

International Workshop on Practical Implementation of
Clinical Audit for Medical Exposure to Ionizing Radiation
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CLINICAL AUDIT

Summary and checklist for practical implementation

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Elements comprising complex system.



- Explanation of the concept
- Legislation
- Organisation
- Internal audit
- Professional and scientific organisations - groups of clinical experts
- Money
- Standards of good practice.
- Auditors

Explanation of the concept



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- If the concept is not clear to all parties (government, scientific and professional organisations and hospital/staff) or parties are reluctant to accept the concept than the EU recommendation may help.
- Many staff members don't see difference between regulatory inspections and clinical audits or they don't know what it is at all.

Legislation



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- No European law expected
- European level: trigger and foster national action (should this project become the EU recommendation or amendment to MED 97/43?)
- **initiation – implementation – harmonization.**
- National level – at least a provision making clinical audits mandatory should be implemented to national law
- The extent of the national regulations may vary from country to country.

Organisation – two major tasks



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1. To supervise the overall process in the country, especially at the beginning
2. To carry on clinical audits.

Tasks for 2 independent entities

Structure and actions depend on the organisation of the health sector, tradition, etc. – may vary from country to country

- government or private
- non-profit, for profit.

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Internal audit



- It is essential that hospitals/units carry on **internal** clinical audits on regular basis
- It increases an understanding of the concept and shows its value for patient care improvement
- My opinion – it is hardly possible to succeed with external audit if the hospital/unit has never performed internal audit or other type of self-assessment.

Money



- There has to be money in the system available
- It is important to define who pays for what and how.
- Money is needed not only to carry on clinical audits but to support expert group which supervises audit performance, evaluate standards, etc.
- Different financing systems exist inside EU – no call for the uniformity - systems should be efficient and meet the goals.

Professional and scientific organisations

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- To be a driving force – not be sided by business organisations or employee unions which look to earn money or secure the corporate interests.
- To offer guidance and share knowledge on the concept
- To elaborate and review standards of good practice
- To be a provider of competent auditors
- To perform audits (in some countries).

Standards of good practice



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- Without clearly defined national standards of good practice it is difficult to point the deviations
- These standards may vary from country to country – no legal requirements to harmonise within EU (national competence)
- Clinical Audit may be a promoter of the definition of standards as their lack becomes evident during the audit.

Auditors



- Competent
- Working in the team comprising several disciplines and overall patient pathway
- Motivated to work
- Independent as much as possible
- Should they be recruited from the country or also from abroad.

Summary



- Clinical audit system is a complex organisation of several elements and actions.
- Should all elements be in place and actions initiated makes system to work.
- The concept needs constant promotion