First Steps in Clinical Audit in Romania

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Background/Introduction

As the use of radiation in medicine is still the biggest contributor to radiation exposure caused by man, improving and maintaining a high quality of radiological medical procedures is of primary importance.

The EC Directive 97/43/EURATOM introduced the concept of Clinical Audit for the assessment of medical radiological practices and the requirement that all Member States should implement clinical audit in accordance with national procedures.

Since 2011 within the frame of the "National Programme for Monitoring Environmental Life and Work Determinants, Objective 2 - Health care and prevention of diseases associated with ionizing radiation", the National Institute of Public Health started the national project "Clinical audit of medical ionizing radiation practices". The project originally aimed at developing for the first time a national procedure to perform the clinical audit in the practice of diagnostic and interventional radiology in accordance with current national and international regulations and then implementing it in radiology departments at national level.

The preliminary clinical audit procedure developed on the basis of IAEA Publication "Comprehensive clinical audits of diagnostic radiology practices: a tool for quality improvement. Quality assurance audit for diagnostic radiology improvement and learning" (QUAADRIL), 2010 [1] was applied as a pilot study in a few representative medical institutions in Cluj-Napoca, in 2011 - 2015.

After applying this preliminary clinical audit procedure:

- have been identified numerous benefits when applying clinical audit in radiological practice, the most important being the improvement of radiological medical services in terms of quality of care and patient radiological protection;

- have been highlighted a series of important problems concerning organizational and infrastructure issues related to the practical implementation of clinical audit at national level.

Thus, every year, the project objectives have changed, focusing on addressing the identified issues.

Since 2014 it has been identified as a need the development of a national legislative act regarding the implementation of clinical audit in radiological medical practices, in the context of transposition into national law of Directive 2013/59/EURATOM [2] and the most recent international specific recommendations.

So, the entire project was carried out in parallel on two inter-dependent components:
Component I - aimed the application of the preliminary audit procedure as a pilot study in representative health care facilities from Cluj-Napoca, as an iterative process in order to:

- assess the current radiological practice and compare it with selected international standards;
- determine the final form of audit procedures based on feedback obtained from the pilot study.

Component II - with the following objectives:

- the development of a draft for a legislative act regarding rules on clinical audit in radiological medical practices, by the specialists of the National Institute of Public Health;
- the development of national good-practice guidelines based on the most recent international recommendations, by the medical professional societies.
Description of activity and work performed

Component I

The pilot study was applied from 2011 to 2015 in the diagnostic radiology departments of two regional public hospitals, considered representative because of the high risk/high volume procedures and for the potential benefit to practice and patient.

Special attention was given to breast imaging departments with good technical infrastructure and implemented quality control programmes in order to prove/enhance their ability to conduct breast screening programs.

It was created a multidisciplinary team of auditors comprising dedicated medical professionals of different specialties (radiologists, radiographers, radiation oncologist, expert medical physicist and technical engineer) with high expertise in diagnostic radiology and with special interest in breast imaging.

Clinical audit was applied for the whole patient clinical pathway (structure, process and outcome).

It was found that, currently, clinical audit comes across clinical activity already overloaded by accreditation and quality management evaluation systems that overlap in many aspects with it.

To simplify clinical audit process so that it does not overlap with the quality management system evaluation, accreditation or regulatory inspections, clinical audits were conducted focused on:

- justification of medical exposure procedures,
- optimization procedures for medical exposures, by assessing the radiological image quality in relation to patient dose,
- clinical protocols for special procedures.

For all clinical audits applied the following five stages were performed [3] (Figure 1).

*Figure 1. The clinical audit cycle Fig. 1 on page 9*

**Results obtained following the application of the pilot study (component I):**

1. Identification of nonconformities and improvement proposals (Table 1):

*Table 1. Examples of audit findings and improvements Table 1 on page 9*
2. The breast imaging departments, audited against specific criteria [7, 8], proved their ability to conduct breast screening programs, in terms of dedicated and experimented professionals, technical infrastructure, implemented quality assurance and quality control programmes, number of patients addressed, organizational and management expertise.

3. Identification of numerous benefits of implementing clinical audit in radiological practice: increasing communication and awareness of best practices in health care facilities; practice optimization by increasing the benefit/risk ratio, better standardization of procedures and practices; highlighting the needs in terms of resources.

4. Highlighting some important issues related to the implementation in practice of clinical audit at national level such as: lack of fundamental understanding of the benefits of clinical audit application in practice, clinical audits overloading activity due to overlap with other systems of quality management assessment, accreditation and regulatory inspections, lack of trained/certified external auditors, shortages of qualified internal staff (in number and dedicated work time) need to clarify financing sources.

5. Review of clinical audit procedures based on the feedback obtained after their first application taking into account the latest recommendations of the European Society of Radiology [4].

**Component II**

In order to elaborate a draft legislative act regarding clinical audit of medical activity with ionizing radiation were conducted the following activities:

1. SWOT analysis on factors influencing the development of a draft legislative act on clinical audit in medical radiological practices (Table 2):

   **Table 2. SWOT Analysis Table 2 on page 10**

2. Drawing up a strategic plan on developing draft legislation act and establishing priority actions (Table 3) which set general objectives, ways of achieving these objectives at national level (specific objectives) and priority activities.

   **Table 3. Strategic plan - priority actions Table 3 on page 10**

Since the audit involves assessing radiological medical practice in relation to a referential, there have been analyzed and selected international best practice standards and recommendations based on the latest scientific evidence specific for each type of radiological practice [5, 6, 7, 8].

Together with medical professional societies, has been started the transposition of these recommendations, in good-practice guidelines that were meant to be clear, representative, cost-effective, flexible, clinically applicable, revisable, capable for being transposed into explicit audit criteria, which will be subject to Ministry of Health approval.
In order to increase awareness among medical specialists it has been developed an informative material on the need and benefits of clinical audit addressing both medical institutions with the personnel involved and professional organizations.

In order to elaborate draft legislative act and harmonize national requirements on clinical audit with the European data were analyzed:

- ways of transposing EC requirements into national laws of European countries regarding audit program, best practice standards, training of auditors;

- the degree of practical implementation of these requirements;

- practical methods of clinical audit implementation [9].

It has been developed the draft legislative act which introduces compulsory implementation of clinical audit as professional and organizational responsibility at all public and private medical radiological practices and establishes the main responsibilities regarding the implementation and enforcement of the clinical audit.

Rules on clinical audit in medical radiological practices (diagnostic and interventional radiology, nuclear medicine and radiotherapy), as a transposition of the "European Commission guidelines on clinical audit for medical radiological practices", Radiation Protection no 159 [10], describe the objectives of clinical audit, the frequency of internal and external clinical audits, the minimum requirements concerning topics audited, the audit team, the individual responsibilities, the information from audit recordings, and examples of standards and applicable good-practice criteria.

Since international recommendations on the criteria of good-practice and radiation protection in radiological practice and even those about the implementation of clinical audit are continuously changing, in order to keep pace with the rapid development of technologies used in medical exposures, it was considered useful that the rules on clinical audit in medical radiological practice should contain only general requirements for the implementation of the clinical audit, and in the future to transpose the international recommendations into guides for each type of practice (diagnostic and interventional radiology, nuclear medicine and radiotherapy) which may be reviewed periodically, in accordance with the latest international recommendations, without the need to change the default order.

**Results obtained in component II:**

As a result of the activities conducted in component II of the Project were developed the following documents which will be submitted for approval by the Ministry of Health (Table 4).

*Table 4. Developed national documents Table 4 on page 11*
Fig. 1

<table>
<thead>
<tr>
<th>Clinical audit topic</th>
<th>Audit findings</th>
<th>Improvements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical exposure justification</td>
<td>No formalized, written records for justification of special procedures in the breast imaging departments</td>
<td>Development of a registration form for justification of special procedures</td>
</tr>
<tr>
<td>Medical exposure optimization</td>
<td>Even though DAP/AGD/DLP for individual exposures are registered and compared with DRL, these values are not always analyzed compared with image quality</td>
<td>Formalized, written procedures with image quality criteria</td>
</tr>
<tr>
<td>Clinical protocols for special procedures</td>
<td>No formalized, written protocols for special procedures</td>
<td>Formalized, written protocols for special procedures, including interventional techniques and breast investigations for pregnant and breast feeding women</td>
</tr>
</tbody>
</table>

Table 1

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<table>
<thead>
<tr>
<th>STRENGTHS</th>
<th>WEAKNESSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Activities developed in the project „Clinical audit of medical activity with ionizing radiation“ (2011 – 2015):</td>
<td>1. Lack of vision regarding the implementation in practice of clinical audit according to international recommendations:</td>
</tr>
<tr>
<td>- Existence of clinical audit procedure draft</td>
<td>- Who conducts clinical audit</td>
</tr>
<tr>
<td>- Results of pilot study implemented in representative medical units</td>
<td>- Who certifies internal/external auditors</td>
</tr>
<tr>
<td>- Informative material disseminated on website</td>
<td>- Who coordinates clinical audit at national level</td>
</tr>
<tr>
<td>- Results of the analysis of specific requirements for radiological practices and their implementation in european countries</td>
<td>- Who supports the financial costs of audits</td>
</tr>
<tr>
<td>2. Existence of national good practice standards</td>
<td></td>
</tr>
<tr>
<td>- Norms for radiological security (National Commission for Nuclear Activities Control and Ministry of Health)</td>
<td></td>
</tr>
<tr>
<td>OPPORTUNITIES</td>
<td>THREATS</td>
</tr>
<tr>
<td>1. Legally: the necessity for national transposition of Directive 59/2013/EURATOM and specific recommendations by February 2018</td>
<td>1. Legally:</td>
</tr>
<tr>
<td>2. Professionally: the necessity to elaborate/revisate national good practice guidelines, based on latest scientific evidence</td>
<td>- Lack of legislation regarding clinical audit in the Romanian health care system</td>
</tr>
<tr>
<td>3. Socio-economically: the necessity to improve medical services quality in regard to safety, efficiency, efficacy, rentability and patient orientation, in order to increase patient satisfaction</td>
<td>- Lack of designated persons or organisms responsible for national implementation of clinical audit</td>
</tr>
<tr>
<td></td>
<td>2. Professionally:</td>
</tr>
<tr>
<td></td>
<td>- Lack of fundamental understanding of the benefits of clinical audit implementation</td>
</tr>
<tr>
<td></td>
<td>3. Economically:</td>
</tr>
<tr>
<td></td>
<td>- Insufficient number of medical physicists</td>
</tr>
<tr>
<td></td>
<td>- Lack of adequate infrastructure (lack of dosimetric and quality control devices in radiology departments)</td>
</tr>
<tr>
<td>General Objectives</td>
<td>Specific Objectives</td>
</tr>
<tr>
<td>--------------------</td>
<td>--------------------</td>
</tr>
</tbody>
</table>
| 1 National good-practice guidelines | Development of good-practice guidelines by Medical Professional Societies and/or interdisciplinary committees organized by the Ministry of Health | - Selection of international good-practice guidelines and recommendations based on the latest scientific evidence  
- Elaboration of national adapted good-practice guidelines |
| 2 Awareness among medical specialists | Informative campaigns organized by the Ministry of Health and dissemination of informational materials on website | - Elaboration of informative materials regarding the need and benefits of clinical audit |
| 3 Organizational structure for clinical audit | Development of structures for:  
- training/certifying clinical auditors  
- external clinical audit | - Establishing needed human and material resources for clinical audit  
- Establishing responsibilities for persons involved in clinical audit  
- Ensuring informational support for personnel training and certification |
| 4 Legislative act regarding clinical audit | Development of a legislative act regarding clinical audit in radiological medical practices | Elaboration of the final form of the Norms regarding clinical audit in radiological medical practices |

**Table 3**

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| 1 Good-practice guideline for Radiology and Medical Imaging, elaborated by Romanian Breast Imaging Society and Romanian Radiology and Medical Imaging Society |
| 2 Information material disseminated on the website of National Institute of Public Health, regarding the necessity and benefits of implementing clinical audit in medical radiological practices |
| 3 Draft of legislative act and Norms regarding clinical audit in medical radiological practices |

**Table 4**

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Conclusion and Recommendations

Periodical application of clinical audit in clinical radiological practice (as a pilot study) showed that:

- clinical audit is a good management tool, providing an overview of the essential elements of medical care quality, of the weaknesses of clinical services and the responsibilities of employees;

- there are many benefits when applying clinical audit in radiological practice (increased interdisciplinary communication, awareness of best practices, optimization of medical practices by increasing the benefit/risk ratio, highlighting the need for improvement on procedures and resources);

- for audited breast imaging departments, the results of clinical audit confirm the good practice applied in accordance with breast screening programs criteria;

- in a blame-free environment, clinical audit can lead and to an improved and more content situation for patients, staff and referring physicians;

- clinical audit can be a good tool for continuing education resulting in an environment of continuous development;

- it is important to establish the line between clinical audit and the certification/accreditation audit and regulatory inspections.

We expect the adoption of the proposed legislative act to have a positive impact on:

- the quality of medical care services and efficient resource utilization

- the state of health of the population and patient satisfaction.

In order to implement clinical audit in medical radiological practices remains necessary to create/establish structures for training and certification of auditors and nationwide clinical audit coordination.

Until then, National Institute of Public Health will be involved in the development of specific information resources for staff training and useful tools in implementing customized internal clinical audits.

By adopting this draft legislative act on clinical audit in medical radiological practice, the national legal framework applicable for protection against ionizing radiation will be completed with these requirements, thus contributing at the transposition of the Directive 59/2013/EURATOM.
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References


