

| Developing a clinical audit strategy





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1 Overview

This document is the result of wide consultation and workshops with clinicians, service managers, and clinical audit staff, as well as representatives of a range of professional bodies including the Academy of Medical Royal Colleges.

Clinical audit is one of a range of quality improvement methodologies that can deliver improved processes and outcomes for service users.

The [NHS Long Term Plan](#) states: “Systematic methods of quality improvement (QI) provide an evidence-based approach for improving every aspect of how the NHS operates. Through developing their improvement capabilities, including QI skills and data analytics, systems will move further and faster to adopt new innovations and service models and implement best practices that can improve quality and efficiency and reduce unwarranted variations in performance. A programme to build improvement capability is established in around 80% of the trusts rated ‘outstanding’ by the Care Quality Commission.”

Similarly, the [NHS Patient Safety Strategy](#) states that the NHS “must support continuous and sustainable improvement, with everyone habitually learning from insights to provide safer care tomorrow than today. Quality improvement provides the necessary coherence and aligned understanding of this shared approach to maximise its impact. It offers tools to understand variation, study systems, build learning and capability, and determine evidence-based interventions and implementation approaches to achieve the desired outcomes.”

This begs the question as to whether there is a need for a clinical audit, strategy policy, or programme that stands apart from wider policies and programmes of quality improvement. Some NHS 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 such 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.

However, 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](#).¹ Our guidance on clinical audit strategy, 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.

2 Introduction to the guidance

HQIP suggests that the four organisational documents below are necessary for the effective management of clinical audit. These documents are closely linked and should be read together:

- **A policy for the use and conduct of clinical audit:**
To set 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 for the development of clinical audit:**
To describe how a healthcare provider will implement the policy, and increase the impact of audit on clinical services
- **A clinical audit programme:**
To present 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:**
To provide 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:

- Cover a defined number of years, so that it is time-limited
- Provide a vision for clinical audit developments, i.e. over three to five years
- Incorporate clinical audit into organisational governance and assurance systems, and corporate objectives
- Set out a number of Specific, Measurable, Achievable, Relevant, Time-based, Evaluated, Resourced (SMARTER) objectives.

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 is carried out 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 guide [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 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 document development, version control, equality impact assessment, and the implications of failing to follow the strategy.

The following guidance provides a recommended approach, including examples of potential 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 improvement or 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 flourish²

- 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 organisations³
- Quality: including providing quality accounts and ensuring that services delivered are safe, effective, and provide a positive patient experience⁴
- 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 outcomes⁵

How the choice of clinical audit topics support 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 or near-misses
- Complaints and other forms of patient feedback: auditing in response to themes arising
- Service improvement: involving transformation and quality improvement teams in discussions about clinical audit topic choice
- Regulation: ensuring requirements such as the fundamental standards of the Care Quality Commission are being met.
- Information governance: ensuring that clinical audit activity meets the requirements of information governance legislation and General Data Protection Regulation (GDPR)
- Membership council/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), National Clinical Audit and Patient Outcomes Programme (NCAPOP), and national service reviews
- NHS Resolution initiatives: such as the Maternity Incentive Scheme
- 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 assurance about the quality of its services and the effective management of risk.

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

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 example see HQIP's guide, [Developing a Clinical Audit Policy](#).⁶

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 ensure 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 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, and 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 take in order to deliver the agreed SMARTER objectives.

The following is an example of a basic template.

Objective	Action	Responsible individual	Potential barriers/ constraints	Expected outcome	Monitoring/ date for completion

[Appendix 1 of this document](#) 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 (covering 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

1. Statutory and mandatory requirements in clinical audit (HQIP): www.hqip.org.uk/resources/hqip-statutory-and-mandatory-requirements-in-clinical-audit-guidance/
2. Clinical governance and the drive for quality improvement in the new NHS in England (BMJ); 317:61-5. Scally G, Donaldson LJ, 1998)
3. Integrated Governance Handbook: A Handbook for Executives and Non-executives in Healthcare Organisations (Department of Health. Deighan M, Bullivant J, 2006)
4. Quality Governance in the NHS – A guide for provider boards (National Quality Board, 2011)
5. Transforming participation in healthcare (NHS England, 2013)
6. Developing a Clinical Audit Policy (HQIP): www.hqip.org.uk/resources/clinical-audit-policy-and-clinical-audit-strategy/
7. Clinical audit: A guide for NHS Boards and partners (HQIP): www.hqip.org.uk/resources/clinical-audit-a-guide-for-nhs-boards-and-partners/
8. Guide for clinical audit leads (HQIP): www.hqip.org.uk/resources/guide-for-clinical-audit-leads/
9. Patient and public involvement in quality improvement (HQIP): www.hqip.org.uk/resources/patient-and-public-involvement-in-quality-improvement/
10. Documenting local clinical audit: A guide to reporting and recording (HQIP): www.hqip.org.uk/resources/guide-to-clinical-audit-reporting
11. Guide to involving junior doctors in clinical audit and quality improvement (HQIP): www.hqip.org.uk/resources/involving-junior-doctors-in-clinical-audit/

Appendix 1 – Strategic challenges and performance measures

Challenges	Performance Measures
<p>Clinical audit policy is out of date.</p>	<ul style="list-style-type: none"> • Timetable for drafting, consulting on, agreeing, and ratifying an up-to-date clinical audit policy fulfilled. <p>(See HQIP's <i>Developing a clinical audit policy</i>)⁶</p>
<p>Clinical audit policy is clear and up-to-date but does not deliver the outcomes we need to meet statutory, regulatory, or commissioner requirements:</p> <ul style="list-style-type: none"> • Need to identify why this is the case, to develop and adopt the appropriate strategy and performance measures • Can the Trust meet the statutory, regulatory, and commissioning requirements? 	<p>The Trust:</p> <ul style="list-style-type: none"> • Meets the CQC registration requirements in respect of clinical audit • Is able to produce quality clinical audit reports to evidence compliance with all statutory, regulatory, or commissioners' requirements • Reports on participation in clinical audit as part of the Trust's quality account • Can demonstrate that participation in clinical audit has resulted in improvements to the quality of care.
<p>Lack of Board engagement in clinical audit:</p> <ul style="list-style-type: none"> • Need to identify why this is the case, to develop and adopt the appropriate strategy and performance measures • Can the Trust meet the statutory, regulatory, and commissioning requirements? 	<ul style="list-style-type: none"> • Trust clinical lead for clinical audit in place • Reviewed and revised terms of reference for clinical audit committee • Agreed timetable for presenting updates on the implementation of the clinical audit strategy and progress on the annual clinical audit programme to the Board • Minuted discussion of clinical audit and quality improvement at Board meetings • Offer and uptake of clinical audit training to non-exec directors. <p>(See HQIP's <i>Clinical audit: A guide for NHS Boards and partners</i>)⁷</p>
<p>Lack of engagement by clinical staff:</p> <ul style="list-style-type: none"> • Need to ensure there is clinical leadership, both at directorate/divisional/Board level, and for individual clinical audit projects • Need to build good working relationships between clinical audit specialists and clinical teams • Need to ensure clinicians have the opportunity to meet their clinical audit requirements for professional revalidation • Need to ensure that clinicians are held to account for clinical outcomes highlighted through clinical audit • Need to ensure that clinical audit activity is discussed and agreed as part of consultant job plans. 	<ul style="list-style-type: none"> • All directorates/divisions appoint a clinical audit lead clinician <p>(See HQIP's <i>Guide for clinical audit leads</i>)⁸</p> <ul style="list-style-type: none"> • All clinical audits have a named clinical lead • Number of requests for advice/assistance • Number of clinical staff attending clinical audit training sessions • Effective monitoring arrangements in place to ensure all clinical audit activity is recorded • Number of clinical audit projects completed • Number of clinical audit action plans implemented in full • Number of clinical audit projects abandoned • Number of consultant job plans where clinical audit activity is documented.

<p>Lack of involvement of patients, carers, and the public.</p>	<ul style="list-style-type: none"> 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. <p>(See HQIP's Patient and public involvement in quality improvement)⁹</p>
<p>Lack of engagement of non-clinical staff, leading to:</p> <ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 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.
<p>Poor quality in clinical audit practice:</p> <p>Strategy must address the need to reduce cases of:</p> <ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> Availability/uptake of clinical audit training Reporting templates/guidance available <p>(See HQIP's Documenting local clinical audit: A guide to reporting and recording: www.hqip.org.uk/resources/guide-to-clinical-audit-reporting)¹⁰</p> <ul style="list-style-type: none"> 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.
<p>Lack of co-ordination of clinical audit activity:</p> <p>Directorates/clinical teams take responsibility for their own actions but:</p> <ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 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.
<p>Junior doctor audit is of poor quality:</p> <ul style="list-style-type: none"> Lacks co-ordination and fails to deliver either to the Trust or to the participating doctors. 	<ul style="list-style-type: none"> 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. <p>(See HQIP's Guide to involving junior doctors in clinical audit and quality improvement: www.hqip.org.uk/resources/involving-junior-doctors-in-clinical-audit)¹¹</p>



Further information is available at: www.hqip.org.uk

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