EUROPEAN SOCIETY OF RADIOLOGY

ESR AUDIT TOOL

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INTRODUCTION

As stated by the European Society of Radiology (ESR), Clinical Audit is defined as a tool designed to improve the quality of patient care, experience and outcome through formal review of systems, pathways and outcome against defined standards and the implementation of change based on the results.

The ESR recognises that Clinical Audit represents good practice and should be a routine activity within radiology departments with which individual radiologists should engage.

This web-based resource is designed to facilitate the development of local Clinical Audit across the spectrum of the services provided by Clinical Radiology. It provides an outline of the principles of Clinical Audit combined with a library of templates for audit in a variety of situations as well as a compendium of useful resources. It is the ESR's intention that, by developing this in a web-based format it can be readily updated and expanded. To this end we would wish individual radiologist and national societies to submit further templates and resources that they have found useful.

BACKGROUND

The European Commission (EC) Euratom 97/43 Directive stated that Clinical Audit should be carried out in relation to nuclear medicine, diagnostic radiology using ionising radiation and radiotherapy. Thus, carrying out Clinical Audit in line with national processes is a statutory duty. The subsequent (November 2009) publication of the EC Guidelines for Clinical Audit suggested a framework within which this could be carried out and detailed definitions of the processes. The ESR has summarised this very long document in a short summary document entitled "Clinical Audit—ESR perspective".

Clinical Audit, though related, is not the same as quality assurance but it looks at the whole radiology service, and the aim is continuous improvement rather than a pass/fail approach. Although the requirement to carry out clinical audit in relation to ionising radiation investigations and treatments is compulsory in the EU, the specific recommendations of the guideline document are not binding and the actual frequency and the methods for audit may, and will, vary from state to state.

In 2011 the ESR published a document entitled "Is the radiological community within Europe ready for clinical audit?": the document pointed out there was and there is still wide variation in the understanding and implementation of Clinical Audit within Europe. Interpretation of the term Clinical Audit and its differentiation from regulation, quality assurance, accreditation and research also differed across Europe. Little has changed in the intervening period. The document concluded there is still much developmental work required before Clinical Audit is widely practised in member states, and Europe-wide uniformity of understanding and practice of audit can be achieved. The EC guidelines seem aspirational rather than achievable in the short term for most member states, but the statutory requirement for Clinical Audit must be fulfilled, and this may lead to closer adherence to the detailed EC guidelines on how it is best implemented.

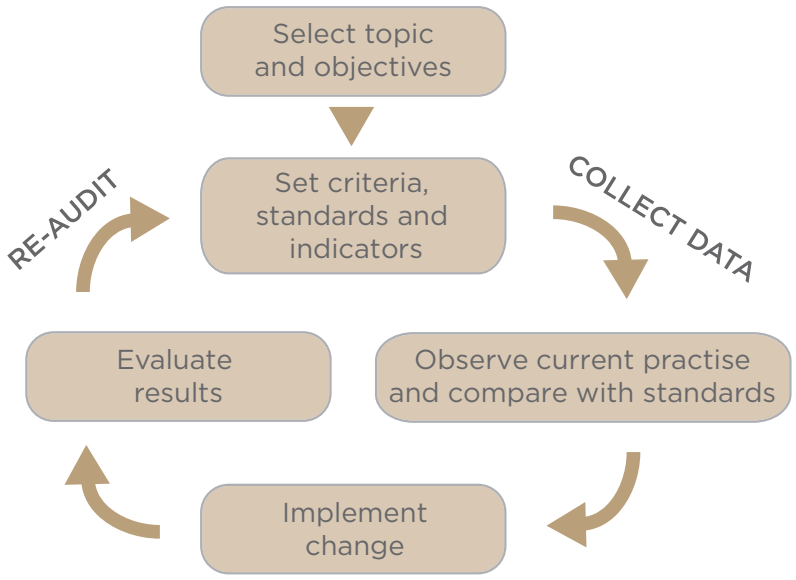
We believe that one of the reasons for this is a lack of understanding of audit methodology. The ESR Audit Tool aims to provide guidance on how to design and perform a Clinical Audit. This is supplemented by examples of Clinical Audits that have been demonstrated to work effectively. Although initially there are only a small number of templates presented to the reader, it is the ambition of the ESR to increase this library with example provided by radiology departments throughout Europe, covering the complete range of services and issues where audit can provide benefit.

Participation in Clinical Audit has many benefits which include the demonstration of a commitment to the delivery of a high quality service. It may also indicate areas of the service where further investment is required.

WHAT IS CLINICAL AUDIT

Clinical Audit is a tool designed to improve the quality of patient care, experience and outcome through formal review of systems, pathways and outcome of care against defined standards, and the implementation of change based on the results. Audit uses specific methodology in which performance is compared with a preselected standard. If the standard is not achieved, reasons for this are explored, change is implemented and a re-audit is carried out to ensure improvement. This methodology is often described in terms of the audit cycle, illustrated in Fig. 1.

Audit can be described as internal or external. Internal audit, which is more commonly carried out, refers to audit carried out within a department or institution and external audit refers to audit performed by professionals from outside the department or institution. Whether internal or external, audit should not be carried out without the knowledge of those involved in the delivery of the service and should be a planned, scheduled process.



WHO SHOULD PERFORM AUDIT?

AUDIT CAN BE PERFORMED AT THREE LEVELS

- Individual clinician
- Service (e.g interventional radiology, ultrasound etc)
- Department

At whichever of these levels it is performed, Clinical Audit, as the title implies should be clinically led. Health professionals, including radiologists together with other professional staff such as radiographic/nursing/technical staff and physicists who are directly involved in service delivery are often best placed to know those areas which are either particularly important in the delivery of a safe service, or where improvement may be required. Equally, they are best placed to suggest specific improvement strategies where necessary.

It is a professional duty of all radiologists to examine both the quality of their work and the systems within which that work is carried out, and self audit is a valuable learning tool as well as ultimately being beneficial

to patient care. Audit has an important role in continuing professional development and education for both individuals and departments. Improvements in the quality of the delivery of radiological services should be focused on self-improvement aided by identifying areas where further investment in services is required. The results of audit should be used within a positive, constructive and forward-looking framework and not used in a non-statistically valid way to judge individual performance.

SCOPE OF AUDIT

All aspects of the patient experience in a radiology service can benefit from audit. This not only refers to those activities which directly involve the patient but also to all the other supporting processes which underpin a safe and effective service.

TYPES OF AUDIT

Audit can be divided into three main categories.

1. **Structure audit** — Examination of the systems within which we work, e.g the management structure, accommodation, equipment, staffing and training
2. **Process audit** — Examination of the processes involved in the delivery of care throughout the patient journey
3. **Outcome audit** — Examination of the outcome or results of the delivery of care, which may include medical outcome and patient satisfaction

The above is based on a simple equation which is often used in healthcare:

Structure + Process = Outcome

This would imply that if two departments have the same structures and processes in place they would achieve the same outcome. This is patently not the case and therefore there is a missing component, which is "Culture". Although more difficult to define standards for culture, audits of culture are also possible and in fact an effective Clinical Audit programme is in itself a facilitator of an open, supportive culture.

STANDARDS

Ideally an audit is to assess a particular component of the service against an agreed preset standard. Such standards are not always available. This is particular true in in measuring patient outcomes in a radiology service and therefore this type of audit is the most difficult to carry out.

Standards against which local performance can be measured can be found from a variety of sources:

1. Local, European or international legislation. Compliance with these standards is compulsory.
2. Peer-reviewed research. These will provide benchmark standards but may have to be interpreted in the light of local facilities and expertise.
3. Recommendations or consensus statements from learned or national societies and organisations. These will usually have been developed to be applicable in routine practice.

If no standards are available, it is possible to develop a local standard by consensus agreement. This can be informed by locally sourced data e.g. comparative investigations, pathology, surgical findings, peer group review. In setting such standards it is important not to set an easily achievable standard which does not result in any measurable improvement. As long as the there is a culture of continuous improvement, it is perfectly acceptable to set an aspirational goal to encourage maximum improvement.

If the selected target standard is based on the average expected performance, then initially, 50% will be expected to fall below it. A low or minimum target standard may be regarded as the minimum acceptable level of performance. The level of the standard selected should be taken into account in interpretation of results.

INDICATORS

The indicator or indicators are measurable variables related to the standard. An indicator or series of indicators should be identified at the start of the project to decide what data will need to be collected to calculate the value of the indicator and hence to decide if the chosen standard has been met. Examples of indicators in radiology include the examination volume per modality as a productivity indicator, the report turnaround time as a reporting efficiency indicator, access to an imaging modality as an access indicator and the expenditure on contrast media as a financial indicator.

DATA COLLECTION

Data to be collected may include items such as observations or measurements. Collection should aim to ensure that the data are complete, accurate and representative so that valid conclusions can be reached.

PROSPECTIVE VERSUS RETROSPECTIVE AUDIT

Data may be collected prospectively over a period of time, for a predetermined number of cases, or retrospectively from existing information sources.

Both options have advantages and disadvantages.

Prospective collection is more likely to ensure completeness of information, but the process of collection may influence the behaviour of participants and therefore the outcome of audit. It may also take longer to gather the data.

Retrospective collection from records may however result in incomplete data being available.

A not uncommon scenario would be a retrospective audit which shows areas for improvement, followed by prospective re-audit after the appropriate changes have been made.

ACCURACY OF AUDIT

Audit is a sampling process and unlike research is not primarily designed to be statistically robust since it is for the purpose of improving local quality of care rather than influencing others' practice. When audit data are interpreted, this potential, although not inevitable statistical weakness, should be taken into account. Various statistical methods can be employed to increase confidence in the statistical validity of the results.

ANALYSIS OF AUDIT RESULTS

When the chosen standard is attained, this can be taken as affirmation of the quality of the service and reassurance that no change is necessary. Audit is primarily a quality improvement tool, and in those cases where the chosen standard is not reached, the results should be interpreted in a culture which does not seek to blame individuals. Analysis of the results should examine all the possible reasons for the results not meeting the standard, including the target level chosen, system, process, and technical reasons.

IMPLEMENT CHANGE

It is essential to realise that the results of the primary audit are not the end of the **audit cycle**. The results of the audit should be discussed in a relevant forum. Where the audit demonstrates that the agreed standard has not been met, an agreement should be sought for a checklist of suggested changes to improve performance should be then be drawn up and implemented.

RE-AUDIT

When change has been implemented, it is mandatory to repeat the same audit process to ensure that the changes introduced have led to the expected improvement. This 'closes the loop'.

TIME/RESOURCES REQUIRED

Professional input into the design and standards chosen for audit is mandatory, but data collection and analysis can be delegated to suitably trained staff. Audit is potentially time consuming and needs to be allocated sufficient time and financial resources.

AUDIT PROFORMA

Topic of audit:

Type of audit: structure/process/outcome/ culture

Standard: (including target performance)

Source of standard: legislation/publication/learned society guidance or consensus/locally generated standard/other

Indicator: quantifiable variable(s) to be calculated

Data to be collected:

Number of patients:

or volume of information to be collected:

Results: Standard met? Yes/no

Analysis of potential causes: (if standard not met)

Action plan for implementation of change:

Re-audit date:

Re-audit outcome:

GLOSSARY OF TERMS

Audit cycle	The basic framework upon which all audit projects are based. An audit topic is chosen and a standard to be met is defined. Data are collected to identify what is really happening and these are compared with the standard. If the required standard is not achieved, changes are introduced to improve performance. The cycle should then be repeated to assess whether changes have led to the standard now being met.
Clinical guidelines	Statements of principle and good practice developed in order to assist practitioner and patient decisions about appropriate health care in specific clinical circumstances. Guidelines are usually produced and agreed upon by a national body.
Closing the loop	Completion of the full audit cycle. Practice is changed following the initial audit and the audit is repeated to ensure that the changes introduced have been effective.
Data to be collected	Specifies what data need to be collected so that the indicator can be calculated.
Effectiveness	The extent to which application of a technology or intervention brings about a desired effect, e.g. change in diagnosis, altered management plan, improvement in health. It is a measure of the degree of conformity between the actual result and the desired outcome. Effectiveness is not synonymous with efficacy.
Efficiency	Assessment of efficiency determines whether acceptable levels of effectiveness are achieved when using a prudent or optimal set of resources.
Evaluation	A systematic and ideally scientific process determining the extent to which planned intervention(s) achieve predetermined objectives.
Indicator	A measurable variable related to the standard. An indicator, or series of indicators, should be identified within an audit project which will clarify what data need to be collected.
Local guidelines	Guidelines may be developed and introduced locally. They are commonly adaptations of national guidelines designed to meet local conditions and constraints. The process of developing a local guideline involves consensus of all relevant clinicians.
Outcome (patient health)	An alteration in the health status of an individual patient directly attributable to clinical action (or inaction). It is customarily abbreviated to "outcome" although this may lead to confusion in blurring distinction between patient-based measures and other metrics. WHO defines "health" as a complete state of physical, mental and social well being, classified under four headings: • Quantity of life (e.g. 5 year survival) • Process-based measures (e.g. complication and readmission rates) • Quality of life (e.g. measures of pain, handicap, depression) • Satisfaction, including entitlement to privacy, courtesy, etc. (e.g. score on a satisfaction survey) Outcome audits look at what is done as a whole from the patient's point of view. Problems that such an audit may reveal (e.g. 25% chance that diagnosis is not correct) may prompt audits of each link in the whole diagnostic chain. These would be process audits.
Performance	The quality of care achieved, judged by both the process and outcome of that care. Process: The activity undertaken (what was done? how well was it done? what should have been done?).

Protocol	A system of rules about the correct way to act in formal situations or an adaptation of a clinical guideline designed to meet local conditions and constraints. The latter is the same as a local guideline
Quality	The level of excellence. Many attempts have been made to define the quality of medical and health care. In general, six aspects are usually emphasised: access to services, relevance to need, effectiveness, equity, social acceptability, efficiency/ economy.
Quality assurance	The managed process whereby the comparison of care against predetermined standards is guaranteed to lead to action to implement changes, and ensuring that these have produced the desired improvements.
Research	A systematic investigation to establish facts or principles, and collect valid information on a subject. Research explores new ideas with the aim of defining and setting the standards of care for best clinical practice. This can be contrasted with audit, which aims to establish whether the actual care given to patients meets set standards. Research identifies what can and should be done, whilst audit identifies whether it is actually being done. For example, a study to determine whether endoscopic stent insertion or open surgical bypass provides the better palliation for malignant biliary obstruction is research. However, a study to determine whether the palliation of malignant biliary obstruction at a given hospital is carried out in accordance with the association of hepato-biliary surgeons' guidelines would be audit.
Sample	A subgroup of a population selected for audit in such a way as to allow inferences to be made about the whole population, i.e. a representative subgroup. The method of choosing the sample is crucial to the validity of the audit.
Standard	A conceptual model against which the quality or excellence of a particular activity may be assessed. It is the specification of process and/or outcome against which performance can be measured. In the context of health care, a standard indicates the best practice of clinical care to which all patients should be entitled. This may be determined by research, consensus statements, local agreement or recom- mendations from learned societies. The standard incorporates a target performance which specifies the expected level of achievement that performance should meet or exceed. An example of a standard would be the following: the risk of pregnancy should be established in women of childbearing age undergoing planned or inadvertent computed tomography (CT) of the pelvis in 100% of cases.
Structure	The availability and organisation of resources (human and material) required for the delivery of a service.
Target (see standard)	Specification of the expected level of achievement which performance should meet or exceed.

RESOURCES

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