Developing a clinical audit strategy
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1 Overview

The Healthcare Quality Improvement Partnership (HQIP) has published guidance on a range of topics associated with clinical audit and quality improvement. In 2009, HQIP published guidance and templates covering the development of clinical audit strategies and policy, clinical audit reports, and how to devise and manage the annual clinical audit programme. Many NHS organisations and other healthcare providers have used these publications to develop their own policies, strategies, programmes, and report templates.

The guidance was updated in 2012, and reviewed as part of a series of workshops for clinical audit practitioners held by HQIP in 2013. At that time it was felt that while still useful, the guidance needed further updating to reflect contemporary practice.

Although the principles of good quality clinical audit have remained unchanged, the context in which clinical audit is carried out has evolved. There is now a greater understanding and appreciation of the relationship between clinical audit and other quality improvement activities, and many NHS Trusts have moved to integrate clinical audit into wider programmes of quality improvement and service development.

This begs the question as to whether there is a need for a clinical audit policy or programme that stands apart from wider policies and programmes of quality improvement. Some Trusts are now moving towards full integration of all aspects of service improvement, and are reaping the benefits that this can yield. Different approaches to this process of integration work well in different organisations, and at present there is no single consensus on how such an integrated approach should be achieved or governed.

There are distinct statutory and contractual requirements for clinical audit, which healthcare providers must meet. The statutory and mandatory frameworks that regulate clinical audit within the NHS in England continue to evolve, and are detailed within HQIP’s publication, Statutory and mandatory requirements in clinical audit. Our guidance on policy and programme development aims to support NHS Trusts in meeting these requirements, as well as ensuring that they use clinical audit effectively to improve the quality of their services. While the guidance itself refers to clinical audit, many aspects can be applied to other quality improvement methods, and can be used to develop integrated policies. It is for each Trust to determine how they should approach clinical audit and quality improvement, and how they use this guidance.
HQIP suggests that the four organisational documents below are necessary for the effective management of clinical audit. These documents are intimately linked and should be read together.

- **A policy on the use and conduct of clinical audit:** which sets out the principles, roles, responsibilities and practices a healthcare provider will follow in auditing clinical practice, and improving the quality of services to meet the needs of patients, healthcare commissioners, healthcare regulators, and others

- **A strategy on the development of clinical audit:** which describes how a healthcare provider will implement the policy, and increase the impact of audit on clinical services

- **A clinical audit programme:** which presents a prioritised summary of planned clinical audit activity and outcomes, that is regularly updated and scrutinised in accordance with the above clinical audit policy and strategy

- **A clinical audit report template:** which provides consistency in clinical audit reporting

The aim of this publication is to support healthcare providers in developing their organisational strategy for clinical audit.

A clinical audit strategy should:

- Be a time-limited document, i.e. covering a defined period of one or more years

- Link clinical audit with organisational governance and assurance systems, and corporate objectives

- Provide a vision for clinical audit development, i.e. over three to five years

- Set out a number of Specific, Measurable, Achievable, Relevant, Time-based, Evaluated, Resourced, (SMARTER) objectives for the period covered

Unlike a clinical audit policy, which sets out the “rules” for conducting clinical audit, a clinical audit strategy forms an operational action plan. The process of developing the strategy should therefore begin with a critical analysis of the way in which clinical audit functions within an organisation, looking for both successes and areas for improvement. Risks should be identified and managed, and any recommendations made by healthcare commissioners or regulatory authorities should be taken into account. See HQIP’s *Best practice in clinical audit* for criteria which can be used to evaluate organisational preparedness and practice, and HQIP’s *Clinical audit: A guide for NHS Boards and partners*. The strategy should include objectives and an action plan to meet these. Progress in delivering this plan – measured by meeting the service objectives and reducing levels of risk – should be monitored on a regular basis and reported to the Board as appropriate. The plan itself should be revised and updated annually.

The strategy should be developed following any approved organisational process for developing procedural documents regarding version control, document development, equality impact assessment, and the implications of failing to follow the strategy.

The following guidance provides a recommended approach, including examples of text, however all are intended to be adaptable for local use.
3 Executive statement

Most organisations will expect corporate strategy documents to be approved at Board level. It is therefore recommended that a clinical audit strategy begins with a high-level statement of organisational commitment both to the process of clinical audit and to delivering the objectives set out in the document. This should reflect the principles set out in the organisation’s clinical audit policy and might repeat the definition of clinical audit and key commitments made within the policy.

**Example statement:**

The Trust is committed to delivering effective clinical audit in all the clinical services it provides. The Trust sees clinical audit as essential to continually evolve, develop and maintain high quality patient-centred services.

When carried out in accordance with best practice standards, clinical audit:

- Provides assurance of compliance with clinical standards
- Identifies and minimises risk, waste and inefficiencies
- Improves quality of care and patient outcomes

The Trust is committed to ensuring that clinical audit delivers these benefits, and has adopted a policy on the governance and practice of clinical audit, which applies to all staff (include reference to policy).

Achieving the objectives set out in this strategy will ensure that the Trust policy is implemented and effective, resulting in sustained improvements to the quality of care provided to patients.

4 Organisational context

It is recommended that the executive statement is followed by a section that describes the role of clinical audit in terms of organisational context. When writing a clinical audit strategy, an organisation may, for example, wish to make reference to the links between clinical audit and any number of wider quality/governance frameworks or initiatives.

For example:

**How clinical audit contributes to the delivery of the organisation's corporate objectives and overall vision for any or all of the following:**

- Clinical governance: the framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish

- Corporate assurance: including meeting the statutory and mandatory requirements for clinical audit set out in the clinical audit policy

- Integrated governance: systems, processes and behaviours by which organisations lead, direct and control their functions in order to achieve organisational objectives, safety and quality of service, and in which they relate to patients and carers, the wider community and partner organisations

- Quality: including providing Quality Accounts and ensuring that services are delivered so as to be safe, effective, and to provide a positive patient experience

- Patient and public involvement: ensuring that service user voices are central from planning to delivery, using insightful methods of listening and working in co-production with patients, families and carers to improve outcomes
How the choice of clinical audit topics supports other key streams of governance and quality activity, such as:

- Clinical effectiveness: examining clinical outcomes and making improvements
- Evidence-based practice: ensuring practice is based on current research findings
- Clinical risk management/patient safety: auditing in response to concerns highlighted proactively by risk assessment and reactively by adverse incidents
- Complaints and other forms of patient feedback: auditing in response to themes arising
- Service improvement: involving transformation teams in discussions about clinical audit topic choice
- Regulation: ensuring requirements such as the fundamental standards of the Care Quality Commission are being met

How clinical audit supports ongoing expectations and initiatives, for example:

- Care Programme Approach (CPA): in mental health Trusts/partnerships
- Consultant appraisal, revalidation, and health professional registration: enabling clinicians to comply with their professional codes of conduct
- Information governance: ensuring that clinical audit activity meets the requirements of information governance legislation
- Membership councils/council of governors for foundation Trusts: as per the duty to involve patients and the public, i.e. engaging members in clinical audit activity
- National recommendations and guidance: issued by national bodies such as the National Institute for Health and Care Excellence (NICE), the Clinical Outcomes Review Programme (CORP – covering National Confidential Enquiries and Inquiries), National Clinical Audit and Patient Outcomes Programme (NCAPOP), and national service reviews
- National Service Frameworks: defining standards of care, e.g. for cancer, coronary heart disease, chronic obstructive pulmonary disease, diabetes, kidney disease, long-term conditions, mental health, old age, and stroke care
- NHS Litigation Authority initiatives: such as the Sign Up to Safety campaign
- Research and development: mutually supportive of clinical audit
- Service evaluation: clinical audit may form a part of service evaluation projects
- Statements of Internal Control: clinical audit's contribution to the process by which an organisation gains assurances about the quality of its services and the effective management of risk
5 Scope

This section should establish and define the target audience and breadth of application of the strategy. The strategy is principally aimed at those responsible for overseeing the direction and development of clinical audit within the organisation. This will typically include corporate and specialty leads, managers, committees/steering groups, and commissioners.

6 Definition of clinical audit

This definition should mirror the contents of the organisation’s clinical audit policy. The organisation may wish to include a visual description of the clinical audit cycle. For examples see HQIP’s Developing a clinical audit policy.

7 Strategic aim

For the sake of clarity and brevity, it is suggested (although by no means essential) that the organisation develops a single statement describing the overall aim of the strategy.

Example statement:
The aim of this strategy is to use clinical audit as a process to embed clinical quality at all levels of the organisation over the next three years. The strategy focuses on creating a culture that is committed to learning and continuous organisational development through measurement of evidence-based practice to deliver demonstrable improvements in patient care.
8 Objectives

This section of the strategy should describe the areas of clinical audit practice the organisation is committed to developing throughout the lifetime of the document. The strategic aim should be supported by a number of action-oriented service objectives. There is no suggested limit on the number of these objectives; this will depend on each organisation’s circumstances and its position in terms of the development of clinical audit services to date. These objectives are likely to vary in their specificity, however all objectives must be supported by actions that are Specific, Measurable, Achievable, Relevant, Time-based, Evaluated, Resourced (SMARTER).

Explicit SMARTER objectives should be set locally, covering aims for improving clinical audit practice, such as:

- To overcome barriers to healthcare staff participating in clinical audit
- To develop a partnership approach to clinical audit
- To establish a robust system for reporting the outcomes of clinical audit activity
- To ensure that staff have the necessary competency, support and time to participate in clinical audit
- To ensure that the Trust is fully compliant with the requirements of the National Clinical Audit and Patient Outcomes Programme
- To link clinical audit to appraisal and revalidation
- To ensure organisational compliance with regulatory standards
- To demonstrate and celebrate the benefits of clinical audit
- To ensure clinical audit activities are fully integrated with other quality improvement approaches and programmes

9 Operational action plan

The final section of the strategy document is an operational action plan. This should describe the actions that the organisation will be taking in order to deliver the agreed SMARTER objectives.

The following is an example of a basic template.

<table>
<thead>
<tr>
<th>Objective</th>
<th>Action</th>
<th>Responsible individual</th>
<th>Potential barriers/ constraints</th>
<th>Expected outcome</th>
<th>Monitoring/ date for completion</th>
</tr>
</thead>
</table>

Appendix 1 lists strategic challenges to the development of effective clinical audit practice and corresponding performance measures that were identified during a series of workshops on the development of a clinical audit strategy, hosted by HQIP and the Health Foundation.
10 Clinical audit programme

Some organisations may wish to add a section to the strategy, providing details of their annual clinical audit programme (i.e. the specific clinical audit projects that will be carried out). Other organisations may prefer to publish this as part of their annual report for the previous year, or as a stand-alone document.

Inclusion in the strategy document might be appropriate however if, for example, the strategy document is written to cover the period of a single financial year.

References


# Appendix 1 – Strategic challenges and performance measures

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Performance Measures</th>
</tr>
</thead>
</table>
| **Clinical audit policy is out of date**                                  | • Timetable for drafting, consulting on, agreeing and ratifying an up to date clinical audit policy (See HQIP’s *Developing a clinical audit policy*)^
| **Clinical audit policy is clear and up-to-date but does not deliver the outcomes we need to meet statutory, regulatory or commissioner requirements** | The Trust:                                                                                                                                           |
| • Need to identify why this is the case in order to be able to develop and adopt the appropriate strategy and performance measures (see sections below) | • Meets the CQC registration requirements in respect of clinical audit                                                                                   |
| • Can the Trust meet the statutory, regulatory and commissioning requirements? | • Is able to produce quality clinical audit reports to evidence compliance with all statutory, regulatory or commissioners’ requirements                    |
| **Lack of Board engagement in clinical audit**                            | • Reports on participation in clinical audit as part of the Trust’s Quality Account                                                                       |
| • Need to ensure the Board understands its role and responsibilities      | • Can demonstrate that participation in clinical audit has resulted in improvements to the quality of care                                                   |
| • Need to establish clear lines of communication and accountability       |                                                                                                                                                       |
| • Need to ensure the clinical audit programme delivers what the Board needs – assurance and improvement |                                                                                                                                                       |
| • Need to ensure the Board is aware of how it can and should use clinical audit |                                                                                                                                                       |
| **Lack of engagement by clinical staff**                                  | • Trust clinical lead for clinical audit in place                                                                                                       |
| • Need to ensure there is clinical leadership, both at directorate/divisional/Board level, and for individual clinical audit projects | • Review and revise terms of reference for clinical audit committee                                                                                     |
| • Need to build good working relationships between clinical audit specialists and clinical teams | • Agreed timetable for presenting updates on the implementation of the clinical audit strategy and progress on the annual clinical audit programme to the Board |
| • Need to ensure clinicians have the opportunity to meet their clinical audit requirements for professional revalidation | • Minuted discussion of clinical audit and quality improvement at Board meetings                                                                      |
| • Need to ensure that clinicians are held to account for clinical outcomes highlighted through clinical audit | • Offer and uptake of clinical audit training to non-exec directors (See HQIP’s *Clinical audit: A guide for NHS Boards and partners*)^
| • Need to ensure that clinical audit activity is discussed and agreed as part of consultant job plans |                                                                                                                                                       |
| **All directorates/divisions appoint a clinical audit lead clinician**     | • All directorates/divisions appoint a clinical audit lead clinician (See HQIP’s *Guide for clinical audit leads*)^
| **All clinical audits have a named clinical lead**                        | • All clinical audits have a named clinical lead                                                                                                        |
| **Number of requests for advice/assistance**                             | • Number of requests for advice/assistance                                                                                                               |
| **Number of clinical staff attending clinical audit training sessions**   | • Number of clinical staff attending clinical audit training sessions                                                                                   |
| **Effective monitoring arrangements in place to ensure all clinical audit activity is recorded** | • Effective monitoring arrangements in place to ensure all clinical audit activity is recorded                                                          |
| **Number of clinical audit projects completed**                           | • Number of clinical audit projects completed                                                                                                          |
| **Number of clinical audit action plans implemented in full**             | • Number of clinical audit action plans implemented in full                                                                                             |
| **Number of clinical audit projects abandoned**                          | • Number of clinical audit projects abandoned                                                                                                           |
| **Number of consultant job plans where clinical audit activity is documented** | • Number of consultant job plans where clinical audit activity is documented                                                                        |
### Lack of involvement of patients, carers and the public

- Trust clinical audit policy is reviewed and revised to include explicit statements about patient and public involvement
- Accurate and complete information about participation in clinical audit is included in the Trust Quality Account
- Number of audits where patients and carers are identified as key stakeholders
- Number of audits where there is active participation of patients and/or carers
- Number of audits that include patient identified outcomes
  (See HQIP's *Patient and public involvement in quality improvement*)

### Lack of engagement of non-clinical staff, leading to:

- Lack of co-operation by practice staff, medical secretaries, clinic co-ordinators, records staff, etc.
- Service/practice managers unwilling to contribute to clinical audit proposals and unwilling to co-operate in implementing action plans
- Number of non-clinical staff participating in clinical audit training
- Number of clinical audits where non-clinical staff are included in the project steering group, identified as key stakeholders or otherwise engaged in the audit process

### Poor quality in clinical audit practice

#### Strategy must address the need to reduce cases of:

- Poor audit methodology
- Failure to document process/results
- Failure to produce/implement action plans
- Failure to communicate results and action plans with clinical team/stakeholders

- Availability/uptake of clinical audit training
- Reporting templates/guidance available
  (See HQIP's *Documenting local clinical audit: A guide to reporting and recording*: [www.hqip.org.uk/resources/guide-to-clinical-audit-reporting](http://www.hqip.org.uk/resources/guide-to-clinical-audit-reporting))
- Availability/uptake of training in action planning and change management
- Number of clinical audits presented at directorate/specialty meetings
- Frequency and attendance at directorate/specialty clinical audit meetings

### Lack of co-ordination of clinical audit activity

- Directorates/clinical teams take responsibility for their own actions but:
  - Effective practice isn’t shared
  - Resources are being used inefficiently with the same or similar audits taking place in different clinical areas
  - Major effort required to pull together information for Quality Accounts, CQC compliance reviews, etc

- Trust-wide clinical audit register implemented
- Effective practice shared
- Reviewed and revised process for agreeing and prioritising the annual clinical audit programme implemented
- Central database of clinical audit reports which include action plans and outcomes in place scrutinised for quality

### Junior doctor audit is of poor quality

- Lacks co-ordination and fails to deliver either to the Trust or to the participating doctors

- Trust clinical audit policy is reviewed and revised to include explicit statements about junior doctor audit
- All audits undertaken by junior doctors are registered and reported on in accordance with the Trust clinical audit policy
- All audits undertaken by junior doctors are supervised by a senior clinician who takes overall responsibility for ensuring that the project is registered and completed
- System is implemented to ensure junior doctors receive appropriate acknowledgement of their participation in clinical audit
