

| Developing a clinical audit policy





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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.

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 policy for clinical audit.

A clinical audit policy should cover:

- How clinical audit helps the organisation deliver its vision and values
- A working definition of clinical audit
- A best practice framework of clinical audit systems and processes
- Standards for good governance in clinical audit.

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

This guidance provides a recommended approach, including examples of text, however all are intended to be adaptable for local use.

Template for a clinical audit policy

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1 National context

1.1 Statutory and mandatory requirements for clinical audit

It is suggested that a clinical audit policy document begins with a description of the national policy context within which clinical audit is practised.

A summary of the key [Statutory and mandatory requirements in clinical audit](#)¹ is available on the [HQIP website](#).

Example statement:

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

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

Participation in both national and local clinical audit is a statutory and contractual requirement for healthcare providers. [The NHS Standard Contract](#)² forms the agreement between commissioners and providers of NHS-funded services, who must:

- Participate in national clinical audits within the National Clinical Audit and Patient Outcomes Programme (NCAPOP) relevant to their services
- Make national clinical audit data available to support publication of consultant-level activity and outcome statistics
- Implement and/or respond to all relevant recommendations of any appropriate clinical audit
- Implement an ongoing, proportionate programme of clinical audit of their services in accordance with best practice
- Provide to the co-ordinating commissioner, on request, the findings of any audits carried out, in particular locally-agreed requirements such as Commissioning for Quality and Innovation (CQUIN) audits.

In addition, the regulatory framework of the Care Quality Commission (CQC) requires registered healthcare providers to monitor the quality of their services. [The CQC fundamental standards](#)³ describe the care patients should expect, with prompts for providers to consider when aiming to meet requirements for governance and audit, set out in [Regulation 17: Good governance, of the Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2014](#),⁴ whereby:

“To meet this regulation, providers must have effective governance, including assurance and auditing systems or processes. These must assess, monitor and drive improvement in the quality and safety of the services provided, including the quality of the experience for people using the service. The systems and processes must also assess, monitor and mitigate any risks relating to the health, safety and welfare of people using services and others. Providers must continually evaluate and seek to improve their governance and auditing practice.”

Providers must use the findings from clinical audit and other quality improvement initiatives, including those undertaken at a national level – such as national confidential enquiries and inquiries, and national service reviews – to ensure that action is taken to protect people who use services. They must also ensure healthcare professionals are enabled to participate in clinical audit in order to satisfy the demands of their relevant professional bodies (for example, for revalidation and evidence of continuing professional development).

(For Foundation Trusts only): The Board is required by NHS Improvement to declare via an annual governance statement⁵ the effectiveness of the system of internal control, the role and conclusions of clinical audit, and a plan to address weaknesses and ensure continuous improvement of the system – covering an outline of the actions taken, or proposed, to deal with any significant gaps in control.

(For Trusts required to produce quality accounts): Under the [Health Act 2009](#),⁶ the Trust is required to produce

annual quality accounts,⁷ which must include information on participation in national and local clinical audits, and the actions that have been taken as a consequence to improve the services provided.

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

2 Purpose of this policy

2.1 Statement of purpose

It is suggested that the organisation agrees a local statement, expressed in broad terms, summarising the overall purpose of the policy (i.e. as opposed to describing the purpose of clinical audit).

Example statement:

The purpose of this policy is to set out the rationale for clinical audit and provide a framework for such activity, including standards, guidance and procedures, as well as details of the support available from the Clinical Audit Team:

- For registering and approving clinical audit project proposals
- For developing and designing clinical audit projects

This policy aims to support a culture of best practice in the management and delivery of clinical audit, and to clarify the roles and responsibilities of all staff involved.

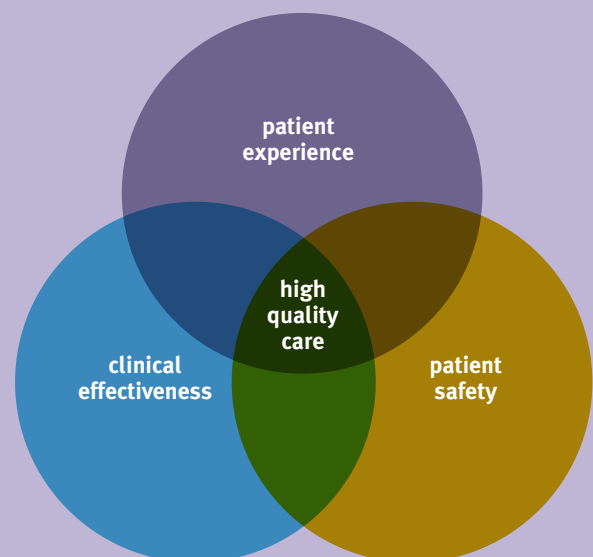
2.2 Improvement and assurance

The organisation may want to include a statement confirming its position on the role of clinical audit in driving quality **improvement** and providing quality **assurance**.

Example statement:

Quality in the NHS was defined in *High quality care for all: NHS next stage review*,⁸ led by Lord Darzi, and enshrined in legislation through the *Health and Social Care Act 2012*.⁹ This set out three dimensions, seen in diagram 1, which must all be present to provide a high-quality service:

Diagram 1 The three dimensions of a high-quality healthcare service



The three dimensions of a high-quality healthcare service:

- **Patient experience:** quality care is delivered for a positive experience, including being treated according to individual wants or needs, and with compassion, dignity, and respect
- **Clinical effectiveness:** quality care is delivered according to the best evidence regarding what is clinically effective in improving an individual's health outcomes
- **Patient safety:** quality care is delivered to prevent all avoidable harm and risks to an individual's safety.

Quality improvement in healthcare is a process that seeks to enhance patient experience and individual health outcomes, through measuring and improving the effectiveness and safety of clinical services.

Quality assurance in healthcare is the planned and systematic monitoring of activity to ensure that the standards for safe, clinically effective services and positive patient experience are met. Quality assurance aims to provide confidence and certainty in the quality of services.

While clinical audit is fundamentally a quality improvement process that provides the opportunity for ongoing review and service development, it also plays an important role in providing assurance on the quality of services.

HQIP's [A guide to quality improvement methods](#)¹⁰ offers an overview of a range of quality improvement techniques that might be combined with clinical audit activity.

The prime responsibility for auditing clinical care lies with the clinicians who provide that care.

Support from appropriately trained and experienced clinical audit staff, which includes training in processes and practice, is provided for clinicians who carry out clinical audit, and for non-clinical staff, patients, and members of the public who may be involved in clinical audit projects. Associated information governance guidance can be found in HQIP's guide, [Information governance in local quality improvement](#),¹¹ available on the HQIP website.

The organisation is committed to ensuring:

- Participation in all national clinical audits, national confidential enquiries and inquiries, and national service reviews relevant to the services provided
- All clinical audit activity within the Trust, or conducted in partnership with external bodies, is registered both locally and nationally as appropriate, and conforms to nationally agreed best practice standards (see HQIP's guide, [Best practice in clinical audit](#))¹²
- The annual programme of clinical audit activity meets Board assurance framework objectives, and includes all of the clinical audits necessary to meet the requirements of regulators and commissioners
- Records of reviews of the annual programme of clinical audit, individual clinical audit projects, as well as the results of national clinical audits, national confidential enquiries and inquiries, and national service reviews, are maintained, to:
 - Help facilitate effective clinical audit activity through robust governance systems
 - Demonstrate compliance with requirements of regulators and commissioners.

3 Definitions

3.1 Locally accepted definition of clinical audit

This is an essential section of the policy document, which needs to be determined locally, but should reflect nationally agreed best practice definitions.

Example statement:

Clinical audit is a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes.¹³

Diagram 2 demonstrates the four stages of the clinical audit cycle:

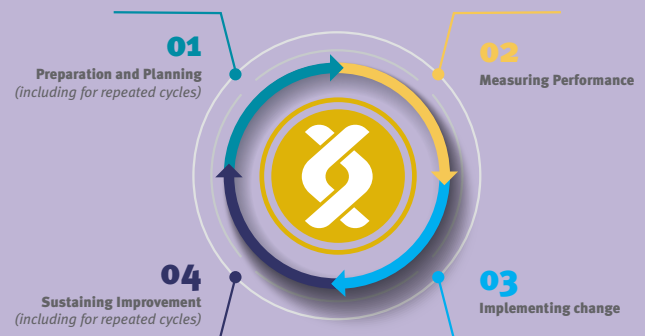
- **Stage 1 – Preparation and Planning:** to agree required standards and clinical audit methodology
- **Stage 2 – Measuring Performance:** data collection in order to evaluate performance against required standards
- **Stage 3 – Implementing Change:** using action planning where shortfalls are identified
- **Stage 4 – Sustaining Improvement:** through monitoring and service development, with repeated clinical audit cycles as required

3.2 Other definitions

There may be other relevant local definitions included here as appropriate.

Clinical audit against evidence-based standards as part of an ongoing, planned annual quality assurance programme ensures that high quality care is always delivered. Although there are similarities, the clinical audit cycle should not be confused with the Plan, Do, Study, Act cycle, which is a separate quality improvement tool used to drive and increase compliance with a standard against which there is an identified shortfall, or to investigate the impact of changes to practice within a defined timeframe.¹⁰

Diagram 2 The clinical audit cycle



4 Scope

4.1 Target audience

This section should establish/define the target audience for the policy, making it clear that the policy applies to everyone within the organisation, including students, volunteers, patients, and staff.

Example statement:

This policy applies to anyone engaged in the clinical audit process within the Trust, including:

- All staff, including management, senior management, and Trust Board Members, both clinical and non-clinical, and those on short-term or honorary contracts
- Students and trainees in any discipline
- Patients, carers, volunteers, and members of the public.

This policy also applies when clinical audit is undertaken jointly across organisational boundaries.

Example statement:

The Trust encourages clinical audit to be undertaken jointly across professional and organisational boundaries. Partnership working with other local and regional organisations will be encouraged where improvements to the patient journey may be identified through shared clinical audit activity.

The Trust also supports collaboration on multi-professional clinical audits of interest to other parts of the local health and care economy, both within and outside of the NHS, e.g. community/secondary care, local authorities, independent health and social care providers, etc.

4.2 Multidisciplinary and multi-professional audit, and partnership working with other organisations

Multi-disciplinary and cross-organisational working are essential clinical audit practice to support smooth integrated care pathways, and a statement is required to highlight organisational commitment to these approaches.

4.3 Involving patients and the public

Patients and carers view quality of care differently to healthcare professionals, and provide a unique perspective based on their personal experience. Their views should be captured to design services to meet their needs.

This section of the policy should set out the organisation's chosen approach to involving patients, carers and members of the public, including Trust members in the case of Foundation Trusts, in the clinical audit process. Involvement might range from passive input, whereby the organisation decides to audit an issue highlighted by patient complaints, to active engagement, whereby patients are directly involved in programme steering groups or through the stages of the clinical audit/quality improvement cycle.

It is important to recognise the difference between patient surveys undertaken for clinical audit purposes to determine whether a clinical standard has been met, and those undertaken for other purposes, for example, to determine patient satisfaction, such as the Friends and Family Test. It is of course possible that a patient survey may examine clinical standards and patient satisfaction. In either case, representatives from the target group should be actively involved in the design of any survey carried out. HQIP fully encourage direct patient and public involvement in clinical audit and quality improvement activity, for more innovative and impactful, patient-centered success.¹⁴

Reference should be made to other Trust policies that address patient and public engagement. See HQIP's guide, [Patient and public involvement in quality improvement](#)¹⁴ for more information.

Example statement:

The Trust promotes a commitment to involving patients, carers, and members of the public in the clinical audit process, either indirectly through the use of patient surveys and questionnaires, or directly through participation of patients, carers, and members of the public on clinical audit project steering groups or quality improvement patient panels.¹⁵

4.4 Involving medical students and junior doctors

Some organisations, especially teaching Trusts, may wish to include a statement underlining their commitment to collaborative working with local academic bodies. For example, medical students may choose clinical audit for their Student Selected Component (SSC) study module. Where this is the case, the organisation may wish to outline their particular approach to allocating projects to students (or vice versa).

Relevant organisations may also wish to set out a policy position in terms of their expectations for junior doctors' participation in clinical audit. HQIP has published a [Guide to involving junior doctors in clinical audit and quality improvement](#),¹⁶ which includes a template policy that may be used as a stand-alone policy, incorporated into the clinical audit policy, or built into wider policies, such as those covering quality, governance, or training.

5 Duties, roles, and responsibilities

5.1 Identifying key staff and committees

This section should outline the key staff and committees in the organisation that have a responsibility for clinical audit. For example:

- Who is the executive/Board lead and what are this person's responsibilities in respect of clinical audit?
- Who is the operational lead for clinical audit (i.e. who fulfils the role of clinical audit manager)?
- Is there a central clinical audit team, and if so what is its composition? What are the duties of clinical audit staff?
- Who is responsible for providing and co-ordinating clinical audit training?
- Which committee has prime responsibility for oversight of clinical audit practice and what exactly is its role (e.g. clinical audit committee, clinical governance committee, patient safety and quality committee)? What are the routes of escalation for concerns raised by these committees?
- Are there designated clinical leads and facilitators in clinical divisions/directorates/services, and what is their function?
- Who has responsibility for ethical oversight of clinical audit?

Example statement:

The chief executive is accountable for the statutory duty of quality, and takes overall responsibility for this policy, for effective prioritisation to participate in national clinical audit, and for decisions about local clinical audit.

5.2 Roles and responsibilities

Details of duties and responsibilities may be summarised in the policy, or full role descriptions, lines of accountability from Board to ward and ward to Board, and terms of reference, might be included as appendices.

As per the example governance structure in diagram 3, individuals, committees, and groups whose duties should be described in this section include:

Chief Executive

Role and accountability of the chief executive in relation to effective quality assurance, oversight and scrutiny of the clinical audit programme and reporting, prioritisation of participation in national clinical audit, and decisions about local clinical audit should be set out.

Trust Board

Roles and responsibilities of the Trust Board in relation to effective prioritisation for participation in national clinical audit and decisions about local clinical audit should be set out. HQIP's *Clinical audit: A guide for NHS Boards and partners*¹⁷ describes the role of clinical audit in healthcare quality improvement and good governance, for Trust Boards and managers.

Committees/Groups

Roles and responsibilities of the committees/groups involved in oversight and scrutiny of the clinical audit programme and reporting for quality assurance, prioritisation of participation in national clinical audit, decisions about local clinical audit, and the review of audit reports, including progress through repeated clinical audit cycles, should be set out. The method of communication from ward to Board, and Board to ward should be described, along with the process for sharing audit results and findings, and how the implementation of change will be supported and managed through action planning. This section should also describe the committee(s) that have responsibility for ethical considerations. Example terms of reference for a clinical audit committee are included at Appendix 1 of this guide.

Example statement:

The clinical audit committee is the corporate committee tasked with oversight and scrutiny of the Trust's clinical audit activities, prioritisation of participation in national clinical audit, decisions about local clinical audit, and the review of audit reports, including progress through repeated clinical audit cycles.

Diagram 3 Example Clinical Audit Governance Structure



Nominated director(s)

Roles and responsibilities of the nominated director(s) with responsibility for effective prioritisation for participation in national clinical audit and decisions about local clinical audit should be set out.

Medical director(s)

Roles and responsibilities of the medical director(s) and their involvement in national and local clinical audit should be documented.

Example statement:

The executive/Board lead for clinical audit is the medical director. His/her responsibilities in respect of clinical audit are:

- To ensure that the Trust clinical audit strategy and annual programme of work are aligned to the Board's strategic interests and concerns
- To ensure that clinical audit is used appropriately to support the board assurance framework
- To ensure this policy is implemented across all clinical areas
- To ensure that any serious concerns regarding the Trust's policy and practice in clinical audit, or regarding the results and outcomes of national and local clinical audits, are brought to the attention of the Board.

Senior manager(s)/managers

Roles and responsibilities of the senior manager(s) and their involvement in national and local clinical audit should be set out. The policy should also include a clear statement of intention to work in partnership with clinical managers. It is particularly important to involve clinical managers if the anticipated outcome of a clinical audit project raises resource implications.

Example statement:

Managers are responsible for ensuring that service development and delivery is underpinned by an effective programme of clinical audit, which forms part of the Continuing Professional Development regime for their team.

Clinical audit and effectiveness department

Roles and responsibilities of the clinical audit and effectiveness department should be set out. This section may be used to describe the principles that staff conducting clinical audits will be expected to follow. Similarly, the section may also detail the principles for conducting clinical and non-clinical audits that ensure compliance with the standards set out in the organisation's approved documents, in support of quality assurance and improvement processes.

Clinical audit manager

Roles and responsibilities of the manager responsible for clinical audit and their involvement in national and local clinical audit should be set out, including compiling the annual clinical audit programme, supported by the medical director, the Trust Board, and relevant Board sub-committees.

Clinical directors/clinical lead(s) for clinical audit

Roles and responsibilities of the clinical lead(s) and their involvement in national and local clinical audit should be set out, and [HQIP's Guide for clinical audit leads](#)¹⁸ offers further useful information to consider.

Example statement:

All clinical directors must ensure that a senior clinician within their directorate is nominated as the directorate lead for clinical audit (they may choose to take on this role themselves). The responsibilities of the directorate leads for clinical audit are:

- To ensure that this policy is implemented throughout their directorate
- To ensure that all clinical audit activity within their directorate is registered on the Trust database and complies with nationally accepted best practice standards
- To ensure that their directorate participates in all national clinical audits, national confidential enquiries and inquiries, and national service reviews that are relevant to the services provided
- To work with clinicians, service managers, directorate and divisional governance and quality managers, and clinical audit staff, to ensure that the clinical audit programme meets all clinical, statutory, regulatory, commissioning, and Trust requirements.

Individuals

This section should define the responsibilities of all clinical staff, and any other staff involved in the clinical audit process.

Example statement:

All staff employed by the Trust have a responsibility for the continual improvement of the quality of the service they provide, and all clinical staff are individually accountable for ensuring they audit their own practice in accordance with their professional codes of conduct and in line with the standards set out within this policy.

If the organisation has a code of conduct for staff participating in clinical audit activities, it could be referenced in this section of the policy.

6 Conduct of clinical audit

This section should outline how the organisation's clinical audit programme will be developed, and the principles that will be followed in the conduct of clinical audits.

6.1 Agreeing an annual programme of activity

This section should provide details of the annual process by which an organisation-wide programme of clinical audit activity is determined and agreed, for example, through a process of considering ward (clinical staff/services, patients, etc.) to Board (Trust committees, business groups, or external/regulatory/commissioner, etc.) requirements. The organisation should adopt an overarching system for categorising/grading clinical audit proposals to ensure clarity about 'must do' activity, and prioritisation. Reference should also be made to other Trust policies that address the management of recommendations made by national service reviews, and national confidential enquiries and inquiries, which may also require clinical audit activity.

The organisation may wish to include a specific statement clarifying its approach in respect of national clinical audits. For example, an organisation may determine that it will treat all projects described as national clinical audits as priorities, including those national projects contained within the [National Clinical Audit and Patient Outcomes Programme](#).¹⁹

More detailed information and ideas on the process of developing an annual clinical audit programme can be found in HQIP's guide, [Developing a clinical audit programme](#).²⁰

It is important to remember that for organisational quality assurance purposes, the implementation of the processes outlined within this policy should be monitored, as described at [Section 9](#) of this document, with an overarching annual report. The report should be programmed, so that any shortfalls in practice identified, either at an organisational level, or within particular clinical divisions or operating units, can be addressed.

It would be expected that the proposed annual programme would be ratified by the organisation's Board, or an appropriate sub-committee of the Board, and the policy should include a statement to this effect.

Example statement:

Prior to the start of every financial year, the Trust will agree an appropriate planned programme of clinical audit activity. This programme should meet the Trust's corporate requirements for assurance, but must be owned by clinical services.

6.2 Working with commissioners

The policy should include a statement outlining how the provider organisation will consult/work collaboratively with its commissioners, e.g. in determining programmes of activity, etc.

6.3 Choosing and prioritising local clinical audit topics

It is important for the organisation to maintain a strategic overview of how clinical audit time and resources are used to deliver quality improvement and assurance activity. Alongside mandatory activity, the organisation should outline how work is prioritised, and more detailed information and ideas on the process of prioritisation can be found in HQIP's [Developing a clinical audit programme](#).²⁰

Example statement:

The Trust is committed to supporting locally determined clinical audit activity to significantly contribute to the process of continuous service quality improvement. It is acknowledged that individual clinicians may initiate a clinical audit project on the basis of personal interest, personal development, or as part of an educational or training programme. It is important that these are registered with the Trust and reported through existing clinical governance structures to maximise organisational learning.

Example statement:

For each clinical audit project:

- An audit proposal form must be completed by the project lead
- The proposal must be approved by the clinical audit committee.

All clinical audit activity must be registered with the clinical audit department, irrespective of the level of facilitation being requested of the department, to ensure project consistency, and to enable progress review and monitoring for quality assurance purposes.

The organisation may have a separate system for approving patient and public involvement activity, and if so, this should be described here. For example, depending on the system the organisation has adopted, a clinical audit project that includes a patient survey may require approval from clinical audit leads and from a patient panel.

6.4 Use of databases

Organisations will maintain some form of central clinical audit registration database incorporating details of clinical audit activity, whether a Word table, Excel spreadsheet, Access database, or similar. The policy should explain the records that will be held on this database, how the information will be

used, who will maintain it, who will have access to it, and how completed clinical audit project reports are stored centrally (they may be embedded within the database), for future review and quality monitoring and assurance purposes. See HQIP's guide, [*Documenting local clinical audit: A guide to reporting and recording*](#).²¹

Example statement:

Data provided on registration will be used to compile a database of all clinical audit activity undertaken throughout the Trust. This database will be updated regularly by the clinical audit manager and will be used to report to the clinical audit committee on the progress of the annual clinical audit programme. The format and content of the database will be subject to review and approval by the clinical audit committee.

6.5 The use of standards (or criteria) in clinical audit

By definition, clinical audit involves measuring clinical practice against standards of best practice. This section of the policy should make clear the organisation's expectations in respect of the use of standards in clinical audit, and how these should be presented. Publications such as HQIP's *New principles of best practice in clinical audit*¹³ describe how standards should be constructed. The policy should also describe the acceptable evidence base to be used to formulate local standards, and to ensure the standards that are audited are effective in providing useful results. If project proposal documentation is included as an appendix to the policy, this would normally include the organisational model for developing standards.

This section of the policy should also explain how the organisation will ensure that each policy, procedure, guideline, protocol, or any other document describing practice to be monitored through audit, will be thoroughly interrogated so that the standards or criteria described therein are auditable and used to determine any associated audit proforma. This will help to ensure that all clinical audits undertaken test appropriate standards or criteria for meaningful results, essential for effective use of resources

in quality improvement and quality assurance. See HQIP's guide, [Ensuring data quality in clinical audit](#)²² for advice on defining data collection parameters.

If the Trust chooses to adopt a quality improvement policy, which covers both clinical audit and other quality improvement methodologies that do not rely on standards, there should be a clear statement about how such projects will be registered, and how governance and ethical issues raised by such projects will be addressed.

6.6 Reporting

This section of the policy should detail how the results of clinical audit will be reported to the organisation's management and governance leads, as well as to relevant clinicians. It should specify minimum reporting requirements for all clinical audits. If the Trust uses a standardised template for reporting, this should be provided as an appendix to the Policy. See HQIP's guide, [Documenting local clinical audit: A guide to reporting and recording](#).²¹

6.7 Dissemination

The organisation should set out expectations for the sharing, scrutiny and debate of findings set out in clinical audit reports, for example, the responsibilities of clinical audit/governance meetings and forums.

Example statement:

Regular summary clinical audit reports, together with recommendations, should be communicated to all relevant areas of the organisation and Trust committees. An effective audit carried out in one area of the Trust may be transferable to other parts of the organisation. Once a round of data collection has been completed and the data has been analysed, the results and findings should be presented at specialty audit meetings, for discussion, agreement of action plans and a commitment to complete another audit cycle within a designated timeframe.

The clinical effectiveness group will review all summary clinical audit reports on completion.

6.8 Action plans for improvement

The main purpose of clinical audit is to deliver improvements in clinical practice. Where the results of a clinical audit indicate sub-optimal practice, an action plan must be developed and implemented and its effects monitored. A systematic approach to the development and implementation of clinical audit action plans is essential for effective improvement, and a standardised action plan template should be provided as an appendix to the policy, and described here. Advice on the development and use of action plans can be found in HQIP's *New principles of best practice in clinical audit*.¹³ See also HQIP's [Documenting local clinical audit: A guide to reporting and recording](#).²¹

Effective action planning depends on the identification of the root cause of any shortfall in practice. HQIP's guide, [Using root cause analysis techniques in clinical audit](#)²³ offers advice to support the identification of system and process issues impacting upon compliance with standards. Robust action planning means changing systems and processes to make it easier for staff to meet standards, and harder not to meet them.

Example statement:

Actions should be specific, measurable, achievable and relevant. They must have clear implementation timescales, with identified leads for each action.

Action plans must be approved by the relevant head of service or department.

Not all clinical audits will require an action plan, e.g. where an audit shows that standards are consistently and repeatedly being met, and practice is effective.

For such audits there should be an explicit statement within the summary report that no further action is required, along with the reason(s) for this.

The organisation should also include an overall statement explaining the process by which it will monitor that action plans have been satisfactorily completed, and gather assurance that service improvements have resulted.

Example statement:

The clinical audit committee will monitor the implementation of actions, ensuring that any identified required changes are incorporated into practice and into relevant business plans and/or risk registers as appropriate.

6.9 Repeating audit cycles

The clinical audit cycle is not complete until agreed actions are implemented according to the corresponding action plan, and evidence is obtained of the impact of the action plan on compliance with standards. This may be achieved by repeating data collection or by instituting a programme of ongoing monitoring. Repeated cycles of clinical audit may be carried out to ensure standards and criteria are consistently and repeatedly met, and practice is effective. This section of the policy should set out the organisational plan for repeating clinical audit cycles. For example, an organisation may take the approach that a certain proportion of its annual clinical audit programme should be accounted for by repeated audit cycles.

6.10 Clinical Audit Annual Report

In this section of the policy the organisation should include information regarding the content of the clinical audit annual report, and how it will be approved, disseminated and publicised. An example format for an annual report is attached at Appendix 2, and this may also be the case in the policy.

7 Governance and ethics

7.1 Ethics and consent

By definition, clinical audit projects should not require formal approval from a research ethics committee. However one of the principles underpinning clinical audit is that the process should do good and should not do harm.

Clinical audit must always be conducted within an ethical framework, and a statement to this effect should be included in the policy.

The ethical framework should consider the following four principles:

1. There is a benefit to existing or future patients or others that outweighs potential burdens or risks
2. Each patient's right to self-determination is respected
3. Each patient's privacy and confidentiality are preserved
4. The activity is fairly distributed across patient groups.

See HQIP's [Guide to managing ethical issues in quality improvement or clinical audit projects](#)²⁴ for more information.

This section of the policy should describe individuals and committees within the organisation who have responsibility for ethical oversight of the clinical audit programme. This ethical oversight will ensure that:

- The clinical audit programme is managed efficiently to make best use of resources, and performance management issues associated with poor audit design, poor execution, or failure to deliver improvements in patient care, are addressed
- Any ethical concerns that arise during the design and planning of individual clinical audits are addressed
- Any instances of serious shortcomings in patient care that come to light through clinical audit are communicated to the clinical director of the service involved at the earliest opportunity, and appropriate steps are taken to address them

- Risk management issues identified through clinical audit results are addressed in clinical audit action plans, and those plans are implemented effectively.

Example text:

The clinical audit committee is responsible for the ethical oversight of clinical audit across the organisation and any person who has concerns regarding the ethics of clinical audit should refer them to the Chair of the committee.

7.2 Equality and diversity

This section of the policy should establish the principle that clinical audit practice must take account of equality and diversity issues. For example the organisation must ensure that the process for determining choice of clinical audit projects, and the manner in which patient samples are selected, does not inadvertently discriminate against any societal groups based on their race, disability, gender, age, sexual orientation, religion, or belief. If the organisation uses equality impact assessment tools in the context of clinical audit, these should be described here. The organisation might also commit to collecting equality data as part of clinical audit activity, in order to determine whether any particular groups of patients are experiencing variations in practice.

Example text:

The Trust aims to ensure that its healthcare services and facilities are not discriminatory and, wherever possible, attend to the physical, psychological, spiritual, social, and communication needs of any patient or visitor, showing no discrimination on the grounds of ethnic origin or nationality, disability, gender, gender reassignment, marital status, age, sexual orientation, race, trade union activity, or political or religious beliefs.

The process for determining choice of clinical audit projects, and the manner in which patient samples are selected, should not inadvertently discriminate against any groups in society based on their race, disability, gender, age, sexual orientation, religion, or belief. Any person who has concerns regarding the ethics of clinical audit activity within the Trust should refer them in the first instance to the clinical audit committee, who may require equality impact assessments to be undertaken and/or equality data to be collected as part of clinical audit activity, in order to determine whether any particular groups of patients are experiencing variations in practice.

7.3 Information governance: collection, storage and retention of data and confidentiality

All clinical audits must adhere to information governance policies and standards, paying special attention to the [Data Protection Act](#)²⁵ and the [Caldicott Principles](#),²⁶ whereby data should be:

- Adequate, relevant, and not excessive
- Accurate
- Processed for limited purposes
- Held securely
- Not kept for longer than is necessary.

In its policy, the organisation should describe the methods used for the appropriate collection, storage and retention of data collected for clinical audit purposes.

This section of the policy should also draw upon wider information management policies in place that impact upon clinical audit practice, e.g. rules governing the use of memory sticks, laptops, etc.

Detailed guidance can be found in HQIP's guide, [Information governance in local quality improvement](#).¹¹

8 Training and development

8.1 Overall organisational approach

This section of the policy may start with contextual information to set out the need for appropriate clinical audit training. It would be usual to include a statement that reflects the organisation's overall approach to education, training and professional development, and to describe the need to improve clinical audit activity through enhanced skills and competence as part of professional development. Organisational policies for training and development should be referenced, along with any training prospectus.

Example statement:

Some aspects of clinical audit require specialist skills, for example using the correct clinical audit methodology. This policy sets out how the Trust will ensure that all clinicians and other staff and patients conducting and/or managing clinical audits are given the appropriate time, knowledge and skills to facilitate the successful completion of clinical audit cycles. Clinical audit education and training are key to the delivery of this policy, in order to promote activity led by healthcare professionals.

Training raises the profile of clinical audit and best practice standards, builds capacity and capability for the reflective practice of all those involved, and acts as a driver for quality improvement.

8.2 Provision of clinical audit training

The policy should describe the organisation's approach to the provision and development of the clinical audit training programme, considering all of those identified as the policy target audience, set out at section 4.1. Organisation-specific information on training programmes and schedules may include:

- Who will be offered the training, including all healthcare professionals that are responsible for auditing the quality of care they deliver
- Who will deliver the training
- The different types/levels of training offered
- The frequency of the training
- How to access the training.

Example statement:

The Trust will make available suitable training, awareness and support programmes to all relevant staff regarding the systems and arrangements for participating in clinical audit. This will ensure:

- An introductory clinical audit training session is available to any member of staff
- An ongoing programme of clinical audit training of different levels is available to all staff to enable them to undertake clinical audit
- Training for local, regional, and national clinical audit activities, and bespoke training, will be given to groups and individuals on request
- Appropriate training is available to any patients and other members of the public who participate in clinical audit activities.

Educational resources on clinical audit processes are available through the [HQIP website](#)

8.3 Employment and development of clinical audit staff

The policy should include a statement establishing the organisation's responsibility for employing and developing suitably-skilled clinical audit staff. A broad statement setting out the organisation's approach to the training and development of its clinical audit support staff should also be included.

Regional clinical audit networks are in place throughout England, and healthcare providers should consider advocating membership of these networks as a route to professional development for clinical audit staff.

Example statement:

The Trust will employ a team of suitably skilled clinical audit staff to support the programme of clinical audit activity. The Trust will also ensure that staff have access to further relevant training in order to maintain and develop their knowledge and skills.

Clinical audit staff will be expected to participate in professional training and development activities including those organised by HQIP, the National Quality Improvement (including Clinical Audit) Network (N-QI-CAN) and (insert name of local clinical audit network).

9 Monitoring

9.1 Monitoring the effectiveness of clinical audit activity

This section should describe any systems in place to monitor the progress of the organisation’s clinical audit programmes and associated outcomes. More detailed information can be found in HQIP’s *Developing a clinical audit programme*.²⁰

9.2 Monitoring the implementation of the policy

For quality assurance and improvement purposes, in common with all policy documentation, this section should describe how the implementation of the clinical audit policy will be monitored within the organisation, when, and by whom.

According to local organisational systems and process, this section might describe how the organisation will monitor that:

- Clinical audits are approved and registered
- Clinical audits are based on standards and conducted in line with this policy
- Projects are meeting data protection and confidentiality guidelines
- Results are being reported and disseminated
- Action plans are being agreed and implemented
- Timely progress reports are being sent to commissioners.

- The lead committee for clinical audit is discharging its responsibilities
- Staff are receiving training
- There is a rigorous system for determining what goes into the annual clinical audit programme
- Stakeholders are being involved

Appendix 3 provides an example of a table format for summarising policy monitoring requirements for quality assurance and improvement purposes. Using such a table helps healthcare providers to determine how they will monitor that clinical audit policies and procedures are being properly implemented. This section should also describe the structure and purpose of the clinical audit policy monitoring reports, which will be routinely reviewed by the clinical audit committee (or equivalent), the Board (or its sub-committees), and/or commissioners of services, and which might make use of such a table format. It should set out:

- Who will perform the monitoring
- When and how the monitoring will be performed
- What will happen if any shortfalls are identified
- Where the results of the monitoring will be reported
- How the resulting action plan will be progressed and monitored.

Appendix 1. Example terms of reference for a clinical audit committee

Note: The following is an example of how a clinical audit committee's terms of reference might be set out, and is provided for the purposes of illustration only. In practice each organisation will have a standardised format for terms of reference, and the detail of the document will vary according to local arrangements.

1 Purpose and responsibilities

- 1.1 To inform and advise the Board whether the Trust is meeting its contractual obligations to participate in clinical audits, including the National Clinical Audit Patients Outcome Programme and any other national audits, particularly where participation must be reported in Quality Accounts.
- 1.2 To inform and advise the Board whether clinical audit activity is meeting the expectations of the Care Quality Commission's Fundamental Standards, including:
 - Effective processes and systems in place to enable healthcare professionals to participate in quality improvement activity such as clinical audit
 - The organisation's clinical audit policy is implemented and adhered to
 - The organisation's clinical audit strategy is being delivered
 - Clinical audit is being used to evaluate compliance with national guidance, such as that produced by the National Institute for Health and Care Excellence (NICE) and the Royal Colleges
 - The organisation is participating in relevant national audits
 - The organisation is using the findings from clinical and other audits, including those undertaken at a national level, national service reviews, and national confidential enquiries and inquiries, to ensure that action is taken to protect people who use services from risks associated with unsafe care.
- 1.3 To inform and advise the Board whether clinical practice at the Trust is compliant with organisational policy. The committee will monitor:
 - The process to compile and prioritise the annual clinical audit programme
 - The process to ensure appropriate standards of performance are audited
 - The conduct of clinical audits, including the process for disseminating audit results, findings and reports, and the format for audit reports, to ensure audits are conducted in line with policy
 - The process for making improvements, monitoring action plans, and repeating audit cycles.

Where any deficiencies are identified through this monitoring, the committee will require the relevant divisions, directorates, clinicians and/or clinical audit staff to develop recommendations and implement actions to remedy those deficiencies.
- 1.4 To work collaboratively with the clinical audit manager to:
 - Ensure appropriate distribution of audit resources with the organisation
 - Ensure that clinical audit staff and others carrying out clinical audit have access to relevant and appropriate education and training
 - Support clinical audit leads and facilitators in their respective roles.
- 1.5 To ensure all clinical audit activity within the Trust is conducted in an ethical manner, and with due regard to equality and diversity.

2 Reporting

2.1 To receive the following reports:

- Annual forward plans for clinical audit activity
- Regular updates on the progress of the clinical audit programme including key national clinical audit activity
- Regular reports on the conduct of clinical audits, including:
 - Whether stakeholders are being involved
 - The use of appropriate clinical standards
 - Whether projects are meeting data protection and confidentiality guidelines
 - The dissemination of clinical audit results and outcomes and the quality of completed clinical audit reports
 - The agreement and implementation of clinical audit action plans.
- Reports on how the organisation's clinical audit budget is being used
- The draft annual clinical audit report, including committee compliance with these terms of reference.

2.2 To provide the following reports, which will be drafted in the first instance by the clinical audit manager:

- A quarterly progress report to the Board via its governance committee
- The annual clinical audit report to the Board in March each year, including content for the Trust's quality accounts relating to clinical audit.

3 Membership of the committee

Core members are:

- Non-executive director Chair
- Clinical audit manager (deputy Chair)
- Representatives from each clinical division
- Clinical effectiveness manager
- Director of governance and quality

Meetings will be deemed to be quorate when the Chair or deputy Chair are in attendance, supported by representatives from at least three clinical divisions.

4 Frequency of meetings

The committee will meet every two months.

5 Monitoring

Committee compliance with these terms of reference will be monitored as part of the annual clinical audit report.

Appendix 2. Example format for the annual clinical audit report

1 Introduction

This section should include information pertaining to the clinical effectiveness/audit department such as the number of staff, backgrounds and experience of employees. It is an opportunity to highlight the achievements of the department during the year and is usually written by the head of department.

2 Overview of clinical audit activity

This section should contain a broad overview of clinical audit strategy developments in the past year, and information on the way in which strategic objectives have been achieved.

A general summary of clinical audit activity statistics (e.g. number of audits registered, number completed, etc.) for the Trust as a whole should be included. This provides opportunity for comparison year-on-year, or with other Trusts. In order to avoid duplication of effort, this information can be structured in the same way as the clinical audit section of the Trust quality accounts.

3 Clinical audit/effectiveness committee

This section provides the opportunity for Trusts to outline the mechanisms for reporting and monitoring clinical audit/effectiveness/governance activity. It should include a summary of compliance with the committee terms of reference (i.e. fulfilment of the committee purpose, reporting arrangements, member attendance, frequency of meetings, and committee responsibilities).

4 Education and training

The content of this section will vary depending on the type of organisation and the size of the clinical audit/clinical governance department. It should include:

- A summary of types of clinical audit training undertaken, including purpose
- Description of the target audience (e.g. staff groups, patients, and the public)
- Training attendance figures and feedback from sessions
- Developments in education and training that year.

(e.g. new training courses and course materials developed, workshops delivered at conferences, etc.).

5 Patient and public involvement

This section should include local initiatives to involve patients and the public in clinical audit.

6 Monitoring

This section should detail the results of clinical audit policy compliance monitoring activity undertaken in accordance with the monitoring section of the policy, for quality assurance and improvement. If this has resulted in the identification of shortfalls, the report should include an action plan, and evidence of actions that have been implemented.

7 Plans for forthcoming year

In this section, Trusts should set key objectives for the forthcoming year and clinical audit strategy, including any development plans identified, along with the planned clinical audit programme and departmental priorities.

8 Links with clinical governance/quality

Some Trusts integrate clinical audit, clinical governance, and/or quality improvement activity, and consequently produce joint reports. This section provides the opportunity to explain how this activity is linked, if necessary, within your Trust.

9 Links with other organisations

As patient care pathways usually involve more than one NHS organisation, clinical audit at the interface (e.g. between community and secondary care Trusts) is essential. Associated commissioner and integrated care system requirements should also be explained.

A distinguishing feature of interface audit is that there is active involvement from both organisations. A summary of interface audits and audits of integrated patient care pathways should be included in this section.

10 Additional sections relevant to the local organisation

The above headings are intended to be generic and applicable to acute, community care, mental health, and ambulance Trusts. It is likely that particular sectors will need to provide additional information on other topics within their annual report, which could be set out within this section.

11 Detailed account of clinical audit activity

Each organisation must decide the amount of detail that it includes, and whether this information should be in the body of the report or appendices. The following suggestions will vary in their application, depending on local requirements.

11.1 Directorate/division summaries

These could include:

- Name of directorate/division
- Tabular summary of activity including statistics
- Significant shortfalls identified and actions taken or planned.

For each directorate/division the above information should be supplemented with an example of a clinical audit that has led to improvement in practice. This might cover a clinical audit topic of local importance, rather than a Trust or national priority.

Requesting clinical leads from each directorate/division to contribute to this section encourages organisation-wide participation in the clinical audit programme.

11.2 Standardised summary reports of clinical audits

Some Trust clinical audit departments choose to report on every audit project undertaken in the year, which can result in a lengthy document. Some departments select projects of most interest to Trust Boards to report in more detail in a section such as this, using the directorate/division summary section to cover all clinical audits, which can lead to a more user-friendly document accessible to patients and the public. See HQIP's [*Documenting local clinical audit: A guide to reporting and recording.*](#)²¹

Appendix 3. Clinical audit policy implementation monitoring requirements for quality assurance and improvement

POLICY MUST DESCRIBE:	FOR EACH ASPECT OF THE POLICY		
	How will implementation be monitored and how frequently?	Who is the accountable individual or committee/ group responsible for monitoring?	When and where will the results of monitoring (including the implementation of any actions required to remedy deficiencies) be reported?
a. The responsibilities of staff in relation to clinical audit			
b. How the organisation sets priorities for clinical audit, including local and national requirements			
c. The requirement that clinical audits are conducted in line with the approved process for clinical audit			
d. How clinical audit reports are shared			
e. The format for all clinical audit reports, including methodology, conclusions, action plans, etc.			
f. How the organisation makes improvements through action planning and repeated audit cycles			

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