

Documenting local clinical audit: A guide to reporting and recording





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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.”

Some NHS Trusts have integrated their clinical audit activities into a wider programme of quality improvement. 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 that 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.

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.

This publication describes how clinical audits undertaken at a local level should be documented. It includes a template for a clinical audit report that is intended to be adaptable for local use. While the focus of the guide is on clinical audit, a similar approach can be used in documenting any quality improvement project undertaken by clinicians and clinical teams working at a local level.

The purpose of documentation

The proper documentation of clinical audit is an essential element of good practice (see HQIP's [Best practice in clinical audit](#)).² Documentation serves a number of purposes:

- It is required in order to register projects as part of the Trust's clinical audit programme
- Sharing plans for clinical audit with members of the clinical team and other stakeholders facilitates agreement and buy-in to the process
- It allows the audit methodology, set out in an audit protocol, to be shared, reviewed, and tested
- Sharing the plans throughout the organisation prevents duplication of work by allowing other clinical services to make use of the design
- It facilitates monitoring of the audit process and outcomes
- It provides a permanent record of the audit
- It provides evidence of quality of service and of actions undertaken to improve quality, which can provide assurance for the Trust Board and other stakeholders
- It allows the audit to be shared with the wider community, through posters, presentations, and other publications

Producing the clinical audit report

Appendix 1 is a template for a full clinical audit report, to be used as the permanent record of a local clinical audit. This full report should be retained for a minimum of five years in accordance with the [Records Management Code of Practice for Health and Social Care - Retention Schedules](#); see also HQIP's guide, [Information governance for local quality improvement](#).³

However this final full report is not the only documentation that might be required. Information about a clinical audit needs to be shared with colleagues, project stakeholders, the Trust and others at various stages in the clinical audit cycle. Producing the full report on a clinical audit is often seen as an activity that happens after the audit itself is complete, but in practice the most effective way to compile the final report is to make use of the interim documentation that should be produced as part of the audit process. The following table sets out how this can happen.

Please note that in this document, 'audit lead' means the individual, normally a clinician, who takes responsibility for ensuring that a specific clinical audit is carried out. 'Clinical lead' means the clinician who takes responsibility for clinical audit activities across a clinical service or division. See HQIP's [Guide for clinical audit leads](#).⁴

Stage in the clinical audit process	Documentation required
Audit proposal/ registration as part of the clinical audit programme	<p>Audit proposal/registration documentation to be completed in accordance with Trust policy (see HQIP's guide, Developing a clinical audit programme)⁵. Should include title of the audit, name of audit lead, standards to be audited, etc.</p> <p>Approved and signed off by the clinical lead and clinical audit manager.</p>
Developing, piloting, and agreeing the clinical audit methodology	<p>A full audit protocol should be developed based on the audit proposal/registration form. It should include details of the audit sample and sample identification process, the data collection process including any modifications made as a result of piloting data collection, and an analysis plan showing how the data will be used to measure compliance with the audit standards (see HQIP's guide, Analysing quality improvement and assurance data)⁶.</p> <p>Approved and signed off by the clinical lead and stakeholders in accordance with Trust policy.</p>
Sharing audit findings with stakeholders	<p>Analysed data should be presented in accordance with the plan set out in the audit protocol. Any changes to the audit method made during the data collection process should be explained, together with any additional analysis necessary to inform action planning.</p> <p>In many cases this information will be shared in a presentation that summarises the findings, but the full background and detail should be available so that the validity of the findings can be understood.</p> <p>Reviewed and acted upon by the audit lead and stakeholders.</p>
Action planning	<p>A clinical audit action plan should be developed that addresses any shortfalls in compliance with the audit standards – see Appendix 1 for a template. Where necessary, root cause analysis may be undertaken into any shortfalls. Where possible, system improvements should be proposed to prevent or reduce the likelihood of identified non-compliance with standards.</p> <p>– See HQIP's guide, Using root cause analysis techniques in clinical audit⁷ – and the details of the analysis should be included in the full audit report.</p> <p>Approved and signed off in accordance with Trust policy – as a minimum by the clinical lead and stakeholders, but depending on the nature of the actions, this may require sign off by senior management or at Trust Board level.</p>
Implementation of the action plan and evidence of impact	<p>Implementation of the action plan should be monitored, and the audit cycle is not complete until evidence of the impact of the action plan has been documented. Depending on the nature of the actions, this evidence may take a variety of forms:</p> <ul style="list-style-type: none"> • Analysis of a second round of data collection using the same audit protocol – sometimes referred to as 're-audit' • A summary of the outcomes of repeated 'plan-do-study-act' (PDSA) cycles, or other QI methods used to achieve change (see HQIP's A guide to quality improvement methods)⁸ • Annotated time series data such as process control charts showing the impact of interventions. <p>Approved and signed off by the clinical lead and clinical audit manager.</p>
Production of the final clinical audit report	<p>Before the final report is completed, the whole project should be reviewed by the audit lead in order to identify areas for improvement in relation to the clinical audit methodology. This review should include how the data set has been defined, the sampling strategy, data collection, data cleansing and analysis. The report of the National Advisory Group on the Safety of Patients in England (The Berwick Report, 2013) highlighted the failure of the NHS to learn from past mistakes. Ensuring that any problems with an audit are documented should mean that a repeat of the audit will be more successful.</p>

Summary reports for clinical assurance and Trust management

The need for NHS Trust Boards to take the lead in reviewing clinical audit processes and outcomes was emphasised in the 2010 [Francis 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.

Robert Francis Inquiry report into Mid-Staffordshire NHS Foundation Trust, 2010

The responsibility for reviewing clinical audit outcomes is generally delegated to a Board committee or subcommittee that takes responsibility for clinical audit and clinical effectiveness. Each clinical division should submit regular reports to this committee, summarising both the clinical audit activity that has taken place, and the outcomes of completed audits. See HQIP's guide, [Developing a clinical audit policy](#)⁹ Appendix 1 – Example terms of reference for a clinical audit committee.

Trust clinical audit policy should specify the form that these summary reports should take. The aim should be to ensure that the committee has sufficient information to assure themselves that:

- The clinical audit programme is progressing satisfactorily
- Any clinical risks or ethical issues raised by audits are being properly addressed (see HQIP's [Guide to managing ethical issues in quality improvement or clinical audit projects](#))¹⁰
- Action is being taken to address any shortfalls in compliance with standards
- Action plans are supported and resourced.

Given the volume of clinical audits that are undertaken, these summary reports will inevitably lack the detail included in the full documentation. While in most cases a standard summary report will be sufficient, there may be occasions when a more detailed report is required. It is the responsibility of both the audit lead and the clinical lead to ensure that the report that is reviewed by the committee contains all the necessary information to highlight any areas of particular concern, and that appropriate action is taken.

Reporting requirements at different organisational levels

The reporting requirements at different organisational levels are described in the following table. NOTE: the full audit report should be available for anyone at any level in the Trust to review.

Organisational level	Reporting requirement
Clinicians, multidisciplinary care teams, and managers directly responsible for the service being audited and any other audit stakeholders	Should be fully involved in the development of documentation through the clinical audit process, including the full audit report.
Audit leads, clinical leads and management at clinical service level	Should review and approve the full audit reports and ensure that the executive summary includes all necessary information, including drawing to the attention of the clinical director and directorate management any areas of concern or areas requiring directorate level action. Should also review progress by completing the directorate clinical audit programme.
Clinical directors and directorate management, directorate level clinical audit and/or clinical effectiveness committees Note: clinical audits that affect more than one clinical directorate should be reviewed in all of the affected directorates	Should review the executive summaries for all clinical audits and ensure that the report that goes to the clinical audit and/or clinical effectiveness committee includes all the necessary information. Should also review progress in completing the directorate clinical audit programme, including the implementation of action plans, and should take action as necessary to address any delays.
Trust clinical audit and/or clinical effectiveness committee	Should review the reports provided to them by clinical directorates and ensure that the attention of the Trust Board is drawn to any areas of concern or requiring Board action.
Trust Board	Should review the reports provided to them and take action to address any issues. See HQIP's Clinical audit: A guide for NHS Boards and partners . ¹¹

In addition to this clinical oversight of the programme, Trusts are increasingly relying on their overarching audit committee to review the effectiveness of clinical audit and other quality improvement activities as part of the Board assurance framework. HQIP's [Clinical audit: A guide for NHS Boards and partners](#)¹¹ includes assurance questions that can guide Trust divisions and departments on the information that should be available to the audit committee.

Sharing reports with commissioners

Clinical audit reports should be shared with local commissioners as part of a joint approach to improving the quality of local services. HQIP's guide, [Using clinical audit in commissioning healthcare services](#)¹², includes guidance on what information should be shared and how commissioners should make use of this information.

Involving patients and the public in clinical audit reporting

Patients and the public have an important role to play in all aspects of clinical audit and quality improvement, and HQIP has produced a range of guidance to explain the benefits of involving patients (see HQIP's resources, www.hqip.org.uk/involving-patients/¹³). As key stakeholders in the audit process, patients can help with ideas on how to communicate audit outcomes to the public, as well as champion projects to promote them and gain additional support for actions from the Trust Board.

At a national level, HQIP has published guidance on producing patient-friendly reports (www.hqip.org.uk/resources/how-to-develop-patient-friendly-clinical-audit-reports/¹⁴). However at a local level, the aim should be to ensure that every report is as accessible as possible. While the full report might have to include a level of technical detail that cannot be simplified, the aim should be to produce reports that use plain English and avoid or explain any technical terms, jargon or abbreviations. These universal design principles benefit all readers.

Publicising and promoting clinical audit and QI

All staff should have access to a central repository of completed clinical audit reports, generally through the Trust intranet. This allows good practice to be shared and provides a valuable resource for developing new clinical audits.

Selected audit reports e.g. to demonstrate improvement can also be made available on Trust external websites, and examples of local audits should be included in the Trust's quality accounts.

Posters displaying the outcomes of clinical audits and other quality improvement projects are an increasingly common sight in the waiting areas of hospitals, clinics, and GP surgeries. Posters may be entered into local, regional, and national competitions and clinical audits may be submitted to journals for publication. All of these activities have merit in that they publicise the steps that Trusts are taking to meet their obligation under the NHS Constitution to monitor and continually improve the quality of care they provide. However some basic rules should be followed in order to ensure that the Trust and the patients whose care has been audited are protected from any potential pitfalls.

First, all clinical audits carried out in the Trust should be registered on the clinical audit programme, and subject to the monitoring and approval process specified in the Trust clinical audit policy – See HQIP's guides, [Developing a clinical audit policy](#)⁹ and [Developing a clinical audit programme](#).⁵ Publication of a clinical audit report in any form must be approved in accordance with Trust policy.

Secondly, care must be taken to ensure that personal confidential data is not disclosed. This applies both to the patients whose care has been audited, and to the staff of all grades and professions who have provided that care. As a matter of good practice, all personal confidential data should be anonymised at the earliest possible stage in the audit process – See HQIP's guide, [Information governance for local quality improvement](#)³. If the audit is to be published, particular care needs to be taken to ensure that patients cannot be identified – for example, if sample size is small, or exceptional cases are highlighted.

A note on clinical audit posters

HQIP employees are sometimes invited to judge clinical audit poster competitions, both for Trusts who are holding internal events and for regional and national events and conferences. These events are a very good way of sharing best practice and ideas for improving the quality of care, but excellent projects can be let down by poor posters. Some specific points that apply to clinical audit posters:

- Explain the problem. Why was this particular audit carried out – was it in response to new guidance being issued? A clinical risk being identified? Remember the audience will not necessarily be familiar with the technical terms used in a specialist service, so give clear explanations of any abbreviations
- Quote the standards being audited, with references
- Give brief but clear information about how the audit sample was identified and how the data was collected, but remember this is only to put the findings in context – the poster is an abstract of your work, not a substitute for a full report
- Always state the sample size; failure to do so is one of the most common mistakes, but without the sample size, quoting percentage compliance with standards is meaningless
- The point of any clinical audit is to improve care, so be clear about what actions have been taken or are planned, and what evidence you have to show those actions have been successful.

Appendix 1. Clinical audit report template

Department/Organisation name

Clinical audit title

Clinical audit number

Audit cycle number

Division/type of organisation

Specialty/service/operational area (locality)

Project team

Name of project lead	Title and grade	
Name	Title and grade	
Name	Title and grade	Data period
Name	Title and grade	Report completion

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Executive summary

An executive summary may not be required for all projects but can be a useful way, either as part of the full report or a stand-alone document, of presenting the relevant data in a quick and easy-to-read manner for a chief executive, medical director, director of nursing, operational manager, practice manager, patient representative, etc. This will help the reader to identify whether they need to read the full report.

The executive summary should briefly describe the background and rationale for the project, the main aims and objectives, key findings and recommendations, and should be written after the clinical audit report has been completed.

Background/rationale

Briefly describe the reasons for undertaking this clinical audit, e.g.

- New guidance issued
- Evidence of a potential quality problem
- Recent clinical incidents.

Aims/objectives

What will the audit tell us? Specify the main objectives in undertaking this piece of work. These should be identified from the outset of the clinical audit as part of the process of proposing the clinical audit and registering it as part of the clinical audit programme, e.g.

- To ensure that births after a previous caesarean section are managed in accordance with the national guideline
- To ensure that the removal of wisdom teeth is undertaken as per National Institute for Health and Care Excellence (NICE) guidance

Key findings

The executive summary should include a clear statement of how the care measured by the audit compares with the standards being audited, and how this has changed as a result of actions taken as part of the audit. Where possible, comparison with previous rounds of data collection should be included.

Trusts have adopted a number of different ways of displaying this data in summary form, and one approach in common use is a system of “traffic light” or “red, amber, green (RAG)” ratings, as shown in the table on the next page, which may be supplemented by annotated time series data such as process control charts to show the impact of interventions. Such annotated time series data also helps to identify how the day of the week, time of day, or particular staff on duty affect compliance with standards, enabling further exploration for improvement, for example through root cause analysis (see HQIP guides, [Using root cause analysis techniques in clinical audit](#)⁷, and [A guide to quality improvement methods](#)).⁸

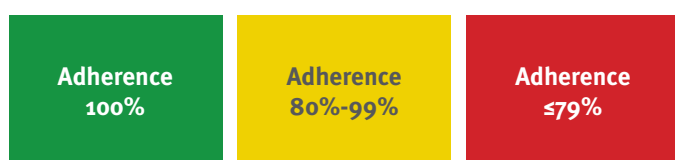
The table key can be adapted to suit your particular project, i.e. it may be agreed that only the areas achieving the 90% threshold or above should be coloured amber. A decision as to the appropriate thresholds for your clinical audit should be agreed by the multi-disciplinary team. This decision should be made following identification of the clinical guidance/evidence base to be measured against. The scheme is a simple way to inform the reader of areas of good practice and areas for improvement, at a glance, as red has come to signify “danger”, and green “safety”. This is useful, but it must be implemented with caution. For example, a green threshold indicating “safety” at 75% adherence suggests that in practice it is “safe” if one in four/a quarter of cases do not meet the threshold. However, if a quarter of cases are non-compliant with an audit standard that relates to missed essential steps in a quarter of cases of clinical care, this can be considerably unsafe. **Green should be reserved for a 100% compliance rate.**

The table below provides space for each standard to be listed along with the “N” or “n” (number or fluctuating number) and the relevant results. For repeated audit cycles, extra columns can be added to allow for comparison to previous cycles. A column could also be added to compare the findings within a particular department with those across the Trust as a whole,

which is useful in benchmarking and to encourage collaborative improvement. Rows can be added for further explanation of the data if this is necessary. Arrows can also be used to indicate areas where adherence to standards has increased, decreased or remained the same.

No.	Standard	N 2015	Compliance 2014	Compliance 2015	▲▼
1.	All patients should be admitted within 2 hours	90	80%	100%	▲
2.	All patients should receive drug A unless contraindicated or already receiving it	70	100%	100%	◆
On admission all patients should have the following observations:		N 2015	Compliance 2014	Compliance 2015	
3.	Blood pressure	90	81%	50%	▼
4.	Pulse	90	36%	85%	▲
5.	Oxygen saturations	90	25%	25%	◆
6.	Temperature	90	87%	100%	▲

Key:



If your findings do not fit into a tabular format, this section could include the key observations in bullet point format, or other adjusted format to suit.

Implementation of actions

Key actions taken as a result of the audit findings should be summarised, together with evidence of their implementation.

Data on the impact of the action plan should be presented either as comparison data from second stage data collection (as described above) or in other formats as appropriate.

If for any reason actions have not been implemented, the reasons should be stated.

Clinical audit report

Clinical audit title

Specify the clinical audit title followed by number if used. The title should be no more than one sentence and should clearly and concisely state the focus of the audit.

Where applicable the following should be included in the title:

- Whether the audit is a repeated cycle
- Whether the audit has been undertaken on a national, regional, or local basis.

For example:

- *Third audit cycle of the recognition of and response to acute illness in adults in hospital, in line with NICE Clinical Guideline 50 (Project 199)*
- *Regional audit of breast cancer follow-up in accordance with the cancer network guideline (Project 293).*

Division/type of organisation

Detail division here (if used) and type of organisation, for example:

- *General surgery/acute Trust*
- *Substance misuse/mental health Trust.*

Specialty/service/operational area (locality)

Detail specialty/service/operational area (locality) here, for example:

- *Paediatrics/dietetics/Shropshire*
- *Orthopaedics/physiotherapy/Slington.*

Disciplines involved

Detail all types of healthcare professionals involved, for example:

- *Consultants*
- *Physiotherapists*
- *Occupational therapists.*

Project lead

The full name, title, and base of the designated project lead (the person with overall responsibility for the project), for example:

- *Mr F Bloggs, Consultant Cardiothoracic Surgeon, St Elsewhere University Hospital*
- *Dr N Simpson, Senior Partner, Park Surgery, Wykley, Coventry.*

Other staff members involved

List full names and titles of those involved and state their role in the clinical audit, for example:

- *Dr R Smith, F2 – data collection, presentation, and report writing*
- *Mr K Franks, Consultant Obstetrician – advisor*
- *Ms T Jones, lay representative – proforma design.*

Background/rationale

Briefly describe the reasons for undertaking this clinical audit, for example:

- *Evidence of a potential quality problem*
- *Recent clinical incidents*
- *Following a previous audit, actions were implemented to improve practice and a further audit cycle is now required*
- *An audit is required to ensure adherence to new clinical guidelines following their implementation.*

Aim

State what you expect the audit to achieve. The aim should specify clear improvement focused goals, for example:

- *To ensure that a particular practice is safe*
- *To ensure that a recent change in practice has improved compliance with evidence-based standards*
- *To ensure that practice is compliant with NICE guidance.*

Objectives

Identify how you will conduct the audit project to address the aim. See HQIP's [Guide to ensuring data quality in clinical audits](#)¹⁵ for guidance on setting effective objectives. Objectives should be identified from the outset of the clinical audit project and SMART (Specific, Measurable, Achievable, Realistic, and Timely), for example:

- *To collect data on the management of births following a previous caesarean section, and to change practice if management is not in accordance with the national guideline*
- *To increase the proportion of patients with type II diabetes who have annual assessments to prevent and enable management of foot problems and to improve the education of patients in foot care*
- *To ensure that the removal of wisdom teeth is undertaken as per NICE guidance*
- *To ensure adherence to the WHO surgical safety checklist.*

Standards/guidelines/evidence base

What standards and guidelines have you compared practice with? What criteria have been used? Specify the full title, reference, and source, for example:

- *Royal College of Obstetricians and Gynaecologists (RCOG) (October 2015). Green-top Guideline No. 45: Birth after previous caesarean birth*
- *St Elsewhere NHS Trust (January 2020). Guideline for the prevention and management of foot problems in patients with type II diabetes.*

Sample

Which patients will be included in the audit, and from which time period has the sample been selected? Give details, for example:

- *All patients with post-partum haemorrhage (PPH) during the three-month period from 1st May 2015 to 31st July 2015 were included in the audit*
- *All patients with diabetes in the year from 1st January to 31st December 2015 were included in the audit.*

See HQIP's [An introduction to analysing quality improvement and assurance data](#)⁶ for guidance on sample size and sample selection. Specify the total sample size/population, any specific inclusion/exclusion criteria, and explain in detail how you selected the sample for clinical audit purposes (e.g. random sample, stratified sample, etc.). Include justification for your sample size and method of selection, for example:

- *There were a total of 1158 deliveries during this period and 146 (12.6%) cases of post-partum haemorrhage. The health records of 138/146 patients experiencing post-partum haemorrhage were reviewed as eight sets of health records could not be accessed because they were in use for other clinical purposes during the data collection period, thus N=138.*
- *143 wisdom teeth removals were identified from 1st January to 31st December 2019. Information on 105/143 cases was needed in order to achieve 95% confidence in a result +/- 5%, thus N=105.*

Describe how you identified your sample; this could be via clinic codes, ICD10 codes, OPCS4 codes, registers such as theatre logs, computer records, prospectively at an appointment, upon presentation etc., for example:

- *Patients with a primary diagnosis of stroke were identified using ICD10 codes I61, I63 or I64*
- *All patients who attended clinic 9 from 1st May 2019 to 31st May 2019*
- *All caesarean section patients identified from theatre logs for two months from 1st November 2020 to 31st December 2020*
- *All diabetes patients were identified from GP computer records from 1st January to 31st December 2019.*

Data source

Which data sources have been used in the clinical audit? Give details, for example:

- Health records
- X-ray reports
- Clinical management system
- Patient survey
- Observation.

Methodology - including data collection methods

Describe how the clinical audit was undertaken. This should be written in narrative format (including bullet points where required) and the following should be considered:

- Establishing the project team, e.g. grades and disciplines of the staff who provided advice and relevant expertise when planning the clinical audit, frequency of meetings, etc.
- Developing and piloting a data collection tool (this can be included as an appendix)
- Data collection:
 - How data were obtained, for example:
 - From the drug kardex/partogram/ambulance sheets/ GP computer system, patient health records, etc.
 - Prospectively/retrospectively/real-time
 - Who collected the data, e.g. practice nurse, F2, paramedic, etc.
 - Where the data were collected e.g. on the ward, in clinic, in theatre, etc.
 - How the data collection process was piloted, the outcome and any changes that were made as a consequence

- Data validation – were the data validated, if so, explain how this was completed and by whom, e.g. the first 10% of the patient sample was reviewed twice, by a consultant and by an F2, and the results were compared before continuing with data collection
- Data analysis:
 - Detail the packages used, e.g. SPSS, MS Excel, MS Access
 - You may wish to include whether the data analysis was validated and by whom, e.g. in order to validate the data, a draft set of findings was produced and checked/ randomly checked by a second facilitator for accuracy
- Report writing:
 - Detail who completed the report including their job title, e.g. Mr R Singh, Clinical Audit Facilitator, Mr R Lowe, Community Pharmacist, Mrs B Wise, Occupational Therapist, etc.
- Presentation:
 - Include the date, the meeting title, where the presentation took place, and the presenter.

Each aspect of the methodology should detail the member(s) of staff responsible.

The description of the methodology should be sufficient to allow the clinical audit to be repeated by someone who has had no previous involvement in it. This is particularly important with regard to staff changes, as audits may require further cycles after staff have moved on, as is often the case with junior doctors.

Caveats

Occasionally there may be caveats that are required to explain some of the data. This section should contain an explanation of any factors the reader should be aware of that may affect the results. These are factors that have usually been discovered during/following data collection, for example:

- *A valid consent form should be present in all cases. 5/50 (10%) cases did not contain a consent form, therefore these cases are excluded from the total sample for the standards relating to consent forms; the finding that 10% of cases did not contain a consent form would be reported*
- *Consent is often wrongly equated with a patient's signature on a consent form; a signature on a form is evidence that consent has been sought, but it is not proof of valid consent*
- *In cases where the relevant information had not been documented on the proforma this was taken to be non-compliance with the standard.*

Findings

Initially state your "N" number; N represents the total number of cases identified as the representative sample for inclusion in the clinical audit, for example:

- *50 cases were identified for inclusion in the audit of thromboprophylaxis, thus N=50*

Fluctuating N: Please note that the N may fluctuate, that can be shown by using "n", for example:

- *Standard: All patients should receive drug A*
- *Exceptions: Patient has a contraindication to drug A or is already prescribed it.*

- *Note: Five cases were exceptions. In three cases patients were already prescribed drug A and in two cases there was a contraindication to drug A. Thus either subtract the five cases that were exceptions from the total number of cases (therefore, the n will be 45) or include the cases that are exceptions because they represent clinically acceptable care (therefore, the N will remain at 50).*

The standards used in the clinical audit should be highlighted in bold. Compliance against the standards should be detailed, to include the number and percentage compliance with further explanation of non-compliance where required, for example:

- ***Standard: All diabetic patients must have an annual review (N=125)***
- *Exceptions: None*
- *Compliance: 120/125 (96%) diabetic patients had an annual review*
- *Non-compliance: In 4/125 (3%) cases, patients were offered an annual review on two occasions but, on both occasions, did not attend. In 1/125 (1%) case there was no record that an annual review had been offered.*

Present data in table form where possible (this is usually sufficient for most clinical audits), for example:

Standard: **The following signs should be recorded on admission** (N=51):

Criteria	Adherence	
	n	(%)
Heart rate	50	(98%)
Respiratory rate	50	(98%)
Temperature	48	(94%)
Blood pressure	45	(88%)

Be selective with the use of charts, remembering to use the most appropriate method to present the data, e.g. pie charts to show proportions and bar charts for comparisons between different areas/time periods/audit cycles. See HQIP's [An introduction to analysing quality improvement and assurance data](#)⁶ for guidance on the analysis and presentation of clinical audit data.

Individual clinicians/sites/wards whose practice is being audited should not be identified within the report. When presenting data, only an identifier should be used, for example:

- Clinician A
- Clinician B, etc.

If required, individuals could be informed of their own identifier, e.g. clinician A/site A, before or after the presentation.

Patient identifiable data, e.g. surname, date of birth, NHS number, hospital number, etc., should never be included in a clinical audit report, in line with Caldicott Principles. See HQIP's guide, [Information governance for local quality improvement](#)³ for further information.

NOTE: The full report for a completed clinical audit should include comparative data from at least two rounds of data collection, in order to assess the impact of actions taken to improve compliance. See section below - Evidence of improvement.

Observations

What overall observations can be drawn from your findings? Detail any key themes arising from the analysis of data or any other information gained as part of the audit process (use bullet points), in terms of good practice, and areas for improvement. Ensure your observations are supported by the project findings and include the key points (this section of the report is more likely to be read than any other), and known root causes of gaps in systems or care. Definitions of good practice and areas of practice requiring improvement should be determined by the project team, for example:

Areas of good practice:

- All asthmatic patients were given a yearly review
- 98% of people with schizophrenia had their physical health monitored by a GP or primary healthcare professional at least once a year.

Areas for improvement:

- Only 50% of patients with schizophrenia had documentation to confirm they were routinely monitored for co-existing conditions, because the relevant proforma weren't routinely made available
- The doctor's signature was present on the consent form in only 75% of cases.

Presentation/Discussion

Include information on where and when the project was presented and the discussion following the presentation (this can be copied from the minutes of the relevant meeting), for example:

- The audit was presented at the cardiology clinical audit meeting on 19th February 2020, and the following comments and observations were made:

Recommendations

Recommendations should be made based on the clinical audit results and any other relevant finding identified during the course of undertaking the audit, for example:

- *An audit of consent in radiology identified a process where consent forms were scanned onto a system; some staff were not scanning the whole consent form. It is recommended that the process for recording consent should be reviewed and changed to ensure all details are scanned.*

Action plan

An action plan must be developed to address any shortfalls in compliance with the audit standards, and the report should explain, in narrative form, how the action plan has been developed, for example:

- *The audit findings were presented to the multidisciplinary care team at the monthly planning meeting. A root cause analysis exercise identified a number of key areas for improvement, and a working group was set up to develop an action plan to address these areas.*

The action plan must be based on a clear understanding of the reasons for shortfalls in the quality of care identified by the audit – see HQIP's guide, [Using root cause analysis techniques in clinical audit](#)⁷ for guidance on techniques that can be used in developing action plans.

Where possible, system improvements should be proposed within the action plan to prevent or reduce the likelihood of identified non-compliance with standards – for example, patient record redesign, rather than repeated use of reminder stickers, which lose impact over time.

The action plan should be SMART – that is, all the actions should be:

- *Specific – target a specific area for improvement*
- *Measurable – quantify or at least suggest an indicator of progress*
- *Achievable – specify who will do it, given available resources*
- *Realistic – state what results can realistically be achieved*
- *Time-related – specify when the result(s) can be achieved.*

All recommendations in the clinical audit report should be numbered and mirrored in the action plan. For example:

1. *By 31st May 2020, the lead consultant for fractured neck of femur will have updated the local guidelines for the management of fractured neck of femur patients, to include standards for the transfer of patients from the Emergency Department to the Orthopaedic ward within two hours of arrival.*

Evidence of improvement

The clinical audit cycle is not complete until evidence has been obtained to show that compliance with standards, and hence quality of care, has improved. This evidence should be obtained by a second round of data collection, so that comparative data from both rounds can be included in the audit findings section above.

This is not the only way that evidence of the impact of changes may be obtained, and any other evidence should be documented here. This may include:

- *Annotated time series data such as process control charts showing the impact of interventions*
- *A summary of the outcomes of repeated 'plan, do, study, act' (PDSA) cycles*
- *An improvement in patient satisfaction demonstrated by patient reported experience measures*
- *Evidence of reductions in length of stay or changes in prescribing habits that will generate financial savings for the Trust.*

Learning points

Include any learning points relating to the clinical audit methodology and process that may need to be considered and addressed before undertaking a re-audit, for example:

- *Difficulties with identifying the patient sample*
- *Required updates to the clinical audit proforma.*

References

Where applicable detail any references in Harvard format, for example:

- *NICE (March 2014). Clinical Guideline: Psychosis and schizophrenia in adults: prevention and management.*

There is no need to repeat any references already detailed in the standards/guidelines/evidence base section. References to previous audit reports should also be included here, for example:

- *St Elsewhere Community Trust (January 2020) Audit of asthma management in paediatrics (Audit number 111)*

Audit Number:

KEY (Change status)

1. Recommendation agreed but not yet actioned
2. Action in progress
3. Recommendation fully implemented
4. Recommendation never actioned (please state reasons)
5. Other (please provide supporting information)

Clinical Audit Action Plan

Project title	Ensure this is exactly the same as the title detailed on the front cover of the report.		
Action plan lead	Name:	Job Title:	Contact No:

Ensure that the recommendations detailed in the action plan mirror those recorded in the “recommendations” section of the report. The “actions required” should specifically state what needs to be done to achieve the recommendation. All updates to the action plan should be included in the “comments” section.

Recommendations	Actions required (specify “None”, if none required)	Action by date	Person responsible (name and grade)	Comments/action status (provide examples of action in progress, changes in practices, problems encountered in facilitating change, reasons why recommendation has not been actioned, etc.)	Change stage (see Key above)
1. Need to incorporate the standard for transfer of patients with fractured neck of femur from Emergency Department to ward within two hours, into the local guideline.	Update the local patient management guideline for fractured neck of femur to include standards for the transfer of patients from the Emergency Department to the Orthopaedic ward within two hours of arrival. Replace previous version of guideline with updated version on the Trust electronic guideline system.	31st May 2020	Mrs R Riding, Lead Consultant for Fractured Neck of Femur	29th May 2020 – Mrs R Riding forwarded the updated local guideline to the clinical audit department as evidence that the action has been completed.	3
2.		5th June 2020	Mr A Smith, Clinical Guidelines Administrator	4th June 2020 – Awaiting Clinical Guideline Group sign off, 10 June 2020.	2

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. Best practice in clinical audit (HQIP): www.hqip.org.uk/resources/Best-Practice-in-Clinical-Audit-hqip-guide/
3. Information governance for local quality improvement (HQIP): www.hqip.org.uk/resources/information-governance-for-local-quality-improvement/
4. Guide for clinical audit leads (HQIP): www.hqip.org.uk/resources/guide-for-clinical-audit-leads/
5. Developing a clinical audit programme (HQIP): www.hqip.org.uk/resources/developing-a-Clinical-Audit-Programme/
6. An introduction to analysing quality improvement and assurance data (HQIP): <https://www.hqip.org.uk/resource/an-introduction-to-statistics-for-local-clinical-audit-and-improvement/#.Xhrgyb77Rdg>
7. Using root cause analysis techniques in clinical audit (HQIP): www.hqip.org.uk/resources/using-root-cause-analysis-techniques-in-clinical-audit/
8. A guide to quality improvement methods (HQIP): www.hqip.org.uk/resources/guide-to-quality-improvement-methods/
9. Developing a clinical audit policy (HQIP): www.hqip.org.uk/resources/clinical-audit-policy-and-clinical-audit-strategy/
10. Guide to managing ethical issues in quality improvement or clinical audit projects (HQIP): www.hqip.org.uk/resources/ethics-for-clinical-audit-and-qi/
11. Clinical audit: A guide for NHS Boards and partners (HQIP): www.hqip.org.uk/resources/clinical-audit-a-guide-for-nhs-boards-and-partners/
12. Using clinical audit in commissioning healthcare services (HQIP): <https://www.hqip.org.uk/resource/using-clinical-audit-in-commissioning/#.Xhr1Bb77Rdg>
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15. Guide to ensuring data quality in clinical audits (HQIP): www.hqip.org.uk/resources/hqip-guide-to-ensuring-data-quality-in-clinical-audits/



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