

Public health aspects in medico-legal imaging

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Abstract: In the context of extensive use of ionising radiation procedures for diagnostic and treatment, medical exposures are becoming one of the main source of radiation exposure. The medico legal exposures, or forensic radiology, application list is also expanding. But, this special category of ionising radiation procedures are raising complex and rather difficult issues in terms of appropriateness, justification, legal framing and uniform practice, issues that classify the medico-legal examinations among emerging public health problem. The paper in a descriptive approach is reviewing the current status, dynamics and characteristics of medico-legal exposures, legal international and european framework in the context of national available information and regulatory framework dynamics.

Key Words: Ionizing radiation exposures, medico-legal practices, legal aspects.

All the new internationally radiation protection documents developed during the last few years, starting with the ICRP in their 2007 document ICRP 103 [1], have stated that "certain exposures should be deemed to be unjustified without further analysis, unless there are exceptional circumstances". These include of course self referred exams or inadequate medical examinations but also most of the medico-legal examinations undertaken without reference to clinical indications, unless the examination is expected to provide useful information on the health of the individual examined or in support of important criminal investigations, and according to justification principles for new practices.

METHODOLOGY

The study is a descriptive approach based on review of the existing literature and legislation applicable to medico-legal ionising radiation procedures at international and national level. Information on effective dose of medical exposures is based on the National

Institute of Public Health survey on medical exposures and associated doses.

Current status on ionising radiation procedures dynamics, effects and related awareness

Words as radiography, radioscopy, computed tomography, radiotherapy, due to their proved importance in the medical diagnostic, screening and therapy, are becoming common words of the contemporary lexicon. They reflect the common practice of the 3,6 billion of medical examination performed yearly in the world [2].

Despite the indubitable contribution to appropriateness, adequacy and quality of the medical act, medical exposures become now the dominant source of the human dose from manmade radiation, bringing globally an additional annual per capita effective dose of 0.64 mSv and, in some developed country as US, with 3 mSv/year even an exceeding dose even to the that one due to natural background exposure [3]. Unfortunately, several health related effects, the most important being the cancer risk, have to be considered always when speaking about the ionising radiation procedures.

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According to the same ICRP 103, based on long term epidemiological studies the relationship between lifetime attributable cancer risk and radiation dose, has nominal probability coefficients for corrected cancer risk of 5.5×10^{-2} detriment Sv^{-1} for the entire population, in common words, meaning an increase from 1:1,000,000 additional cancers for a chest radiography to 1:1,000 for a CT performed to a young girl [4].

About the knowledge and understanding of those dose related effects according to recent studies [5], the associated population health literacy reveals that only about 3% of the patients believed that their lifetime risk for cancer was increased as a result of a CT scan, and, surprisingly, the medical specialist knowledge and awareness on dose effect relationship are scattered, studies among British physicians [6] showing a tendency to severely underestimate radiation doses for 56% of respondents. Figures confirmed by another recent study [7] where radiologists estimated that a CT scan dose is equivalent to 10 chest radiography, when the true value is the that it brings the dose of about 500 chest radiography. Similar percents, over 50% were obtained for the radiology staff, according to the NIPH study on radiology staff knowledge, attitudes and practices, performed in 2011[8].

In this context, and on the background of latest ionising radiation techniques development, it is fairly probable to assist to a further rising in ionising radiation use, from the beneficial use in medical imaging to all kind of scanners from non medical purposes or to other unjustified unbeneficial, frivolous or dangerous uses in ionising radiation. A review of existing regulatory framework and practice in order to identify further radioprotection instruments is in this context necessary.

Medico legal exposueres related issues

Based on the technological development of the last years the spectrum of medico-legal exposures was extended far beyond the initial X-rays exposures "for insurance purposes or within legal procedures" as initially defined by international documents [9], to a broad range of applications including forensic radiology applications [10,11] to security scanners performed by non medical personnel. Addressed by several international workshops, starting since 1998, the latest in 2009 [12], the issue of medico-legal variability of practices still is a topic of interest for the radiation protection and related public health effects. According to the results of the latest surveys performed in EU countries the list of the main medico legal procedures and their specific features and related issues could be summarized as following.

Medico-legal exposure regulatory framework

In order to improve the risk benefit ratio in ionising radiation procedures a system of radiation protection, based on the recommendations of the International Commission for Radiation Protection (ICRP), the latest updated being the 103 ICRP publication

(ICRP 2007) is currently used across Europe and worldwide. The system is centered on three fundamental principles: justification, optimization and dose limitation. Based on ICRP recommendations IAEA adopted the International Basic Safety Standards (IBSS) the main document on radiation protection at international level, updated in 2011 [13], in close collaboration with with FAO, ILO, the NEA/OECD, PAHO and WHO. In the European Union, the radiation protection legislation relating to ionising radiation, applying the health and safety requirements, set up by articles 30 and to 39 in the Euratom Treaty, are represented by two European Directives: Council Directive 96/29/EURATOM [14], the Basic Safety Standards (BSS) and the Medical Exposure Directive 97/43/EURATOM (MED) [15]. The BSS Directive, based also the principles of justification, optimization and dose limitation, is a general frame for all regulatory aspects related to general public and occupationally exposed workers. The Medical Exposure Directive (MED) is the main legal instrument dealing with the protection of patients undergoing diagnostic and therapeutic procedures which utilize ionising radiation.

The principles of justification and optimization, aiming at eliminating unnecessary or excessive medical exposures are applied both to patients but also to other individuals exposed either in occupational health, health screening, research and medico-legal procedures. The MED defines medico-legal procedures as "procedures performed for insurance or legal purposes without a medical indication", and starting from that definition as a sub-set of medical exposures, it is required that they should comply to radiation protection principles. The non medical exposures, by the other hand should comply with Directive 96/29/Euratom, that lays down basic safety standards for the protection of the workers and of the members of the public; setting dose limits for anthropic ionising radiation exposure of 1mSv/year. Based on that figures dose constraints for non medical exposures have been set up by the members of the public about 0.2-0.3 mSv per year in a single occasion.

The national legislative framework for radiological protection, in line with the public health Community aquis, is represented by the joint Order of the MoH and NCCNA 285/2002 [16] transposing nationally the Directive for medical exposure which requires implementation of radioprotection principles for all medical exposures, including "the exposure of individuals as part of medico-legal procedures". It requires that "special attention shall be given to the justification of those medical exposures where there is no direct health benefit for the person undergoing the exposure and especially for those exposures on medico-legal grounds". Special attention that was proved by issuing a ministerial order for approval of the regulations specific to medical exposure of individuals to ionising radiation when medico-legal examination [17].

Table 1. Medical and non medical exposures types and characteristics

Type and characteristics of exposure	Type of procedure	Content and purpose of procedure	Issues of concern
Non medical exposures			
Performed by non-medical personnel. Consent not necessary. Uses specialized inspection equipment. Images interpreted by a non medical person. Only the new practice should be justified. Benefit for the society: No benefit for the individual exposed. Dose not recorded Public dose limit applied	Security screening	Current X-ray scanning techniques in ports, airports, prisons, governmental institutions , etc.	- Typical doses per scan is <math><0.1 \mu\text{Sv}</math> but frequency may be higher - Doses for frequent traveler - Personnel not always -trained in radiation protection - Harmonization of practice and regulatory aspects
	Prisoners and visitors security screening	Diagnostic to detect swallowed objects	- Concern related to doses and exposures in repeated exposures
	Vehicle inspections	Search on truck or container to discover hidden content	-Typical doses about $10 \mu\text{Sv}$ -No concerns for scanning of goods -Concerns for hidden person exposures
Medical exposures			
Performed by medical personnel (custom offices, social workers). Confidentially ensured medically justified. Informed consent necessary usually beneficial for the individual exposed. Dose recorded DRL limit Special norms required	Civil litigation	Diagnostics to find presence or absence of injuries or diseases to be used as evidences in court	-Based on justice order -Justification by the practitioner possible -Concerns related to consent and dose
	Drugs detection	Search in or on the body for swallowed drugs	- Radiography or CT techniques -Referral criteria for selection of individuals should be developed
	Insurance	Diagnostic of latent diseases in the purpose of risk assessment for insurance risk assessment	-No individual benefit, non ethical exposures
	Age assessment	Assessment of age especially for immigrants, refugees, adoption, usually young persons	-Both dental and skeletal examinations are performed -Concerns related to doses for young persons
	Suspicion of child abuse	Diagnostic of old, hidden fractures or bleedings	-The dose may exceed the public dose limit -In well documented cases the benefit is higher than the risk
	Sportsmen	Regular preventive diagnostic of the health status, health status evaluation in connection with transfers, diagnostic of growth for specific sports (basket, dancers)	-Justified imaging for acute injuries or for supporting decisions related to training or nutrition of athletes -Concerns related to repeated imaging for screening purposes
	Immigration or emigration	Diagnostic of hidden diseases in migrants, e.g. for tuberculosis	-No individual benefit, careful justification for selection of best procedure
	Pre-employment procedures	Diagnostics to find hidden, latent diseases, to protect the employer for miss-buying, or for protecting school children for infections	- No individual benefit, - Concerns related to doses and exposures in repeated exposures
	Determination of identity	Identification of dead persons	-Based on comparison between postmortem antemortem characteristics from dental records, fracturi

Source : adapted by Leitz, W, Marshal Depommier E., RP 130⁵

It clarifies the following issues:

Medico-legal radiological procedures are considered all medical exposures to ionising radiation performed for medico-legal expertise or of insurers request, with or without clear medical indication.

- All medico-legal radiological procedures are individually justified by a written request on an referral.
- Any medical exposure to ionising radiation performed at insurers request without clinical indication is considered unjustified.
- Examination without justification is permitted for specific situation as: suspicion of theft and trafficking of drugs and weapons, for which the net benefit to the exposed person is not relevant.
- Whatever the type of request the responsibility of final decision on the examination goes to the radiologist.
- Establish specific situation when a request for a new examination is required procedure.
- In all justified procedures optimization should be ensured.

Exposures for medico-legal procedures

Based on current national legislation the number

Type of radiography examination	National Average Effective Doses (mSv)	Hospital A (specific medico-legal facility)- Average Effective Doses (mSv)
Head	0.14 ± 0.04	0.26 ± 0.14
Thorax	0.34 ± 0.09	1.04 ± 0.58
Abdomen	0.57 ± 0.15	1.55 ± 0.87
Pelvis & hip	0.51 ± 0.14	3.04 ± 1.71
Cervical Spine	0.17 ± 0.05	1.37 ± 0.76
Lumbar Spine	1.55 ± 0.17	0.71 ± 0.39
Extremities	0.03 ± 0.01	0.31 ± 0.17

of radiological medico-legal exposure is not currently recorded. In order to have an image of the characteristics of doses in medico-legal exposures procedures we compared the doses for the medical examination performed by a specialized medico-legal unit with national average doses per procedure.

A descriptive approach of the dose characteristics reveals that most of the doses (except lumbar spine and head) are higher than the national averages. For several examinations, some of them for radiosensitive organs as abdomen, pelvis and hip, the mean effective doses are almost 5 times higher than the mean effective doses evaluated from national survey. How many of those were medically justified, how many were accompanied by a real consent, how many were repeated, and about the recording of individual doses, those are questions without a systematic answer in the present national legal framework.

The scarcity of available information did not

allow drawing any conclusion: if those doses are simply associated with high doses investigation or if there are some specific litigation procedures. By the other hand, in the national context according to the National Institute of Public Health 2012 Report, the radiological consumption raised for the year 2011 at 8,000,000 radiographs and 750,000 CT scans (mean dose for a CT scan is about 500 times than a pulmonary radiography), of those, some might be related to medico-legal exposure, meaning an important additional risk for individual and public health.

New standards and legislative framework developments

In the new BSS proposal [18], now in the process of technical consultation, the European Commission in close cooperation with the IAEA and other international organisations propose the revision of the Basic Safety Standards Directive and integration of the other four Directives, including the medical exposure directive, trying to ensure the coherence with the international standards, complying in the same time with the to EU legal rules and Euratom Treaty mandate. According to this new proposal a different approach to medico-legal exposures was developed. It propose a new definition of practices involving the deliberate exposure of human for non-medical purposes, giving a special attention to the justification of practices involving non-medical imaging exposure, that should ensure that all types of practices involving non-medical imaging exposure, shall be justified in advance before being generally accepted; each particular application of a generally accepted type of practice shall be justified in advance; all individual non-medical imaging exposure procedures implemented by medical staff using medical radiological equipment shall be justified in advance taking into account the specific objectives of the procedure and the characteristics of the individual involved; the general and particular justification of practices involving non-medical imaging exposure, shall be subject to periodic review by the competent authority

The new International Basic Safety Standards proposed by the EU define two categories of practices involving non-medical exposure: procedures implemented by medical staff using medical radiological equipment and procedures implemented by non-medical staff using non-medical equipment

In the first category are included the medico-legal exposures that take place in a medical radiation facility where is used a medical radiological equipment, performed by radiological personnel. The purposes of non-medical human exposure are the obtaining of legal evidence, the radiological health assessment for insurance purposes, for immigration purposes, for employment purposes and also the radiological age assessment or physiological suitability or status assessment. A special purpose is represented by the use of ionising radiation for the identification of concealed objects within the human

body. Other purposes of non-medical human exposure are the radiological health assessment for other purposes not intended to benefit the health and well-being of the exposed individual and the radiological evaluation of the physical development of children and adolescents with a view to a career in sports, dancing.

In the second category concerning the procedures implemented by non-medical staff using non-medical equipment are included practices involving the use of ionising radiation for legal or security purposes such as the use of ionising radiation for detection of concealed objects on or attached to the human body and also for detection of concealed humans as part of cargo screening. For procedures implemented by medical staff using medical radiological equipment are established the same radiation protection requirements, including those for equipment, optimization, responsibilities and special protection during pregnancy, for exposed persons as if they were patients undergoing a medical exposure, with the exception that specific dose constraint take the place of diagnostic reference level and the dose constraint may be lower than diagnostic reference level.

An important aspect specified in the new BSS is the informed consent of the individual to be exposed is sought, allowing for cases where the law enforcement bodies may proceed without consent according to national legislation.

DISCUSSIONS AND CONCLUSIONS

Difficult decisional roles, both for radiologists and public health practitioner, of balancing between individual and public interest in the condition of the concrete demand of the situation and the existing regulatory context.

Another issue of concern is the lack of information on existing practices and also the weak regulatory framework on institutional responsibilities for information gathering.

Therefore in the future, in the framework of the new framework Directive on BSS that will be adopted at Eu level in order to support the public health measures for preventing overuse of radiation exposures during medico-legal examination several measures should be taken in consideration as following:

- Fostering the collaboration and coordination among the national regulatory body, the public health authority, radiologist and their professional associations and medico legal expert.

- Designation of competent authorities` roles and in authorizing non medical procedures and their role in monitoring of exposures and public information.

- * Updating the legislative framework regulating the medico-legal exposures procedures establishing: clear definition of type exposures incident to that category; justification responsibilities clarification; clarification of the roles of each specialist in: decision, performing the exam, reading the result; clarification of training and licencing procedures for medical personnel or other staff involved in exposures by type of procedures for medical/nonmedical; criteria for authorization of practices; specific provision related to radio sensible persons children, pregnant women; clear requirements related to separate reporting of medico-legal exposures and dose assement; obligation for procedures quality ensurance; information mechanisms for non-medical exposures; clear provisions when written consent is necessary; procedure for radiology medico-legal experts designation.

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