

Critical Review
Draft EC Guidelines on Clinical
Audit for Medical Radiological
Practices (Diagnostic Radiology,
Nuclear Medicine and
Radiotherapy)

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Summary

- Role of Regulatory Body.
- Examine document for its implications.
- Alternative recommendations? Agree or disagree?
- Any other observations for consideration?
- The Irish experience.

Role of Regulatory Body

- The regulatory body is required for operational independence and clear accountability to regulate activities.
- Ensure medical exposure is justified; net benefit.
- Ensure medical exposure is as low as reasonable achievable, optimisation.
- Work within an appropriate insitutional structure where more than one regulatory body has responsibility
- Implement and enforce regulatory requirements through audits and inspections.

Challenges in taking a systematic approach

- Responsibility for implementation across a number of regulatory bodies; health and safety; environmental protection; health.
- Challenge for effective coordination and communication.
- Powers of enforcement and prosecution in the case of non-compliance, is this at odds with principle of clinical audit? Appeals procedure required.

Challenges in taking a systematic approach, continued

- How to get feedback.
- Reauditing.
- How internal audit relates outside of the unit.
- Openness is required internally and between stakeholders with regard to
 - internal and external audit
 - peer review
 - networking
 - exchange of ideas
 - regional/area reviews/committees
 - education

Challenges in taking a systematic approach, continued

- National versus regional; former tends to provide more uniform standards and a better use of skilled human resources whereas latter offers greater accountability.
- Central standards and audit committee?
- Independence, integrity, knowledge of auditors, non-threatening approach, trust.

Logistics and governance

- Frequency of audits can be too onerous for dentistry and perhaps not sufficient in radiotherapy.
- Consider criteria where it is considered that an external audit should be repeated in a shorter time scale, e.g., where an audit result falls in to the third category.
- Clear accountability and dedicated resources, a leader required. Deadlines and headlines have contributed to development of clinical audit to date.

Cost implications

- Establishment of the necessary institutional structure.
- Provision of facilities of an adequate standard to meet the demands of the legislation.
- Adequate trained staff.
- Cost of regulation and surveillance.
- Necessary services, such as standard setting, report writing, etc.

Incident Reporting

- Brief reference.
- Requires more detail on definition, structure, protocols, process.
- Potential for consistency across the EU.
- Open the debate.
- Irish example.

Style of guidelines on audit

- Concise, simple approach, focussed.
- Some rewording of document would be required and better categorisation and grouping together of sections to make it more easily readable.
- Suggest 3-4 page summary/overview.
- Requires proof reading and editing.
- Recommend that it is easy to translate in to other European languages.

Style of guidelines on audit, continued

- Categorise according to reader's perspective, e.g., hospital, private clinic, etc. and highlight individual's responsibilities, e.g., professions; regulatory bodies.
- Provide examples of various EU experiencea such as, a set of standards, a case study of countries that have external audit, e.g., France, Germany, Finland.
- Distinguish between mandatory compliance with audit and what is advisory.
- Don't be too prescriptive as it will be difficult to incorporate in to national and local policy.
- Radiology, radiotherapy and dentistry need to be focussed on separately.

The Irish Experience

- Enforcement and prosecution, appeal procedures.
- Independence of regulatory body.
- Coordination with other regulatory bodies.
- Setting standards, approval of medical procedures.
- Resources for National Radiation Safety Committee, clinical audit, guideline notes, MPE's.
- Incident reporting.

Irish Experience and Irish Task

Force Recommendations

- Independent, autonomous and authoritative external body required, e.g., Health Information and Quality Authority reporting to Department of Health and Children.
- Transition committee; lead to cross-regulatory review group?
- Independent, external (outside country within profession or inside country outside profession) validator or body such as IAEA be invited to review application of regulations in the country.
- Internal audit to be strengthened with some external input.

Irish Experience and Irish Task

Force Recommendations, continued

- Area structures and committees required to be put in place to allow for a national systematic approach.
- Initial baseline audit, a paper exercise to capture national statistics on compliance generally and current and proposed activity on clinical audit.
- Useful outcomes from this audit: guidance is needed to allow clinical audit to take place on a regular basis and to learn from others' experiences. No systematic approach in place currently.
- Dental radiology requires a separate and different approach, such as Finland, suggest that clinical audit only apply to complex dental practices which could be further defined at national committee level.

Thank you

Further information available from our
poster on clinical audit and my
colleagues here; Bernadette Moran,
Brian O'Herlihy.