

Second QuADRANT Workshop 13/14 January 2022

Overview of Clinical Audit – previous key work,
initiatives and the relationship with the EC BSSD

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Clinical Audit - Overview

- Origins and Development
- Key Elements of Clinical Audit
 - Definition
 - The Audit Cycle
 - Types
- Inclusion in EC Directives
- European Commission Initiatives
 - Guidance
 - QuADRANT
- ESR and HERCA Initiatives
- Audit v Inspection
- Summary

Origins and Development

Recent introduction

Late 1980s/early 1990s

UK White Paper 1989 – “Working for patients”

Clinical audit defined as a review of the delivery of healthcare to ensure that best practice is being carried out

UK’s RCR – “Clinical Audit in Radioilogy. 100+ Recipes

de Lacey, Godwin and Manhire

Finnish Experience

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

HERCA

ESR

Key Elements of Clinical Audit

Definitions

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 (NICE 1997)

The Audit Cycle

Selection of practice - establishment of criteria and standards - observation and comparison of the practice against these – implementation of changes where necessary – further monitoring -

Types

Internal

External

Internal with external direction

Inclusion in EC Directives

Motivation

Medical Audit v Clinical Audit

Directives

Medical Exposure Directive 97/43/Euratom

Basic Safety Standards Directive 2013/59/Euratom

“clinical audits shall be carried out in accordance with national procedures”

NB no reference in the Directives’ definitions to type of audit

European Commission Initiatives

Guidance (2009)

European Commission report No. 159 – European Commission Guidelines on clinical audit for medical radiological practices (diagnostic radiology, nuclear medicine and radiotherapy)

QuADRANT (2020 – 2023)

Promotion of constant improvement in quality and safety of radiology, radiotherapy and nuclear medicine through clinical audit

ESR Initiatives

Esperanto

ESR Guide to Clinical Audit in Radiology

3rd edition December 2021

Guidance is evolving and emphasis is changing with each edition

QuADRANT

2020 - 2023

HERCA Initiatives

HERCA Position Paper

Clinical Audit in medical radiological practices
(October 2019)

Regulators' Expectations

Clinical audits are being carried out

Clinical audits are targeted to justification, optimisation etc

NB Clinical audit is not regulatory audit

Inspection v Audit

	Inspection	Audit
Basis	Legislation and regulation	Standards and best practice
Outcome	Requirements and enforcement	Recommendations and suggestions
Organization	Competent authority	Undertaking/peer review systems
Teams	Inspectors and advisors	Proferssionals
Scope	Constrained	Comprehensive

HERCA Initiatives

Addendum to the HERCA clinical audit position paper

(June 2021)

Provides further clarity on the differences between clinical audit and regulatory audit

Strengthens the expectations of competent authorities during inspections regarding regulation of clinical audit

Audit v Inspection

	Clinical audit	Regulatory audit	Inspection
Defined criteria	Good practice or standard	Regulations	Regulations
Expected level of achievement	Locally/nationally defined	100% compliance against self-assessment of regulatory requirements	100%
Aim	Promotes and develops clinical outcomes and quality of care	Demonstrates and may improve regulatory compliance	Checks the compliance with regulations and implement enforcement
Outcome and follow-up	Recommendations to be considered by the audited party	Recommendations to be considered by the audited party	Decision made by the competent authority
Organization	Undertaking/peer review system	Undertaking/peer review system	Competent authority
BSSD	Mandatory	Not applicable	Mandatory

Conclusions

Audit is a part of modern clinical practice

Inspection is a BSSD requirement

Inspection should be used to determine that clinical audits are taking place and are relevant to radiation protection principles etc

BUT Clinical audit, regulatory audit and inspection are different things

Professionals and regulators want the same thing – high quality healthcare and best practice

364:1 Rule