

---

## Volume 9 - Issue 4, 2009 - Cover Story: Clinical Audit in the European Union

### Implementing External Clinical Audits in Radiological Practices: The Experience in Finland

---

Author

**Prof. Seppo**

**Soimakallio**

*Chairman*

*Department of Radiology*

*Tampere University Hospital*

*Tampere, Finland*

[seppo.soiimakallio@pshp.fi](mailto:seppo.soiimakallio@pshp.fi)

In Finland, the introduction of the requirement for clinical audits in the legislation in accordance with Council Directive 97/43/EURATOM has resulted in a systematic approach of regular external auditing, while the legislation also requires self-assessments of radiological units. The external clinical audit system has been supported by the major professional societies and coordinated by an independent National Advisory Committee. In this article, the development and current status of clinical audits in Finland for diagnostic radiology is reviewed.

#### Legislative Basis

According to Finnish legislation (law and decree), clinical audits shall be arranged to supplement, in an appropriate way, the self-assessment of practices. The goal is set so that all radiological practices would be externally audited for all essential parts at a minimum frequency of once every five years. The decree also specifies ten points, which shall, among other things, be considered in external clinical audits. According to the decree, clinical audits shall be carried out by competent and experienced auditors who are independent of the organisation being audited.

#### Practical Implementation Auditing Organisation and Auditors

Finnish legislation has not assigned a specific organisation to carry out clinical audits. Since the decree was issued, the Finnish Medical Association convened two meetings to discuss the matter with the key stakeholders: the radiological departments of university hospitals, societies of radiographers, cardiologists, oncologists, nuclear medicine experts and physicists, the Association of Finnish Local and Regional Authorities, the Society of Private Institutes and the Radiation and Nuclear Safety Authority (STUK). These meetings led to the establishment of a working group to prepare the audit programme, to recruit auditors, to build-up an auditing organisation and to organise training of auditors. After completing the first audit programme and recruiting a number of auditors, the actions of the working group resulted, in 2001, in the establishment of a special organisation to develop and provide the necessary clinical audit services.

The working group then organised several training courses for the auditors, with some financial support from the Ministry of Social Affairs and Health and the Association of Finnish Local and Regional Authorities.

The special auditing organisation was a joint-stock company owned by 20 owners. The auditors work at the request of the company for each individual audit, and are paid for their services, while the audits are charged from the audited organisations. The first complete audit round was carried out solely by the above organisation, while at present there are two organisations offering similar clinical audit services.

#### National Steering Committee

In 2004, the Ministry of Social Affairs and Health set up an advisory committee for the coordination, development and follow-up of clinical audits to ensure the quality and consistency of clinical auditing. The committee is a multidisciplinary group of clinical experts, independent of any auditing organisations. Its tasks include, among other things, evaluating the suitability and coverage of the criteria used in clinical audits and collecting summaries and reviews of the results. The advisory committee has issued four recommendations dealing with practical issues of clinical audits and more recommendations are being prepared. The committee has also conducted a survey of the results of the complete first round of audits in Finland (2000 - 2006).

## Radiation and Nuclear Safety Authority (STUK)

The role of the Radiation and Nuclear safety Authority (STUK) is to control the implementation of clinical audits through regular inspections of radiation practices. Furthermore, STUK has a representative in the National Advisory Committee and provides secretarial services to the Committee.

## International Activities

The development of clinical audits in Finland has given rise to two international meetings organised in Finland, and Finland's leading role in a European Commission project for preparing guidance on clinical audit. The chairman and secretary of the national advisory committee on clinical audit carry the main responsibilities for these activities.

## Review of the Outcome of Clinical Audits

After the first five-year period of auditing (2000 - 2006), the National Advisory Committee conducted a survey of the results of the audits by reviewing audit reports, numbering altogether 346, with the permission of the audited healthcare units. All of the first clinical audits were carried out by the same organisation, employing a total of 38 auditors from volunteered healthcare professionals. Audits were typically carried out by a team consisting of a medical expert (physician) and a radiographer, and in several cases such as for radiotherapy, nuclear medicine and large units of diagnostic radiology, a physicist.

The duration of the audit varied between 0.5 and 4 days depending on the size of the unit, with most typically taking between 1 - 2 days. The audits were based on guidance and check-lists developed by the auditing organisation. The criteria of good practices were derived partly from legislative requirements, and partly from existing recommendations for good clinical practices (e.g. referral guidelines, image quality criteria), while audits also relied to a great extent on the professional judgement of the auditors. Besides interviews and reviews of documents and data, the audits included assessment of the image quality for a sample of patient images.

The total cost for a single audit day with two auditors in Finland is typically about 2,500 euros, also including work prior to the audit visit. It is interesting to note that the costs of clinical auditing are only a few cents when counted per radiological examination. A significant number of recommendations to improve practices have been issued as a result of the audits, on average four - seven recommendations per healthcare unit (see Fig. 1, above). The results suggested that the criteria of good practices, now mainly based on legislative requirements, should be supplemented by more clinical criteria in order to avoid unnecessary overlap with regulatory inspections.

## Conclusions

The organisation of and criteria for external clinical audits in Finland have been successfully developed, providing radiological units with easy access to better standards. The objectives and criteria are in close consistency with the general principles published in the forthcoming EC guideline. The review of the outcome of clinical audits indicates many practical benefits of the audits, such as improvements in the referral practice, quality assurance programmes, distribution of responsibilities, and communication between different professionals. Implementation of clinical audit in Finland has included a lot of stakeholder involvement and has led to successful improvement of clinical procedures and radiation safety in the Finnish healthcare system.

## Further Reading

- Soimakallio S., Järvinen H., Kortelainen K. Proceedings of the International Symposium on Practical Implementation of Clinical Audit for Exposure to Radiation in Medical Practices, Tampere 24 – 27 May, 2003. Available from: [www.clinicalaudit.net](http://www.clinicalaudit.net)
- Järvinen H. (ed.). International Workshop on Practical Implementation of Clinical Audit for Medical Exposure to Ionising Radiation, Tampere Hall, Tampere, Finland, 7 - 10 September 2008.
- Programme, general information and abstracts. Available from: [www.clinicalaudit.net](http://www.clinicalaudit.net)
- Hirvonen-Kari M., Järvinen H. and Kivisaari L. Clinical Audits and Regulatory Inspections – Double Efforts and Expenses for Radiation Protection?, Acta Radiologica (2009), accepted for publication.
- Hirvonen-Kari M., Salo S., Dean K. and Kivisaari L. Effect of Clinical Audits of Radiation use in One Hospital District in Finland., Acta Radiol. 2009;50:389-395.

Published on : Fri, 4 Sep 2009