Healthcare Audit Criteria and Guidance

Introduction

The National Quality and Risk Team in the Office of the CEO have developed a National Quality and Risk Management Standard for the Health Service Executive. There are 22 criteria in the Quality and Risk management standard. Criteria Four pertains to Clinical and Healthcare audit.

4	A comprehensive programme of clinical and healthcare audit is in place that involves staff in multi-disciplinary audits.
	Guidance:
	Clinical and Healthcare Audit involves comparing current practice to evidence based best practice in the form of standards, identifying areas for quality improvement and implementing changes to practice to meet the standards.
	It is the duty of all healthcare professionals to ensure they deliver care to the highest standard to their patients/clients so by definition all staff should be auditing their work. Clinical and Healthcare Audit ideally should be multi-disciplinary but uni-disciplinary audits may also be conducted.
	Each department/specialty/service within the organisation should have an annual programme of audit based on the criteria for audit selection e.g. high risk, high cost, high volume. The effectiveness of the audit and the implementation of changes should be evaluated by re-auditing.

(HSE Quality and Risk Management Standard 2007)

Healthcare audit is audit of current practice against standards in any aspect of health care and includes both clinical and non clinical audit. C*linical audit* is specifically about audit of actual practice against evidenced based clinical standards of care. 'Audit therefore has a role to play in education and management including activities such as cost effectiveness, quality control, risk and resources management' (BMA 1995). While the cycle followed in the management of any healthcare audit project is the same, with clinical audit differences lie in leadership, responsibility and ownership for the audit.

Policy Statement:
As part of the HSE Quality and Risk Strategy it is the policy of the HSE that healthcare audit should be undertaken as a routine part of everyday practice.
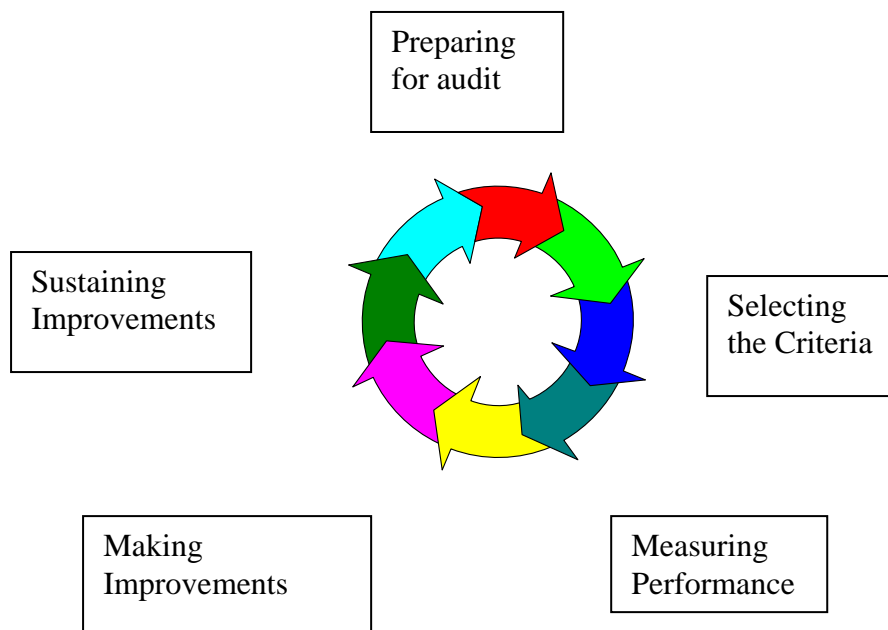
Policy Rationale:
1. To enable staff and service users to evaluate and measure practice and standards
2. To develop and sustain a culture of best practice
3. To establish structures and processes to monitor and evaluate the effectiveness of healthcare audit.

Introduction

Healthcare audit is not new. It is a quality improvement activity that most healthcare employees have done for a long time 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 standards or non clinical e.g. record management standards. In fact healthcare audit is the final step in evidence based healthcare.

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. Clinicians have a duty to use the findings of audit 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 stand alone CQI activity but should be part of a structured organisational quality and risk management programme.

The HealthCare Audit Cycle (Adapted from the Clinical Audit cycle, NICE 2002)

Preparing for audit

Sustaining Improvements

Selecting the Criteria

Making Improvements

Measuring Performance

Glossary of terms

Clinical Audit

'Clinical Audit is the comparison of actual practice against agreed, documented, evidence based standards with the *intention* of improving patient care'.
(M. Ferris 2002)

OR

'Clinical Audit can be defined as the assessment, evaluation and improving the care of patients in a systematic way. Setting of standards, measurement of practice compared to the 'gold standard' identification of deficiencies and addressing deficiencies (closing the loop) is an accepted model of clinical audit. (Medical Council 2006)

Criterion: 'A systematically developed statement that can be used to assess the appropriateness of specific healthcare decisions, services, and outcomes (Institute of Medicine 1992).

Healthcare Audit: The assessment of performance against any standard in a healthcare organisation. These standards include clinical and non clinical standards.

Peer Review 'can be defined as the evaluation of the performance of individuals or groups by members of the same profession or team' (Medical Council 2006)

Research: 'Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods' (Research Governance framework for Health and Social Care 2006).

Service Evaluation: ' A set of procedures to judge a service's merit by providing a systematic assessment of its aims, objectives, activities, outputs, outcomes and costs' (NHS Executive 1997)

Significant Event Audit (SEA) has been defined as occurring when: … individual cases in which there has been a significant occurrence (not necessarily involving an undesirable outcome for the patient) are analysed in a systematic and detailed way to ascertain what can be learnt about the overall quality of care and to indicate changes that might lead to future improvements" (Pringle *et al. 1995)*
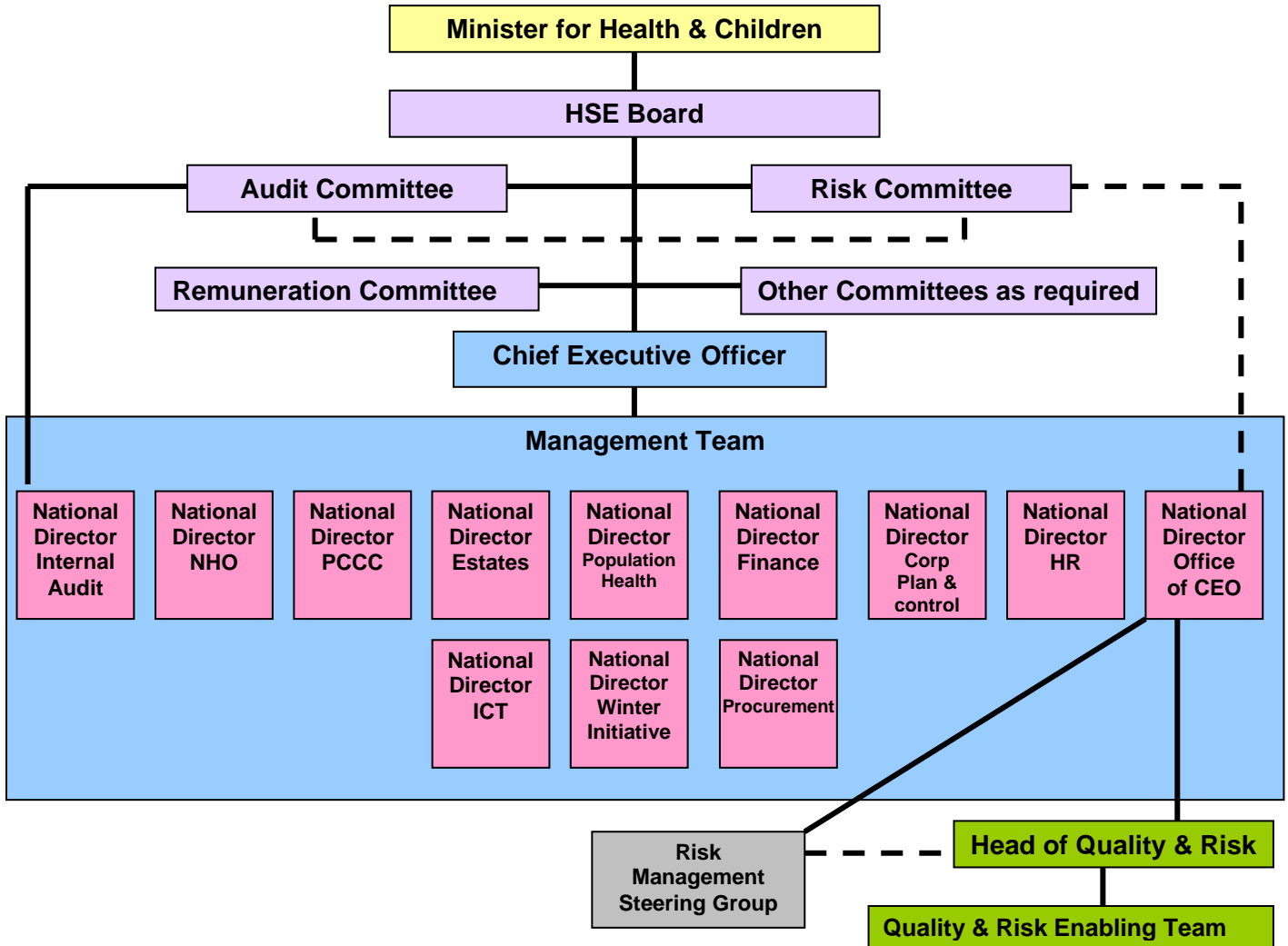
Standard: 'The percentage of events that should comply with the criterion' (Baker and Fraser 1995) A standard is the desired and achievable level of performance against which performance can be measured.

Accountability for Healthcare Audit

(Adapted from National Quality and Risk Management team draft documents)

CORPORATE STRUCTURE

Figure 1 sets out the corporate structure for implementing the quality and risk management strategy.

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                    Minister for Health & Children
                              |
                         HSE Board
                              |
        Audit Committee              Risk Committee
              |                            |
     Remuneration Committee    Other Committees as required
                              |
                   Chief Executive Officer
                              |
                      Management Team
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National Director Internal Audit	National Director NHO	National Director PCCC	National Director Estates	National Director Population Health	National Director Finance	National Director Corp Plan & control	National Director HR	National Director Office of CEO
			National Director ICT	National Director Winter Initiative	National Director Procurement			

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   Risk Management          Head of Quality & Risk
   Steering Group
                           Quality & Risk Enabling Team
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Board of the HSE
The Board, reporting to the Minister for Health & Children, sets out the values for improving quality and reducing risk across the organisation and holds senior management to account for implementing the corporate quality and risk management standard.

Risk Committee
The Risk Committee is a Board sub-committee that provides assurances to the Board in respect of HSE's quality and risk management system as described by the Quality and Risk Management Standard.

Audit Committee
The Audit Committee is a Board sub-committee that provides the Board with assurances in relation to financial risk management and internal control, internal and external audit processes and promotion and auditing of value for money management (VFM) throughout the health system. The work of the Audit Committee is highly complementary to that of the Risk Committee.

Risk Management Steering Group
A Risk Management Steering Group (RMSG) has been set up within the Office of the CEO. The responsibility of the RMSG is to ensure that the quality and risk management standard is integrated into the HSE's overall approach to the management of Quality and Risk. The group comprises members of the National Quality and Risk Team and the Quality and Risk Leads from each Directorate. The group is chaired by the National Director, Office of the CEO.

Quality and Risk Leads for each Directorate
To support the National Directors in their Directorate to implement the corporate quality and risk management standard, there is a designated Quality and Risk Lead for each Directorate' (Draft HSE Quality and Risk Strategy 2007)

Quality & Risk Office in the Office of the CEO

1. It is the responsibility of the Quality and Risk Office to support, monitor and evaluate the implementation of the Clinical Audit criteria and guidance.

2. The Quality and Risk Office will assist in assessing performance as part of their role in monitoring of the Quality and Risk Management Standard.

3. To coordinate the review of this criteria and guidance.

CEO and Management Team
It is the responsibility of the CEO and his management team to ensure implementation of the quality and risk management standard.

National Directors

1. The respective National Directors are accountable to ensure that within their Directorates there are effective structures and processes in place for healthcare audit and for ensuring that all staff are aware of them.
2. As well as identifying areas of good practice, healthcare audit may identify areas for quality improvement. Where the quality improvement required to effectively improve standards of quality and reduce risk lie outside the control of the Area Manager, the relevant National Director is responsible for ensuring that such improvements required are prioritised with all quality and risk quality improvement/Control measures required in their directorate. They allocate resources including financial resources from discretionary funds available, for the implementation of quality improvement/control measures.
3. It is the responsibility of National Directors to develop relevant key performance indicators and to monitor these to ensure the effectiveness of the clinical audit structures and processes. These will be a key source of evidence

for compliance with criteria four of the Quality and Risk Management Standard.

4. It is their responsibility to prepare an annual report of healthcare audit activity for the CEO.

Management Teams

Management team must ensure that mechanisms are in place so that lessons learned from healthcare audit and resultant quality improvement can be shared appropriately across the HSE and Managers should be supported in seeking to improve performance as a result of the lessons learnt.
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Area Manager e.g. Network Manager, PCCC Area Manager or Support Services

1. It is the responsibility of the area manager to assure themselves that appropriate structures and processes are implemented and complied with in relation to healthcare audit in their area.

2. As well as identifying areas of good practice, healthcare audit may identify areas for quality improvement. Where the quality improvement required to effectively improve standards of quality and reduce risk lie outside the control of the general/hospital/local health office manager, the relevant Area Manager is responsible for ensuring that such improvements required are prioritised with all quality and risk Quality Improvement/Control measures required in their area.   They allocate resources including financial resources from discretionary funds available, for the implementation of quality improvement/control measures. Where such resources are not available they refer the matter to their Director.

3. It is the responsibility of the Area Manager to ensure that mechanisms are in place to facilitate learning from healthcare audit and resultant quality improvement are communicated throughout their area of responsibility on a cross functional basis.

4. It is their responsibility to monitor the implementation of identified recommendations following healthcare audit.

5. It is their responsibility to prepare an annual report of healthcare audit activity for the Director.

Senior Local Manager e.g. Hospital GM/CEO or LHM/GM

1. It is the responsibility of this level of management to ensure that the structures and processes for healthcare audit are in place in their area of responsibility including addressing capability issues such as protected time for healthcare audit and staff training. .

2. As well as identifying areas of good practice, healthcare audit may identify areas for quality improvement. Where the quality improvement required to effectively improve standards of quality and reduce risk lie outside the control of the line manager/lead clinician, the relevant general/hospital/local health office manager is responsible for ensuring that such improvements required are prioritised with all quality and risk Quality Improvement/Control measures required in their area.   They allocate resources including financial resources

from discretionary funds available, for the implementation of quality improvement/control measures. Where such resources are not available they refer the matter to their area manager.

3. It is their responsibility to monitor the implementation of identified recommendations following healthcare audit.

4. It is their responsibility to prepare an annual report of healthcare audit activity for the Area Manager.

Line Manager e.g. Department Head, Service Manager

1. The line manager is responsible for ensuring that staff are aware of the structures and processes in place for healthcare audit and that adequate training, staff induction to healthcare audit and protected time for healthcare audit is facilitated and supported.

2. As well as identifying areas of good practice healthcare audits may identify areas for quality improvement. These should be addressed locally by the staff concerned. Where the quality improvement required to effectively improve standards of quality and reduce risk lies outside the their control the relevant line manager is responsible for ensuring that such improvements required are prioritised with all quality and risk Quality Improvement/Control measures required in their area. They allocate resources including financial resources from discretionary funds available, for the implementation of quality improvement/control measures. Where such resources are not available they refer the matter to their general/hospital/local health office manager.

3. It is their responsibility to monitor the implementation of identified recommendations following healthcare audit.

4. It is their responsibility to prepare an annual report of healthcare audit activity for the General/hospital/local health office manager.

All Staff

It is the responsibility of all staff to ensure that they are following best practice and delivering high standards of care. Healthcare audit is one method of assurance that best practice is being followed.
It is also a key component of education and continuing professional development.
Staff are responsible for being aware of healthcare audit structures and processes and undertaking audit within their area of responsibility.

Local Clinical Audit/Quality and Risk/Governance Committee.
Terms of reference to be agreed in each directorate.

Clinical Audit Lead. The Lourdes Hospital Inquiry stated 'it is essential that there should be a clinical audit lead to plan the programme and evolve responsibility for individual projects'. (Harding Clark 2006).
The clinical audit lead has a role in creating the strategy for embedding clinical audit within the organisation, they should have a high profile and be capable of championing clinical audit both with colleagues and management. The clinical audit lead should build up a network of champions in all services; these leads are often on

the Local Clinical Audit/Quality and Risk/Governance Committee. The clinical audit lead should be actively involved in linkages to other aspects of quality and risk management to allow for the dissemination of audit information and the setting of local audit priorities. The clinical audit lead should have adequate dedicated time and resources to achieve these tasks.

Healthcare Audit Support Staff
Healthcare Audit support staff have a number of roles and responsibilities depending on their role on the clinical audit support team. These range from data collection and data entry to planning the healthcare audit programme in conjunction with clinicians and managers.

Role of the following organisations.

Medical Council

Royal Colleges

Professional Bodies

Following consultation with these organisation on the draft documents, this requires further development.

Process

Criteria for Healthcare Audit.

Stage One: Preparing for the audit (NICE 2002)

1.1   Win the support and commitment of colleagues (Sale 1996)

Without the support of colleagues and their commitment to participate any audit will be difficult. It is vital that all employees are involved in the subject of audit, understand the aim of the audit and their role in it. Management should be involved in the audit process, which should reflect the mission statement and the objectives of the organisation they manage. Audit projects are best conducted within a structured programme with effective leadership, participation by all employees with an emphasis on team working and support.

Criterion 1.1.1 If the project is an audit of clinical standards i.e. a clinical audit, then it should have the commitment of the lead clinician within the field of concern. Such commitment need not necessarily involve the clinician's direct participation, but they should at least approve of the audit's conduct.

Criterion 1.1.2 All those involved in the audit should be identified officially before the audit commences, and their approval for involvement sought and agreed. Agreement on leadership and ownership for the audit should be reached at this stage as well as responsibility for management of audit results and recommendations.

Criterion 1.1.3 In addition to identifying those involved, their specific responsibilities within the project should be clarified and agreed by all, before the audit commences.

Criterion 1.1.4 The project should involve or consult those with the authority to sanction any changes that the project might recommend, particularly if they have potential resource consequences or implications for other services/areas (Walshe and Spurgeon, 1997)

Criterion 1.1.5 All those involved in the audit should be committed to change, if necessary as a result of audit. (Kings College Hospital 1999)

Criterion 1.1.6 'The priorities of those receiving care can differ quite markedly from those of [service providers]. Service users should therefore be involved in the audit process. There are practical examples for user involvement in all stages of audit, including the design, the collection of data about performance and in implementing change' (NICE 2002). A recommended standard is 10% of audits should have active user involvement (CGST 2005)

Criterion 1.1.7 'There should be greater multiprofessional working across the different clinical and managerial disciplines that contribute to the patient's episode of care. A standard that 50% of audits are multiprofessional is recommended' (CGST 2005)

Criterion 1.1.8 A cross directorate approach should be adopted, where a service users care is managed across primary, secondary and continuing care. This particularly important in chronic illness and disability' (NHS Executive 1996) A standard that 30% of audits are across services is recommended (CGST 2005)

Guidance
'To determine if any other healthcare professionals should be involved in deciding on the topics and objectives for audit, you should first identify:

- The healthcare practitioners involved in delivering care to the service user.
- Those who receive, use or benefit from the care or service involved.
- If the patients should be involved, e.g. do you want to consider the patients' experience of your clinical care?
- If improvements in care or service can be made directly by the proposed group involved in the audit, or if others will be needed to support action if improvements in care are needed.

So involve all stakeholders as early as possible and give everyone a chance to contribute. Ownership is *essential*! This is particularly important if change in practice is required following the audit' (HSE e-learning centre 2005).

Who might need to be involved?

- Management, Nursing staff, medical staff, GP's, Allied Health Professionals, library staff to assist with accessing the evidence, HIPE staff, Medical Records department staff, etc.
- Healthcare Audit support staff. In the absence of such support find out who else works in your organisation with a remit for quality and/or risk e.g. quality/accreditation/risk/practice development facilitators.
- Researcher or statisticians if you will require complex statistical analysis of your data. This is rarely a requirement and usually only simple descriptive stats involved in Audit
- The patient
- Use a stakeholder analysis tool if you wish (Appendix 1)
- Agree who needs to be involved and seek commitment
- Consider ways of informing them - use pre-arranged meetings, letter, briefing sessions.

1.2   Decide on the area for audit

The starting point for many quality improvement initiatives – selecting a topic for audit, needs careful thought and planning, because any audit project needs a

significant investment of resources during the audit itself and the quality improvement phase of the project.

Criterion 1.2.1 The audit topic should meet one or more of the following criteria:
1.2.2   Is the audit part of a prioritised programme of audit locally, regionally or nationally?(CAAG 2006)
1.2.3   Is the topic of high cost, volume or risk to staff and users? Sources of data to inform this decision could be activity data from HIPE or registers, financial data, or data from your risk register or incident /complaints database?
1.2.4   Is there good evidence available i.e. national guidelines e.g. Breast cancer Guidelines, Record Management guidelines?
1.2.5   Is there evidence of a serious quality problem e.g. patients complaints, incidents, high complication rates, staff concern?
1.2.6   Audit should include assessment of process and outcome of care (CGST 2005)

Guidance

'Another approach to selecting topics for audit-

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

Structure
The setting and resources (*what you need* - staff, buildings and equipment required to deliver a service), e.g.

- Resuscitation equipment in a GP surgery.
- Accessibility of service for disabled individuals.

Process
The practices/methods of care (*what you do*) which may be specific to:

- Clinical process, e.g. post-operative pain management, communication with patients at first appointment in child and mental health service.
- Organisational/administrative process, e.g. system for patient recall, discharge practice, waiting times, medical records management.

Outcome
The effect of healthcare on a patient's health status (*what you expect*), e.g. blood pressure control, weight increase in young people with anorexia after intervention' (HSE e-learning centre 2005).

Other sources of information/indicators for topics for audit could include:
- 'Risk register
- Activity information – e.g. throughput, re-admissions, waiting lists
- Alerts received relevant to your service
- National audits e.g. hygiene audit

- Analysis of consumer feedback e.g. complaints, satisfaction surveys, focus groups, consumer panels.
- Audit reports, inspections, site visits e.g. College visits, accreditation surveys, licensing bodies, regulatory bodies.
- Inquiry reports, national and local.
- Research
- Peer review meetings
- Morbidity and mortality meetings
- Clinical databases e.g. cancer registry, obstetric databases
- Evaluations
- Claims data
- Media reports
- Minutes of team meetings
- Review of external inspection reports e.g. Accreditation reports, Health and Safety Authority reports, Professional Body inspectorates, Irish Medicines board Alert, Ombudsman reports/appeals
- Sickness absence/staff turnover
- Staff concerns
- Visual inspection
- Specialty specific audit topic from professional bodies' (HSE 2007)

Whatever topic is chosen it is important to consider a few practical points:
'Is it realistic?
Is it a real problem?
Can it be measured?
Are there standards/criteria to measure against?
Can a change be made?
Is the effort required acceptable?
Are there sufficient resources to see it through to completion of the audit and change implementation?
Has the group involved the necessary expertise and enthusiasm?
Will this project lead to measurable improvement for service users/staff?
Is this project relevant to the business objectives of the organisation?' (The Pharmaceutical Journal 2005)

The reasons for undertaking the audit project must be systematically examined before the project is started to assess its priority. Not all topics can be audited straight away but each unit should devise an annual audit plan based on their audit priorities. 'It is important to ensure that the views of users, clinical staff, support staff and managers are represented in the selection process. A scoring system could help rank topics in order of importance such as quality impact analysis or use of the nominal group process, The Delphi process or multivoting. See appendix 2 for a sample tool for prioritising topics for audit.

Criterion 1.2.2. Audit or Research? Ensure the project is audit and not research.

Guidance
Clinical audit and research have complimentary roles to play in ensuring clinical effectiveness and quality improvement but are not one and the same. It is important to ensure that the project being undertaken is indeed clinical audit as each has its own purpose and function and in particular as there are different ethical responsibilities. The purpose of research has been described as 'to add to a general body of scientific knowledge which has universal application' while the purpose of audit is to maintain and improve standards. 'Research is concerned with discovering the right thing to do; clinical audit with ensuring that it is done right' (BMA 1995).
There are similarities between audit and research:
Audit methods may be similar to those of research e.g. prospective or retrospective, quantitative or qualitative, both require well designed studies. The following table gives a simple checklist of the differences between audit and research and is useful to ask yourself these questions when the topic is being discussed.

Clinical Audit	Research
• Answers the question 'Are we following best practice' • Measures against standards • A cyclical series for reviews • *Usually* small sample over short time frame • Pragmatic choosing of sample size • Collects routine data • **Never** involves a patient receiving a completely new treatment • Findings influence activities of local clinicians and teams • Does not usually require ethical approval*	• Creates new knowledge about what works and what doesn't • Is based on a hypothesis • A series of once off projects • *Usually* carried out on a large scale over a prolonged period of time • Collects complex data • May involve patients receiving completely new treatment • May involve experiments on patients. • Findings influence activities of clinical practice as a whole • Usually requires ethical approval

* But need to consider ethics of the audit project.

On occasion the lines between audit and research can be blurred and the project may contain elements of both audit and research. You should in that instance apply for formal ethical approval for this project. Clinical audit is the final step of a good clinical research programme i.e. it is in a series with research and not parallel to it. Clinical Audit may also identify where further research is needed.

1.3 Audit and Ethics

Criterion 1.3.1 Audit does by definition not involve anything being done to service users beyond their normal management and therefore does not require formal ethical approval (UBHT 2005). However you should still consider the ethical issues for your project.

The starting point in the consideration of ethics is to remember that your audit project should do good and not do harm. Audit Projects do not routinely need to go before a research ethics committee (REC). Audit committees (quality and risk committees, governance committees – titles may vary) should consider ethical concerns where they arise in relation to the project. Where there are difficulties reaching ethical decision the audit committee should liaise with and seek the opinion of local REC's. The main ethical consideration with an audit project is that of confidentiality – patients confidentiality, staff confidentially and organisational confidentiality. The other issue is that of consent. While express consent is not required currently where audit is being undertaken by the healthcare professional involved in the care of the patient, patients should be made aware that data from their records may be used for audit in an anonymous way. Under the Data Protection Act 2003, where the audit is being conducted by non healthcare professional then consent from the patient/client is required.

Other ethical considerations include ensuring that the audit methodology is appropriate and rigorous.

'Clinicians [and managers] have a duty to use the findings from audit to improve clinical care and move towards best practice i.e. audit is an essential tool for continuous quality improvement' (BMA 1995)

1.4 Who will do the audit?

Decide from the group of stakeholders who will be responsible for the audit and who will actually carry out the work. If it is a clinical audit -'It is usually the clinicians responsible for the audit that collect that data' (UBHT 2005).

Guidance

Select one member of the team to be co-ordinator/lead for that particular audit project with responsibility for the overall management of the project. (CGST 2005). Front line staff may be required to assist with retrieving and recording data.

1.5 Setting the audit objectives

Criterion 1.5.1 The audit objectives should be set and agreed by the audit group.
They should be documented using an audit proposal form.

Guidance

Objectives must be measurable and achievable and in line with the strategy and objectives for the audit programme and the organisation as a whole. 'Once a topic is selected the audit group needs to agree on the objectives for the audit. It is important at the beginning of an audit to have a clear sense of purpose. Ask yourself:

- What do I want to know by undertaking this audit?
- What do I want to achieve by undertaking this audit?

You may find the SMART model outlined here helpful in defining your objective.

Objectives should be:

Specific
Measurable
Achieveable
Relevant
Timely
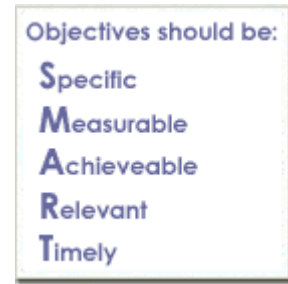
It has been suggested that the following verbs may be useful in defining the objectives of an audit:

- To *improve*, e.g. "to improve the safety of our drug prescribing".
- To *enhance*, e.g. "to enhance the quality of care given to patients by improving assessment of pain, increasing the swiftness of pain relief given and the use of appropriate analgesia".
- To *ensure*, e.g. "to ensure that every infant has access to immunisation against diphtheria, tetanus, pertussis, polio, influenza B and meningitis C before 6 months of age".
- To *change*, e.g. "to change and improve the way patients are allocated appointments". (HSE e-learning centre)

1.6 Project Management
Criterion 1.6.1 A project plan should be developed which explicitly sets out the proposed activities in the completion of the audit cycle about the topic or area, set target dates for completion and assigned responsibility for tasks to individuals. (Walshe and Spurgeon, 1997)

Stage 2. Selecting the criteria

Criterion 2.1 All audit projects must have agreed criteria to measure against. These criteria should be derived from evidence – either from good quality guidelines, reviews of the literature or where this is not available national or local consensus. The next step involves agreeing the standards which in most cases should be 100% or 0% with exceptions listed.

Guidance
Once a topic has been chosen, valid criteria for evaluating against and the level of performance (standard) must be chosen. Criteria can be classified into those concerned with:
1. Structure (what you need)
Examples of criteria relating to structure include the numbers of staff and skill mix, the provision of equipment and physical space.
2. Process (what you do)
Process criteria refer to actions and decisions taken by practitioners and users. Examples include assessment, education, documentation, prescribing, surgical and other therapeutic interventions.
3. Outcome (what you expect)
Outcome criteria are typically measures of the physical or behavioural response to an intervention, reported health status and level of knowledge and satisfaction. Sometimes surrogate or intermediate outcome indicators are used instead.

'Criteria and standards are two audit terms that can cause some confusion. A sporting analogy might help:

- The *criterion* of an athlete might be the high jump.
- The *standard or level of performance* would be the height of the bar.

The table shows the relationship between criteria and standards in clinical audit:	
Criterion	**Target standard**
Administration of diuretics to patients with heart failure.	100% of patients to achieve this level of care.
Adequate facilities for hand hygiene are available i.e. one wash basin per 6 beds or enclosed area	100% of areas (Desford Consultancy 2005)

The use of an objective criterion with an agreed standard of performance is a hallmark of clinical audit.

The criterion and the level of performance must be measurable and acceptable to all the stakeholders involved in an audit. These criteria are explicit statements that define what is being measured, for example:

- The date, vaccine batch and number of a vaccine administered should be entered in the patient's notes' (HSE e-learning Centre)

Poorly defined criteria can be misleading. There are four requirements for good and valid criteria:

1. Relevant.
2. Clearly defined.
3. Easily measured
4. Based on evidence (NICE 2002)

The table shows the relationship between criteria and standards in clinical audit:	
Criterion	**Target standard**
The date, vaccine batch and number of a vaccine administered should be entered in the patient's notes.	100%

Some criteria are so important that the level of performance or standard chosen has to be met all the time, as in the previous example' (HSE e-learning centre)

Sourcing criteria- some ideas
- Royal Colleges or Professional bodies e.g. An Bord Altranais

- Literature

- Guideline Development Organisations e.g. NICE, SIGN

- National and international literature.
- National, and Local policies and procedures.
- Statutory requirements and regulations
- Clinical guidelines.
- Clinical pathways.
- Develop your own:

Criteria should be based on the latest available research and evidence. Your literature search gives an idea of what criteria and standards are recommended or achieved internationally and nationally. If criteria are not available, it is acceptable to develop criteria based on a local consensus. In any event all standards must be agreed by members of the team.

If searching and reviewing the literature before agreeing standards you should follow the stepped approach to Evidenced Based Healthcare:

- To convert the knowledge gap into an answerable question
- To search for and locate the best evidence using appropriate databases and other sources of evidence. Your local librarian can assist you with this.
- To critically appraise the evidence
- To apply the evidence

Stage Three: Measuring Performance

Criterion 3.1 Audit methodology should be appropriate to the objectives of the audit and the criteria being measured.

Guidance
The methodology of audit should be clearly established and made known to all involved. Methods used need to be clearly documented to answer queries in the future and to be able to replicate the audit either elsewhere or at re-audit stage. Issues to consider are:

3.1.1. A data collection tool and protocol for collection are usually required unless you are able to run audit reports from a database.
This ensures validity and reliability of the findings as it may not always be the staff involved in the service who are collecting the data. This tool should be made up of questions that should link to specific objective and criteria. Don't collect information that does not relate to the audit just because it is 'interesting'. See appendix 3 for Top tips for the successful development of Audit data collection tools. It is a good idea to search to see if an audit tool suitable for your audit topic already exists. Sometimes guidelines are accompanied by audit tools. Piloting should be used to check the tool collects the information you require to establish if the criteria are being met or not.

3.1.2. Where to find the data.
Is the data you want collected routinely in the patient notes or databases? If so you can to the audit retrospectively (i.e. collect data from the past). Although data from clinical records is frequently used they are often incomplete. The collections of data from several sources can help overcome this problem. Potential sources for you to

consider are - Patient records, Laboratory reports, GMS drug Records, Radiology reports, Patient Administration Systems, Hospital Inpatient Enquiry System (HIPE), GP records, Community healthcare records.

If not you will need to collect data prospectively (i.e. as and when new patients arrive). In this instance you may require staff/ family/patients to complete data collection tools. Another method of prospective data collection is using observation of practice e.g. hand washing. This form of data collection presents its own challenges in that it can be time consuming, data collected is not always complete and accuracy must be assured.

'Electronic information systems can contribute to audit in many ways, including improving access to research evidence; identifying users, collecting data, and enabling revised systems of care to be introduced' (NICE 2002)

3.1.3 Sampling

Audit often involves pragmatic choosing of the audit sample size. If there is no limitation on resources the whole population could be audited. However, if the number of patients in your population is over 100 you will most probably want to look at taking a sample of those patients. This will merely give you a 'snapshot' of whether standards are being met or not. 'When choosing a sample two questions need to be answered:

- How many users (study population) do I need to select?
- How do I choose a representative sample? (NICE 2002)

'The number needed in the sample will be affected by two factors:
The degree of confidence wanted in the findings
Resource constraints (time, staff, access to data, costs).

Clinical audit doesn't have to involve extensive data collection. It is *not research and does not require large numbers of cases*. It is a *balance* between what is *practical to collect* and what will *confirm the level of performance* in comparison with the standard. For example:

- A sample size of 40-60 cases is practical, can be collected in a reasonable timeframe and will usually permit meaningful comparison of current practice with the agreed standard.
- The type of case to be *included* and *excluded* must be defined and agreed with all stakeholders before data collection commences and must relate to the criteria selected.

The planned *timeframe for data collection* also needs to be defined before data collection starts. It will be influenced by:

- Number and type of cases.
- Inclusion and exclusion criteria.
- Target for audit completion'(HSE e-learning Centre)

There are many sampling types but the ones regularly used are random sampling or convenience sampling.

Simple random sampling 'involves the selection at random from a list of the population of the required number of persons for the sample. A lottery method, random number tables or a computer can be used. This gives each person an equal chance of being included in the sample' (1997). The Hospital In-patient Enquiry System (HIPE) offers a facility for random selection of a sample of patients from a list of the population.

Convenience sampling. 'Convenience sampling is sometimes used as a cheap and dirty way of doing a sample survey. It does not produce representative findings. It involves choosing the nearest and most convenient persons to act as respondents. The process is continued until the required sample size has been reached' (Robson 1997). There are a number of other sampling methods which the reader can familiarise themselves with from any good book on research such as the one referenced here.

3.2 Record Keeping
Proper records should be maintained of the project as it progresses so that progress against objectives can be monitored and changes to methodology recorded.

3.3 Data Protection Act and Freedom of Information
When audit is being undertaken a by a member of the healthcare team, written consent is not required. However, it is good practice to inform service users that as part of their normal care process their personal data may be used for audit and quality improvement e.g. use of a patient information leaflet when they use health services.

Guidance
'Given the fundamental role played by 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 from the health facility itself.

Where the clinical audit may be carried out by persons not involved in the care of the patient, i.e. in this case external to the data controller, informed consent will need to be in place for access by such persons [1]'. (Data Protection Commissioner 2007)

Audit data should be anonymised to ensure confidentially of patient and clinician information.

Audit reports may be accessible under the Freedom of Information Act 1997 but to date this has not been tested in Ireland.

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[1] 'Provider institutions must ensure that the express consent of the patients is obtained for the process of clinical audit by staff not involved in the care of the patient' (EuroSOCAP, 2006) http://www.eurosocap.org/Downloads/European-Standards-on-Confidentiality-and-Privacy-in-Healthcare.pdf. It is recommended that this use of patient information be listed on an information leaflet by the healthcare service providing care and at the first opportune point a person presents to the service.

3.4 Data analysis.

Criterion 3.4.1 The type of analysis to be used should be identified at an early stage, as it influences both the type and amount of data collected. The analysis can range from a simple calculation of percentages, through to relatively sophisticated techniques.' (NICE 2002).

Guidance
The purpose of analysing the data is to establish what criteria are meeting the standards and identify areas where practice needs to be improved. Where possible data analysis should be kept as simple as possible. Pen, paper and a calculator are often sufficient to compute frequencies and percentages. When completing data analysis it is advisable to have a second person check your results to ensure accuracy.

'Data process can be described as a three-step process

Step1

Create a **coding manual** - assign a simple numeric code for all the possible answers in each question in the data set. Using the data collection form, assign a code (numerical value) for the potential answers to each question, e.g.

- Was the blood pressure recorded? Yes = 1, No = 2.
- Smoker =1, Nonsmoker = 2 Unknown = 9.

Step 2

Open a field in the database/spreadsheet for each of the questions in the data collection form.

Step 3

Use the codes created in the coding manual to record the answers to each question.

General principles of data coding[1] are as follows:

- Provide a unique patient identifier.
- Use numerical codes, e.g. options 1-9.
- "9" is the universal code for missing data – if options are higher than 9, use 99.
- Prepare a coding manual.
- Adopt a consistent coding scheme including a code for data that are missing or unavailable.
- Avoid free text if possible.
- Code the text information by allocating categories, e.g. disease groups, therapeutic drug groups.

Electronic data

- Increasing use of routine electronic *data collection* through computerised patient records will facilitate data capture for clinical audit.
- As with manual methods, clearly defined data that are linked to audit objectives, criteria and standards are required.
- Data transfer can be computerised, bypassing the need for manual data entry.
- With the appropriate software, *data analysis* can also be done directly.
- As with paper records, *attention to detail* is required to ensure that electronic data capture will be complete, accurate, timely and efficient'(e-learning centre)

For further detailed information on data analysis see the United Bristol Healthcare Trust 'How to' guide on data analysis:
http://www.ubht.nhs.uk/clinicalaudit/docs/HowTo/Analysis.pdf
If you require detailed data analysis using statistics you should contact a research department for advice and support.

3.5 Root cause analysis
Criterion 3.5.1 Establish why the criteria and standards weren't met.

Guidance
Once data analysis is complete you should have identified the criteria that are not meetings the standards. However, it will be necessary to present these results to the audit team to establish the causes of why this has happened. It is only be looking at the root causes that you can identify what changes are required and put in place your quality improvement plan. There are a number of tools to assist you in root cause analysis such as
The **fishbone diagram** (also known as Ishikawa diagram or cause and effect diagram)-it's a problem solving tool that helps identify the particular cause of a problem or a desired effect. A problem or an effect is written in the head of the fish. A common set of major categories of causes are written in the bones of the fish such as personnel, work methods/procedures, materials and equipment.
Process mapping- each step of a process is mapped out so that problem areas/bottlenecks in the process can be identified and improved.
The five why's – asking the question why something has happened five times –each times drilling down further to get to the root cause of the problem.

By identifying the root causes you can then move towards identifying the changes needed to improve.

3.6 Report writing
Criterion 3.6.1 All audits should be completed by writing an Audit report.

Criterion 3.6.2 The Audit report should be made available to management.

Guidance

'An audit report should report the *actual practice* compared with the *standard*. The report should identify shortcomings and needed improvements.

Planning the way forward should be done in consultation with all the stakeholders involved in the audit. At the end of this process, you should be in a position to agree the final report.

The report should identify:

- *Shortcomings,* e.g. practice unrecorded, practice not occurring, poor levels of satisfaction.
- *Causes,* e.g. poor documentation, inadequate staffing, training and practice issues.
- *Needed improvements,* e.g. the introduction of a structured assessment proforma for patients with *asthma*, so that all relevant patient data and examination findings are checked.
- Information that explains *why* some cases do not meet the standard.
- *Relevant*, *meaningful* and *useful information* that will help to identify and address the issues arising from the audit.

The report should:

- Be simple and clear.
- Use plain English.
- Use a structured, systematic approach, e.g. IMRAD (introduction, method, results, analysis, discussion which would include recommendations and an agreed action plan if required).
- Present descriptive statistics graphically where useful.
- Make sense and follow a logical progression.
- Be easily understood. A good yardstick is to ensure that the report would be clear to a colleague from a different discipline or a different aspect of the service. A good report will make even a complex issue understandable to all'(HSE e-learning Centre)

Stage 4. Making Improvements

Criterion 4.1 All audits should be accompanied by a quality improvement plan.

Criterion 4.2 There should be a mechanism for prioritisation of areas to be addressed as a result of audit as part of a wider programme of prioritisation of all areas for improvement identified by all quality and risk activities.

Guidance
Once the changes needed to improve have been identified, a continuous quality improvement plan needs to be drawn up. The audit group need to examine and decide:
- Who's responsible?
- What resources are required?
- What timescale?
- Accountability structures

A simple action plan table or a Gant chart can be useful tools in helping to keep the changes on track.

Action	Resources required	Person responsible	Timeline	Evidence of completion

It is unlikely that one change alone will improve the standard. 'In audit the use multifaceted intervention chosen to suit the particular circumstances is more likely to be effective in changing performance than the use of a single intervention alone' (NICE 2002). If possible the evidence in the area of the change should be reviewed to establish effective strategies for change. For example in a recent antibiotic audit it was found that introducing guidelines alone was not effective. Education and monitoring were also required to ensure effective improvement in practice.

Some simple quality improvement tools such as the Plan- Do –Check-Act cycle could be used to implement the quality improvement.

Some issues are more of a concern than others, so you may want to prioritise which criteria you want to improve first. One method of prioritisation may be to use a risk matrix – in other words what issue if is not addresses will cause the greatest risk to patients/clients or staff. See appendix 4 for the HSE risk matrix.

When making changes you should follow the steps you followed at the start of your audit. Identify your stakeholders. Ownership of the change is vital. If change in practice is needed, participants must be able to see why or commitment to change will not be present. Establish a change management group with a lead responsible for co-ordinating/managing the change. Write a project plan. Keep good records. Enlist the support of quality improvement support staff within your organisation if possible. When identifying your quality improvement plan it is important to liaise with your risk management dept, quality improvements staff, practice development staff, accreditation staff as they may already have identified successful methods of dealing with similar issues e.g. improving documentation, reducing rates of infection etc.

It is also important to involve management in the change planning and implementation stage. They may need to designate resources to the quality improvement but also they should be advised on what quality improvement activities are underway in their areas of responsibility.

Stage Five: Sustaining improvement

5.1 Monitoring and Evaluation

Criterion 5.1.1 all audits and their quality improvement plan should be subject to on-going monitoring and evaluation.

Guidance

This is where the audit cycle continues. If quality improvement plans were agreed then you need to monitor to see if they were implemented according to the project plan. See appendix 5 for a sample checklist for monitoring change.

You need to evaluate to see if these changes have effectively raised the standards. This is your re-audit. A rapid re-audit is advised to assess the effectiveness of the changes. You can use the same audit tool and protocol. All the steps need to be followed so identification of resources is important.

5.1.2 Performance indicators

Performance Indicators can be used to monitor improvements as a result of Quality improvement activities. 'However, although the organisation must invest in facilities, personnel and training to monitor indicators, it is important to realise that only the minimum number of essential indicators should be included in the monitoring' (NICE 2002).

Criterion 5.1.3 Audit improvement should be integrated into the overall quality improvement strategy in the organisation.

Guidance

Quality improvement plans will be identified using a number of methods in any healthcare organisation. These include the service planning process, needs assessment, complaint and incident reviews, risk registers, health and safety statements, external inspectorate reports etc. It is important that all QI plans are prioritised and managed in an integrated way and that there is a structured programme of quality improvement..

Criterion 5.1.4 Evaluating audit quality
'The quality of an audit programme must be evaluated as part of the wider [quality and risk management] agenda' (NICE 2002).

Guidance

A useful self assessment tool for Audit Departments is available from the South Yorkshire Strategic Health Authority (Appendix 6). This enables organisation to assess their structures, processes and outcomes and resources for audit activities.

Criterion 5.1.5 External Audits

External audits will be conducted by a number of other agencies to fulfil statutory, regulatory and monitoring requirements. These include HIQA, the Medical and Dental Councils. The Mental Health Commission, the HSE Quality and Risk Team, Internal Audit (this list is not exhaustive).

Criterion 5.1.6 Each Hospital/Local Health Office/Service Area should produce an Audit Annual Report.

Capability

Protected Time

To engage fully in healthcare audit as part of a structured programme of quality and safety improvement, staff require protected time from their day to day duties. 'All [employees] involved in the delivery of [healthcare services] should participate in audit and should be allowed the appropriate time and facilities to complete this contractual requirement' (CGST 2005). Evidence on the required amount of protected time for audit is weak, with most of the literature only relating to the required amount of time for medical staff to participate in audit.

In the recent review of medical consultant contracts in Ireland 'there is no evidence in any hospital of dedicated time where audit outcomes are presented, debated and decisions made on how to move forward from present practices on the basis of audit findings' (CAAG 2006). 'One organised half day should be set aside each month for a full clinical audit of the previous months work. The attendance of consultants and registrars should be compulsory except for attendance at emergency case in the theatre or labour ward' (Harding Clarke 2006)

In one study of a surgical audit team the time required for audit was calculated to be one third of an NCHD's time per week, one third of secretary's time per week and approximately a half day per month per consultant to oversee and supervise the work (Reference HSE SE Audit). In Northern Ireland medical staff have an average of one day per month protected time for audit and all other staff have to negotiate locally for time to facilitate audit.

Levels of protected time should be reviewed on an on-going basis.

Those involved in audit should maintain records of attendance at meetings and presentations. 'This is essential as part of the process and records should be held within the clinical audit department' (CGST 2005). This would provide valuable evidence for inspections and accrediting bodies.

'Managers should be actively encouraged to attend audit meetings as they share responsibility for overall quality of care and have a key role to play in helping clinicians to improve services by the development of action plans' (CGST 2005)

Healthcare Audit Support Staff

The literature supports this. NICE states that audit support staff have a number of important roles although these may differ between organisations. They need to have a good understanding of audit methods, as well as significant organisational and analytical skills. Local audit staff can provide the expert help required to assist staff undertaking audit.

Training

Education and training is a critical factor with regard to the successful implementation of this guidance. Education and training in all aspects of healthcare audit should be provided to all staff.

'Lack of training and audit skills is highlighted in the review of the evidence as a barrier to successful audit' (NICE 2002)

Their evidence found that an on-going programme of training in clinical audit for clinical professionals should be available to members of staff from different specialties and disciplines. There could be a number of approaches to training.

1.   Basic 1-2 hour information session on clinical audit for all staff. This would ensure everyone has an understanding of audit and their role and responsibilities in relation to audit.
2.   A two-three day audit skills course for audit leads or staff who are directly involved in carrying out audit. This could be delivered 'in house' by clinical audit support staff or externally by education providers. This should be accredited and form part of staff continuing professional development programme.
3.   A module of post graduate training programmes for all staff e.g. MSC in Nursing, MA in management.
4.   Introduction on undergraduate training programmes as part of quality management education.
5.   Accredited training for Clinical Audit Support staff

Information Technology

'Electronic Information Systems can contribute to audit in many ways, including improving access to research evidence, identifying users, collecting data, prompting change through record templates, and enabling revised systems of care to be introduced' (NICE 2002)
.
Requirements:
   1. Databases with audit report functionality
   2. Databases to record Audit activity maintained the audit department
   3. Standalone data collection systems such as the Infection Control Nurses Association hand held audit device and software.
   4. Data analysis software with statistical capability for more complex audits.

For further development by ICT Quality and Risk Scoping Group with Clinical Audit input.

Budget to resource all the above

Comprehensive costing for audit in the Irish healthcare system needs to be conducted. Some work has been done on costing a model for medical audit only.
The Medical Council determined costs of implementing a model of Clinical Audit appropriate to the needs of an individual medical practitioner enrolled in Competence Assurance Structures in (2001). This costing model examined direct and indirect

costs of employing clinical audit support staff and not all the other resource requirements which are listed above. The estimate at that time was €18 million. There is a limited amount of information about the cost and cost implications of audit' (NICE 2002). 'Programmes with little or no support and resourcing are unlikely to be effective' (Walshe and Spurgeon 1997).

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Appendices

Appendix 1.

Stakeholder Analysis

Stakeholder	Oppose	Permit	Help	Make

For each stakeholder place an O in the column representing where they currently stand and an X in the column where you need them to be for the successful completion of the project

Appendix 2.

Prioritise your Potential Topics

Topic 1
Topic 2
Topic 3

For each statement on the checklist please rate the proposed audit topics using the following scale:

3 – High   2 – Medium   1 – Low   0 – No evidence

Criteria	Score		
	Topic 1	Topic 2	Topic 3
Identified as part of the service plan for GRH			
Topic is national/regional priority			
There is evidence of a serious quality problem e.g. patient complaints, high complication rates			
Local evidence suggests unwanted variation in practice			
There has been a high level of investment in new equipment/intervention requiring effectiveness to be measured			
There have been major changes in procedures or national/regional standards (mandatory or voluntary) published within the last 6 months			
*The topic concerned of high cost, volume or risk to staff or users			
*There is realistic potential for improvement i.e. not simply a data collection exercise			
*Is the problem concerned amenable to change			
*The proposed project team will include input from all relevant professional groups			
*Criteria against which practice can be measured will be agreed and based on evidence of best practice			
*Changes made following the audit are likely to have a high impact on patients/clients/service delivery			
TOTAL			

* These should be scoring 2 or 3

Source: Galway University Hospitals

Appendix 3
Top tips for the successful development of Clinical Audit data collection tools (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 is vital that you 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-rate 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 you are seeking feedback from patients/carers or staff members it will be important to ensure that the questions are worded clearly and follow the same basic principles used in developing research interview schedules.

Quantitative vs: Qualitative Clinical Audit data collection

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

The majority of Clinical Audit projects 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 are required it is necessary to develop data collection questions for use in interviews/focus groups or via questionnaire.

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

Remember: The data collection tool may be used by others long after you have left your post.

Pilot your data collection tool

Always pilot your data collection tool using a small number of cases.
This will help you:

- 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 maximise the efficiency of data entry and analysis.

Keep it simple.

Do not collect data that you do not require. 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 you can use directly or one that requires a minor amount of modification. It is usually less time-consuming to develop your own 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 you 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 your **good** data collection tools and good audit proposal schedule.

Appendix 4. HSE RISK MATRIX

3. RISK MATRIX	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare/Remote (1)	1	2	3	4	5

Appendix 5. Checklist for monitoring the audit action plan.
NAME OF PROJECT, Follow up on actions in report

Recommendation	Implementation complete within timeframe		If implementation complete, what evidence can you provide to support this	If implementation not fully complete can you state why
	Yes ☐ No ☐ Partially ☐			
	Yes ☐ No ☐ Partially ☐			
	Yes ☐ No ☐ Partially ☐			
	Yes ☐ No ☐ Ongoing ☐			
	Yes ☐ No ☐ Ongoing ☐			
	Yes ☐ No ☐ Ongoing ☐			
	Yes ☐ No ☐ Ongoing ☐			

Signed: _____

Grade: _____

Date: _____

For office use only _____

_____

Total number of recommendations: _____

_____

% of recommendations fully implemented within timeframe: ____

_____

% of recommendations partially implemented within timeframe: _

_____

% of recommendations with no action taken within timeframe:

_____

Appendix 6.

Self Assessment Tool for Clinical Audit Departments
Developed by Martin Ferris, South Yorkshire Strategic Health Authority

Ref No	Criterion	Data Source / Evidence	Target	Comment
1	The organisation has suitably qualified staff in post to support clinical audit	Human Resources	Staff / resources available to support the clinical audit programme. All staff should be suitably qualified or receiving appropriate training.	The staff in post may be employed by another NHS organisation provided that there is a written agreement, typically a Service Level Agreement, that specifies what level of service may be expected. The agreement should consider the audit criteria below.
2	There is a clinical audit budget that delivers the clinical audit strategy, programmes and associated activities	Audit dept / Finance	There is a budget allocated for clinical audit that will enable the organisation to fulfil its programme and supports audit training and staff development. There is evidence that the budget allocation has been linked to the business planning process of the Trust.	This may be encompassed within a joint clinical audit / effectiveness budget
3	The organisation has a steering committee or other formal group for clinical audit that meets at least quarterly	Organisational structure / Minutes of meetings	Committee/group in place and meeting at least quarterly	This could be encompassed within a joint audit and effectiveness group
4	There is a clinical audit strategy that	Copy of strategy /	Strategy exists and has been	For PCTs, this strategy should

	has been approved by the steering committee and clinical governance committee	minutes of meetings	communicated to all appropriate staff	also be submitted to the PEC for approval. The strategy should be current.
5	The strategy has been implemented throughout the organisation	Various including staff newsletter / intranet / minutes of meetings	All services to be aware of and following the strategy	Some evidence should be available to demonstrate dissemination of the strategy to clinical audit leads and that it is being followed.
6	There is a up-to-date trust-wide database of clinical audit projects	Audit dept	Database in current use	This need not be an actual electronic database, but there needs to be a record of audits undertaken by the organisation. A paper list or spreadsheet could be acceptable.
7	An annual audit programme exists for the organisation that includes national priorities and is agreed with partner organisations and with trust staff, and has also been approved by the trust's audit committee or steering group.	Clinical audit committee minutes / Audit dept database	All national audits e.g. relevant NICE guidance (see right), NSFs, national sentinel audits, confidential enquiries and other identified priorities are considered for inclusion in the audit programme. Unnecessary, wasteful or inappropriate audits are not initiated with the reasons documented.	"Relevant" NICE guidance is not necessarily all that applies. If an organisation can demonstrate that it already complies with NICE guidance then audit is not necessary. It may also be that funding has not been secured to implement national guidance, in which case appropriate audit(s) may be deferred. However, it is imperative that

				such exclusions are fully documented, with reasons, in case of external review.
8	There is evidence that unnecessary, wasteful or inappropriate audits are not initiated with the reasons documented	Clinical audit committee minutes / Audit dept database	There should be no inappropriate audits in the annual programme	There is a massive demand for robust or national audits, with limited resources to carry them out.
9	There is regular feedback from the clinical audit sub-group to the clinical governance committee	Clinical governance committee minutes / terms of reference for both groups	Each clinical governance meeting receives feedback from clinical audit and provides advice and direction as appropriate. The chair of the clinical audit sub-group or other nominated is a full member of the clinical governance committee.	
10	Board-approved trust-wide audit programme	Board minutes	Approved audit programme exists	This may be PEC-approved for PCTs.
11	There is a board member lead for clinical audit	Board minutes	Named board member exists	The lead may be for clinical governance, but is expected to be able to lead on issues relating to audit
12	Clinical audit training is available to all staff	Audit dept records	All staff are aware of and have access to training	There should be a range of training options available to all staff from a basic introduction to the opportunity for advanced accredited training for key individuals,

				including those working wholly within clinical audit
13	Each service has audit projects completed that comply with the definition in "Principles of Best Practice in Clinical Audit"	Audit dept database	At least two per service per year, but see comment (right) and footnote.	Where a management unit of the organisation e.g. directorate contains a number of separate "services", then this is an aggregate total of those services (see footnote).
14	All audits are standards based	Audit dept database	100%. The standards used are recorded when the audit is conducted	
15	There is evidence of multi-professional audit throughout the organisation	Audit dept database	50% of audits within the trust should be multi-professional	All audits should be multi-professional unless there are compelling and recorded reasons why this is not so. It is recognised that there are many opportunities to improve the quality of care by improved working between groups. It is also noted that Ambulance Trusts are essentially uni-professional and that this standard may need to be refined for their particular circumstances. It is expected that this target will be increased over time.

16	There is evidence of multi-service audit throughout the organisation	Audit dept database	30% of audits within the trust are across services	See above
17	There is evidence of audit with other local organisations	Audit dept database / audit committee minutes	10% of audits within the trust are with partner organisations	See above
18	There is evidence that audits have identified a need for a change in practice.	Audit dept database / spot check	90% - it is possible but rare for an audit to be done and no change in practice identified/documented	
19	There is evidence that that action plans have been generated as a result of audits	Audit dept database / spot check	All those that have identified a need for change should create an action plan.	Consideration should be given to random spot-checks of action plans to confirm changes identified
20	There is evidence that all audits which have generated an action plan are re-audited.	Audit dept database	90% of those that have an action plan. All audits that have generated an action plan should be audited, but it is unlikely that this will be 100% of this group, due to service changes, resource limitations etc.	It is recognised that some audits will not need to be repeated.
21	There is evidence that audits involve patients / carers where appropriate	Audit dept database	10% of audits have active patient involvement.	Active patient involvement requires patients etc to be included in the design, conduct and actions within an audit project – not just have audits done to them. N.B. Patients should not be involved in those audits in which they cannot have

				an impact. This requires careful consideration by staff. It is expected that the target percentage will rise over time.
22	There is evidence of audits which were initiated by other clinical governance areas e.g. risk, complaints	Clinical governance committee minutes	Connection is made between clinical audit and other pillars of clinical governance	No quantifiable target can be set, BUT scrutiny of the minutes of clinical governance meetings would show whether audits had been identified from other sources.
23	There is evidence of audits which feed into other clinical governance areas	Clinical governance committee minutes	Connection is made between clinical audit and other pillars of clinical governance	No quantifiable target can be set, BUT scrutiny of the minutes of clinical governance meetings would show whether audits had been identified from other sources. It is possible, but unlikely, that clinical audit has not interfaced with other clinical governance areas. If so, this should be documented.
24	All audit meetings are multi-professional and include representation from all professions who may be involved and / or affected by audits identified by	Audit dept records / Individual dept records	100%	All clinical audit meeting should be multi-professional. It is noted that Ambulance Trusts are essentially uni-professional and that this standard may

				need to be refined for their particular circumstances
25	All staff should attend service audit meetings and a record should be kept	Individual dept records	Each staff member should attend 70% of service meetings	Individual attendance is unlikely to reach 100% due to patient care / annual leave / other commitments, but every individual should attend most meetings. Where it is not possible for all staff to attend there needs to be some evidence that all staff have an input to and receive information from these meetings.
26	Each service should have an identified lead for clinical audit	Individual dept records / audit dept records	100% of services have an identified lead	