialists and Trainees*. London: RCOG Press; 1999. p. 147–60.
15. Gillham B. *Developing a Questionnaire*. London: Continuum; 2000.
16. McColl E, Jacoby A, Thomas L, Soutter J, Bamford C, Steen N, *et al*. Design and use of questionnaires: a review of best practice applicable to surveys of health service staff and patients. *Health Technol Assess* 2001;**5**(**31**):1–256.

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