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Clinical Audit Standard

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Recognition of pre-hospital emergency care providers

Pursuant to S.I. No 109 of 2000 as amended by S.I. No 575 of 2004, one of the function of the Pre Hospital Emergency Care Council (the "Council") is to recognise, in accordance with rules made by Council, those prehospital emergency care service providers which undertake to implement the clinical practice guidelines prepared by the Council.

These rules set out the procedure for recognition which will apply to all pre-hospital emergency care service providers who apply to the Council for such recognition.

Licensed CPG Provider clinical audit requirements

Licensed CPG providers apply to Council annually for approval to implement CPG's. The recognition process rules include the completion of a Statutory Declaration under which, the licensed CPG provider agrees that, if recognition granted, a summary of the clinical audits completed during the previous twelve months will be included in the CPG report. In addition the application form must include details of a minimum of three clinical audits undertaken in the previous year.

The clinical audit process involves five stages which must be undertaken to ensure that an audit is systematic and successful:

Stages	
Stage 1	Planning for audit
Stage 2	Criteria selection
Stage 3	Measuring performance
Stage 4	Making improvements
Stage 5	Sustaining improvements

For clinical audit to be effective it requires commitment and support by the licensed CPG provider.

Every licensed CPG provider should implement a clinical audit strategy supported by a clinical audit policy which will set out the procedures for the conduct of clinical audit within the CPG provider.

We wish to acknowledge the Quality and Patient Safety Directorate, authors of the Guide herein, for permitting PHECC to adopt the "Practical Guide to Clinical Audit" as the PHECC Clinical Audit Standard.

A Practical Guide to Clinical Audit



Table of contents	Page
1 Introduction	6
1.1 Background	6
1.2 Setting the scene	8
1.3 Scope of document	10
2 The five stage approach to clinical audit	11
2.1 Stage 1: Planning for audit	12
2.2 Stage 2: Standard/criteria selection	22
2.3 Stage 3: Measuring performance	29
2.4 Stage 4: Making improvements	46
2.5 Stage 5: Sustaining improvements	49
2.6 Summary – The five stage approach to clinical audit	52
3 Resources required to support clinical audit	53
3.1 Service provider support	53
3.2 Clinical audit facilitation	57
4 Wider considerations	58
4.1 Ethical issues	58
4.2 Issues of data protection	61
5 References	66
6 Additional resources	69
7 Glossary	71

Appendices

Appendix one:	Clinical audit proposal proforma
Appendix two:	Clinical audit checklist
Appendix three:	Types of data
Appendix four:	Top tips for the successful development of clinical audit data collection tools
Appendix five:	Glossary of terms in relation to descriptive statistics
Appendix six:	Presentation of data using table, graphs and charts
Appendix seven:	The clinical audit report
Appendix eight:	Twelve tips for successful clinical audit

Abbreviations

HIPE	Hospital In Patient Enquiry (Scheme)
HIOA	Health Information Quality Authority
HSE	Health Service Executive
MHC	Mental Health Commission
NCEC	National Clinical Effectiveness Committee
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NOCA	National Office of Clinical Audit
RCSI	Royal College of Surgeons in Ireland
SIGN	Scottish Intercollegiate Guidelines Network

1. Introduction

1.1 Background

On 23rd September 2010, the Patient Safety First initiative was launched in response to recommendations of the Report of the Commission on Patient Safety and Quality Assurance – *Building a Culture of Patient Safety* (Department of Health and Children, 2008). A key component of the Patient Safety First initiative is the National Framework for Clinical Effectiveness. The purpose of this framework is to provide formal structures and processes to support clinical effectiveness.

Clinical effectiveness involves a number of processes, but primary among these are:

- (i) the development or adaptation and use of **clinical guidelines** to support evidence-based practice; and
- (ii) the use of **clinical audit** to improve service user care and outcomes.

National Clinical Effectiveness Committee (NCEC)

The oversight of the National Framework for Clinical Effectiveness is provided by the National Clinical Effectiveness Committee (NCEC). The NCEC is a partnership between key stakeholders in service user safety. The NCEC mission is to provide a framework for national endorsement of clinical guidelines and audit to optimise service user care.

The NCEC terms of reference are to:

- Apply criteria for the prioritisation of clinical guidelines and audit for the Irish health system.
- Apply criteria for quality assurance of clinical guidelines and audit for the Irish health system.
- Disseminate a template on how a clinical guideline and audit should be structured, how audit will be linked to the clinical guideline and how and with what methodology it should be pursued.
- Recommend clinical guidelines and national audit, which have been quality assured against these criteria, for Ministerial endorsement within the Irish health system.
- Facilitate with other agencies the dissemination of endorsed clinical guidelines and audit outcomes to front-line staff and to the public in an appropriate format.
- Report periodically on the implementation of endorsed clinical guidelines.

1. Introduction

Definition of a clinical guideline

The term 'clinical guideline' has synonyms that may elsewhere be considered to be broadly interchangeable. These include 'guideline', 'health guideline', 'clinical practice guideline', 'evidence-based guideline', 'evidence-based guidance' and 'guidance'. For the purpose of consistency, the NCEC utilises the term 'clinical guideline' in its work. The following identifies the specific meaning that should be inferred for this term:

Clinical guidelines are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances, across the entire clinical spectrum.

Adapted from Field and Lohr (1992).

Definition of clinical audit

The term 'clinical audit' is used to describe a process of assessing clinical practice against standards. The Commission on Patient Safety and Quality Assurance (2008, p.152) defined clinical audit as:

'a clinically led, quality improvement process that seeks to improve patient care and outcomes through the systematic review of care against explicit criteria and to act to improve care when standards are not met.'

The Commission further described clinical audit as involving:

'... 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.'

This description echoes the definition endorsed by the UK's National Institute for Clinical Excellence in the seminal text *'Principles of Best Practice in Clinical Audit'* (2002).

The Commission also recognised clinical audit as a key and essential component of clinical governance (2008, p. 12), stating that it:

'...constitutes the single most important method which any healthcare organisation can use to understand and ensure the quality of the service that it provides.'

1. Introduction

1.2 Setting the scene

Why clinical audit?

Clinical audit is a tool which can be used to discover how well clinical care is being provided and to learn if there are opportunities for improvement.

Clinical audit may be used to improve aspects of care in a wide variety of topics. It can also be used in association with changes in care provision or to confirm that current practice meets the expected level of performance.

There are many reasons to undertake clinical audit:

- Clinical audit offers a way to assess and improve patient care, to uphold professional standards and 'do the right thing'.
- Through clinical audit, healthcare staff may identify and measure areas of risk within their service.
- Regular audit activity helps to create a culture of quality improvement in the clinical setting.
- Clinical audit is educational for the participants. It involves being up to date with evidence based good practice.
- It offers an opportunity for increased job satisfaction.
- It is increasingly seen as an essential component of professional practice.
- It can improve the quality and effectiveness of healthcare.

Current drivers for clinical audit in the Irish Health Service (this list is not exhaustive).

- *The National Standards for Safer Better Healthcare* (HIQA, June 2012) are an important driver for participation in audit at all levels of healthcare. Monitoring and evaluation of performance by developing and implementing clinical audits and implementing improvements based on audit findings is required under these National Standards. In the future this will be reinforced by licensing legislation.
- *The Quality Framework for Mental Health Services in Ireland* (MHC, 2007) lists clinical audit as a mechanism through which healthcare staff can demonstrate a clinical governance system in compliance with Standard 8.3.
- Professional regulatory bodies, for example, the Medical Council of Ireland and An Bord Altranais, endorse audit as a mechanism for improving the quality and effectiveness of healthcare.

1. Introduction

- As part of the enactment of Section 11 of the Medical Practitioner Act 2007, participation in clinical audit is now required for all registered medical practitioners. Since May 2011, medical practitioners must be enrolled in a professional competence scheme and engage in professional competence activities. All registered medical practitioners should engage in clinical audit, and at a minimum participate in one audit exercise annually. The Act recommends that practitioners spend a minimum of one hour per month in audit activity.
- Clinical Audit in radiological practices is a legal requirement set out under Statutory Instrument 478 (2002), of the European Communities Regulations. This currently places a requirement on service providers to engage an external auditor, appointed by the HSE, to audit radiological practice every five years.
- Although not currently a legal requirement, many Health and Social Care Professional Bodies endorse audit as a way of measuring the quality of healthcare, for example, The Chartered Society of Physiotherapy and The College of Occupational Therapists.
- The Commission on Patient Safety and Quality Assurance (2008) recognised clinical audit as a key and essential component of clinical governance, which should be at the heart of clinical practice. The Commission also recommended that all health practitioners should actively participate in clinical audit in compliance with national standards and priorities.
- *The National Clinical Programmes Checklist for Clinical Governance* developed by the HSE Quality and Patient Safety Directorate (HSE, 2011) identifies a structured programme of clinical audit as an integral component of clinical governance and continuous quality improvement for the clinical care programmes. In order to ensure that the quality of care provided meets defined standards, a comprehensive system of clinical audit is required to support clinicians in identifying where standards are being maintained and where improvements are needed.
- The HSE '*Quality and Patient Safety Clinical Governance Development: an assurance check for service providers*' (HSE, 2012) identifies 'having a structured programme of clinical audit which is monitored for appropriateness and effectiveness on an annual basis (including participation in national audits)' as a corporate responsibility of the Board/CEO or equivalent.

1. Introduction

1.3 Scope of document

What is this document and who is it for?

The aim of this document is to support healthcare staff in understanding the concept and processes of clinical audit, to support best practice in clinical audit and improve awareness of clinical audit as an essential and integral component of clinical practice. To this end, this document provides a practical guide to the methodology of clinical audit. This document is primarily for all healthcare staff involved in or who have an interest in carrying out clinical audit.

What does it cover?

This document describes:

- The five step approach to clinical audit.
- Resources required to support clinical audit.
- Wider considerations (ethical issues/data protection/confidentiality).

This document also provides links to useful resources should more detailed information be required.

What does it not cover?

Although mentioned, it is not the aim of this document to define the management of or organisational structures required for clinical audit (locally or nationally).

The National Office of Clinical Audit (NOCA) oversees the running of national clinical audits. This document does not define the methodologies and governance structures employed by NOCA.

In addition, this document does not describe how to develop a clinical guideline. NCEC and other relevant resources to support Clinical Guideline Development Groups are available on the NCEC website www.patientsafetyfirst.ie

2. The five stage approach to clinical audit

2. The five stage approach to clinical audit

Clinical audit is a cyclical process which can be outlined in five stages:

Stage 1	Planning for audit
Stage 2	Standard/criteria selection
Stage 3	Measuring performance
Stage 4	Making improvements
Stage 5	Sustaining improvements

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

Figure 1 The clinical audit cycle



2. The five stage approach to clinical audit

2.1 Stage 1 – Planning for audit

If a clinical audit is to be successful in identifying areas of excellence or areas for improvement, it requires effective planning and preparation. The amount of planning and preparation will depend on the specific circumstances of each audit.



For example, an individual healthcare professional wishing to carry out an audit may not need to involve other stakeholders in the audit process. This is especially true if external support and resources are not required to carry out the audit or to support any subsequent changes in practice. On the other hand, when a multidisciplinary team are working together on an audit there will be greater need for planning to ensure a successful outcome for the audit.

Planning for audit can be described in three main steps:

Planning for audit

- **Step 1: Involving stakeholders**
- **Step 2: Determining the audit topic**
- **Step 3: Planning the delivery of audit fieldwork**

Step 1: Involving stakeholders

All relevant stakeholders should be given the opportunity to contribute to the clinical audit. A common question asked is 'which should come first: deciding on the topic for audit or involving stakeholders?' Ashmore, Ruthven and Hazelwood (2011a) recommend that stakeholders should be involved from the beginning of the clinical audit cycle through to completion. However, the answer to the question of 'which should come first' will depend on individual circumstances and the driver(s) for carrying out the clinical audit.

2. The five stage approach to clinical audit

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 topics and objectives of audit, it is necessary to identify:

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



Who is involved in the delivery of care?

The support of those involved in the delivery of care and their commitment to participate is essential for any audit.

The specific responsibilities of all those involved should be clarified and agreed before the audit commences (HSE, 2008) i.e. everyone should understand the aim of the audit and their role in it.

The lead clinician sponsoring the audit does not necessarily need to directly participate in the clinical audit but they should at least be aware of, and approve of, the performance of the audit (HSE, 2008).

As the majority of clinical practice involves multi-professional teams, clinical audit should cover the practice of the different clinical and managerial disciplines that contribute to the relevant audit topic area. The NHS Clinical Governance Support Team (2005) recommends that 50% of audits are multi-professional.

When preparing for clinical audit, agreement on leadership and ownership of the audit should be reached as well as responsibility for the management of audit results and recommendations (HSE, 2008).

Where possible, all those involved in the audit should be supportive of and committed to change(s) shown to be necessary by the audit results and recommendations arising.

2. The five stage approach to clinical audit

Who is in receipt of, uses or benefits from the care or service?

'The priorities of those receiving care can differ significantly from those involved in the delivery of care.'

(National Institute for Clinical Excellence, 2002, p9).



When planning any clinical audit, the audit team should consider the possible benefits of including service users in the audit process. For example, would it be beneficial to consider their experience of receiving clinical care?

Again the NHS Clinical Governance Support Team (2005) recommends that 10% of all audits should have active service user involvement.

Common methods of including service users in the clinical audit process

- **Gathering service user feedback, for example letters of complaint.**
- **Analysis of comments made at service user forums.**
- **Interview with service users.**
- **Service user surveys.**
- **Focus groups.**
- **Expert user groups.**
- **Examining critical incidents.**
- **GP liaison group.**

Where service users are involved in clinical audit programmes, their roles need to be clearly defined and appropriate support and guidance provided to enable delivery. (This should include the provision of information and guidance in relation to data protection requirements; *See Section 4.2, pages 61-65 for further information*).

2. The five stage approach to clinical audit

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.

(Walsh and Spurgeon, 1997 cited in HSE, 2008, p. 10).



Stages for stakeholder involvement

Various stakeholder groups may have different roles and be involved in different stages of the clinical audit. They can:

- Contribute to decisions regarding the topics and objectives of the clinical audit.
- Contribute to and/or comment on the clinical audit methodology, including the proposed clinical audit criteria.
- Assist with drafting and reviewing the project plan.
- Grant permission to access service user (patient) group.
- Provide support to the clinical audit team.
- Act as a source for data.
- Collect data.
- Review cases that do not achieve the expected level of performance (when the stakeholder is an expert).
- Provide explanations as to how a care process happens currently.
- Contribute to the analysis of audit findings, including analysis of problems identified.
- Assist in identification of actions to address areas requiring improvement.
- Secure resources required to support change.
- Monitor the implementation of agreed actions.
- Contribute to the analysis of the findings of repeat measurement.

Adapted from Dixon (2009a).

2. The five stage approach to clinical audit

Step 2: Determining the audit topic

This is a very important step that must be given careful consideration. Subjects for clinical audit should be selected with a view to improving the quality or safety of care or of service provision.



The Donabedian (1966) classification system of structure, process and outcome can be used to focus on areas of practice from which a topic may be selected:

Structure

Includes the:

- **resources required to deliver care;**
- **environment in which care is delivered;**
- **facilities made available (e.g. availability of single rooms);**
- **equipment made available (e.g. resuscitation equipment);**
- **and**
- **documentation of policies, procedures, protocols and guidelines.**

Process

- **the procedures and practices implemented by staff in the prescription, delivery and evaluation of care – these may be specific to the clinical process or service /administrative processes.**

Outcome

- **the effect of care received by service users as a result of healthcare provision and the costs to the service of providing care i.e. the result of clinical interventions.**

2. The five stage approach to clinical audit

Prioritising possible audit topics

Selection of the audit topic needs careful thought and planning, as clinical staff and service providers have limited resources with which to deliver clinical audits. Mandatory audits will take resource priority. All other audits should therefore be prioritised to ensure that available resources are used effectively. These audits should focus on areas with the greatest need to improve practice.



Questions to assist with prioritising audit topics

- Is the topic concerned of high cost, volume or risk to staff or users?
- Is there evidence of wide variation in clinical practice?
- Is good evidence available to inform audit standards (for example, systematic reviews or national clinical guidelines)?
- Is the problem measurable against relevant standards?
- Is auditing the problem likely to improve healthcare outcomes as well as process improvements?
- Is there evidence of a (serious) quality problem (for example, 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 audit process, or is a different process more appropriate (for example, root cause analysis, activity analysis or workload analysis)?
- How much scope is there for improvement, and what are the potential benefits of undertaking this audit?

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

2. The five stage approach to clinical audit

Other questions which can be asked include:

- Have there been major changes recently?
- Are there resource implications?

Levels of priority

Clinical audit activity may be managed according to different levels of priority:

- External 'must do' audit where participation is required due to government or regulatory requirements or as part of an accreditation scheme. As participation in national audits is recommended in the *'National Standards for Safer Better Healthcare'* (HIQA, June 2012), voluntary national audits should also be considered (for example, NOCA audits).
- Internal 'must do' audit where audit topics are based on requirements of the service provider's management team in response to incidents, risk management or complaints.
- Service/directorate priorities where audit topics are based on best practice guidelines, local policies, issues identified by professional bodies or other relevant topics arising from issues receiving regional or national attention.
- Clinician interest – locally initiated audits not covered by the above but which will contribute to the overall work of the service.

Using a scoring system to prioritise audit topics

Consideration should be given to all available audit topics and topics should be prioritised. A scoring system can help to rank topics in order of importance.

An example of a simple scoring system is where each topic is given a score between 1 and 5 based on importance (with 1 being the lowest and 5 being the highest) on two measures:

- (i) The impact of a resulting continuous improvement plan on clinical effectiveness and quality of care.
- (ii) The importance/urgency of the audit topic.

Further examples of scoring systems for prioritising audit topics may be found at:

<http://www.hqip.org.uk/assets/Downloads/Clinical-Audit-Program-Guide-and-Guidance-Tools.pdf>



2. The five stage approach to clinical audit

Clinical Audit Programme

Service providers should develop and implement a programme for clinical audit activity. This programme should give direction and focus with regard to how and which clinical audit activity will be supported in the service.

(Refer to Pages 54-55 for further information on clinical audit programmes).



Step 3: Planning the delivery of audit fieldwork

Understanding the aims and objectives of the clinical audit

The audit team must understand the overall purpose of the audit they are to perform. The delivery of an audit topic with no clear purpose will deliver little or no improvement to the quality and effectiveness of clinical care.

The purpose of the audit may be outlined in the form of aims and objectives. Buttery (1998) suggested that audit aims and objectives may be defined through the use of verbs such as:

Improve

Increase

Enhance

Ensure

Change

For example, an audit of healthcare records might have as its overall aim:

*'The **improvement** of adherence to healthcare records policy and procedures'.*

More detailed statements may be used to describe the different aspects of quality which will be measured to show how the aim of the clinical audit will be met, for example, an objective of the audit of healthcare records might be:

*'To **ensure** the content of the healthcare record provides an accurate chronology of events'.*

2. The five stage approach to clinical audit

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 be dependent on the size of the audit.

Skills required for clinical audit process

- **Leadership, organisational and management skills.**
- **Clinical, managerial and other service input and leadership.**
- **Project management skills.**
- **Change management skills.**
- **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. Depending on the nature of the topic that is being audited, the 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 a sustainable continuous improvement programme.

For a clinical audit to be delivered effectively, all staff should be appropriately trained and briefed with regard to their role. All team members should have:

- A basic understanding of clinical audit.
- An understanding of and commitment to the plans and objectives of the audit.
- An understanding of what is expected of the audit team – this needs to be clarified at the outset and may be expressed in a terms of reference document.

(Ashmore, Ruthven and Hazelwood, 2011a).

2. The five stage approach to clinical audit

Providing the necessary structures

Appropriate structures should be in place prior to the commencement of clinical audit work.

The clinical audit team should complete a clinical audit proposal proforma (see *Appendix one for sample template*). 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, audit tool and other documentation should be submitted to the appropriate responsible clinical lead, directorate or governance committee for consideration to ensure that the proposed audit meets the requirements of the service provider. Whether or not formal decisions to proceed are required will depend on local policy.

The team delivering the clinical audit should ensure that appropriate resources are available with which to perform the audit and to implement a sustainable continuous improvement programme. Where there is an insufficient level of resources available to deliver an audit and a sustainable continuous improvement programme, this issue should be raised through the appropriate governance structures as and when they arise. The clinical audit proposal proforma should include a system for requesting any support required for the clinical audit.

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 audit.

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

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 *Appendix two*).



2. The five stage approach to clinical audit

2.2 Stage 2 - Standard and criteria selection

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

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



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; and
- clinical guideline development organisations such as NICE, SIGN, etc..

If national or local guidelines are not available, a literature review may be carried out to identify the best and most up to date evidence from which audit criteria may be generated. Access to and assistance in utilising a vast library of knowledge resources is available through HSE library services at: www.hselibrary.ie

Section 6 of this document provides further information on relevant resources.

Defining terms

The terms 'standard' and 'criterion' often lead to confusion as these terms have been used differently by various professional groups and writers across healthcare.

For some, a standard is a statement of best practice. For others, a standard is the performance level or target for expected compliance (usually expressed as a percentage).

Whilst recognising the confusion that has occurred, the approach taken in this guide is consistent with the approach taken by the Health Service Executive when specifying standards; 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).

2. The five stage approach to clinical audit

Standard

Structures and processes needed to identify, assess and manage specified risks in relation to the subject area.



A standard describes and defines the quality of care to be achieved. Each standard has a title, which summarises the area on which that standard focuses. The standard statement which follows explains the level of performance to be achieved. 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.

Standard title	summarises the area on which that 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.

Standard criteria

Explicit statements representing elements of care which need to be achieved in order for that standard to be reached.

For criteria to be valid and lead to improvements in service user care, they should be consistent with SMART guidance:

- Specific (explicit statements, not open to interpretation).
- Measurable.
- Achievable (of a level of acceptable performance agreed with stakeholder).
- Relevant (related to important aspects of care).
- Theoretically sound or timely (evidence based).

2. The five stage approach to clinical audit

Criteria can be classified as:



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 physical space.**

Process criteria

- **(What is done), refers to the actions and decisions taken by healthcare professionals together with users and includes communications, assessments and prescription of surgical and other therapeutic interventions. The importance of process criteria is determined by the extent to which poor design and/or non adherence with processes in place influences care quality.**

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.**

2. The five stage approach to clinical audit

Measuring care

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



Target/level of performance

- **A defined level or degree of expected compliance with audit criteria; may be expressed in percentage or proportion of cases.**

Selecting and developing appropriate performance levels

Audit criteria should consist of measurable statements of what should be happening with explicit and quantifiable performance levels. These performance levels or targets may be expressed as percentages.

There are a number of ways to set targets for compliance, including discussion and development of a consensus opinion among audit team members and relevant stakeholders and benchmarking against national rates.

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

Clinical Importance

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

2. The five stage approach to clinical audit

Practicability

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 time frame within which service users should be seen in a particular outpatient clinic, a target of 90% may be deemed appropriate.



Acceptability

An optimum level of performance is set when the best care possible is identified given the resources available and normal conditions of care-giving. 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).

Inclusion/exclusion criteria

In order to ensure that the 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

- **Identify a target population to whom a clinical guideline is intended to apply.**

Exclusion criteria

- **Define areas outside the remit of the clinical guideline.**

Many evidence based clinical guidelines identify inclusion and exclusion criteria.

2. The five stage approach to clinical audit

Example 1

In a clinical audit on compliance with the clinical guideline NICE CG 52 (NICE, 2007) '*Drug misuse: opioid detoxification*', the following inclusion/exclusion criteria apply:



Inclusion criteria:

- Adults and young people who are dependent on opiates, who have been identified as suitable for a detoxification programme and who have made an informed decision to take part in a detoxification programme.

Exclusion criteria:

- Adults and young people whose primary drug of misuse is a non-opiate.
- Adults and young people who misuse alcohol, where the primary diagnosis and focus of intervention is alcohol misuse.
- Adults and young people who misuse other prescription drugs (for example, benzodiazepines).
- Adults and young people who misuse solvents (for example, aerosols and glue) or other street drugs (for example, LSD [lysergic acid diethylamide]).
- Adults and young people prescribed opiates and related drugs for therapeutic purposes unrelated to substance misuse.

Example 2

In a clinical audit on compliance with clinical guideline NICE CG61 (NICE, 2008) '*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.

2. The five stage approach to clinical audit

Exceptions

There may be a justifiable reason why some cases from the identified sample may not comply with specific audit criterion. In such cases the sample is not included in the data analysis.



Exceptions

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

Consensus on exceptions should be agreed before the start of the audit.

Example 1

The criterion involves treatment with a specific medication.

Possible exceptions:

- There is a contra-indication to the medication.
- Treatment had to be stopped due to side effects of medication.
- Patient choice – the patient declines this course of treatment.

Care should be taken that an exception is not a failure to comply with standard. For example, 'patient choice' may mask the fact that the patient was not given sufficient information about risks and benefits to confidently agree to treatment (UH Bristol Clinical Audit Team, 2009a).

Example 2

An audit on compliance with 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.

2. The five stage approach to clinical audit

2.3 Stage 3 – Measuring performance

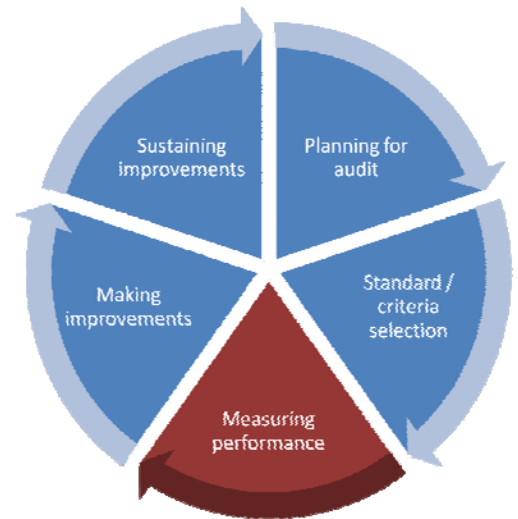
This stage may be described in steps as follows:

Step 1: Data collection

Step 2: Data analysis

Step 3: Drawing conclusions

Step 4: Presentation of results



Step 1: Data collection	Step 2: Data analysis	Step 3: Drawing conclusions	Step 4: Presentation of results
<ul style="list-style-type: none">• Collection of relevant data about current practice in order to facilitate comparison.	<ul style="list-style-type: none">• Convert a collection of facts (data) into useful information in order to identify the level of compliance with the agreed standard.	<ul style="list-style-type: none">• Identify the reasons why the standard was not met.	<ul style="list-style-type: none">• Maximise the impact of the clinical audit on the audience in order to generate discussion and to stimulate and support action planning.

Step 1: Data collection

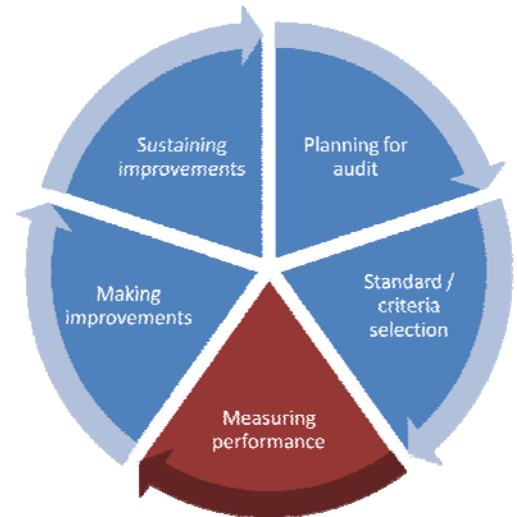
The overall objective of clinical audit is to improve the quality of care and outcomes by measuring current practice against best practice. When the standards against which the audit will be conducted have been identified, the next step in the audit process is the collection of relevant data about current 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 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 user group to be included, with inclusion/exclusion criteria defined.
- The consent required to access user group information.
- The healthcare professionals involved in the service user's care.
- The time period over which the criteria apply.
- The analysis to be performed.

2. The five stage approach to clinical audit

Resources should be used effectively to collect the minimum amount of data necessary to achieve the audit objectives. Resource utilisation decisions should be made at the outset of the audit and revised, if appropriate, during the audit process. Due cognisance should be given to data protection requirements. (See section 4.2, pages 61-65 for further information).



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 and accurate.

Questions to assist when 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 or not performance levels have been met for each standard?**
- **What data sources will be used to find the data?**
- **Will a data collection tool need to be designed?**
- **Will I need to collect data prospectively and/or retrospectively?**
- **What size is the target population and will I need to take a sample?**
- **How long 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 (2011b).

Data type

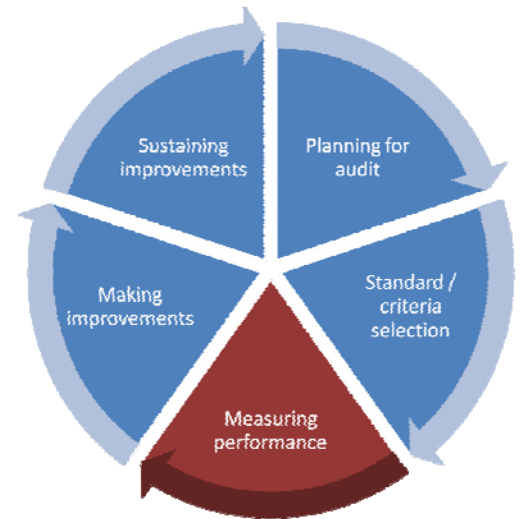
The type of data required is dependent on the audit question and objectives. The aim of data collection is to enable comparison of current practice against the audit standard; therefore the type of data collected must facilitate this comparison.

Appendix three of this document provides further information on data type and classification.

2. The five stage approach to clinical audit

Data items

All data collected must be relevant to the aims and objectives of the audit. It is equally important that each data item is adequate and not excessive for the purpose of measurement of practice against the relevant audit criteria. Collection of data which is not required for the purposes of measurement provides little or no benefit, is more time consuming and may infringe compliance with information governance requirements and practices. (See section 4.2, pages 61-65 for more information).



When standards of best practice, 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 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 an audit should be specified and agreed by the audit team. The source specified should provide the most accurate and complete data as readily as possible.

Where possible, relevant, routinely collected raw data from existing sources should be used for the purposes of the clinical audit as this avoids duplication of information and work and allows for repeated data collection and re-audit with minimum effort. Examples of such sources are clinical information systems, service user records, HIPE and observation of practice.

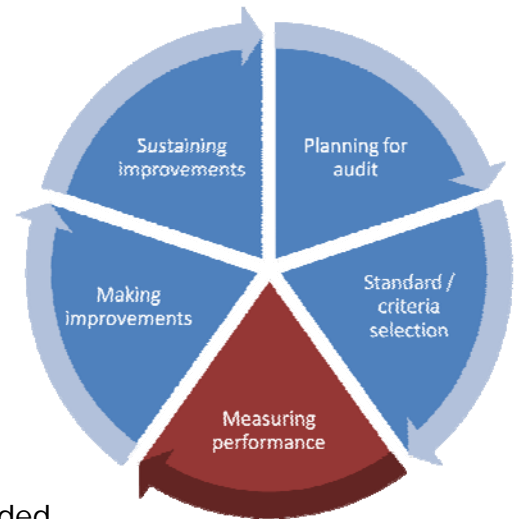
However, such records may be incomplete. Collection of data from several sources may overcome this problem. The audit may only need data specific to the question at hand and as a result the collection of new data is necessary. In such cases, only data relevant to the audit is collected rather than collecting a large amount of data and then deciding what is needed.

2. The five stage approach to clinical audit

Data collection tool

The following principles should apply when a data collection tool is being developed (for example, data collection forms or questionnaire):

- The data to be collected should be relevant to the objectives and criteria for the audit and the expected performance levels.
- Acronyms, jargon and technical terms should be avoided.
- Definition of terms used should be included where necessary (involves defining terms in the audit criteria and known exceptions).
- There should be space to record exceptions.
- Questions should be episode-specific i.e. relate to a specific episode of care.
- Closed questions should be used, these should be clearly worded and contain no ambiguity i.e. clarify the format for the answer (for example, date: day/month/yr).
- 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.
- Filters should be used in order to make the process of completing the tool as quick and efficient as possible, for example, 'if Yes, go to question four'.
- Data items should be presented in a logical order i.e. the tool should not require the person collecting or analyzing the data to skip backwards and forwards.



Appendix four of this document provides further tips for the successful development of clinical audit collection tools.

Data collection strategy

A data collection strategy should be decided following consideration of the audit topic and objectives. Factors affecting selection of a data collection strategy for a clinical audit include:

- Feasibility in terms of resources and time frame to implement the data collection strategy.
- What data collection strategy is most likely to result in complete and reliable data?

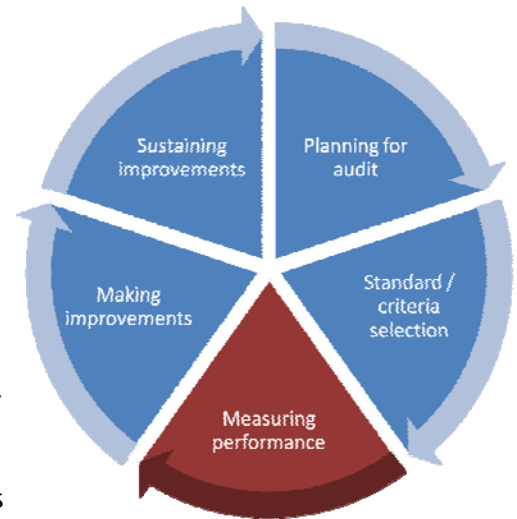
2. The five stage approach to clinical audit

Retrospective data collection

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

Advantages include:

- The data already exists and may be gathered quickly.
- The possibility of identifying all service users meeting the inclusion criteria may be increased; however, this is dependent on being able to identify relevant service users through coding or other records systems.



However, such data can quickly become out of date and the data available may not be complete and accurate.

Concurrent/prospective data collection (looking forward)

Concurrent data is collected while treatment/care is being provided. Prospective audit involves planning the recording of data on care which will be provided. The terms concurrent and prospective are sometimes used interchangeably. If the data required is not routinely collected, a prospective or concurrent audit should be undertaken.

Disadvantages to prospective data collection include:

- Time is required to collect the data.
- When data is collected concurrent with patient care, there is a potential for bias - will clinical practice be affected by the knowledge that an audit is ongoing?

Deciding on a population or a sample

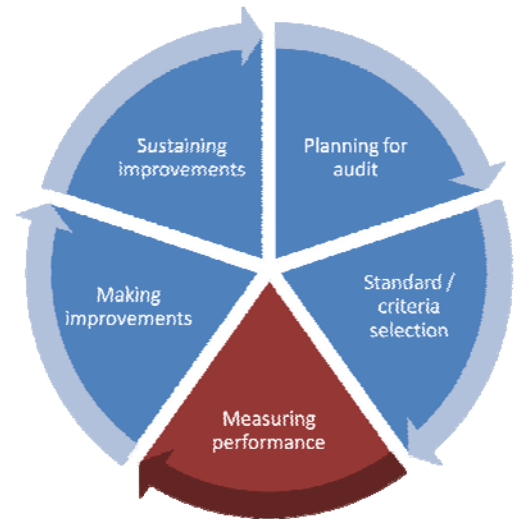
In order to decide on a population or a sample, it is first necessary to define the population of concern (target population). A population can be defined as including all the service users, events, cases, situations or items on which the audit is focused. A sample is a part of the population of interest.

In order to determine which is suitable for the purposes of the clinical audit, the following should be considered:

- The audit's inclusion/exclusion criteria (in order to identify the relevant population).

2. The five stage approach to clinical audit

- Timeframe/time interval, for example, the previous year, the next three months - is the time period from which cases are to be drawn appropriate for the objectives of the audit?
- The size of the population.
- What resources are available for the audit?
- Whether sampling or population is most appropriate?
- What sample selection method should be employed?



Sample selection methods

It is often not possible or necessary to gather data on all service users, events or items for 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 In-patient 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.

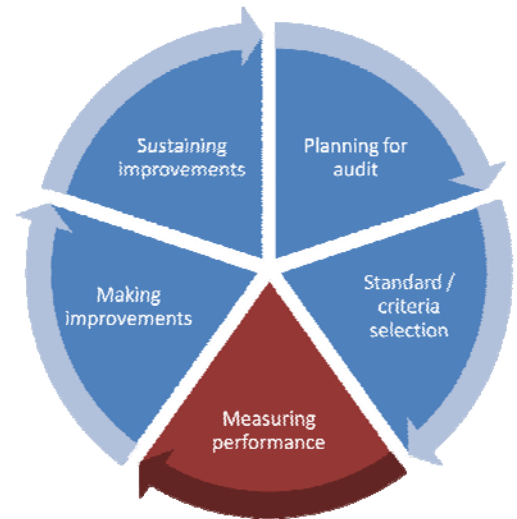
Sample size

Clinical audit is not research. It is about evaluating compliance with 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 i.e. time, access to data, costs.

2. The five stage approach to clinical audit

When determining the number of sample subjects, consideration should be given to the level of assurance required from audit results and any constraints which may impact upon the audit.

For many audit topics, a small amount of data may be sufficient for the purposes of the audit; however, if a contentious issue is being audited a larger sample size may be required.



- 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.

The sample should be small enough to allow for speedy data collection but large enough to be representative. In some audits the sample will be time driven and in others it will be numerical.

- If the data collection takes too long, interest will be lost and data completeness will suffer.
- In numerical audits, the number of cases selected should reflect the commonness of the condition or therapy, but should be of reasonable number to draw subsequent conclusions.
- In time based audits one to three months should be adequate for the majority of audits.

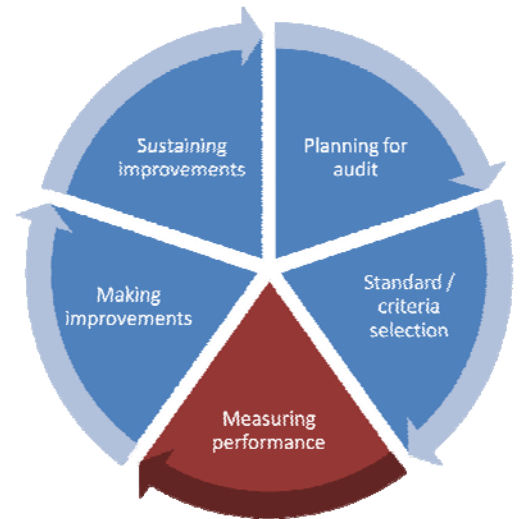
(NHS Clinical Governance Support Team, 2005).

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

2. The five stage approach to clinical audit

How should data be collected (manually and/or electronically)?

The most appropriate method for data collection should be utilised, for example, pocket PCs or paper based audits. As clinical audit records must be retained for five years (National Hospitals Office, 2007), electronic storage is optimal.



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 audit completion.

Who collects the data?

Depending on the 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 know and understand who is responsible for the various elements including what, how and where the data is to be recorded.

Ensuring data quality

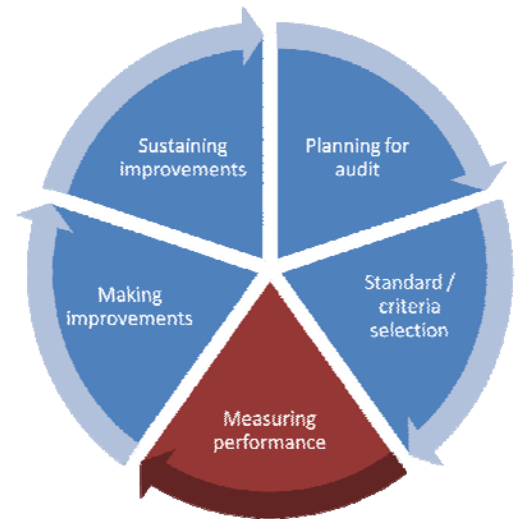
Data can be said to be of good quality when it does what it is needed to do. There should be clear definitions for each data item to be collected to ensure that data collectors have a good understanding of what, how and when data needs to be collected. There should also be routine data quality checks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

(Health Information and Quality Authority, 2010).

2. The five stage approach to clinical audit

Pilot

Before collecting the data for the full audit sample, a pilot should be considered. Piloting a planned audit and its methodology can provide evidence as to whether the proposed methodology is feasible. Potter, Fuller & Ferris (2010) suggest pilot testing of a 10% sample of the planned sample size has the potential to save a great deal of time.



A pilot may:

- reveal problems such as a data collection tool which is difficult to understand or to complete; or
- be used in order 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.

Step 2: Data analysis

Data collection is only part of the process of measuring performance, in order 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 in order identify the level of compliance with the agreed standard.

Collation of clinical audit data

Collation of data involves the gathering together of all data collected during the period of the audit. This may involve transferring the data collected from the data collection tool onto summary sheets (manual data collection) or onto a spreadsheet or database (manual or electronic data collection) for interpretation. When electronic files are used, service user data should be recorded anonymously with the use of a unique identifier and files should be password protected.

2. The five stage approach to clinical audit

Coding of data

Use of a data coding sheet or a coding manual may assist if data is to be entered onto a spreadsheet or a database for analysis. This is where a simple numeric code is assigned to all the possible answers for each question in the data set.

A number of variables (characteristics) may be measured for each subject, for example, in the case of a person; variables could include gender, age and ethnicity.

A variable such as age may be entered directly into a database, however for variables such as gender or ethnicity it is necessary to identify a coding system. For example, in the case of gender, 1 may be assigned for 'male' and 2 for 'female', similarly if one question requires a yes or no answer, 1 may be assigned for 'yes' and 2 for 'no'. In the case of questions such as ethnicity, each ethnic group is allocated a different number and the appropriate number is entered onto the spreadsheet/database.

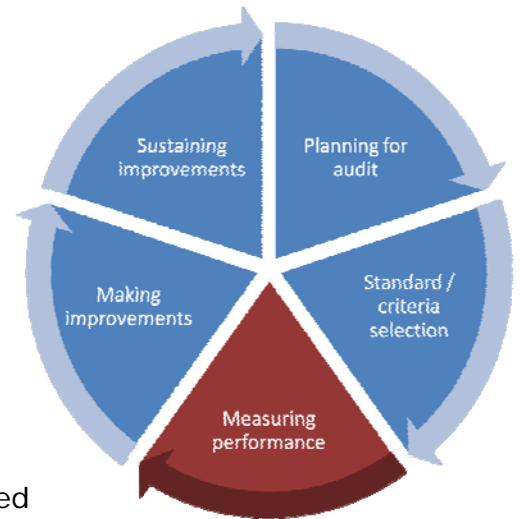
When a coding manual is used, a clear consistent coding scheme should be used, including codes for missing or unavailable data. 9 is the universal code for missing data or 99 if options are higher than 9. Where free text is used, code the text information by category wherever possible, for example, disease groups, therapeutic drug groups. A key question to ask is whether an independent person could review the spreadsheet, understand it and draw the same conclusions from their own independent analysis.

Organisation of clinical data

Once the data is collated, it needs to be organised in a logical way to enable analysis. This may involve preparing tables of data, grouping the data, for example, waiting time <1hour, 1- 4hours, > 4hours or summarising using descriptive statistics.

Checking/interpreting the data

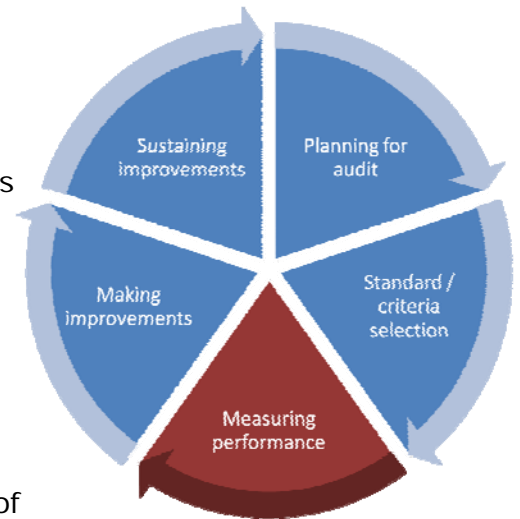
Interpretation of data involves looking for patterns in the data sets. Inconsistent or missing data should be reviewed as errors in data collection or transfer may have occurred. It may be necessary to check back to the original records to identify errors.



2. The five stage approach to clinical audit

Type of data analysis

The main aim of data analysis is to answer the questions posed by the 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 in order 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 sophisticated statistical techniques.



For the majority of 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 required in order to stimulate change.

For the single healthcare professional carrying out an audit with a small dataset, a pen, paper and calculator may be all that is required to carry out a simple analysis. Alternatively a spreadsheet program such as Microsoft Excel may be a useful tool. By using this program it is possible to perform the calculations required and to produce tables, charts and graphs for presenting and comparing information in a simple, easy to understand format.

Calculating compliance with clinical audit criteria

The basic requirement of an audit is to identify whether or not performance levels have been reached. This requires working out the percentage of cases that have met each 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 denominator group that met the criterion (the numerator).

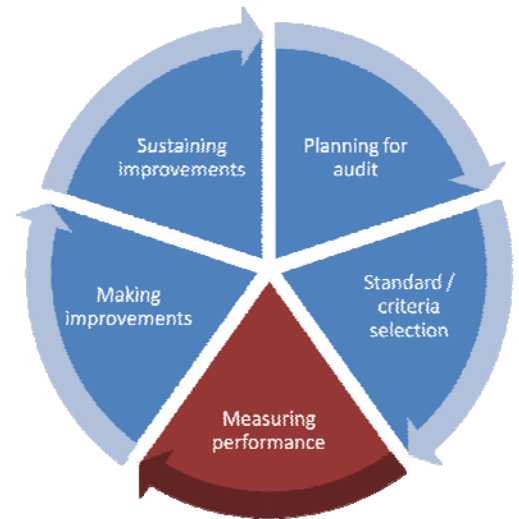
The percentage is then calculated by dividing the numerator by the denominator and multiplying the answer by 100.

$$\frac{\text{Numerator}}{\text{Denominator}} \times 100$$

2. The five stage approach to clinical audit

The most important factor in preventing errors when calculating the percentage of cases that have met the audit criterion is ensuring identification of the correct denominator.

The denominator is the total number of cases to which the audit criterion applies.



This figure is obtained by subtracting cases meeting any agreed exceptions for a particular criterion (*refer to Stage 2, page 28*) from the total number of cases which meet each of the inclusion criteria and none of the exclusion criteria.

Example

Using the previously referenced clinical guideline NICE CG61 (NICE, 2008) '*Irritable bowel syndrome in adults; diagnosis and management in primary care*':

Audit 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.

The total number of cases to which this audit criterion applies, is identified by determining the number of cases which may be included/excluded in the audit sample using the inclusion/exclusion criteria below and then subtracting any case which meets the agreed exception:

- *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 laxative or anti-motility agent.

2. The five stage approach to clinical audit

Descriptive statistics

Descriptive statistics may be used to describe the basic quantitative (numerical) features of data in a study.

A descriptive statistic reduces lots of data into a simpler more understandable summary.

The nature of the 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 standard deviation.

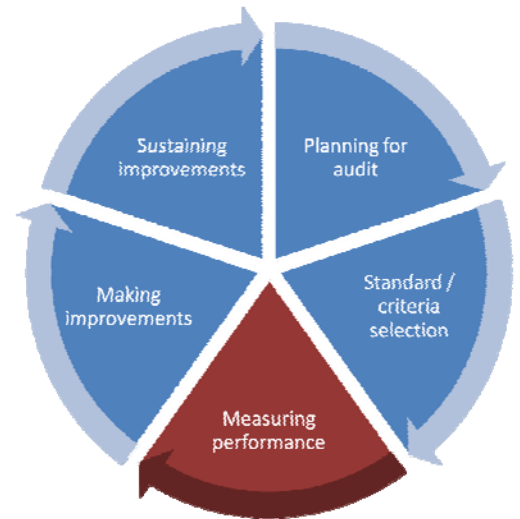
More elaborate statistical manipulation is possible but not necessary in any clinical audit – effecting change is more important.

Appendix five contains a glossary of terms relating to descriptive statistics.

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 different 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 audit results against previous audit results.

Please refer to Step 4, Presentation of results (pages 44-45), for further information on effective data display and presentation.



2. The five stage approach to clinical audit

Step 3: Drawing conclusions

After results have been compiled and the data has been analysed against the standards, the final step in the process (where applicable), is to identify the reasons why the standard was not met.

In order to understand the reason for failure to achieve compliance with clinical audit criteria, the audit team should carefully review all findings. Individual cases where care is not consistent with criteria should be reviewed to find any cases which may still represent acceptable care.

Cases of unacceptable care should then be reviewed in order for the team 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.

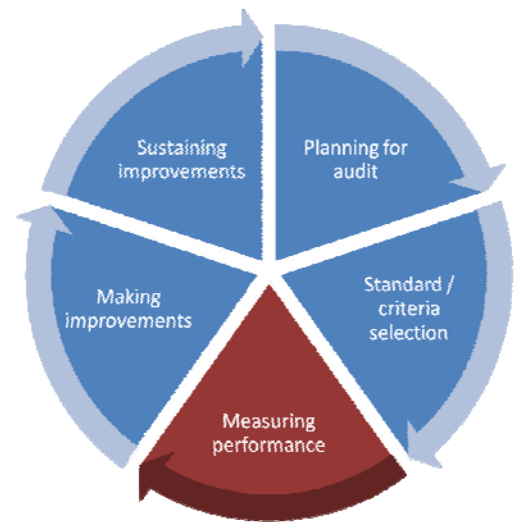
There must be a clear understanding of the reasons why performance levels are not being reached to enable development of appropriate and effective solutions. There are a number of tools that can be utilised to facilitate a root cause analysis, including process mapping, the 'five whys' and cause and effect diagrams (fishbone diagramming).

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

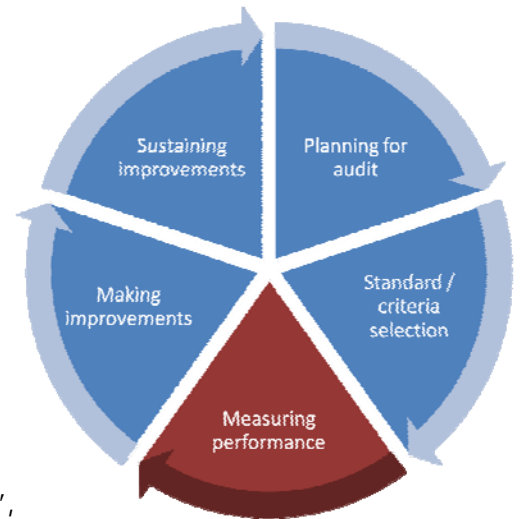
Involves repeatedly asking the question 'why?' in order to drill down further into an issue which can lead to the cause of the problem. The reason for any problem can often lead to another question. Asking 'why' five times is only a guide as depending on the issue, the question may be asked a lesser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



2. The five stage approach to clinical audit

Cause and effect (fishbone) diagramming

This is a graphic problem solving tool that can be used to explore and display the possible causes for effects or problems. It can be used to structure a brainstorming session as it can help to sort ideas into various useful categories.



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.

2. The five stage approach to clinical audit

Step 4: Presentation of results

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

There are various different methods for the presentation of clinical audit results including:

- Visual presentations, for example, posters which are useful ways of reaching as many stakeholders as possible. Data can also be presented visually using tables, charts and graphs in both written and verbal presentations (for example, through using presentation software like Microsoft PowerPoint).
- Written reports for submission to the relevant clinical lead, directorate or governance committee.
- Verbal presentations at relevant meetings.

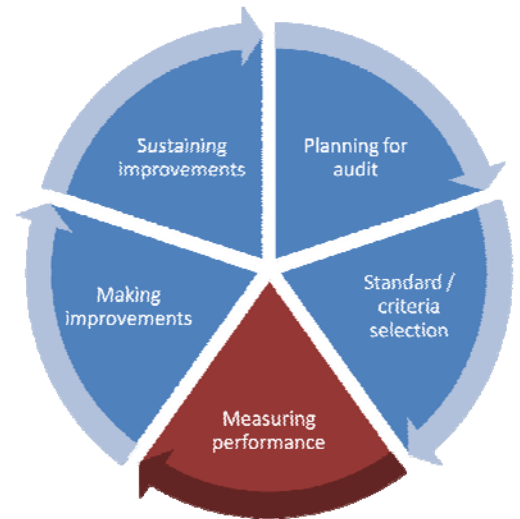
Visual presentation of data

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 much stronger than just describing the data.

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

Appendix six of this document contains further information on the presentation of data using tables, graphs and charts.

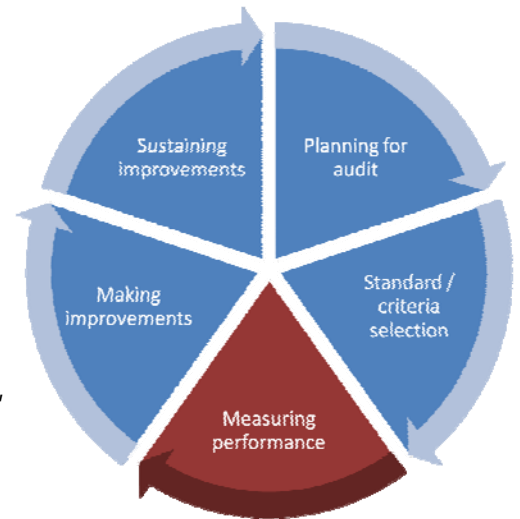


2. The five stage approach to clinical audit

Written Reports

An audit report should be written as soon as all audit data has been analysed. Graphical analysis should be used to visually demonstrate audit results.

The audit report should outline the purpose of the audit, the criteria measured, the actual performance achieved and a comparison of actual performance against the selected best practice benchmarks or high quality evidence based standards of care.



The report should clearly identify:

- Areas for improvement, for example, unrecorded practice, practice not occurring, poor levels of service user satisfaction.
- Causes, for example, poor documentation, inadequate staffing, training and practice issues.
- Needed improvements, for example, the introduction of a structured assessment pro-forma for service users with asthma so that all relevant service user data and examination findings are checked.
- Information explaining why some cases do not meet the required standards.
- Relevant, meaningful and useful information that will help to identify and address issues arising from the audit.

Appendix seven contains further information on the clinical audit report.

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

2. The five stage approach to clinical audit

2.4 Stage 4 – Making improvements

The purpose of performing clinical audit is to assess the degree to which the clinical services offered comply with the accepted evidence based practice standard.

Clinical audit results may show areas of excellent or 'notable practice' and this should be acknowledged. For such audits there should be an explicit statement saying 'no further action required' in the audit summary report and a rationale why re-audit is not required.



Clinical audit results may also identify 'areas for improvement' where the required standards are not being met.

Ashmore, Ruthven and Hazelwood (2011c) identify clinical audit as a change process, stating:

'audit that simply measures but does not drive change to address problems identified, is not good audit. All good audit projects must include a programme of change activity and post-identification of the findings from audit, to ensure necessary changes happen.'

The clinical audit group should interpret and discuss the findings in order to clarify the areas where action is required so as to improve the quality of clinical care and its outcomes. Where audit has shown that there are serious concerns regarding the practice of an individual, these should be conveyed immediately to the audit sponsor, who should inform the manager of the service for urgent action.

All audit reports should be shared with the service, specifically with the relevant Head of Department, Head of Service and Governance Group. Where audits are instigated by a particular committee/group, reports should be submitted to the committee/group for review and action.

2. The five stage approach to clinical audit

Change is often the most difficult part of the audit. When the audit team have developed the recommendations, decisions should be made on how changes can be introduced and monitored. Results should be used in conjunction with feedback and local consensus to change clinical practice and to improve standards.



Priorities for action should be identified and these should be clearly documented. All audits should be accompanied by a quality improvement plan in order to achieve the required improvements in practice.

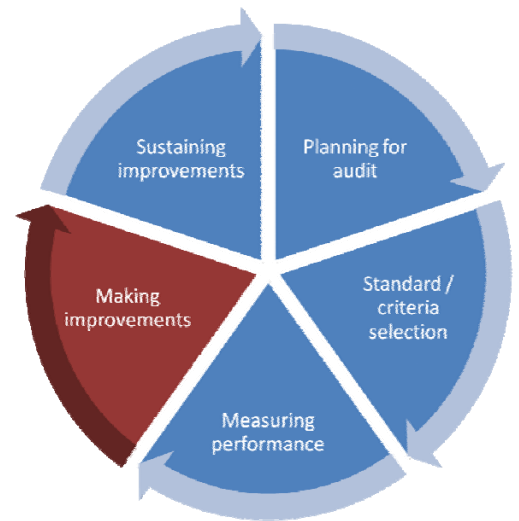
Quality improvement plans (QIPs)

Quality improvement plans can be developed to address those areas requiring improvement. It is important that improvement tasks or actions outlined in the QIP relate to local and national priorities or targets and the service provider's own available resources. QIPs should also be integrated into the existing management system of the service provider to monitor implementation.

Quality improvement plans should be time limited with clear milestones and concrete recommendations. Responsibilities for implementing tasks or actions should be clearly allocated to staff who carry the necessary authority to effect such change. Sometimes, QIPs and associated actions or tasks are beyond the scope or domain of individuals. In these cases, the support and backing of the service is fundamental to the success of the audit.

Note: There may not be QIPs against every standard; priorities should be identified, for example, through risk assessment to identify areas of highest risk. Risks identified as a result of clinical audit should be submitted for inclusion on the appropriate risk register. The governance committee should be responsible for escalating those high and very high risks up the line for possible inclusion in higher level risk registers, for example, hospital, regional or national risk registers.

2. The five stage approach to clinical audit



Writing quality improvement plans

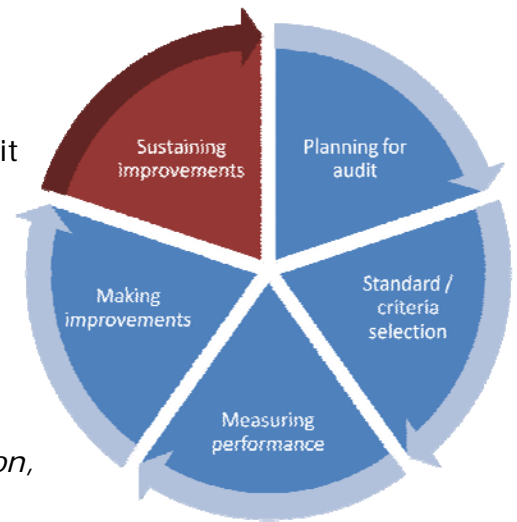


2. The five stage approach to clinical audit

2.5 Stage 5 – Sustaining improvements

The audit cycle is a continuous process. A complete audit cycle as described by Ashmore, Ruthven and Hazelwood (2011d, p.93):

'... ideally involves two data collections and a comparison of one with the other, following implementation of change after the first data collection, in order to determine whether the desired improvements have been made. Further cycles may be necessary if performance still fails to attain the levels set at the outset of the audit. At this stage there may be justification for adjusting the desired performance levels in the light of the results obtained.'



Where quality improvement plans are put in place, monitoring should be performed to ensure plans are implemented as agreed and within the agreed timeframe.

Clinical leads and/or managers who agree to implement quality improvement plans are accountable for the delivery of quality improvement plans and sustaining quality improvement. A summary report of progress should be submitted through the appropriate lines of responsibility at regular intervals.

The appropriate governance committee is responsible for monitoring and reporting the progress of implementation through the reporting structure. The progress of any quality improvement plan associated with an audit should be formally assessed at regular intervals and appropriate actions to be taken should be determined where progress is not being maintained.

Where plans have not been implemented, a rapid re-audit is recommended to ensure that changes have indeed improved practice and to ascertain whether further audit procedures are required in the short term.

2. The five stage approach to clinical audit

Performance indicators

Performance indicators can be used to monitor improvements as a result of quality improvement activities. A small number of key performance indicators may be developed for each quality improvement programme to monitor implementation of the improvement plans.



A red, amber and green traffic light system can be used to monitor implementation status. This system can also be used to measure the impact of change on practice when performing rapid re-audits.

Evaluating audit quality

It is recommended that the quality of an audit programme is evaluated as part of the wider quality and risk management agenda (NICE, 2002). Service providers should assess their structures, processes, outcomes and resources for audit activities. All clinical audits should be conducted in a manner that complies with legislation, guidance and service provider policies relating to confidentiality and data protection.

Dissemination and celebrating success

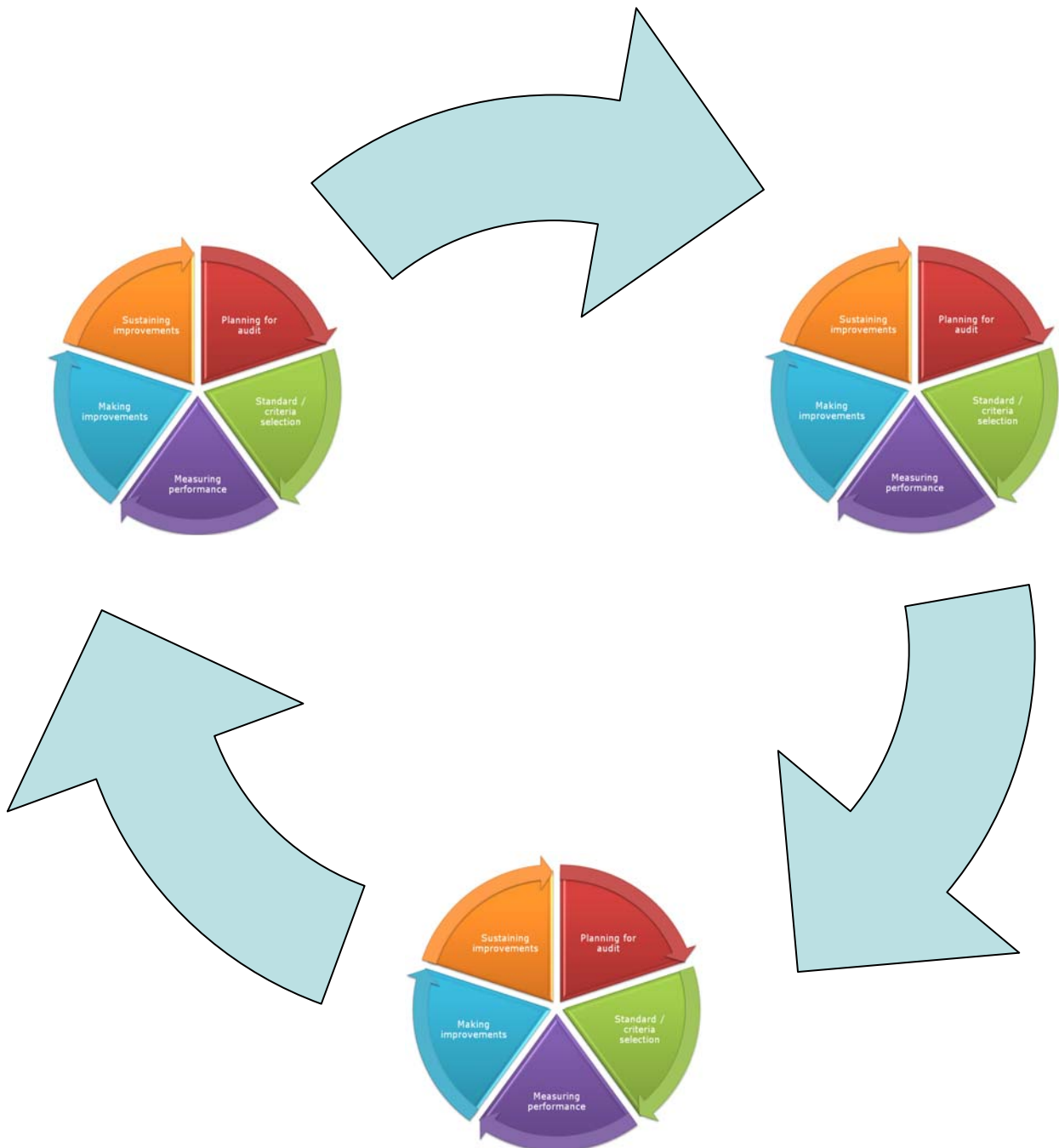
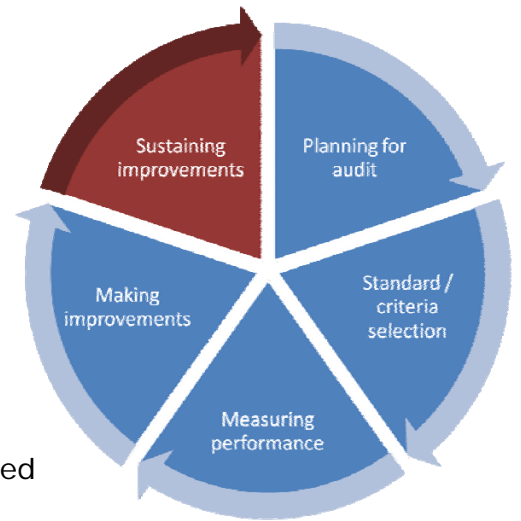
Completion of an audit cycle will usually result in improvements in practice. This should be communicated to all stakeholders.

A successful audit in one service may be transferable to other parts of the service. Completed audits should be shared locally via the most appropriate mechanisms, including department quality and safety meetings, journal club meetings, the intranet, newsletters and local conferences and seminars. Consideration should also be given to sharing clinical audit work regionally and nationally through relevant journals, conferences and other media.

2. The five stage approach to clinical audit

Remember to close the loop by re-auditing

Audit is a continuous cycle. If following an initial audit it is found that desired performance levels are not being reached, and a programme of change activity has been put in place; then the audit should be repeated to show whether the changes implemented have improved care or whether further changes are required. This cycle is repeated until the desired performance levels are being achieved.



2. The five stage approach to clinical audit

2.6 Summary – The five stage approach to clinical audit

The Stages of Clinical Audit



Stage 1 - Planning for audit

- **Involving stakeholders**
- **Determining the audit topic**
- **Planning the delivery of audit fieldwork**

Stage 2 – Standard and criteria selection

- **Identification of standards and audit criteria**
- **Selecting and developing appropriate performance levels**
- **Inclusion/exclusion criteria**
- **Exceptions**

Stage 3 - Measuring performance

- **Data collection**
- **Data analysis** – measure actual performance against standard
- **Drawing conclusions**
- **Presentation of results**

Stage 4 – Making improvements

- **Development of quality improvement plans (QIPs)**

Stage 5 – Sustaining improvements

- **Monitoring the quality improvement plan**
- **Performance indicators**
- **Dissemination and celebrating success**
- **Remember - close the loop - re-audit**

3. Resources required to support clinical audit

3. Resources required to support clinical audit

3.1 Service provider support

For clinical audit to be effective it requires commitment and support throughout the service including senior management. Clinical audit should be seen to be recognised as a valued activity and should be included as a priority in service planning.

Recommendation 7.8 of the *Report of the Commission on Patient Safety and Quality Assurance – Building a Culture of Patient Safety* (2008, P. 161) states:

'Every healthcare facility should develop and implement an Annual Clinical Audit Forward Plan as part of its annual planning and delivery cycle for clinical audit activities and the facility's safety and quality governance framework. This Plan should reflect the national, service, team and individual audit requirements on the facility. It should be the responsibility of the Clinical Leader, with accountability for safety and quality at Board level, to ensure that the Plan is developed and implemented with effective clinical engagement and reported to the Board of the facility.'

A. Clinical audit strategy

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

Clinical audit strategies should begin with a statement of the service provider's commitment to the process of clinical audit and to delivering the objectives set out in the strategy.

3. Resources required to support clinical audit

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 its corporate objectives.
- Provide a medium to long term vision for the development of clinical audit for example, 3 -5 years.
- Set out a number of service objectives for the period covered by the strategy.

Healthcare Quality Improvement Partnership (2012).

Progress in delivering the plan and meeting objectives should be monitored on a regular basis. The plan should be revised and updated annually.

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

B. Clinical audit policy

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

The target audience of a clinical audit policy should be everyone involved in the clinical audit process.

C. Clinical audit programme

Each service provider should have a 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.

It should be based on the service providers priorities for clinical audit (*see section on prioritising audit topics and levels of priority on pages 17-18 of this document*).

Acknowledging that the audit cycle includes re-audit, a proportion of topics for re-audit should also be included in the annual audit plan.

3. Resources required to support clinical audit

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.

Resources to support the delivery of a clinical audit programme

- 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.

Adapted from Dixon and Pearse (2011).

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

D. Clinical audit leads

There are different levels of clinical audit lead, for example, at service, divisional or speciality level. At service level the clinical audit 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.

3. Resources required to support clinical audit

E. Fostering a culture which is supportive of clinical audit

Requirements of a culture supportive of clinical audit:

- 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 audit programmes including a designated lead whose responsibility is to organise, develop, improve and support the performance of clinical audit within the service.
- Strategy and planning in audit programmes.
- Resources and support for audit programmes.
- Monitoring and reporting of 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 involving and relevant and thus fosters positive attitudes to further participation.

F. Practical supports for clinical audit

Provision of practical supports 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 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.

3. Resources required to support clinical audit

3.2 Clinical audit facilitation

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

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

- Project planning.
- Proforma 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, computing, and statistical analysis. The training needs of clinical audit facilitators should be recognised and resources should be made available in order to facilitate their attendance at appropriate courses.

In relation to clinical audit, the aim of clinical governance is to support changes to improve practice identified by the clinical audit process through ensuring the engagement of senior management and senior clinicians in the process of oversight of audit thus providing the leadership and managerial commitment which is required for successful clinical audit practice.

Clinical audit can provide the required evidence to show how well a service is meeting a desired standard of clinical care and providing quality care to service users. It can also demonstrate the effectiveness of implemented changes and leadership.

4. Wider considerations

4. Wider considerations

Consideration also needs to be given to ethical and data protection issues in relation to clinical audit.

4.1 Ethical issues

A. *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 that data is collected and stored appropriately (UH Bristol Clinical Audit Team, 2009b).

No clinical audit should examine the work of another professional or speciality without their knowledge. All those whom the audit will directly affect should be informed of and if possible, involved in, the 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 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, anonymisation of data) and the length of time for which their personal information will be held.

4. Wider considerations

Anyone conducting an 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 audit.

Clinical audits involving questionnaires posted to service users' homes should be accompanied by a written explanation of the purpose of the questionnaire/audit along with an identified contact name and number (usually the audit lead or an audit facilitator). While encouraging participation for improvement purposes, the letter should also state that recipients are under no obligation to take part in the 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.

Where there is a possibility that the audit may be intrusive to service users, for example, in cases where a service user is asked to complete a questionnaire or undergo an interview which may involve asking sensitive questions, those involved in managing the audit should seek ethical advice.

B. *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 required 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 audit and research*'.

Guidance from the Irish Council of Bioethics (2004) suggests that clinical audits do not require the approval of the Research Ethics Committee. This guidance assumes that audit never involves disturbance to the service user beyond that required for normal clinical management.

4. Wider considerations

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 the activity subject a service user to more than a minimal burden or risk if it requests sensitive information or is 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 user records include clinical staff providing direct patient 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 audit team is concerned about the ethicality of their audit, ethical advice should be sought.

4. Wider considerations

4.2 Issues of data protection

A. *Data protection responsibilities*

Legislation around data protection and service user record confidentiality must be complied with when performing clinical audits. The Data Protection Acts 1988 & 2003 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.

B. *Data protection principles*

Anyone processing personal data must comply with the eight rules of data protection in line with the Data Protection Acts, 1988 and 2003:

- Obtain and process information fairly.
- Keep it only for one or more specified, explicit and lawful purposes.
- Use and disclose it only in ways compatible with these purposes.
- Keep it safe and secure.
- Keep it accurate, completed and up to date.
- Ensure it 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.

C. *Data protection 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 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 audit is to be carried out by the health facility itself.'

However, the Data Protection Acts 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.

4. Wider considerations

Where access to service user identifiable information is not accompanied by explicit consent, the Data Protection Acts require 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.

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 2003.

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.

D. 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 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).

4. Wider considerations

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 anonymised. *(See section F, pages 64-65 for further information.)*

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.

E. Confidentiality and access to service user health information

The 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 audit conclusions, service users or healthcare staff should be possible.

All 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 2003:

- 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 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.

4. Wider considerations

- 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 five 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 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 audit purposes should be made anonymous by appropriately authorised individuals before being made available for review and consideration by others.

F. Anonymisation of data

The anonymisation 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.

4. Wider considerations

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 recognised 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 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 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. At the time of writing this document, a Health Information Bill is being drafted. It is likely, when enacted, that it will contain a number of provisions around the governance of personal health information.

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UH Bristol Clinical Audit Team (2009a). *How to: Set an Audit Aim, Objectives & Standards*. Available at: <http://www.uhbristol.nhs.uk/files/nhs-ubht/4%20How%20to%20Aim%20Objectives%20and%20Standards%20v3.pdf>

UH Bristol Clinical Audit Team (2009b). *How to: Apply Ethics to Clinical Audit*. Available at: <http://www.uhbristol.nhs.uk/files/nhs-ubht/10%20How%20To%20Ethics%20v3.pdf>

Wade, DT (2005). Ethics, audit, and research: all shades of grey. *British Medical Journal*, 330: 468-73.

6. Additional resources

Additional reading

G Johnston, I Crombie, E Alder, H Davies, and A Millard. (2000). Reviewing audit: barriers and facilitating factors for effective clinical audit. *Quality in Health Care*. 9(1): 23–36. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1743496/>

A series of helpful clinical audit guides have been produced by the University Hospital Bristol Clinical Audit team and can be accessed at: <http://www.uhbristol.nhs.uk/for-clinicians/clinicalaudit/how-to-guides>

The Health Information and Quality Authority has published a useful guide for front-line health and social care staff about the importance of data quality as part of the process of providing safe and effective services. This can be accessed at: <http://www.higa.ie/publications/what-you-should-know-about-data-quality-guide-health-and-social-care-staff>

Professional bodies and organisations offering support for clinical audit

<http://www.patientsafetyfirst.gov.ie/>

- This website outlines ongoing patient safety initiatives and activities in Ireland including progress of the 12 project groups which are driving the implementation of recommendations from the Commission on Patient Safety and Quality Assurance.

<http://www.hseland.ie/tohm/default.asp>

- Health Service Executive online resource for learning and development. Register for clinical audit e-learning programme.

<http://www.hselibrary.ie/>

- Developed and maintained by a team of librarians across the Health Service Executive, this library website provides a gateway for HSE employees to access local HSE library resources to support clinical audit.

<http://www.noca.ie/>

- The National Office of Clinical Audit (NOCA). Established in 2012, NOCA will design, develop and implement national clinical audit programmes in order to improve patient outcomes and promote patient safety in hospitals.

<http://www.icgp.ie/audit>

- Irish College of General Practitioners website. Provides specific guidance and tools for clinical audit in general practice.

<http://gain-ni.org/>

- Guidelines and Audit Implementation Network (GAIN). Promotes good clinical audit practice in Northern Ireland through commissioning of regional guidelines and audits, dissemination of audit results and the publication and facilitation of implementation of regional guidelines.

<http://www.hqip.org.uk/>

- Healthcare Quality Improvement Partnership (HQIP) provides guidance and support for clinical audit in England and Wales.

6. Additional resources

Sources of clinical guidelines

www.patientsafetyfirst.ie

National Clinical Effectiveness Committee (NCEC).

www.nice.org.uk

National Institute for Clinical Excellence (NICE).

www.sign.ac.uk

Scottish Intercollegiate Guideline Network (SIGN).

www.guideline.gov

National Guideline Clearinghouse (USA) is a public resource for evidence-based clinical practice guidelines.

Some clinical guidelines contain audit criteria and targets for compliance based on the guidelines key recommendations, for example National Clinical Guideline 1 – *National Early Warning Score* (NEWS). Available at: <http://www.patientsafetyfirst.ie>

Other clinical guidelines are accompanied by support tools for clinical audit, including NICE CG 52 (NICE 2007) '*Drug misuse: opioid detoxification*' and NICE CG61 (NICE, 2008) '*Irritable bowel syndrome in adults: diagnosis and management in primary care*' used as examples in this document.

7. Glossary of terms and definitions

Audit criterion

The measurement of compliance against criteria of care is at the heart of clinical audit. An 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 the systematic review of care against explicit criteria and to act to improve care when standards are not met.

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.

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 set

A group of data items.

GP liaison group

An individual or group tasked with improving communication between primary and secondary care providers.

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.

7. Glossary of terms and definitions

Healthcare Quality Improvement Partnership (HQIP)

Body funded by the English Department of Health to promote best practice in clinical audit and to re-invigorate audit activity.

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.

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 audit to optimise patient care, within the health system, both public and private.

National clinical guideline

A guideline that meet specific quality assurance criteria and has been mandated by the designated national body – National Clinical Effectiveness Committee (NCEC).

National Institute for Health and Clinical Excellence (NICE)

The National Institute for Health and Clinical Excellence was established as a Special Health Authority by the UK Department of Health and is one of the key elements of the NHS in England and Wales. It was set up to reduce variation in the availability and quality of treatments and care in the National Health Service. Its principal role is to provide authoritative, robust and reliable guidance on best practice procedure.

National Office of Clinical Audit (NOCA)

The National Office of Clinical Audit was established in 2012 through the collaboration of the HSE's Quality and Patient Safety Directorate and Clinical Strategy and Programmes Directorate together with the Royal College of Surgeons in Ireland (RCSI) and the College of Anaesthetists. Its role is to design, develop and implement national clinical audit programmes in order to improve patient outcomes and promote patient safety in hospitals. The RCSI is responsible for the administration and operation of NOCA on behalf of the HSE.

Personal data

Data relating to a living individual who is or can be identified either from the data or from the data in conjunction with other information that is in, or is likely to come into, the possession of the data controller.

Sample

Some of the service users, events, cases, situations or items that are drawn from the population on which the 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.

7. Glossary of terms and definitions

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*).

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 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 audit is focused. A population can range from a very small limited number to a large or infinite number.

Appendix one Sample template for clinical audit proposal proforma

Name		Department	
Title		Contact details	

Audit title

Is this a re-audit? Yes <input type="checkbox"/> No <input type="checkbox"/> <i>If Yes, have previous audit's actions been implemented?</i>

Why are you proposing to conduct this audit? <i>Why was this topic chosen?</i>

What standards will you be auditing against? Please attach a copy of the relevant standard(s) to the submission

Describe the audit tool you intend to use? Please attach a copy of the audit tool to the submission

Appendix one

Please tick additional reasons (if any) for carrying out this audit:

Patient centeredness	<input type="checkbox"/>	Professional development	<input type="checkbox"/>
High volume activity	<input type="checkbox"/>	Service improvement	<input type="checkbox"/>
High risk activity	<input type="checkbox"/>	Re-audit	<input type="checkbox"/>
High cost activity	<input type="checkbox"/>	Risk management	<input type="checkbox"/>
Policy/guideline recommendation	<input type="checkbox"/>	Specify if: Local <input type="checkbox"/>	National <input type="checkbox"/>

Other, please state:

Each audit should satisfy all of the following:

- It should aim to improve patient care.
- It should be multidisciplinary where possible.
- It should have support within your department, including a willingness to implement changes.
- Data Protection legislation.

Have all the potential stakeholders been identified? Yes No

List relevant stakeholders by name

Are these stakeholders aware of this audit?

_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Has a literature search been undertaken?		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Sample size:			
Length of time to audit and target completion date:	date		
I confirm that all data collection/storage will comply with (insert name of service provider) ICT policies:	Yes <input type="checkbox"/>		

The final section of the clinical audit proposal submission will depend on the resources/supports available within the service i.e. request for assistance with carrying out the clinical audit, who has the authority to approve performance of the audit etc.

Signed: _____
Audit lead

Signed: _____
Audit sponsor

Date received:

Date discussed:

Appendix two

Clinical audit checklist

Stage 1 : Plan for audit	Steps		Checklist (√)
	Step 1	Involve stakeholders	
	Step 2	Determine the audit topic	
	Step 3	Plan the delivery of audit fieldwork	
Stage 2 : Select standard/criteria	Steps		Checklist (√)
	Step 1	Identify standard (evidence based)	
	Step 2	Identify audit criteria - measurable statements of what should be happening	
	Step 3	Set targets/expected performance levels	
	Step 4	Agree acceptable exceptions (if appropriate)	
Stage 3 : Measure performance	Steps		Checklist (√)
	Step 1	Collect data	
	Step 2	Analyse data	
	Step 3	Draw conclusions	
	Step 4	Present results	
Stage 4 : Make improvements	Steps		Checklist (√)
	Step 1	Share audit report	
	Step 2	Review areas for improvement and agree priorities for action	
	Step 3	Identify appropriate interventions	
	Step 4	Develop quality improvement plan (if required)	
	Step 5	Identify: - persons responsible for each task / action - reasonable timescale for completion - how and when progress will be measured	
	Step 6	Ensure that change is supported by those with the necessary authority to effect such change	
Stage 5 : Sustain improvements	Steps		Checklist (√)
	Step 1	Monitor implementation of changes	
	Step 2	Report on progress of implementation as required	
	Step 3	Re-audit to ensure changes have improved practice and decide if further audit procedures are required	

Appendix three Types of data

There are different types of data and each type can be described in different ways.

Data may be quantitative (sometimes referred to as objective or 'hard data') which is concerned with numerical or specific data, for example, age, gender, length of stay.

Data may be qualitative which is usually descriptive i.e. concerned with words rather than numbers (sometimes referred to as subjective or 'soft data'), for example, comments on questionnaires. Qualitative data may sometimes be represented in a quantitative form (i.e. 8 out of 10 people...) or responses may be themed into different categories (for example, levels of satisfaction with care).

The table below provides further information on how data may be classified.

Table 1 Classification of data

Type of data	Level of measurement	Examples	Examples of presentation methods
Categorical Data which can be sorted into separate (distinct) categories, where each subject in a sample can only fit in one category	Nominal Data in separate categories which have no inherent order (numerical relationship) Some nominal data will only have two categories	Eye colour, ethnicity, diagnosis, level of satisfaction Gender: Male/Female Answers options: Yes/No	Pie chart/Bar chart Usually expressed as a ratio or % rather than graphically
	Ordinal Data in separate categories which have an inherent order/relationship. Can be counted and ordered but not measured.	Job grade, age groups 1-5, 6-10 etc	Pie chart/Bar chart
Quantitative/numerical (Interval/ratio) (NB units of measurement used)	Discrete – arise from a count or a scale (usually whole numbers)	Number of non-attendees at a clinic. (ratio) Level of satisfaction, rated from 1 to 10 (ratio)	Histogram
	Continuous measurement (can, in theory, take any value in a range, although necessarily recorded to a predetermined degree of precision)	Temperature °C/°F (no absolute zero) (interval) Age, weight, Hb level, length of stay. (ratio)	Histogram, Scatter graph

Interval/ratio data: Data recorded on a scale with equal distances between points. Data can be continuous or discrete. Interval data cannot be multiplied or divided. Data at ratio level has an additional quality of an 'absolute zero' and numbers are multiples of one another. Therefore temperature (in °C or °F) is measured at interval level. Age, height, etc are at ratio level. Ratio data can be multiplied and divided because not only is the difference between 1 and 2 the same as between 3 and 4, but also that 4 is twice as much as 2.

(Adapted from: <http://hsc.uwe.ac.uk/dataanalysis/quantIssuesTypes.asp>)

Appendix four Top tips for the successful development of clinical audit data collection tools

Developed by the Irish Clinical Audit Network 2006

Validity

As in research, the data collection tool should have a high level of 'validity' i.e. it collects the data that it purports to collect. This is why it is important to start with clear clinical audit objectives and use evidence-based standards from the outset.

Reliability

As in research, the data collection tool should have a high level of reliability, i.e. different personnel collecting the data will record the exact same or highly similar data using the tool.

Inter-rater reliability: If data is being collected by many personnel it is important that a check is made to ensure that inter-rater reliability is high.

Sequencing

Data collection questions should flow logically based on the sequence of events in the data source i.e. patient records etc. If feedback is sought from service users or staff members questions should be worded clearly and follow the same basic principles used in developing research interview schedules.

Quantitative versus qualitative clinical audit data collection

Clinical audits can use either quantitative or qualitative data to meet the clinical audit objectives.

- The majority of clinical audits focus on quantitative data. Data collection tools of this type should ensure that clear closed questions are used i.e. Yes/No, Documented/Not documented etc.
- Where qualitative data is required it is necessary to develop data collection questions for use in interviews/focus groups or via questionnaire.

Drafting closed questions

When drafting closed questions:

- use mutually exclusive options, for example Yes/No; Male/Female
- include an option for all responses, for example Yes/No/Don't know/Not applicable
- where appropriate, give more than two options, for example, 4 or 6 (an even number is better as this may assist selection of the middle option as a default). Reliability tends to rise as the number of options rise.

Presentation

Ensure that the data collection tool is present in such a way that it is visually appealing to those collecting the data:

- Use standard fonts.
- Ensure that the font size is readable.
- Do not overcrowd each page – ensure that there is space for recording all relevant information and additional comments.

Comments

Ensure that there is sufficient space for including comments during data collection

Include the date of data collection

Ensure that the date of data collection is recorded clearly on each data collection sheet. This is particularly helpful when data is collected over an extended timeframe.

Include data collection site

Include the name (or unique ID code) for the data collection site. This is helpful if data is being collected on several sites or wards etc and will make comparison of data across sites more efficient.

Include data collector

Include the name of the data collector on each data collection tool. This is particularly helpful when data is been collected on different site or if issues arise at a later stage.

Ensure confidentiality

It is best practice to ensure that each data collection tool does not include the name of the relevant service user or healthcare professional. A unique ID code should be used. This unique ID can link to a separate list of names/case record numbers etc that should be stored securely and used only in accordance with all relevant data privacy regulations.

Include data collection instructions

Instructions for collecting the data or using specific codes should be included on each data collection tool. This is helpful if there are several data collectors. These instructions might include items such as: Where to find the specific data or any special instructions regarding the location of data, different codes.

Pilot the data collection tool

Always pilot the data collection tool using a small number of cases.

This will help:

- highlight any difficulties relating to sequencing;
- identify missing data items; and
- identify unclear data collection questions or instructions.

Code each data collection item

Ensure that each item on the data collection tool is numbered/coded so in order to maximise the efficiency of data entry and analysis.

Keep it simple

Do not collect data that is not required:

- Avoid the 'I might as well collect this information too now that I have the notes open' syndrome.

Don't re-invent the wheel!

Check if there is another clinical audit data collection tool that can be used directly or one that requires a minor amount of modification. It is usually less time-consuming to develop a data collection tool than search and adapt tools already available.

Beware! Do not fall into the trap of buying 'off-the-shelf' data collection tools that promise the earth. Most of them can't.

Quality control

It is useful for a percentage of data collection records to be checked to ensure data accuracy.

Sharing best practice

Increase the clinical audit knowledge base - share **good** data collection tools and good audit proposal schedule.

Appendix five Glossary of terms in relation to descriptive statistics

Analysis of free-text data

Some clinical audits include the collection of qualitative data, for example descriptive elements such as additional comments in a questionnaire or where service user's experiences are being captured. Analysis of such data can be assisted by grouping comments into themes or categories and can often produce ideas for improvements.

Distribution of data

Even or normal distribution is seen when most of the values in the range are close to the average, with a smaller number closer to either extreme of the range of values. If a graph is used to illustrate normal distribution, the graph will appear to be bell shaped around a centre point i.e. the graph is symmetrical in appearance (the two sides are mirror images of one another).

Skewed or non-normal distribution occurs when there are a number of extreme values which may result in an asymmetrical curve with a long tail on one side or the other or more than one peak i.e. not mirror images.

Mean or average

This is the most commonly used method of describing the 'centre' of a distribution of values. To calculate the mean, all the individual values are added together and then divided by the number of data points (values). However, the mean can be affected by extreme values i.e. when the values are not evenly distributed throughout the range of values.

Median

This is the mid-point of all values in a data set when all the values are arranged in numerical order. The median is a better measure for instances where data distribution is skewed as it is less sensitive to extreme scores than the mean.

Mode

This is the most frequently occurring value or score in the data set. Where two or more values are equally frequent there is more than one modal value. The mode can be valuable where there is more than one modal value or when both mean and median are affected by extreme values.

Range

The range is a measure of dispersion and refers to how spread out the data is. The range states the highest and lowest values in a data set.

Standard deviation

The standard deviation is a more accurate and detailed estimate of dispersion because a single extreme value or outlier can greatly exaggerate the range. The standard deviation (SD) is a measure of the dispersion of values around the mean and allows conclusions to be made about specific scores in the distribution of data. A small SD implies that the data are mainly concentrated around the mean while a large SD implies that the data are distributed widely.

Appendix six Presentation of data using tables, graphs and charts

Tables

The basic structure of a table is a set of columns and rows that contain the data and usually contain either row and/or column headings to organise the data. When using tables, the amount of information included should be kept to a reasonable level.

Various techniques can be employed to highlight certain information contained within a table if required, for example through using bold or different coloured text or by using a different background colour in relevant cells.

A table is generally less effective than a graph because it only shows data, whereas a graph can be used to show an interpretation of the data, which may be easier to understand.

Graphs and charts

A graph or chart provides for the graphical representation of one or more sets of data. There are several different types of charts and there are no strict rules as to which one should be used in any given circumstance. The most important thing is to use those which illustrate the point in the clearest way possible.

Line graphs

Line graphs show sets of data points plotted over a time period and connected by straight lines. Line graphs are useful for displaying any set of figures that need to be shown over time and can be used to compare two or more groups compared over time, for example a vital signs observation chart consists of a line graph.

Pie charts

Pie charts may be used for showing proportions in relation to the whole, with each wedge representing a percentage of the total. When a different colour/shading is used for each section, the proportions of the component parts of the whole are easily comparable. Each pie chart can only represent one set of variables for a subject.

Bar charts

Bar charts show quantities represented by horizontal or vertical bars and are a practical way of illustrating several categories of results at once. For each category an individual bar is drawn to indicate the frequency or percentage of that category. There are usually gaps between the bars to indicate that the categories are discrete. Bar charts may be simple, grouped (comparative) or stacked/divided.

A simple bar chart sorts data into simple categories. A grouped bar chart divides data into groups within each category and allows comparisons between individual groups as well as between categories, therefore giving more useful information than a simple total of all the components, for example, showing changes in results between initial audit and re-audit. Stacked/divided bar charts show proportional relationships between data within each bar. In addition, these bar graphs can show changes over time. This type of bar chart illustrates both the sum of the parts and each group's contribution to the whole.

Histograms

A vertical or horizontal bar graph whose lengths indicate quantities/relative frequency and the width of the bars represent the various categories or data range. It differs from the bar chart in that the bars may have differing widths, but the key feature is that, for each rectangle, the area is proportional to the frequency represented. There are no spaces between each bar as the data is continuous on a numerical scale. Histograms may be used for displaying ranges, for example, height, weight.

Appendix seven The clinical audit report

The clinical audit report should:

- Be simple and clear.
- Be written in plain English.
- Use a structured, systematic approach, for example, IMRAD (introduction, method, results and discussion which would include recommendations and an agreed quality improvement plan).
- Present descriptive statistics graphically where possible.
- Make sense and follow a logical progression.
- Be easy to understand – the report should be written in such a way that it could be understood by a colleague from a different discipline. A good report will make even a complex issue understandable to all.

Layout of report

The audit report should follow a standard audit report template. For example:

- **Introduction**
Explain the reasoning why the audit was undertaken.
Outline when the audit undertaken and how many people/items were surveyed.
Outline the aims and objectives of the audit.
- **Method and Sample**
Briefly explain the method used and how the sample was chosen.
This section should include enough detail to allow anyone re-auditing to use the same approach and methodology.
It should include: Who was involved; what type of data collection tool or scale was used; any difficulties experienced; timescales and any expectations.
- **Results**
There should be no commentary in this section.
Anonymity should be heeded i.e. don't refer to specific people.
Where possible use visual aids such as tables or charts. All tables and figures should have a title and be understood without reference to the text.
Be consistent with data presentation, e.g. decimal places, percentages, format.
- **Discussion**
This section should not contain any new data.
It should draw on the results and make careful interpretation of the findings.
Compare the results to other audits.
Discuss the strengths and weakness of the audit, are there any discrepancies?
Discuss the meaning of the findings and possible implications for health care professionals.
- **Conclusion and recommendations**
Use this section to summarise.
Put forward recommendations for change, for example, better documentation, training requirements, change of practice.
Recommendations should be realistic and achievable.
Suggest areas for further works and plans for re-audit if appropriate.

Appendix seven

- **Quality improvement plan**
The quality improvement plan is a fundamental part of the audit, without it the audit is not effective and has just wasted time, money and effort.
The audit loop is completed by developing and implementing the quality improvement plan, use bullet points to keep it short and to the point.
The quality improvement plan should identify the person/s responsible for each action.
Plan a date for re-audit.
- **Acknowledgements**
All those who helped should be mentioned.
- **References**
Should be numbered or in alphabetical order.
- **Appendices**
It may be appropriate to include a copy of the data collection form.

Another version of a template for a clinical audit report is provided on the next page.

Appendix seven

Sample Template for Clinical Audit Report (Version 2)

Title of Audit:		<i>For office use: audit number</i>
Date of report:		
Department/Speciality:		Re-audit date:

Audit lead/author:		Job title:
Service provider:		Job title:
Key stakeholders:	Names:	Department/ Speciality:

<p>Background & aim:</p> <p>Say why the audit was done. Perhaps a problem had been identified? Statement of what the project is trying to achieve:</p>	
---	--

<p>Standard:</p>	
-------------------------	--

<p>Methodology:</p> <p>State</p> <ul style="list-style-type: none"> • Chosen population • How sample selected • Retrospective or prospective • Sample size • Describe tool used 	
---	--

<p>Results:</p> <p>(State the results. Start with total number (n=). Data may be presented visually (graphs, tables)</p>	
---	--

Appendix seven

<p>Conclusion: (List key points that flow from results)</p>	
---	--

<p>Recommendation: (bullet point action plan-with review date and initials of person in charge of implementation)</p>	
---	--

A report must be written up for each Clinical Audit done. This is the official record of what has been done, which can be returned to in future years.

Title

This should be the same as the title on the proforma.

Background & aim(s) of the audit (Introduction)

This is essentially narration, clarifying why the audit was done. For example, was the project prompted by an identified local problem or concern? The background should explain the rationale for doing the audit. Summarise the evidence base for the audit topic, giving any references at the end. If a team was convened to undertake this audit, say how this was organised and who was involved. This will explain what the project is trying to achieve and should have been identified before the audit commenced.

Standards

Clinical audit must measure against standards, guidelines or benchmarks of some sort, these should be identified and where they come from (the source and strength of evidence). State if the intention was to set standards at the end of the project and if so, which aspects of care those standards pertain to.

Methodology

State the chosen population for this study (for example, "patients referred to the one-stop breast clinic for suspected cancer") and then to say how the sample was selected the sample for the audit, specifying whether a retrospective or prospective approach was used (for example, for a prospective audit, "the first 100 patients referred to the clinic starting from 1/10/04", or for a retrospective 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 stated, 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

The number of subjects (for example, patients) included in the 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 been 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.

Conclusions

List the key points that flow from the 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, i.e. don't say "it is obvious that..." or "clearly, what is happening is ... "

Recommendations & Quality Improvement Plan

Recommendations for change should be made. Make sure these are realistic and achievable.

A quality improvement plan (action plan) should be agreed saying 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-audit to complete the audit cycle.

Appendix eight

TWELVE TIPS FOR SUCCESSFUL CLINICAL AUDIT

- 1. Keep audits simple**
- 2. Get everyone involved**
- 3. Determine the topic**
- 4. Have a plan**
- 5. Do not confuse clinical audit with research**
- 6. Do not collect needless data**
- 7. Take care with statistics – errors can lead to inaccurate conclusions**
- 8. Close all clinical audit loops**
- 9. Keep data only for as long as it is needed**
- 10. Share learning - tell everyone about your audit**
- 11. Tell 'The Organisation' about your audit**
- 12. Re-audit to ensure improvement in clinical care**



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