Clinical audit is a quality improvement process that aims to improve patient care and outcomes by carrying out a systematic review and implementing change. Aspects of patient care – including structure, processes and outcomes – are selected and evaluated against explicit criteria and, where necessary, changes are implemented at an individual, team or service level. Further monitoring can then be used to confirm the improvements in healthcare delivery. This definition is endorsed by the National Institute for Clinical Excellence (NICE).

Clinical audit provides the framework to improve the quality of patient care in a collaborative and systematic way, as outlined in current NHS policy statements.


Clinical governance presents a new challenge – to take audit ‘at its best’ and incorporate it within organisation-wide approaches to quality (see What is clinical governance?).

Topics for audit projects should reflect national and/or local targets; for example, in cancer services, coronary care or mental health. Projects may also need to focus on the implementation of National Service Frameworks (NSFs), Health Improvement and Modernisation Plans (HIMPs) or NICE guidelines and appraisals.

Clinical audit has a mixed history in the NHS. For it to become an important component in the management of health services, a change needs to take place in the standing of audit programmes. Audit can no longer be seen as a fringe activity for enthusiasts within clinical governance. Instead, the NHS needs to make a commitment to support audit as a mainstream activity.

Clinical audit, when it is conducted well, provides a way in which the quality of care can be reviewed objectively, within an approach which is supportive and developmental.
What is clinical audit?

Clinical audit should be an integral part of clinical practice. All clinicians want to provide the best possible care for patients, and clinical audit is one tool that can help this to happen in a systematic way. It can be a powerful tool for positive change, resulting in improved practice and outcomes for patients, and it has become integral to NHS policy.

- As a first step, clinical audit was integrated into clinical governance systems.\(^2\) (See What is clinical governance?)\(^3\)
- Full participation in clinical audit by all hospital doctors was subsequently made an explicit component of clinical governance.\(^2,4\)
- The NHS Plan\(^5\) took these policies further, with proposals for mandatory participation by all doctors in clinical audit, and support for the involvement of other staff, including nurses, midwives and therapists. Meanwhile, *Improving health in Wales*\(^6\) introduced annual appraisals to address the results of audit.
- Clinical audit in Scotland is a multiprofessional activity which is supported locally, but also nationally, by the Clinical Resource and Audit Group (CRAG) via effectiveness programmes and national audits. Standards for audit are increasingly being drawn from recommendations in the Scottish Intercollegiate Guidelines Network (SIGN) guidelines, and from topics selected by the Clinical Standards Board for Scotland (CSBS) for quality assurance.\(^7\) Current plans are that the CSBS, along with Scotland’s two other central clinical effectiveness organisations (the Health Technology Board for Scotland and the Scottish Health Advisory Service), will be integrated into a single new health board, NHS Quality Improvement Scotland.

The report of the public inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984–1995 (2001) highlights the importance of clinical audit.\(^8\) The General Medical Council now advises all doctors that they ‘must take part in regular and systematic medical and clinical audit, recording data honestly. Where necessary, you must respond to the results of audit to improve your practice, for example by undertaking further training’.\(^9\)

The Nursing and Midwifery Council (formerly the UKCC) stated that in clinical governance, assisting the co-ordination of quality improvement initiatives is ‘the business of every registered practitioner’.\(^10\)

The history of clinical audit

Clinical audit has a mixed history in the NHS. Many projects have been run into the ground without having demonstrated much of a contribution to the quality of services – but there have also been significant successes. Many local projects have provided a systematic structure through which clinical teams can deliver real improvements in patient care. In some cases, national projects have been able to play an important role in service-wide changes, improving access and quality of care throughout the country (the national audit of stroke care is the most well-known example).\(^11\)

In 1989, the White Paper *Working for patients* defined medical audit as ‘the systematic critical analysis of quality of medical care including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient’.\(^12\)

Medical audit later evolved into clinical audit and a revised definition was announced by the NHS Executive: ‘Clinical audit is the systematic critical analysis of quality of medical care including the procedures used for diagnosis, treatment and care, the use of resources and the resulting outcome and quality of life for the patient’.\(^13\)

NICE recently published *Principles for best practice in clinical audit*,\(^14\) which defines clinical audit as ‘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.

Box 1. Making clinical audit work

Audit cycle of the marking of breast wide local excision specimens
An audit was set up by Dr Lucy James at the Frenchay Breast Care Centre in Bristol to identify whether all breast wide local excision (WLE) specimens were being marked correctly prior to histopathological examination. The audit resulted in the introduction of a simple sticker as an adjunct to the standard pathology form, which improved standards for the marking of breast WLE specimens by 64.4%.

Marking of this type of specimen not only aids the pathologist in orientating the tumour within the surgical specimen, but also allows the surgeon to identify exactly which border requires further surgery if the histological examination reveals the tumour to be too near the excision margins. The greatest impact may be for the patient, however, as the cosmetic result will be more favourable if subsequent surgery is as conservative as possible.

Policy objective measured

- Reduce death/complications from cancers and their treatment

Indicator title

- NB1 4 node status
- Percentage of cases in which histological node status was ascertained
- Percentage of cases in which histological node status was ascertained by clearance or sampling of at least four nodes

Performance assessment framework (PAF) domain

- Effective delivery of appropriate healthcare (ED)

References

- COG recommendation 100%
- BASO standard 100%

Touch preparation cytology from breast core biopsies for one-stop diagnosis
Ultrasound-guided biopsy is rapidly replacing cytological diagnosis in the triple assessment of solid breast lumps. Touch preparations of 112 consecutive patients undergoing ultrasound-guided core biopsies were compared retrospectively with the core histological diagnoses. Results gave a sensitivity of 91%, a specificity of 95%, a positive predictive value of 99% and a negative predictive value of 72%, suggesting that touch preparation from ultrasound-guided core biopsy of solid breast lumps provides a reliable, accurate diagnosis in a one-stop clinic.

Policy objective measured

- Reduce death/complications from cancers and their treatment

Indicator title

- NB1 6 triple assessment
- Percentage of patients with breast cancer receiving triple assessment on first visit

PAF domain

- ED
- Fair access (FA)
- Efficiency (EF)
- Patient/carer experience (PEx)

References

- COG (should be available on first visit)
- BASO (less than 10% of patients should have to attend the hospital on more than two occasions for diagnostic purposes)

Types of audit

Standards-based audit – A cycle which involves defining standards, collecting data to measure current practice against those standards, and implementing any changes deemed necessary.

Adverse occurrence screening and critical incident monitoring – This is often used to peer-review cases which have caused concern or from which there was an unexpected outcome. The multidisciplinary team discusses individual, anonymous cases to reflect upon the way the team functioned and to learn for the future. In the primary care setting, this is described as a ‘significant event audit’.

Peer review – ‘An assessment of the quality of care provided by a clinical team with a view to improving clinical care’. Individual cases are discussed by peers to determine, with the benefit of hindsight, whether the best care was given. This is similar to the method described above, but might include ‘interesting’ or ‘unusual’ cases rather than problematic ones. Unfortunately, recommendations made from these reviews are often not pursued as there is no systematic method to follow.

Patient surveys and focus groups – These are methods used to obtain users’ views about the quality of care they have received. Surveys carried out for their own sake are often meaningless, but when they are undertaken to collect data they can be extremely productive.

Selecting an audit project

The clinical team has an important role in prioritising clinical topics, and the following questions may be a useful discussion guide.

- Is the topic related to high cost, volume or risk to staff or users?
- Is there any evidence of a serious quality problem; for example, patient complaints or high complication rates?
- Is good evidence available to inform standards; for example, patient surveys or national clinical guidelines?
- Is the problem amenable to change?
- Is sustainable improvement possible?
- Is there any potential for involvement in a national audit project?
- Is the topic pertinent to national policy initiatives?
- Is the topic a priority for the organisation?
What is clinical audit?

In many NHS organisations, a committee or clinical effectiveness/governance team decides which clinical audit projects should be undertaken each year. Their decisions are usually based on local health priorities which reflect national targets; for example, in cancer services, coronary care or mental health (see Box 1, page 3). Projects may also need to focus on the implementation of NSFs, HIMPs or NICE guidelines and appraisals. For example, in March 2002, NICE issued guidance on the use of selected therapies for advanced colorectal cancer. The guidance stated the following.

- On the balance of clinical and cost-effectiveness, neither irinotecan nor oxaliplatin in combination with 5-FU/FA are recommended for routine firstline therapy for advanced colorectal cancer.
- Oxaliplatin in combination with 5-FU/FA should be considered as firstline therapy in advanced colorectal cancer in patients with metastases that are confined solely to the liver and may become resectable (down-staged) following treatment.
- Irinotecan monotherapy is recommended in patients who have failed an established 5-FU-containing treatment regimen.
- On the balance of evidence relating to clinical and cost-effectiveness, raltitrexed is not recommended for the treatment of advanced colorectal cancer.

Box 2: The role of audit in the implementation of NICE guidance

In December 2001, the government issued directions making it mandatory for health authorities to act on NICE recommendations. Clinical audit programmes should now record the proportion of treatments adhering to NICE guidance.

Example 1: NICE Technology Appraisal Guidance No. 33: ‘Guidance on the use of irinotecan, oxaliplatin and raltitrexed for the treatment of advanced colorectal cancer’

In March 2002, NICE issued guidance to the NHS on the use of selected therapies for advanced colorectal cancer. The guidance stated the following.

- On the balance of clinical and cost-effectiveness, neither irinotecan nor oxaliplatin in combination with 5-FU/FA are recommended for routine firstline therapy for advanced colorectal cancer.
- Oxaliplatin in combination with 5-FU/FA should be considered as firstline therapy in advanced colorectal cancer in patients with metastases that are confined solely to the liver and may become resectable (down-staged) following treatment.
- Irinotecan monotherapy is recommended in patients who have failed an established 5-FU-containing treatment regimen.
- On the balance of evidence relating to clinical and cost-effectiveness, raltitrexed is not recommended for the treatment of advanced colorectal cancer.


In September 2001, NICE reviewed its guidance for taxanes in breast cancer and reinstated the original guidance that was issued in June 2000. The guidance stated the following.

- The use of docetaxel in combination with an anthracycline in firstline treatment of advanced breast cancer is not currently recommended. As paclitaxel is not licensed for firstline use with anthracycline, its use has not been considered in this indication.
- Docetaxel and paclitaxel are recommended as an option for the treatment of advanced breast cancer where initial cytotoxic chemotherapy (including an anthracycline) has failed or is inappropriate.
- The taxanes are not currently licensed in the UK for adjuvant treatment of early breast cancer and their use in this indication should, therefore, be limited to randomised clinical trials.

Clinical audit – the process

Clinical audit can be described as a cycle or a spiral – see Figure 1 (opposite). Within the cycle there are stages that follow the systematic process of:

- Establishing best practice;
- Measuring care against criteria;
- Taking action to improve care; and monitoring to sustain improvement. As the process continues, each stage aspires to a higher level of quality. Figure 2 (page 6) outlines the five stages of clinical audit, which involves the use of specific methods, but also requires the creation of a supportive environment.

Stage 1: Preparing for audit

National audit projects reviewed by NICE suggest that two broad areas of preparation must be addressed:

- Project management, including topic selection, planning and resources, and communication
- Project methodology, including design, data issues, ease of implementation, stakeholder involvement, and the provision of support for local improvement.

In practical terms, preparing for audit can be broken down into five elements:

- Involving users in the process (‘users’ include patients, carers and the groups and organisations that represent their interests)
- Selecting a topic
- Defining the purpose of the audit
- Providing the necessary structures
- Identifying the skills and people needed to carry out the audit, and training staff and encouraging them to participate.
What is clinical audit?

Stage 2: Selecting criteria/standards
In clinical audit, criteria or standards are used to assess the quality of care provided by an individual, a team or an organisation.11 These criteria are explicit statements that define what is being measured and represent elements of care that can be measured objectively.11

Recent government publications indicate that health professionals will be expected to develop criteria and standards that measure a wide range of aspects of quality, such as access to care and patient satisfaction.5,11

Criteria can be classified into those concerned with:11
● Structure (what you need)
● Process (what you do)
● Outcome of care (what you expect).

Stage 3: Measuring performance
To ensure that the data collected are precise, and that only essential data are collected, certain details of what is to be audited must be established from the outset.11 These are:11
● The user group to be included, with any exceptions noted
● The healthcare professionals involved in the users’ care
● The period over which the criteria apply.

Sampling is sometimes a contentious issue in audit. It is necessary first to define the population to which the audit applies; for example, all women presenting to the breast clinic during a specific year. However, it might be impractical to collect data on every single woman in the population, so a representative sample can be used instead. The necessary sample size can be calculated scientifically, as long as it is possible to estimate the proportion of patients who are likely to meet the criteria, and the level of confidence that is required in the results. Pragmatic sample sizes are more commonly used because of limitations in timescale and resources. A time frame is often used to define the sample: for example, all women referred to the breast clinic in a one-month period. Alternatively, a consecutive sample of patients might be used; for example, the last 100 referrals. It is important that all those likely to be affected by the audit results agree on the sample sizes and agree that they will act on the results.

Data are collected in order to measure current practice against agreed standards. Some data may already be available in computerised clinical information systems. In other cases, appropriate data may have been collected routinely by other methods. Where data are not routinely collected, or are held only in paper records, it may be necessary to devise a data collection form on which to record information (see Figure 3, page 7).11

The data collected should relate only to the objectives of the audit – do not be tempted to collect additional, ‘interesting’ information. Respect patient and staff confidentiality; identifiable information should not be used. Ethical consideration should also be given to the design of the project, and any potentially sensitive topics should be discussed with the local Research Ethics Committee, particularly where patients’ views are to be sought.

If the data collection strategy includes asking users/carers for their views, care must be taken in developing a questionnaire. It is a good idea to pilot the form on a number of users to ensure that it works. Simple statistical analysis is usually all that is required of audit data. Were the standards met? If not, why not?

Stage 4: Making improvements
Once the results of the audit have been published and discussed, an agreement must be reached about the recommendations for change. Using an action plan to record...
What is clinical audit?

these recommendations is good practice; this should include who has agreed to do what, and by when. Each action point needs to be well defined, with an individual named as responsible for it, and an agreed timescale for its implementation.

People have lots of good reasons to change ... and not to change. There are many strategies for altering behaviour to enable change. Kurt Lewin’s famous model of ‘unfreeze’ (obtaining consensus that a change is required), ‘move’ (making the change); and ‘refreeze’ (ensuring the change is embedded in practice) is a useful one.\(^\text{20}\) The best way to get everyone to agree that the change will be beneficial is to ensure that they participate in the whole process.

Aside from those individuals who will never agree to the need for change – regardless of the evidence – there are potential barriers to change in terms of resources, politics or environment. Change needs to be implemented in a systematic way, ensuring that communication and dissemination are sustained throughout the process.

Stage 5: Sustaining improvements

After an agreed period, the audit should be repeated. The same strategies for identifying the sample, methods and data analysis should be used to ensure comparability with the original audit. The re-audit should demonstrate that the changes have been implemented and that improvements have been made. Further changes may then be required, leading to additional re-audits.

Evidence suggests that multifaceted change strategies achieve the optimum maintenance of improvements. Feedback of results to clinicians (anonymously) can highlight achievements, while training and education help to ensure that new practice is embedded as routine. Dissemination of guidelines or protocols is useful if accompanied by training and awareness campaigns, and decision support or reminders may also help to introduce new practices effectively.

Conclusion

Increasing multiprofessional participation is the key to a successful audit. Successful audit means good-quality studies that are based on agreed, evidence-based standards of care, that have agreed outcomes and that achieve sustained improvements in care for patients.

Further reading


References

What is clinical audit?
Campto® (irinotecan hydrochloride trihydrate)

**Prescribing Information**

**Presentations:** Vials of concentrate for infusion containing either 40 mg or 100 mg irinotecan hydrochloride trihydrate.

**Indications:** Treatment of adult patients with advanced colorectal cancer. **Dosage & Administration:** Solution must be prepared aseptically. Campto should be administered as an intravenous infusion over 30 to 90 minutes. In first line: combination therapy of 180 mg/m² every 2 weeks followed by folinic acid and 5-fluorouracil; in second line: monotherapy 150 mg/m² every 3 weeks. Subsequent cycles should follow appropriate recovery of all adverse events to grade 0 or 1 NCI-CTC and resolution of diarrhoea. Dose reduction of 15-20% is recommended if patients experience grade 4 neutropenia, febrile neutropenia, thrombocytopenia, grade 4 leucopenia or grade 3-4 non-haematological toxicity. **Impaired hepatic function:** Monitor liver function regularly. Blood bilirubin levels (up to 3 times ULN) in patients who have not received prior treatment for liver disease is recommended. Patients with liver function impairment should not be treated with Campto. **Impaired renal function:** Not recommended. **Elderly:** Care due to the greater frequency of decreased biological functions. **Contraindications:** Chronic inflammatory bowel disease and/or bowel obstruction; severe hypersensitivity reactions to Campto; pregnancy; breastfeeding; severe bone marrow failure; WHO performance status > 2. **Warnings and Precautions:** Use in patients stabilised on oral contraceptives is recommended. Dose adjustments: Subsequent cycles should follow handling guidelines when preparing or handling Campto. **Legal category:** POM. **Pl Number:** 40 mg: 0012/0302, 100 mg: 0012/0303. **Basic NHS Price:** Campto 40 mg: £53.00; Campto 100 mg: £130.00. Further information is available on request from Aventis Pharma Ltd, 50 Kings Hill Avenue, West Malling, Kent. ME19 4AH.

**Last revision of text:** Jan 2002.

**Taxotere® (docetaxel)**

**Prescribing Information**

**Presentation:** Vials of concentrate for infusion containing 20mg docetaxel or 80mg docetaxel with accompanying vials of solvent. **Indications:** Locally advanced or metastatic breast cancer in combination with doxorubicin for patients who have not received prior treatment for that condition. Locally advanced or metastatic breast cancer after failure of cytotoxic therapy, which should have included an anthracycline or alkylating agent. **Dosage and Administration:** Taxotere is administered as a one-hour infusion every three weeks. The recommended dosage in breast cancer is 100 mg/m², or 75 mg/m² in combination with doxorubicin (50 mg/m²). The recommended dosage in NSCLC is 75 mg/m². Premedication with an oral corticosteroid is recommended. **Dosage Adjustments:** Subsequent cycles should follow handling guidelines when preparing or handling Campto. **Legal category:** POM. **Pl Number:** 40 mg: 0012/0302, 100 mg: 0012/0303. **Basic NHS Price:** Campto 40 mg: £53.00; Campto 100 mg: £130.00. Further information is available on request from Aventis Pharma Ltd, 50 Kings Hill Avenue, West Malling, Kent. ME19 4AH.

**Date of Revision:** May 2002.

---

*Sponsored by an educational grant from Aventis Pharma*
‘What is…?’ bulletins

faxback form fax no. 01732 584080

If you would like to receive more information about the What is…? series simply print out this form, fill in your details and fax it to: Team Assistant to the Health Economics Unit, Aventis.

Name: _____________________________________________________________

Position: __________________________________________________________

Address: __________________________________________________________

____________________________________________________________________

____________________________________________________________________

Postcode: _______________________________ (For mailing purposes a postcode must be supplied)

Tel: _______________________________ Fax: _______________________________

Email: _____________________________________________________________

www.evidence-based-medicine.co.uk