National Health Regulatory Authority
Kingdom of Bahrain

GUIDANCE ON CLINICAL AUDIT
FOR HEALTHCARE FACILITIES
IN THE
KINGDOM OF BAHRAIN

THE PURPOSE OF THIS DOCUMENT IS TO PROVIDE GUIDANCE ON CONDUCTING CLINICAL AUDIT IN HEALTHCARE FACILITIES IN THE KINGDOM OF BAHRAIN

ADDITIONAL SUPPORT AND GUIDANCE IS ALSO AVAILABLE ON A NUMBER OTHER KEY AREAS

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1. Introduction

Healthcare audit is not new. It is a quality improvement activity that has been carried out in successful healthcare facilities across the world as part of everyday practice. The purpose of healthcare audit is to monitor to what degree standards for any given healthcare activity are met, identify reasons why they are not met, and identify and implement changes to practice to meet those standards.
These standards should be evidenced based. These standards can be clinical e.g. breast cancer management, trauma management and surgical procedure standards or non clinical e.g. medical record management and cleaning procedure standards.

It is the duty of all clinicians to ensure that they deliver the best care to their patients. All clinicians should be auditing their work, whether they are part of a large multidisciplinary team or a single handed practitioner. Clinicians have a duty to use the findings of their audits to improve clinical care and move towards best practice i.e. audit is an essential tool for Continuous Quality Improvement (CQI). Audit should not be seen as a standalone activity but should be part of a structured quality, safety and risk management program. (See the NHRA Guidance on Quality, Safety and Risk management.)

1.1 Scope of document

- What is this document and who is it for?

This aim of this document is to support healthcare facilities and their 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 facilities and 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, this document is not aimed at defining the local management of or organisational structures for clinical audit. In addition, this document does not describe how to develop a clinical guideline or standard and does not define what guidelines or standards must be used.

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

2.1 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 in carrying out the audit or to support any subsequent changes in practice. On the other hand, when a multi-disciplinary team are working together on an audit there will be greater need for audit planning to ensure a successful outcome for the audit.

Planning for audit can be described in three main steps:

2.1.1 Involving stakeholders
2.1.2 Determining the audit topic
2.1.3 Planning the delivery of the audit

2.1.1 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)[1] 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 reasons for carrying out the 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 the implementation of any identified changes?

Where service users are involved in clinical audit programs, their roles need to be clearly defined and appropriate support and guidance provided to enable delivery. Common methods for involving service users in the clinical audit process include:

- gathering service user feedback, for example letters of compliant
- comments made at service user forums
- interviews with service users
- service user surveys
- focus/liaison groups
- reviewing critical incidents

Various stakeholder groups may play different roles and may 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 or comment on the clinical audit methodology, including the proposed clinical audit criteria
- 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 actually 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.

[1] Ashmore, S., Ruthven, T., and Hazelwood, L. (2011a). Stage 1: Preparation, planning and organisation of clinical audit. In Burgess, R. (ed) NEW Principles of Best Practice in Clinical Audit. Healthcare Quality Improvement Partnership (HQIP). Abingdon, Radcliffe Medical Press,pp 23-58.

Adapted from Dixon (2009a)[2]

2.1.2 Determining the audit topic

The Donabedian (1966)[3] 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, the environment that the care is delivered, the facilities available, equipment available, and the documentation, policies, protocols, procedures and guidelines.
- Process – the procedure and practices implemented by staff in the prescription, delivery and evaluation of care, these can be specific to clinical processes or administrative/service processes.
- Outcome – the effect of care received by service users as a result of healthcare provision.

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.

To assist with prioritising topics, the following questions should be considered:

- 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 (e.g. systematic reviews or national/international 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 (e.g. service user complaints or high complication rates, adverse outcomes or poor symptom control)?
- Is the topic of key professional or clinical interest?
- Are reliable sources of data readily available for data collection purposes?
- Can data be collected within a reasonable time period?
- Is the problem concerned amenable to change?
- Is the topic pertinent to national or local initiatives or priorities?
- Does the topic lend itself to the audit process, or is a different process more appropriate (e.g. 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?
- Have there been major changes recently?
- Are there resource implications?

Adapted from Ashmore, Ruthven and Hazelwood (2011a)[4]

[2] Dixon N. (2009a). Getting Clinical Audit Right to Benefit Patients. Romsey: Healthcare Quality Quest.
[3] Donabedian (1966). Evaluating the quality of medical care. Milbank Memorial Fund Quarterly. 44(3): Suppl: 166-206.
[4] Ashmore, S., Ruthven, T., and Hazelwood, L. (2011a). Stage 1: Preparation, planning and organisation of clinical audit. In Burgess, R. (ed) NEW Principles of Best Practice in Clinical Audit. Healthcare Quality Improvement Partnership (HQIP). Abingdon, Radcliffe Medical Press,pp 23-58.

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

- External 'must do' audit where participation is required due to government or regulatory requirements.
- 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 national/international 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.

2.1.3 Planning the delivery of the 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)[5] suggested that audit aims and objections may be defined through the use of verbs such as:

(i) Improve (ii) Increase (iii) Enhance (iv) Ensure (v) 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 records provide an accurate chronology of events'.*

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.

- Leadership and management
- Clinical, managerial and other service input and leadership
- Audit methodology
- Change management skills
- Data collection and data analysis skills
- Facilitation skills

[5] Buttery, Y. (1998). Implementing evidence through audit. In: Bury, T and Mead, J. (eds) Evidence-based Healthcare: A Practical Guide for Therapists. Oxford, Butterworth-Heinemann, pp. 182-207.

The skills outlined should be drawn from all relevant groups involved in the delivery of care. 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 program.

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.

Structures should be in place prior to the commencement of clinical audit work; these structures are dependent on the size of the audit, the number of people involved and the audit topic etc. The clinical audit person/team should complete a clinical audit proposal proforma (see appendix 6 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.

The person/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 program. The clinical audit proposal proforma should identify what support is required for the clinical audit. The structures should also include a mechanism for the review of findings and progress reporting. If a number of professionals are involved in the audit, clear lines of accountability should be agreed at the outset of the audit and a timetable agreed for the design and carrying out the 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.

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

In general, a standard is a statement of best practice. For example 'a statement which outlines an objective with guidance for its achievement in the form of criteria sets which specify required resources, activities and predicted outcomes' and a criterion is 'an item or variable which enables the achievement of a standard and the evaluation of whether it has been achieved or not' (RCN, 1990)[6].

Whilst recognising the confusion that has occurred, the approach taken in this guide will be consistent with the approach taken by the NHRA when specifying the licensing standards; standards are defined as structures and processes needed to identify, assess and manage specified issues in relation to the subject/service area (e.g. healthcare records management, decontamination, recruitment and selection etc).

[6] Royal College of Nursing (1990). Quality patient care – the Dynamic Standard Setting System. Scutari, Harrow.

Audit criteria should consist of measurable statements of what should be happening. 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/international practice.

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

Where a criterion is critical to the safety of service users, targets may be set at 100% or 0%, for example, a clinical audit relating to safe administration of medication could have a target of 100% for the following criterion '*medication is not administered to a service user with a known allergy to the medication*'. However where clinical importance is not as significant, resources required to fulfil the target performance level should be considered and an acceptable performance level (one which is seen as both reasonable and attainable by those delivering and receiving care) should be identified.

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).

2.2.1 Inclusion / exclusion criteria and exceptions

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 i.e. inclusion and exclusion criteria.
Many evidence-based clinical guidelines identify a target population to whom the guideline is intended to apply and may also define areas outside of the remit of the guideline. For example, if a clinical audit is being conducted on compliance with the clinical guideline NICE CG61 (NICE, 2008) 'Irritable bowel syndrome in adults: diagnosis and management in primary care', the inclusion/exclusion criteria for the audit should reflect those to whom the guideline applies to, i.e.
Inclusion criteria:

- adults (18 years and over) who present to primary care with symptoms suggestive of IBS.

Exclusion criteria:

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

Exceptions:
An exception is a clinically acceptable reason or circumstance for not complying with specific criteria (Dixon, 2009a)[7]; in such cases the sample is not included in the data analysis. Consensus on exceptions should be agreed before the start of the audit. Examples include, where the criterion involves treatment with a specific medication but a contra-indication to the medication exists.

[7] Dixon N. (2009a). Getting Clinical Audit Right to Benefit Patients. Romsey: Healthcare Quality Quest.

2.3 Stage 3 – Measuring performance

This stage may be described in the 4 steps as follows:

- data collection
- data analysis
- drawing conclusions
- presentation of results

2.3.1 Data collection:

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 and exclusion criteria defined
- the consent required to access user group information
- the healthcare professionals involved in the service users' care
- the time period over which the criteria is applied
- the analysis to be performed.

Resources should be used effectively to collect the minimum amount of data necessary to achieve the audit objectives. Suggested questions to assist when preparing for data collection:

- What type of data do I need to collect? (qualitative or quantative)
- What data sources do I have to use?
- Do I need to design a tool to collect the data?
- How large is the target population and do I need to take a sample size?
- How will data be collected? (manually or electronically)
- How long will it take to collect the data?
- Who will collect the data?

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 and be relevant to the aims and objectives of the audit. Appendix 1 of this document provides further information on data type and classification.

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 on Data protection for more information.)

The source of data 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. E.g. service user records.

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.

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

- the data to be collected should be relevant to the objectives and criteria for the audit and the expected performance levels
- acronyns, 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/year)
- free text or open questions should be avoided as free text inclusion 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 2 of this document provides further tips for the successful development of clinical audit collection tools.

Retrospective data collection (looking back at care given in the past) is advantageous as:

- 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) is collected while treatment/care is being provided. This involves planning the recording of data on care which will be provided. If the data required is not routinely collected, a prospective / 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 – i.e. will clinical practice be affected by the knowledge that an audit is ongoing?

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 and exclusion criteria (in order to identify the relevant population)
- 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

It is often not possible or necessary to gather data on all service users, events or items for audit purposes; therefore sampling is a preferred method. It is important to ensure that any sample selected is representative of the population of service users 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. 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 – often determined by a time period e.g. 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.
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 to provide validity.

- 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

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

2.3.2 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 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.

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.

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 e.g. waiting time <1hour, 1- 4hours, < 4hours or summarising using descriptive statistics.

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.

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. 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.

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.

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 presenting 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. Appendix 3 of this document contains a glossary of terms relating to descriptive statistics. More elaborate statistical manipulation is possible but not necessary in any clinical audit – effecting change is more important.

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. Refer to 'Presentation of results', for further information on effective data display and presentation.

2.3.3 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.
Individual cases where care is not consistent with a criterion 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:

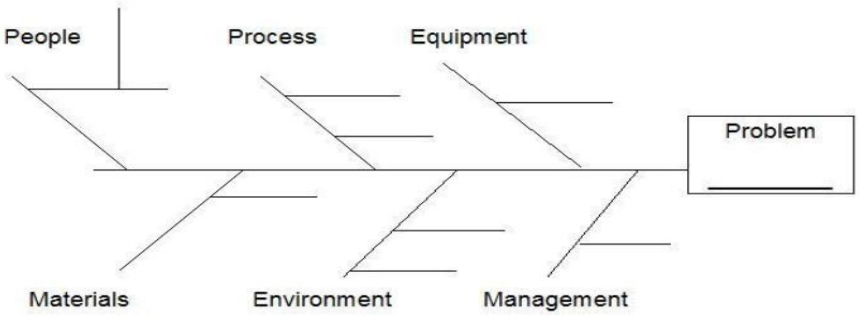
- clearly identify and agree on areas for improvement identified by the clinical audit.
- analyse the areas for improvement to identify what underlying, contributory or deep-rooted factors are involved.

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 root 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.

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 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, processes, materials, equipment and environment etc. 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 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 of 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 is then enabled to discuss / lead discussions around recommendations for improvements.

2.3.4 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 (e.g. through using presentation software like Microsoft PowerPoint).
- Written reports for submission to the relevant clinical lead, directorate or committee
- Verbal presentations at relevant meetings

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

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, e.g. unrecorded practice, practice not occurring, poor levels of service user satisfaction
- Causes, e.g. poor documentation, inadequate staffing, training and practice issues Needed improvements, e.g. 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 5 contains further information on the clinical audit report.

2.4 Stage 4 – Making improvements

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)[8] 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 program of change activity and post-identification of the findings from audit, to ensure necessary changes happen*.'

Where audit has shown that there are serious concerns regarding the practice of an individual, these should be conveyed immediately to the manager of the service for urgent action. All audit reports should be shared with the service, specifically with the relevant Head of Department/service and staff. Where audits are instigated by a particular committee/group, reports should be submitted to the committee /group for review and action.

Change is often the most difficult part of the audit. When the audit team has developed the recommendations, decisions should be made on how changes can be introduced and monitored. Priorities for action should be identified and these should be clearly documented. All audits should be

[8] Ashmore, S., Ruthven, T., and Hazelwood, L. (2011c). Stage 3: Implementing change. In Burgess, R. (ed) NEW Principles of Best Practice in Clinical Audit. Healthcare Quality Improvement Partnership (HQIP). Abingdon, Radcliffe Medical Press,pp 81-92.

accompanied by a quality improvement plan to address those areas requiring improvement. See figure 2 below.

It is important that improvement tasks or actions outlined relate to the available resources. 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 that carry the necessary authority to effect such change.

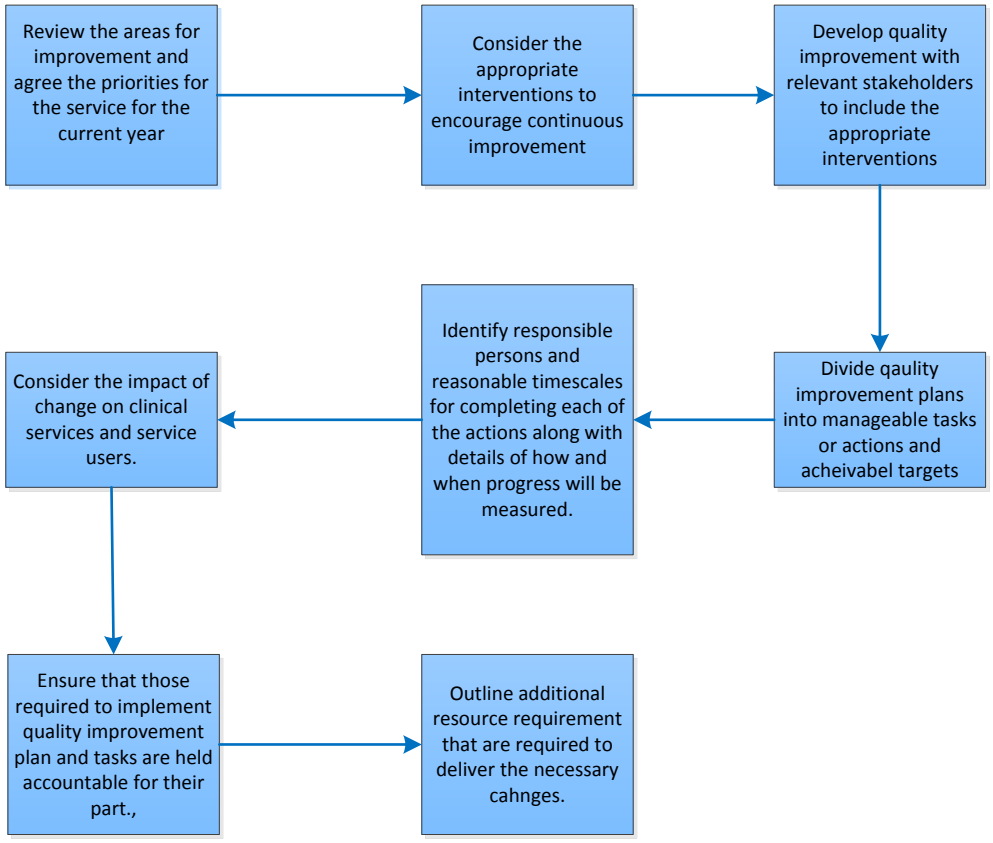


Figure 2 – Writing quality improvement plans

2.5 Stage 5 Sustaining Improvements

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 agreed to implement quality improvement plans are accountable for the delivery of quality improvement plans and sustaining quality improvement.

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 program 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.

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 meetings, journal club meetings, the intranet, newsletters and local conference and seminars. Consideration should also be given to sharing clinical audit work regionally and nationally through relevant journals, conferences and other media.

3. Wider Considerations

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

3.1 Ethical Issues

Ethics is the inquiry into the morality of an action. There should be consideration of ethical principles in relation to all aspects of clinical care including clinical audit. Clinical audit should be conducted within an ethical framework, i.e. the clinical audit process should:

- respect each service users' 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. 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 (e.g. anonymisation of data) and the length of time for which their personal information will be held. 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.

3.2 Issues of data protection:

Data protection and service user record confidentiality must be considered when performing clinical audits. Anyone with access and processing personal data must comply with the eight general rules of data protection in line:

- obtain and process information fairly
- keep it only or 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.

3.3 Confidentiality

Members of a healthcare team 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.
Consent is not required where the personal health information is 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.
Where a clinical audit is carried out by persons who are not involved in service user care, 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 ensure that the patient/client understands the consequences of such disclosure, what will be disclosed, the reasons for the disclosure and the consequences of having given consent.

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 follow some simple rules:

- Data collection sheets which contain 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 should be anonymised before it is entered into a computer database,
- No service user identifiable information should be stored on a computer with raw data.
- Anonymised data sheets/ questionnaires should be kept only for as long as is necessary and destroyed as soon as all information has been retrieved from the questionnaires,
- Any waste material that contains personal, private or confidential information should be eliminated in a manner which ensures that privacy rights and confidentiality obligations are not compromised,
- 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,
- Archived clinical audits should be stored on a secure computer,
- All computers are password protected and all laptops used to store data should be encrypted
- If laptops are removed from the work location, the person responsible for that laptop must ensure that it is secure at all times.

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

4. Additional Resources

The following is a list of resources that may be useful for any health care professional and facility when undertaking an audit.

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

Alternatively guidance can be accessed through the patient safety first website, http://www.patientsafetyfirst.gov.ie/

Health Service Executive online resource for learning and development. Register for clinical audit e-learning programme. http://www.hselibrary.ie/

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. Sources of clinical guidelines

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

5. 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 measurable outcome of care, aspect of practice or capacity set out in policies, procedures and requirements. For example, 'parents / carers are involved in negotiating or planning their child's care'.

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

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.

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.

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 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 care services.
- Members of the public and communities who are potential users of health care services.

Stakeholder
A person, group, organisation, or system which affects or can be affected by an organisation's actions. For example, health service providers 'stakeholders,, include its service users, employees, healthcare staff, government, insurers, industry and the community.

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.

Appendix 1

Types of data

There are different types of data and each data 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 e.g. 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') e.g. 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 (e.g. 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) (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

Appendix 2.

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

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

Reliability
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.

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 member questions should be worded clearly.

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.
- Where qualitative data are 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.

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.

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
- 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 maximize 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' trap.

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 do not deliver on their promises.

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 3

Glossary of terms in relation to descriptive statistics

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 towards 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.

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.

Appendix 4.

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, e.g. 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 e.g. height, weight.

Appendix 5.

The Clinical Audit Report

The clinical audit report should:

- Be simple and clear
- Be written in plain English
- Use a structured, systematic approach e.g. 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 – Results should be reported withoutcommentary. Anonymity should be maintained. 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 that was not included in the Results section. 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 in which 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.
- 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 and in alphabetical order.
    - Appendices - It may be appropriate to include a copy of the data collection form

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

Appendix 6

Sample Template for Clinical Audit Report

Title of Audit:		*For Office use: (Audit Name / Number)*
Date of report:		
Department / specialty:		Re- Audit Date: _____

Audit Lead / Author:		Job title:
Service provider:		Job Title:
Key Stakeholders:	Names:	Dept / Speciality:

Background and Aim: *Say why the audit was done. Perhaps a problem had been identified? Statement of what the project is trying to achieve:*	

Standard:	

Methodology: State: • Chosen Population • How sample was selected • Retrospective or Prospective • Sample size • Describe the tools used.	

Results: *State the results. Start with the total number (n), Data may be presented visually (graphs, Tables etc.)*	

Conclusion: *List the key points that flow from the results*	

Recommendations: *Bullet point action plan with review date and intilas of person in charge of implementation.*	

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 (e.g. "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 (e.g. 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, e.g. "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 (e.g. patients) included in the audit is the initial 'n' number. If data is incomplete, explain why, e.g. 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, e.g. 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 6

Sample template for Clinical Audit Proposal Proforma

Name:		**Department:**	
Title:		**Contact Details:**	

Audit title:

Is This a re-audit? Yes ☐ No ☐ *(If Yes, have previous audits actions been implemented)*

Why are you proposing to conduct this audit? *(Why was this topic chosen?)*

What **Standards** will you be auditing against? Please attach a copy of the relevant standard(s) to this proposal.

Describe the audit **tool** you intend to use? Please attach a copy of the audit tool to this proposal.

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

Patient centeredness	☐	**Professional development**	☐
High volume activity	☐	**Service improvement**	☐
High risk activity	☐	**Re-audit**	☐
High cost activity	☐	**Risk management**	☐

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 potential stakeholders been identified? **Yes ☐ No ☐**

List relevant stakeholders: **aware of the audit?**

_____ **Yes ☐ No ☐**
_____ **Yes ☐ No ☐**
_____ **Yes ☐ No ☐**
_____ **Yes ☐ No ☐**

Has a literature search been undertaken?	**Yes ☐ No ☐**	
Sample Size:		
Length of time to audit & target completion date:	**Time:**	**Date:**