SAMIRA Action Plan

Steering Group on Quality and Safety

Position paper on Clinical Audits

(13/06/2023)

This position paper was prepared by the Working Group on Clinical Audit, a sub-group of the Steering Group on Quality and Safety of medical applications of ionising radiation (SGQS) under the SAMIRA Initiative. It was adopted by the SGQS on 13/06/2023. It is addressed to Member States authorities to support them in the implementation of the provisions of the Basic Safety Standards Directive on the clinical audit of radiological procedures.

1. Medical uses of ionising radiation are an essential component of modern medical diagnosis and treatment which, if conducted appropriately, offer significant benefits to patients and society. At the same time, medical procedures remain by far the largest artificial source of exposure to ionising radiation of European citizens, with particular safety and quality challenges identified in diagnostic and interventional radiology, radiotherapy, and nuclear medicine procedures.

2. Council Directive 2013/59/Euratom[1] (the Basic Safety Standards Directive, BSSD) establishes standards for the protection of the health of individuals subject to occupational, medical and public exposure against the dangers arising from ionising radiation. These standards apply, among others, to medical uses of ionising radiation for diagnostic, therapeutic, interventional, planning, guiding and verification purposes.

3. The BSSD defines clinical audit as "a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary", and, in its Article 58(e), requires Member States to carry out clinical audits in accordance with national procedures. The same definition and clinical audit-related requirement were included in Council Directive 97/43/Euratom[2] (the "Medical Exposure Directive"), which was repealed by the BSSD in 2013.

4. In 2008, the European Commission tendered out a review of the status of implementation of clinical audit[3] and this work identified variable, and often lacking or minimal, clinical audit practice across the Member States. More recent work in a study commissioned by the European Commission[4], and also a review conducted by Member States authorities[5] and national professional societies[6] has demonstrated persisting variation in clinical audit uptake and implementation by Member States.

5. In 2009, the European Commission published in the Radiation Protection series guidelines[7] providing comprehensive information on procedures and criteria for clinical audits in radiological practices. HERCA, the European association of competent authorities for radiation protection,

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1 Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

2 Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom

3 EC Tender Contract N° TREN/07/NUCL/S07.71512 European Commission guidelines on clinical audit for medical radiological practices (diagnostic radiology, nuclear medicine and radiotherapy)

4 EC Tender Contract N° ENER/16/NUCL/SI2.730592 Evaluation of National Actions Regarding the Transposition of Council Directive 2013/59/Euratom's Requirements in the Medical Sector (BSS Transposition in the Medical Sector), Executive Summary 2017

5 HERCA European action week – results of a coordinated Inspection initiative assessing justification in radiology E.G. Friberg, Heads of the European Radiological Protection Competent Authorities (HERCA) 2016

6 European Society of Radiology (ESR) (2019) The Current Status of Radiological Clinical Audit – an ESR Survey of European National Radiological Societies, Insights into Imaging 2019;10(1):51, https://doi.org/10.1186/s13244-019-0736-4

7 RP 159 European Commission Guidelines on clinical audit for medical radiological practices (diagnostic radiology, nuclear medicine and radiotherapy) 2009

provided further insight into the definition of clinical audit under the BSSD and its differences from regulatory audit and inspection[8].

6. Similar to findings from 2008, a recent European study[9] found that, despite some progress, clinical audit uptake and implementation still remain variable across the Union. The study concluded that clinical audit, as defined in the BSSD, is most effective when incorporated as a core element of existing clinical audit infrastructure within the wider healthcare system. It further identified common barriers and areas of future work for enhancing clinical audit uptake and implementation in Member States.

7. Good practices, guidance and various resources relating to clinical audits have been developed by Member States[10], professional bodies and international organisations including examples and practical guidelines and manuals in the medical disciplines of radiology[11], radiotherapy[12] and nuclear medicine[13].

8. In 2015, the Council issued conclusions[14] stressing the importance of properly established rules for conducting clinical audits and urged Member States to strengthen the application of clinical audits in relation to justification of medical radiological procedures.

THE STEERING GROUP ON QUALITY AND SAFETY

In fulfilment of its mandate[15], in particular its role to support the implementation in Member States of activities in the area of Quality and Safety of medical applications of ionising radiation,

ACKNOWLEDGES that clinical audit of medical radiological procedures, required as per BSSD article 58(e), is an essential tool within clinical governance that ensures continuous quality and safety improvement of healthcare services,

EMPHASISES that, while clinical audit is an essential part of ensuring quality in healthcare, the use of ionising radiation is only one of the many practices and risks that must be managed. Moreover, clinical audit of practices and risks not covered by the BSSD, such as contrast agents, magnetic resonance and ultrasound imaging, would contribute to their quality and safety,

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[8] HERCA Position Paper Clinical Audit in medical Radiological practices (October 2019), Addendum to the HERCA clinical audit position paper (June 2021)

[9] Radiation Protection 198 (RP198) "Current Status and Recommendations for Improving Uptake and Implementation of Clinical Audit of Medical Radiological Procedures", European Commission, 2022

[10] See RP198, section 5.1 for useful links

[11] IAEA QUAADRIL, ESR ESPERANTO, WHO. See RP198, section 5.2 & 5.3 for useful links

[12] IAEA QUATRO. See RP198, section 5.3 for useful links

[13] IAEA QUANUM. See RP198, section 5.3 for useful links

[14] Council conclusions on the "Justification of medical imaging involving exposure to ionising radiation" (ATO 75/SAN 403 of 3/12/2015)

[15] SAMIRA - Strategic Agenda for Medical Ionising Radiation Applications. Steering Group on Quality and Safety of medical applications of ionising radiation (SGQS). Mandate version 14/06/2022

HIGHLIGHTS that the concept of clinical audit is complementary to, and must not be confused with, inspections, performed by the competent authorities, and regulatory audits, which may be performed by the undertaking,

TAKES INTO ACCOUNT the conclusions of the QuADRANT study[9] carried out for the European Commission to review the implementation of clinical audit across Europe and to provide further guidance and implementation support to Member States,

RECOGNISES that Member States differ in the level of implementation of clinical audit and face differing challenges in establishing or developing an effective clinical audit infrastructure,

CONSIDERS that implementation of clinical audit by Member States should include the following:

<u>National framework and infrastructure for clinical audit</u>

1. Establish national framework and infrastructure including legal and administrative provisions, associating the appropriate bodies[16] and providing human and financial resources, for effective implementation of clinical audit in all medical practices using ionising radiation (including those carried outside the radiology, nuclear medicine and radiotherapy departments), commensurate with the level of radiological risk.
2. Ensure that health and radiation protection authorities and national professional and clinical speciality societies are involved in developing the national framework and infrastructure for clinical audit.
3. Identify the relevant standards of good clinical practice to carry out clinical audits of medical radiological procedures
4. Seek to incorporate clinical audit of medical procedures using ionising radiation into wider systems of audit and quality of healthcare, where already in place.
5. Assign to the appropriate body(-ies) at national level the following responsibilities:
    a) define clinical audit policy and responsibilities and identify and allocate available financial, human and technical resources.
    b) provide administrative support to clinical audit implementation.
    c) develop audit guidance and manuals and share these and other relevant references and good practices among entities involved in clinical audit.
    d) provide effective mechanisms for the collection and communication of quantitative and qualitative data for clinical audit, supported whenever possible, by functional IT solutions.
    e) compare and benchmark clinical audit results at national and as far as possible, European level, and provide feedback to the radiation protection and healthcare policy and decision-makers.

[16] See for instance Finnish experience: https://healthmanagement.org/c/imaging/issuearticle/implementing-external-clinical-audits-in-radiological-practices-the-experience-in-finland

f) ensure access to training programmes for auditors[17] and identify trained auditors.

g) develop appropriate educational resources in clinical audit for the relevant groups of healthcare professionals and support their introduction in education and training programmes.

Regulatory control of clinical audit

6. Include a regular assessment of the implementation of clinical audits in the inspection programmes of authorities responsible for radiation protection in medicine and quality of healthcare.

7. Ensure that the regulatory control includes aspects, such as training of auditors, composition of the audit team, relevance of the audit topic(s), identification of agreed standards, clinical audit report, and follow-up (including adjustment of practices if needed).

8. Apply a graded approach to the inspection of clinical audit by adapting frequency, timing and depth, depending on the radiological risk associated with the practice, from an individual patient perspective as well as from a population perspective.

9. Provide regular information on inspection outcomes with regard to clinical audit, including any relevant metrics and indices, as part of the public activity reports of the competent authorities.

Hospital and medical practice accreditation and/or certification

10. Include criteria for clinical audit in accreditation and certification standards and programmes concerning medical practices using ionising radiation.

11. Ensure that the implementation of clinical audit is systematically verified in initial and follow-up accreditation and certification activities concerning medical practices using ionising radiation.

Enablers and support for the successful implementation of clinical audits

12. Support the incorporation of clinical audit teaching in initial and continuous education and training curricula of healthcare professionals, including administrative and manager profiles.

13. Strive to establish a culture of clinical audit involving a no-blame, holistic, and positive attitude to clinical audit for effective implementation of clinical audit in all medical practices using ionising radiation.

14. Ensure that clinical audit is an integral part of the organisation of relevant departments and that hospital management is engaged in, and provides support and resources, for the implementation of clinical audits.

[17] See for instance Finnish experience: https://healthmanagement.org/c/imaging/issuearticle/implementing-external-clinical-audits-in-radiological-practices-the-experience-in-finland

15. Share information on clinical audits[18], such as clinical audit guidelines, standards for good medical radiological procedures, audit outcomes and other reference documents, making full use of digital technology[19].

Patient involvement and access to patient data

16. Support the involvement of patient representatives in clinical audit projects and in developing national/local clinical audit policies and guidelines. Where appropriate, collect patients' feedback and expectations in clinical audits.

17. Ensure access to patient data to the extent needed for clinical audits, by using anonymised data as necessary, in full compliance with GDPR[20] requirements.

[18] The compilation of ressources reported in publication RP 198 sections 3 and 5 is considered as a good starting point for constituting this platform.

[19] The SGQS recommends to the Commission to support the development of a common digital platform for this purpose.

[20] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)