On exposure justification in pediatric CT examinations

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Abstract. The prescriber as well as the practitioner are involved in the exposure justification process according to BSS 115 and 97/43/EEC Directive. The aim of this paper is to assess the medical exposure justification by means of the guide for the usage of medical imaging and to analyze if this approach is appropriate to ensure a suitable and objective justification.

The study was performed in a Romanian pediatric emergency hospital. More than 300 records of CT investigations were analyzed and statistically processed in order to estimate the conformity with the guide recommendations and the risk in terms of effective dose received by patients. The result of this study shows that 35\% of the investigations performed were not prescribed according to the guide recommendations. This result is significantly affected by the interpretable cases of the guide’s comments. Consequently, the previous result decreases to 20\%. Corresponding dose in this case is 17\% of total dose due to all the exposures.

In spite of the real progress in the field of patient radioprotection achieved by adopting of 97/43/EEC Directive and of the Good Practice Guide, the last one should be completed, improved, and disseminated especially to the prescribers.

KEYWORDS: exposure justification; patient radioprotection; pediatric CT; Good Practice Guide.

1. Introduction

Council Directive 97/43/Euratom \cite{1} on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure has been transposed in Romania by the 285/79/2002 Joint Order of the President of the National Commission for Nuclear Activities Control (CNCAN) and the Ministry of Health approving Norms on protection of individuals against ionizing radiation in relation to medical exposures \cite{2}. The Medical Exposures Directive requires that all medical exposures to ionizing radiation must be justified prior to the exposure being made.

The implementation of the Directive consists in a set of steps taken by Romanian authorities and the other involved bodies. Therefore, in 2006 the Romanian Society of Radiology and Medical Imaging has adopted the Guide for the Usage of Medical Imaging \cite{3}. The Guide is a translation – with adaptations and changes – of the Good Practice Guide adopted in 2005 by the French Society of Radiology \cite{4}.

According to the provisions of the Directive, the practitioner is responsible for the justification of each individual medical exposure. This should be based on his knowledge of the hazard associated with the exposure and the clinical information supplied by the prescriber but some referral criteria are needed. The Computed Tomography (CT) has a significant contribution to the collective population dose from medical X-ray examinations and the clinical justification practice differs significantly between centres \cite{5}. This study is trying to assess the medical exposure justification by means of the Guide for the usage of medical imaging.

2. Material and Methods

The study was performed in a pediatric emergency hospital in Bucharest – Romania. The hospital has a Department of Radiology and Medical Imaging where standard X-ray (radiography and radioscopy),

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computed tomography – CT and ultrasound investigation are performed. There are no IRM, SPECT or PET equipments available in hospital.

More than 300 of CT investigations, achieved in the first quarter of 2007, were retrospectively analysed. The records were statistically processed in order to assess the conformity or non-conformity with the Good Practice Guide recommendations [3].

A total of 309 CT investigations of children patients (158 male and 151 female), aged between 0 and 18 years (Fig. 1), were analysed. The presumed diagnoses, examination type (Fig. 2), results of investigation, confirmation of presumed diagnosis, conformity with the Guide were noted. The conformity with the Guide recommendations was assigned to be positive if the CT examination was recommended in Guide either in pediatrics chapter or in any other chapter of the Guide. This approach was decided for the reason that the pediatrics chapter does not contain many of our analysed cases (for example the pediatric chapter does not contain any pediatric cancers and in the adult cancer chapter introduction it is specified that pediatric cancers is not included). In the absence of definite indications (or non-indications) in pediatric cases it was preferred to consider an indicated examination according to Guide recommendations if there are either pediatric or adult recommendations. Also, the Guide reference index, the recommendation type (indicated, specialised investigation, etc) and effective dose class for each examination were noted.

**Figure 1:** Patients’ age distribution

![Figure 1: Patients’ age distribution](image)

**Figure 2:** CT examination type distribution

![Figure 2: CT examination type distribution](image)
In order to evaluate the collective dose the mean dose of Guide’s dose interval was considered (for example the Guide II dose class, 1-5 mSv interval, was considered mean dose of 3 mSv). For Guide IV dose class it was taken into account 11 mSv as a reasonable mean value for high dose CT examinations. For collective dose estimation, the CT successive acquire on the same volume was neglected. For the multiple examinations (e.g. abdomen + cranial) the dose class was adequately increased.

3. Results

In the previous hypotheses regarding conformity with the Guide recommendations, the 199 examinations were prescribed according to the Guide recommendations and 110 examinations were not. The examinations untenable according to the Guide recommendations represent 35.6 % of all analysed examinations.

It is important to highlight that there are clinical problems in the Guide where CT examination is “not indicated” (this means untenable - see RP 118 [6]) but the corresponding comment suggest that it can be done. The most frequently such case was 03M reference index (epilepsy) in pediatrics chapter of the Guide. In this case, the CT examinations is “not indicated’, but the comment is “unless IRM is not available”.

Also, there are clinical problems in the Guide with no references regarding CT (neither “indicated” nor “not-indicated”) but in some cases the CT examination is mentioned in the comment.

A number of 60 examinations not prescribed according to the Guide recommendations, i.e. 19.42% of all examinations, remain after excluding these debatable (interpretable) cases.

Nevertheless, for 38 of these 60 untenable examinations the presumed diagnosis was confirmed and this demonstrates the net benefit of the exposure.

Regarding to the collective dose estimating, the Table 1 shows the distribution on Guide’s dose class for all examinations and Table 2 the same for the untenable examinations according to the Guide recommendations.

Table 1: Distribution on Guide’s dose class for all examinations.

<table>
<thead>
<tr>
<th>Class</th>
<th>Number of examinations</th>
<th>Mean dose / examination (mSv)</th>
<th>Collective dose (mSv)</th>
<th>Total collective dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>2</td>
<td>0.5</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>187</td>
<td>3</td>
<td>561</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>108</td>
<td>7.5</td>
<td>810</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>12</td>
<td>11</td>
<td>132</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>1504</strong></td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Distribution on Guide’s dose class for the untenable examinations according to the Guide recommendations.

<table>
<thead>
<tr>
<th>Class</th>
<th>Number of examinations</th>
<th>Mean dose / examination (mSv)</th>
<th>Collective dose (mSv)</th>
<th>Total collective dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>0</td>
<td>0.5</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>43</td>
<td>3</td>
<td>129</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>13</td>
<td>7.5</td>
<td>97.5</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>4</td>
<td>11</td>
<td>44</td>
<td><strong>270.5</strong></td>
</tr>
</tbody>
</table>
The number of examinations and collective dose are shown in Figure 3.

**Figure 3:** The number of examinations and collective dose for (a) all examinations, (b) the untenable examinations according to the Guide recommendations.

![Graph showing number of examinations and collective dose](image)

(a)

(b)

The total collective dose for the untenable examinations, according to the Guide recommendations, is 17.98% of total collective dose for all examinations.

Trying to verify if this approach is appropriate, it was made the same calculation taking into account the minimum value of dose for dose class (this means 0, 1, 5 and 10 mSv, respectively) and also the maximum value of dose for dose class (1, 5, 10 and 12 mSv, respectively). The percentages of total collective dose for the untenable examinations are 17.47%, respectively 18.19%. These values prove the validity of our approach.
4. Discussion


"Medical exposure referred to in Article 1 (2) shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation." and "all individual medical exposures shall be justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved."

The key legal requirement of this section is that each individual medical exposure should be justified in advance. This may require a quantitative assessment ("weighting") of detriment versus benefits but it is not easy for a practitioner to evaluate the individual detriment and the benefits of every exposure.

A quantitative assessment of the risk involved by the CT procedure could be made based on the risks factors supplied by the ICRP [7], but the benefit is more difficult to be quantified for every exposure. Thus, the implementation of the regulations should not be based only on the risk-benefit assessment. Moreover, it seems to be very difficult to implement the requirements of the Directive (Art.3.1) on the individual medical exposure justification based on the weighing of the total potential diagnostic benefits it produces against the individual detriment that the exposure might cause.

The approach based on BSS 115 of IAEA [8] requires the justification of the medical exposure by weighing the diagnostic benefits against the radiation detriment but for an exposed group, not for an individual.

On the other hand, referring to individual medical exposure justification (level 3), the ICRP Recommendation 103 [7] asserts:

"Justification of individual exposures should include checking that the required information is not already available and that the proposed examination is the most suitable method of providing the clinical information required. For high-dose examinations, such as complex diagnostic and interventional procedures, individual justification is particularly important and should take account of all available information. This includes the details of the proposed procedure and of alternative procedures, the characteristics of the individual patient, the expected dose to the patient, and the availability of information on previous or expected examinations or treatment. It will often be possible to speed up the justification process by defining referral criteria and patient categories in advance."

At this level, there are no recommendations regarding quantitative assessment on detriment-benefit balance. The Good Practice Guide is almost the only instrument needed to make the required justification.

In order to estimate the level of use of the Guide, more than 100 radiologists country-wide spread were asked about knowledge and implementation of the Good Practice Guide. The results show that 74 % of them declare they know about the existence of the Guide, but 42 % have read it and use its recommendations. Moreover, 85 % of practitioners think that the prescribers do not know the Guide and do not use it. It seems that most of the assessments needed for the justification of a radiological exposure in diagnostic are made on the basis of professional experience (71%).

The guide highlights the need, where practicable, to chose techniques without exposure to ionizing radiation. These are to be preferred where they have the same objective. In practice, the use of such techniques is definitely influenced by their availability. The implications of delaying diagnosis in order to provide the recommended method should be judged case by case taking into account the medical reasons. The prescriber should provide to the practitioner sufficient medical data relevant to the medical exposure requested to enable the practitioner to decide whether the exposure can be justified.
5. Conclusion

It appears that it is not necessary to justify each individual medical exposure based on a quantitative assessment of the individual detriment and benefit.

The Directive's requirement should be expressed more flexible and its implementation could be satisfactory performed by using the Good Practice Guide recommendations. The Guide should be revised and improved based on the medical experience and disseminated to all medical staff involved.

The results highlight a certain level of implementation of the guide recommendations in the hospital where the study was performed. The collective dose due to the untenable examinations according to the Guide recommendations could be mitigated by ensuring the endowment with non-Xray equipments (IRM).

The responsibility to justify medical exposures is placed on the practitioner. This requires the practitioner to have a full knowledge of the potential benefit and detriment associated with the procedure under consideration. All practitioners need to be adequately trained to undertake this function.

Also, the prescriber has to be involved in the justification process. Therefore education and training on investigations methods, associated risks and radiation protection issues should be given during the medical schools. More future actions should be taken by the regulatory body in collaboration with professional bodies in order to ensure that appropriate training is provided to all the involved physicians and the Guide provisions are disseminated.

However, the results of this study have no statistic value because it has been done on a limited number of cases in only one hospital having a specific staff and endowment. This kind of studies should be developed in the future in order to obtain more useful data to support regulatory actions.

REFERENCES