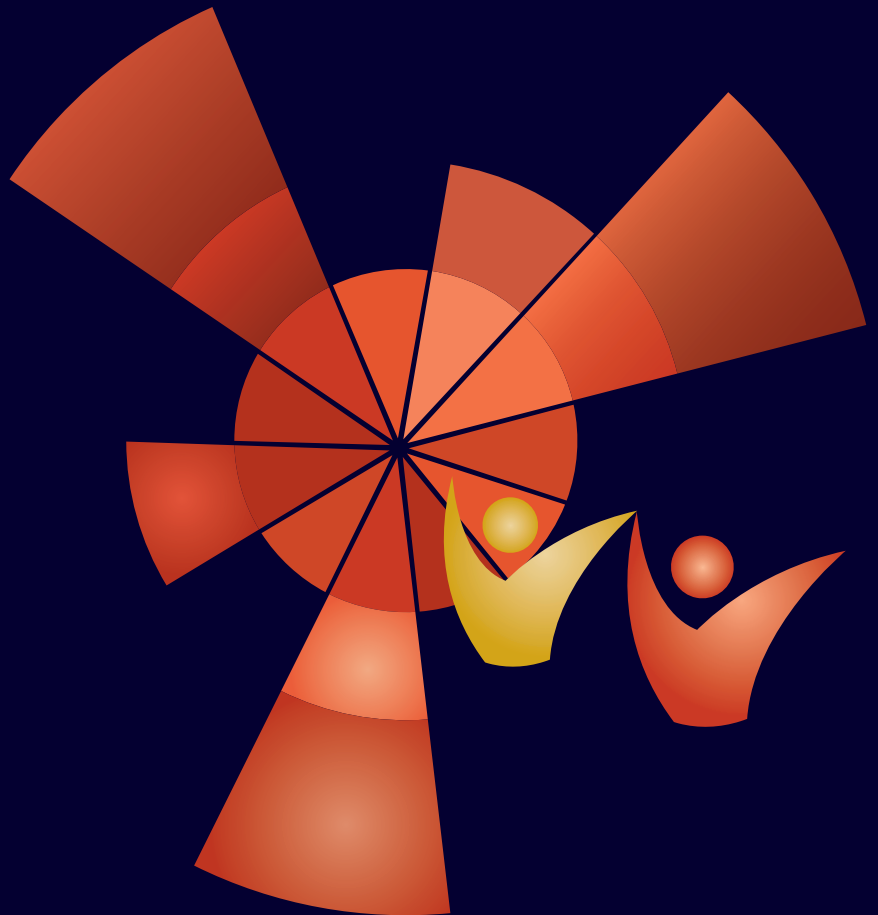


Best practice in clinical audit



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1 Introduction

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*. Audit and feedback aim to improve patient care by reviewing clinical performance against explicit standards and directing action towards areas not meeting those standards.

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.”

At a national level, projects such as the National Clinical Audit and Patient Outcomes Programme (NCAPOP) allow service providers to compare their performance with others and against nationally agreed standards, but the improvements that should flow from these comparisons must be made at the local service delivery level. This also helps organisations to answer the following questions:

- Do we know how good we are?
- Do we know where we stand relative to the best?

* The term ‘service user’ includes patients and carers

** The term ‘clinician’ is used throughout to refer to all clinical professionals and staff at all grades, unless otherwise specified

- Do we know where and understand why variation exists in our organisation?
- Over time, where are the gaps in our practice that indicate a need for change?
- In our efforts to improve, what’s working?

Many of the criteria described within this guidance also apply to national projects, but there are complexities in designing and carrying out national clinical audit and quality improvement projects that are beyond the scope of this document. The NCAPOP has continued to develop, and in 2014 HQIP published *‘The Audit of Audits’*, which identified good practice within audit work streams. By providing advice for improvements to national clinical audit design and delivery, HQIP aims to help individual national audit providers enhance their roles in delivering high quality national audits that can contribute to improvements in the quality of patient care provided in NHS organisations.

The purpose of this document is to set out updated criteria for best practice in local clinical audit. These criteria will:

- Provide guidance for **clinicians** and clinical audit staff** on how to plan, design and carry out clinical audit projects that will deliver improvements in the quality of services
- Support **Boards and management of healthcare providers** to evaluate and improve the quality of clinical audit activities that take place within their organisations
- Support **those who commission or monitor healthcare services** to assess the quality of clinical audit evidence provided to them
- Provide **service users** with information on how they can participate in clinical audit, increasing their involvement and understanding of the process so that they can assess and improve the quality of the projects they are involved in.

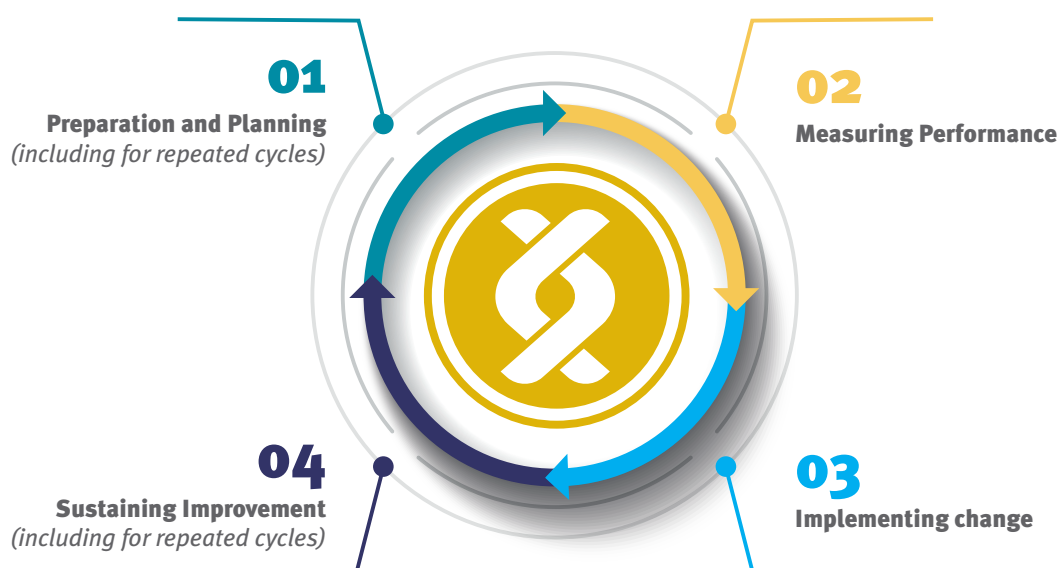
Where possible we have linked specific criteria to **more detailed and extensive guidance**, which can be found in supporting publications and resources from HQIP and other organisations.

The definition of clinical audit

With stages outlined in the diagram below, and in more detail at Section 3 of this guide, clinical audit is defined as:

‘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.’

HQIP ‘New Principles of Best Practice in Clinical Audit’,
Radcliffe Publishing, 2011.



2 Prerequisites to maximise the impact of clinical audit

If organisations are to gain the greatest benefit from clinical audit, there are certain prerequisites that must be in place. The role of Trust Boards in ensuring that clinical audit is undertaken in accordance with best practice standards was emphasised in the 2010 [Francis Inquiry](#) report.

Recommendation 5:

The Board should institute a programme of improving the arrangements for audit in all clinical departments and make participation in audit processes in accordance with contemporary standards of practice a requirement for all relevant staff. The Board should review audit processes and outcomes on a regular basis.

The Francis Inquiry report, 2010

	Clinical audit best practice criteria	Links to further information
1	Clinical audit is a quality improvement activity and therefore it functions best as part of a planned programme of quality improvement, or a continuous improvement strategy, that has been approved by the Board and senior management of the organisation.	HQIP, A guide for NHS Boards and partners
2	The Board should have dedicated time set aside to review both the clinical audit programme and the outcomes of individual projects.	HQIP, A guide for NHS Boards and partners
3	An effective clinical audit programme will cover the requirements and needs of a number of stakeholders including the Board, clinicians, service users and commissioning bodies. The programme should be developed in accordance with clear policy and agreed following consultation with clinicians, managers and patient representatives. The programme should be closely monitored and progress reported regularly at Board and service delivery level. An annual report, linked where appropriate to the Trust's quality account, should be presented to both the Board and/or relevant clinical/divisional/directorate committee meetings and patient groups for scrutiny before publication.	HQIP, Clinical audit policy and strategy guidance HQIP, Developing a clinical audit programme
4	Service user and public involvement in clinical audit should be embedded in the organisation's public engagement strategy. The clinical audit programme should include patient-focused projects, and the roles played by service users and lay representatives should be acknowledged in clinical audit reporting at all levels.	HQIP, Patient and Public Involvement (PPI) Strategy HQIP, Patient and public involvement in quality improvement HQIP, Developing a patient and public involvement panel for quality improvement HQIP, Introduction to quality improvement for patients and public

5	<p>In deciding which clinical audits should be undertaken, the following factors should be considered:</p> <ul style="list-style-type: none"> • Clinical priorities, including clinical risks, adverse incidents, near-misses, and patient safety • Organisational priorities, including service redesign and development • Patient and service user priorities • Commissioner priorities and specifications, including Commissioning for Quality and Innovation frameworks (CQUINs), Best Practice Tariffs (BPTs), National policies such as the NHS Long Term Plan, and NHS Standard Contract requirements • Outputs from the National Clinical Audit and Patient Outcomes Programme (NCAPOP), and other national clinical audits • Professional revalidation, appraisal, and training needs. 	<p><i>HQIP, Developing a clinical audit programme</i></p> <p><i>HQIP, Using clinical audit in commissioning</i></p> <p><i>HQIP, Statutory and mandatory requirements for clinical audit</i></p> <p><i>Guide to involving junior doctors in clinical audit and quality improvement</i></p> <p><i>GMC, Guidance on revalidation</i></p>
6	<p>Clinical audit is only one of a range of quality improvement methodologies and should not be used if another is more appropriate.</p>	<p><i>HQIP, Guide to quality improvement methods</i></p>
7	<p>Organisations must have governance arrangements in place to ensure that clinical audits are planned, prioritised, undertaken and reported in a way that maximises the benefit of the audit to the organisation.</p> <p>The findings from clinical audits may be used as part of the Board Assurance Framework, but full assurance can only be obtained if the quality improvement aims of the project have been achieved.</p> <p>Governance plans should include arrangements for participation in local and regional cross-organisational audits.</p>	<p><i>HQIP, A guide for NHS Boards and partners</i></p> <p><i>HQIP, Clinical audit policy and strategy guidance</i></p> <p><i>HQIP, Developing a clinical audit programme</i></p>
8	<p>Policies and procedures must be in place to ensure that clinical audits (and all other quality improvement activities) are undertaken in a way that complies fully with current information governance legislation and guidance, and in consultation with local information governance leads and Caldicott Guardians.</p>	<p><i>HQIP, Information governance in local quality improvement</i></p>
9	<p>All staff within an organisation should be made aware of, and comply with, the governance arrangements in place, including local policy and protocols on proposing, registering, undertaking and reporting on clinical audits.</p>	<p><i>HQIP, Clinical audit policy and strategy guidance</i></p> <p><i>HQIP, Developing a clinical audit programme</i></p> <p><i>HQIP, Guide for clinical audit leads</i></p>

10	<p>The organisation must enable the conduct of good quality clinical audit by providing appropriate resources to support the process. This includes dedicated time for audit and an appropriate level of funding.</p> <p>Organisations should have in place:</p> <ul style="list-style-type: none"> • A senior clinician able to lead on clinical audit across the whole organisation • Clinical leads for quality improvement at service delivery level in all specialties • Clinical audit practitioners who can manage the audit programme and support the process • A programme for supporting doctors in training to ensure that the clinical audit and quality improvement activities they undertake as part of their training deliver benefits to the organisation. 	<p><i>HQIP, Developing a clinical audit programme</i></p> <p><i>HQIP, Guide for clinical audit leads</i></p> <p><i>Guide to involving junior doctors in clinical audit and quality improvement</i></p>
11	<p>The organisation should seek to improve the knowledge and skills of all staff in quality improvement. Training in clinical audit should be available for all staff and where appropriate for lay representatives. All staff should be encouraged to participate in clinical and other networks that provide knowledge sharing and opportunities for staff development.</p>	<p><i>A promise to learn – a commitment to act: improving the safety of patients in England (the Berwick report)</i></p> <p><i>Guide to involving junior doctors in clinical audit and quality improvement</i></p> <p><i>HQIP, Developing a patient and public involvement panel for quality improvement</i></p>

3 Stages of the clinical audit cycle

Stage 1: Preparation and planning

	Clinical audit best practice criteria	Links to further information
1	Every quality improvement, project should be reviewed to ensure that the topic is amenable to improvement and to determine the quality improvement method most likely to deliver improvement. Clinical audit should only be undertaken if it is deemed the most suitable methodology.	<i>HQIP, Developing a clinical audit programme</i> <i>HQIP, Guide to quality improvement methods</i>
2	Every clinical audit should have a clearly-stated quality improvement aim and clearly-stated objectives.	<i>HQIP, Guide to ensuring data quality in clinical audits</i>
3	The audit should measure performance against standards for process and outcomes that are based on the best available evidence and clearly referenced.	<i>HQIP, Guide to ensuring data quality in clinical audits</i>
4	Every clinical audit should be carried out under the leadership of a named clinician. If the named lead is a junior doctor working on rotation, a more senior clinician should oversee the project to ensure that it is completed, and that the quality improvement aims are met.	<i>Guide to involving junior doctors in clinical audit and quality improvement</i>
5	All clinical audits should be carried out in compliance with local governance arrangements, including local policy and protocols on proposing, registering, undertaking and reporting on clinical audits.	<i>HQIP, Clinical audit policy and strategy guidance</i> <i>HQIP, Developing a clinical audit programme</i>
6	All aspects of the clinical audit must be carried out in full compliance with the law and best practice on information governance, General Data Protection Regulation (GDPR), and data security. This includes sample identification, data collection and analysis.	<i>HQIP, Information governance in local quality improvement</i>

<p>7</p>	<p>All members of the clinical team engaged in delivering the service to be audited should be informed about the project from the start.</p> <p>In addition, a stakeholder group should be identified and engaged in the project. This should include:</p> <ul style="list-style-type: none"> • Representatives of the clinical team • Other clinicians whose practice may be impacted by the findings of the audit • Service managers responsible for the service to be audited • Relevant service users, carers, and lay representatives. <p>Requirements for the registration and monitoring of clinical audit should ensure that senior clinicians and management are aware of the project, but in some projects the stakeholder group might include senior clinicians and managers, Board members, commissioners, and others.</p> <p>NOTE: The size of the stakeholder group and the degree to which members are engaged in the project will depend on the nature of the audit and this criterion should be applied proportionately. The key factor is to ensure that anyone who may be involved in acting on the findings of the audit is engaged from the beginning.</p>	<p><i>HQIP, Clinical audit policy and strategy guidance</i></p> <p><i>HQIP, Developing a clinical audit programme</i></p>
<p>8</p>	<p>Any ethical or information governance concerns should be escalated to the appropriate clinical lead and acted on in accordance with best practice.</p>	<p><i>HQIP, Information governance in local quality improvement</i></p> <p><i>HQIP, Ethics guide for clinical audit and quality improvement</i></p>
<p>9</p>	<p>Wherever possible, the stakeholder group must sign off the audit aim, objectives, standards, and audit method before data collection begins.</p> <p>Data collection without stakeholder sign off must only be undertaken on the authorisation of the senior clinician leading the project.</p>	<p><i>HQIP, Clinical audit policy and strategy guidance</i></p> <p><i>HQIP, Developing a clinical audit programme</i></p>

Stage 2: Measuring performance

	Clinical audit best practice criteria	Links to further information
1	The data set to be collected should be defined with reference to the audit standards, which should then be turned into valid measures of performance. Data that is not required to measure compliance with the audit standards should not be collected.	<i>HQIP Guide to ensuring data quality in clinical audits</i>
2	The population of patients to be included in the audit should be defined with reference to the audit standards. The audit sample size should be set, and the sample selected, in accordance with best practice guidance. The rationale behind the size and selection method should be documented.	<i>HQIP, An introduction to analysing quality improvement and assurance data</i>
3	Where data is to be extracted from electronic health records, the data extraction process should be tested to ensure that the correct data source is being used, and the correct sample and data are being extracted.	<i>HQIP, Guide to ensuring data quality in clinical audits</i>
4	Where the data is to be collected from paper health records, the following factors should be considered: <ul style="list-style-type: none"> • Design of the data collection tool - an existing validated tool may be used, or a tool should be designed and piloted, and the results from the piloting process reviewed before full scale data collection begins • Data collectors should be appropriately qualified. Where data collection takes place over an extended period, or multiple data collectors are involved, a protocol for data collection should be developed. This should define the data sources and provide all the information necessary to ensure that data is collected consistently. The protocol should be piloted alongside the data collection tool. 	<i>HQIP, Guide to ensuring data quality in clinical audits</i>
5	Clinical audit data should be analysed to measure compliance with standards. The statistics used should be appropriate for the purpose and should aim to provide the clearest possible picture of performance.	<i>HQIP, An introduction to analysing quality improvement and assurance data</i>
6	In planning the analysis, consideration should be given to the level of granularity* required for reporting, particularly if clinicians wish to use clinical audit findings as part of their appraisal and revalidation. *Breaking down results by ward, consultant, or clinic etc.	<i>HQIP, Guide to clinical audit reporting</i>
7	Full details of the clinical audit method must be recorded, to ensure that any necessary repeat data collection to measure the impact of interventions is carried out in exactly the same way. Any unavoidable variation in the repeat data collection method must be documented and reported alongside the results.	<i>HQIP, Guide to clinical audit reporting</i>

Stage 3: Implementing change

	Clinical audit best practice criteria	Links to further information
1	<p>The results should be shared with the stakeholder group. If the findings show non-compliance with standards, the underlying causes for non-compliance must be established using various methods/tools/creative approaches to enhance understanding of results.</p>	<p><i>HQIP, Using root cause analysis techniques in clinical audit</i></p> <p>https://improvement.nhs.uk/improvement-hub/quality-improvement/</p> <p>https://q.health.org.uk/get-involved/creative-approaches-problem-solving-caps/</p>
2	<p>Once the underlying causes have been established, an action plan must be developed to address them. Improvements may be designed through techniques such as process-mapping and adjustment, introducing communication tools, decision trees, new technology, ‘plan, do, study, act’ (PDSA) cycles, and Lean Six Sigma.</p> <p>Where possible, system improvements should be proposed to prevent or reduce the likelihood of identified non-compliance with standards.</p> <p>The action plan must be signed off by the stakeholder group and in accordance with local governance arrangements.</p>	<p><i>HQIP, Guide to quality improvement methods</i></p> <p><i>HQIP, Guide to using quality improvement tools to drive clinical audit</i></p>
3	<p>The action plan must be implemented, and the effects monitored. Any unforeseen negative impacts must be addressed, and data must be collected to ensure that the impact of the action plan has improved compliance with standards. This will usually be by repeat data collection, although other monitoring methods such as run charts may be used.</p>	<p><i>HQIP, Guide to using quality improvement tools to drive clinical audit</i></p>

Stage 4: Sustaining improvement

	Clinical audit best practice criteria	Links to further information
1	The audit cycle is not complete until evidence has been obtained to demonstrate that implementation of the action plan has resulted in an improvement in the quality of services.	<i>HQIP, 'New Principles of Best Practice in Clinical Audit', Radcliffe Publishing, 2011</i>
2	In order to ensure that the improvement is sustained, the stakeholder group should determine whether the audit needs to be repeated, and if so, when. They should also determine whether refinements are required to the audit protocol and data collection tool for greater focus on shortfalls identified. Alternative approaches to ensuring that quality of service is maintained, such as some form of ongoing monitoring, should also be considered.	<i>HQIP, Clinical audit policy and strategy guidance</i> <i>HQIP, Developing a clinical audit programme</i>
3	The results of the audit, including the outcome of the implementation of the action plan, should be documented and shared with key stakeholders and the rest of the organisation. The results and outcomes should also be shared with service users and with the public.	<i>HQIP, Guide to clinical audit reporting</i>
4	Where possible, share the learning from the audit project with colleagues, both within the organisation (at board and clinical/divisional/directorate committee meetings), and across partner organisations, including commissioners, clinical networks, and other professional groups. Learning points could include: <ul style="list-style-type: none"> • Audit methodology • How change was implemented • Impact on patient care / clinical outcomes • Impact on service efficiency • Challenges and how they were overcome. 	<i>HQIP, Guide to clinical audit reporting</i>



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

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Dawson House, 5 Jewry Street, London EC3N 2EX

T 020 3857 5030

E communications@hqip.org.uk

www.hqip.org.uk

Registered Office: 70 Wimpole Street, London W1G 8AX

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