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CLINICAL AUDIT

Summary of the results of the European Questionnaire on the implementation of Clinical audit

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Summary of the European Questionnaire on Clinical Audit



Introduction

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- Questionnaire concerned**
- **National regulatory frameworks, i.e. the national provisions for the implementation of the requirements of Article 6.4 of Council Directive 97/43/Euratom on Clinical Audit**
 - **Existing audit programmes, inspection and accreditation systems**
 - **Organizational, technical and administrative provisions for clinical auditing, in particular relevant criteria, standards and procedures, documentation and reporting requirements, monitoring and control systems.**

Summary of the European Questionnaire on Clinical Audit



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Introduction

The Questionnaire was addressed to

- **The national societies for diagnostic radiology, radiotherapy and nuclear medicine**
- **The competent or radiation protection authorities.**

For the questions of legislative requirements, the instructions of the questionnaire gave advice to consult appropriate ministries and/or radiation protection authorities.

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Introduction

The response to the questionnaire was about 80 %. Only a few countries did not supply any reply in spite of repeated enquiries to several recipients.

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Status of legislation

The basic requirements of the Council Directive 97/43/Euratom for clinical audit (Article 6.4) have generally been implemented in the national legislations

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Status of legislation

- **The conditions (technical, infrastructural) in which RADIOLOGICAL practices should be performed have been regulated in most countries by law, decree or other regulation.**
- **The regulations are usually given by the Health Ministry or a special radiation protection authority.**
- **In many countries, there are also recommendations on these conditions, usually given by the radiation protection authority or the national scientific societies.**

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Status of legislation

- **The practical implementation has been regulated in most countries.**
- **In most cases, this concerns both external audits and internal audits, or self-assessments.**
- **In several countries, also recommendations on the implementation have been given, usually by the radiation protection authority or the national scientific societies.**

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Status of legislation

- **In about half of the countries, the legal requirements give some specification of the practices to be audited**
 - E.g., in Finland, conventional dental practices have been excluded from the requirement of external audits.**
- **In a few countries, there are also recommendations on the practices to be audited**

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Status of legislation

- **For Quality Systems**, about half of the countries have regulations while some countries have also recommendations, or only recommendations.
- **Certification of the quality system** was reported as a requirement in three countries only, while in a few countries there are recommendations for it.
- **Regulations or recommendations on accreditation** were reported in about one fourth of the countries.
- **In a few countries**, there are regulations or recommendations also on **other types of quality assessments**.
- **Relation of clinical audit with other quality assessment systems** has been regulated or recommended only in a few countries, while the relation of clinical audit with **regulatory inspection** has been regulated or recommended in about one third of the countries.

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Status of legislation

- **The performer of clinical audits and requirements on auditor's competence and experience, auditor's training and independence have been regulated in about one third of the countries. Some countries have also, or only, recommendations which are usually given by authorities.**
- **The methods of audit have been regulated in about every fourth country, while recommendations are given in about every third country.**
- **The agreed standards of good practice have been regulated or recommended in about every third country; these are usually national or international standards, or recommendations by national professional societies or special committees.**

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Status of legislation

- **The frequency of clinical audits has been regulated in about one third of the countries and seems to be 1-3 years when specified.**
- **The reports and follow-up of audits have been regulated also in about one third of the countries, and in a few countries there are also, or only, recommendation on them.**

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Practical Implementation

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- **The practical implementation of clinical audits in many countries is still not completed or in a very early development stage.**
- **The approaches in the practical implementation also vary considerably between the Member States.**

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Practical Implementation

- **Clinical audits are mainly occasional.**

Clinical audits are carried out more regularly in Finland, France, Germany, Lithuania, Poland, Slovakia, Slovenia, UK and Switzerland.

In some cases regular clinical audits are only internal (Spain, UK).

- **Specific organizations for external clinical audits have been established in several countries, often by the Ministry of Health.**
- **Individual peer reviews are carried out besides the clinical audits by specific organizations.**

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Practical Implementation

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- Financing of (external) clinical audits is implemented either**
- **by charging the recipients (fees) or**
 - **by government support**
 - **in some cases the financing is based on "mutual agreements".**

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Practical Implementation

- **Professional experience and independence are generally required from the auditors, and they usually work as a team.**

Independence is usually interpreted so that the auditors have to be from different health care unit.
- **Training of the auditors is not adequate and usually covers only audit techniques, not the applied criteria.**

There are various approaches with training institutes (ministries, universities, private institutes, accreditation authorities, auditing organizations etc)

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Practical Implementation

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- **National coordination of clinical audits** has been established in most cases, either by Ministry or an organization established by the Ministry
 - **In one case this is by a scientific society.**
- **There is a high variation of tasks of these coordinating organizations.**
- **Local coordination has been established only in a few cases.**

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Practical Implementation

- A checklist for carrying out clinical audits usually exists.
- Criteria for good practices have been defined in most cases and are based on national or international standards or guidelines or recommendations by professional societies.

In some cases the criteria have been prepared by the auditing organization.

- The practical methods in the existing systems of clinical audits tend to follow common principles of auditing (entrance and exit meetings, reviews and interviews, reporting, follow-up etc).

The clinical audits include measurements (quality control, performance, radiation safety) in about half of the countries.

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Practical Implementation

- **The certifications of the quality systems or accreditations of the health care units for radiological practices are not very common, only from 0 to 20 % of the units.**
- **Regulatory inspections are carried out in most countries, with measurements mainly for occupational protection.**

The overlap of clinical audits with regulatory inspections was reported only in a few cases (Finland, UK, Switzerland).

Regular meetings of authorities and auditing organizations are not very common.

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Practical Implementation

- **The need for harmonization of clinical audits has been recognized by all countries replied. For the items to be harmonized, most of the replies quote audit program, standards of good practice training of auditors practical methods of auditing.**
- **However, all possible items have been quoted at least once when summing up all the replies.**
- **Also the borderline between clinical audit and certification, accreditation and regulatory inspections has been stated as an important point of consideration.**

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Practical Implementation

- **The major problems identified in the replies were among other things**

Incomplete national legislation for clinical audit

Methods of financing

Lack of formal framework of auditing

Poor understanding of the purpose and contents of clinical audits

Lack of criteria for the standards of good practices

Difficulty to employ sufficient number of auditors

Insufficient time available for auditors

Lack of specific training of auditors

Need of technological modernization of radiology equipment to meet quality standards

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Practical Implementation

- **The major benefits reported include:**
 - A tool for quality improvement**
 - Recognition for quality**
 - Prevention against litigation**
 - Improvement of practice**
 - Motivation of staff to increase quality**
 - Benefit to patients**
 - Improvement of local standards and adherence to national standards**
 - Recognition of malpractices**
 - Improvement of communication within the institution**
 - Increased communication and awareness of good practices**
 - Revealing weak points**
 - Promoting development of quality systems**

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- **Some specific proposals presented in the replies:**

Organization of European team to perform "model" audit in a reference centre in the country

Assessment outcome system which allows comparing the outcome of clinical audit European wide

More attention to the resources of the health care unit for audits

More unifying feedback from the results should be given to audited units

"Guidance is needed but should be simple and friendly".