Journal of Medical Imaging

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Hannu Järvinen, Jenia Vassileva, Ehsan Samei, Anthony Wallace, Eliseo Vano, Madan Rehani, "Patient dose monitoring and the use of diagnostic reference levels for the optimization of protection in medical imaging: current status and challenges worldwide," *J. Med. Imag.* **4**(3), 031214 (2017), doi: 10.1117/1.JMI.4.3.031214.

Patient dose monitoring and the use of diagnostic reference levels for the optimization of protection in medical imaging: current status and challenges worldwide

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Abstract. Optimization is one of the key concepts of radiation protection in medical imaging. In practice, it involves compromising between the image quality and dose to the patient; the dose should not be higher than necessary to achieve an image quality (or diagnostic information) needed for the clinical task. Monitoring patient dose is a key requirement toward optimization. The concept of diagnostic reference level (DRL) was introduced by the International Commission on Radiological Protection as a practical tool for optimization. Unfortunately, this concept has not been applied consistently worldwide. To review the current strengths and weaknesses worldwide and to promote improvements, the International Atomic Energy Agency organized a Technical Meeting on patient dose monitoring and the use of DRLs on May 2016. This paper reports a summary of the findings and conclusions from the meeting. The strengths and weaknesses were generally different in less-developed countries compared with developed countries. Possible improvements were suggested in six areas: human resources and responsibilities, training, safety and quality culture, regulations, funding, and tools and methods. An overall conclusion was that radiation protection requires a patient-centric approach and a transfer from purely reactive to increasingly proactive optimization, whereby the best outcome is expected from good teamwork. [DOI: 10.1117/1.JMI.4.3.031214]

Keywords: medical imaging; optimization; patient dose monitoring; diagnostic reference levels.

Paper 17096SSR received Apr. 12, 2017; accepted for publication Sep. 26, 2017; published online Oct. 4, 2017.

1 Introduction

Optimization is one of the three main concepts of radiation protection. In medical imaging, this means a compromise between the image quality (or diagnostic information) and dose to the patient; the dose should not be higher than what is necessary to achieve an image quality (or diagnostic information) needed for the clinical task. This principle demonstrates that knowing and monitoring patient dose is of key importance for optimization. The general principle of keeping the associated doses commensurate with the medical purpose, introduced by the International Commission on Radiological Protection (ICRP),[1] is the fundamental concept for optimization whereas the concept of the diagnostic reference level (DRL), based on measurable quantities and again introduced by the ICRP,[1–3] provides a practical tool for promoting and implementing optimization. The importance of optimization and the use of DRLs have increased with the worldwide increase of high-dose examinations and procedures. The requirement for establishing and using DRLs in diagnostic and interventional radiology has been introduced in the International Basic Safety Standards (BSS).[4] The International Atomic Energy Agency (IAEA) has been supporting member states in their efforts to implement patient dosimetry, set DRLs, and use them for optimization.[5–14] Unfortunately, the concept of DRL has not been applied worldwide in an optimum way. Further, fast development of technologies may drastically change the patient dose level—either increase or decrease—and this has an impact on DRLs and their use. The ICRP is soon to publish a comprehensive set of guidelines for DRLs.[15] The European Commission (EC) will soon publish specific guidelines for the establishment of pediatric DRLs.[16] This paper reports the summary of the findings and conclusions of a Technical Meeting on patient dose monitoring and the use of DRLs for the optimization of protection of the patient in medical imaging, organized by the IAEA on May 30 to June 3, 2016. The governments of all IAEA member states were invited to nominate their representatives for the meeting. More than 60 experts from 35 different countries and 11 international organizations and professional bodies participated. A list of participating countries that provided presentations at the meeting is shown in Table 1. A list of participating international organizations and professional bodies is shown in Table 2. The focus of

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Table 1 Participating countries grouped as less-developed or developed. Only countries which had a presentation in the technical meeting are included.

Less-developed countries (developing economies and newly industrialized countries)	Developed countries
Albania	Australia
Algeria	Finland
Armenia	France
Brazil	Germany
Egypt	Greece
India	Italy
Indonesia	Lithuania
Kenya	Netherlands
Malaysia	Singapore
Moldova	Slovenia
Romania	Spain
Russia	Sweden
Ukraine	UK
United Arab Emirates	USA

the meeting was twofold: first, to understand the current situation, present strengths and weaknesses in setting and using DRLs for optimization of patient safety and improving imaging practice, and second, to discuss and collect viewpoints on possible solutions and actions to improve the situation. In addition to this review of the meeting outcome, a more extensive set of recommendations on patient-centric strategy were developed in the summit along the lines of the meeting conclusions, which is captured in a companion publication.[17]

2 Current Status, Strengths, and Weaknesses

The current status, the strengths, and weaknesses were generally different in less-developed countries compared to developed counties. Therefore, the following review treats the two situations separately. For the classification of countries as less-developed countries, the following criteria were applied: developing economies and newly industrialized countries.[18] The grouping of countries is shown in Table 1.

It should be noted that the observations below are based on the given presentations and discussions at the meeting and not on a comprehensive questionnaire to all countries involved and, therefore, the results might not be exhaustive and must be considered with caution. For example, an observation for one country is reported because it was represented at the meeting but a similar observation may be possible for another country (while not reported at the meeting).

2.1 *Less-Developed Countries*

Fourteen countries were considered in the category of less-developed country (Table 1). While each of these countries has taken some actions to survey patient doses or to establish local DRLs, seven have not established national DRLs. In a few countries, no nationwide patient dose surveys had been carried out.

In this group of countries, some (e.g., Indonesia, Malaysia, and Ukraine) have set up regulations for setting and using DRLs. In Indonesia, regulatory authorities have taken actions for patient dose surveys and in Malaysia support at Ministry level was provided. The use of DRLs has been promoted by a special steering committee and champion system in Egypt. In several countries, extensive patient dose surveys have been conducted but still not representative enough to set DRLs (e.g., Algeria, Armenia, and Brazil). The positive impact of DRLs was demonstrated by successful dose reductions in radiography in Kenya. Networking and international cooperation organized by the IAEA were considered to provide effective support.

Overall there appeared to be three different successful approaches: National actions (e.g., in Algeria, Armenia, Indonesia, Malaysia, and Romania), efforts at the level of local institutions (e.g., in Brazil, India, Kenya, and Russia), and efforts by individuals with high motivation (e.g., in Egypt, India, Kenya, Moldova, and United Arab Emirates). However, the acknowledgment of these approaches at country level is somewhat arbitrary, and in many cases, the success can be due to their combination.

Major problems in less-developed countries seem to stem from the lack of appropriate infrastructure and funding, regulations, staff [in particular medical physicists (MPs)], awareness of radiation protection, and lack of training in radiation protection and technical resources. In some countries, patient dose recording is not mandatory, providing no legal basis for patient dose collection and DRL development. Lack of technical resources include out-dated equipment, lack of dosimetric equipment, and lack of convenient data handling resources, such as picture archiving and communication system (PACS) and dose management systems, contributing to insufficient data validation. Participants from India considered the development of DRLs for interventional radiology to be particularly problematic. It was also difficult to see good examples of professional societies making successful contributions to the development of DRLs.

Table 2 Participating professional societies and international organizations.

Professional societies	International Organization for Medical Physics (IOMP) International Society of Radiology (ISR) American College of Radiology (ACR) American Association of Physicists in Medicine (AAPM) European Society of Radiology (ESR) European Association of Nuclear Medicine (EANM) European Federation of Organizations for Medical Physics (EFOMP)
International organizations	World Health Organization (WHO) United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) International Commission on Radiological Protection (ICRP) Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA)

Major challenges included the extension of some good hospital-based actions beyond the facility to other parts of the country and ultimately to national programs. The support of the IAEA had been invaluable but also created a challenge on how to continue without this support. Recognition of DRL programs as an ongoing quality improvement program is considered a key requirement for progress.

2.2 *Developed Countries*

Fourteen of the participating countries (Table 1) were noted as having a high level of resources for patient dose management. They were found to have both national and local DRLs based on extensive patient dose surveys and being in the process of establishing new and updated DRLs.

The establishment of DRLs was typically carried out by authorities, supported by regulations with explicit legal demands for DRLs, and by good cooperation between authorities and professional societies or clinical and medical physics experts. This cooperation included periodic stakeholder reviews and providing mutual feedback or consultations with the hospitals and clinical experts, or establishing specific joint committees or working groups to conduct patient dose surveys (in Australia, Finland, Italy, and UK). There were generally well-organized patient dose surveys with good coverage of health care units and facilities, good data analysis, and good coverage of national DRLs for different types of examinations. Electronic systems of dose monitoring were already providing useful data in some of these countries, for example, in Lithuania a national electronic health record system was used and Slovenia reported on the introduction of online dose tracking and comparison with DRLs as part of the quality assurance. Data validation by MPs was stressed (in Australia and Italy), and the role of dose management systems was promoted by research efforts (in Germany and Finland).

The existence or development of national patient dose or dose index registers was reported in at least four countries: a remarkable national Dose Index Registry developed in the USA, national databases for patient doses in the UK and France, and a new versatile web-based "reference dose" register developed in Sweden. All these registries are patient deidentified, i.e., the data are collected anonymously without patient ID. The US Dose Index Registry with automatic collection of data was reported to be less resource demanding, enabling the management of a very large volume of data. These registries are used to produce national summaries of data with associated trend analysis and to provide feedback to the clinical facilities. The analysis of trends (in Finland, France, and UK) was reported to be particularly important considering establishing DRLs as a dynamic process, and the trends in the DRLs often reflect the trends in the development of imaging equipment and practices (e.g., the introduction of iterative reconstruction in CT examinations or other imaging postprocessing software). Appropriate use of DRLs can thus promote optimization by providing timely evidence supporting the need for developing the imaging practice or upgrading imaging equipment.

Unique dose monitoring advances in some of these countries included ensuring the proper use of DRLs by regulatory inspections and addressing image quality in clinical audits (e.g., in Finland), proposing DRLs for positron emission tomography (PET) examinations (in Australia), establishing pediatric DRLs in a form of DRL curve (in Finland), introducing achievable dose levels (in Finland and The Netherlands) and dose monitoring online, and setting skin dose alert levels in cardiac and interventional radiology procedures (in Spain).

A major problem reported in the developed countries seemed to be the lack of sufficient patient dose data to cover all the needs; in particular, the small number of patient dose data in pediatric examinations, typically in nonspecialized facilities (reported in Australia, Finland, France, Germany, The Netherlands, and UK). Introducing DRLs in interventional radiology procedures, including cardiology procedures, was reported to need much more work (in Finland and The Netherlands). The effectiveness of patient dose collection was reported to be highly dependent on the availability of automatic data collection systems; while there were strong efforts to establish automatic data collection based on the utilization of digital imaging and communications in medicine header information and radiation dose structured reports (RDSR), the main approaches to patient dose data collection are still largely semiautomatic.

3 Contributions of Professional Societies and International Organizations

A list of participating professional societies and international organizations is shown in Table 2.

All professional societies have some specific strategies or actions toward improving optimization of protection in medical imaging. For example, International Organization for Medical Physics (IOMP) cooperates with international organizations in establishing standards and requirements of medical physics workforce, the International Society of Radiology (ISR) advocates a patient-centric approach for radiation protection, the American College of Radiology (ACR) has introduced ACR Dose Index Registry, and its Image Gently and Image Wisely campaigns have increased global awareness on radiation protection, the American Association of Physicists in Medicine (AAPM) provides comprehensive guidelines and training in medical physics, the European Society of Radiology (ESR) runs the EUROSAFE program to implement the European perspective on the Bonn Call for Action, the European Association of Nuclear Medicine (EANM) has a long tradition in providing procedural guidelines, such as the pediatric dosage card, and the European Federation of Organizations for Medical Physics (EFOMP) provides advanced training and substantial professional collective expertise in radiation protection. As for international organizations, the World Health Organization (WHO) has introduced a global initiative and collaboration for radiation protection in medicine, to enhance the Bonn Call for Action and support the implementation of the IAEA BSS, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) provides global estimates of collective effective dose to the population, including the medical use of radiation, with analysis of trends, staffing etc., the ICRP provides recommendations and guidelines that are widely accepted by most countries, and the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA) supports continuous development of electronic data recording and transfer.

4 Possible Solutions and Actions Needed

Based on the analysis of weaknesses and challenges, the meeting identified six main points to consider (Table 3) and then proposed several possible solutions and actions to solve the problems and improve the situation. A brief summary of the

Table 3 Main system components requiring development to improve outcomes for patient dose monitoring and the use of DRLs for optimization.

Main point	Possible solutions
Human resources and responsibilities	Increase the number and recognition of MPs; raise the awareness, motivation, and responsibilities of the principal professionals using a graded approach.
Training	Improve basic and continuous training in radiation protection, in particular targeted training adapted to the role of each professional group. Make quick reference guides. Ensure proper mentoring and oversight.
Safety and quality culture	Encourage and enhance accountability, awareness, motivation, both at leadership level and among all professionals. Emphasize team work.
Regulations	DRL, quality assurance, and MPs access should be required by legislation wherever lacking. Advocacy to authorities.
Funding	Increasing resources needs funding. Most work can be done without additional funding but funding can facilitate quality of data collection. Motivate governments for funding
Tools and methods	Provide national program for patient exposure data management, including system of classification and nomenclature of examinations, organization, technology resources, and mechanism. Turn local initiating actions into nationwide programs, improve DRL strategy, including image quality consideration, promote automatic/electronic data collection, upgrade technology, and promote cooperation across countries.

possible solutions has been presented in Table 3 and further discussed below. Most of these solutions and actions are useful whatever the status with the resources is and therefore, no distinction between less-developed and developed countries is warranted.

4.1 *Human Resources and Responsibilities*

In general, the availability of professionals with adequate expertise in radiation protection issues in medical imaging is a key requirement also highlighted in the International BSS,[4] which includes MPs, imaging and nuclear medicine physicians, and radiographers. For MPs, the most fundamental issue is the adequacy of their staffing numbers and their expertise (e.g., per published recommendations[19–22]). In some cases, the availability could be addressed by consultant medical physics services. The MP profession should be legally recognized and, accordingly, medical physics specialization taken into consideration in educational programs at both undergraduate and graduate level. The role and responsibilities of MPs for radiation protection in imaging should be strengthened and clarified, and radiation protection should be a key element in their training programs. Following a graded approach based on training, experience, and certification, other technical staff could carry out specific practical work after the initial acceptance testing and commissioning led by a certified MP.

For imaging and nuclear medicine physicians, this means above all improved training on radiation protection. For radiographers, the basic effort would be to strengthen their motivation and involvement in patient dose monitoring. In practice, radiographers should be the major player in patient dose data collection, and their preparedness for this work and other radiation protection issues should be improved by specialized training. A particular role of the radiographer is to support the radiologist in maintaining effective patient dose vigilance in interventional radiology procedures.

4.2 *Training*

Closely related to the above actions for improved availability of professionals and their responsibilities is a general need to strengthen the training and knowledge in radiation protection for all key professionals. This would best be achieved by targeted training and communication, adapted to the role and responsibilities of each profession. Key issues of training for all practitioners should include (among other things) proper understanding of dose monitoring and the DRL concept as a tool for optimization, with due considerations of dose versus image quality (or diagnostic information), the importance and application of dose reduction technologies, and understanding of benefits versus risks in medical imaging.

The training efforts should be supported by unified radiation protection curricula and by producing or revising training material to cope with the latest knowledge and developments in practical radiation protection. Specialized training material and quick reference guides on the use of DRLs (crib-sheets, possibly provided by the IAEA) could well support the training process. For practical on-site training of the staff, the quick reference guides could be most effective to explain key concepts, for example, the difference between the local median value of patient dose (typical dose) and the local DRL. To secure the knowledge transfer, this should be carried out in a planned, systematic way and be supported by a proper documentation of procedures. Finally, it should be understood that specialized training on the concept of optimization, DRLs, and dose monitoring is needed also for regulatory officers.

4.3 *Safety and Quality Culture*

For the development and promotion of safety and quality cultures, it is crucial to improve government's and leaders' awareness on the importance of radiation protection in medicine. Coordinating actions between authorities should be increased together with the efforts to improve the competence of regulatory authorities. Accountability, awareness, and motivation on radiation protection should be increased on all levels through communication, training, and collaboration. In this dialog, the clinical value of imaging should be emphasized, increasing the awareness of both professionals and the public on the fundamental benefits versus risks of medical imaging. Public communications beyond the medical physics community in an

understandable format, possibly through short videos, could be very helpful to achieve this goal.

The practical path to improvements in this area should rely on a holistic strategy and could include increasing the contribution of professional societies, establishing a leading group (e.g., a professional society) to stimulate actions, better recognition of the value of team work, introducing models of champions (to acknowledge successful efforts in radiation protection), and increased effort in social marketing, persuasion, and encouragement.

The awareness about the importance of radiation protection could be promoted by presentations at national conferences showing examples of good results of optimization, for example, giving evidence on how the use of DRLs has led to procedural improvements (reported in the UK and Finland). The high numbers of reported unjustified examinations should lead to better understanding of the need for justification and considerations of alternative examinations.

4.4 *Regulations*

Legislation should be established to justify the development and improvement of infrastructure for radiation protection and optimization based on the requirements of the International BSS.[4] Patient dosimetry, DRLs, and quality assurance should be made mandatory. Legislation should include enforcement to employ MPs in medical imaging facilities or have access to consultant MPs. Personnel resources for radiation protection and optimization should be increased for both health care facilities and authorities.

4.5 *Funding*

Many of the proposed solutions and actions will not be possible without increased funding to both health care units and authorities. To increase the funding, suitable lobbying and increased public pressure should be applied to governments and health care providers. Particular attention should be focused on the potential of appropriately functioning equipment and dose monitoring to minimize the level of inappropriate or repeat examinations with consequent cost savings. In addition to the major budgetary provisions, creation and use of appropriate focused sources of funds (microfunding) should be promoted.

4.6 *Tools and Methods*

Required tools and methods fall into multiple categories as detailed below.

4.6.1 *National programs*

There is a need to undertake specific national programs to establish and promote the use of DRLs. This should be a systematic and sustainable approach ensuring periodic updating of the DRLs to reflect current clinical practice. It should include adequate standardization or classification and nomenclature of the examinations and procedures, building up suitable organization infrastructure and ensuring sufficient technology resources and mechanisms for patient exposure data management. The mechanism should include improved strategy of using DRLs, integrated informatics, and automated tools for dose collection and reporting, and provisions for efficient data analysis and national dose registries to enable both the setting of DRLs and estimations of collective effective doses to the populations (population dose).

4.6.2 *Classification of examinations*

Classification of patient exposure data requires a mechanism for a harmonized nomenclature for radiological examinations and procedures. Detailed specification is needed to allow meaningful comparison of truly similar examinations or procedures conducted for similar purpose and requiring similar technique, i.e., to allow the comparison of "apples with apples" rather than a mixed bag of fruit. For classification of examinations, advice can be taken from medical stakeholders, international guidelines, and existing systems (e.g., Refs. 23 and 24).

4.6.3 *Organization*

Regulatory bodies should take actions to conduct or facilitate patient dose surveys (e.g., by inviting professionals for working groups and providing practical support for their work); collaboration with professional societies is of high importance to ensure clinical expertise and the full support of the clinical community. A successful program should include a coordinator and a multidisciplinary team with key stakeholders involved. The team should plan representative surveys covering the most important examinations and at least a representative sample of facilities (public and private, old and new); a small sample with a committed group of professionals can be a minimum start.

Efforts should be taken to ensure that effective actions initiated by leading hospitals are translated to nationwide implementations. Cooperation across countries and support from regional or continental actions can also prove valuable. The final goal should be to build up sustainable approaches that go beyond pilots and are not dependent on any continuous external support.

4.6.4 *Technology resources*

An essential component of "tools" is the actual imaging equipment and accessories, including the dosimetric equipment (dosimeters, phantoms, etc.). There is a need to ensure an adequate number of health care facilities with an adequate number of equipment with upgraded technology (e.g., replacement of film systems by digital technology and replacing legacy equipment with those supporting RDSR). Attention should be paid to appropriate calibrations and quality control procedures, to ensure sufficient accuracy of patient dose monitoring; the role of MPs is crucial in this area.

4.6.5 *Improved strategy of diagnostic reference levels*

For the further development of patient dose monitoring, important also for ongoing national programs and advanced situations, there is a need to improve the strategy of DRLs. DRLs should be based on clinical tasks (clinical indications) for imaging rather than on anatomical regions. Patient size should be properly addressed: the standard patient size should match the average size of the population (considering the level of obesity) while carefully grouping the patients in accordance with their size or weight, particularly in pediatric patients.[15,16] In interventional radiology, the use of DRLs is more challenging as DRLs should take into account also the complexity of procedures, in addition to the clinical indication.[25]

Image quality considerations are essential for a proper application of the DRLs as an optimization tool. At present there is no agreed, convenient methodology to quantify clinical image quality in an objective way. Peer evaluations and exchange of experience of radiologists, cardiologists, and nuclear medicine experts, with possible use of a reference image library, can be applied to ensure that the image quality in patient dose surveys meets the requirements of the given clinical tasks. More details in terms of more clinically focused optimization are provided in the companion paper.[17]

In the analysis of data to produce DRLs, the dose distributions should be utilized more completely with indicators beyond the third quartile; 50% level has sometimes been used to denote the achievable level while lower levels should be used with caution (because the reasons for low doses may be manyfold).

The proper use of DRLs should also include the implementation of corrective actions when typical patient dose values are higher than DRLs.

4.6.6 *Integrated informatics and automated data management*

In medical imaging, convenient access to the substantial amount of patient dose and other data is a challenge. This should be addressed by integrated (not multiple) informatics units. For the mechanism of data collection, analysis, and reporting, electronic data transfer and automated systems should be preferred whenever available, whereby the data management should be integrated with general electronic health records systems. Dose management systems (software packages) are developing very fast and already provide very versatile features for data handling and analysis, thus becoming more and more desirable components in the overall data management systems; this development should also work as an incentive for healthcare financing to promote effective dose monitoring. It is understood, however, that for data acquisition periods into the foreseeable future simpler resources, such as templates, spreadsheets, and web-based queries, would be needed.

The integrated informatics should deal with all data related to radiation protection issues (besides patient dose monitoring), for example, data from imaging protocols, quality assurance data, and referral guidelines, and decision support systems should be included. The comprehensiveness and versatility of the data contents require improved sorting (mapping, syntaxing, etc.) and design efforts to produce the most useful exports or output for different purposes of different user groups.

In building-up the dose management systems, increased attention should be paid to data validation as there are several steps in the process to introduce errors even in most automatic systems. Further, due attention should also be paid to confidentiality issues, data anonymization and security are needed for all data exports outside individual purposes.

4.6.7 *Dose registries and population dose evaluation*

National (or regional) databases or dose registries are a useful ultimate goal for efficient patient dose data management; these should store and make available not only the original data but also statistical descriptors (e.g., histograms, median, and third quartile values and uncertainty estimates).

For population dose estimations, which are important to enable follow-up of trends, comparisons and focusing of resources, the Top 20 methodology introduced by the EC[23,26] is a good starting point when more comprehensive evaluation is not yet possible. It provides a reasonable estimate of population dose, the accuracy of which can be significantly improved by iteratively adding more examinations over time.[26]

5 Support by Professional Societies and International Organizations

The possible solutions and actions needed, as suggested above, will, in many cases, greatly benefit from a versatile range of support, which the professional societies and international organizations can provide. The patient-centric, multistakeholder, and holistic approaches should generally be advocated by these societies and organizations. The support by professional societies could also be applied in a very practical manner, e.g., by providing "crib-sheets" or quick reference guides on important topics, such as how to use the DRLs, targeted at hospital staff. Many proposals from the Technical Meeting audience called for continuation of the IAEA's versatile support and guidance to member states, including several new ideas such as establishing a "DRL center" and central repository for DRLs in pediatrics and a training course (with demonstration sessions) on DRLs.

6 Conclusions

The IAEA Technical Meeting on patient dose monitoring and the use of DRLs for the optimization of protection in medical imaging have indicated that several countries still lack the legislative basis and appropriate infrastructure for effective patient dose management. Some good examples of program development could, however, be seen even in the less-developed countries. Likewise, there are a number of possibilities for further development in developed countries. As an overall conclusion, radiation protection for today's imaging practices and facilities requires a patient-centric approach and a transfer from purely reactive to increasingly proactive optimization, whereby the best outcome would be expected from good teamwork.

Disclosures

There are no conflicts of interest.

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