

RADIATION PROTECTION AND RESPONSIBILITIES OF PUBLIC HEALTH

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Abstract: Statistics highlight the increasing number of medical equipments and procedures using ionizing radiation in Romania. Some of these procedures involve high doses, the exposures may be repeated, and recording and saving information on patient doses are still inadequate, despite the existing legal provisions; in this context, recent studies confirm that practitioners are still reluctant to refuse unjustified examinations, and the issue of radiation protection of the patient becomes an actual public health problem. Public health specialists are confronted with the dilemma of the alternatives to solve existing problems, between a new excessive regulation or better information, assisted by control and the mechanisms of internal and external clinical audit, not as punitive means, but appealing to the professional deontology of the professionals.

Cuvinte cheie: expuneri medicale la radiații, justificare, protecție radiologică

Rezumat: Cifrele statistice semnalează creșterea numărului de echipamente și proceduri medicale care folosesc radiații ionizante efectuate în ultimii ani în România. În contextul în care unele dintre acestea aduc doze mari, expunerile se pot repeta, iar înregistrarea și păstrarea dozelor pacientului rămâne necorespunzătoare, în ciuda cadrului legislativ existent, iar studiile recente confirmă că practicienii încă sunt ezitanți în refuzul examinărilor nejustificate, problema radioprotecției pacientului devine o actualitate a sănătății publice. Dilemele specialiștilor de sănătate publică sunt legate de alternativa de soluționare a problemelor existente, între un nou exces de reglementare sau o mai bună informare, completată de control și mecanismele auditului clinic intern și extern implementate, ca mijloace de apel la deontologia profesioniștilor din domeniu și nu prin adoptarea unor noi măsuri punitive.

Medical procedures using ionizing radiation have become, in the context of present developments of medical technology and their benefit for diagnostic and therapy, a core component of the medical management of the patient. Unfortunately, unlike other types of diagnostic procedures, for example ultrasonographic investigation, the procedures using ionizing radiation sometimes involve high doses, and their repetition during short time intervals adds to the increased risk of effects associated to the exposure to ionizing radiation, the carcinogenic effects being the most serious of them.

While with regard to the radiologists, the most visible of the practitioners, the ethical aspects of radiological practice (1,2,3,4) are investigated by many studies carried by specialists and scholars of the field, the issues of the role and ethical dilemmas of other specialists involved in radiological protection, are merely beginning to be discussed.(5) Thus, ensuring adequate patient protection with regard to the medical examinations, and maintaining the balance between regulation, control, and the individual decision made by the specialists based on deontological codes and ethical principles, becomes an actual public health problem (6), that impacts on the specialists involved in all the phases of radiological medical exposures, from regulation, dose monitoring, clinical audit, to the management of medical facilities. The ethical dilemma is to find the optimum balance between self-regulation, regulation, and control, as means to ensure the patient right to be informed, and

to observe individual autonomy, while ensuring patient protection from the hazard of unjustified medical exposure.

Size and dynamics of the phenomenon

Medical exposure is the main route of population exposure to anthropic ionizing radiation. According to the latest international registries, UNSCEAR Report 2008 (7), approximately 3.6 billion radiological examinations are performed each year worldwide, which contribute about 20% to the annual effective dose for each person. In the developed countries, there is a trend to exponential increase; for example, according to the same UNSCEAR report, the contribution of medical exposure in USA reaches 6.2 mSv per year, medical exposure becoming comparable to the natural exposure.

Recent speciality studies reveal that 20-50% of these procedures, depending on the context, are unjustified. Consequently, a waste of resources added to an unnecessary exposure, possibly hindering the medical management of the patient, along with the dilemmas for the responsible persons at all levels of decision making, may occur. Similar to international dynamics, the number of authorised equipments for radiological diagnostic has also increased in Romania during the last 5 years. According to the National Committee for Control of Nuclear Activities (NCCNA) 2006 and 2011 Reports (8,9), the number of equipments for dental radiology has increased from 803 to 1400, and the number of equipments for radiological diagnostic and interventional radiology has increased from 1841 to 2150, including 211 CT equipments. It is an obvious increasing

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tendency, although according to the OECD Report, Health at Glance 2012 (10), Romania is still placed the last in the hierarchy of accessibility to CT scan equipments, with 5.8 equipments/1 million inhabitants, compared to the EU average of 20.4 equipments/1 million inhabitants. With this background, and despite the accessibility, financial, individual, and health system limitations, according to the National Institute of Public Health (NIPH) (11), the estimated values for year 2011 in Romania reach 8,000,000 radiographs, to which 1,000,000 fluoroscopic examinations, and 750,000 CT scans are added, which, of course, also imply and additional risk associated to these exposures.

Characteristics of medical exposures

A number of characteristics differentiate medical exposures from other types of exposure. Medical exposures to ionizing radiation are planned exposures that directly benefit the patient, observing the principle of doing more good than harm. The dose is intentionally delivered, its magnitude is adequate for the diagnostic or therapeutic purpose intended, and cannot be unlimitedly reduced without diminishing the planned diagnostic, or therapeutic result. Thus, according to NIPH results, the average effective dose per procedure vary with the type of procedure, from 0.4 mSv for pulmonary radiography, to 1.7 mSv for urography, and to 4-14 mSv for thoracic or abdominal CT scan. Medical exposures involve not only patients, but also affect caretakers, most often family or friends, who are close to the patient during the diagnostic procedures, or after an intake of radiopharmaceuticals. Thus, a radiological protection system, based on three basic principles: justification, optimization, and dose limitation, was developed and established in the European Union, by means of two Directives, a framework Directive, adopted in 1996 (12), and a specific Directive (13) dedicated to medical exposures. Radiological protection, i.e. reducing the risk associated to these exposures, includes, depending on the type and purpose of the exposure, choosing the most adequate and less harmful procedure, and avoiding unnecessary exposures in diagnostic examinations and interventional radiology, or delivering only the necessary dose for the volume to be treated in radiotherapy; these require adequate justification and optimization, both instruments within the expertise and responsibility of the practitioner.

Furthermore, the exposure has a consensual character. The patient, or his/her legal representative, should participate in the decision to take the procedure, based on the informed consent regarding the risk, the benefit, and the alternatives to the proposed procedure. Thus, justification is the process through which the referent physician decides, for each individual patient, whether the necessary information for making the diagnostic is not already available, the proposed examination is the most adequate procedure to elicit the necessary clinical information, there are no alternative procedures, and the dose for the proposed examination is within a favourable risk/benefit balance for the patient, or for the society.

The patient should receive information regarding all these issues, while the given circumstances include difficulties in understanding the detriment associated to the dose, the small numbers of personnel, and the emphasis on the bureaucratic aspects of the medical act, that consume most of the effective working time of the medical staff. On the other hand, the ultimate, fundamental role in making the decision, is attributed to the radiologist, who should ensure that: the probability of unnecessary, excessive, or inadequate exposure is minimized; the procedure is the best choice for the individual patient, and the dose is as low as reasonably possible; the patient is correctly informed on the procedure and the risk associated to the particular exposure. Sometimes, however, in the context of the same personnel shortage, or of the telemedicine, the exposure

itself is given not by the radiologist, but by medical personnel to whom the task of performing the procedure is delegated, but not also the requirement to have the knowledge necessary in order to correctly and completely inform the patient.

Most often, as a consequence of the significant information asymmetry, and of the paternalist physician-patient relationship, in the context of the complexity of the procedures involving ionizing radiation, and of the risk associated, the core role in reducing unjustified exposures is attributed to the medical staff, who are responsible for the justification and optimization of the procedure, and for informing the patient.

The effects of exposure to ionizing radiation

In the ICRP 60 publication (ICRP, 1991) (14), the International Commission on Radiological Protection, the main international scientific board in radiological protection has classified the effects of ionizing radiation into two broad categories: deterministic effects, which result in tissue reaction; and stochastic effects, namely the radioinduced cancer, and hereditary diseases. According to the latest publication, ICRP 103 (15), the Commission proposes, based on epidemiological studies, some of them over more than 40 years study period, risk coefficients for cancer of 5.5×10^{-2} Sv⁻¹ for the overall population, and of 4.1×10^{-2} Sv⁻¹ for the active population, used as reference in risk computation by most of the national professional associations.(16) Thus, the excess lifetime risk attributed to radiation exposure range from 1:1,000,000 attributed to a single thoracic radiography, to 1:1,000 for a young girl subject to a thoracic CT scan (17), with variations depending on location, type of examination, and patient characteristics. According to the EU Guidelines 136 (18), the risk associated to dental radiological examinations, for example, varies as follows: for an intra-oral radiography, with an average dose of 0.001-0.1mSv, the cancer risk is 0.2-0.6: 1,000,000; for a panoramic radiography, the risk increases to 0.21: 1,000 000; risk within the range of 18 -88:1,000,000 for a lower jaw CT scan; and 8-242/1,000,000 for an upper jaw CT scan. Another way to express risks associated to medical exposure to ionizing radiation is proposed by the Clinical Guidelines for Radiological Examinations (19), adopted in the European Union in year 2000: it attributes to the dose from medical exposure an equivalent in time intervals of natural, unavoidable, exposure. Thus, while a thoracic radiography has the equivalent of 3 days natural exposure, an abdominal or pelvic radiography has the equivalent of 6-8 months of natural exposure, a cranial CT scan gives an excess equivalent to 1 year natural exposure, and an abdominal or pelvic CT scan equal between 3.6 and 4.5 years of natural exposure.

Patients' perception

Patients' perception, their interest for the new diagnostic means, as a determinant of patients' satisfaction with the quality of the medical act, becomes a stress factor for the practitioner. Such arguments are brought by the latest EHCI report (Euro Health Consumer Index, 2009) (20), which, in 2011, reported Romania on the last place in Europe from the patients' point of view; the list of 6 basic indicators includes waiting time, immediate access to a general practitioner and to a specialist physician, along with cancer therapy, access to surgical interventions, and access to a CT scan examination. The fact that Romania is placed, according to this study, in the medium accessibility class, with an average waiting time of less than 21 days, should raise questions both to the practitioners, and to the public health decision makers, who should place more emphasis on information regarding the risk associated to this type of examinations.

Moreover, confusion and incomplete knowledge on the indications and periodicity of mammographic examinations,

the efforts of the authorities to implement population based screening programmes for early breast cancer diagnosis, particularly the very appealing commercial offers, lead the women to repeated examinations in the absence of clinical indications, or even when they are not part of the target population for this type of examination.

A particular situation was brought to attention by the colleagues from other countries during the latest technical meeting on justification in medical imaging: among the internet offers for low-cost products or services there were also offers for prophylactic segmental CT scan examinations. This brings again into attention the conflict between the commercial interest of the investors who bought the radiological equipment and aim to quick reimbursement of their investment, and the deontology of the practitioner involved in the procedure.

Development of legal framework

In order to regulate the actual use of the principles and mechanisms of radiological protection as part of the Community Acquis for public health, a complex regulation body of the Ministry of Health is in place, to ensure translation and implementation of the Directive for medical exposure, which should ensure justification, optimization, and dose control. Thus, the joint Order of the MoH and NCCNA 285/2002 (21) adopted in 2002, translates the Directive and sets important hallmarks for the responsibility in justification and optimization of radiation exposure. This Order includes the provision “all individual medical exposures should be justified according to the specific objectives of the exposure, and the characteristics of the person involved”, the procedure being overruled in absence of justification. The responsibility lies “Both the referent physician, and the practitioner must be involved in the justifying process at the corresponding level, as provided by the area of expertise established by the Ministry of Health” and “Any exposure specified in art. 1 par. 2 is given under the medical responsibility of a practitioner, as provided by the regulations of the MoH”, a shared responsibility, without clear roles and responsibilities, implying further clarifications in order to make justification responsibility obvious.

Radioprotection dilemmas that might be solved by the regulatory roles and duties of public health. Public Health responsibilities tended to be implemented by the Order of the Ministry of Health no. 1334/2004 (22), providing the establishment of specific regulations at hospital level, in order to ensure: a) “clear definition of the expertise and responsibility of the prescribing physician, and of the practitioner; b) justification of medical exposure for the persons who knowingly, and willingly, offer to assist during the medical exposure of other persons; c) written protocols and standardized techniques for each radiological practice, including criteria for patient selection according to their individual characteristics, the possibilities and limits of the radiological procedures, and the availability of alternative procedures not involving ionizing radiation”. Normative act that has produced limited effects and than was forgotten in the useless legislation archive. Consequently, a series of other four regulation acts have been adopted in 2005, setting the coordinates for the medico-legal examinations (23), examination of children (24), pregnant women (25), and recording patient doses.(26) These four latter regulations finally clarify the responsibilities: “The prescribing physician must present the practitioner in writing all information pertaining to the justification of the required examination. The prescribing physician should notify the purpose and the motivation of the exposure, the particular clinical elements of the required examination, and other prior medical exposures”, while “The final decision for the radiological examination of a child belongs with the practitioner (the radiologist); in order to decide on the

most adequate procedure, a consultative relationship between the prescribing physician and the practitioner is essential”. The first practical guide was also published in 2005, adopted by the Romanian Imaging Society. This guide was adopted by Order of the Ministry of Health (27), thus becoming obligatory. However, as provided by the Order, this is a “Guidelines for medical practice in radiology-medical imaging and nuclear medicine”, included in the Annex “Guidelines for the use of radiological examinations and medical imaging”, to be observed by the “Specific Directorates of the Ministry of Health, the district Public Health Directorates, the members of the specialty boards of the Ministry of Health, the public and private medical facilities, and the medical personnel involved in providing health services in the mentioned specialties”, i.e. the public health, and medical imaging specialists, and not the prescribing physicians. Moreover, according to the legal framework approved by the NCCNA, in order to exercise their profession, the radiologists are required to be examined every 5 years; the legal provisions applicable to radiological practice are an important part of the curriculum for the training.

Coordinates of radiological protection

For an evaluation of the cumulative impact of all these factors on patients’ radiological protection, we can refer to a recent study carried out at the NIPH (28) on the knowledge, attitudes and practices of the specialists in radiological procedures. This study confirms very good knowledge of the legal responsibilities on optimization of the exposure, recording of information regarding exposure, and issuing the individual record of the magnitude of exposure; but the results were not so good with regard to knowledge of the most important provision, namely that the ultimate decision on performing or not performing a radiological examination in the absence of a prescription from the prescribing physician is the fundamental role of the radiologist. The study revealed high rates of correct answers for questions regarding radiological protection, including information on the risk and benefit of radiological examinations, posting warnings for pregnant women, obtaining the written consent, and issuing and requiring the patients’ dose records. The practice, as well as the knowledge, seems hesitant with regard to performing an examination they think is not fully justified (50% of the responses confirm that refusing an unjustified procedure is a rare/very rare event), or refusing examinations in the absence of a prescription, merely on patient demand.

With regard to the practitioners’ attitude, the agreement on the usefulness of the guidelines for use of the radiological examinations as well as of the written protocols and the radiological protection training courses, are worth mentioning. The practitioners tend to be less satisfied with the aspects regarding recording and reporting patients’ doses, and the clarity of the existing regulations.

Questions, ethical dilemmas and potential solutions facing the Public Health specialists

Concluding all the above discussions, it is obvious a moral duty for the public health specialists to initiate measures to improve radiological protection. In principle, these measures should comply with the following requests: address all types of specialists involved in radiological procedures, depending on their type and level of responsibility, from the manager of the medical facility, the prescribing physician, and the radiologists, to the nurses and technicians; ensure the adequate information of patient in order to obtain real, active implication in exposure decision making; ensure a minimum radiation protection module, and a systematic and consistent training framework for all practitioners, prescribing physicians, and nurses; ensure availability of the results and doses of prior examinations

undertaken by the patients; develop materials and ensure active information for the general population, not only for patients; ensure consistency, and especially availability of the regulations; periodically verify that the legal provisions are enforced; regulate the procedure and provide for the obligatory character of the clinical audit in radiological procedures; ensure availability, visibility, and information regarding the European and international guidelines.

A sum of measures that might have two implementation alternatives: one specific to the autocratic coordination, with a new Order of the Ministry to be added to the existing provisions; or, to appeal to the specialists' deontology, while verifying the implementation of the Order 1334/2002, and propose the clinical audit as a measure to assist and persuade the specialists.

Apparently to many duties comparing to the existing human, funding or authority available resources, but they should be honoured by the public health specialists.

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