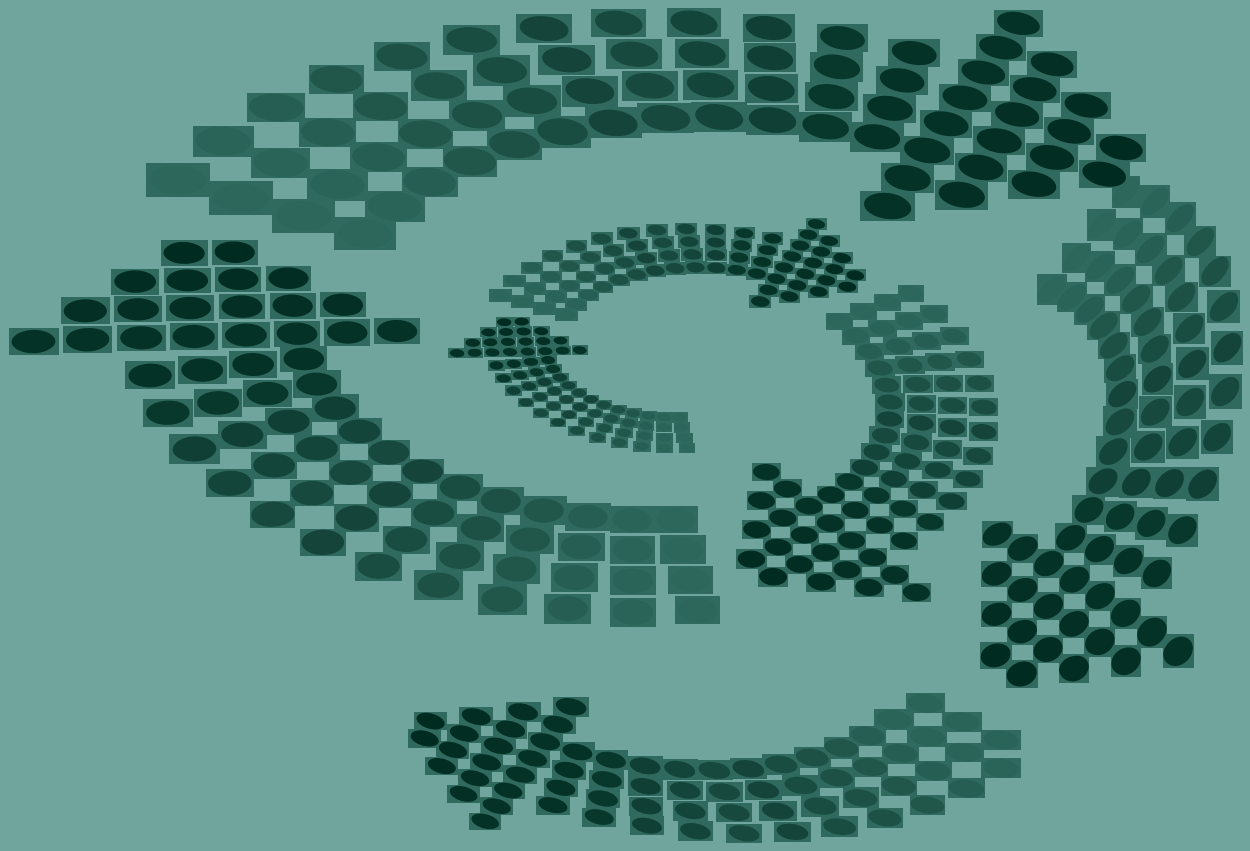
Ionad Náisiúnta d'Iniúchadh Cliniciúil
An Stiúrthóireacht um Ardchaighdeáin agus Sábháilteacht Othar

National Centre for Clinical Audit
National Quality and Patient Safety Directorate

HSE National Centre for Clinical Audit

Clinical Audit

A Practical Guide 2023



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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). 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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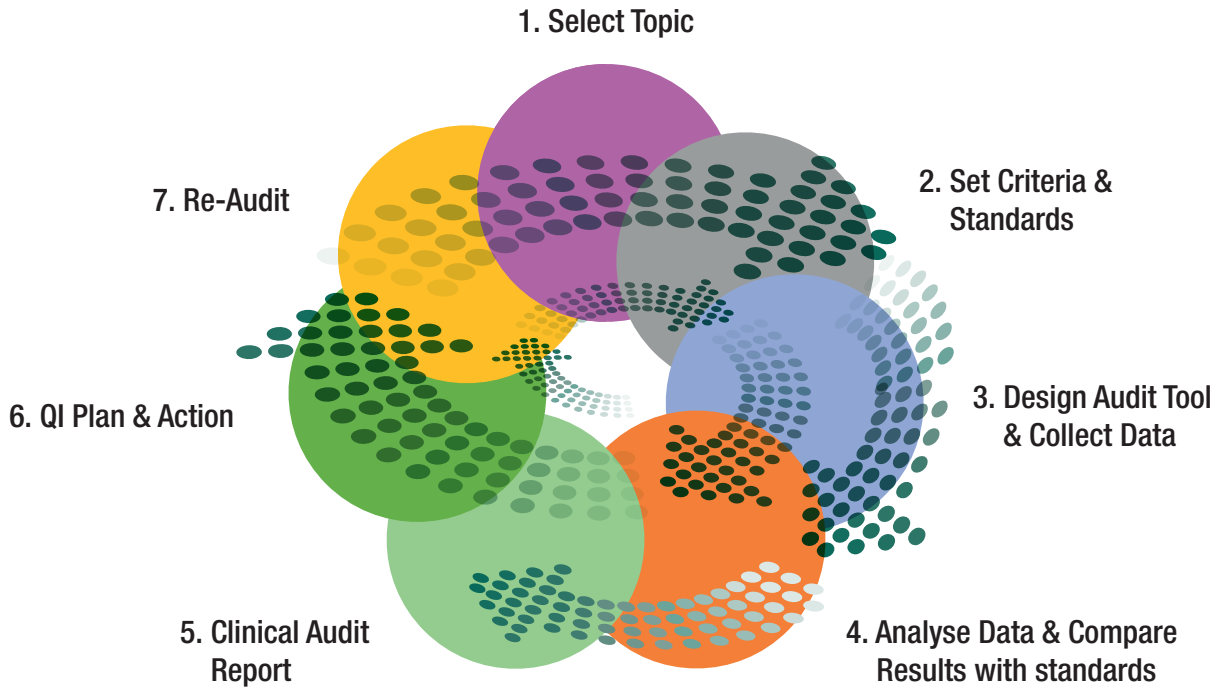
The Seven Stages of Clinical Audit

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 the National Quality and Patient Safety Directorate (NQPSD) in 2022, following 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.

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 criteria and acting to improve care when standards 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 criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements."

DOHC (2008, p.152)

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

(HSE NCCA Nomenclature document, A Glossary of Terms for Clinical Audit, 2022)

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.

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
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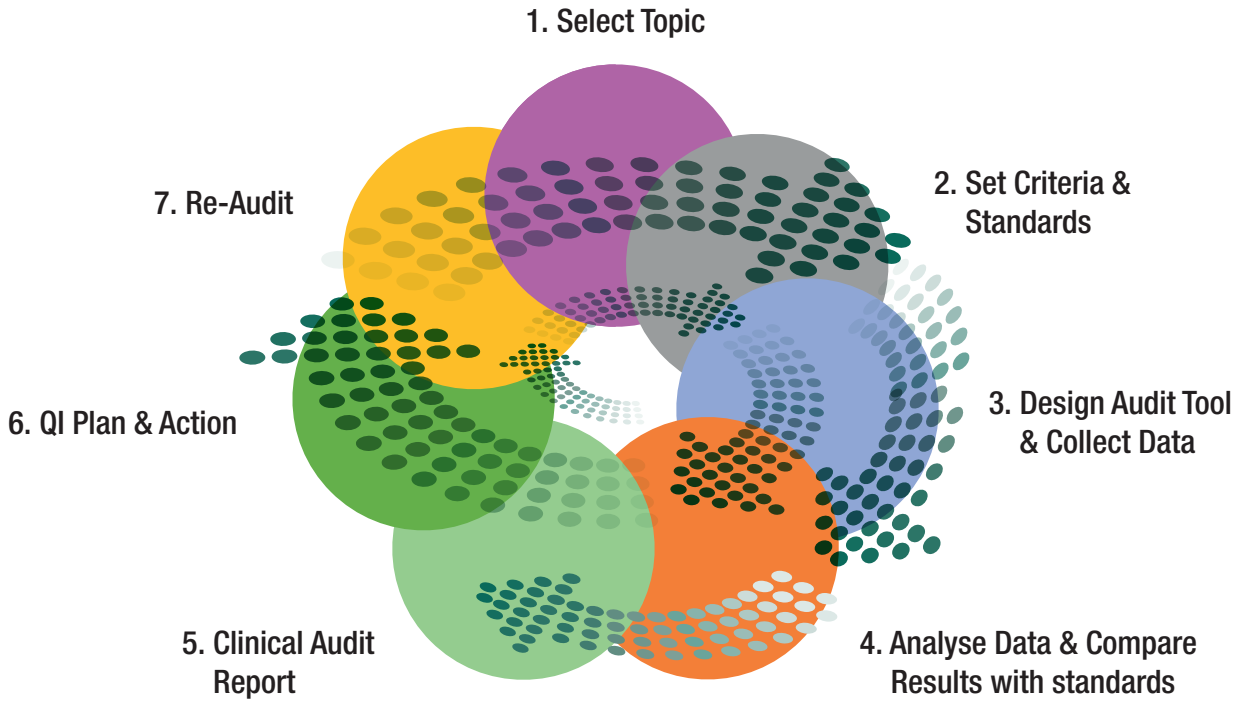
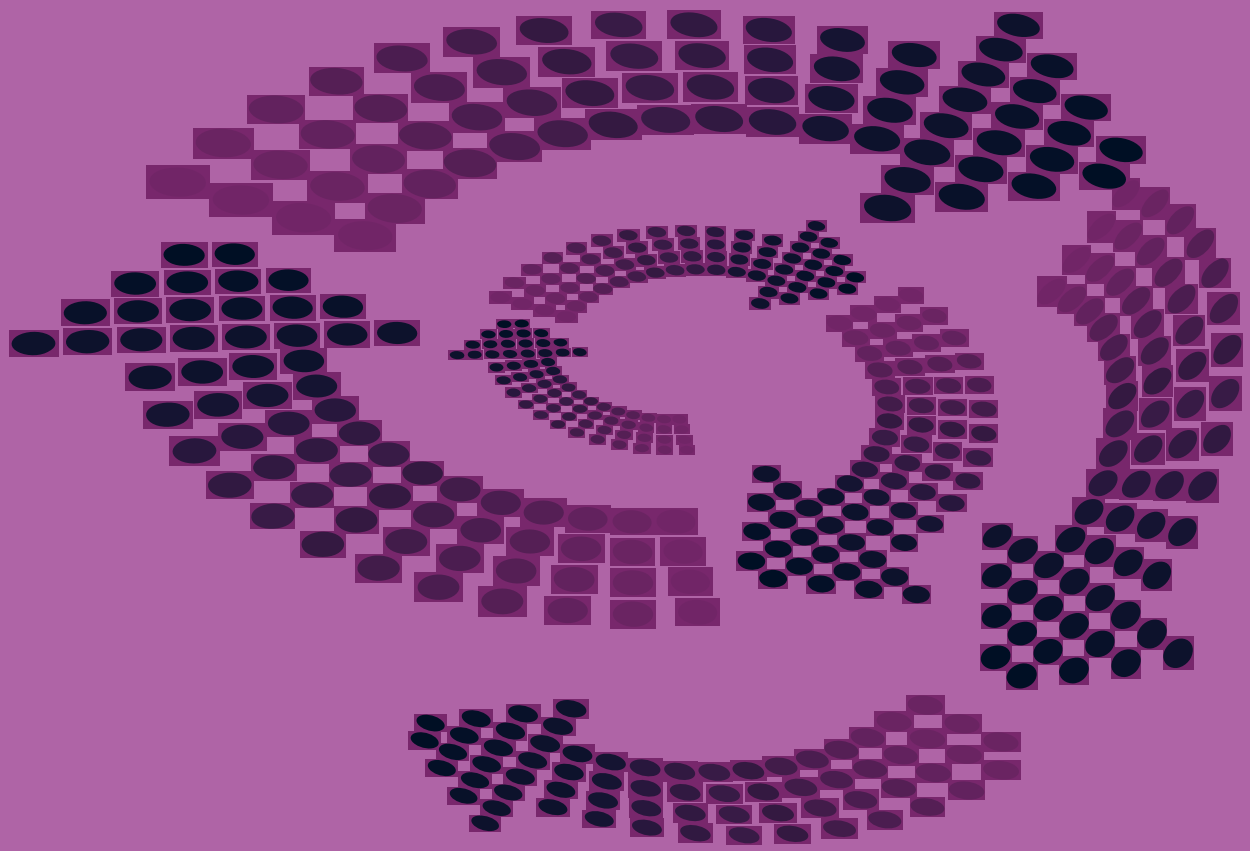


Figure 1: The Seven Stages of the Clinical Audit Cycle

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

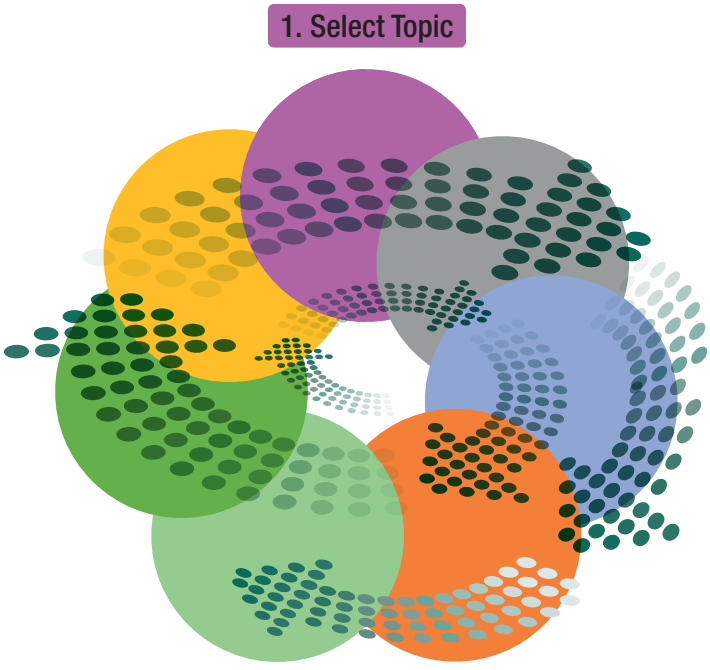


Figure 2: Clinical Audit Cycle Stage 1– Select Topic

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.

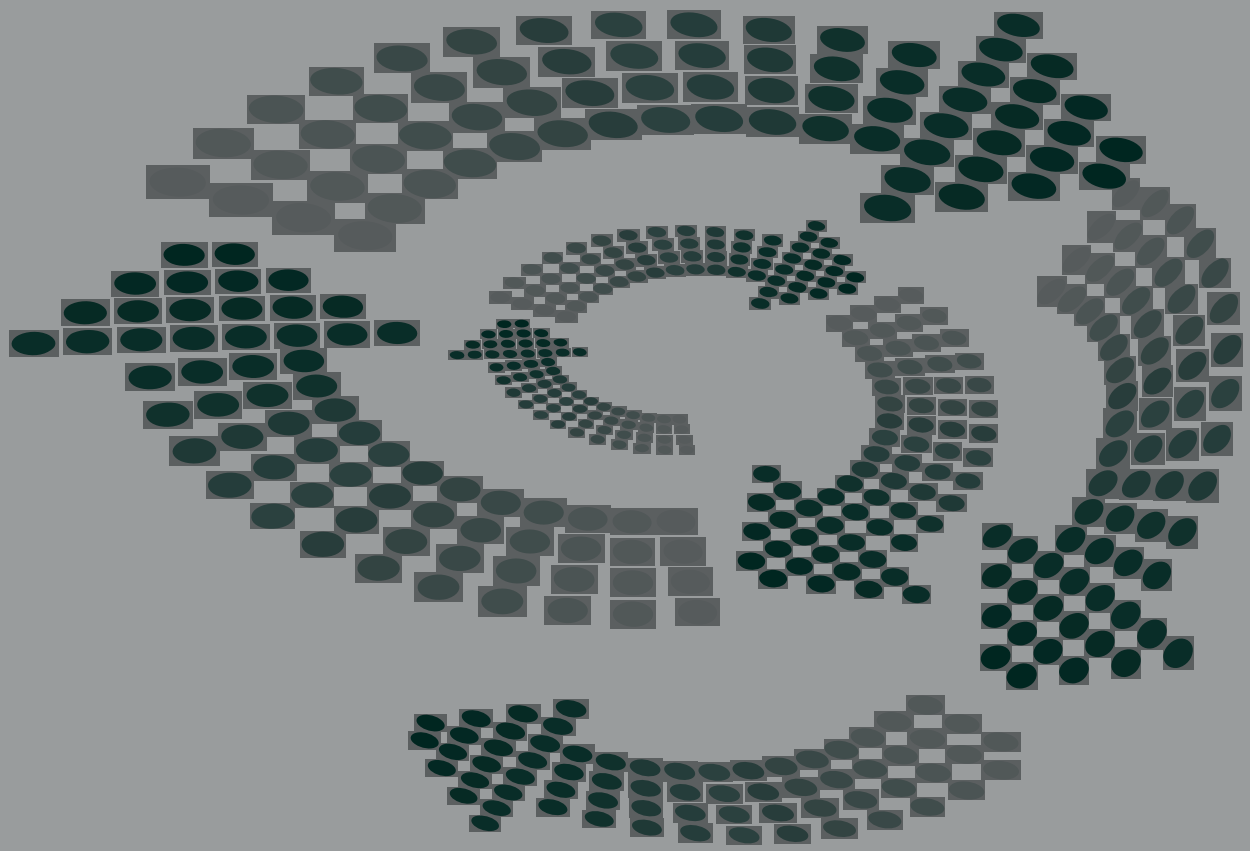
The team carrying out the clinical audit should ensure that appropriate resources are available with which to perform the clinical audit and to implement quality improvements. Where there is an insufficient level of resources available to carry out a clinical audit and the improvements, this issue should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

The structures should include a mechanism for the review of findings and progress reporting to the appropriate clinical lead, directorate or governance committee. Clear lines of accountability should be agreed at the outset of the clinical audit.

It may be appropriate to consider and discuss the question of possible publication of clinical audit results via conference proceedings, poster, oral presentation or journal article at the planning stage, particularly if the planned clinical audit is large.

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).**

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.

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

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.

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).

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'.

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.

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.

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.

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

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

*Consensus with the clinical audit team on exceptions should be agreed before the start of the audit.

Example

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

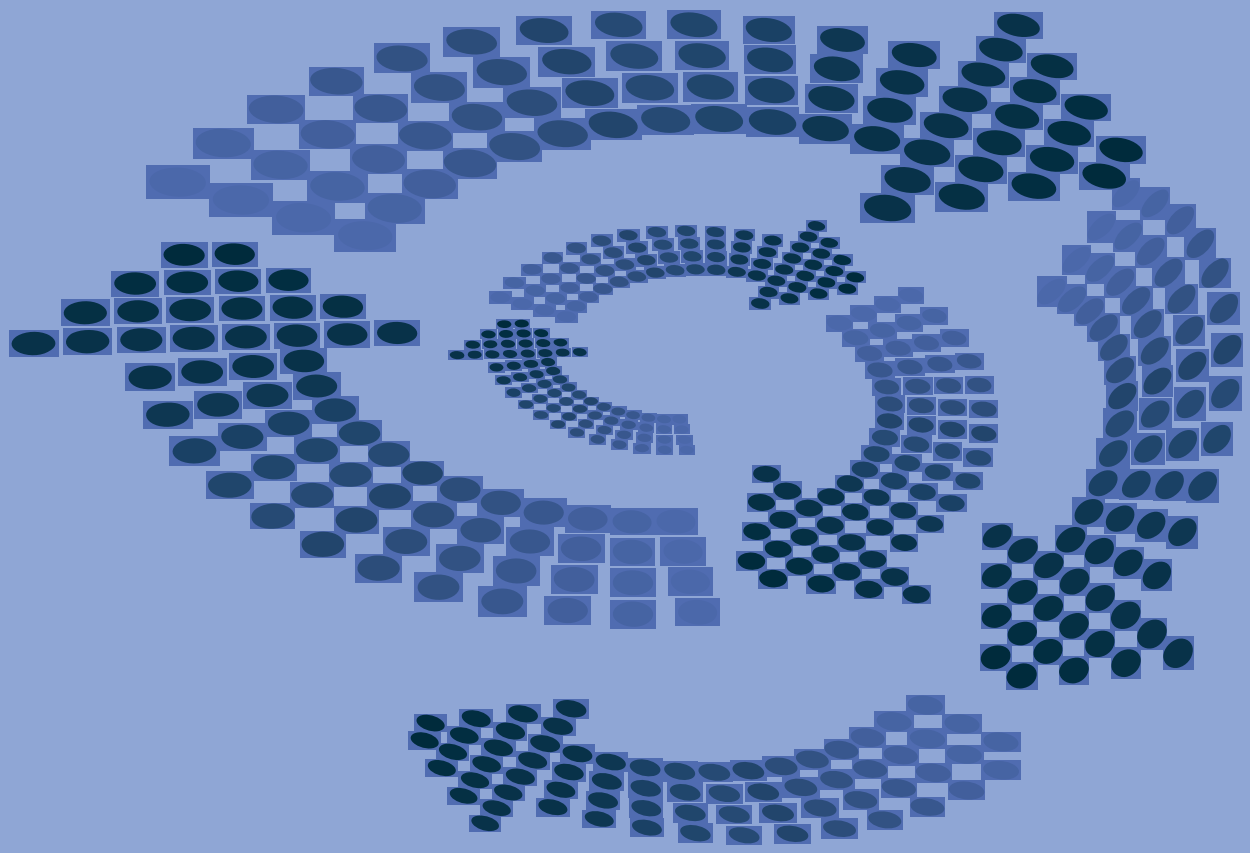
Criterion:

- 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.

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).

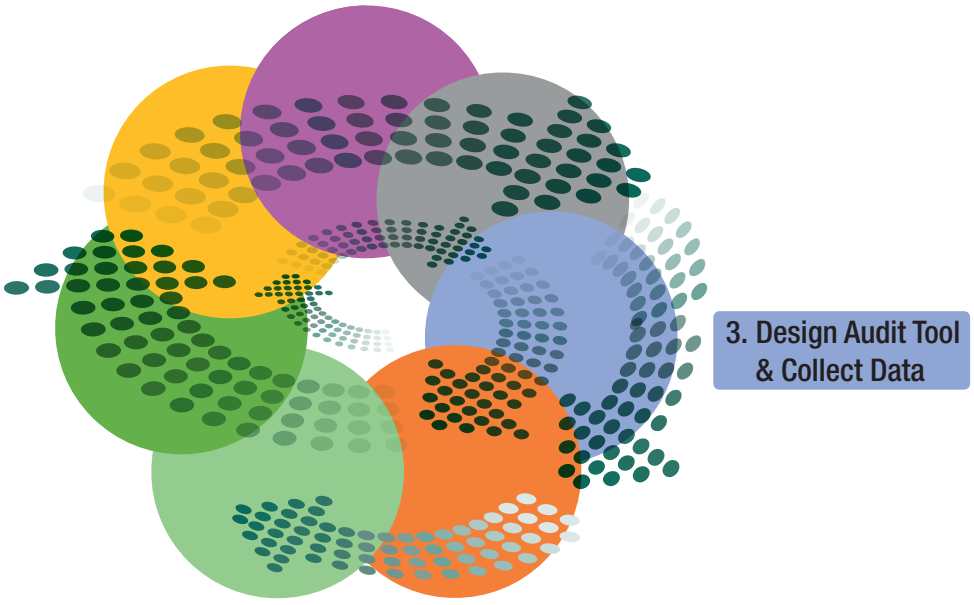


Figure 4: Clinical Audit Cycle Stage 3– Design Audit Tool and Collect Data

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?

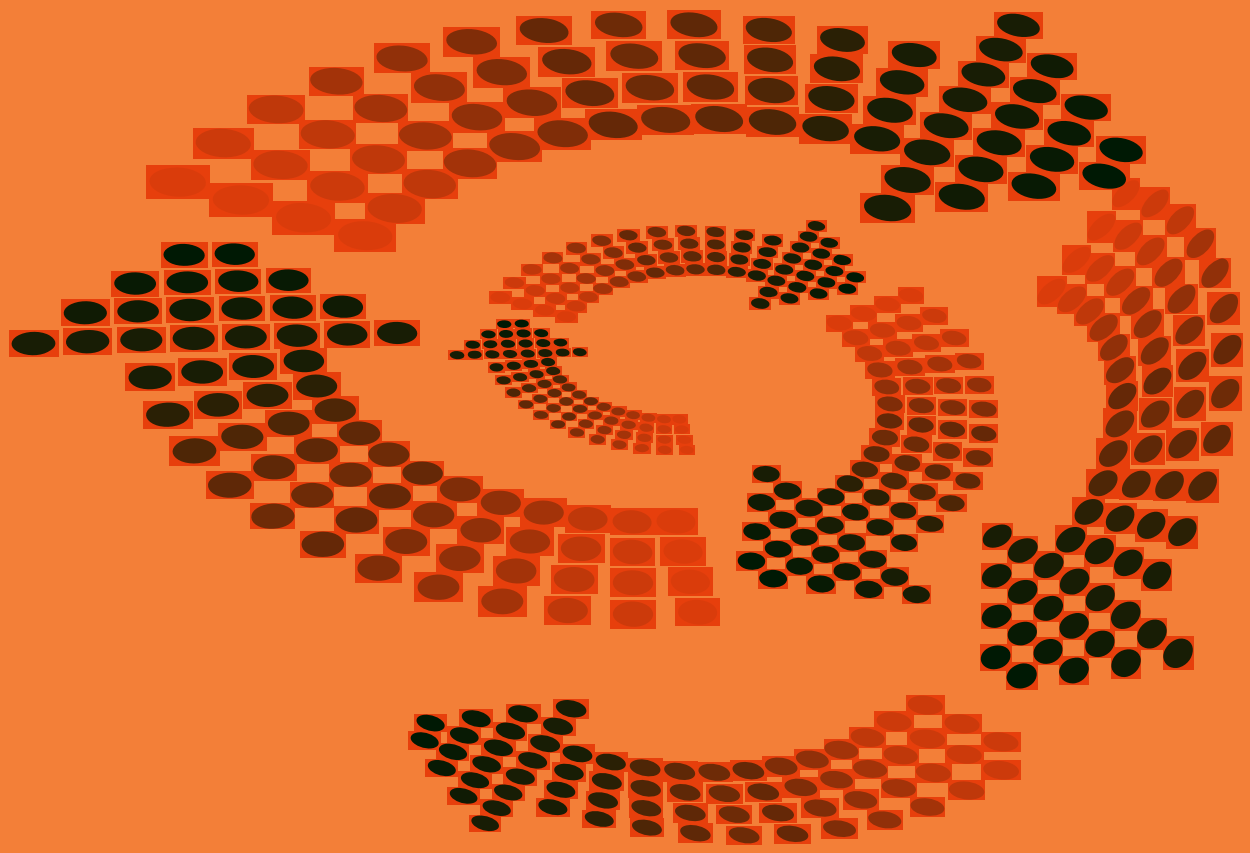
Depending on the clinical audit, data may be collected by more than one person or different people may be responsible for completing different data sets.

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)

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.

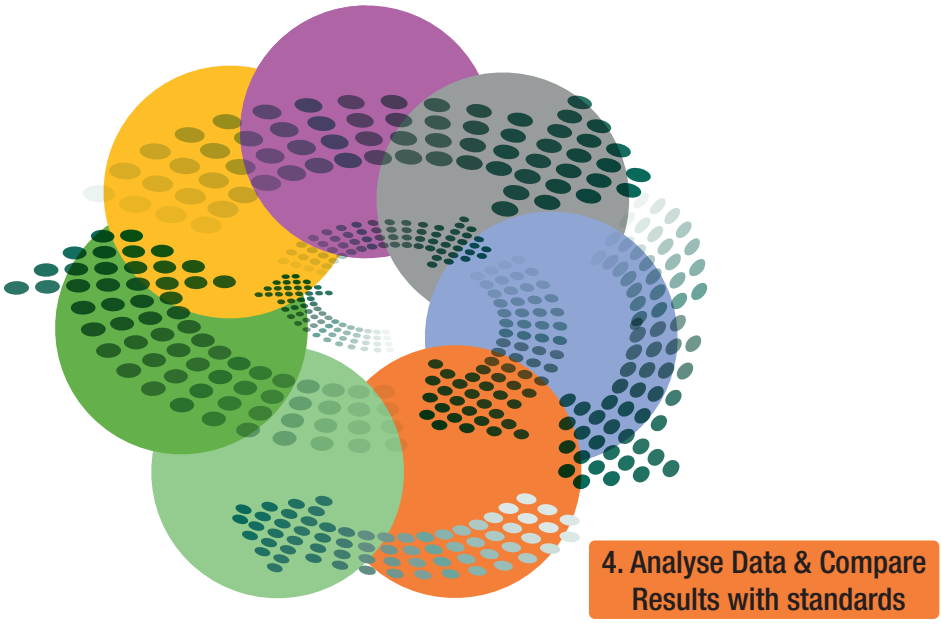


Figure 5: Clinical Audit Cycle Stage 4– Analyse Data and Compare Results with Standards

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.

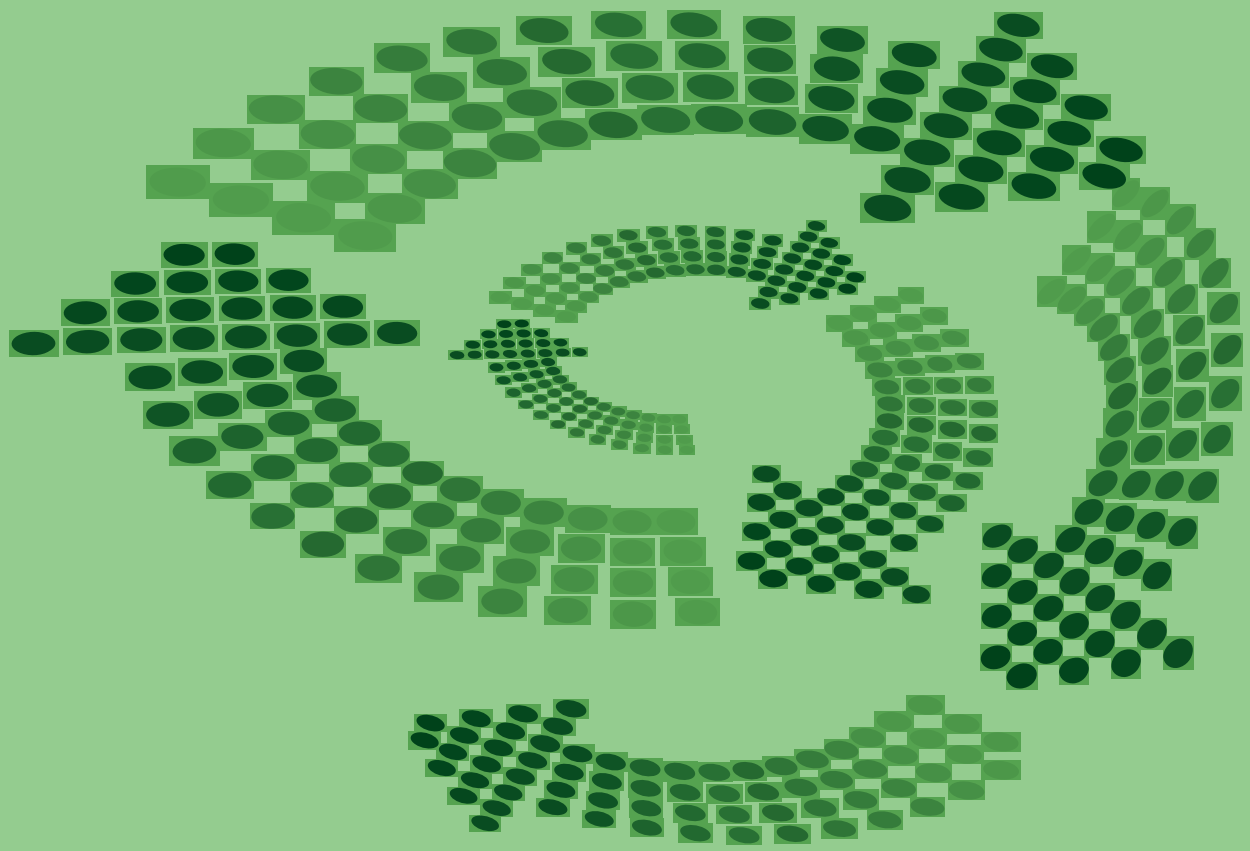
Data graphics are a good way of communicating this information to others, such as infographics. The most commonly used form of data graphics in clinical audit are tables, graphs and charts, using Excel.

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

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 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

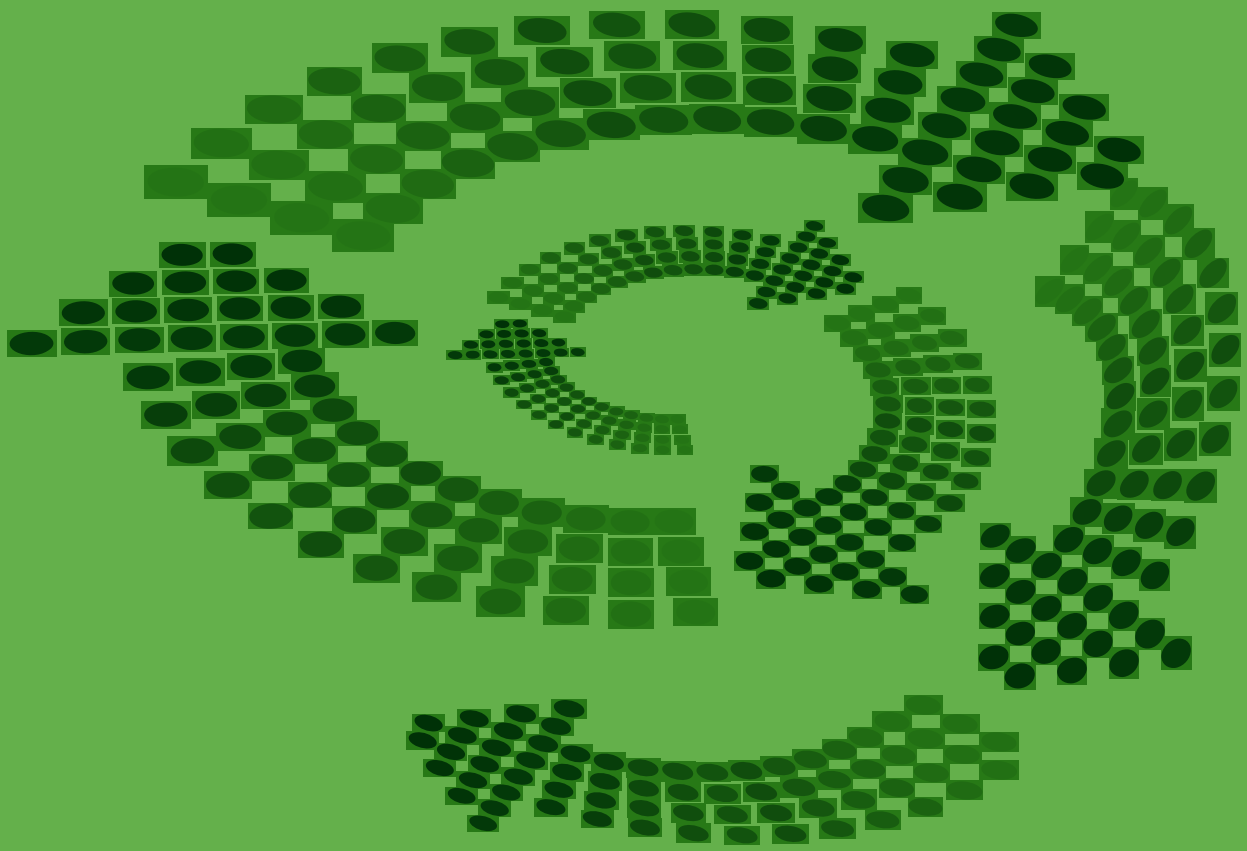
Conclusion/Summary – a progress report and comparison to the previous clinical audit must be included. This can be contained as a summary or a table.

Consider what has changed, either for the better or worse since the previous clinical audit. (Healthcare Quality Improvement Partnership (HQIP), 2012.

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?

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

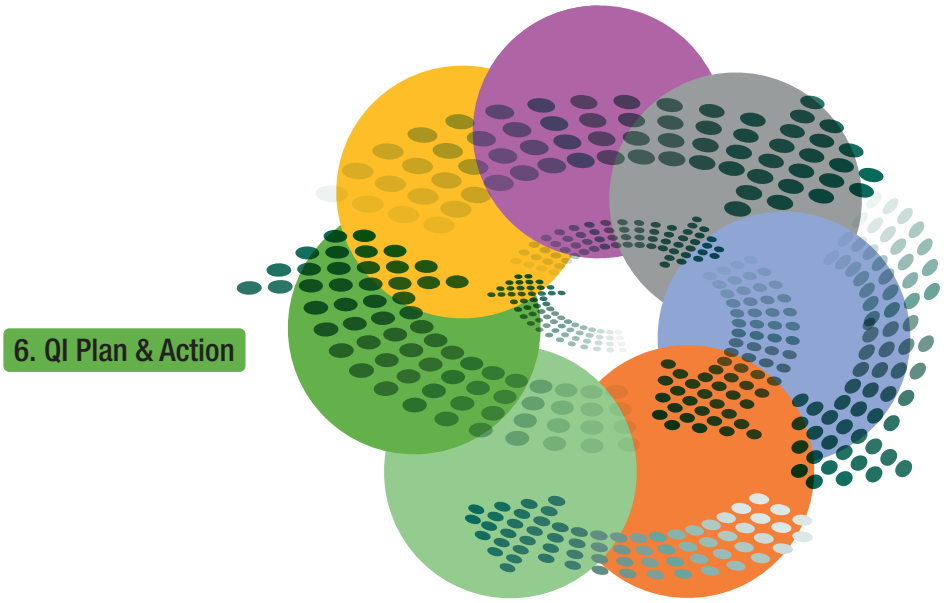


Figure 7: Clinical Audit Cycle Stage 6– QI Plan and Action

3.6 Step 1: Development of a Quality Improvement 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.

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.

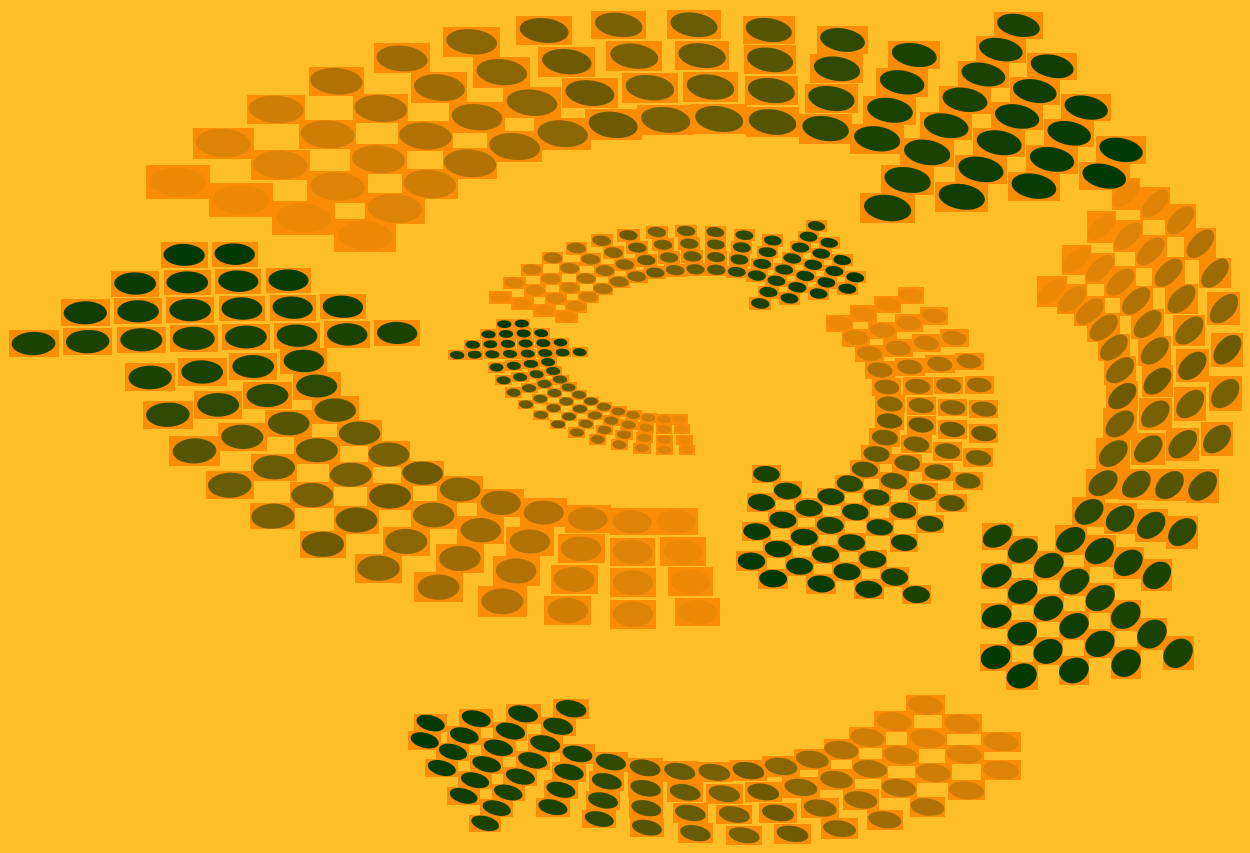
Cause and Effect Diagram (Fishbone Diagram)

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.

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.

4.0 Data Protection, General Data Protection Regulation and Ethical Issues for Clinical Audit

4.1 Data Protection and GDPR Responsibilities

Legislation around data protection and service user record confidentiality must be complied with when performing clinical audits. The Data Protection Acts 1988 and 2018 provide the legislative basis for the approach of the Office of the Data Protection Commissioner with regard to personal data across all sectors of society - public, private and voluntary.

4.2 Data Protection and GDPR Principles

Anyone processing personal data must comply with the eight rules of data protection in line with the Data Protection Acts, 1988 - 2018:

- Obtain and process information fairly
- Keep data only for one or more specified, explicit and lawful purposes
- Use and disclose it only in ways compatible with these purposes
- Keep data safe and secure
- Keep it accurate, completed and up to date
- Ensure data is adequate, relevant and not excessive
- Retain it for no longer than is necessary for the purpose or purposes
- Give a copy of his/her personal data to that individual on request

4.3 Data Protection and GDPR Guidelines

Data Protection Guidelines on research in the Health Sector (Data Protection Commissioner, 2007, P.12) states:

> **"Given the fundamental role played by clinical audit in patient care, implied consent is normally all that is required when the clinical audit could likely be of benefit to that patient. Implied consent will also be considered as sufficient in those cases where no direct benefit is likely to accrue to the patient concerned and where the clinical audit is to be carried out by the health facility itself"**

However, the Data Protection Act provides an exemption from obtaining consent from the service user for processing for statistical, research or scientific purposes carried out by the data controller itself (i.e. the treating healthcare professional/service provider) where there are no disclosures of personal data to any outside third parties.

Where access to service user identifiable information is not accompanied by explicit consent, the Data Protection Act requires that access is necessary for medical purposes; and access is only given to:

- a health professional; **or**
- a person who, in the circumstances, owes a duty of confidentiality to the service user that is equivalent to that which would exist if that person were a health professional.

The National Office of Clinical Audit (NOCA) in Ireland also provides guidance on understanding the GDPR Definitions:

- Personal data includes identifiable and pseudonymised data
- Pseudonymised data is data that has a link back to enable identification. This link is usually retained for use by the Data Controller and not by the Data Processor
- Processing of personal data can include gathering, processing and use of personal data
- If the data in question can no longer be linked back to any identifiable individual, then it will constitute anonymised data, is not personal data and is not subject to the GDPR. For example, if NOCA has received data for clinical audit purposes but does not have access to any other information which would enable it to identify the underlying individuals, then this data will not constitute personal data (NOCA, 2019).

4.4 Ethical Issues

What is Ethics?

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.

4.5 Is Ethical Review Required for Clinical Audit?

Previously, decisions regarding whether an activity required ethical review related directly to whether the activity was classed as clinical audit or research. If an activity was classed as clinical audit it was automatically deemed not to require ethical review, whereas research proposals require ethical review and approval. However, due to the many similarities between clinical audit and clinical research, the boundaries between them can be blurred. As a result, Wade (2005) recommends that 'Decisions about the need for ethical review should be based on the morality of all actions rather than arbitrary distinctions between clinical audit and research'.

The National Office of Clinical audit (NOCA) provides guidance which states that clinical audit does not require ethical approval but, as always and in line with best practice, ethical issues should still be considered while also adhering to data protection principles (NOCA, 2019).

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.

Exceptions to the healthcare profession's duty of confidentiality to the service user:

Where a service user gives explicit consent to the disclosure of information to third parties.

When disclosure is required by or under any enactment or by a rule of law or order of a court

When disclosure is necessary to protect the vital interests of the service user or of another individual (consent should be obtained if possible in such situations)

(Data Protection Acts, 1988 and 2018).

Other exceptions provided for in legislation include:

Health (Provision of Information) Act 1997 allows for provision of information to the National Cancer Registry without the consent of the service users concerned.

Infection Diseases Regulations (1981 and 2011) set out legal obligations to disclose details of notifiable diseases with or without consent.

4.6 Guidance Regarding Consent Requirements for Clinical Audit

In general, clinical audit does not require informed consent (HSE, 2013). Members of a healthcare team (or their support staff, for example, clinical audit staff) delivering direct care to a service user can perform a review of service user data without consent. However, it is good practice to inform service users that as part of normal care processes, personal data may be used for clinical audit and quality improvement purposes and also about the importance of the clinical audit function within the service. This may be achieved through informing service users through a statement of information practices or leaflets or posters which are clearly displayed/made available by the service provider (HIQA, October 2012).

Consent is not required where the personal health information is irrevocably anonymised by the data controller prior to disclosing to a third party. Care must be taken to ensure that the service user is completely unidentifiable even when the data is anonymized.

Where a clinical audit is carried out by persons who are not involved in service user care (i.e. persons who are external to the data controller (the service provider)), informed consent is required to enable such persons to access personal data.

If a service user gives consent to the disclosure of records to third parties, the health professional ensures they understand the consequences of such disclosure, what will be disclosed, the reasons for the disclosure and the consequences of giving consent. Service users' healthcare records are only disclosed in accordance with the conditions of their consent. Service users have the right to withdraw consent to disclosure of their healthcare records information at any time.

4.7 Confidentiality and Access to Service User Health Information

The clinical audit methodology should be designed so that the confidentiality of personal health information is not compromised. When reporting on clinical audits, data is completely anonymised in every case. No link between clinical audit conclusions, service users or healthcare staff should be possible.

All healthcare staff must make every effort to preserve the confidentiality of personal health information and ensure that they work within the requirements of the Data Protection Acts 1988 and 2018:

- Data is only accessible by appropriately authorised staff on a need-to-know basis
- Data collection sheets containing any personal identifiable information should only be kept for the length of time they are absolutely required (for the purposes of the clinical audit). Once they are no longer required, they should be destroyed immediately
- Raw data is anonymised before it is entered into a computer database
- Data is checked to ensure confidentiality and accuracy
- No service user identifiable information is stored on a computer with raw data
- Anonymised data sheets/questionnaires should be kept only for as long as is necessary and destroyed as soon as all information has been retrieved from the questionnaires
- Any waste material that contains personal, private or confidential information should be eliminated in a manner which ensures that privacy rights and confidentiality obligations are not compromised
- There should be a designated point of storage for data in current use. This should be a locked filing cabinet, to comply with data protection requirements
- All data should be stored together i.e. the physical raw data, the first data input into the computer, any subsequent analysis, and the final draft
- The data must be archived, so that it remains available throughout the subsequent phases of the clinical audit and for seven years afterwards
- Archived clinical audits should be stored on a secure computer
- All computers are password protected
- All devices used to store data are encrypted (for example, laptops and USB devices)
- If laptops are removed from the work location, the person responsible for that laptop must ensure that it is secure at all times
- The service provider should have a central location for the storage of final clinical audit reports (both in hard and soft copy). It is also recommended that a log be maintained for traceability purposes of the reports and where they are at any given time
- All data recorded for clinical audit purposes should be made anonymous by appropriately authorised individuals before being made available for review and consideration by others

4.8 Anonymisation of Data

The anonymization of data involves removal of all data elements that could be used to identify an individual, for example, name or healthcare record number. It is recommended that service user data be anonymised before it is accessed for clinical audit purposes:

- Irrevocable anonymisation of personal data puts it outside data protection requirements as the data can no longer be linked to an individual and therefore cannot be considered to be personal data
- Where service user data is anonymised, there is no need from a data protection perspective to seek consent for the use of the data for clinical audit purposes

However, care needs to be taken when rendering data anonymous, as depending on the nature of the illness and the profile of the service user, there may be instances in which the data may actually still be identifiable. Where this might possibly be the case, an extra effort should be made to further remove any potential identifying information. Where this is not possible it would be advisable to either refrain from using the identifiable information or seek the consent of the person for such use.

Equally, it is recognized that in some instances where there is a need to link episodes of care and prevent duplication of data; information may need to be capable of being matched or linked. This can be achieved through appropriate pseudonymisation (e.g., use of initials, coding) methods without the need to retain all identifying characteristics with the data.

Pseudonymisation (or "reversible anonymisation") involves the use of a coding system, for example, allocating individuals with unique, reference numbers. The look-up list from which the true identities may be obtained is then held securely and only accessed by authorised persons for specific, pre-defined purposes. Similar to the advice in relation to anonymisation, where pseudonymisation methods are used, it is recommended that extra efforts, beyond use of initials etc, be incorporated where a condition is particularly rare. Unique identifying numbers should also be given to healthcare professional that may be involved in the clinical audits. Individuals should not be named in any of the reports.

In certain cases where anonymising data may be impractical and detrimental to the clinical audit, such as during the ongoing data collection to prevent duplication of data collection, the clinical audit team must ensure that the data is kept purely for the purposes of analysis by those directly involved in the management of the clinical audit. Identifiable data must not be transferred to third parties without the permission of the service user.

Further data protection information and advice is available from the Office of the Data Protection Commissioner website **www.dataprotection.ie**.

To ensure that those involved in clinical audit are aware of and supported in their efforts to be compliant with any legislative changes affecting clinical audit, clear and consistent information is provided across the HSE in relation to legislation that supports both patient safety and advancing and improving care.

All HSE services, staff and clinical audit service providers carrying out clinical audit locally and nationally should understand and comply with GDPR and the Patient Safety Bill 2019 requirements.

General Data Protection Regulation (2018) and clinical audit outcomes:

- Dedicated guidance on GDPR and Data Protection and its application to clinical audit
- The HSE will advise and share this guidance to ensure consistency across all clinical audit service providers
- The HSE will form a national healthcare Data Protection Officer (DPO) network to support the process of consistent guidance to the system
- The HSE will provide timely guidance on any changes or updates to legislation and guidance which affects clinical audit and this will be published on the dedicated clinical audit web portal that has been recommended by the national clinical audit review report
- General Data Protection Regulation (GDPR) training on HSeLanD to be completed by all HSE staff
- HSE staff to follow the HSE_GDPR Policy (2019) when conducting any clinical audit activity

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.

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.

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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 criteria and acting to improve care when standards 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 criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re- evaluated to confirm improvements." DOHC (2008, p. 152) "Clinically-led" includes all health and social care professionals.
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: http://www.hse.ie/go/clinicalgovernance
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)
Data Controller	Refers to a person who, either alone or with others, controls the contents and use of personal data.
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	A computer or person that carries out operations on data to retrieve, transform, or classify information.
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 Audit	"Healthcare audit, in line with the design and practice of Internal audit, is an independent, objective assurance activity designed to add value and improve an organisation's operations. It helps an organisation accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes." HSE (2019a, p. 2) "Under the HSE's Code of Governance, Healthcare Clinical audit sits alongside and mirrors the organisation's Internal Clinical audit function by providing 'third line of defence'[1] assurance in relation to risks and controls in care related activities in both clinical and non-clinical settings. The HSE's Healthcare clinical auditors are members of the Chartered Institute of Internal Clinical auditors (CIIA) and are required to comply with the professional and general standards set by the CIIA." HSE (2019a, p. 2)
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, 2018, p. 5).
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 Look Back Review is a process that is initiated where it has been determined that a number of people have been exposed to a specific hazard. The process seeks to identify if any of those exposed to the hazard have been harmed and what needs to be done to ameliorate the harm. This process consists of three key stages: Preliminary Risk Assessment, Clinical audit and Recall." HSE (2018, p. 29)

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 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 (NOCA) 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	Data relating to a living individual who is or can be identified either from the data or form the data in conjunction with other information that is in, or is likely to come into, the possession of the data controller.
Quality Assurance	"Quality assurance is defined as all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and comply with agreed standards." HSE (2019b)

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." HSE (2016b, p. 4) "All methods highlight the importance of accessing the unique knowledge that frontline staff possess and involving them in any change and improvement process. Improving the quality of care, and sustaining it, requires all programmes to have a theory of change that is based on the application of improvement science." HSE (2016b, p. 15)
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. (2019)
Research	"Research is designed and conducted to generate new generalisable or transferrable knowledge. It includes both quantitative and qualitative studies that aim to generate new hypotheses as well as studies that aim to test existing or new hypotheses." Health Research Board (2018)
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

An Stiúrthóireacht um Ardchaighdeáin agus Sábháilteacht Othar
Oifig an Phríomhoifigigh Cliniciúil
National Quality and Patient Safety Directorate
Office of the Chief Clinical Officer

Ionad Náisiúnta d'Iniúchadh Cliniciúil
An Stiúrthóireacht um Ardchaighdeáin agus Sábháilteacht Othar
National Centre for Clinical Audit
National Quality and Patient Safety Directorate

CLINICAL AUDIT PROPOSAL FORM SAMPLE TEMPLATE

(*This is a sample Clinical Audit template which can be adapted for National/Local use)

For Further Information please see HSE NCCA Nomenclature/Glossary of Terms for Clinical Audit:
https://www.hse.ie/eng/about/who/nqpsd/ncca/nomenclature-a-glossary-of-terms-for-clinical-audit.pdf

Clinical Audit Topic –

Title of Clinical Audit –

CLINICAL AUDIT & PROJECT LEAD:

Clinical Audit Lead (Name/Job Title): _____

Clinical Audit Project Lead (Name/Job Title): _____

WHY WAS THE TOPIC CHOSEN?

Under whose initiative was the audit instigated? *(Tick all boxes that apply)*

☐ Local

☐ National

☐ Other Quality/Patient Safety Initiative, please specify: Triage Accuracy in EDs

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

☐ High Cost Activity ☐ High Risk Activity ☐ High Volume Activity

☐ Based on evidence based healthcare and clinical effectiveness issues (best practice)

☐ Local initiative which centres on processes that may have a significant effect on provision of patient care and/or outcome

☐ Risk Management Issues

☐ Re-audit of previously accepted project

Each clinical audit project must satisfy all of the following:

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

1

☐ 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 team

☐ Willingness to agree recommendations from the audit and agreed action plan(s).

PARTICIPANTS:

Medical ☐ ☐ Nursing

Allied Health Professionals ☐ Other Speciality / Dept ☐ BIU

Other: ☐ Add as required: _____

Have all potential members of the project group been identified? Yes ☐ No ☐

Has the clinical audit been discussed with them? Yes ☐ No ☐

Please note the relevant groups involved:

AIM OF CLINICAL AUDIT:

AIM Statement*:

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

OBJECTIVE(s) OF CLINICAL AUDIT:

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 https://www.kch.nhs.uk

2

1.
2.

3.

4.

5.

6.

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

METHOD:
Has a literature search been undertaken Yes ☐ No ☐

Key words used in search and databases used:

INCLUSION/ EXCLUSION CRITERIA:

Inclusion Criteria:

The sample identified for the review must

Exclusion Criteria: These outside of the date ranges above

DATA COLLECTION: Concurrent ☐ Retrospective ☐ Prospective ☐

How will cases be identified?

METHOD OF DATA COLLECTION: Chart Review ☐ Patient Questionnaire ☐

Staff Questionnaire ☐ Telephone Interview ☐

Observation ☐ Other:

SAMPLE SIZE:

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

Anticipated Time-scale Proposed: Target completion date:

RESOURCES:
Involvement or resources that you wish to request from your Local Clinical Audit Support Team *(where available locally)*

Literature Search	☐	Topic Selection	☐
Proforma Design	☐	Questionnaire Design	☐
Data Analysis	☐	Data Collection	☐
Dissemination	☐	Report Production	☐
Other	☐		

ACKNOWLEDGMENT:

PATIENTS INCLUDED IN THE AUDIT:

a. Are all patients included in this audit under the care of the Audit Lead? Yes ☐ No ☐
b. If no, please complete the form overleaf ***(Request for inclusion of patients in a Clinical Audit)***
c. Is there a patient representative on the clinical audit sub group? Yes ☐ No ☐
If No, please state the reason for this.

PROJECT ORGINATOR/LEAD:
This proposal and its possible (clinical and managerial) implications have been discussed with the relevant participants previously noted who undertake to support the audit and the implementation of any necessary changes identified as a result of the audit.

Signed _____ ***Date*** _____

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

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Request for inclusion of patients in Clinical Audit

(Insert Title of Clinical Audit):_____

Dear Colleague,

I would be grateful if your patient's anonymous details could be included in the clinical audit proposed above.

This will be undertaken in conjunction with the Local Clinical Audit Support Team and with the support/supervision of _____.

Yours sincerely,

Agreed (Signature & Date)

_____ _____
_____ _____
_____ _____
_____ _____
_____ _____
_____ _____

References and Further Information

https://www.hse.ie/eng/about/who/nqpsd/ncca/nomenclature-a-glossary-of-terms-for-clinical-audit.pdf

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

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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 Proposal Form
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	

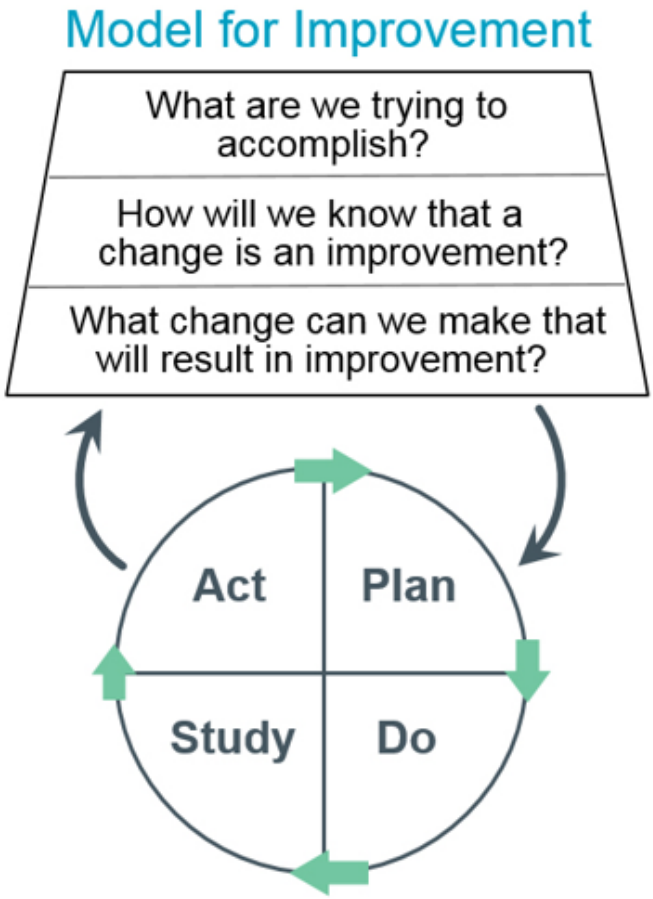
Resource 4
Quality Improvement / Action Plan

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.

https://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx

An Stiúrthóireacht um Ardchaighdeáin agus Sábháilteacht Othar
Oifig an Phríomhoifigigh Cliniciúil

National Quality and Patient Safety Directorate
Office of the Chief Clinical Officer

About the HSE National Centre for Clinical Audit
National Quality and Patient Safety Directorate

The National Quality and Patient Safety Directorate (NQPSD) was established within the Office of the Chief Clinical Officer in Summer 2021, following the HSE Corporate Centre review. It merged a number of functions from the former national Quality Assurance and Verification Division (QAVD) and National Quality Improvement Team (NQIT). National QPSD is anchored in the HSE Patient Safety Strategy 2019-2024. It works to embed a culture of patient safety improvement at every level of the health and social care service. This is achieved through developing a collaborative culture aimed at repeating and improving on positive outcomes and minimizing adverse outcomes.

The HSE National Centre for Clinical Audit (NCCA) established within the QPSD, follows publication of the HSE National Review of Clinical Audit Report in 2019, and will be 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.

Clinical audit is an integral component of safety in all modern healthcare systems and the programme will ensure delivery of a standardised approach. 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 multi-disciplinary stakeholders.

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