

■ Developing a Clinical Audit Programme





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Contents

1	Introduction	4
1.1	Background	4
1.2	Functions of the clinical audit programme	5
1.3	Requirements for external monitoring	5
2	Compiling the annual clinical audit programme	6
2.1	Roles and responsibilities	6
2.2	Stakeholders	6
2.3	External ‘must-do’ audits	6
2.4	Internal ‘must-do’ audits	7
2.5	Registering clinical audit proposals	7
3	Review, prioritisation, and formal approval	8
3.1	Reviewing the draft programme	8
3.2	Prioritising the draft programme	8
3.3	Approval of the clinical audit programme	9
3.4	Additions to the clinical audit programme	9
3.5	Practical steps in compiling an annual Trust clinical audit programme	10
4	Monitoring the clinical audit programme	11
4.1	Responsibilities	11
4.2	Monitoring progress	11
4.3	Monitoring the implementation of action plans	11
4.4	Identifying risks	11
5	References	12
	Appendix 1. Minimum data set for a clinical audit database	12
	Appendix 2. Quality impact analysis	13
	Appendix 3. Clinical audit progress report for ‘Insert name here’ division/directorate	14

1 Introduction

1.1 Background

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 clinical audit programme, with tools for ongoing management and annual review.

A clinical audit programme should:

- Reflect key national and local drivers for quality improvement
- Balance key drivers with directorate/division/service/clinician priorities
- Include a system for prioritisation of clinical audit
- Enable monitoring to ensure clinical audits selected for the programme are completed.

1.2 Functions of the clinical audit programme

The clinical audit programme may exist in a variety of forms, either paper-based or electronic. At the most basic level, it will be a simple list of all the clinical audit projects planned or undertaken by the healthcare provider in a given period of time – normally a financial year. For a small organisation such as an individual GP practice, a single list may suffice. For a large, acute hospital Trust, the programme may be broken down into several lists, including one for Trust-wide projects, one for projects undertaken in collaboration with other local providers, as well as separate lists for each clinical division or directorate. In this case, it is essential that these separate lists are also integrated so that they are monitored as one overall programme.

The programme allows the healthcare provider to fulfil several functions:

- Meeting requirements for external monitoring – see 1.3 below
- Monitoring progress made in completing the programme
- Monitoring the quality of clinical audit activity
- Monitoring the impact of the programme.

In most cases the list will be incorporated into a database that includes a range of key information about each of the individual clinical audit projects. A minimum data set for a clinical audit programme database is given at Appendix 1. It includes basic information that should be obtained when projects are first registered, together with other quality management and monitoring information that should be added as projects progress.

1.3 Requirements for external monitoring

HQIP's *Statutory and mandatory requirements in clinical audit*⁴ guidance presents key requirements for clinical audit, which must form the basis of the healthcare providers' approach to compiling their annual clinical audit programmes.

The clinical audit programme must:

- Meet the healthcare provider's contractual obligations to those who commission its services; this includes meeting the terms of the NHS Standard Contract, which requires participation in the National Clinical Audit Patient Outcomes Programme (NCAPOP) audits relevant to the services they provide, and Commissioning for Quality and Innovation (CQUIN) audits, including any locally agreed CQUIN requirements
- Use the findings from clinical and other audits – 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
- 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 professional development)
- Meet the requirements of the regulatory framework operated by the Care Quality Commission (CQC), which requires registered healthcare providers to assess and monitor the quality of services provided through audit, to ensure that action is taken to protect people who use services from risks associated with unsafe care
- Provide Foundation Trust Boards with the assurance they need to certify that they have effective arrangements in place for monitoring and continually improving the quality of healthcare provided to patients, using systems, processes and procedures to monitor, audit, and improve quality
- Enable healthcare providers to produce required quality accounts to efficiently compile the information they need.

2 Compiling the annual clinical audit programme

2.1 Roles and responsibilities

A healthcare provider's clinical audit policy should set out the roles and responsibilities of all who will be involved in compiling and managing the clinical audit programme. For NHS Trusts this should include the role of the Trust Board in setting Trust priorities and requirements, the role of the medical director in ensuring that the annual programme is aligned to the Board's strategic interests and concerns, and the roles and responsibilities of the committees/groups involved in the prioritisation of the programme and the subsequent review of reports and re-audits.

A key consideration is to decide who has overall responsibility for compiling the annual clinical audit programme, and for the purposes of this guidance it is assumed that this will be the clinical audit manager (or the manager who takes overall responsibility for clinical audit, whatever their job title might be). In larger organisations, the manager will need to work closely with each directorate lead for clinical audit, who will have delegated responsibilities, including:

- Ensuring that all clinical audit activity within their directorate is registered
- Ensuring that their directorate participates in all national clinical audits, national confidential enquiries and inquiries, and other reviews relevant to the services that it provides
- Working with clinicians, service managers, divisional governance and quality managers and clinical audit staff, to ensure that the clinical audit programme for their directorate meets all clinical, statutory, regulatory, commissioning, and other Trust requirements.

HQIP's [Guide for clinical audit leads](#)² provides detailed guidance on the role of the clinical audit lead in compiling and monitoring the clinical audit programme.

2.2 Stakeholders

Compiling the clinical audit programme requires close co-operation between all key stakeholders, including commissioners, clinical leads at all levels of the organisation, clinical governance managers, and all those responsible for formulating organisational policies.

All staff working in the organisation should have the opportunity to propose projects, and the views of patients, service users, carers, and the public should be sought. Both national and local priorities should influence the development of the clinical audit programme.

2.3 External 'must-do' audits

The first step in developing a comprehensive annual programme is the identification of all the clinical audit projects that **must** be undertaken by the provider.

Every healthcare provider will have a number of clinical audits that it must complete on a regular – perhaps annual – basis in order to meet the external monitoring requirements outlined above. It is essential to ensure that these audits are treated as priorities and that appropriate resources are provided to support this.

Failure to participate in or deliver on these externally driven audits may carry a penalty for the Trust, either financially, or in the form of a failed target, or non-compliance with regulations – though may ultimately amount to unmonitored high-risk services. External 'must-do' audits should be core to the annual clinical audit programme.

The list of ‘must-do’ audits will vary between types of healthcare provider, but may include:

- *NCAPOP and other national clinical audits relevant to the services provided, and/or where participation must be reported in quality accounts**
- *Audits demonstrating compliance with regulatory requirements, e.g. audits with the aim of providing evidence of implementation of National Institute for Health and Care Excellence (NICE) guidance, NHS Outcomes Framework Indicators, and other national guidance such as that generated by the Clinical Outcomes Review Programme (CORP – covering national confidential enquiries and inquiries)*
- *Audits required by external accreditation schemes, e.g. cancer peer review audits, etc.*
- *Audits that must be undertaken in order to comply with provider policies, particularly those that are subject to external review*
- *Commissioner priorities including national and regional Commissioning for Quality and Innovation (CQUIN) audits.*

** See HQIP www.hqip.org.uk/national-programmes/quality-accounts/*

It should also be noted that while most healthcare providers will follow an annual clinical audit programme, many of these projects will need to be undertaken regularly, so a forward plan for future years can be maintained.

2.4 Internal ‘must-do’ audits

Every healthcare provider will also be able to compile a list of internal ‘must-do’ clinical audits, based on identified high-risk or high profile matters arising locally. Many of these clinical audits will arise from governance issues or high profile local initiatives, and may include national initiatives with local relevance, without penalties for non-participation. They may include:

- Audits undertaken to meet organisational objectives and service developments
- Clinical risk issues
- Audits undertaken in response to serious incidents/ adverse incidents/near-misses/complaints, to ensure corrective actions taken to prevent a recurrence have been implemented
- Organisational clinical priorities
- Priorities identified via patient and public involvement initiatives.

2.5 Registering clinical audit proposals

Once ‘must-do’ audits have been identified, stakeholders should be asked to propose projects that they believe would be of benefit to the patients and service users of the healthcare provider, in terms of care provided.

The most effective way of managing this part of the process is to stipulate that anyone who wants to propose an audit must complete an audit registration form, or proposal document. This form, which could be in hard copy, or electronic, should act as a prompt to ensure that the proposer has considered all of the issues that need to be addressed, in order to decide if the proposal is realistic and relevant to the organisation. In addition to providing the basic information required to enter the project onto the programme database, it should also provide the information that will be required to prioritise the project – see [3.2](#) overleaf.

3 Review, prioritisation, and formal approval

3.1 Reviewing the draft programme

Each Trust should have a framework to support effective clinical audit that relies on strategic planning and prioritisation. Clinical audits should contribute to the overall priorities of the organisation and should clearly improve patient care. However, resources are finite – both in terms of clinician time and central support function resource, and this places a limit on the number of audits that can be carried out over the course of a year. Therefore, when all the various needs have been considered and a draft programme compiled, the projects that have been proposed need to be reviewed and prioritised in a systematic way. This process of review must be clinically led, and must take into account resource implications.

In smaller organisations the review may be dealt with centrally, but in larger providers, the review is likely to require a staged process, with reviews at service unit or directorate/division level, followed by a final review by the clinical audit committee and sign off by the Trust Board.

Issues to be considered during the review include:

- *Is each project a clinical audit? Does it aim to improve patient care by implementing change, where quality of care under review falls short of defined standards and criteria? (Projects that do not meet this definition, e.g. patient surveys, and service reviews with no agreed standards, may still be of value to the provider but there should be a clear statement in the clinical audit policy about whether such projects will be registered as part of the clinical audit programme and how the governance and ethical issues raised by such projects will be addressed).*

- *Is each audit topic of relevance to the organisation?*
- *Are all clinical services represented on the programme?*
- *Are the requirements for clinical audit training for junior doctors and revalidation for more senior staff being met?*
- *What priority should be given to each clinical audit?*

3.2 Prioritising the draft programme

It is important to distinguish between the need to prioritise audits in order to make appropriate plans for the use of resources, and the need to register and monitor clinical audit activity in order to meet external monitoring requirements.

The highest priority must be given to the ‘must-do’ audits. Once they have been identified, the next priority should be given to projects that are important at the directorate/division/service unit level. Directorate priorities may include:

- Local clinical interest audit agreed by the directorate/division/service as a priority
- National audits where participation is not required to be reported in quality accounts
- Participation in regional audits undertaken as part of clinical specialty networks or regional clinical audit networks.

Factors that should be taken into account in determining directorate priorities are listed in HQIP's guide, *Best practice in clinical audit*.³ Others include:

- *Is the topic concerned with high cost, high volume or high risk to staff, or to patients/service users?*
- *Is there evidence of a quality problem, e.g. patient complaints, high complication rates, adverse outcomes or poor symptom control?*
- *Is there evidence of wide variation in practice?*
- *Is robust evidence available to inform audit standards, e.g. systematic reviews or national clinical guidelines?*
- *Is the problem measurable against relevant standards?*
- *Is auditing the problem likely to improve healthcare outcomes as well as process improvements?*
- *Is auditing the problem likely to have economic and efficiency benefits?*
- *Is the topic a key professional or clinical interest?*
- *Are reliable sources of data readily available for data collection purposes?*
- *Can data be collected within a reasonable time frame?*
- *Is the problem concerned amenable to change?*
- *Is the topic pertinent to national or local initiatives or priorities?*
- *Does the topic lend itself to the process of audit, or is a different process more appropriate e.g. root cause analysis, activity or workload analysis?*
- *How much scope is there for improvement, and what are the potential benefits of undertaking this audit?*

Scope for the direct involvement of patients and carers should also be considered, and whether the project crosses organisational or disciplinary boundaries.

Some of these factors may be applied using a quality impact analysis – [Appendix 2](#) provides an example.

The lowest priority for use of resources must be given to those audits that are proposed by individual clinicians or

clinical teams. This might include audits undertaken by junior doctors for training purposes or by more senior staff as part of the revalidation process. While staff should not be discouraged from undertaking projects that can bring about real improvements in patient care, it must be made clear to all staff that the need for training or revalidation can be met by undertaking projects that also meet directorate, divisional, or organisational priorities.

It is important to ensure that the views of all stakeholders are taken into account during prioritisation. This means consulting with commissioners, patients, and the public.

3.3 Approval of the clinical audit programme

In order to be effective in achieving improvements in the quality of care and patient outcomes, the clinical audit programme must have the support and backing of both the clinical leadership and the senior management. In NHS Trusts, the medical director, chief executive, and Trust Board all have direct responsibilities for the quality of the services they provide, and therefore must be directly engaged in developing and signing off the clinical audit programme.

3.4 Additions to the clinical audit programme

Compiling and prioritising an annual clinical audit programme at the start of the year should not stifle projects that emerge during the year that will contribute to improvements in care.

Some of these projects might be new 'must-do' audits that could not be determined at the outset of the financial year, for example those required in response to near-misses or adverse incidents arising. Others may represent innovative ideas from clinicians, which are just as valid and important as ideas proposed when the programme was originally developed. A transparent system for decision-making around whether or not (and to what extent) a project proposed later in the year should attract support from clinical audit resources is required.

Organisations may wish to update their annual clinical audit programme as part of the regular review of progress, or alternatively record these additional projects on a separate but complementary clinical audit programme. Whichever approach is taken, all clinical audits must be registered so that processes and outcomes can be monitored and the maximum benefit gained for the organisation.

3.5 Practical steps in compiling an annual Trust clinical audit programme

This is a summary of the steps that should be taken in compiling the Programme:



4 Monitoring the clinical audit programme

4.1 Responsibilities

Each clinical audit project on the programme should have a clinical lead who is ultimately responsible for the conduct of the audit. However in order to ensure that the organisation as a whole benefits from the programme, it must be monitored, and it is up to each healthcare provider to decide who should be responsible for this. Responsibility for directorate/division/service unit programmes may be delegated to clinical leads or clinical audit facilitators who work within each of those service levels, while organisation-wide projects may be monitored centrally by the clinical audit manager, or the whole process may be dealt with centrally. These responsibilities must be reflected in the organisational clinical audit policy.

The healthcare provider's clinical audit policy should set out clear lines of reporting for monitoring the clinical audit programme.

4.2 Monitoring progress

[Appendix 3](#) gives an example of a progress report that might be submitted quarterly to the relevant committee. The report gives basic information about all projects, and uses a traffic light system/RAG (red-amber-green) rating to indicate progress (or lack of it).

This summary report is based on detailed information held within the clinical audit programme database, and within some databases can be automatically generated as a report.

In order to be able to decide whether a project is progressing satisfactorily, the clinical lead or clinical audit facilitator who maintains the database must receive regular updates on progress from the audit lead. There should be an agreed process for following up on projects that are failing to progress, including provision for escalating concerns to the committee overseeing clinical audit.

4.3 Monitoring the implementation of action plans

Once a cycle of data collection has been completed, an action plan will be developed, and the progress in implementing this action plan should also be monitored. All actions should include target dates for completion, and reporting may therefore be by exception. There should be an agreed process for following up any actions that have not been implemented by the target date.

4.4 Identifying risks

If the failure to progress or complete a clinical audit, or the failure to implement an action plan, poses a risk to patients, staff, or the healthcare provider as a whole (e.g. a reputational or financial risk due to failure to meet standards), appropriate entries must be made on the provider risk register.

5 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. Guide for clinical audit leads (HQIP): www.hqip.org.uk/resources/guide-for-clinical-audit-leads/
3. Best Practice in clinical audit (HQIP, Radcliffe Publishing, 2011): www.hqip.org.uk/resources/best-practice-in-clinical-audit-hqip-guide/

Appendix 1. Minimum data set for a clinical audit database

- Unique identifier
- Title of the clinical audit
- Directorate(s)/division(s)/service unit(s) affected
- Audit aims and objectives
- Is the audit an external ‘must-do’ audit? If so, why?
- Is the audit an internal ‘must-do’ audit? If so, why?
- Priority level
- Clinician who takes overall responsibility for the audit
- Name(s) of any other clinicians directly involved in carrying out the audit (e.g. junior doctors)
- Name(s) of the clinical audit facilitator(s) who have been involved in the audit
- Key stakeholders and their involvement in the audit
- Involvement of patients or carers – who and how?
- Work plan for carrying out the clinical audit, including expected and actual dates for completion of key stages including re-audit
- Date final report approved and distributed
- Committee/group with responsibility for review of results and ensuring actions are taken, including actual date report received, and actions taken and approved.

Appendix 2. Quality impact analysis

This table can be used to provide a transparent system for deciding whether or not (and to what extent) a locally-conceived clinical audit project should attract clinical audit resources. Each project should be scored against the following criteria.

Criteria	No relevance (0)	Some relevance (1)	Almost met (2)	Fully met (3)	Score
High cost					(x2)
High volume					
High risk					(x2)
Evidence of a quality problem					(x2)
Wide variation in practice					
Good evidence available to inform audit standards					
Likely to improve healthcare outcomes as well as process improvements					
Likely to have economic and efficiency benefits					(x2)
Topic is a key professional or clinical interest					
Reliable sources of data readily available					
Reasonable time frame for completion					
Potential for improvement					(x2)
Scope for direct involvement of patients and carers					
Multidisciplinary project					
Interface project *					
TOTAL SCORE					

* When projects cross organisational boundaries, consideration should be given to the priority the project has in each organisation.

If the criterion has no relevance, score = 0
 If the criterion has some relevance, score = 1
 If the criterion is met in part, score = 2

If the criterion is fully met, score = 3
 NB Multipliers are used to weight the most important criteria

Appendix. 3 Clinical audit progress report for 'Insert name here' division/directorate

Project reference number	Project title	Clinical audit contact	Lead clinician	Project start date	Current Status				Comments	Priority level	Support level
					Q1	Q2	Q3	Q4			

Current Status	
Red	Cause for concern. No progress towards completion. Needs evidence of action being taken.
Amber	Delayed, with evidence of actions to get back on track.
Green	Progressing on schedule, evidence of progress.
Blue	Completed, evidence of compliance with standards or action plans to achieve compliance.
White	Audit not planned to start this quarter.

	Priority level	Support level
1	External 'Must-do'	I Minimal support – registration and advice only
2	Internal 'Must-do'	II Moderate support – review design, practical assistance
3	High local priority	III Full facilitation
4	Medium local priority	
5	Low local priority	



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

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