QuADRANT Workshop

Monday 14th December 14:30-17:00 CET

Webinar 1: QuADRANT, Clinical Audit and Radiation Protection- An overview with Emphasis on key WHO/IAEA Initiatives

Clinical audit as Defined in the European-Basic Safety Standards Directive

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HERCA is a voluntary association

- HERCA, the Heads of European Radiological protection Competent Authorities, was founded in 2007
- It is a voluntary association in which the heads of the Radiation Protection Authorities work together in order to identify and discuss common interests in significant regulatory issues.

32 countries (EU MS + IS, NO, CH, RS)
56 organisations (RPA + TSO),
310 nominations
Observers
EC, IAEA, OECD/NEA, WHO, US FDA
Introduction

In 1997, the UK’s National Institute for Health and Clinical Excellence (NICE) published the paper “Principles for best practice in clinical audit” and defined clinical audit as:

“a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, process and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery”
The Medical Exposure Directive of 1997 introduced clinical audit for the first time, including it within the article relating to procedures.

“The Directive defined clinical audit as

“a systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary”
The definition is consistent in its approach with other definitions of clinical audit, but recognises the context of the Directive and is therefore specific to medical radiological procedures.

The Directive included requirements for clinical audit under Article 6, relating to Procedures, and stated:

“clinical audits shall be carried out in accordance with national procedures”
The requirement is not prescriptive in itself, but its inclusion in the Directive, which had to be be transposed through a legal framework implied that Member States should include some requirement for clinical audit in their legislation and regulations relating to radiation protection.

Introduction of requirements for clinical audit in 97/43/Euratom:

The Council of the European Union

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 109 thereof;

Having regard to the proposal from the Commission, drawn up after consulting the opinions of a group of experts appointed by the Scientific and Technical Committee;

Having regard to the opinion of the European Parliament;

Having regard to the opinion of the Economic and Social Committee;

(1) Whereas the Council has adopted Directives laying down the basic safety standards for the protection of the health of workers, and the general public against the risks arising from exposure to ionizing radiation, as last amended by Directive 96/29/Euratom (4);

(2) Whereas in accordance with Article 10 of the Treaty, the Member States have taken measures to ensure compliance with the basic standards which have been established and take the necessary measures, with regard to teaching, education and vocational training;

(3) Whereas, on 1 September 1994 the Council adopted Directive 94/29/Euratom laying down the basic safety standards and basic protection requirements for medical use of radiological equipment, and underlining that the implementation of the Directive is to ensure an adequate level of protection for the population and personnel involved in the use of such equipment;

(4) Whereas, in 1984, medical exposure continued to increase due to the major share of patients treated in nuclear medicine and in the diagnosis of eye disease caused by radiation effects, the Commission considered that the situation would be improved by adopting an action plan in order to establish guidelines for the protection of the population and personnel involved in medical exposure to medical radiation equipment and materials;

(5) Whereas, in 1988, the Committee of Ministers of the Council of Europe adopted on 6 November 1988 Recommendation R(88)14 on medical treatment on a radiological basis in EU and for the protection of the population and personnel involved in the treatment of eye disease by medical radiological means, and also the setting up of an ad hoc committee;

(6) Whereas detailed requirements are needed for the correct application of the fundamental and justification principles in relation to exposure within the scope of the Directive;

(7) Whereas the guidelines for the application of the Justification principle to medical use of radiological equipment, and the guidelines for the application of the Danish and German calculations to medical use of radiological equipment, should be set out;

(8) Whereas a European Committee should be set up to propose appropriate means to achieve the objective of the Directive;

(9) Whereas the requirement is not prescriptive in itself, but its inclusion in the Directive, which had to be be transposed through a legal framework, implied that Member States should include some requirement for clinical audit in their legislation and regulations relating to radiation protection.
Lack of understanding within the radiological community on how regulatory requirements for clinical audit should be met lead the European Commission’s Working party of Medical Exposure under the Article 31 Group of Experts to advise that European guidance should be developed on implementation of clinical audit of medical radiological procedures

The guidance was published in 2009
European guidelines on clinical audit for medical radiological practice *(RP No.159)*

The report describes:

- The basic principles and prerequisites of clinical audit
- The interrelation of clinical audit with other audit systems
- The Interrelation with regulatory control
- The practical implementation of clinical audit
- Generic criteria of good practice
- Specific audit criteria
The general objectives of clinical audit should be to:

1. Improve the quality of patient care
2. Promote the effective use of resources
3. Enhance the provision and organisation of clinical services
4. Further education and training
Requirements for clinical audit in the EC Basic Safety Standards

**Directive (BSSD) 2013/59/Euratom**

- Article 58(e), relating to Procedures, of the BSSD repeats previous requirements for clinical audit, making clear that Member States shall ensure the requirements are met.

- The definition of clinical audit is largely unchanged from 1997, with only “where appropriate” replacing “where indicated” in relation to the modification of practices.
Main weaknesses identified concerning clinical audit were:

1. The concept of clinical audit is not fully understood
2. Lack of national or local procedures for performing clinical audits
3. Clinical audits are rarely performed in medical imaging
4. Review of national regulatory frameworks indicated that clinical audits were not fully implemented at a national level

• 17 European countries participated
• 148 inspections were carried out
• All inspections were performed according to a common inspection template.
Meetings with ESR, EANM and ESTRO

Discussions on their activities regarding clinical audit and their understanding of the differences between audit and inspection

HERCA became aware of some lack of understanding within the radiological community on how regulatory requirements for clinical audit should be met and what the differences are between clinical audit and inspection.
HERCA WGMA initiatives regarding clinical audits

HERCA Position Paper
Clinical Audit in medical Radiological practices

October 2019

This document was approved by the Board of HERCA on 30 October 2019

https://www.herca.org/highlight_item.asp?itemID=16

Heads of the European Radiological protection Competent Authorities - HERCA
HERCA position paper on clinical audit

• Executive Summary

• Key messages

• Introduction and background

• Definitions of clinical audit and the clinical audit cycle

• Clinical audit relating to Euratom

• Clinical audits, other audits and inspections of radiological practices
HERCA position paper on clinical audit

• Expectations of radiation protection competent authorities regarding clinical audit

• Challenges for implementing clinical audit

• Conclusions

• References

• Appendix: National and International initiatives relating to Clinical audit
Clinical audit

• The intention of Clinical Audit is to improve the outcome of patient care

• Clinical audit should be systematic and ongoing

• There is a role for both internal and external clinical audit

• Clinical audits should be carried out by individuals with a comprehensive understanding of audit technique
Internal Clinical audit

- Internal clinical audit is to be carried out by the establishment itself at a local level (individual, departmental, hospital) on its own initiative and consistent with national requirements.

- The objectives of internal clinical audits should be set by the management of the department, hospital.
Internal Clinical audit

- Internal clinical audit can also take place with external direction – a system whereby guidance or direction is provided from an external body, e.g. national professional society.

- Internal clinical audits can be implemented by nominating auditors from another department of the establishment.

- Should this not be possible, the internal audit can be carried out by auditors from the audited department in the form of a self-assessment.
External Clinical audit

- External clinical audit is carried out by auditors who are external to the establishment to be audited. These can be carried out by international, national or regional audit organisations.

- For external audits, the objectives should be agreed between the auditing organisation and establishment to be audited.

- Auditors performing external clinical audits should be independent to the audited establishment in order to evaluate the practice of their peers without any bias.
Other types of audits

• Dose audits, of staff and patient doses are conducted regularly in most departments

• Healthcare audits are important in improving aspects of clinical services

• Regulatory audit verifies compliance with regulations and standards

• Regulatory audit is helpful to the employer but does not replace the need for inspection
Inspection

- Defined as “an investigation by or on behalf of any competent authority to verify compliance with national legal requirements”

- Significant differences between clinical audit and inspections

- Both are required

- An inspection will result in a pass/failed, measures need to be taken, outcome

- Clinical audit will result in recommendations and suggestions for improvement
## Differences between inspection and clinical audit

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Expectations of competent authorities regarding clinical audit

- Inspection must address whether clinical audit is being carried out or not.
- Clinical audit provides an on-going assessment of clinical practice in a way inspection cannot.
- Clinical audit is a continuous process and can demonstrate whether quality and safety are embedded within a service.
- Inspection takes place periodically, has a short duration and only focuses on legal compliance.
Expectations of competent authorities regarding clinical audit

• For example, an inspection of justification would include discussions concerning the process itself and responsibilities, while an audit relating to justification might focus on the impact of a procedure on patients’ healthcare management and outcome.

• Similarly, inspection of optimisation might include verification that QA programmes, protocols and diagnostic reference levels are in place, while an audit might address the impact of reducing exposure factors on resulting diagnostic accuracy and subsequent patient management.
Expectations of competent authorities regarding clinical audit

- Clinical audits are not meant to replace inspections as a means of demonstrating regulatory compliance.

- HERCA is of the opinion that the two processes, clinical audit and inspection, are complementary and that whatever form of clinical audit is in place, its primary role is to ensure improvements in the quality and outcome of patient care.
Expectations of competent authorities regarding clinical audit

• When conducted on a national scale clinical audit may provide a mechanism for transfer of best practice between institutions, as well as the setting of higher and more appropriate standards

• Clinical audit can demonstrate cooperation between professional groups which is a key element of optimisation and therefore of interest to the regulator
Expectations of competent authorities regarding clinical audit

• HERCA is of the opinion that it is the responsibility of those who carry out clinical audit to bring non-compliance with radiation protection principles and specific regulatory requirements to the attention of the audited organisation/undertaking.

• It is the undertaking’s responsibility to carry out corrective measures.
Challenges for implementing clinical audit

• HERCA is of the opinion that for clinical audit to be implemented financial and human resources need to be made available and particularly education and training of auditors needs to be put in place.

• The establishment of a national auditing organisation that will coordinate and develop clinical audit could be a good solution for clinical audit implementation
Clinical audit is a requirement of the BSSD 2013/59/Euratom and has to be transposed into national legislation and implemented in the European Union. It is an excellent tool for improving the quality of healthcare and has to be undertaken by the undertaking or a peer review system.
Thank you for your attention

For further information see

www.herca.org