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

  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 Radioiology. 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

<table>
<thead>
<tr>
<th></th>
<th>Inspection</th>
<th>Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Basis</strong></td>
<td>Legislation and regulation</td>
<td>Standards and best practice</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td>Requirements and enforcement</td>
<td>Recommendations and suggestions</td>
</tr>
<tr>
<td><strong>Organization</strong></td>
<td>Competent authority</td>
<td>Undertaking/peer review systems</td>
</tr>
<tr>
<td><strong>Teams</strong></td>
<td>Inspectors and advisors</td>
<td>Professionals</td>
</tr>
<tr>
<td><strong>Scope</strong></td>
<td>Constrained</td>
<td>Comprehensive</td>
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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

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