Insights Imaging (2011) 2:97–98
DOI 10.1007/s13244-011-0065-8

STATEMENT

European Commission guidelines on clinical audit. Statement by the European Society of Radiology

European Society of Radiology (ESR)

Received: 3 January 2011 / Accepted: 3 January 2011 / Published online: 4 February 2011

Background

In October 2009, the European Commission published guidelines relating to clinical audits for radiological practice, including all investigations and therapies involving ionising radiation [1].

This is in line with the European Atomic Energy Community's remit to establish uniform safety standards to protect workers and the general public from the dangers of ionising radiation. The relevant pre-existing Council Directives are 96/29/Euratom [2] and 97/43/Euratom [3]. The latter introduced the requirement for clinical audits of diagnostic radiology, nuclear medicine and radiotherapy. Article 6.4 in the section on *procedures* states that *'Clinical audit shall be carried out in accordance with national procedures'*. Clinical audit of procedures is therefore mandatory. The guidelines give recommendations and suggestions for the implementation of clinical audit in member states, taking a wide interpretation of the procedures/processes that should be audited. MRI and ultrasound imaging are not included, as the guidelines cover only ionising radiation, although the same principles can be applied to these modalities.

This ESR document aims to summarise the guidelines, but the EC document is 110 pages long, and the interested reader is referred to the original publication.

Definitions

Clinical audit in the document is defined as a 'systematic examination or review of medical radiological procedures. It seeks to improve the quality and outcome of patient care through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures. Modifications of practices are implemented where indicated and new standards applied if necessary'. It emphasises that clinical audit is not research, quality system audit, accreditation or a regulatory activity, but a multi-professional activity that is both scheduled and systematic, carried out by auditors with knowledge of the procedures, combining internal assessment of performance with external review and identifying areas for future improvement. All those involved in audit should respect the confidentiality of patient data, staff discussions, audit reports and other performance data. Much emphasis is placed on the difference between clinical audit and other quality systems and regulatory inspections, there being clear differences in the purpose, focus, scope, methods and consequences of the results of the observations, their impact and use. Regulatory bodies should neither carry out clinical audits directly not exclusively set up the criteria for the audits.

Scope of clinical audit

The document recommends that the whole patient pathway should be subject to clinical audit under the categories of structure, process and outcome, and that it should address both radiation protection for the patient and key components of the overall quality system, which are enumerated in the guidelines. Under structure, lines of authority, radiation safety responsibilities, staff issues, premises and equipment are included. In process, justification and referral processes, protocol and process availability, optimisation procedures, patient dose, image quality, emer-

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gency incident procedures and reliability of information transfer are key themes. Outcome audit includes methods for follow-up of the outcome of examinations both short and longer term. This is acknowledged as providing the greatest challenge, particularly in relation to diagnostic accuracy.

The process is one of sampling of performance and comparing the results with a preselected standard of good practice. If the standard is not met, reasons for this are sought, changes implemented and a re-audit carried out to ensure improvement.

Standards may come from various sources, which are enumerated in the document.

Internal vs. external audit

Internal assessment within units or departments, which should employ standard audit methodology, is recommended as a systematic and continuing activity with a significant annual output of departmental audit data. Emphasis is however placed on external clinical audits whereby an external auditing body or auditors carry out the audit. A cycle of external audits carried out every 5 years is recommended. To carry this out, the guidelines recommend the development of special auditing organisations. These should preferably be non-profit organisations, if possible, supported by professional and/or scientific societies. These auditing organisations should be accredited by a national accreditation body. International audit services may be exploited where no national systems exist. Auditors would require a suitable professional background and would comprise a multidisciplinary team, which could include radiologists, radiographers and medical physicists. They should have received specific training in auditing and should be independent of the process/unit being audited.

The costs of the external audit process should be borne directly by the radiological unit unless the organisation of audits is carried out through a directly funded government body. The unit to be audited should foster an open and constructive atmosphere amongst its staff towards the process. Emphasis should be placed on avoiding misunderstanding or confusion with other quality assessment activities. The guidelines suggest that a special national or regional advisory group, or steering committee of clinical experts, independent of the auditing organisations, may prove useful in the overall coordination and development of clinical audit implementation, criteria and procedures. The group should preferably be established by the Health Ministry or other government organisation in order to ensure appropriate authority and financing. The role of professional/scientific societies, it is suggested, can be of great value in developing standards of good practice and in providing practical advice, stimulus and support for the establishment of appropriate clinical audit organisations.

Conclusions

For many, clinical audit will be a relatively new concept. This guideline reinforces EC support for the concept and suggests how it can be developed nationally within member states.

Acknowledgements This article was kindly prepared by the ESR Subcommittee on Audit & Standards (Chairman: E. Jane Adam. National Societies Committee Chairman: Guy Frija. Members: Hudaver Alper, Éamann Breatnach, Maurizio Centonze, Elisabeth Dion, Birgit Ertl-Wagner, Robert Manns) on behalf of the European Society of Radiology (ESR). It was approved by the ESR Executive Council in October 2010.

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