

Is the radiological community within Europe ready for audit?

European Society of Radiology (ESR)

Received: 11 April 2011 / Accepted: 19 April 2011
© European Society of Radiology 2011

Bullet points:

- Clinical audit in radiology is not yet universally practised.
- The EC Euratom Directive states that clinical audit should be carried out in the field of radiology.
- EC Guidelines on Clinical Audit for Medical Radiological Practices are now available.
- Much developmental work is required before clinical audit is comprehensively practised throughout Europe.

Introduction

Clinical audit in radiology is not universally practised. However, few would argue that the definition of audit, which is ‘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’ [1], represents good practice and should be a routine activity within radiology departments with which individual radiologists should engage.

European Commission guidelines on clinical audit

The European Commission (EC) Euratom 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 [2]. The subsequent (November 2009) publication of the EC Guidelines for Clinical Audit [3] 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 [4]. Clinical audit, though related, is not the same as quality assurance. Clinical audit 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’ (European Commission, G. Simeonov, personal communication).

The guidelines are however based on the responses to a widely distributed questionnaire together with consultation with stakeholders, and the EC expectation would be that the ESR will support the implementation of the guidelines among their members (European Commission, G. Simeonov, personal communication).

Key points from the EC guidelines:

1. Audit should be carried out on structure, processes and outcome, examples being:

Structure: lines of authority, radiation safety responsibilities, staff numbers, premises and equipment

Process: justification and referral processes, protocol availability, optimisation procedures, patient dose, image quality, emergency incident procedures and reliability of information transfer

Outcome: methods for follow-up of the outcome of examinations short and longer term. This is acknowledged as providing the greatest challenge, particularly in relation to diagnostic accuracy.

European Society of Radiology (ESR) (✉)
European Society of Radiology (ESR),
Neutorgasse 9/2,
1010 Vienna, Austria
e-mail: communications@myESR.org

2. Audit should be carried out in a no-blame manner. The aim should be to improve services, not a pass/fail approach.
3. It should be carried out in a confidential environment.
4. It should be carried out by suitably qualified professionals, i.e. radiologists, radiographers and medical physicists.
5. Internal audit should be carried out annually within each organisation with an external audit every 5 years by a visiting team of professionals.
6. Regulatory bodies should neither carry out clinical audit directly nor exclusively set up the criteria for, but there should be the development of special auditing organisations, preferably non-profit organisations supported by professional and/or scientific societies.
7. Auditors should have undergone suitable training and be accredited by a national accrediting body. International audit services may be used.

Survey

In order to establish the current awareness, status and role of clinical audits within European member states, a survey was conducted by the ESR Subcommittee on Audit and Standards. This was sent to all 39 National Societies, with a 100% response rate.

Questions and responses

Are you aware of the requirement for clinical audit in the Euratom directive?

- Yes, 32 (82.05%)
- No, 7 (17.95%)

Have the EC Clinical Audit Guidelines come to your attention?

- Yes, 30 (76.92%)
- No, 9 (23.08%)

How binding is the requirement for external clinical audit considered to be in your country?

- Binding, 14 (35.9%)
- Not binding, 13 (33.3%)
- Not known, 12 (30.77%)

Is your member state currently in a position to comply with the requirement for external audit of diagnostic radiology, nuclear medicine and radiotherapy?

- Yes, 13 (33.33%)
- No, 26 (66.67%)

How do you envisage such processes will be funded?

- State, 25 (64.1%)
- Individual, 14 (35.9%)

Is internal clinical audit of their own diagnostic radiology services routinely carried out within institutions?

- Most institutions, 11 (28.21%)
- A minority of institutions, 16 (41.03%)
- Very few institutions, 12 (30.77%)

Is clinical audit as a concept and specific methodology understood amongst radiologists?

- Yes, the majority, 10 (25.64%)
- A minority of radiologists, 24 (61.54%)
- Very few radiologists, 5 (12.82%)

Commentary on responses

No clear geographical or regional trends were seen in the responses.

Although there seems to be a high degree of awareness amongst National Societies of the EC guideline, there is no agreement as to whether it is considered to be legally binding, and indeed its interpretation may vary across Europe. The communication from the European Commissioner does however help to clarify this by indicating that exact methods of audit may vary from state to state.

Only a minority of states are ready to comply, but it is not clear whether even this minority is confident that they are in a position to fulfil all the detailed requirements of the guidelines, including the requirement for multiprofessional external audit teams to carry out a comprehensive audit on a 5-yearly basis. Funding is an issue, with most assuming that the State will pay rather than individual institutions, although the latter is the funding method favoured in the guidelines.

Finally, it seems that clinical audit is not widely understood by radiologists; the survey indicated that only 25% of respondents thought that clinical audit was understood by the majority of radiologists, and only 28% of National Societies considered that internal audit of practice was routinely undertaken.

Implementation of clinical audit in Europe

The results of the survey suggest that there is a continuing need for the education of radiologists in the concept and methodology of audit for this to become a part of routine and accepted clinical practice. If carried out as envisaged,

audit should not be a threatening process, but one that all parties can accept as being a learning and development tool. There are two potential approaches to national implementation of the guideline: top down or bottom up. The top down approach would be to institute a comprehensive clinical audit system at national level. This in turn would encourage individual institutions to begin to fulfil the requirements in terms of data gathering and carrying out an internal or local audit to assess readiness for the external team visit. The alternative is to spread awareness of clinical audit and to use the methodology locally at departmental level, and subsequently build on this to form a national system. It is open to debate as to how the ESR might assist in this process.

Conclusion

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.

Acknowledgements This article was kindly prepared by the ESR Subcommittee on Audit and 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 March 2011.

References

1. European Society of Radiology (2010) Clinical audit—ESR perspective. *Insights Imaging* 1:21–26
2. European Commission (1997) EC medical exposure directive 97/43/EURATOM
3. European Commission (2009) Guidelines on clinical audit for medical radiological practices no. 159 (Diagnostic Radiology, Nuclear Medicine and Radiotherapy). ISSN 1681–6803 http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/159.pdf
4. European Society of Radiology (2011) European commission guidelines for clinical audit: statement by the European society of radiology. *Insights imaging* 2:97–98