

Healthcare Audit Criteria

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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.
	<p>Guidance:</p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>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.</i></p>

(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. *Clinical 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:

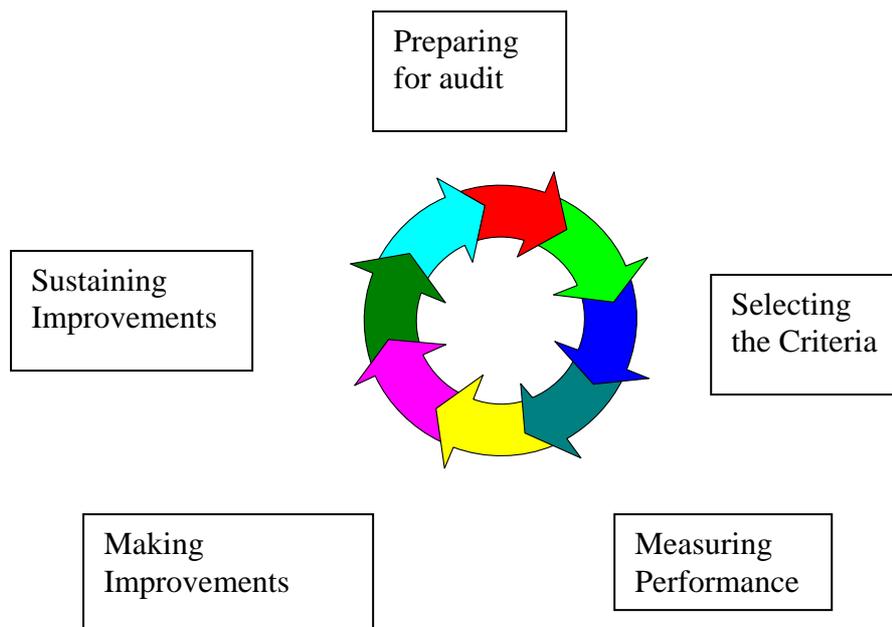
1. To enable staff and service users to evaluate and measure practice and standards
2. To develop and sustain a culture of best practice
3. To establish structures and processes to monitor and evaluate the effectiveness of healthcare audit.

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 employees to ensure that they deliver the best service to their service users. All employees 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)



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)

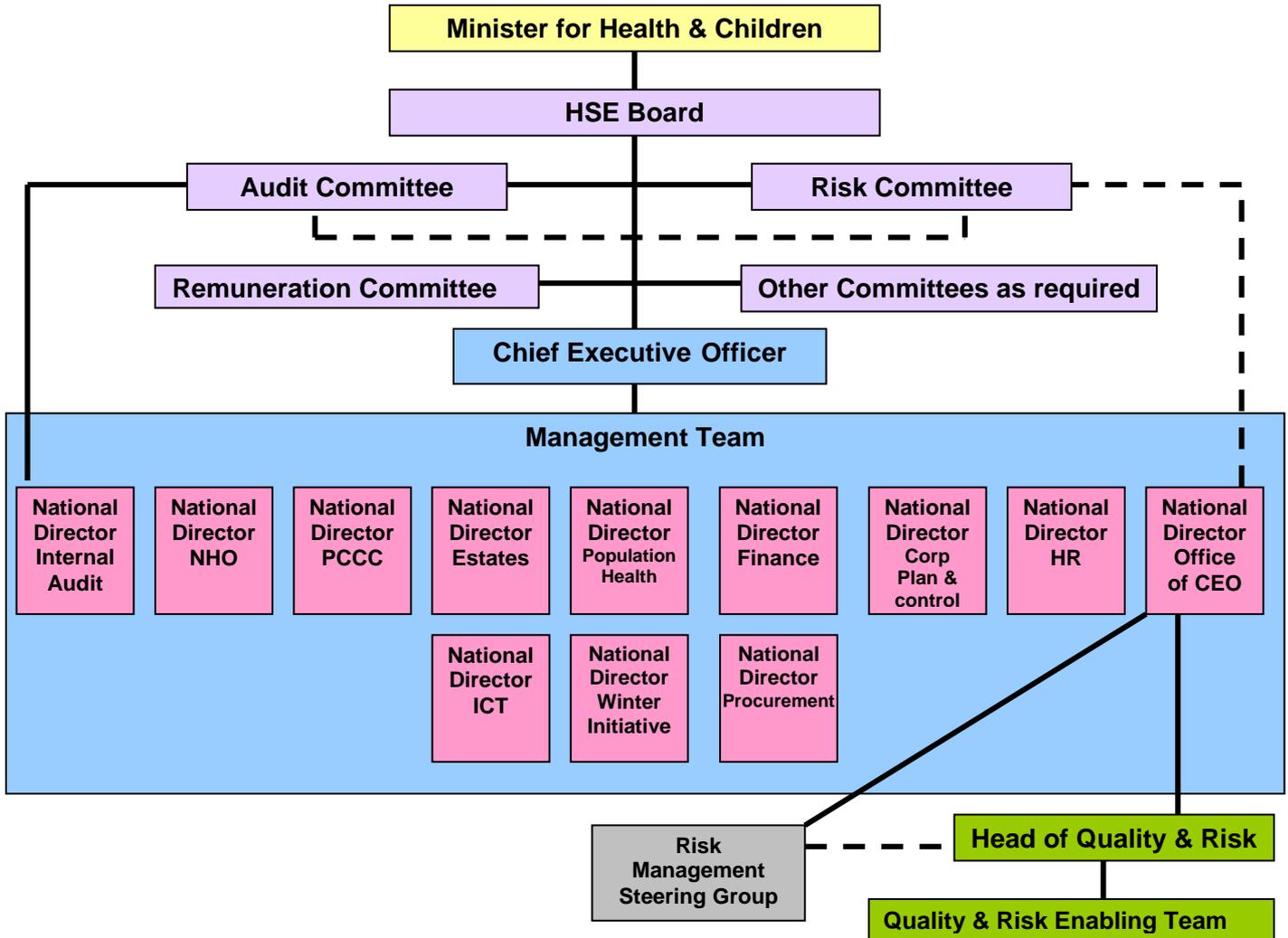
Standard: ‘The percentage of events that should comply with the criterion’ (Baker and Fraser 1995) A standard is the desired and achievable level of performance against which performance can be measured.

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.



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.

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 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 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 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 organisations 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)

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)**

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

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.

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).

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.

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.

Stage Three: Measuring Performance

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

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 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.

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).

3.5 Root cause analysis

Criterion 3.5.1 Establish why the criteria and standards weren’t met.

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.

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.

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.

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.

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).

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, employees 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 outcome 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)

Audit Support Staff

The literature supports the role of audit support staff. 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 audit for employees 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 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 audit support staff or externally by education providers. This should be accredited and form part of employee 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 Audit Support staff

Information Technology

‘Electronic Information System 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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