Clinical audit: A simple guide for NHS Boards & partners

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Executive summary

Whilst this guide is specifically about clinical audit, much of what is described here is relevant to the way in which NHS Boards can monitor clinical quality as a whole within the context of clinical or integrated governance.

Clinical audit has been endorsed by the Department of Health in successive strategic documents as a significant way in which the quality of clinical care can be measured and improved. Originally, clinical audit was developed as a process by which clinicians reviewed their own practice. However, clinical audit is now recognised as an effective mechanism for improving the quality of care patients receive as a whole. It offers a crucial component of the drive to improve quality. Boards have not always done enough in the past to measure quality, now they must do so, and clinical audit provides a mechanism for this.

There are a variety of related processes which also have a role in measuring and improving quality, such as confidential or significant event enquiries, patient surveys, research, peer review, internal audit and so on. None of these replace clinical audit and systematic clinical audit is the main way of assessing compliance of ongoing clinical care against evidence-based standards.

Clinical audit needs to be a strategic priority for boards as part of their clinical governance function. Clinical audit is effectively the review of clinical performance against agreed standards, and the refining of clinical practice as a result. It is one of the key compliance tools at a board’s disposal and has an important role within the assurance framework. Clinical audit needs to be carefully compared with, and is complementary to, internal audit; however they are different processes.

Boards have a role in driving quality assurance, compliance, internal audit and ‘closing the loop.’ They need to ensure that the recommendations of reviews and clinical audits are actioned by seeking assurance that improvements in care have been made. Ideally this should be part of an overall quality framework and should be reported in the trust’s publicly reported ‘Quality Accounts.’

Trusts will be regulated and performance managed against their participation in clinical audit and the findings.

Boards will want assurance that there is a clinical audit strategy in place that meets their strategic priorities:

• Meets national commitments and expectations.
• Prioritises local concerns.
• Integrates financial and clinical audit.

• Delivers a return on investment.
• Improvements are implemented and sustained.

A PCT has specific responsibilities in relation to clinical audit that should be managed through the Professional Executive Committee (PEC) or an equivalent committee.

Boards should use clinical audit to confirm that current practice compares favourably with evidence of good practice and to ensure that where this is not the case that changes are made that improve the delivery of care.

Clinical audit can:

• Provide evidence of current practice against national guidelines or NHS standards.
• Provide information about the structures and processes of a healthcare service and patient outcomes.
• Assess how closely local practice resembles recommended practice.
• Check “Are we actually doing what we think we are doing?”
• Provide evidence about the quality of care in a service to establish confidence amongst all of its stakeholders – staff, patients, carers, managers and the public.

Boards will want to be assured that clinical audits are:

• Material – i.e. that they are prioritised to focus on key issues and that the value outweighs the cost.
• Professionally undertaken and completed – i.e. clinical audits are undertaken and completed to professional standards including the quality of data being analysed.
• Producing results that are shared and acted upon.
• Followed by improvements that are made and sustained.

Boards have clear questions they should ask about any clinical audit programme in their trust. To advance clinical audit, roles and responsibilities need to be clearly established. The board’s role is to ensure that clinical audit is strategic; it happens regularly, is clinically and cost effective; and is linked to the Quality, Innovation, Productivity and Prevention (QIPP) agenda.

1. Use clinical audit as a tool in strategic management; ensure the clinical audit strategy is allied to broader interests and targets that the board needs to address.

2. Develop a programme of work which gives direction and focus on how and which clinical audit activity will be supported in the organisation.

3. Develop appropriate processes for instigating clinical audit as a direct result of adverse clinical events, critical incidents and breaches in patient safety.

4. Check the clinical audit programme for relevance to board strategic interests and concerns. Ensure that results are turned into action plans, followed through and re-audit completed.

5. Ensure there is a lead clinician who manages clinical audit within the trust, with partners/suppliers outside, and who is clearly accountable at board level.

6. Ensure patient involvement is considered in all elements of clinical audit, including priority setting, means of engagement, sharing of results and plans for sustainable improvement.

7. Build clinical audit into planning, performance management and reporting.

8. Ensure with others that clinical audit crosses care boundaries and encompasses the whole patient pathway.

9. Agree the criteria of prioritisation of clinical audits, balancing national and local interests, and the need to address specific local risks, strategic interests and concerns.

10. Check if clinical audit results evidence complaints and if so, develop a system whereby complaints act as a stimulus to review and improvement.
What is clinical audit?

The universally accepted definition for both national and local clinical audit as defined by the National Institute for Health and Clinical Excellence (NICE) in their ‘Principles for Best Practice in 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.”

NICE, 2002

Clinical audit is a key element of clinical governance. This guide sets out a range of actions and roles an NHS board should adopt to ensure that clinical governance supports the strategic direction of their organisation and enables them to promote and measure their commitment to quality. Much of what is described here, although specifically written about clinical audit, can be translated to apply to the way quality in clinical care is monitored and addressed.

Clinical audit should be seen as a continuous cycle of:

- Deciding which topics to audit.
- Measuring care delivered against standards.
- Acting on the findings – making improvements and changes.
- Sustaining improvements, including re-audit where necessary.

The re-invigoration of clinical audit has been set as a priority by the Department of Health (DH). In 2006 the Chief Medical Officer’s report, ‘Good Doctors, Safer Patients’ called for the reinvigoration of clinical audit to enable it to reach its potential as a rich source of information to support service improvement, better information for patients and other activities such as the revalidation of clinicians. In February 2007 the White Paper ‘Trust Assurance and Safety’ and in 2008 the Next Stage Review, ‘High Quality Care For All’ also recognised the crucial value of clinical audit in assessing the quality of clinical care and maintaining high quality professional performance. In the current NHS climate, the contribution of clinical audit is vital to achieve efficiency savings while improving the quality of service – a goal defined by the DH as a focus on quality, innovation, productivity and prevention (QIPP).

The rationale behind this is clear, but boards have been slow to recognise this opportunity and clinical focus at board level can still be described as modest.

The Burdett Report (2006) found that only 14% of items in meetings were rated as clinical. Trusts with higher levels of clinical issues discussed generally had a chief executive officer with a clinical background who ensured that clinical issues were closely linked to all trust developments including finance and information technology.

The Audit Commission report “Taking it on Trust” (2009) found that “few trusts could set out how clinical audit was being used in a systematic way to address risks” and the failure to use clinical audit to support the Board Assurance Framework (BAF) was identified as a significant weakness.

The Audit Commission also criticised NHS organisations’ checks of the accuracy of clinical and activity data, finding “very little evidence of board level discussion or challenge of data quality”. Where high-level involvement did exist, “this was the exception rather than the rule” (Figures You Can Trust, AC 2009).

There is also some concern that, in spite of the exhortations of the Integrated Governance Handbook (2006) and the Audit Committee Handbook (2005), that boards continue to assess and review performance of cost and quality separately.

NHS Boards need to be aware of the value and usefulness of clinical audit to their role in effective governance and delivering high quality services. Clinical audit should not dictate strategy, but be used to confirm that trust strategies are working and delivering improvements. Clinical audit programmes should include national and local clinically led projects. National initiatives should be balanced with local priorities or concerns.

In this guide we have attempted to clarify the roles and responsibilities of all stakeholders and then spell out the kinds of questions board members might like to ask (with acceptable and unacceptable answers). The guide looks in more detail at the importance and materiality of clinical audit to NHS Boards and their partner organisation(s) with sections on the importance of having a clinical audit strategy to focus and resource efforts for quality improvement.
By the 1980s in the UK, the Department of Health was emphasising the need for quality of care. Systematic use of clinical audit was significantly supported by the White Paper ‘Working for Patients’, published by the Department of Health in 1989. This White Paper sought to set up an internal market within the NHS and suggested a systematic and comprehensive system of medical audit within the internal market. Protected funding was to be made available for Regional and District Health Authorities to develop strategies, set up clinical audit committees and to produce annual reports of clinical audit activity in their local areas. To help secure buy-in from the professions it was recognised that clinical audit was to be carried out by healthcare professionals themselves, and that the results of clinical audit were not to be shared beyond the professional group concerned.

Gradually the role of clinical audit has widened into a facility which also supports management and regulation, although, at its core, it remains a clinical self-appraisal process. However, clinical audit still falls under the remit of the wider ‘audit committee’ of a provider organisation. In 2005, the Department of Health published their Audit Committee Handbook. This sought to require audit committees to reflect better practice across industry and to broaden committee interest from merely financial issues to all assurance activities. All governance mechanisms were to be discussed by audit committees as part of the assurance given to boards that governance systems were functioning within an organisation. The Integrated Governance Handbook of 2006, published by the Department of Health, recommended the inclusion of clinical audit in the board assurance framework as a key part of the control mechanism of boards.

In 2006 the Chief Medical Officer’s report, ‘Good Doctors, Safer Patients’, called for the reinvigoration of clinical audit to enable it to reach its potential as a rich source of information to support service improvement, better information for patients and other activities such as revalidation of clinicians. In February 2007 the White Paper ‘Trust Assurance and Safety’ agreed with this analysis.

National Standards, Local Action (2005/06 – 2007/08) stated that providers should participate fully in comparative clinical audit and take account of the results to support local and national clinical governance.

3. Clinical audit as part of the modern healthcare system

The Care Quality Commission (CQC) recognises clinical audit as a professionally led exercise, which is an essential component in clinical governance and the delivery of high-quality clinical care. CQC will look for professional engagement in clinical audit and assess whether the local environment, created by the board, enables participation in clinical audit activity to ensure that organisations are embracing the full potential of these methods in informing service delivery.

Operationally, this level of support for clinical audit is translated into a requirement to participate in clinical audit and is emerging as part of other diverse elements of managing and reviewing quality. This includes NHS provider organisations seeking CQC Registration; the requirements for reporting in Quality Accounts; and in new standards issued by the NHS Litigation Authority.

Key points:
- The aim of clinical audit has always been quality improvement.
- Clinical audit is a team endeavour.
- In the NHS in England, the Department of Health has consistently supported clinical audit.
- Clinical audit is now also a mainstream accountability and not solely clinician owned. It is a quality management and governance activity alongside being a professional development activity.
- Board involvement in clinical audit is very recent and has been minimal to date.
- A requirement to demonstrate active engagement in local and national clinical audit is now becoming more clearly a statutory requirement for NHS trusts.
In this section we clarify what is meant by clinical audit, and how it differs from other forms of inquiry such as research or investigation. The different kinds of clinical audit taking place are also discussed.

The key features of clinical audit are that it:

• is a circular process system by which clinicians review their own clinical practice, but which can be used organisationally to review effectiveness
• has a quality improvement intent
• is systematic
• is undertaken with the active involvement of those directly involved in the care process
• looks beyond the immediate care process and may encompass resources devoted to a particular care pathway
• considers processes allied to the direct pathway of care, such as the initial selection of patients for the care pathway concerned
• uses established and agreed standards, which are in themselves proxies for good quality care leading to better outcomes
• compares actual practice to these standards
• confirms compliance with standards or that necessary remedial action is taken
• re-measures to gauge improvement.

As with all audit, clinical audit identifies the extent of control failures within any given system, identifies the reason for the control failure, makes recommendations for improved systems and compliance and follows up recommendations.

### Types of clinical audit

#### National clinical audit
National clinical audits can assess compliance with published existing national standards of care and some can have a role in defining, adding and refining existing standards as a result of the data that emerges which can be incorporated into subsequent clinical audits. Other national clinical audits seek to assess incidence or development of services and processes for new or emerging interventions against guidance and standards for service delivery. Local healthcare providers supply the data for national clinical audits and participation in each relevant national clinical audit should be made on the basis of the utility to local needs, unless centrally mandated. Local providers have a responsibility for acting on the findings of national clinical audits which can also form the basis for complementary local clinical audits on related matters.

#### Local clinical audit
The main type of clinical audit at local level is clinical audit against agreed standards, which involves defining standards where these do not exist nationally, collecting data to measure current practice against those standards, implementing any changes deemed necessary and re-measuring practice to verify improvement.

Both national and local clinical audit should involve identification of issues to address, an action plan to tackle these issues, and re-measurement to assess progress. The clinical audit needs to have board oversight to ensure this cycle is complete and that the clinical audit is also not solely owned by the immediate clinical team but by management.

There are other processes similar to and related to clinical audit:

#### Peer review
Peer review is where clinicians have their work reviewed by others in their profession or field of practice – their peers. It is an assessment of the quality of care provided by a clinical team with a view of providing feedback and thereby supporting reflection on practice. The intent is that this will lead to improvements in the quality of care. Often individual patient cases are discussed with peers to determine, with the benefit of hindsight, whether the best care was given. Peer review might include ‘interesting’ or ‘unusual’ cases rather than problematic ones. Peer review may take place within an individual care setting, or be organised between care settings. Some of the professional societies organise national peer review schemes as part of their ongoing commitment to professional development.
Adverse occurrence screening/critical incident monitoring is peer review of cases that 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’. Within an acute setting these case meetings are sometimes termed ‘morbidity and mortality’ meetings.

Confidential enquiries are not normally based on standards but are an investigation triggered by an event such as death. These are not normally based on standards but are termed ‘morbidity and mortality’ meetings.

Within an acute setting these case meetings are sometimes referred to as a ‘significant event audit’. Asking patients about the treatment they have received (i.e. what happened?) rather than “did you like what happened?” In short, the patient is acting as a data collector and is recalling whether particular elements of the care process occurred or not. A survey of patient views may be useful in many clinical audits.

Patient experience surveys and focus groups are methods used to obtain service users’ views about the care they have received. Surveys undertaken to determine what actually happens in order to improve services can be extremely productive. They differ from patient satisfaction interventions as they ask, “What happened?” rather than “did you like what happened?” In short, the patient is acting as a data collector and is recalling whether particular elements of the care process occurred or not. A survey of patient views may be useful in many clinical audits.

Research Clinical Audit Service Evaluation

| The attempt to derive generalisable new knowledge, including studies that aim to generate hypotheses, as well as studies that aim to test them. | Designed and conducted to produce information to inform delivery of best care. | Designed and conducted solely to define or judge current care. |
| Addresses clearly defined questions, aims and objectives in a rigorous manner. | Measures against a standard. | Measures current service without reference to a standard or defined system or approach. |
| 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. | Usually involves analysis of existing data, but may include administration of simple interview or questionnaire. | Usually involves analysis of existing data, but may include administration of simple interview or questionnaire. |
| May involve randomisation. | No randomisation. | No randomisation. |

**BOX 1: DIFFERENTIATING CLINICAL AUDIT FROM RESEARCH – SOME NOTES FROM THE NATIONAL PATIENT SAFETY AGENCY**

*Patient Reported Outcome Measures*

**Non-audit** or **quasi-audit** activities

Alongside clinical audit there are various other investigation or data collection activities. Some of these, which boards should be aware of, include:

- research
- service evaluation
- patient outcomes programmes
- patient satisfaction inquiries
- formal investigations.

**Research** is different from clinical audit; obtaining new knowledge and finding out what treatments are the most effective. Clinical audit is about quality and finding out if best practice is being adhered to. In short, research tells us what we should be doing whereas clinical audit tells us whether we are doing what we should be doing and how well we are doing it. The National Research Ethics Service makes a clear distinction between clinical audit and research and states that, unlike research, although there may be ethical issues present, clinical audit should not usually need approval from a research ethics committee. (See Box 1)

http://www.nres.npsa.nhs.uk/

**Patient outcomes review programmes** (such as PROMS®)

Complement clinical audit. Many clinical audits contain some measure of what the benefit was to the patient against the priority outcomes they anticipated. However clinical audit also measures process standards so patient outcome reviews only partially overlap. Outcomes monitoring helps define standards for future clinical audits.

**Patient satisfaction inquiries** supplement patient outcome review programmes. Asking patients about the treatment they have received (i.e. what happened?) can be a vital part of clinical audit, as it can be used to assess the degree to which care was offered against standards. Other forms of patient survey have a different utility.

**Registries and clinical databases** collect data about procedures or conditions without always having any quality improvement element. Only those registers where the data is used to drive quality improvements should be classified as clinical audits (for example, the National Joint Registry which, as well as counting the number of implants of various kinds, is used to assess the performance of individual surgeons and the quality of different makes or manufacturers of implant).

**Internal and external audit** are not activities undertaken by the clinical professions themselves. Healthcare organisations will, in the same way as industry, have internal audit teams who will carry out studies on behalf of management or the audit committee as part of compliance checking. The audit committee in NHS bodies has a degree of independence reflected in its formal structure and membership and it has a duty to ensure that the systems and processes of the organisation are fit for purpose. This includes the scope and execution of clinical audit. However the ‘audit committee’ is different from a ‘clinical audit committee’ which directly oversees the clinical audit programme.

**Investigations** differ from clinical audit in a number of ways; improvement is not usually the sole aim. Healthcare is a high-risk activity and failures in care can have catastrophic consequences for the patient(s) concerned. At any given time every healthcare organisation will be carrying out a range of internal investigations into care, and may also be subject to various forms of external audit or investigation too. They are often concerned with accountability as well as learning points. As such, an investigation may be followed by a disciplinary, judicial or quasi-judicial process.

**Key points:**

- Clinical audit is an established, systematic review process with quality improvement at its core.
- Both national and local clinical audits may be valuable but the purpose of some national clinical audits needs to be carefully assessed by local services before they participate.
- Alongside clinical audit there are various highly important review or investigation activities; some are clearly distinct from clinical audit and some are parallel, even partially congruent to clinical audit activity.
- Clinical audit does not require ethics committee permission, being essentially different to research.
- Investigations have a different purpose to clinical audit, and while the language of clinical audit and investigation and internal audit processes are often interchangeable, they should be viewed as very different activities.
Clinical audit is a critical and under-used resource for NHS Boards. In this section we reflect on the role of the board, and their contribution to quality in the NHS. We look at some of the ways in which boards can make better use of clinical audit across a variety of functions.

The relationship between clinical governance and boards

NHS Boards are the first line of regulation. Whilst they have accountability for strategic decision-taking for the trust, they must also represent their stakeholders; the public, patients and funders. This is a difficult balancing act and requires great skill and expertise to reflect national and local priorities, to ensure safe, cost effective and integrated care that is constantly striving for improvement, whatever the financial climate.

Historically, clinical audit was not used by boards as part of their suite of processes which were used to drive and measure quality of clinical care; it was a separate, clinically managed activity. Whilst it must still have that primary function for clinicians, boards can shape and manage the programme to meet their strategic objectives as well.

Boards need to consider the extent to which they use clinical audit appropriately:

- Is the approach systematic and focused on locally identified risks as well as on national issues?
- Are the results regularly reported to the board and used as evidence in the assurance framework?
- Does clinical audit give a comprehensive view of the quality of clinical services across the trust’s portfolio?

NHS internal audit activity provides one resource to boards. However it is rare for NHS internal audit providers to have access to specialist clinical knowledge whereas, for example, an insurance company’s internal audit function would almost certainly employ, or have access to, an actuary. Trusts should require that internal audit providers need to reflect whether they have the appropriate skills to enable them to provide meaningful assurance over the effectiveness of the compliance function and to scrutinise clinical risk management arrangements. Similarly, trusts need to consider how they can best gain assurance over clinical risk management. As stated above, this internal audit function is different from clinical audit, although the internal audit committee may investigate clinical matters and consult clinical audit results. In undertaking this function, internal audit committees will have to review where they get technical and clinical advice to carry out this role.

The Integrated Governance Handbook (2006) sets out the logic of merging clinical governance into the overall governance framework, rather than operating it in parallel. The different dimensions of clinical governance have been described as:

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<th>Education</th>
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Clinical audit is effectively the review of clinical performance against agreed standards, and the refining of clinical practice as a result. It is one of the key compliance tools at management’s disposal and has an important role within the assurance agenda. However, few trusts have historically included clinical audit as a direct source of assurance in their BAF*. It would be reasonable to expect it to appear as a significant source of assurance for all trusts.

Used in this way, clinical audit can be a strategic priority for boards. There is scope to maximise the assurance provided by the clinical audit function through considering how programmes can be better aligned to the trust’s individual risks as well as taking account of national priorities. For example, if local complaints or surveys illustrate specific, persistent and/or local concerns, then the clinical audit programme can be designed to include the monitoring of standards related to these concerns. Clinical audit can also be used as a systematic tool to address issues which arise about care and treatment priorities from a strategic rather than a more limited local clinical interest.

Boards have a role in driving quality assurance, assessing compliance, conducting internal audit and thus ‘closing the loop’ to ensure that reviews and clinical audits are actioned, and seeking assurance that improvements have been made. Ideally this should be part of an overall quality framework.

* Board Assurance Framework
The board will also need to think about how they report and disseminate clinical audit results and participation rates. One location for this is in the trust’s publicly reported ‘Quality Account’. A clear set of requirements for how trusts should report in these accounts will be issued by the Department of Health. Clinical audit data and participation rates will need to be present.

Clinical audit and Patient and Public Engagement (PPE)

More generally the board should ensure clinical audit results are disseminated widely to staff, commissioners and patients. A trust should not just select material from clinical audit that is positive but also results that are critical, giving patients information about quality improvement activity undertaken to address any problems. The results should be disseminated using a variety of communication channels including websites, newsletters and ward notice boards.

Trusts should also widely publicise participation in clinical audit because it affirms the board’s attention to quality. A greater understanding of the process and what their role is within it is more likely to increase patient’s and carers support.

Patients can participate more extensively in clinical audit, contributing to the PPE initiatives of a trust. Clinical audit offers opportunities to engage patients in work on a variety of levels including in the topic selection process and in data collection. HQIP’s PPE guidance 2009 illustrates a selection of case studies and suggested standards to aid a trust in involving patients and the public in clinical audit.

HQIP will also be publishing material in 2010 for patients to set out why clinical audit is the sign of a good healthcare provider.

The importance of clinical audit within regulation

Regulatory bodies will increasingly look to see how clinical audit has been implemented. CQC measures national priorities set by the Department of Health. Assessment of performance against the existing national priorities was a component of the Healthcare Commission’s Annual Health Check (AHC) in 2008/2009 for PCTs and acute and specialist trusts, and are part of the new systems that replace this at CQC. Clinical audit is included in the registration requirements of provider bodies as highlighted in section 2.

In March 2009, the Care Quality Commission undertook a ‘Special Data Collection’ through which acute and specialist trusts were assessed on their responses to six following questions that relate to clinical audit. The basic approach set out in that document is likely to remain the basis of CQC’s continuing review work. (See Box 2)

Clinical audit and Commissioning

Although the standard 5d (See Section 3) does not apply to commissioners, PCTs should ensure for all commissioned services that, “the PCT has appropriate mechanisms through which they could identify and, where appropriate, respond to any significant concerns arising from their commissioned services with regard to the overall standard.”

It is likely that there will need to be increased participation in local and national clinical audits required to meet the needs of commissioners, and these may include “service evaluations” as well as more narrowly defined “traditional” clinical audits (e.g. assessing compliance with NICE standards for a Health Technology Appraisal). PCTs in their commissioning role should ask for clinical audits to be conducted according to the services they commission, or participation in national clinical audits that are relevant, and review results.

World class commissioning, the Operating Framework 2009/10, Payments by Results (PBR) and Commissioning for Quality and Innovation (CQUIN)

These recent approaches from the Department of Health set out the next steps in the development of commissioning and reward, and, in particular, provide details of the payment for quality scheme that will run with the new national standard contracts. The world-class commissioning competencies provide a blueprint of what the Department of Health believes a good commissioner of the future will look like, and attention to clinical audit is part of that requirement. CQUIN and PBR will require clinical audit participation and good results in the data supplied to merit such payments for key conditions.

From April 2010, the NHS Litigation Authority will be introducing a new specific standard on clinical audit within the cross cutting standards contained in its section 5. This will mean the importance of clinical audit will be increased and trusts will need to demonstrate ownership of the processes and strategies described above to achieve the standards.

Trusts will be assessed on their responses to the following:

Did the trust participate in local and/or national clinical audit of the treatment and outcomes for patients?

All five stages of clinical audit have been completed at least once in each directorate in the last 12 months in line with the ‘Principles of Best Practice in Clinical Audit’ (NICE, 2002):
1. preparing for clinical audit;
2. selecting criteria;
3. measuring performance;
4. making improvements; and
5. sustaining improvements. (See note about the stages of clinical audit on page 23)

Did the trust have a clinical audit strategy and programme related to both local and national priorities with the overall main aim of improving patient outcomes?

There is in place a programme of work which gives direction and focus on how and which clinical audit activity will be supported in the organisation. This may be part of a wider strategy within the organisation.

Also appropriate processes for reviewing the need for a clinical audit as a direct result of adverse clinical events, critical incidents, and breaches in patient safety. This may be part of a specific clinical audit strategy or other strategy within the organisation.

Did the trust make available suitable training, awareness or support programmes to all clinicians regarding the trust’s systems and arrangements for participating in clinical audit?

The training, awareness, or support programmes covered all the five phases of clinical audit in line with the ‘Principles of Best Practice in Clinical Audit’ (NICE, 2002) outlined as:
1. preparing for clinical audit;
2. selecting criteria;
3. measuring performance;
4. making improvements; and
5. sustaining improvements.

Did the trust ensure that all clinicians and other relevant staff conducting and/or managing clinical audits were given appropriate time, knowledge and skills to facilitate the successful completion of the clinical audit cycle?

The provisions have been in line with the ‘Principles of Best Practice in Clinical Audit’ (NICE, 2002) and include at least all of the following:
• opportunity to gain the relevant skills and knowledge
• access to relevant facilities for managing and conducting
• access to relevant facilities for managing and conducting clinical audit
• protected or allocated time to manage and conduct clinical audit.

Did the trust undertake a formal review of the local and national clinical audit programme undertaken in the trust to ensure that it meets the organisation’s aims and objectives as part of the wider quality improvement agenda?

The trust has carried out an annual formal review, recorded the outcomes of the review and any subsequent action that should be taken. For example, clinical audit annual report ratified at relevant governance committee.

Did the trust’s management or governance leads receive regular reports on the progress being made in implementing the outcomes of national clinical audits and review the outcomes, with additional or re-audits being conducted where necessary?

The trust has completed a review of the clinical audit outcomes and put forward an action plan (or equivalent) on the necessary actions required and ensured that reports on progress being made had taken place and that both of the above had taken place at least once or in line with the clinical audit strategy or programme, whichever is more stringent.


4 Patient and Public Engagement (PPE) in Clinical Audit, HQIP and National Voices, 2009. Also available on www.hqip.org.uk.
This section gives guidance on the content and organisation of a strategy from a board perspective. HQIP publishes guidance in more detail for those operationally responsible for strategy development on its website.

**What should be the process involved?**

- Boards will want assurance that there is a clinical audit strategy in place that:
  - meets their strategic priorities
  - meets national commitments and expectations
  - prioritises and addresses local concerns
  - integrates financial and quality audit
  - delivers a return on investment
  - improvements are implemented and sustained
  - is a significant part of their clinical governance strategy and programme.

**What makes for a good quality clinical audit and clinical audit programme?**

HQIP has published ‘Criteria and Indicators of Best Practice in Clinical Audit’ (2009) which covers both national and local audit, and which specifies the ideal components of a clinical audit project. This includes the necessity for senior management ownership of the project or the programme.

HQIP also publishes guidance on developing a policy for clinical audit and for developing a model strategy on clinical audit, both available at www.hqip.org.uk.

The detail of such a strategy and policy needs to be agreed at board level. It must balance specific local clinical priorities with those national ones which are expressed in national audits which have required participation and which regulators may investigate. Whilst there will need to be specific local clinical interests represented, the board should take the opportunity to shape this strategy in such a way that the programme addresses wider interests, such as cross cutting themes of care, patient interests and concerns and so on.

Clinical audits also need to be of high quality, as set out in HQIP’s ‘Criteria and Indicators of Best Practice in Clinical Audit’ (2009) which covers both national and local clinical audits. The ‘Practical Handbook for Clinical Audit’ (2005) published by the NHS Clinical Governance Support Team identified 12 Criteria for ‘Good Local Clinical Audit’, available at www.hqip.org.uk (See Box 3).

There are various other guides to the content of an ideal programme. The Royal College of Nursing (RCN) guidance* on selecting a clinical audit topic as a priority says that a clinical audit topic should concern an area that has at least one of the following characteristics:

- high risk
- high volume
- high cost
- caused concern.

It states that clinical audit often involves looking at:

- the frequency or volume of a service provided
- risks associated with aspects of providing care or a service
- problems associated with delivering care or a service
- effectiveness of aspect(s) of the delivery of care or a service
- cost of aspect(s) of delivering care or a service.

**6. The content and oversight of a clinical audit strategy**

Most crucially, boards can demand that the full cycle of clinical lead to real changes.

ensure that clinical audit does not simply measure, but does audit, especially the quality improvement part, takes place to that key issues that affect data quality have been addressed.

demanding that the technical quality of clinical audit is high and these various criteria. Boards can and should be rigorous in

Boards will need to ensure that the strategy they endorse meets

and identify those responsible for service improvement.

Re-audit should be applied to ascertain whether improvements in care have been implemented as a result of clinical audit.

Systems, structures and specific mechanisms should be made available to monitor service improvements once the clinical audit cycle has been completed.

Each clinical audit should have a local lead.

Example:
The clinical audit strategy at South Staffordshire and Shropshire Healthcare NHS Foundation Trust is intended to deliver a programme of clinical audit activity over 3 years.

The strategy reflects that the focus of the team has changed direction from having a broad quality improvement agenda to concentrating on clinical audit. The strategy provided an opportunity to examine ways of working and ensure they are clear and documented.

With a growing number of external accreditation and validation requirements as well as an increase in relevant NICE guidance and guidelines, the need of the trust to demonstrate compliance and improvements through clinical audit has also necessitated a shift in priorities of the clinical audit team.

Clinical audit supported by the clinical audit team now serves five functions:

1. using clinical audit as a tool for quality improvement following the process described in the clinical audit cycle;
2. supporting teams throughout the trust to examine and look to improve, the quality of care/services provided;
3. using clinical audit as a tool for demonstrating compliance and monitoring;
4. evaluating performance in order to support the assurance of quality within the trust;
5. supporting the organisation in building quality into systems and processes through seeking views and experiences of staff and service users to inform planning and future direction.

The strategy details the key roles of the clinical audit team and describes the processes and systems being adopted to ensure clinical audit projects are able to justify the time and resources afforded and lead to improvements in the quality of care provided.


Commissioning Primary Care Trusts (PCTs) and clinical audit

Commissioning PCTs have specific roles they need to carry out in relation to promoting clinical audit as well as specifying it within their commissioning function.

A model clinical audit strategy development process for a PCT might cover the following:

• The professional executive committee, or PEC (or the equivalent group which manages these functions) in conjunction with the PCT clinical audit lead, supports and advises on when and how the overall clinical audit strategy should be drawn up, and who (including patients and relevant partner organisations and groups) must be consulted, as a part of this process when the draft must be presented to the PEC.
• The PEC debates the strategy, identifies resource, education and training and other implications, and adopts the strategy (which may then be endorsed by the clinical governance committee and the PCT board).
• The PEC (clinical governance committee, in conjunction with the PCT clinical audit lead, identifies who will initiate specific clinical audit programmes, the requisite resources, the time frame and the fit with PEC/clinical governance committee reporting cycle.
• An analysis of clinical audit data is undertaken or, where necessary, commissioned, and the implications for clinical and organisational practice are identified, including those that have a bearing upon other technical components of clinical governance (i.e. risk management, education and training).
• The PEC/clinical governance committee, in conjunction with the PCT clinical audit lead, identifies and agrees actions necessary as a result of the data analysis from specific clinical audits, and mandates whoever will carry out the specific actions (including identifying and acting upon the implications for other clinical governance functions).
• After an appropriate interval, the PEC/clinical governance committee, in conjunction with the PCT clinical audit lead, initiates a re-audit to identify sustained improvement/slippage, and mandates any necessary action.
• The PEC/clinical governance committee in conjunction with the PCT clinical audit lead undertakes a meta-analysis of the outcomes of all clinical audits undertaken within the cycle to identify ‘underlying themes’ which may require action.

More generally, PCTs have a useful role in promoting and ensuring clinical audit strategy is developed; absorbing a requirement for clinical audit to be included in contracts for services; and following up results as part of contract management.

Key questions (from ‘Taking it on Trust AC’ 2009) relevant to clinical audit strategy:

• Are the strategic aims and objectives clearly defined?
• How can the board be sure that they have identified all of the strategic risks?
• Is the scope and level of investment in clinical audit appropriate?
• Does the board use assurances appropriately, balancing them across the risk profile of the trust?
• How does the board systematically test and evaluate the sources of assurance?
• Would the self-declarations stand up to rigorous external scrutiny?
• What controls does the board have to ensure that the quality of data used for decision making is good enough?

NHS Clinical Governance Support Team

Key role of boards

Boards need to ensure that the strategy they endorse meets these various criteria. Boards can and should be rigorous in demanding that the technical quality of clinical audit is high and that key issues that affect data quality have been addressed.

Most crucially, boards can demand that the full cycle of clinical audit, especially the quality improvement part, takes place to ensure that clinical audit does not simply measure, but does lead to real changes.
As described throughout this guide, boards should use clinical audit to confirm current practice compared with evidence of good practice and to ensure that changes are made to improve the delivery of care.

Clinical audit can:

• Provide evidence of current practice against national guidelines or NHS standards.
• Provide information about the structures and processes of a healthcare service and patient outcomes.
• Assess how closely local practice resembles recommended practice.
• Check “Are we actually doing what we think we are doing?”
• Provide evidence about the quality of care in a service to establish confidence amongst all of its stakeholders – staff, patients, carers, managers, and the public.

Clinical audit will happen at different levels within an organisation.

Clinical audits can:

• Identify major risk, resource and service development implications in an NHS trust.
• Reinforce implementation of evidence-based practice.
• Influence improvements to individual patient care.
• Provide assurance on the quality of care.

Clinical audit can be described as a cycle or a spiral and the board can follow the clinical audit cycle thereby influencing the focus of the clinical audit in line with their strategic objectives; concerns identified elsewhere; and as a backstop for areas that are otherwise neglected. Boards should seek assurance that areas that are high risk, high volume or high cost are being delivered effectively and may use clinical board assurance prompts (BAPs) as a means of clarifying whether clinical areas are meeting agreed standards and evidenced based practice.

Within the cycle there are stages that follow a systematic process of establishing best practice, measuring care against criteria, taking action to improve care, and monitoring to sustain improvement. The spiral suggests that as the process continues, each cycle aspires to a higher level of quality.

Note: the cycle identified on page 17 contains five stages, whereby re-audit is the fifth stage. This is the cycle as published in ‘Principles of Best Practice in Clinical Audit’ (NICE 2002). HQIP’s refinement of this model in 2009, (as pictured above) is based on extensive consultation and simplifies this to four stages but follows the same approach. Further explanation of HQIP’s clinical audit cycle can be found in ‘Criteria and indicators of best practice in clinical audit’ (2009).*

Boards can match the clinical audit circle/spiral with their own actions. (See Box 4)

In Scotland each NHS board is expected to set a programme of prioritised clinical audit for the year. The clinical governance committee approves and monitors achievement of the clinical audit programme. Progress against the clinical audit programme will also be used as an indicator of performance and a basis of assessment for external monitoring.

BOX 4

<table>
<thead>
<tr>
<th>Clinical action</th>
<th>Board action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Identification of issue</td>
<td>Establish clinical audit strategy.</td>
</tr>
<tr>
<td></td>
<td>Be clear what trying to achieve by prioritisation of boards interests in clinical audit.</td>
</tr>
<tr>
<td>2 Methodology &amp; criteria</td>
<td>Determine appropriate methodology and criteria to suit issue.</td>
</tr>
<tr>
<td></td>
<td>Ensure governance structures are fit for purpose.</td>
</tr>
<tr>
<td>3 Analysis</td>
<td>Analysis will identify progress, variations against standards, any concerns over costs and implementation.</td>
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<tr>
<td></td>
<td>Agree criteria for alerting board.</td>
</tr>
<tr>
<td>4 Change</td>
<td>Ensure recommended actions are planned and implemented.</td>
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<tr>
<td></td>
<td>Seek assurance that changes have been implemented in timely manner.</td>
</tr>
<tr>
<td>5 Re-audit/monitor</td>
<td>Plan that projects will be subject to a re-audit and/or monitoring of key performance indicators to demonstrate the actual improvements that have been implemented and any further constraints.</td>
</tr>
<tr>
<td></td>
<td>Seek assurance that changes have resulted in improvements that are sustainable.</td>
</tr>
</tbody>
</table>

Following a review of our governance structures the audit committee took on an increased scrutiny function in relation to clinical audit, thus moving on from the more traditional focus on finance and resources. A regular report is provided to the committee. This includes details of the clinical audits completed and the follow up of outstanding actions. This approach mirrors that used with the internal audit reports. This provides the Non Executive Directors with an increased level of detail about the work of clinical audit and links closely with the Standards for Better Health declaration which they have a key role in supporting. The Annual Report regarding clinical audit goes to the full trust board.

Lancashire Care NHS Foundation Trust
Trusts make a substantial, but often un-quantified, commitment to clinical audit. Over and above the costs of any central clinical audit team, there is also a significant hidden cost to trusts arising from the ‘supporting professional activity sessions’ within the consultant contract. These comprise a significant part of the contract and are typically used for clinical audit work, continuing professional development, and additional managerial responsibilities.

It is critical that all members of staff and patients as well as board members understand their respective roles. There is no prescriptive structure for effective clinical audit but it is likely that your organisation will have a set of governance roles and committees and a set of management/clinical functions and groupings.

The role of the board within the clinical audit process is the purpose of this guidance. Specifically the role of its members and committees is in gaining assurance that strategic objectives are achieved and that services commissioned or provided are safe and cost effective. In respect of clinical audit, boards will want to be assured that clinical audits are:

- **Material** – i.e. that they are prioritised to focus on key issues and that the value outweighs the cost (note that assurance has a cost).
- **Professionally undertaken and completed** – i.e. clinical audits are undertaken and completed to professional standards and quality including the quality of data being analysed.
- **Produce results** that are shared and acted upon.
- **Followed by improvements** that are made and sustained.

The issue of cost effectiveness is crucial in the current financial climate and the importance of the Quality Innovation Productivity and Prevention (QIPP) agenda. The board clearly has the key role in ensuring that QIPP principles are factored in to their oversight of clinical audit.

Clinical audits do have costs, particularly in staff time. The recommendations they make may require changes in the organisation or delivery of clinical services, training and additional capacity that will require additional costs. However this needs to be balanced against the finding that efficient and effective care can be cheaper. A clinical audit can be useful in identifying processes that are inefficient or ineffective. They can lead to changes in practice that are not only cheaper but are also preventative.

Boards will need to consider these factors. Clinical audit should be able to demonstrate its value in having a direct impact on care, rather than simply measuring care standards, if it is to be justifiable in the QIPP environment. Boards will need to be assured that:

- Clinical audits are not just measurement activities but have a quality improvement element.
- Those conducting clinical audits and making recommendations for actions do these with a view to efficiency, productivity and demonstrable impact.
- Clinical audits are not simply conducted for the requirements of professional purposes (such as revalidation, professional membership etc) but also have an equal secondary purpose of improving services.
- Clinical audits involve patients and the public wherever possible and all results and recommendations are made publicly available.
- Clinical audit recommendations are realistic and practical.
- There are clear timescales and plans for when the clinical audit will be conducted and results acted upon – boards can ensure action does not ‘slide’.
- Clinical audit actions have led to sustained improvements and clinical practice or service delivery has not ‘reverted’.

This guide has argued throughout that the board should be instrumental in selecting clinical audit topics. Many of these will be dictated by national clinical audit programmes required by the Department of Health and regulators, but there should be room for the board to determine topics that reflect the trust’s strategic priorities, concerns or gaps in independent assurance. It is likely that board selected topics will be high risk, high cost, high volume, however care should be taken to recognise some areas; for example the cost of diabetes drugs will be high volume, medium cost for PCTs but still add up to a significant proportion of the PCT budget.

The trust’s audit committee (not the clinical audit committee) should ensure the processes are robust to ensure the governance structures are fit for purpose. The focus is one of process rather than content but audit committees should also be looking to ensure that audits are integrated across quality, finance and resources. The line of accountability and responsibility to the board needs to be clear. These groups do not usually have routine responsibility for clinical audit committees but will focus attention on clinical audit work for specific reasons.
Check that all clinical audits are registered and that teams are responsible for those undertaking clinical audit. They can also be prioritised, funded, and supported by a clinical governance work. Its role is to ensure that clinical audits are recorded, professionally completed and accepted, and that protocols on use of patient data are in place and adhered to. The board has assured of the quality and integrity of data.

The trust is likely to have a Clinical Audit Coordinating Group or Clinical Audit Committee, often a clinical governance group which oversees the clinical audit programme alongside other governance work. Its role is to ensure that clinical audits are prioritised, funded, recorded, professionally completed and action taken to implement and sustain change.

In many trusts there is a centralised clinical audit department/support team where the manager, facilitators and clerks are sited within one location. This model was the one recommended by the Bristol Royal Infirmary Inquiry (Department of Health, 2001), it is important that this team is adequately resourced and has a clear line of accountability to the board. The support team provides technical support and explains the responsibilities of those undertaking clinical audit. They can also check that all clinical audits are registered and that teams are completing the clinical audit cycle by:

- following an appropriate methodology
- engaging patients and the public in the process
- implementing changes in practice as a result of initial clinical audit
- planning to repeat the clinical audit process (a re-audit) to ensure that the changes have been effective.

It is important to ensure there is a senior clinician who leads clinical audit within the trust and with partners/suppliers outside, and who is clearly accountable at board level. The clinical audit team may also have a manager to facilitate and coordinate clinical audit and its relationship with research and risk. The clinician or manager will be responsible for creating a clinical audit strategy, setting priorities, agreeing and implementing the clinical audit strategy and annual clinical audit programmes.

For individual clinical audit projects there should be a clearly identified lead who will register the clinical audit and ensure reports are completed and disseminated. On completion the clinical audit leads should include a short summary of their project including aims, methodology, timeframe, sample size, clinical audit results, conclusions and action plan.

Responsibilities of staff:
- To undertake (cooperate in/register clinical audit.
- Ensure they have training for their role.
- Encourage and work towards Patient and Public Engagement (PPE) in the entire clinical audit process.
- Follow protocols on confidentiality and security of data.
- Act on results.

Box 5 presents a list of questions for board members to ask (with acceptable and unacceptable responses).

Key points:
- The clinical audit governance structure and clinical audit programme is signed off by the audit committee.
- There is independent assurance that clinical audits are professionally completed, that staff are trained for their role and that protocols on use of patient data are in place and adhered to.
- The board is assured of the quality and integrity of data.
- The board is advised of significant variation from standards or norms highlighted in clinical audits.
- The board is assured that action has been taken to implement change, make and sustain improvements.

Those responsible for clinical audits should:
- Ensure a summary of clinical audit results, in an appropriate format and with recommendations for action, is distributed to all relevant stakeholders.
- Ensure a summary of any recommendations and action plans is shared with other interested parties.
- Ensure that clinical audit results having potential significance, due to the identification of a risk, are brought to the attention of the clinical governance committee, either by contacting the chair or professional secretary in the first instance. The clinical governance committee will assume responsibility for making sure any action needed is carried out, confirming at a senior level that the resource commitments, if any, can be met.
- Present clinical audit results at various forums as appropriate and as agreed with their line manager, for example directorate clinical governance meetings.

Question | Acceptable response | Unacceptable response
--- | --- | ---
1 | Do we have a clinical audit strategy based on national and local priorities? | Strategy has been developed, based on good practice and is being implemented with a budget and guidelines. | We have an existing clinical audit plan, mostly focused on national clinical audits.
2 | Do we have a relevance test to approve commitment of resources? | Decision to embark on clinical audit is based on test (criteria agreed with board) that area is of relevance and we have competencies & capacity to complete. | We rely on a clinical group to define priorities.
3 | Does our focus on national clinical audits mean we have no resource to advise on local priorities? | No, we have earmarked sufficient funds for a programme of local and relevant activity. | Yes as we cannot find the additional resources for these areas.
4 | What proportion of approved clinical audits has been completed to time and budget? | All clinical audits are logged with clinical audit lead, resources and timescales identified. Variations are logged and reported to board or delegated subcommittee. | We do not have a formal budget for clinical audit.
5 | Has the board agreed what constitutes materiality, unacceptable variation in clinical audit results a) standards and b) comparisons with others? | The clinical audit strategy includes a process which involves the board to determine materiality and trigger points for escalation to board and benchmarking to compare with norms and emerging practice. | No the board has not addressed this issue.
6 | For all clinical audits that identify unacceptable variation is there an action plan? | Yes, results which breach the materiality/trigger points require an action plan. | This is patchy depending on interest of clinicians.
7 | Is our board assurance framework supported by clinical audit as assurance? | Yes, we have identified where clinical audit can provide assurance and where there are gaps. These gaps are being addressed in forthcoming plans and budgets. | No, or patchy where clinical audits have coincided with strategic priorities.
8 | Have we assurance that clinical audits have led to improved service delivery? | All clinical audits which prompt action plans are reviewed to determine impact and any barriers to implementation and sustainable improvement. | We have records of improvement but cannot tell if it is due to clinical audit activity and action plans.
9 | Do we share our clinical audit results with others? | We share our results with local partners (providers/commissioners) and with our regional clinical networks including patient networks. Clinical audits with national implications are shared with appropriate professional groups, patient organisations and SHA/Monitor. | Yes but based on clinical networks and personal contacts, so not systematic.
10 | Do our contracts with suppliers / providers require cooperation in clinical audits e.g. in CQUIN regime? | Our contracts are being redrafted over a planned timescale to include quality measures and requirement to undertake and /or cooperate in agreed clinical audit programmes. | We expect our suppliers/providers to undertake their own clinical audit programme.

As suppliers/providers the clinical audit programme is our business.

11 | Are we using clinical audits for quality assurance usage, and do they fit with our trust’s agreed quality process? | Yes, aligned with quality policies and duties. Modest action on quality assurance but included in clinical audit strategy for coming years. | We cannot find the resources for these areas.

12 | Are areas such as mental health, primary care neglected in local clinical audit programmes? | No, we have made provision for these areas examples would be… | We cannot find the resources for these areas.
Materiality is a convention within auditing and accounting relating to the importance/significance of an amount, or variation from norms. The objective of an audit of financial statements is to enable the auditor to express an opinion whether the financial statements are prepared, in all material respects, in conformity with recognised financial reporting frameworks. The assessment of what is material is a matter of professional judgment.

Materiality is defined by the International Accounting Standards Board (IASB) in the following terms:

“Information is material if its omission or misstatement could influence the decision of users taken on the basis of the financial statements. Materiality depends on the size of the item or error judged in the particular circumstances of its omission or misstatement. Thus, materiality provides a threshold or cut-off point rather than being a primary qualitative characteristic which information must have if it is to be useful.”

In public sector auditing, the political sensitivity to adverse media exposure often concerns the nature rather than the size of an amount, such as illegal acts or corruption. Qualitative materiality is therefore likely to be more important in a public body such as the NH

3. These are a series of guides targeted at NHS Board members and planners of health care improvement. They are intended to improve the quality of care by reducing variation and increasing reliability of timely, cost effective treatment when patients transfer from one part of the healthcare system to another. They describe common high profile pathways of care and critical interventions and then identify a series of questions (and acceptable answers) that board members might ask to ensure that they are adopting strategies that will improve the reliability of care for people; for example with diabetes, seeking to ensure that plans are in place to support members of the population at risk. The guides include a maturity matrix focused on improving decision taking in commissioning.

More information is available from the GGI at www.good-governance.org.uk.

4. As defined by other guidance published by HQIP and available via our website.

9. References

1. Materiality
2. The four roles given in the 2007 Guidance, ‘Fit for the Future’:
3. More information is available from the GGI at www.good-governance.org.uk.
4. As defined by other guidance published by HQIP and available via our website.

10. Further reading

References and source material


Clinical governance and re-validation: the role of clinical audit. (2002; 117:47-50) Education in Pathology


Criteria and Indicators for best practice for clinical audit. (2009) HQIP

Figures You Can Trust. (2009) Audit Commission


