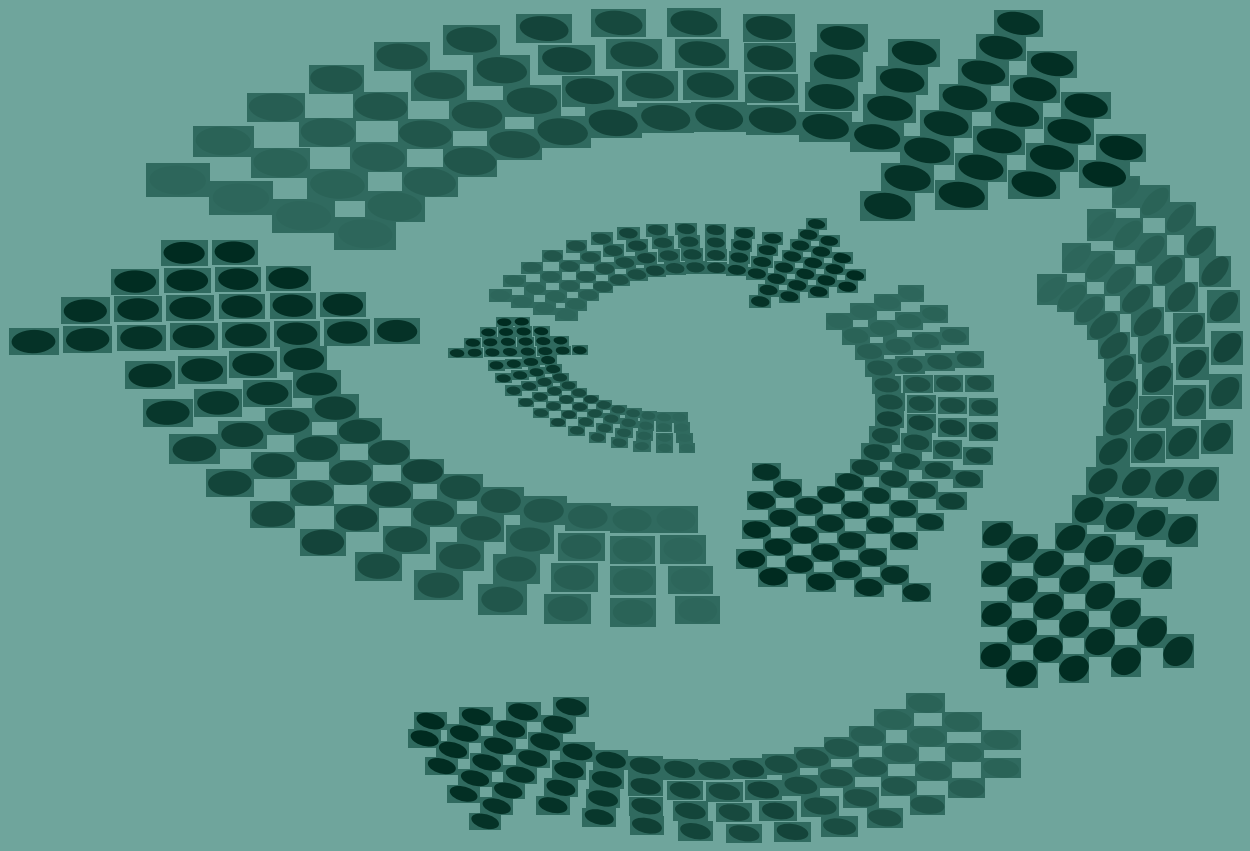
Ionad Náisiúnta d'Iniúchadh Cliniciúil
Cáilíocht Náisiúnta agus Sábháilteacht Othar
National Centre for Clinical Audit
National Quality and Patient Safety

HSE National Centre for Clinical Audit

Clinical Audit

A Practical Guide



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Reader Information

Title:	HSE National Centre for Clinical Audit Clinical Audit – A Practical Guide
Purpose:	This document replaces the previously published "A Practical Guide to Clinical Audit" (HSE 2013 and HSE 2023). It forms part of a series of resources being developed to support services and all healthcare professionals to ensure the continuation and development of effective clinical audit across the Irish healthcare system as recommended by the National Review of Clinical Audit (HSE 2019). Clinical Audit – A Practical Guide should be read in conjunction with HSE NCCA Nomenclature (see web link below).
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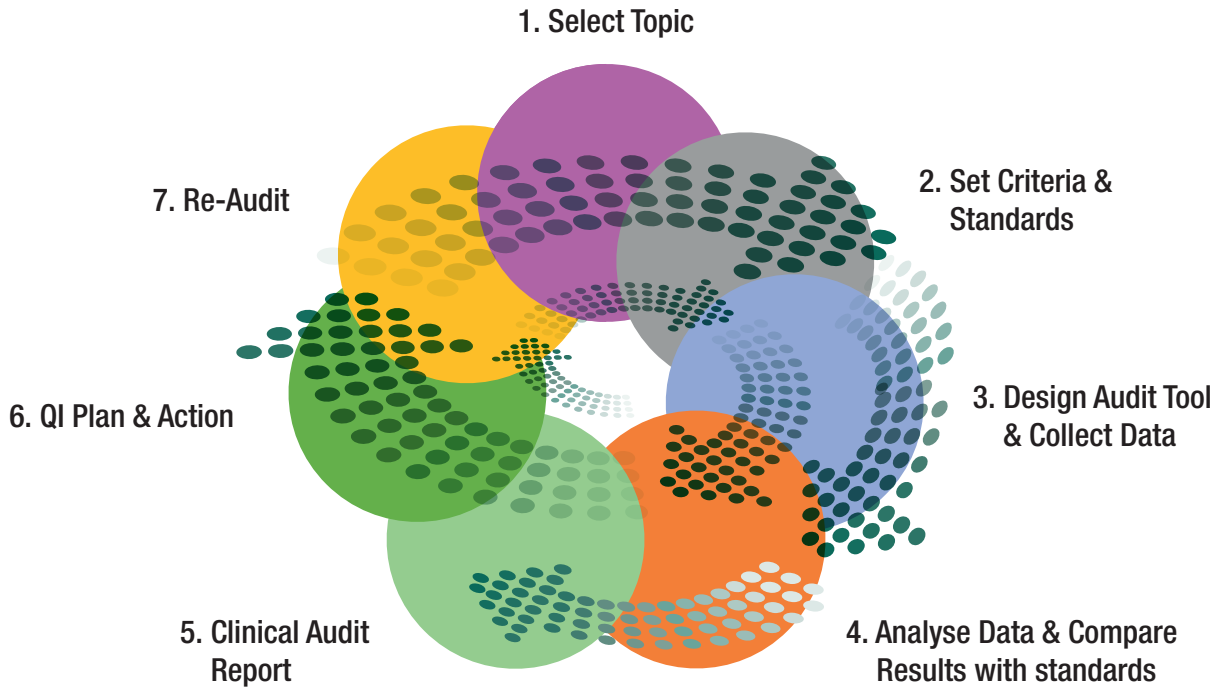
Publication Date:	May 2025
Version Number:	3
ISBN Number:	978-1-78602-220-2
Target Audience:	All HSE staff, clinical audit service providers and all agencies involved in clinical audit
Cite this document as:	Health Service Executive (HSE), National Centre for Clinical Audit, Clinical Audit – A Practical Guide, National Quality and Patient Safety, May 2025.
Contact Details for further information:	HSE National Centre for Clinical Audit E-mail: ncca@hse.ie **https://www2.healthservice.hse.ie/organisation/ncca/**
Related/ Associated documents:	HSE National Centre for Clinical Audit Nomenclature **https://www.hse.ie/eng/about/who/nqpsd/ncca/nomenclature-a-glossary-of-terms-for-clinical-audit.pdf** Health Service Executive (HSE) National Review of Clinical Audit Report, November 2019 **https://www.hse.ie/eng/services/publications/national-review-of-clinical-audit-report-2019.pdf**
Revision date:	May 2027
Access:	**https://www2.healthservice.hse.ie/organisation/ncca/**

The Seven Stages of Clinical Audit

Stage 1	Select Topic
Stage 2	Set Criteria and Standards
Stage 3	Design Clinical Audit Tool and Collect Data
Stage 4	Analyse Data and Compare Results with Standards
Stage 5	Clinical Audit Report
Stage 6	QI Plan and Action
Stage 7	Re-Audit



Contents

1. Background and Context

The Health Service Executive (HSE) National Centre for Clinical Audit (NCCA) was established within National Quality and Patient Safety (NQPS) in 2022, following the publication of the HSE National Review of Clinical Audit Report 2019. Establishing the HSE NCCA marks an important step in the HSE's continued efforts to improve the quality and safety of healthcare for patients. This will strengthen the development of an end-to-end process for clinical audit in accordance with the recommendations in the report and meet the needs of clinical audit service providers and multidisciplinary stakeholders.

The NCCA is primarily responsible for implementing the HSE National Review of Clinical Audit Report recommendations under five key pillars:

- National Governance of Clinical Audit
- Local Governance of Clinical Audit
- Clinical Audit Training
- Clinical Audit Education Resources
- Legislative Changes affecting Clinical Audit (i.e. GDPR and Data Protection)

The National Review of Clinical Audit Report 2019 identified the importance of developing guidance for Clinical Audit, one of which includes "A Practical Guide for Clinical Audit should be updated to reflect best practice in clinical audit and healthcare professionals should use this new guidance to design and develop their clinical audits". This will support and improve the consistency and quality of clinical audit across the health service to support the planning and management of high-quality healthcare.

The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 was signed into law in May 2023 and came into effect on 26 September 2024. Part VI of the Act- Clinical Audit, offers significant legal protections to clinicians undertaking clinical audit. This means that the Act should ensure healthcare professionals are encouraged to carry out clinical audit, comparing the care they are delivering to best practice standards and delivering and maintaining the highest standards of patient care. Where necessary, the seven stages of the clinical audit cycle have been updated following a review of the PSA. Section 6 of this guide also provides some further information for staff.

2. Introduction

Following the establishment of the NCCA and progression of the agreed recommendations and programme of work, we are very pleased to present Clinical Audit – A Practical Guide, which contains the agreed seven stages produced following the publication of the Report. The Practical Guide should be adopted by the HSE and become the national standard for clinical audit for all agencies involved in clinical audit. The National Review of Clinical Audit found that there were a number of different definitions for clinical audit across the healthcare system, resulting in confusion around clinical audit design.

The definition contained in this document provides clarity with the stages of the clinical audit cycle:

"Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit specific clinical standards or clinical guidelines and acting to improve care when clinical standards or clinical guidelines are not met.

The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit specific clinical standards or clinical guidelines."

(Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023)

"Following clinical audit, improvements, if required, should be implemented at an individual, team or organisation level, and then the care re-evaluated to confirm improvements. "

(DOHC 2008, p. 152) (HSE NCCA Nomenclature, Glossary of Terms for Clinical Audit, 2025).

Clinically-led includes the breadth of clinical professionals working in health and social care services

The aim of this guidance document is to assist and support healthcare staff in understanding the stages of the clinical audit cycle, to help support best practice in clinical audit and to improve awareness of clinical audit as an essential and integral component of clinical practice. Clinical audit provides the ability to improve the quality of patient care in a collaborative and systematic way. When clinical audit is conducted well, it enables the quality of care to be reviewed objectively within an approach which is supportive, developmental and focused on quality improvement.

3. The Seven Stages of Clinical Audit

The agreed seven stages of clinical audit in this guidance document, produced as a result of the National Review of Clinical Audit, should be adopted by the HSE, and become the national standard for clinical audit for all agencies involved in clinical audit. Each of the seven stages of the Clinical Audit cycle has individual steps involved which are detailed in sections 3.1 to 3.7 of this document.

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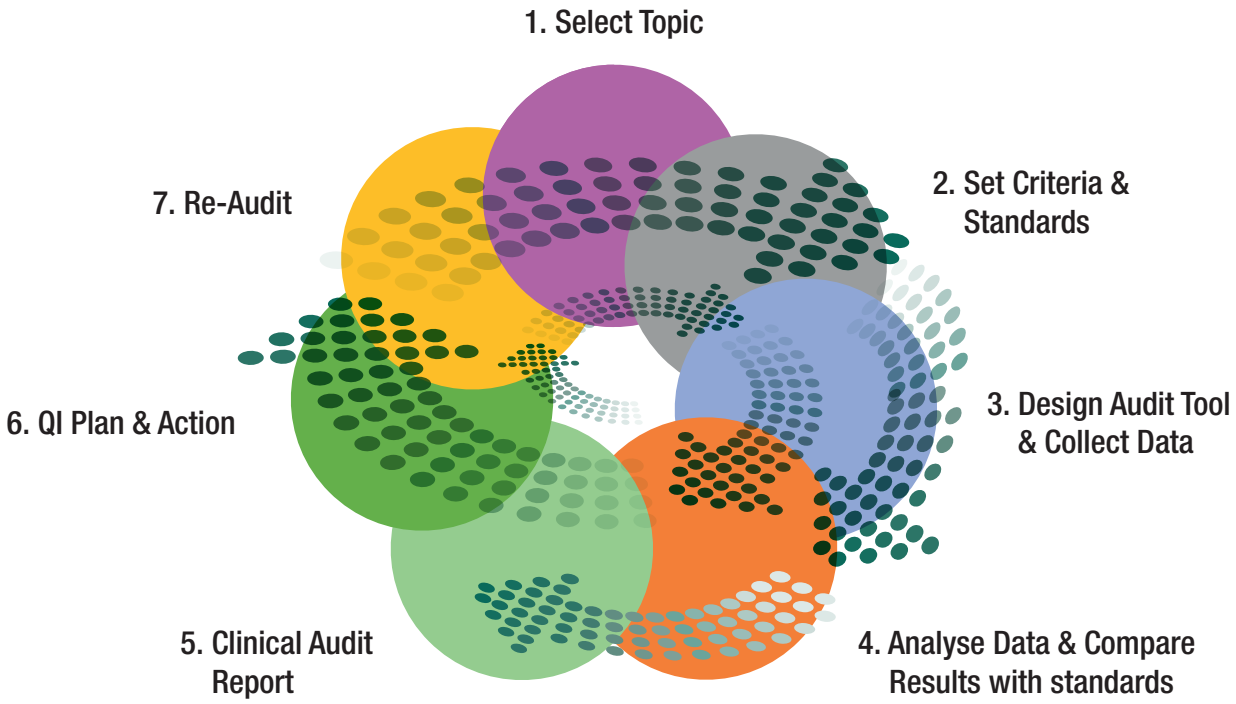
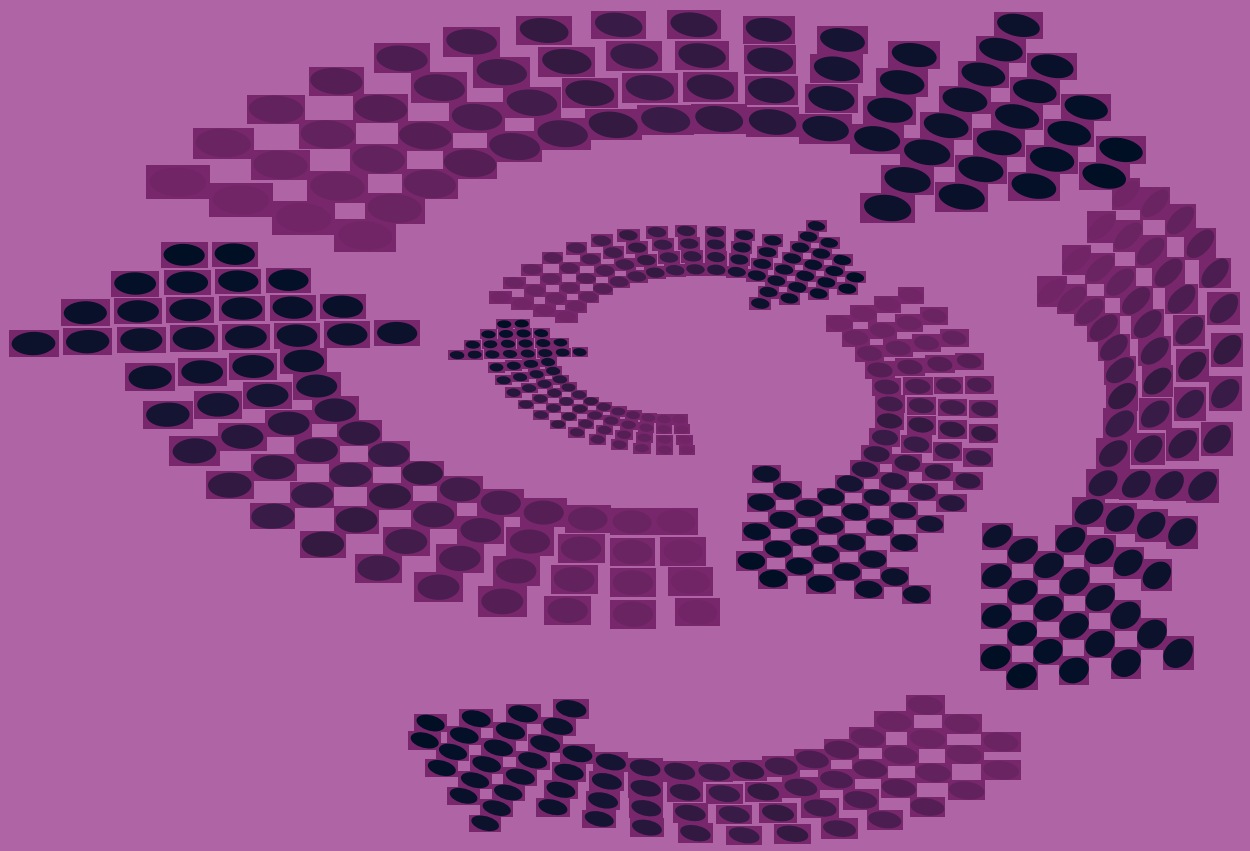


Figure 1: The Seven Stages of the Clinical Audit Cycle

Each stage of the clinical audit cycle must be undertaken to ensure that a clinical audit is systematic and successful.

Stage 1: Select Topic



Stage 1: Select Topic	
1	The clinical audit should focus on improving care, patient safety and service delivery for patients and healthcare professionals
2	A clear singular aim stating why the clinical audit needs to be undertaken should be agreed, documented, and shared with all key stakeholders
3	A clinical audit lead with the necessary clinical audit skills must be identified to plan, oversee and co-ordinate the clinical audit
4	A sub-group of multi-disciplinary key stakeholders needs to be identified to support delivery of the clinical audit
5	Any topic selected for clinical audit should ideally incorporate patient/service-user views
6	Stakeholders must consider local and national reporting arrangements for proposed clinical audits
7	A clinical audit proposal form must be completed and submitted to the local Clinical Audit/QPS Committee for review and approval
8	Following approval, the proposal form must be completed

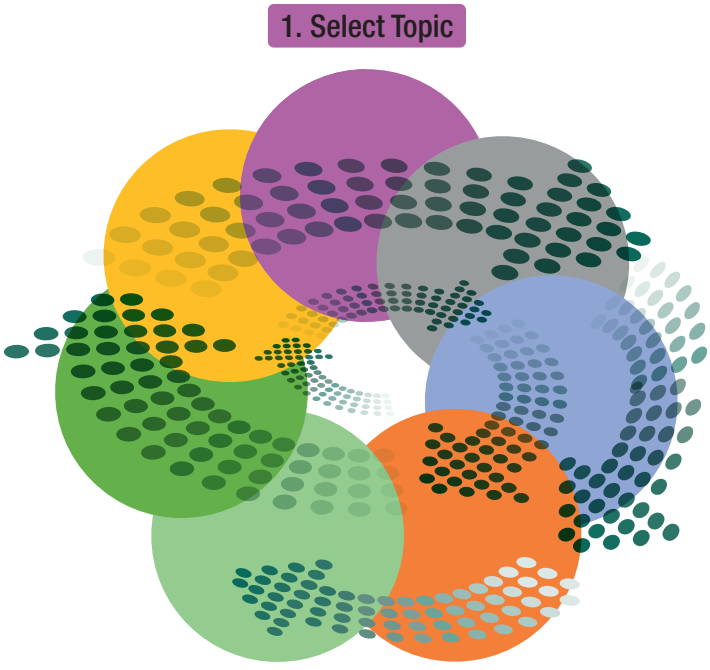


Figure 2: Clinical Audit Cycle Stage 1– Select Topic

3.1 Step 1: Involving Stakeholders

Anyone involved in providing or receiving care can be considered a stakeholder in clinical audit. Therefore, to determine who should be involved in deciding on the topic and objectives of an audit, it is necessary to identify:

- Who is involved in the delivery of care?
- Who is in receipt of, uses or benefit from the care or service?
- Who has the authority to support implementation of any identified changes?

When planning a clinical audit, the audit team should include service users in the audit process. For example, would it be beneficial to include their experience of receiving clinical care?

Common methods of involving service users in the clinical audit process are:

- Gathering service user feedback, for example letters of complaint or compliment
- Analysis of comments made at service user forums
- Interview with service users
- Service user surveys
- Focus groups
- Expert user groups
- Examining critical incidents

Where service users are involved in clinical audit, their roles need to be clearly defined and appropriate support and guidance provided to them to enable delivery. (This should include the provision of information and guidance in relation to data protection requirements).

Who has the authority to support implementation of any identified changes?

Commitment to the clinical audit process should be sought from those with the authority to approve changes arising from audit recommendations, particularly if they have potential resource consequences or implications for other service areas.

3.1 Step 2: Determining the clinical audit topic

Topics for clinical audit should be selected with a view to improving the quality or safety of care or of service provision. The classification system of structure, process and outcome can be used to focus on areas of practice from which a topic may be selected:

Structure

- Resources required to deliver care
- Environment in which care is delivered
- Equipment made available
- Documentation of policies, procedures, protocols and guidelines

Process

The procedures and practices implemented by staff in the prescription, delivery and evaluation of care

Outcome

The effect of care received by service users as a result of healthcare provision and the costs to the service of providing care, e.g., the result of clinical interventions

Questions to assist with determining an audit topic:

- Is the topic of high cost, high volume or high risk to staff and/or service users?
- Is there evidence of wide variation in clinical practice?
- Is good evidence available to inform clinical audit standards (systematic reviews or clinical guidelines)?
- Is the problem measurable against relevant standards?
- Is clinical auditing the problem likely to improve healthcare outcomes as well as process improvements?
- Is there evidence of a (serious) quality problem (e.g., service user complaints or high complication rates, adverse outcomes or poor symptom control)?
- Is the topic of key professional or clinical interest?
- Are reliable sources of data readily available for data collection purposes?
- Can data be collected within a reasonable time period?
- 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 clinical audit process or is a different process more appropriate (e.g., look back review, service evaluation)?
- How much scope is there for improvement and what are the potential benefits of undertaking this clinical audit?

3.1 Step 3: Planning the delivery of the clinical audit

Aims and objectives of the clinical audit

The audit team must understand the overall purpose of the audit they are about to perform. The purpose of the audit must be outlined in the form of aims and objectives. Audit aims and objectives must be defined through the use of verbs, such as:

- Improve
- Increase
- Enhance
- Ensure
- Change

Clinical audit is a quality improvement process so your audit objectives need to show the intent to improve. For example, an audit of healthcare records might have as its overall aim:

‘To ensure the content of the healthcare record provides an accurate chronology of events’.

Verbs **+ aspects of quality** can be used for the purpose of designing the clinical audit:
(Safe, Effective, Patient-Centred, Timely, Efficient and Equitable)

'Increase the timeliness of …'

'Improve the effectiveness of …'

'Ensure the safety of …'

Identifying the skills and people needed to carry out the audit

For a clinical audit to be successful and achieve its aim and purpose, it needs to involve the right people with the right skills from the outset. Therefore, the identification of skills required and of individuals possessing these skills should be a priority. The level of skill required for a clinical audit will also be dependent on the size of the clinical audit.

Skills required for the clinical audit process:

- Leadership, organisational and management skills
- Clinical, managerial and other service input and leadership
- Project management skills
- Change management skills
- Clinical audit methodology expertise
- Understanding of data protection requirements
- Data collection and data analysis skills
- Facilitation skills
- Communication skills
- Interpersonal skills

The skills outlined should be drawn from all relevant groups involved in the delivery of care and the clinical audit team should be multidisciplinary. To achieve the best possible results, all relevant staff groups should have a degree of involvement in the performance of the clinical audit and in the implementation of quality improvements.

For a clinical audit to be carried out effectively, all staff should be appropriately trained and briefed about their role in the clinical audit. All members of the team should have:

- A basic understanding of clinical audit
- An understanding of and commitment to the plans and objectives of the clinical audit
- An understanding of what is expected of the clinical audit team and this should be clarified at the outset (Ashmore, Ruthven and Hazelwood, 2011a).

Providing the Necessary Structures

Appropriate structures and processes should be in place prior to the commencement of clinical audit work. The clinical audit team should complete a Clinical Audit Proposal Form **(see Resource 2)**. This ensures that all aspects of the proposed clinical audit have been considered and that the clinical audit will be robust and of high quality.

Completed forms along with supporting standards, clinical audit tool(s) and other documentation should be submitted to the appropriate responsible clinical lead, directorate or governance committee for consideration to ensure that the proposed clinical audit meets the requirements of the service provider through local clinical audit channels.

The team carrying out the clinical audit should ensure that appropriate resources are available with which to perform the clinical audit and to implement quality improvements. Where there is an insufficient level of resources available to carry out a clinical audit and the improvements, this issue should be raised through the appropriate governance structures as and when they arise.

The structures should include a mechanism for reviewing findings and reporting progress to the appropriate clinical lead, directorate or governance committee. Clear lines of accountability should be agreed upon at the outset of the clinical audit. The clinical audit must be led by a health practitioner as defined by the Patient Safety Act 2023, including but not limited to doctors, nurses, pharmacists, dentists, and practitioners registered with CORU.

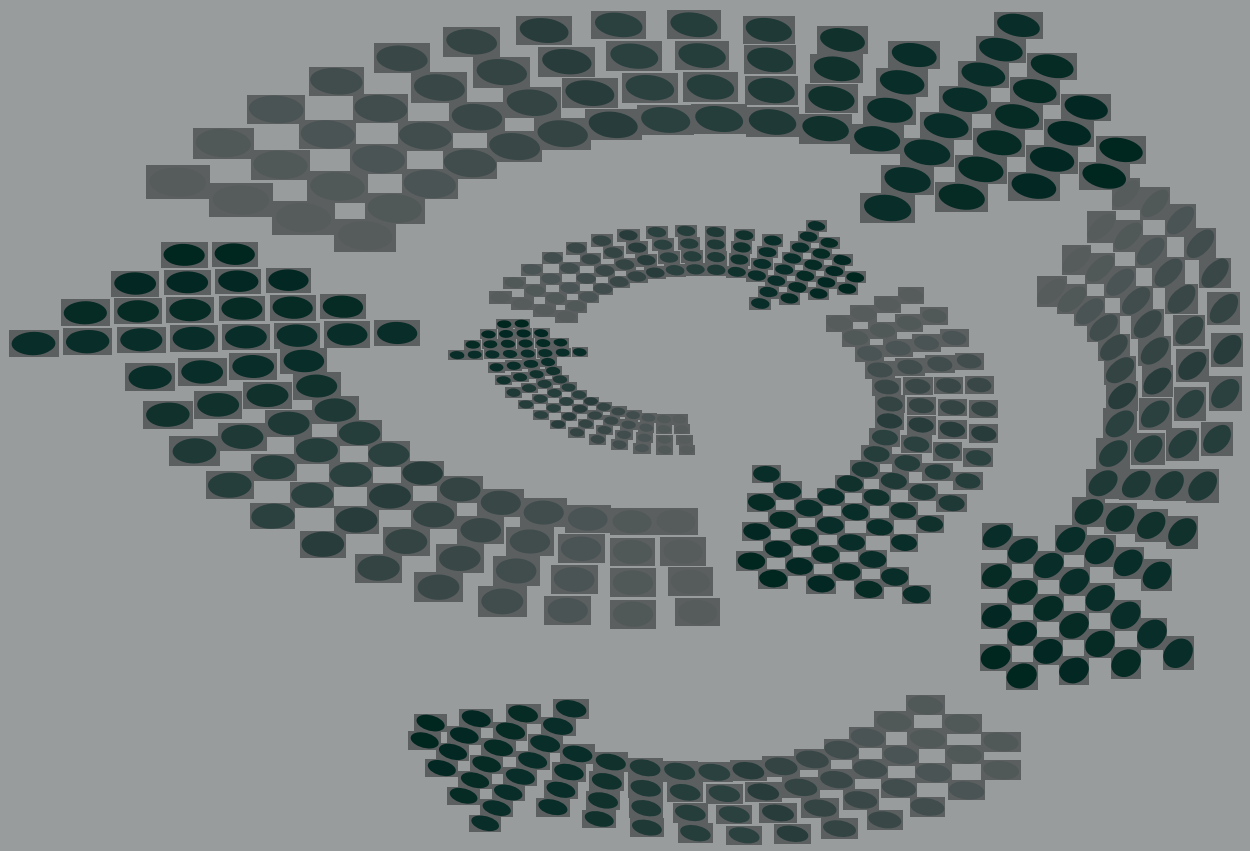
See Stage 6 QI Plan and Action for further information on publications.

A timetable should be agreed for designing and carrying out the clinical audit. A simple **Clinical Audit Checklist** may also be a useful tool **(see Resource 1).**

For a quick reference on key steps to ensure best practices throughout your audit process, refer to Resource 1: Checklist for Best Practice in Clinical Audit.

To document and formalise your audit plan, please refer to Resource 2: Clinical Audit Proposal Form.

Stage 2: Set Criteria and Standards



Stage 2: Set Criteria and Standards	
1	The clinical audit must measure performance against standards
2	Standards for clinical audit must reflect current best practice, be evidence-based and agreed by all stakeholders
3	The clinical audit standards may measure structure, process and/or outcome
4	The clinical audit standards need to be clearly referenced to their source document
5	The clinical audit standards must be SMART (specific, measurable, achievable, realistic and time-bound)
6	The clinical audit standards must be unambiguous and not be open to interpretation
7	The clinical audit standards must clearly state the target level of compliance that enables a clear comparison to be made with current practice.

Figure 3: Clinical Audit Cycle Stage 2– Set Criteria and Standards

3.2 Step 1: Selecting Best Practice Standards

When the clinical audit topic has been selected, the next essential step is to review the available evidence to identify the standards and clinical audit criteria against which the clinical audit will be conducted.

Standards should be 'robust' and evidence based (Potter, Fuller & Ferris, 2010) and current.

When specifying standards, they are defined as structures and processes needed to identify, assess and manage risks in relation to the subject area (for example, healthcare records management) (HSE, 2013).

What are clinical audit standards?

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

A standard is the desired and achievable level of performance against which performance can be measured.

See **Glossary of Terms** for the full definition of clinical standards.

Useful sources for standards include:

- Local standards, in the form of evidence-based guidelines
- Nationally endorsed clinical guidelines
- Standards and clinical guidelines from relevant quality and safety programmes, clinical care programmes and professional bodies
- Clinical guideline development organisations such as NICE, SIGN, NCEC, Royal Colleges

The HSE Central Repository for Policies, Procedures and Guidelines is the single trusted source for accessing, storage and document control of HSE National policies, procedures, protocols, guidelines and clinical guidelines and can be accessed at **https://www2.healthservice.hse.ie/organisation/national-pppgs/**

If national or local guidelines are not available, a literature review can be carried out to identify the best and most up to date evidence from which clinical audit standards and criteria may be generated.

> **'A clinical audit may be carried out for the purpose of establishing a new clinical standard or clinical guideline that will in turn be used for the carrying out of the clinical audit or be evaluated in a subsequent clinical audit'**
>
> *(Patient Safety Act 2023)*

Standard Title:	Summarises the area on which that particular standard focuses
Standard Statement:	Explains the level of performance to be achieved
Standard Criteria:	Provides the detail of what needs to be achieved for the standard to be reached

For standards to be valid and lead to improvements in care, they should be consistent with SMART guidance.

- **S**pecific (explicit statements, not open to interpretation)
- **M**easurable
- **A**chievable (of a level of acceptable performance agreed with stakeholder)
- **R**elevant (related to important aspects of care)
- **T**heoretically sound or timely (evidence based)

Structure Criteria

(What is needed), refers to those resources that are required to deliver care, including the numbers of staff and skill mix, current knowledge, skills and attitudes, materials and drugs, equipment and space.

Process Criteria

(What is done), refers to the actions and decisions taken by healthcare professionals together with service users and includes communications, assessments and prescription of surgical and other therapeutic interventions.

Outcome Criteria

(What is expected to happen as a result), refers to the expected outcomes of care. Increasingly the measurement of outcomes of care is being seen as the most appropriate measure of effectiveness.

Measuring Care

The measurement against criteria of care is at the heart of clinical audit. In order to compare actual care with care that should be provided, each clinical audit criterion should have an expected level of performance' or 'target' assigned to it (Ashmore, Ruthven and Hazelwood, 2011a).

3.2 Step 2: Set the Target/Level of Performance

Three factors should be considered and assessed when setting targets. These factors are clinical importance, practicality, and acceptability. The expected level of performance or target can range from 0% (the criterion is something that must never be done) to 100% (the criterion is something that must always be adhered to).

Clinical Importance

Where a criterion is critical to the safety of service users, targets may be set at 100% or 0%, for example, a clinical audit relating to safe administration of medication could have a target of 100% for the following criterion 'medication is not administered to a service user with a known allergy to the medication'.

Practicality

However, where clinical importance is not as significant, resources required to fulfil the target performance level should be considered and an acceptable performance level (one which is seen as both reasonable and attainable by those delivering and receiving care) should be identified, for example, in a clinical audit relating to the timeframe within which service users should be seen in a particular outpatient clinic, a target of 90% may be deemed appropriate.

Acceptability

An optimum level of performance is set when the best care possible is identified, given the resources available and normal conditions of caregiving. This will lie somewhere between the minimal acceptable level of care and the highest possible level of care (possible under ideal conditions, with no restrictions on resources).

Target / Level of Performance:

A defined level or degree of expected compliance with clinical audit criteria may be expressed as a percentage or proportion of cases.

3.2 Step 3: Consider Inclusion / Exclusion Criteria

In order to ensure that the clinical audit sample is representative of the target population and to collect data which is fit for purpose, it is necessary to define what information should be collected and what information should not be collected.

Inclusion Criteria

Define areas included in the remit of the clinical guideline/standard.

Exclusion Criteria

Define areas outside the remit of the clinical guideline/standard.

Many evidence based clinical guidelines identify inclusion and exclusion criteria.

Step 4: Consider Exceptions

There may be a justifiable reason why some cases from the identified sample may not comply with specific clinical audit criterion. In these circumstances the case is not included in the data analysis, they are *exceptions* in the clinical audit.

Exceptions

Example

In a clinical audit of NICE clinical guideline CG61 (NICE, 2008; updated April 2017) *'Irritable bowel syndrome in adults: diagnosis and management in primary care'*, the following apply:

Inclusion criteria:

- Adults (18 years and over) who present to primary care with symptoms suggestive of irritable bowel syndrome (IBS).

Exclusion criteria:

- Adults with other gastrointestinal disorders such as non-ulcer dyspepsia, coeliac disease or inflammatory bowel disease.

'An exception is a clinically acceptable reason or circumstance for not complying with specific criteria'
(Dixon, 2009a)

Example

A clinical audit on the previously referenced NICE CG61 *'Irritable bowel syndrome in adults'* could have the following criterion and exceptions:

Criterion:

- Percentage of service users with irritable bowel syndrome (IBS) advised how to adjust their doses of laxative or anti-motility agent according to the clinical response.

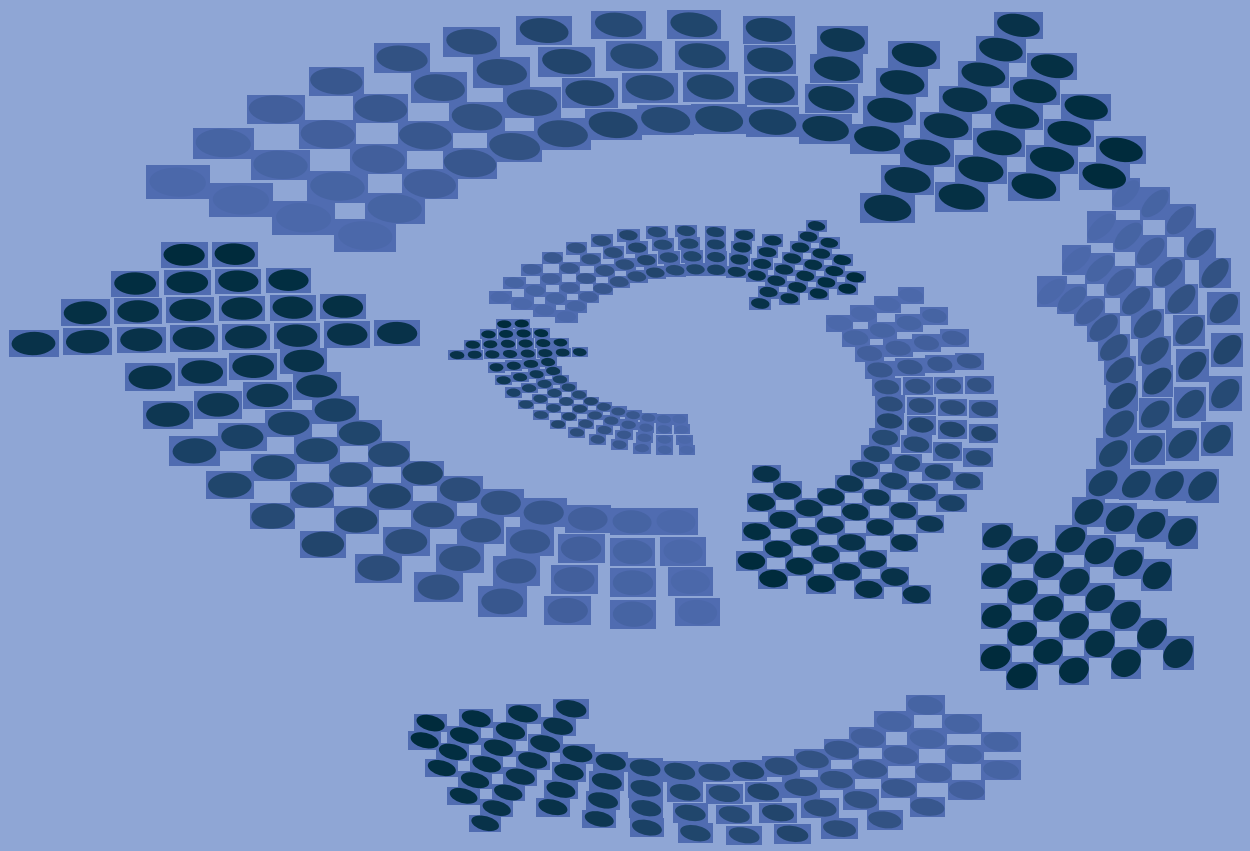
Exceptions:

- Service users with IBS who are not using laxative or anti-motility agent.

For key considerations on setting criteria and standards, refer to Resource 1: Checklist for Best Practice in Clinical Audit.

To ensure your audit criteria and standards are correctly defined, refer to Resource 2: Clinical Audit Proposal Form.

Stage 3: Design Clinical Audit Tool and Collect Data



Stage 3: Design Audit Tool & Collect Data	
1	Design a questionnaire or data collection tool
2	Agree the sample size. As a minimum, data collected must be adequate to determine if the clinical audit standards are being achieved
3	Agree data collection methodology. There are a range of options for collecting clinical audit data including: concurrent, retrospective and prospective data collection
4	Inclusion and exclusion criteria must be considered prior to the collection of data
5	Data collection must be in accordance with the agreed standards and sample size. Data not required to measure if clinical audit standards are being met, should not be collected
6	The data collection tool must be piloted
7	The data collection tool must not capture patient identifiable data. All data collected must be in compliance with HSE Data Protection Policy and General Data Protection Regulation (GDPR).

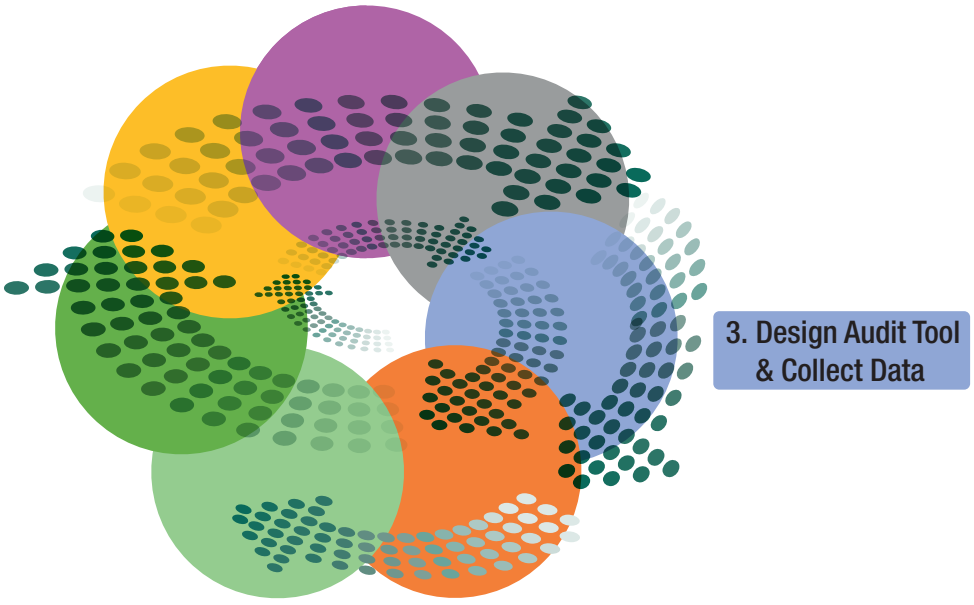


Figure 4: Clinical Audit Cycle Stage 3– Design Audit Tool and Collect Data

3.3 Step 1: Devise Audit Tool

The following principles apply to designing a data collection sheet:

- The data to be collected should be relevant to the objectives and criteria for the clinical audit and the expected performance levels.
- Acronyms, jargon, and technical terms should be avoided.
- Definition of terms used should be included where necessary.
- There should be space to record exceptions.
- Questions should be episode-specific, they relate to a specific episode of care.
- Closed questions should be used, these should be clearly worded and contain no ambiguity to clarify the format for the answer (for example, date: day/month/year).
- Limit the use of free text or open questions to clinical audits with qualitative elements as free text is difficult to code and analysis is very time consuming.
- Data items should be presented in a logical order. The tool should not require the person collecting or analysing the data to skip backwards and forwards.

There are 3 methods for data collection in a clinical audit: **Retrospective, Concurrent and Prospective.**

Retrospective Data Collection

Retrospective data is collected after completion of treatment/care to service users.

Advantage:
- The data already exists and may be gathered quickly.

Disadvantage:
- The data can quickly become out of date and the data available may not be complete and accurate.

Concurrent Data Collection

Concurrent data is collected while treatment / care is being provided.

Prospective Data Collection

If the data required is not routinely recorded, a prospective clinical audit must be undertaken.

Advantage:
- If the data required is not routinely recorded, a prospective clinical audit must be undertaken

Disadvantages:
- Time is required to collect the data
- There is a potential for bias.
- The care provided may be affected by the knowledge that a clinical audit is ongoing

3.3 Step 2: Data Collection Process

The overall objective of clinical audit is to improve the quality of care and outcomes by measuring current practice against best practice. When the standards against which the clinical audit will be conducted have been identified, the next step in the clinical audit process is the collection of relevant data about current practice in order to facilitate comparison.

It is important that data collected in the course of any clinical audit is precise and pertinent to the clinical audit being performed. To ensure that data is collected appropriately, there are a number of details which need to be established at the outset. These are:

- The population or sample to be included, with inclusion/exclusion criteria defined
- The consent required to access the population or sample information
- The healthcare professionals involved in the service user's / patient's care
- The time period over which the criteria apply
- The analysis to be performed

Resources should be used effectively to collect the minimum amount of data necessary to achieve the clinical audit objectives. Resource utilisation decisions should be made at the outset of the clinical audit and revised, if appropriate, during the clinical audit process. Due cognisance should be given to data protection requirements.

Planning data collection

Before data collection commences, a structured approach should be taken to the identification of relevant data and to ensuring that the data collection process is efficient, effective, accurate and clear.

Questions to assist with preparing for data collection

- What type of data do I need to collect (quantitative and/or qualitative)?
- What data items will need to be used to show whether performance levels have been met for each standard?
- What data sources will be used to find the data?
- Will a data collection tool be piloted?
- Will I need to collect data concurrently, prospectively and/or retrospectively?
- What size is the target population, and will I need to take a sample?
- How will data be collected (manually and/or electronically)?
- How long will it take to collect the required amount of data?
- Who will be collecting the data?
- How will I ensure data quality?

(Adapted from Ashmore, Ruthven and Hazelwood (2011))

Collection of data which is not required for the purposes of measurement is more time consuming and may infringe compliance with information governance requirements and practices.

When standards of best practice, clinical audit criteria, expected compliance rates and known exceptions have been identified, definitions and instructions for data collection should be compiled. This involves defining terms in the clinical audit criteria and known exceptions for data collection purposes and also defining where evidence should be obtained.

Sources of Data

The source of data for a clinical audit should be specified and agreed by the clinical audit team. The source specified should provide the most accurate and complete data as readily as possible.

Sample Size

The sample should be small enough to allow for speedy data collection but large enough to be representative.

Clinical audit is not research. It is about evaluating care against best practice standards rather than creating new knowledge; therefore sample sizes for data collection are often a compromise between the statistical validity of the results and pragmatic issues around data collection such as time, access to data, and costs.

When determining the number of sample subjects, consideration should be given to the level of confidence required from clinical audit results and any constraints which may impact upon the clinical audit. For many clinical audit topics, a small amount of data may be sufficient for the purposes of the clinical audit; however, if a contentious issue is being audited, a larger sample size may be required.

Sample selection methods

It is often not possible or necessary to gather data on all patients/service users, events or items for clinical audit purposes; therefore sampling is often required. It is important that any sample selected is representative of the population under examination. There are numerous sampling methods which may be used; however random sampling and convenience sampling tend to be the most commonly used methods.

The simplest form of random sampling involves selecting service users at random from an overall population listing, for example every 3rd, 6th case etc. The Hospital Inpatient Enquiry System (HIPE) offers this facility (HSE, 2008). Random number generation can also be used.

Convenience sampling is sometimes used as a simple and effective way of carrying out a sample survey. It involves choosing the nearest and most convenient persons to act as respondents; it therefore does not produce findings that can be taken to be representative, for example, the first 10 cases presenting after a specific time.

Interval sampling – is often determined by a time period. For example, all cases in a specific timeframe. The sample size should be sufficient to generate meaningful results.

- Where necessary the sample should allow for adjustment for case mix
- The clinical audit should use pre-existing data sets where possible

Piloting the Data Collection Tool

Piloting a data collection tool and its methodology can provide evidence as to whether the proposed methodology is feasible. A pilot may reveal problems such as a data collection tool which is difficult to understand or to complete; or be used to identify themes in answers provided to open questions on data collection forms and these in turn can be reformed as tick-box options for ease of analysis.

If the data collection takes too long, interest will be lost and data completeness will suffer.

- In numerical clinical audits, the number of cases selected should reflect the most common of the condition or therapy, but should be of a reasonable number to draw subsequent conclusions
- In time based clinical audits, one to three months should be adequate for the majority of clinical audits

(NHS Clinical Governance Support Team, 2005)

How long should it take to collect the required amount of data?

The time period chosen depends on the number of cases that are treated on a daily basis and the number needed to make a confident judgment of the care provided. (NICE, 2002).

Timeframe for data collection is influenced by:

- The sample (size and population)
- Inclusion and exclusion criteria
- Target date for clinical audit completion

A credible sample of subjects should be agreed with stakeholders. If the clinical audit intends to include the perspective of service users, the aim should be to ensure that the sample of service users recruited to the clinical audit is as representative of the relevant population as possible. In addition, different clinical audit techniques might be needed to engage the views of different groups, such as a questionnaire/survey.

Who collects the data?

Depending on the clinical audit, data may be collected by more than one person or different people may be responsible for completing different data sets.

There should be no confusion over terminology. A definition should be provided for each data item so that it is collected consistently (inter-rater reliability). In addition, everyone involved in data collection should be recorded.

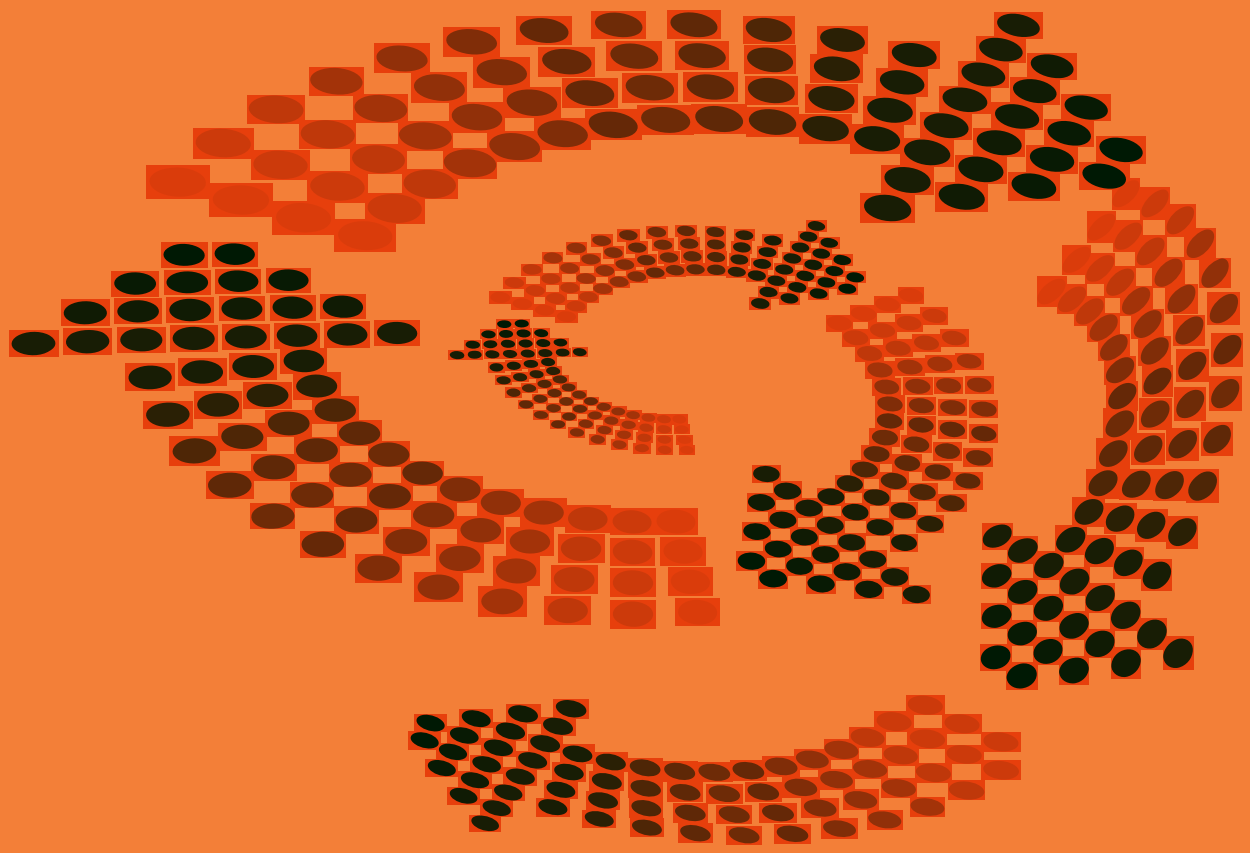
Ensuring data quality

Data can be said to be of good quality when it does what it is needed to do. There should be clear definitions for each data item to be collected to ensure that data collectors have a good understanding of what, how and when data needs to be collected. There should also be routine data quality checks to minimise the occurrence of reporting and input errors. (Health Information and Quality Authority, 2010)

For key considerations in designing your audit tool and data collection, refer to Resource 1: Checklist for Best Practice in Clinical Audit.

To assist in documenting your audit tool and data collection methods, refer to Resource 2: Clinical Audit Proposal Form.

Stage 4: Analyse Data and Compare Results with Standards



Stage 4: Analyse Data and Compare Results with Standards	
1	Clinical audit data should be analysed by the team within the agreed timeline and comprehensively checked for accuracy
2	Clinical audit data must be analysed to determine if best practice standards have been achieved
3	The clinical audit data analysis process should identify relevant trends/data that meet the standard/patterns/variations
4	Consideration must be given to how clinical audit results will be generated via the data analysis process. Clinical audit results must be shared in the most appropriate format to allow key stakeholders to gain the most accurate and understandable picture of performance
5	Clinical audit data must not display named individual healthcare professionals
6	Clinical audit results must explain how missing or not applicable data has been managed
7	Clinical audit results must be effectively communicated and presented to all relevant stakeholders, ideally including patients.

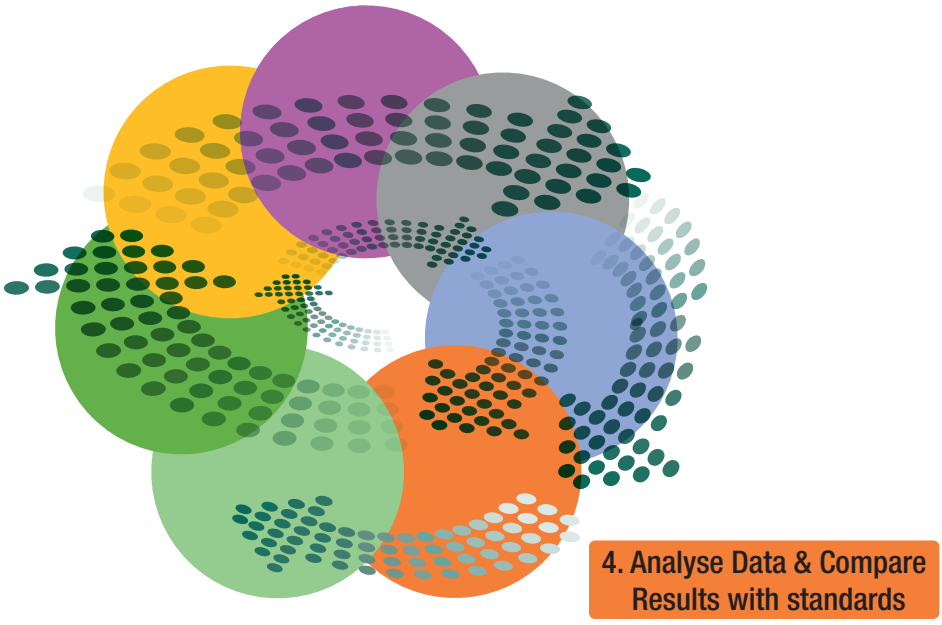


Figure 5: Clinical Audit Cycle Stage 4– Analyse Data and Compare Results with Standards

3.4 Step 1: Data Analysis

To compare actual practice and performance against the agreed standards, the clinical audit data must be collated and analysed. The basic aim of data analysis is to convert a collection of facts (data) into useful information. The main aim of data analysis is to answer the questions posed by the clinical audit objectives; highlighting areas of good practice and areas that require particular attention or improvement.

It is often necessary to perform basic calculations on the raw data collected to get results from which conclusions can be arrived. The type of data analysis depends on the type of information collected. This can range from simple averages and percentages to other statistical techniques.

For most clinical audits, complex statistical analysis is not necessary or appropriate. A simple, clear and concise analysis which can be easily understood by everyone involved in the provision of care is all that is required to stimulate change.

3.4 Step 2: Calculating compliance with clinical audit criteria

The basic requirement of a clinical audit is to identify whether or not required performance levels have been reached. This requires working out the percentage of cases that have met each clinical audit criterion. In order to calculate the percentage, it is necessary to identify both the total number of applicable cases for a criterion (the denominator) and the total number within the sample that met the criterion (the numerator). The percentage is then calculated by dividing the numerator by the denominator and multiplying the answer by 100.

This figure is obtained by subtracting cases that are agreed exceptions for a particular criterion, from the total number of cases which meet the inclusion criteria minus exclusions.

Example

Using the previously referenced **Clinical Guideline NICE CG61** (NICE, 2008; updated April 2017) *'Irritable bowel syndrome in adults; diagnosis and management in primary care'*

Clinical Audit Criterion:

- Number of patients/service users with irritable bowel syndrome (IBS) advised on how to adjust their dose of laxative or anti-motility agent according to clinical response.
- Inclusion criteria: Adults (18 years and over) who present to primary care with symptoms suggestive of irritable bowel syndrome (IBS).
- Exclusion criteria: Adults with other gastrointestinal disorders such as non-ulcer dyspepsia, coeliac disease or inflammatory bowel disease
- Agreed exception: Service users with IBS who are not using a laxative or anti-motility agent

Displaying Data

To facilitate the drawing of conclusions from analysed data, the data should be displayed in the simplest, clearest, and most effective way possible. There are many ways of displaying data, through comparing data from one area against data from another area, to comparing results against expected level of performance or current clinical audit results against previous clinical audit results.

The nature of the clinical audit topic and the data measured will determine which type of descriptive statistic will be most useful for presentation of information. Useful descriptive statistics include information on the distribution of data, the mean or average, median, mode and measures of dispersion i.e. the range and possibly the standard deviation.

3.4 Step 3: Drawing Conclusions

After results have been compiled and the data has been analysed, the final step in the process is to identify if the standard was met or not met.

To understand the reason(s) a standard was not met, the clinical audit team should carefully review all findings to:

- Clearly identify and agree on areas for improvement identified by the clinical audit
- Analyse the areas for improvement, to identify what underlying, contributory or deep-rooted factors are involved
- Have a clear understanding of the reasons why performance levels are not being reached, to enable development of appropriate and effective solutions.

3.4 Step 4: Sharing Results

The aim of any presentation of results should be to maximise the impact of the clinical audit on the audience to generate discussion and to stimulate and support action planning.

To facilitate the drawing of conclusions from analysed data, the data should be displayed in the simplest, clearest and most effective way possible. Reading or listening to lots of facts and figures is not always an effective way to convey information and may prove difficult for an audience to interpret and understand the information being conveyed. Visual methods can make the point more effectively than data alone.

Data graphics are a good way of communicating this information to others, such as infographics. The most commonly used form of data graphics in clinical audit are tables, graphs and charts, using Excel.

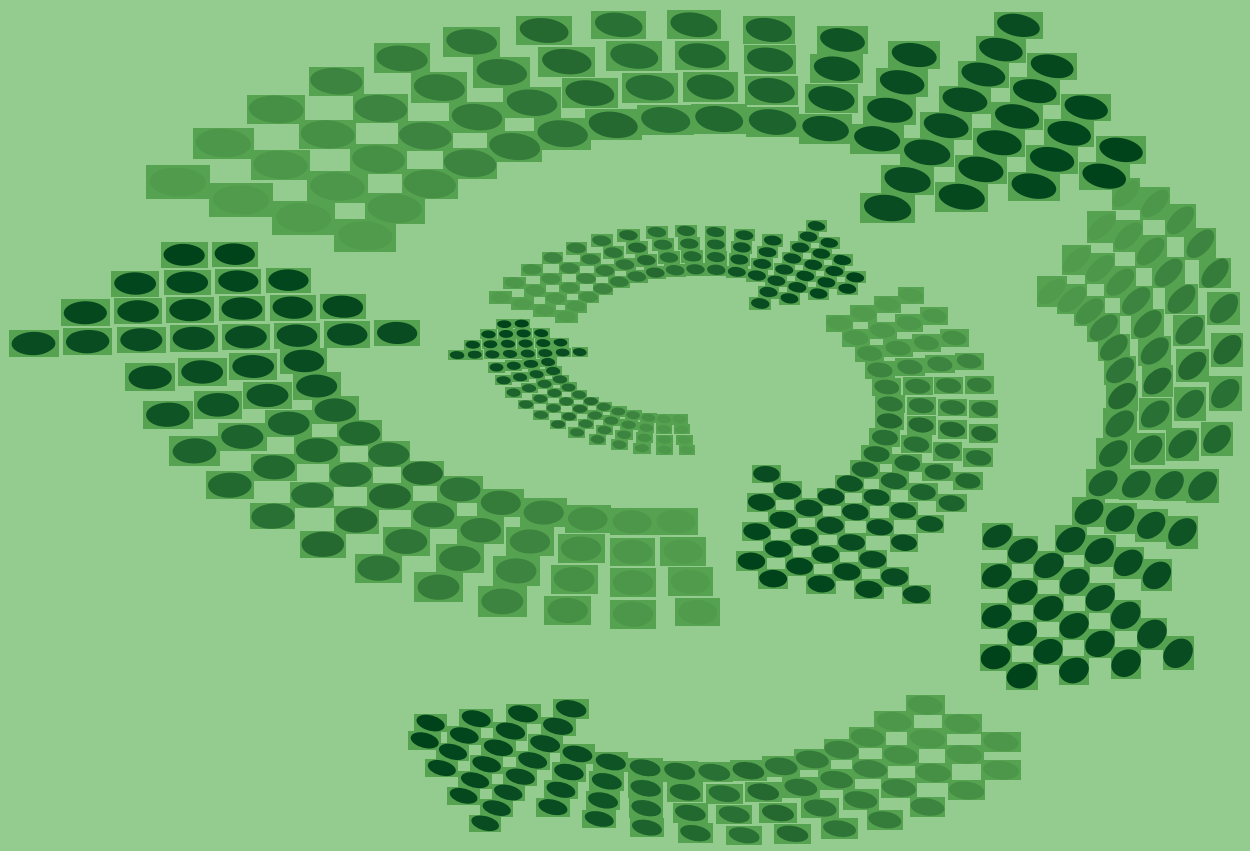
When deciding on which form of data graphics to use, consideration of the following may be helpful:

- What information is to be communicated?
- Who is the audience?
- What might prevent them from understanding this information?

*In compliance with Data Protection legislation, unless presentation of clinical audit results are confined to the clinical care team, only irrevocably anonymized data should be disclosed

To help structure and document your audit results, refer to Resource 3: Clinical Audit Report Template

Stage 5: Clinical Audit Report



Stage 5: Clinical Audit Report	
1	All clinical audits should be written into a clinical audit report. The clinical audit report should utilise relevant local or national clinical audit report templates
2	The clinical audit report should follow the required sub-headings: background, aim, objectives,methodology, results, conclusion, recommendations, quality improvement plan
3	The clinical audit report should clearly state the rationale for undertaking the clinical audit
4	The clinical audit report must have a clearly described methodology
5	The clinical audit report must not include data for named individual healthcare professionals
6	A list of all specialist vocabulary, acronyms and abbreviations are included in the clinical audit report
7	The clinical audit report should be disseminated to all key stakeholders.

Figure 6: Clinical Audit Cycle Stage 5– Clinical Audit Report

3.5 Step 1: Layout of the Clinical Audit Report

Your clinical audit report should follow a standard Clinical Audit Report template **(See Resource 3).**

Additional items to include in a Re-Audit Report

Background – information should be provided about the previous clinical audit and the key actions that were implemented as a result

Action plans – previous action plans must be evidenced when later re-auditing and an assessment made of the success of any actions taken

Conclusion/Summary – a progress report and comparison to the previous clinical audit must be included. This can be contained as a summary or a table.
Consider what has changed, either for the better or worse since the previous clinical audit. (Healthcare Quality Improvement Partnership (HQIP), 2012.

Patient Safety Act and Clinical Audit Publication Guidance

The advice is that "publish", as per the Act, requires that aggregated data be disseminated in some form to the public. Therefore, data shared only at a multidisciplinary team or departmental meeting will not be considered "published".

The data must be made publicly available in a form or manner determined by the health service provider in line with local policies, procedures, or guidelines for those wishing to benefit from the clinical audit section of the Act. Examples of publication opportunities include but are not limited to websites, leaflets, infographic output, posters, conferences and local audit days.

Another approach to meet these requirements includes registering clinical audit proposals with local quality and patient safety teams or the clinical audit department. They should then publish a collated log of audits in an annual report made publicly available. This will also support embedding clinical audit in quality & patient safety governance structures.

Meeting the definition of clinical audit under the Act provides an opportunity to ensure that clinical audits conducted are to a publishable standard.

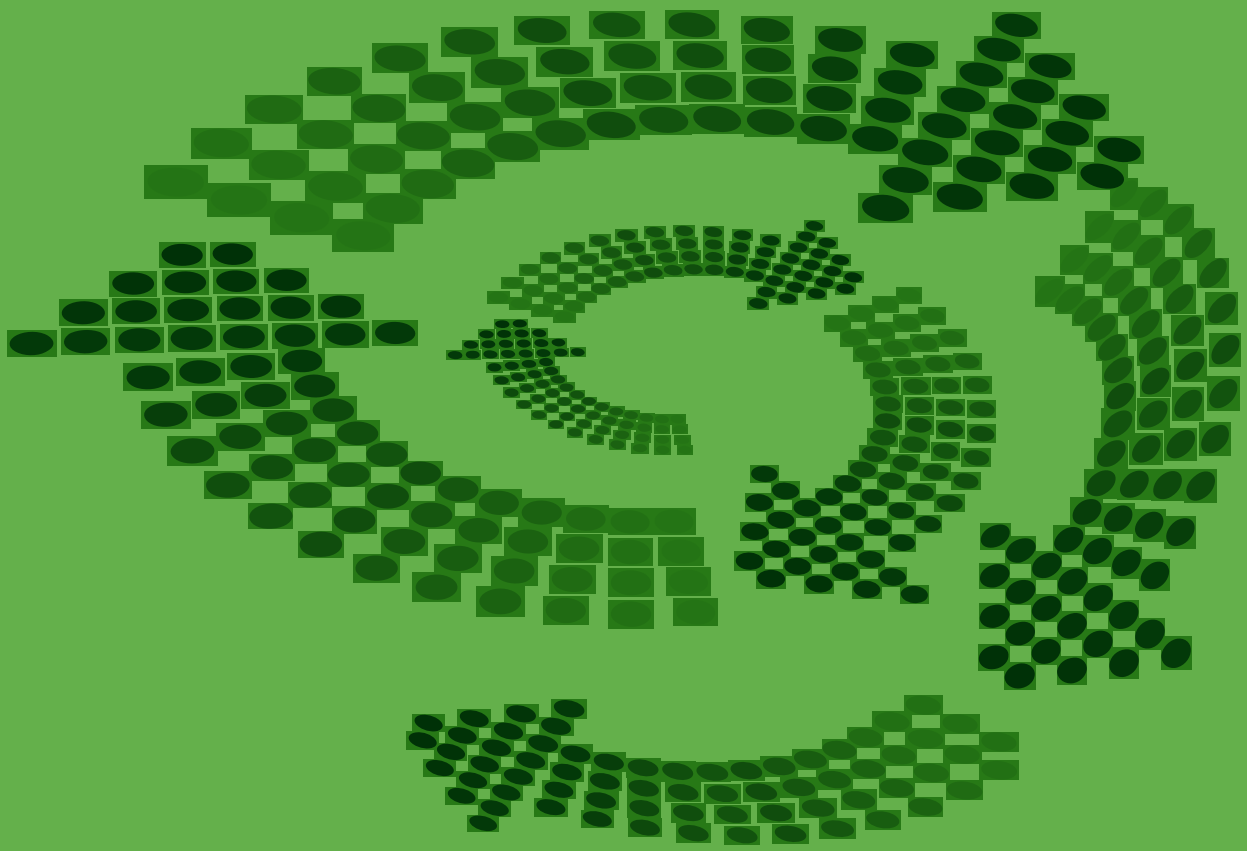
3.5 Step 2: Reflection

What has the team learned from completing this clinical audit? What went well? Looking back, what would you have done differently? Has anything changed in practice? Has the clinical audit been of any benefit to the patients, the practice and/or the team?

For guidance on structuring your audit report, refer to Resource 3: Clinical Audit Report Template.

To develop an action plan based on your audit findings, refer to Resource 4: Quality Improvement and Action Plan Template.

Stage 6: QI Plan and Action



Stage 6: QI Plan and Action	
1	Based on the findings and conclusion, the clinical audit stakeholders should agree a QI plan with actions that will be implemented to improve care
2	The QI plan will include ownership of actions and agreed timelines
3	The clinical audit QI plan should utilise agreed templates. This will ensure consistency.
4	The QI plan should be disseminated and communicated to all relevant stakeholders and governance reporting lines
5	Implementation of the action(s) must be closely monitored, with progress reported to key stakeholders
6	The re-audit should not commence until all actions have been completed

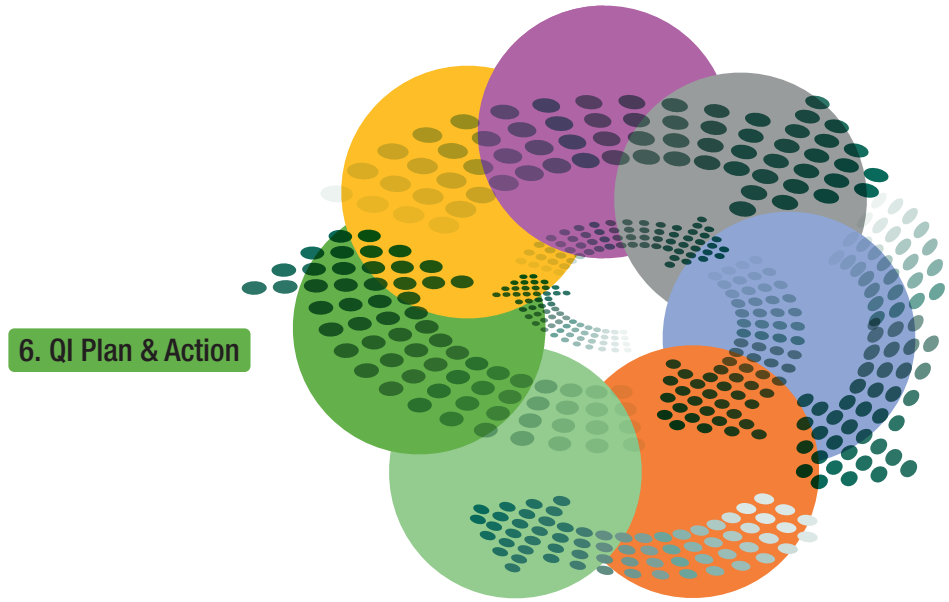


Figure 7: Clinical Audit Cycle Stage 6– QI Plan and Action

3.6 Step 1: Development of a Quality Improvement (QI) Plan

Clinical audit results may show areas of excellent or notable practice and this should be acknowledged. Clinical audit results may also identify areas for improvement where the required standards are not being met.The Quality Improvement Plan is a fundamental part of the clinical audit cycle; without it, the clinical audit is not effective. It is an important change management tool; however, to be effective a QI plan must explicitly contain the following information:

1. Highlight what needs to change (recommendation)
2. Indicate the action(s) that must be taken in order to achieve change
3. Give a deadline by which time the actions must be carried out
4. Show who is responsible for making sure that the actions are carried out
5. Indicate the evidence required to prove that the actions have been implemented

Implementing change is often the most difficult part of the clinical audit. QI plans are live documents and will need to be updated and reviewed regularly to ensure progress is being made and maintained. (Healthcare Quality Improvement Partnership, (HQIP) 2012)

The clinical audit loop is completed by developing and implementing the QI plan (the QI plan is often referred to as an action plan).

3.6 Step 2: Action

Priorities for action should be identified and these should be clearly documented. All clinical audits should be accompanied by an improvement plan which should be consistent with **SMART** guidance. QI Plans should be:

- **S**pecific (explicit statements, not open to interpretation)
- **M**easurable
- **A**chievable (a level of acceptable performance agreed with stakeholders)
- **R**elevant (related to important aspects of care)
- **T**heoretically sound and timely (evidence based)

QI Toolkit

There are a number of QI tools that can be utilised to facilitate improvements: Process mapping, the 'Five Whys,' Cause and Effect Diagram (Fishbone Diagramming) and the Model for Improvement (MFI), Plan, Do, Study, Act (PDSA) cycles. See the HSE Quality Improvement Toolkit web link **https://www2.healthservice.hse.ie/documents/4545/HSE_Quality_Improvement_Guide_and_Toolkit_2024.pdf**

Process Mapping

This involves mapping out each step of a process in sequence so that areas for improvement can be identified. Process maps are an effective way to identify constraints and ineffective or unnecessary process steps.

The Five Whys

Involves repeatedly asking the question 'why?' in order to drill down further into an issue, which can lead to the cause of the problem. The reason for any problem can often lead to another question. Asking 'why' five times is only a guide as depending on the issue, the question may be asked a lesser or greater number of times before reaching the origin of the problem.

Cause and Effect Diagram (Fishbone Diagram)

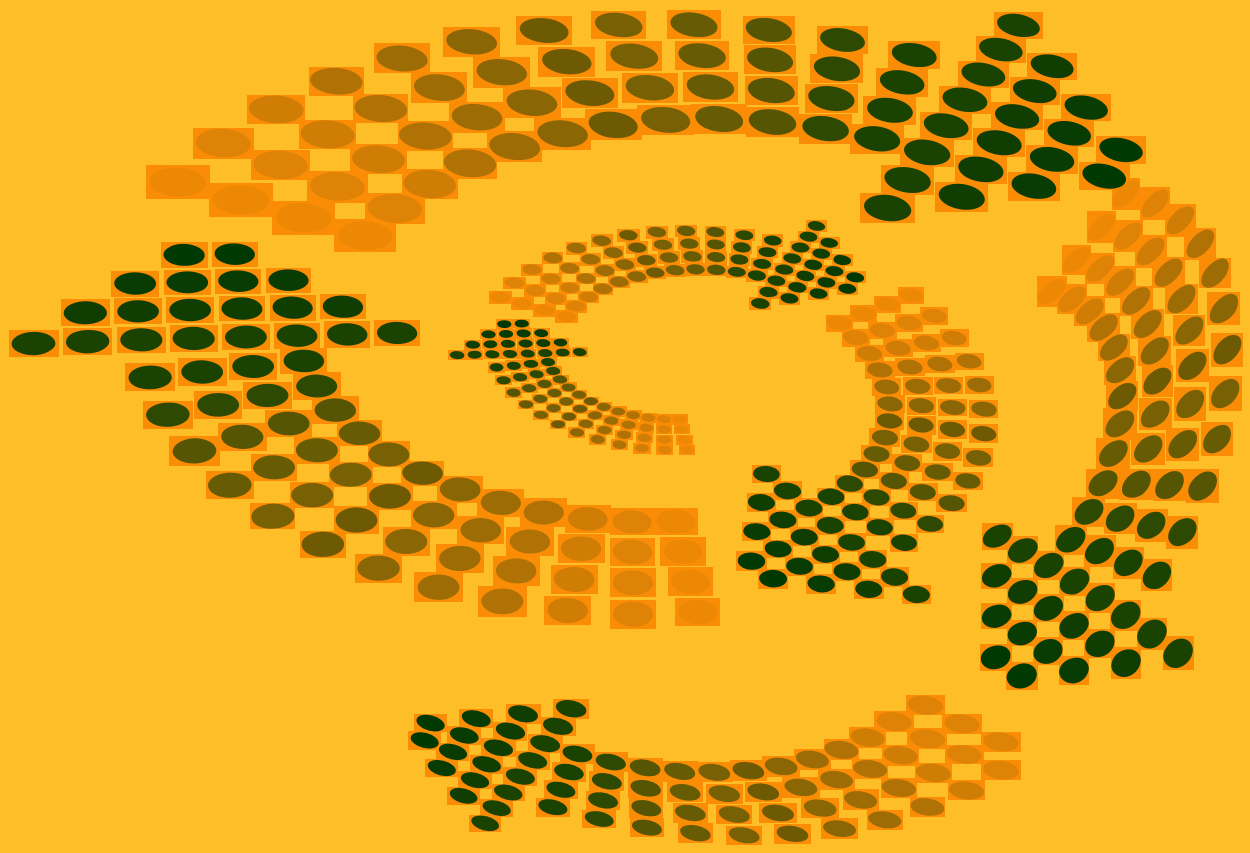
This process can be used independently or as part of a Cause and Effect Diagram (Fishbone Diagram). A problem or an effect is written at the head of the 'fish', then a common set of major categories of causative factors are written on diagonal lines branching from the main arrow, 'the bones'. Examples include people, procedures, materials, equipment and environment. In order to develop the various categories, it is necessary to think in terms of each major step in the process.

A list of possible causes for each category should be generated through brainstorming by asking the question 'why does this happen?' in relation to each cause. The causes and sub-causes are then listed on branch bones (branching off from the main branch/cause). This will highlight relationships among the causes. It is necessary to keep asking 'why?' until a useful level of detail is reached and an appropriate solution may be developed.

By establishing the reasons why performance levels for specific criteria were not met, the team are then enabled to discuss/lead discussions around recommendations for improvements.

To assist in developing and documenting your quality improvement plan, refer to Resource 4: Quality Improvement and Action Plan Template.

Stage 7: Re-Audit



Stage 7: Re-Audit	
1	If the clinical audit results demonstrate that all standards are being achieved, a re-audit is not required
2	The methodology applied in the re-audit must be the same as in the first cycle. For example, best practice standards and data collection tools need to be replicated. The re-audit must measure a comparable dataset to the first clinical audit cycle in terms of number of patients/ cases, timeframes, etc.
3	The re-audit should be carried out in an agreed timeframe. The re-audit should not be carried out prior to changes being implemented. Re-audit should take place within a maximum of 12 months of changes being recommended
4	The results of the re-audit are collated and disseminated to all stakeholders
5	If re-audit results demonstrate that care does not meet the agreed standard, an action plan/QI plan should be developed to support the changes required and a re-audit done.

Stage 7: Re-Audit

3.7 Step 1: Completing the Clinical Audit Cycle

The clinical audit cycle is a continuous process. If the first data collection cycle demonstrates that the required standard was met, the clinical audit does not need to be re-audited.

If the clinical audit shows that the standard was not met, completing the clinical audit cycle involves two data collections and a comparison of one with the other, following implementation of change after the first clinical audit completion, to determine whether the desired improvements have made a difference. Further cycles may be necessary if performance still fails to attain the levels set at the outset of the clinical audit. At this stage, there may be justification for adjusting the desired performance levels in light of the results obtained.

3.7 Step 2: Sharing Results

Completion of a clinical audit cycle will usually result in improvements in practice. This should be communicated to all stakeholders.

A successful clinical audit in one service may be transferable to other parts of the service. Completed clinical audits should be shared locally via the most appropriate mechanisms.

Consideration should also be given to sharing clinical audit work regionally and nationally through relevant journals, conferences and other media.

See **Resource 1** for **Summary Checklist of Best Practice** for steps involved in the clinical audit process.

To ensure all key steps are followed during the re-audit process, refer to Resource 1: Checklist for Best Practice in Clinical Audit.

4.0 Data Protection and General Data Protection Regulation as it Applies to Clinical Audit and Ethical Issues

4.1 Introduction

This chapter contains specific guidance related to Data Protection legislation and the General Data Protection Regulation (GDPR) as it applies to Clinical Audit. The development of this guidance is in accordance with the recommendations of the HSE's National Review of Clinical Audit Report (2019).

The report states that clear and consistent information across the healthcare system is required. The report recommends that: *"The HSE Data Protection Officer (DPO) should provide guidance regarding the interpretation of GDPR, which should include specific guidance related to the application of GDPR to clinical audit."*

This document, along with FAQ Guidance - **HSE NCCA GDPR FAQ**, is intended to support auditors in the appropriate application of data protection law and the GDPR when conducting clinical audit. It is of crucial importance to note that **this guidance applies to clinical audit only and not to healthcare research.**

4.2 Purpose - Clinical Audit

This document defines clinical audit as:

> **"Clinical audit is a clinically led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit specific clinical standards or clinical guidelines and acting to improve care when clinical standards or clinical guidelines are not met.**
>
> **The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit specific clinical standards or clinical guidelines."**
>
> *(DOHC, 2008, P. 152; Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023)*

Following clinical audit, improvements, if required, should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements. (DOHC 2008, p. 152)

It is noted that clinically led includes the breadth of clinical professionals working in health and social care services.

Explaining the difference between clinical audit, research, and other quality improvement methodologies is beyond the scope of this document. However, it is important to state that there are key differences in the application of data protection legislation to clinical audit versus their application to healthcare research. Consequently, the Health Research Regulations 2018 should not be used as a guide when conducting clinical audits. For further information on definitions, please read the HSE National Centre for Clinical Audit Nomenclature A Glossary of Terms for Clinical Audit.

4.3 Data Protection and the Principles of GDPR

Data protection is Irish law, which safeguards the privacy rights of individuals in relation to the processing of their personal data. The General Data Protection Regulation, or GDPR, is an EU regulation that imposes strict obligations on data controllers that process data and gives individuals more control over their information. All those working in healthcare must lawfully and fairly process the personal data of service users, employees, suppliers and other individuals. By its very nature, clinical audit involves the processing of personal data, so

it is imperative to be aware of the fundamentals of data protection and GDPR in the context of clinical audit before undertaking a new project.

'Processing' is defined as any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

Article 5 GDPR sets out the key principles related to the processing of personal data, which controllers (i.e. those who decide how and why the data will be processed) need to be aware of and comply with when collecting and otherwise processing personal data:

Article 5: The 6 Principles of GDPR

a. personal data shall be processed lawfully, fairly and in a transparent manner in relation to individuals ('lawfulness, fairness and transparency').

b. data should be collected for explicit and legitimate purposes and not further processed in a manner which is incompatible with those purposes.

c. data processed should be adequate, relevant and limited to what the purpose of the data processing is.

d. data must be accurate and kept up to date.

e. data should be kept in a format which permits identification of the data subjects and that data should not be held for longer than is necessary.

f. data should be processed in a manner which ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage.

4.4 Lawful Basis

Individuals processing personal data must have a legal (lawful) basis to do so. Articles 6 & 9 of the GDPR outline the lawful basis for processing personal data. The HSE commonly relies on Article 6(1) (e) and Article 9(2) (h) or (i) of the GDPR as its lawful bases for the purposes of processing data for clinical audit purposes.

It should be noted that in most cases, the HSE does not typically rely on consent as a lawful basis for processing. In fact, consent is just one of six lawful bases (see below) for processing data, and you should only seek consent if none of the other grounds apply.

Article 6: Processing of personal data

1. Processing shall be lawful only if and to the extent that at least one of the following applies:
   a. the data subject has given consent to the processing of his or her personal data for one or more specific purposes;
   b. processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;
   c. processing is necessary for compliance with a legal obligation to which the controller is subject;
   d. processing is necessary in order to protect the vital interests of the data subject or of another natural person;
   e. processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;

Article 9: Processing of special categories of personal data

1. Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited.
2. **Paragraph 1 shall not apply if one of the following applies:**
   a. **processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3;**
   b. **processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;**

4.5 Data Privacy Impact Assessments (DPIAs)

A DPIA is a process to help identify and minimise the data privacy risks of a project or processing activity to ensure that patients' and service users' rights to privacy and confidentiality are appropriately protected. A DPIA is needed when there is a likely **high risk** to the rights and freedoms of data subjects – **privacy-impact-assessment-pia-guidance.pdf**

Clinical audits are generally considered **low-risk** processing activities, where auditors adhere to established procedures for their specific audits. This process will involve evaluating technical and organisational measures to protect privacy and ensure data security, such as controls over access, collection, storage, retention, and anonymisation.

When established clinical audit procedures are followed, completing a DPIA is typically unnecessary, as the risk to individuals is minimal. However, a DPIA Risk Threshold assessment should be completed prior to commencing your audit to determine the risk level for the audit you plan to conduct. If you are unsure whether a DPIA is required, please refer to your local hospital DPO, where available or the Deputy DPO for your Regional Health Area.

Please refer to **Resource 2: Clinical Audit Proposal Form**, which includes the DPIA Risk Threshold assessment.

Example of where a DPIA is not required:
A surgeon in a local hospital wants to carry out a prospective audit of 30 patients to ensure safe site surgery standards are adhered to. They will pseudonymise the data during data collection, and the report will be completely anonymised. They will follow established clinical audit procedures. They used the DPIA risk threshold assessment and determined that there is no processing on a large scale of special category data, and the processing will not result in a high risk to the rights and freedoms of data subjects and other criteria were not met. A DPIA is not required.

Example of where a DPIA is required:

A National Clinical Lead plans to undertake a national audit of their National Clinical Guideline in all hospitals. They plan to audit the whole population to whom the guideline applies over 12 months. They undertake the DPIA risk threshold assessment and find the national audit meets the criteria for processing data on a large scale of special category data. Based on this assessment, a DPIA is required. They seek further advice from the HSE DPO and progress toward completing the DPIA.

4.6 Security of Personal Data

Healthcare professionals must ensure that personal data collected during a clinical audit is processed securely and protected against unauthorised access, loss, or disclosure. Adequate technical and organisational measures should be in place to safeguard the data (GDPR Article 32). Please see some examples of how to protect personal data during a clinical audit:

- Personal data identifiers (names, addresses, phone numbers, DOBs) should be removed from the data set before it is used for a clinical audit or stored as part of the audit record.
- All computers and devices which store personal information should be fully encrypted and password protected. If you are storing any personal data files on a HSE folder during a clinical audit, please ensure you encrypt and password protect the file
- Access to data should be restricted to authorised staff only and strictly on a need-to-know basis.
- Do not bring paper files home, and ensure you lock paper files away in secure storage when not at your desk or at the end of each day.
- Where clinical audit data is pseudonymised, it is still protected by GDPR. Therefore, pseudonymised data should not be processed for research unless fully and irreversibly anonymised.
- For further detailed guidance, please see HSE Information Security Policy available at: **https://www2.healthservice.hse.ie/organisation/national-pppgs/information-security-policy/**
- Data processed for clinical audit activity should only be retained for the minimum period of time required. Auditors should refer to the HSE National Records Retention Policy. **https://assets.hse.ie/media/documents/ncr/20240806_HSE_Record_Retention_Policy_V3.pdf**

4.7 Anonymised and Pseudonymised Data

It is best practice to pseudonymise or, where possible, anonymise personal data used for clinical audit to minimise and protect the privacy of individuals. The difference between anonymised and pseudonymised data is clearly outlined in a Guidance Note by the Irish Data Protection Commission at the following link: **https://www.dataprotection.ie/en/dpc-guidance/anonymisation-and-pseudonymisation**

Anonymised data is data that can no longer be linked back to any identifiable individual. **Pseudonymised data** is data where any identifying characteristics of data are replaced with a pseudonym or a value that does not allow the data subject to be directly identified (e.g. “Participant 1”). A log identifying which participant is which may be kept separately and securely until the clinical audit has been completed.

4.8 Working Remotely

With their manager’s permission, an auditor can work remotely on clinical audit activity. However, it must be noted that your obligations under GDPR are the same whether you are working remotely or in a HSE facility. You

are responsible for the security of all electronic devices and paper records containing personal and confidential information you use while working remotely. It is recommended that patient charts/records are not removed from HSE premises for audit purposes. Auditors should reference the HSE Electronic Communications Policy (2019), available at **electronic-communications-policy.pdf.**

Please note: Clinical audit information (or any other HSE related personal data, confidential or commercially sensitive information) must NOT be sent to personal email addresses (Gmail, Hotmail, etc.) This may be considered a Personal Data Breach and may be reportable to the Data Protection Commissioner.

4.9 Data Subject Rights

Clinical audit data that is irreversibly anonymised and aggregated is generally no longer classified as personal information and is therefore exempt from data protection regulations. Consequently, rights typically associated with data subjects, such as access, rectification, or erasure, do not usually apply to this type of data.

Even when clinical audit is pseudonymised and not fully anonymised, Data Subject Access Requests made by service users or employees should be taken from the source systems rather than clinical audit databases or folders.

Please note: Under Part VI of the Patient Safety Act 2023, patients cannot request access to their personal records contained or derived from a clinical audit held by public bodies and other FOI bodies under the Freedom of Information Act 2014.

Under Article 5 GDPR, data subjects have a right to request:

- **Access** to their personal data.
- **Rectification** of data and correction of inaccuracies.
- **Erasure** of their data ("right to be forgotten").
- **Restriction** on processing of data.
- **Portability** or transfer of data between services.
- **Object** to processing.

However, the above rights are not absolute rights, and each case will be looked at individually on its own merits.

4.10 HSE NCCA Data Protection and GDPR FAQs for Clinical Audit

The NCCA and the DPO have developed further supplementary information in the form of an FAQ, which is available at **HSE NCCA Data Protection and GDPR FAQs for Clinical Audit**.

4.11 Glossary - Key GDPR Terms

Personal Data means any information relating to an identified or identifiable natural person (Data subject). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or by reference to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Processing means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or

otherwise making available, alignment or combination, restriction, erasure or destruction. The terms 'Process' and 'Processed' should be construed accordingly.

Data Controller is a person or organisation that (alone or with others) determines the purposes for which and how any personal data are, or are to be, processed. A Data Controller can be the sole or joint Data Controller with another person or organisation.

Data Processor is a person or organisation that holds or processes personal data according to the data controller's instructions but does not exercise responsibility for or control over the personal data.

Special Categories of Personal Data means certain types of sensitive personal data are subject to additional protection under the GDPR. These are listed under Article 9 of the GDPR as "special categories" of personal data. The special categories are:

- Political opinions.
- Personal data revealing racial or ethnic origin
- Religious or philosophical beliefs.
- Trade union membership.
- Genetic data and biometric data processed for the purpose of uniquely identifying a natural person.
- Data concerning health.
- Data concerning a natural person's sex life or sexual orientation.

Further guidance, including a glossary of terms, is included in the HSE Data Protection Policy **hse-data-protection-policy.pdf**

4.12 Ethical Issues

Ethics is the inquiry into the morality of an action. There should be consideration of ethical principles in relation to all aspects of clinical care including clinical audit.

Clinical audit should be conducted within an ethical framework, i.e. the clinical audit process should:

- Respect each service user's right to make choices concerning their own lives
- Benefit service users and not cause harm
- Treat all service users fairly

At a practical level, this means ensuring service users and staff confidentiality and ensuring data is collected and stored appropriately (UH Bristol Clinical Audit Team, 2009b).

Clinical audits should not examine the work of another professional or specialty without their knowledge. All those whom the clinical audit will directly affect should be informed of and, if possible, involved in, the clinical audit.

Service users should be approached in a sensitive and respectful manner and it should be explained that they are not obliged to be part of the clinical audit and declining to take part will not affect care in any way.

Service users should be assured about the confidentiality of any responses given (for example, anonymization of data) and the length of time for which their personal information will be held. Anyone conducting a clinical audit that involves direct contact with service users for interview or to request completion of a questionnaire should give a full written explanation to the service user, in relevant language, as to the purpose of the clinical audit.

Clinical audits involving questionnaires should be accompanied by a written explanation of the purpose of the questionnaire/clinical audit along with an identified contact name and number (usually the clinical audit lead or a clinical audit facilitator). While encouraging participation for improvement purposes, the letter should also state that recipients are under no obligation to take part in the clinical audit and that declining to take part will not affect their care in any way.

The name and the telephone number of a contact point should be given in case any questions/issues arise in connection with the questionnaire. No consent form is required for questionnaires as consent will be deemed to have been given if the service user returns the questionnaire.

4.13 Is Ethical Review Required for Clinical Audit?

No, but ethical considerations should be considered. (HSE National Centre for Clinical Audit Nomenclature Glossary of Terms for Clinical Audit, 2025).

Possible screening questions to determine if ethical review may be required are outlined in the following table:

Will the Proposed Clinical Audit:
Infringe on the rights of any service user or risk breaching their confidentiality or privacy?
Pose any risk for or burden on a service user beyond those of his or her routine care?
Involve any clinically significant departure from usual clinical care?
Gather any information about any service user other than information that is ordinarily collected as part of providing routine care for the patient?
Collect data directly from any service user and if so could collect the activity subject a service user to more than a minimal burden or risk if it requests sensitive information or is it time consuming?
Collect or disclose any data that could be used to identify any service user or healthcare professional?
Have someone carrying out the activity who does not normally have access to service users' records? People who normally have access to service users records include clinical staff providing direct care and staff employed to support clinical audit when a duty of confidentiality is included in their job descriptions?
Involve a potential conflict of obligation to individual or all service users such as if the activity involves a trade-off between cost and quality?
Involve the use of any untested clinical or systems intervention or testing a hypothesis?
Allocate any interventions differently among groups of service users or staff, for example, in implementing a change in practice?

Adapted from Dixon, N. (2009b)

If the clinical audit team is concerned about the ethicality of their clinical audit, ethical advice should be sought.

5.0 Organisational Requirements to Support Clinical Audit

For clinical audit to be effective, it requires commitment and support throughout the service and the organisation, which includes senior management. Clinical audit should be seen as a valued activity and should be included as a priority in Quality and Patient Safety and service planning.

5.1 Clinical Audit Strategy

A clinical audit strategy is an operational plan primarily aimed at those with responsibility for overseeing the direction and development of clinical audit within the service or organisation. For example, divisional/service/ department leads or quality/ safety and clinical audit committees/ governance groups.

Clinical audit strategies should begin with a statement of a service provider's commitment to the process of clinical audit and to delivering the objectives set out in the strategy in accordance with best practice. A strategy on the development of clinical audit describes how a healthcare provider will implement the policy and increase the impact of clinical audit on clinical services (Healthcare Quality Improvement Partnership, 2020).

A clinical audit strategy should:

- Be a time limited document, i.e., covering a period of one or more years
- Connect clinical audit with the service provider's governance and assurance systems and corporate objectives
- Provide a medium to long term vision for the development of clinical audit, for example, 3 to 5 years
- Set out a number of service objectives for the period being covered by the strategy

(Healthcare Quality Improvement Partnership (2012)

Progress in delivering the quality improvement plan and meeting objectives, should be monitored on a regular basis and reported to the relevant Quality and Safety and/or Clinical Audit Committee.

The strategy should be reviewed and updated annually.

Clinical audit strategies should be supported and underpinned by a clinical audit policy.

5.2 Clinical Audit Policy

A clinical audit policy should set out the procedure for the conduct of clinical audit within the service or organisation, outlining best practice standards which should be met, processes and procedures to be followed and how different issues are to be addressed.

A policy on the use and conduct of clinical audit sets 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 (Healthcare Quality Improvement Partnership, 2020).

5.3 Clinical Audit Programme / Forward Plan

Each service provider should have an agreed programme for clinical audit. This is a plan which specifies what clinical audits will be carried out over the course of the programme duration (usually annually).

It should give direction and focus with regard to how and which clinical audit activity will be supported in the service and should be based on the service provider's priorities for clinical audit. Acknowledging that the clinical audit cycle includes re-audit, a proportion of topics for re-audit should also be included in the annual clinical audit plan.

As with all plans, the clinical audit programme is subject to change as priorities in service provision change. Any changes to the clinical audit plan should be communicated to all stakeholders.

Supports for the Delivery of a Clinical Audit Programme/Forward Plan
Clinical audit committee with members who can provide expertise and experience with clinical audit
Clinical audit support staff who can provide advice and training and refer to other available resources
Clinical and educational leads
Healthcare records manager and staff who can facilitate access to service user records
Information systems access and advice
Training available related to the clinical audit process and how to design and carry out clinical audits
Advice on how to handle ethical issues related to clinical audits
Templates for planning and reporting on clinical audits
Advice on the technical aspects of carrying out a clinical audit
Access to reference materials on clinical audit
Technical support for clinical audit including a database of clinical audits

Proposed clinical audit programmes should be discussed at a meeting of relevant stakeholders (dependent on whether the programme pertains to a particular clinical service or the service in its entirety).

5.4 Clinical Audit Leads

There are different levels of clinical audit leads, for example, at Service, Divisional or Specialty level. At service level, the clinical lead's responsibility is to organise, develop, improve and support the performance of clinical audit within the service whereas the role of the lead for a specific clinical audit is to provide leadership in the completion of the clinical audit cycle.

5.5 Fostering a Culture which is Supportive of Clinical Audit

Requirements of a culture which is supportive of clinical audit are:

- A common vision of the benefits and resource requirements of clinical audit among managers and staff
- A service wide strategy with clear lines of responsibility and accountability
- An overall plan for clinical audit comprising of a comprehensive structured programme aimed at nurturing effective clinical audits

- Leadership and direction of clinical audit programmes including a designated lead whose responsibility is to organize, develop, improve and support the performance of clinical audit within the service
- Strategy and planning in clinical audit programmes
- Resources and support for clinical audit programmes
- Monitoring and reporting of clinical audit activity
- Commitment to, participation in and high levels of clinical audit activity which by its nature and impact, is seen by its participants to be involved and relevant and thus fosters positive attitudes for further participation

Part 6 of the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 means that the Act should ensure healthcare professionals are encouraged to carry out clinical audit, comparing the care they are delivering to best practice standards and delivering and maintaining the highest standards of patient care.

Refer to Resource 6: Patient Safety Act and Frequently Asked Questions.

5.6 Practical Support for Clinical Audit

Provision of practical support for clinical audit includes the provision of the following:

- Policies, procedures, protocols and guidelines (PPPGs) in relation to clinical audit which provide a vision of the goals and purposes of clinical audit within the service and defining how a clinical audit should be undertaken
- Effective training in clinical audit methods
- Dedicated staff to provide expertise and/or advice on clinical audit design and analysis, for example, clinical audit facilitators
- Practical mechanisms to make data collection easier such as good quality information systems and support from service information departments and information specialists
- Allocated (protected) time for clinical audit
- Support for required changes identified by the clinical audit process.

5.7 Clinical Audit Facilitation

Service providers should assess whether additional clinical audit support staff are required to provide hands on help and design of clinical audits.

Clinical audit facilitators can provide support in all aspects of clinical audit, including:

- Project planning
- Form design
- Spreadsheet/database design
- Data checking and entry
- Data analysis
- Presentation design
- Report writing
- Action planning

Clinical audit facilitators should have skills in study design, data collection, and computing data analysis. The training needs of clinical audit facilitators should be recognized and resources should be made available in order to facilitate their attendance at appropriate courses.

6.0 Summary Patient Safety Act Part VI - Clinical Audit

The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 ensures healthcare professionals are encouraged to carry out clinical audit, comparing the care they are delivering to best practice standards and delivering and maintaining the highest standards of patient care.

Clinical audit is a quality improvement process; this means that it is used to ensure that patient care is delivered at certain standards and that improvements to the quality of that care are put in place wherever possible. Recommendations from a clinical audit can make suggestions to further improve processes and outcomes in line with expected standards and best practice. It is essential that the quality and safety of the care delivered by our health service continue to improve. Clinical audit is one of many processes used to drive this improvement in modern healthcare systems across the world.

The Patient Safety Act does not wish to change how clinical audits are carried out. Instead, it adds new protections for clinical audits which meet the definition contained in the Act (definition Page 5). Under the Act, clinical audit will now be afforded the following protections that limit how information from clinical audits can be used.

This new law means that information created during a clinical audit shall not be used:

a. as an admission of fault by a healthcare organisation or professional
b. as evidence in legal cases (civil proceedings) against healthcare professionals or healthcare organisations
c. as evidence to cancel a healthcare professional's insurance
d. as evidence of fault, professional misconduct, poor professional performance or any other failure or omission
e. as evidence in disciplinary or fitness to practice procedures against healthcare professionals

The Act means that Freedom of Information legislation (the laws that allow people to seek access to all personal information an organisation holds about them) will not apply to information derived from clinical audit, provided that the clinical audit is carried out in line with best practice guidance.

Under the Patient Safety Act, for these protections to apply, the data obtained from that clinical audit by a health service provider or health service practitioner (or both of them) must have been:

- collected solely for the purpose of improving patient safety and quality improvement in healthcare of patients,
- collected and analysed by the health services provider or the health practitioner (or both of them) or more than one health services provider or practitioner.
- published as aggregated information, and
- used by that health services provider or health practitioner for the purpose of improving patient safety and quality improvement in healthcare of patients or for sharing with another health services provider or health practitioner solely for the purpose of improving patient safety and quality improvement in healthcare of patients.

"Aggregated information", in relation to data, means data obtained from a clinical audit, which excludes information that identifies or could reasonably lead to the identification of a person in that clinical audit. National and international practice guidance documents on clinical audit state that clinical audit data should be anonymised. This is for a number of reasons, including the need to maintain and protect patient confidentiality. Clinical audit should only use the minimum, relevant data needed, and this does not typically extend to patient specific or personal data as clinical audit is aimed at assessing care against specific standards to identify areas for improvement in the provision of the service.

Further information can be found in Resource 6 of this practical guide'

For further information, see **https://www.irishstatutebook.ie/eli/2023/act/10/enacted/en/html.**

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Glossary of Terms

Clinical Audit Criterion	The measurement of compliance against criteria of care is at the heart of clinical audit. A clinical audit criterion is a criterion of care with an 'expected level of performance' or 'target' assigned to it.
Clinical Audit	"Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit specific clinical standards or clinical guidelines and acting to improve care when clinical standards or clinical guidelines are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit specific clinical standards or clinical guidelines." *(Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023)* Following clinical audit, improvements, if required should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements. *(DOHC 2008, p. 152)* It is noted that clinically led includes the breadth of clinical professionals working in health and social care services
Clinical Governance	Clinical governance is the system through which healthcare teams are accountable for the quality, safety and satisfaction of patients in the care they have delivered. For health care staff this means; specifying the clinical standards you are going to deliver and showing everyone the measurements you have made to demonstrate that you have done what you set out to do. Further information on clinical governance is available at: **https://about.hse.ie/leadership-and-operations/our-clinical-governance/**
Clinical Guidelines	"Clinical guidelines are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum." *NCEC/HIQA (2015, p. 7)* "Clinical Guideline means a statement relating to clinical care – a. That is used to assist in making decisions in relation to appropriate health care for specific clinical circumstances by – i. a health services provider or a health practitioner (or both of them), and ii. the patient and the health practitioner or the health services provider (or as the cases may be, both of them) where a decision is made in consultation with a patient, and b. Which is repeatedly subjected to systematic review and evaluation. *(Patient Safety (Notifiable Incidents and Open Disclosure) Act, 2023)*
Data Controller	Data Controller is a person or organisation that (alone or with others) determines the purposes for which and how any personal data are, or are to be, processed. A Data Controller can be the sole or joint Data Controller with another person or organisation.

Data Item	A single unit of data for which the definition and permissible values are specified by means of a set of attributes.
Data Quality	Refers to data that is accurate, valid, reliable, relevant, legible, timely and complete.
Data Processor	Data Processor is a person or organisation that holds or processes personal data according to the data controller's instructions but does not exercise responsibility for or control over the personal data.
Data Set	A group of data items.
Health Information and Quality Authority (HIQA)	Reporting directly to the Minister for Health, this independent organisation has legal power and responsibility for improving the quality, safety and value of health and social care services in Ireland. HIQA has responsibility across health and social care services (excluding mental health) for setting standards, monitoring and inspecting the quality and safety of service provision, providing guidance on health information and carrying out health technology assessments
Healthcare Quality Improvement Partnership (HQIP)	Body funded by the English Department of Health to promote best practice in clinical audit and to re-invigorate clinical audit activity.
Healthcare Record Review	A Healthcare Record Review is where pre-recorded, person-centred data are used to answer one or more questions. The review is not part of direct patient care. It may be carried out for a number of purposes, including clinical audit, research, or incident review. The purpose will dictate the governance structures to be followed. It can also be referred to as a chart review or case review. A Healthcare Record Review for the purposes of clinical audit collects pre-agreed datasets from a cohort of charts without reviewing the overall care or looking at the context of that care. These datasets are used as inputs to a clinical audit which aims to provide learning and subsequent quality improvement.
Incident Review	An incident review takes place after an individual patient safety incident has occurred. It involves "a structured analysis and is conducted using best practice methods, to determine what happened, how it happened, why it happened, and whether there are learning points for the service, wider organisation, or nationally." *(HSE, 2020)*
Key Performance Indicators (KPI)	Performance Indicators are specific and measurable elements of practice that can be used to assess quality of care. Indicators are quantitative measures of structures, processes or outcomes that may be correlated with the quality of care delivered by the healthcare system.

Look Back Review	"A review where a number of people may have been exposed to a specific hazard in order to identify if any of those exposed have been harmed and how to take care of them. The Look-back Review process consists of four key steps: 1. Consideration of the Preliminary Assessment Form (as per the Incident Management Framework) to identify the need for a Look-back Review 2. Implementation of a Look-back Review Risk Assessment to identify the need to progress to the Audit and Recall Stages of the Look-back Review Process 3. Audit Stage 4. Recall Stage." *(HSE, 2022)*
National Centre for Clinical Audit (NCCA)	The HSE National Centre for Clinical Audit (NCCA) established (April 2022) within the QPSD, follows publication of the HSE National Review of Clinical Audit Report in 2019, and is primarily responsible for implementing the report's recommendations. This step confirms the HSE's commitment to developing clinical audit as an essential quality and patient safety tool in Ireland, promoting improved patient outcomes.
National Clinical Audit	The National Clinical Effectiveness Committee (NCEC) defines National Clinical Audit as: "A cyclical process that aims to improve patient care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards conducted on a national basis." *(NCEC, 2015)* In national clinical audits where it is not possible to include all of the population, the sample size should be statistically significant or sufficiently powered to allow meaningful interpretation of the findings.
National Clinical Effectiveness Committee (NCEC)	A partnership between key stakeholders in service user safety in the Irish health system. The aim of the committee is to provide a framework for national endorsement of clinical guidelines and clinical audit to optimise patient care, within the health system, both public and private.
National Clinical Guideline	A guideline that meet specific quality assurance criteria and has been mandated by the designated national body – National Clinical Effectiveness Committee (NCEC).
National Institute for Health and Clinical Excellence (NICE)	The National Institute for Health and Clinical Excellence was established as a Special Health Authority by the UK Department of Health and is one of the key elements of the NHS in England and Wales. It was set up to reduce variation in the availability and quality of treatments and care in the National Health Service. Its principal role is to provide authoritative, robust and reliable guidance on best practice procedure.

National Office of Clinical Audit (NOCA)	The National Office of Clinical audit was established in 2012 through the collaboration of the HSE's Quality and Patient Safety Directorate and Clinical Strategy and Programmes Directorate together with the Royal College of Surgeons in Ireland (RCSI) and the College of Anaesthetists. NOCA manages a suite of national clinical audits. Each clinical audit focuses on a unique area of healthcare such as hip fracture, major trauma, hospital mortality, ICU care and joint replacements. Governance structures are established both in NOCA and locally in each hospital to oversee the management and sustainability of the clinical audit. All NOCA clinical audits are led at a hospital level by clinicians and supported by their management teams.
Peer Review	"Peer review is the professional assessment, against standards, of the organisation of healthcare processes and quality of work, with the objective of facilitating its improvement." *McCormick (2012, p. 8)*
Personal Data	Personal Data means any information relating to an identified or identifiable natural person (Data subject). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or by reference to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person
Quality Assurance	"Quality Assurance is all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfil requirements for quality." *(American Society for Quality, 2025)*
Quality Improvement	"Quality improvement (QI) is the combined and unceasing efforts of everyone — healthcare professionals, patients and their families, researchers, commissioners, providers and educators — to make the changes that will lead to: • better patient outcomes • better experience of care • continued development and supporting of staff in delivering quality care." *(Framework for Improving Quality (HSE, 2016) (adapted from Batalden, Davidoff Quality Safety Health Care, 2007)* "QI is a data-driven approach that involves identifying problems, analysing them, and implementing solutions to prevent them from recurring. It involves the use of a systematic and coordinated approach to solving a problem using specific methods and tools with the aim of bringing about a measurable improvement within a health care setting." *(The Health Foundation, 2021)*

Registry	"A clinical registry is described as a system which collects a defined minimum data set from patients undergoing a particular procedure or therapy, diagnosed with a disease or using a healthcare resource." *Hoque et al. (2017)*
Research	The HSE Action Plan for Health Research 2019–2029, adopted the definition of research as that of "the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods." *(Terres, 2019 and NHS Health Research Authority, 2017)*
Sample	Some of the service users, events, cases, situations or items that are drawn from the population on which the clinical audit is focused (a sub-set of the population).
Service	Anywhere health or social care is provided. Examples include but are not limited to: acute hospitals, community hospitals, district hospitals, health centres, dental clinics, GP surgeries, home care, etc.
Service Evaluation	"Service evaluation seeks to assess how well a service is achieving its intended aims. It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the sole purpose of defining or judging the current service." *Twycross and Shorten (2014, p. 65)* Unlike clinical audit, it does not compare the service to a predefined standard.
Service Provider	Any person, organisation, or part of an organisation delivering healthcare or social care services – as described in the Health Act 2007 Section 8(1)(b)(i)–(ii).
Service User	The term 'service user' is used in general throughout this document, but occasionally the term 'patient' is used where it is more appropriate. The term 'Service user' includes: • People who use health and social care services as patients • Carers, parents and guardians • Organisations and communities that represent the interests of people who use health and social care services • Members of the public and communities who are potential users of health services and social care interventions

Stakeholder	A person, group, organisation, or system who affects or can be affected by an organisation's actions. Health service provider's stakeholders, for example, include its service users, employees, healthcare staff, government, insurers, industry and the community.
Standard	Standards are defined as structures and processes needed to identify, assess and manage specified risks in relation to the subject area (for example, healthcare records management, decontamination etc). *"A standard is a definable measure against which existing structures, processes or outcomes can be compared."* NCEC/HIQA (2015, p. 9)
Standard Criteria	The standard statement is expanded in the section headed criteria, with different criteria providing the detail of what needs to be achieved for the standard to be reached.
Statement of Information Practices	A document, clearly displayed and accessible to all staff and service users that sets out what information the service collects, how it is used, with whom it is shared and for what purpose, the safeguards that are in place to protect it and how service users can access information held about them.
Target/ Level of Performance	A defined level or degree of expected compliance with clinical audit criteria; may be expressed in percentage or proportion of cases.
Target Population	All of the service users, events, cases, situations or items on which the standard or clinical audit is focused. A population can range from a very small limited number to a large or infinite number.

Resource 1

Checklist of Best Practice in Clinical Audit		
Stage 1	**Select Topic**	
Step 1	Involve stakeholders	
Step 2	Determine the Clinical Audit Topic	
Step 3	Plan the Delivery of the Clinical Audit	
Stage 2	**Set Criteria and Standards**	
Step 1	Select the Standard(s) to be used	
Step 2	Set the Target / Level of Performance	
Step 3	Consider Inclusion / Exclusion Criteria	
Step 4	Consider Exceptions	
Stage 3	**Design Clinical Audit Tool and Collect Data**	
Step 1	Design Clinical Audit Tool	
Step 2	Data Collection Process Discussed and Decided	
Stage 4	**Analyse Data and Compare Results with Standards**	
Step 1	Data Analysis	
Step 2	Calculating Compliance with Clinical Audit Criteria	
Step 3	Drawing Conclusions	
Step 4	Sharing Results	
Stage 5	**Clinical Audit Report**	
Step 1	Layout of the Clinical Audit Report	
Step 2	Write Report	
Step 3	Reflection	
Stage 6	**QI Plan and Action**	
Step 1	Development of a Quality Improvement Plan	
Step 2	Actions discussed, decided and documented	
Stage 7	**Re-audit**	
Step 1	If re-audit is required, start the process again	

Resource 2
Clinical Audit Sample Proposal Form

Cáilíocht Náisiúnta agus Sábháilteacht Othar
Oifig an Phríomhoifigigh Cliniciúil
National Quality and Patient Safety
Office of the Chief Clinical Officer

Clinical Audit Proposal Form

For further information, please see the HSE NCCA Website, including:
HSE NCCA Nomenclature/Glossary of Terms for Clinical Audit
And
HSE NCCA Clinical Audit – A Practical Guide 2023

Title of Clinical Audit -   Clinical Audit Topic -

CLINICAL AUDIT GOVERNANCE:

Who will be the Clinical Audit Sponsor?
(National Clinical Audits must be supported by National Director or equivalent prior to submission)

Clinical Audit Sponsor (Name/Job Title): _____

Committee/Specialty/Work Location: _____

Contact Number: _____

Email address: _____

Who will be the Clinical Audit Lead?
(Chair of the Clinical Audit Project Group, making strategic decisions regarding the clinical audit etc.)

Clinical Audit Lead (Name/Job Title): _____

Work Location: _____

Contact Number: _____

Email address: _____

WHY WAS THE TOPIC CHOSEN?

Project source must be one or more of the following: (Tick all boxes that apply)

☐ High Cost Activity ☐ High Risk Activity ☐ High Volume Activity
☐ Required to meet regulatory requirement
☐ Based on evidence-based healthcare and clinical effectiveness issues (best practice)
☐ Patient Safety Issues/Serious Incidents
☐ Re-audit of previously accepted project
☐ Patient Safety Strategy 2019 - 2024 (Common Causes of Harm)
☐ HSE National Clinical Programmes / Modernised Care Pathway

Each clinical audit project must satisfy all of the following:
Adapted from King's College Hospital http://www.kch.nhs.uk

☐ Aims must be realistic and achievable within available resources
☐ Clear objectives
☐ Multidisciplinary
☐ Clinical and managerial support with a willingness to implement any changes
☐ Agreed and approved standards for audit agreed by the team
☐ Willingness to agree recommendations from the audit and agree action plan(s)

PARTICIPATING PROFESSIONALS:

☐ Medical
☐ Allied Health Professionals
☐ Pharmacy
☐ Nursing
☐ Other Specialty / Dept
Add as required:_____

Have all potential members of the project group been identified? ☐Yes
Has the clinical audit been discussed with them? ☐Yes
Please note the relevant groups involved: _____

AIM OF CLINICAL AUDIT:

AIM Statement*: _____

(*An aim statement answers the first question in the Model for Improvement: What Are We Trying to Accomplish?)
www.IHI.org

OBJECTIVE(s) OF CLINICAL AUDIT:

Sample/prompt text in blue below:
1. To establish if ……..
2. To identify if…….
3. To identify areas for improvement

CRITERIA AND STANDARDS:

(*A Standard is a definable measure against which existing structures, processes or outcomes can be compared. (NCEC/HIQA 2015, p. 9)

Adapted from King's College Hospital http://www.kch.nhs.uk

Please detail all criteria and standards to be included and reference sources.
(E.g. Criterion: All patients must have a wristband. Standard: 100%)

1.
2.
3.
4.
5.
6.

Web link (Please insert web link to Standards source):

METHOD:

Has a literature search been undertaken? ☐ Yes ☐ No

Keywords used in search and databases used: _____

Inclusion/Exclusion Criteria:

Inclusion Criteria: _____

Exclusion Criteria: _____

Data Collection:

☐ Concurrent ☐ Prospective ☐ Retrospective

How will cases be identified?

_____

Method of Data Collection:

☐ Chart Review
☐ Staff Questionnaire
☐ Observation
☐ Interview
☐ Patient Questionnaire
☐ Telephone
☐ Other: _____

Estimated Sample Size:_____

Anticipated Time-Scale:

Proposed Start Date: _____ Target completion date: _____

Estimated Clinical Audit Cycles Required:

☐ Audit & Re-audit only ☐ Repeat Annually

RESOURCES:

What existing resources are available to support this proposed Clinical Audit?

_____

_____

Is additional funding required to commence this clinical audit?

☐ Yes ☐ No

Estimated amount required: _____

What is the additional funding required for?

_____

_____

What is the proposed source of funding?

_____

_____

Involvement or resources that you wish from either your local Quality and Patient Safety Team or, if a National Audit, from the *HSE National Centre for Clinical Audit and the National Steering Group for Clinical Audit (*subject to available resources and priorities).

☐ Approval / Oversight
☐ Operational Support
☐ Data Analysis
☐ Other: _____
☐ Consultancy / Advice
☐ Audit Tool Design
☐ Report Production

PATIENTS INCLUDED IN THE AUDIT:

Is there a patient representative on the clinical audit working group?

☐ Yes ☐ No

If No, please state the reason:

_____

_____

Clinical Audit Sponsor and Clinical Audit Lead:

This proposal and its possible (clinical and managerial) implications have been discussed with the relevant previously noted who undertake to support the audit and the implementation of any necessary quality improvements identified as a result of the audit.

Clinical Audit Sponsor
Signed _____ Date _____

Clinical Audit Lead
Signed _____ Date _____

DATA PROTECTION IMPACT ASSESSMENT RISK THRESHOLD ASSESSMENT

Title of the activity:

Name of person completing this form:

Title:

Is personal data being collected or used?	☐ Yes	☐ No
Are special categories of personal data being collected or used? (as listed below)	☐ Yes	☐ No
If yes, indicate the categories involved:	☐ Health data	
	☐ Data revealing racial or ethnic origin	
	☐ Political opinions	
	☐ Religious or philosophical beliefs	
	☐ Trade union membership	
	☐ Sex life data	
	☐ Genetic data	
	☐ Biometric data	

If you answered 'No' to both questions above, you do not need to complete the remainder of the form, as a PIA is not required.

If you answered 'Yes' to any of the questions above, you may need to complete a PIA - answer the questions below to establish if a PIA is required:

Does the processing include the processing on a large scale of special category data?	☐ Yes	☐ No
Could the processing likely result in a high risk to the rights and freedoms of data subjects?	☐ Yes	☐ No
Does the processing include a systematic monitoring of a publicly accessible area on a large scale, e.g. CCTV?	☐ Yes	☐ No
Does the processing involve the automated processing, including profiling, on which decisions are based that produce legal effects concerning the data subjects?	☐ Yes	☐ No

A PIA is required if you have answered 'Yes' to any of the four questions above.

Note: See HSE Data Protection Website for HSE PIA Process Guidance and HSE PIA Form.

Resource 3
Clinical Audit Report Sample Template

Clinical Audit Lead/Author(s):	
Service Provider:	
Key Stakeholders:	
Service/ Speciality:	
Title of Clinical Audit	This should be the same as the title on the
Date of Report Distribution	
Aim and Objectives:	
Standard(s) / Criteria used:	Clinical audit must measure against standards / guidelines; these should be identified and the source included
Background & Introduction	This is essentially narration, clarifying why the clinical audit was done. For example, was the clinical audit prompted by being a high volume, high risk, problem prone topic? The background should explain the rationale for doing the clinical audit. Summarise the evidence base for the clinical audit topic, giving any references at the end. If a team was convened to undertake this clinical audit, include how this was organised and who was involved.
Aim(s) of the Clinical Audit	Explain what the clinical audit is trying to achieve; the aim and objectives should have been identified in the planning stage of the clinical audit.
Methodology	To include: • Chosen population • How sample selected • Retrospective, concurrent or prospective • Sample size • Describe tool used State the chosen population for this study (for example, 'patients referred to the one-stop breast clinic for suspected cancer') and then how the sample was selected for the clinical audit. Specify whether a retrospective, concurrent or prospective approach was used (for example, for a prospective clinical audit, 'the first 100 patients referred to the clinic starting from 01/10/20', or for a retrospective clinical audit, 'all patients seen at the outpatient clinic during July'). Describe how these patients were identified, the sample size, the time period, and clarify how this was calculated or agreed upon. The data collection method should also be included, for example, 'Data was collected from patients' case notes using a data collection sheet, or 'a query was run in ICT'. List who was responsible for data collection, when this was done, and mention briefly the method of data input (if appropriate) and analysis.

Results	State the results. Start with total number (n=00). Data may be presented visually (graphs, tables) The number of subjects (for example, patients) included in the clinical audit is the initial 'n' number. If data is incomplete, explain why, for example, it might not be possible to find every set of patient notes. How data is analysed depends upon the question/s to be answered. Ensure to include the number and percentage of cases meeting each criteria of the standard, making it clear what number is being taken a percentage of as the 'n' number may change at different points of the report, for example, 45/50 (90%) for criterion A and 81/90 (90%) for criterion B.
Conclusion(s)	List key points that relate to the clinical audit findings. List the key points that flow from the clinical audit results - use bullet points and avoid long paragraphs. Ensure conclusions are supported by the data, or if the data points to no firm conclusions, say so - don't make claims that are not supported by the evidence. Make objective, factual statements, not subjective ones.
Recommendations & Quality Improvement Plan	Quality improvement plan - with review date and person responsible for action. Recommendations for change should be made. Make sure these are realistic and achievable. A quality improvement plan (action plan) should be agreed, stating what changes will be implemented, who will be responsible for carrying them out and when this will be done. If appropriate (i.e. changes are to be made), set a date for a re-clinical audit to complete the clinical audit cycle.
References	
Appendices	

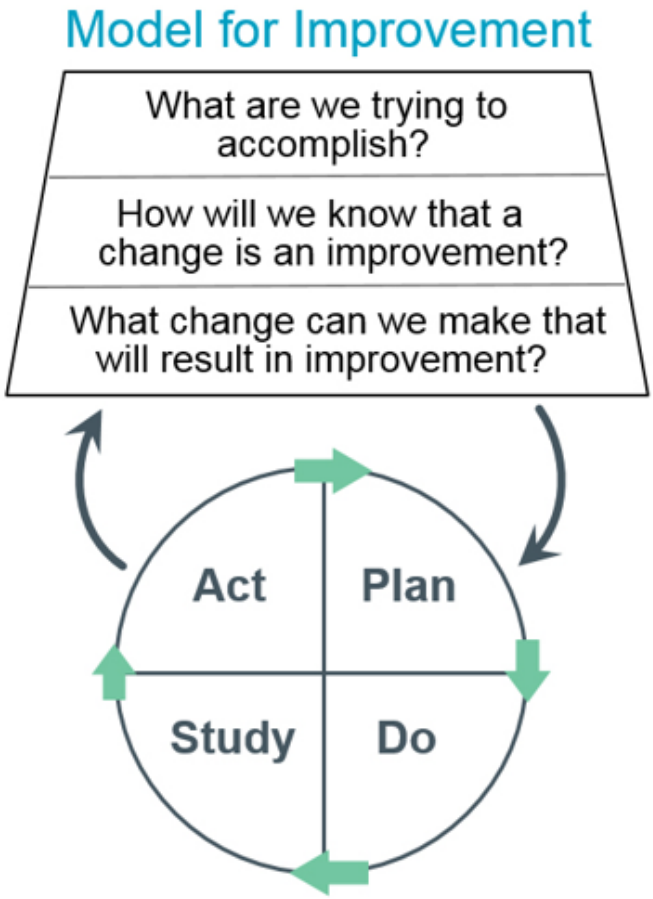
Resource 4
Quality Improvement / Action Plan

No/Ref	Recommendation	Person Responsible	Target Date	Status	Comments

Resource 5
Model for Improvement

Plan-Do-Study-Act (PDSA) Cycles

The Plan-Do-Study-Act (PDSA) cycle is shorthand for **testing a change — by planning it, trying it, observing the results, and acting on what is learned.** This is the scientific method, used for action-oriented learning.



Steps in the PDSA Cycle

Step 1: Plan
Plan the test or observation, including a plan for collecting data.

- State the objective of the test.
- Make predictions about what will happen and why.
- Develop a plan to test the change. (Who? What? When? Where? What data need to be collected?)

Step 2: Do
Try out the test on a small scale.

- Carry out the test.
- Document problems and unexpected observations.
- Begin analysis of the data.

Step 3: Study

Set aside time to analyze the data and study the results.

- Complete the analysis of the data.
- Compare the data to your predictions.
- Summarize and reflect on what was learned.

Step 4: Act

Refine the change, based on what was learned from the test.

- Determine what modifications should be made.
- Prepare a plan for the next test.

Resource 6
Patient Safety Act and Frequently Asked Questions

FAQ	Answer
What is the Patient Safety Act and how does it apply to clinical audits?	The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 means there is now a specific law that provides clear instruction for how open disclosure must be managed for a specific list of incidents within a healthcare setting and which protects the way in which information from a clinical audit shall be used. The Act should ensure healthcare professionals are encouraged to carry out clinical audit, comparing the care they are delivering to best practice standards and delivering and maintaining the highest standards of patient care. The Act is not seeking to change the way clinical audits are conducted, provided they meet the definition of clinical audit and are carried out in line with best practice guidance (see FAQ 7).
What is clinical audit and what are the benefits for patient care?	Clinical audit is a quality improvement process, this means that it is used to ensure patient care is not only delivered at certain standards but that improvements to the quality of that care are put in place wherever possible. Recommendations from a clinical audit can make suggestions to further improve processes and outcomes, in line with expected standards and best practice. It is essential that the quality and the safety of the care delivered by our health service continue to improve. Clinical audit is one of many processes used to drive this improvement in modern healthcare systems across the world. We also use information from clinical audits for planning purposes and in the development of new standards of care. As a patient, it can be reassuring to know that healthcare professionals are engaged with clinical audit as a means to improve patient care.

How does the Patient Safety Act support healthcare professionals in their work?	The Patient Safety Act does not wish to change the way in which clinical audits are carried out but instead adds new protections for clinical audits, which meet the definition contained in the Act. This new law means that information created during a clinical audit shall not be used: a. as an admission of fault by a healthcare organisation or professional b. as evidence in legal cases (civil proceedings) against healthcare professionals or healthcare organisations c. as evidence to cancel a healthcare professionals' insurance; or d. as evidence of fault, professional misconduct, poor professional performance or any other failure or omission e. as evidence in disciplinary or fitness to practice procedures against healthcare professionals An example of how this law will work in practice is as follows: If a clinical audit discovers that a higher rate of post-operative infection than would be expected exists within a hospital, this new information could not be used a) by a patient who had experienced a post-operative infection to take legal action against the hospital, or b) by the hospital to discipline any of the surgeons involved, or c) by the insurance company to cancel the surgeons insurance policy which covers their clinical work. The Act means that Freedom of Information legislation (the laws that allows people to seek access to all personal information an organisation holds about them) will not apply to information that is derived from clinical audit, provided that the clinical audit is carried out in line with best practice guidance. If a patient has concerns relating to the care received as a patient, it is recommended that they are guided to contact their healthcare provider and request information through their local processes. The **Patient Advocacy Service** also provides free, independent and confidential support.

Why are the protections for clinical audit as provided in the Patient Safety Act necessary?	The protections for information created through clinical audit in this Act are intended to help build a culture of blame free analysis, learning and constant improvement within the Irish health service. Nurturing this culture will encourage health service organisations and the healthcare professionals to compare the care they are delivering to best practice standards ensuring the delivery and maintenance of the highest standards of patient care are the primary focus.
Where does the information used for clinical audit come from?	Patient care information is routinely entered into their healthcare record and from there can be used for clinical audit. When the information from the healthcare record is used in this way the information is anonymised i.e. presented in a way that individual patients cannot be identified and therefore consent is not required. Clinical audits must be designed so that the confidentiality of a patient's personal healthcare record is protected. Clinical audit compares the care that was delivered to patients against best practice standards. In doing so, a clinical audit will produce a summary or aggregate report on the clinical area or service being audited as a whole and does not highlight or identify the care provided to an individual patient.
What is the difference between local and national clinical audit?	A local clinical audit uses a relatively small number of patient cases, usually selected randomly in order to discover whether or not a specific standard of care is being met within a healthcare provider e.g. one hospital or one GP practice. NCEC defines National Clinical Audit as: *"A cyclical process that aims to improve patient care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards conducted on a national basis"* (NCEC 2015) The definition of clinical audit in the Act applies to all clinical audits undertaken, whether at a local level e.g. in a hospital department or at a national level carried out by an organisation such as the National Office of Clinical Audit (NOCA), the Royal College of Physicians of Ireland (RCPI), the National Perinatal Epidemiology Centre (NPEC) and the HSE National Centre for Clinical Audit (NCCA).

Do the results of a clinical audit need to be shared in a specific manner to ensure the Act applies?	Completion of the clinical audit cycle will usually result in conclusions, recommendations and action plans to improve practice. This will be communicated to all stakeholders. Completed clinical audits will be shared locally via the appropriate governance structures.
The Patient Safety Act states that protections only apply to data that have been published, what steps must be taken to comply with this?	The advice is that "publish" as per the act requires that aggregated data are disseminated in some form to the public. Therefore, data shared only at a multidisciplinary team or departmental meeting will not be considered as "published". It is clear that the data must be made publicly available, in a form or manner to be determined by the health service provider in line with local policies, procedures or guidelines for those wishing to benefit from the clinical audit section of the Act. Examples of publication opportunities would include but are not limited to website, leaflets, infographic output, posters, conferences and local audit days. By meeting the definition of clinical audit under the Act, this provides an opportunity to ensure that clinical audits conducted are to a publishable standard. Another best practice approach to meet these requirements includes registration of clinical audit proposals, registration of clinical audit reports on completion of the audit with local quality and patient safety teams or the clinical audit department. They should then publish a collated log of audits in an annual report, which is made publicly available. It will also support embedding clinical audit in quality & patient safety governance structures in Regional Health areas. All national clinical audits produce an annual report, which is publicly available on the provider's website. Guidance and several training opportunities are available for staff from the **National Centre for Clinical Audit** and from **HSELand** to ensure a clinical audit is high quality and of a publishable standard.

What happens if a patient safety or adverse incident is detected while a clinical audit is being carried out?	If during the course of collecting information during a clinical audit the audit data collector finds information that indicates a patient safety or notifiable incident has or may have occurred it is their responsibility to bring this information to the attention of the relevant senior manager in that service. The incident will then be reviewed and managed by the service in line with the HSE Incident Management Framework 2020 and the HSE Open Disclosure Policy. The protections within the Act only apply to clinical audit information collected during the audit and they do not apply to individual cases where there is an incident.
Does the Patient Safety Act apply to other quality assurance and quality improvement activities?	No, other processes which can improve the quality and safety of patient care, including, but not limited to quality improvement and service evaluation are not included in this piece of legislation.
As the Patient Safety Act does not apply to other quality assurance & improvement activities, should healthcare professionals stop using these methods or will there be any changes or implications when using these other methods now?	Quality assurance (QA) and quality improvement (QI) activities are essential for the management of healthcare and ensure high-quality patient care is delivered and that processes are continuously improved. This new legislation does not change the existing local governance and process arrangements, which are necessary to ensure the continued support of other quality assurance and improvement activities. It is important that other quality assurance and improvement activities continue in line with existing governance structures and best practice guidance. The National Quality and Patient Safety Directorate have a new QI Guide and Toolkit. This Guide is an upgrade and enhancement of the 2019 QI Toolkit, which provided 17 individual QI tools and resources. **https://www2.healthservice.hse.ie/organisation/qps-improvement/quality-improvement-guide-and-toolkit/**

Does the Patient Safety Act apply to a clinical audit where the data collection took place before the date the Act came into effect?	If a clinical audit is due for publication after commencement of the Act, the Act applies. The Act was implemented on the 26th September 2024 and if the report is published subsequent to that date, then the Act will apply even if the findings within the report are based on analysis of data that were collected before the implementation date. Reports published before the implementation date, would not have the protections of the act, as the legislation was not implemented at that time.

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About National Quality and Patient Safety

National Quality and Patient Safety (NQPS) was established in mid-2021 as a result of the HSE Central Reform Review. NQPS is part of the HSE Office of the Chief Clinical Officer, and is led by Dr Orla Healy, National Clinical Lead, Quality and Patient Safety.

Purpose

Our vision for patient safety is that all patients using health and social care services will consistently receive the safest care possible by:

- Building quality and patient safety capacity and capability in practice.
- Using data to inform improvements.
- Developing and monitoring the incident management framework and open disclosure policy and guidance.
- Providing a platform for sharing and learning; reducing common causes of harm and enabling safe systems of care and sustainable improvements.

For further information, please contact:

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Health Service Executive
Dr Steevens Hospital
Dublin D08 W2A8

e: ncca@hse.ie

w: https://www.hse.ie/eng/about/who/nqpsd/ncca/