SAFETY REPORT SERIES No. XX

PATIENT RADIATION EXPOSURE MONITORING IN MEDICAL IMAGING

IAEA
International Atomic Energy Agency

FOREWORD

The IAEA's Statute authorizes the Agency "To establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property …, and to provide for the application of these standards". When it applies to medical exposure of patients in medical uses of ionizing radiation, the application of the principles of radiation protection and safety as defined in the IAEA Safety Fundamentals, requires a special approach. In accordance with IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, dose limits do not apply to patients. Consequently, the focus for ensuring radiation protection of patients is on the application of the principles of justification and optimization. In medical imaging using ionizing radiation, including X ray diagnostic radiology, diagnostic nuclear medicine and image guided interventional procedures, radiation protection of patients is achieved by selecting the most appropriate imaging procedure for the individual needs of the patient, and keeping the exposure to the minimum necessary to achieve the necessary diagnostic and interventional objective.

Reviews of radiation exposure of patients in medical imaging has proved to be a key tool for the optimization of radiation protection of patients, the analysis of individual as well as population-based exposures, and the process of justification. Information for patient exposure at the level of population is informative for assessing the trends in collective doses and as a basis for epidemiological studies on the radiation effects. The rapid technological developments in medical imaging have improved access to information for accessing exposure of patients and facilitated the analytical uses of this data.

The purpose of this report is to respond to the lack of definitive guidelines on this subject and provide consolidated information and detailed advice for monitoring patient radiation exposure in medical imaging, including recording, collecting and analysing relevant patient exposure data by using manual or automatic means. Considering the ease of access to a large volume of digital data for patient exposure, an emphasis has been laid on the use of automatic digital systems for patient radiation exposure monitoring, where there is also a lack of appropriate guidelines. The purpose is also to encourage the future use and development of automatic digital systems to improve access to information about patient radiation exposure and thus contribute to improved implementation of the requirements for radiation protection of patients throughout the world.

The target audience for this publication are those involved in setting and implementing patient radiation exposure monitoring programmes at the level of a medical facility, groups of facilities, State or region. The scope of this publication is limited to the process of making radiation exposure data available in a meaningful way, framed to the intended purpose and users' group. Guidance on patient dosimetry, as well as on specific actions for improving radiation protection and patient care through proper management and utilization of available exposure data is specific to each imaging modality and is out of the scope of this document.

CONTENTS

1. INTRODUCTION

1.1.   BACKGROUND

The use of ionizing radiation in medical imaging has brought significant benefit to human health. This benefit has encouraged increased utilization of medical imaging in recent decades, and as a consequence, there has been a marked increase in collective doses from radiological imaging [1, 2]. While these increased utilizations are largely justified based on the derived benefit, the consequent increased exposures necessitate a higher degree of oversight of radiation protection for patients. This is of particular importance in view of published reports on the unjustified and unoptimized use of radiological imaging [3-7]. Among different reasons are the increasing use of imaging technology by medical professionals with limited or no training in radiation protection, along with the rising complexity and diversity of imaging systems and features [8, 9].

The above landscape has led to several actions by the IAEA on strengthening patient radiation protection under the umbrella of the International Action Plan on Radiation Protection of Patients and the Bonn Call for Action [10-12].

Following recommendations of the International Commission on Radiological Protection (ICRP) [13, 14] and based on IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [15], IAEA Safety standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [16] establishes requirements for patient dosimetry in diagnostic and interventional procedures and Diagnostic Reference Levels (DRLs) to support and facilitate the optimization of radiation protection of patients. These pertain to performing and documenting dosimetry of patients following internationally accepted or nationally accepted protocols, determining typical doses to patients for common diagnostic radiological and image-guided interventional procedures, and performing local assessments and reviews to compare with DRLs. IAEA Safety Standards Series No. SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiation [17] provides further recommendations but does not detail the methods to meet these requirements.

The IAEA Technical Meetings held in 2015 and 2016 identified gaps in implementation of the GSR Part 3 requirements for patient dosimetry and DRLs and requested the IAEA to provide consolidated information and detailed advice on radiation exposure monitoring of patients in medical imaging for optimized radiation protection [18]. The IAEA Technical Meetings held in 2019 and 2020 focused on reasons for recurrent imaging and recommended further actions to strengthen tracking of exposure history of individual patients and communicating this information to referring medical practitioner and radiological medical professional in support to justification and optimization process [19].

Monitoring of patient radiation exposure provides objective information to healthcare professionals and authorities who are responsible for ensuring justified and optimized use of radiation in medicine. The benefits of monitoring patient doses have been documented in many publications and has proved to be a key tool for continuous improvement in the optimization of radiation protection of patients, the analysis of individual as well as population-based exposures, and the process of justification in medical imaging. For decades, this has been based on periodic patient dosimetry surveys and reviews performed at the level of a medical facility, group of facilities, State or a region. While in the past this process has been based on manual collection of limited samples of analogue data that is still the only option in some States, the rapid development of modern digital imaging systems and the improved access to the exposure data in a digital format, have facilitated the patient exposure monitoring by

utilizing electronic registries and automatic or semi-automatic digital systems for data collection and analysis. Despite their utility and potential, such digital patient exposure monitoring systems have been implemented only at a limited number of radiological facilities in the world, with notable heterogeneity in their implementation. With a lack of comprehensive international guidelines on this subject, a need has emerged for advice for a clear, focused strategy to support initiatives of Member States or healthcare institutions in Member States to strengthen the process of patient exposure data collection and analyses. That includes advice on how patient exposure monitoring programmes, and especially digital exposure monitoring systems, need to be designed and used at local, national, regional, or international levels towards the ultimate goal of improving radiation protection and patient care.

1.2. OBJECTIVE

This document provides consolidated information and detailed advice for monitoring patient radiation exposure in medical imaging to help meet the requirements for medical exposure established in GSR Part 3 [16] and the recommendations provided in SSG-46 [17]. This includes metrics characterizing patient exposure, including demographic, acquisition and processing parameters, dosimetric, and image quality data; mechanisms and processes for data recording, collection, and analysis; and practical implementation considerations.

Patient radiation exposure monitoring in this document refers to any systematic process of monitoring relevant patient exposure data, whether implemented manually or by automatic digital means. While manual systems for data monitoring can still be used and can sometimes be the only available option in many places, the best benefits and effectiveness of patient radiation exposure monitoring can be achieved by utilization of automatic digital systems. Most of the guidelines and principles presented in this document are applicable regardless of the system being manual or digital, but an emphasis has been laid on the use of automatic digital systems. The purpose is also to encourage the future use and development of the automatic digital systems to improve access to information about patient radiation exposure and thus contribute to improved implementation of the requirements for radiation protection of patients throughout the world. Whether manual or automatic, it is essential that the patient radiation exposure monitoring is systematic.

The target audience of this document is all involved in setting and implementing radiation exposure monitoring programme at the level of a medical facility, groups of facilities, State or region. This includes medical physicists, medical radiation technologists (also named radiographers, radiological technologists, nuclear medicine technologists in some countries), radiological medical practitioners (radiologists, nuclear medicine specialists, or other professionals who are competent to perform independently or to oversee diagnostic or image guided procedures), referring medical practitioners (referring physicians), qualified experts (e.g. in medical physics or radiation protection), informational technology specialists in healthcare, researchers, manufacturers and suppliers of medical radiological equipment and software, regulatory bodies, health authorities and policy makers. This report may also be relevant for patients and consumer associations: embedding patient radiation exposure monitoring in national policies on quality of care can enhance the responsiveness of health systems to consumer expectations.

1.3. SCOPE

The document covers medical radiological imaging procedures in diagnostic radiology, image guided interventional procedures, and diagnostic nuclear medicine. It covers all image guided radiological procedures carried out in subspecialty services such as, but not limited to, cardiology,

vascular surgery, urology, orthopaedic surgery, obstetrics and gynaecology, emergency medicine, gastroenterology, and radiation therapy.

The information provided in the report covers the process of monitoring of patient radiation exposure, including the appropriate metrics, mechanisms and processes for data recording, collection, and analysis; and practical implementation considerations. The document outlines different analytical uses of exposure data to help users set the goal of their radiation exposure monitoring programme and properly design its components. The scope of the document is limited to the process of making radiation exposure data available in a meaningful way framed to the intended purpose and users' group. Guidance on specific actions for improving radiation protection and patient care through proper management and utilization of available data is specific to each imaging modality and is out of the scope of this document.

1.4.   STRUCTURE

Following this introductory section, Section 2 outlines the goals and content of patient radiation exposure monitoring.

Section 3 describes components of patient exposure data to be monitored, including image acquisition and processing parameters, exposure metrics, image quality metrics, as well as the risk indices.

Section 4 outlines the patient radiation monitoring workflow including recording, collecting and analysing patient exposure data.

Sections 5 and 6 provide detailed information on data recording and collection, with a focus on methods and techniques, classification and coding of procedures, and available standards for digital exposure data.

Section 7 provides information on different analytical uses of patient radiation exposure monitoring for optimization of protection and practice consistency, and for individual patient exposure analysis.

Section 8 focuses on the implementation considerations of the patient radiation exposure monitoring, including organizational structure, quality control, specification and functionalities of digital systems, training and communication, integration into other healthcare systems, priorities for implementation and obstacles and solutions.

The Appendix provides examples of metrics for the three levels of patient exposure data that are defined in Section 5.

A list of definitions, as well as a list of abbreviations and symbols used in this publication is provided.

2. PATIENT RADIATION EXPOSURE MONITORING GOALS AND STRUCTURE

2.1. GOALS OF PATIENT RADIATION EXPOSURE MONITORING IN MEDICAL IMAGING

Medical imaging is performed for the explicit goal of obtaining useful information to support decision-making about management of patient care. If that goal is compromised, the patient will be subject to clinical risk that can be defined as the risk associated with lowered diagnostic confidence and the associated reduced likelihood of accurate interpretation leading to misdiagnosis. There is also another category of risk in imaging with ionizing radiation, namely radiation risk. These two risks are interrelated and have to be put in balance with respect to one another.

From radiation protection perspective, management of medical exposure of patient is based on the implementation of the radiation protection principles of justification and optimization [13-15].

The first step in this process is justification, carried out at the level of procedure as well as for individual patient. As stated in para 3.155 of GSR Part 3 [16] (footnote omitted):

"Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure."

For the justification of medical exposure for an individual patient, para 3.157 of GSR Part 3 [16] requires that the radiological medical practitioner and the referring medical practitioner take into account, among other elements, "the characteristics of the medical exposure; the characteristics of the individual patient, and relevant information from the patient's previous radiological procedures", and para 3.158 states that "Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure."

The patient radiation exposure monitoring as described in this Safety Report aims to inform the process of justification at the level of generic justification of a given radiological procedure by providing information about associated radiation doses and risk, as well as at the level of individual patient, by providing necessary information about previous radiological procedures and associated exposure levels. This up-to-date information might be included in the referral guidelines for imaging, and used to provide feedback to referring medical professionals and radiological medical practitioners in justification of medical exposure for an individual patient.

Further to justification, Requirement 38 of GSR Part 3 [16] states that "Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure", and defines the optimization of protection and safety for medical exposures of patients as "the management of the radiation dose to the patient commensurate with the medical purpose". In addition, para.1.16 of GSR Part 3 [16] states:

"…the application of the optimization principle to the medical exposure of patients, and to that of volunteers as part of a programme of biomedical research, requires a special approach. Too low a radiation dose could be as bad as too high a radiation dose, in that the consequence could be that … the images obtained are not of suitable diagnostic quality. It is of paramount importance that the medical exposure leads to the required outcome".

In the context of medical imaging, optimization means maximizing the benefit to risk ratio for the patient, that could be interpreted as balancing image quality and dose so as to provide an assurance that the goal of the imaging procedure is achieved. As stated in Table 1 of SSG-46 [17], optimization of protection and safety in diagnostic and interventional medical exposure means "keeping the exposure

of patients to the minimum necessary to achieve the required diagnostic or interventional objective".

Optimization includes consideration of the risk associated with the application of the ionizing radiation used in the process, i.e., radiation risk, but also the likelihood of not delivering the very purpose of imaging, i.e., delivering the desired benefit. Not realising that purpose can be recognized as a clinical risk [20]. Comprehensive optimization of medical imaging combines the radiation and clinical risks as a unified total risk estimate within a process informed by the diagnostic or interventional objective (the clinical task). In dealing with both radiation risk and clinical risk, optimization is characterized in a patient-centred manner. In this wider perspective, optimization leads to increased clinical effectiveness [20].

Requirement 38 of GSR Part 3 [16] requires different components to be in place for optimization of protection of patients in diagnostic radiological and image guided procedures, including:

- appropriate and well-designed medical radiological equipment and associated software, and, for nuclear medicine, appropriate radiopharmaceuticals;
- operational considerations, including appropriate techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfil the clinical purpose of the radiological procedure, with account taken of relevant norms of acceptable image quality established by relevant professional bodies and of relevant DRLs;
- calibrated radiation sources and dosimeters used for dosimetry of patients;
- dosimetry of patients to determine typical doses for common procedures;
- diagnostic reference levels (DRLs);
- comprehensive quality assurance programme.

DRLs and patient dosimetry are recognised as important tools for optimization. For setting DRLs, para 3.148 of GSR Part 3 [16] states:

> "The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.169 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances."

For the radiological facilities, Para. 3.169 of GSR Part 3 [16] requires that local assessments are made and reviews are conducted "to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure: (i) Typical doses or activities exceed the relevant diagnostic reference level; or (ii) Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient."

Thus, the ultimate goal of patient radiation exposure monitoring is advancing towards this optimization at the individual patient and the operational levels. For serving this optimization goal, radiation exposure monitoring in medical imaging has to include not only dose metrics to take into account radiation risk but also image quality metrics to quantify the clinical outcome.

Radiation exposure monitoring of patients also provides feedback to decision makers and international organizations to estimate trends in medical imaging doses and practice and their contribution to the collective doses at population level. The more extensive process of patient radiation exposure data collection might support the regular surveys organized by UNSCEAR, in cooperation with the World Health Organization (WHO), to estimate global exposure from medical exposure [1, 2, 21-24]. Availability of a standardized mechanism of collecting and reporting patient radiation exposure

data would facilitate this analysis and reduce uncertainties in estimation of population doses and their comparison between different countries and regions. This information is also useful to inform epidemiological and other research studies on radiation effects and risks.

Patient radiation exposure monitoring as described in this report aims to support implementation of the requirements of GSR Part 3 [16] related to patient dose reviews in all settings, including radiological facilities in States with limited access to modern radiological equipment. The term "patient radiation exposure monitoring" however aims to reflect the current trend in medical imaging when access to a large volume of exposure data in digital format is easily available. This allows for transition from periodic reviews of patient doses using isolated samples of standard size patients, to more regular or continuous monitoring and more comprehensive analysis of all of the available data to provide more benefit to patients.

2.2. ELEMENTS OF PATIENT RADIATION EXPOSURE MONITORING AND TERMINOLOGY

Patient radiation exposure monitoring includes components, mechanisms, and operational processes related to recording, collecting, and analysing patient radiation exposure data associated with clinical imaging operation. Here monitoring refers to capturing and meaningfully evaluating exposure data, and not the actions for quality improvement, an ultimate goal undertaken by managing patient exposure.

Patient radiation exposure monitoring includes the following steps: recording, collecting and analysing patient exposure radiation data.

Recording is a process of documenting patient exposure data manually or automatically.

Collecting is a process of gathering patient radiation exposure data into a common system. The term can be used synonymously as recording and collecting together.

Analysing patient exposure data is a process of acting upon patient radiation exposure data to provide summaries with statistical, comparative and trend information, to be used for optimizing radiation protection and clinical practice, and to investigate and verify individual doses (incidental and cumulative values) when needed.

The term tracking patient radiation exposure data in this document is reserved to an analysis process of ascertaining and monitoring temporal trends in individual or collective stored data, including evaluation of radiation exposure data for an individual patient over time.

The components of patient radiation exposure data are described in Section 3, and the patient radiation exposure monitoring workflow is detailed in Sections 4, 5, 6 and 7.

3. COMPONENTS OF PATIENT RADIATION EXPOSURE DATA

Patient radiation exposure data is a collection of metrics characterizing patient exposure in medical imaging, including acquisition and processing parameters, dosimetric and image quality data, as well as their associated demographic data (e.g., patient size and age).

The most relevant metrics pertaining patient radiation exposure monitoring are presented in this section, focusing on the metrics that are informed by or reflective of the patient.

3.1. IMAGE ACQUISITION AND PROCESSING PARAMETERS

The process of imaging examination consists of three components: image acquisition, image processing, and image presentation. The three together form the essentials of the quality and optimisation chain which effects the final diagnostic outcome. The image acquisition phase is the only step which directly affects patient exposure, where the latter two effect the exposure indirectly. Thus, the most basic of patient radiation exposure data are image acquisition and processing parameters that are specific to the imaging modality. These parameters govern the image acquisition and processing processes and thus directly influence patient exposure.

In most modern X ray imaging systems, image acquisition is governed by key exposure parameters such as peak tube voltage (kVp), tube current (mA), exposure time (ms), tube current-time product (mAs), and filtration (inherent and added). In fluoroscopy, pulse rate (p/s) for the fluoroscopy mode and frame rate (f/s) for the image acquisition mode are also important basic parameters. Two or more of these parameters are often automatically selected by the Automatic Exposure Control (AEC) of the imaging system. Certain imaging modalities have additional factors that affect exposure. Those include e.g. bowtie filters in computed tomography (CT), target choices in mammography, or pulse width in angiography. Nuclear medicine imaging likewise is governed by the magnitude and type of the administered activity. Imaging systems also deploy processing parameters that influence the image output of the system including those that govern image processing and reconstruction such as kernel size, edge enhancement factor, and noise reduction magnitude [25, 26].

For monitoring patient exposure, understanding and monitoring image acquisition and processing data is necessary but not enough. If all other parameters are unchanged, a longer exposure time or number of images/ frames (in X ray imaging), or a higher administered activity (in nuclear imaging) indicate a higher exposure to the patient. However, between different procedures and patients, exposure parameters can vary and there is no direct correlation between exposure time or administered activity and patient exposure. Thus, an analysis drawn from image acquisition and processing parameters alone, while it carries some value if better metrics are not available, can lead to misrepresentative or false conclusions. In other words, availability of comprehensive and valid exposure data is critical for performing comprehensive patient radiation exposure monitoring, leading to meaningful optimisation processes.

3.2. RADIATION EXPOSURE METRICS

Drawn from image acquisition parameters and patient attributes are exposure metrics. At a foundational level, monitoring patient exposure draws its justification from its connection to the "patient," as the whole process draws its meaning from the need to ascertain and mitigate the radiation risk to the patient. Ideally, patient risk is what needs to be measured and managed. However, individual patient risk is often unknown or unknowable. Alternatively, a host of "surrogates" are used that range along a spectrum from modality-specific quantities to those that are more patient-oriented (Fig. 1). Modality-specific metrics tend to be easier to ascertain and ascribe to an imaging examination. However, they are relevant only to the extent that they can be related more directly to the patient exposure.
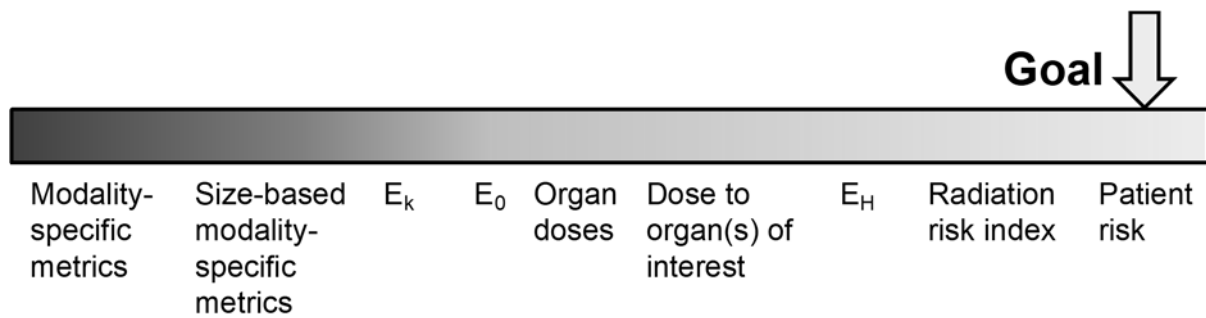
FIG. 1. The spectrum of patient exposure metrics ranging from modality-specific (left) to patient-oriented (right) surrogates falling into a relevance hierarchy in terms of how well they can be related to the risk of the individual patient. E values represent various methods of calculating the effective dose: E_k is calculated from modality-specific standard conversion factors for a generic reference person; E_0 uses organ doses calculated for a generic reference person, and E_H uses organ doses calculated based on the anatomical definition of the actual patient.

Below, we summarize the exposure metrics along the modality-specific to patient-oriented spectrum.

3.2.1. Modality-specific metrics

In accordance with para 1.46 of GSR Part 3 [16] and para 3.199 of SSG-46 [17], the dosimetric quantities and units of the International Commission on Radiation Units and Measurements (ICRU) are to be used for diagnostic radiology and image guided interventional procedures. Detailed guidance on dosimetry in diagnostic radiology is given in Refs [27, 28]. The relevant quantities, their symbols and closely similar quantities are summarized in Table 1 [27–30].

3.2.2. Size-specific metrics

Some of the modality-specific metrics noted above can be adjusted to represent the patient exposure for the patient size that they may represent. The most notable metrics of this kind is the Size Specific Dose Estimate (SSDE). SSDE is a dose estimate for CT scans that considers corrections based on the size of the patient, using linear dimensions measured on or determined from the patient or patient images [31, 32]. As the metric accounts for patient size, it makes the dose metrology more relevant to represent patient exposure.

3.2.3. Organ doses

Patient-oriented exposure metrics include organ dose. Characterizing the exposure of an imaging procedure in terms of organ doses enables the assessment of radiation risk accounting for different radio-sensitivity of different organs [13, 33]. It further accommodates the assessment of radiation injuries in interventional procedures (e.g., radiation injuries to skin or the lens of the eye) [34-38].

Organ doses can be estimated using patient-representing models of body or organ/ tissue and the irradiation field, both of which tend to be patient dependent and variable across patients. This information is often not readily available, necessitating the use of simplistic human models and uniform irradiation fields. In such cases, the estimates are informed by generic attributes of the patient (e.g., size) but there exist large uncertainties in reported organ dose estimates. The resultant uncertainties undermine the utility and value of an otherwise preferred patient exposure metric.

TABLE 1. MODALITY SPECIFIC RADIATION EXPOSURE METRICS

Quantity [27, 28]	Recommended symbols	Unit used in practice	Other common symbols used in literature	Closely related quantity	Modality
Incident air kerma	$K_{a,i}$	mGy	IAK		Diagnostic radiography and fluoroscopy, image guided interventional procedures, conventional radiation therapy simulators and imaging equipment for image guided radiotherapy, dental intraoral radiography, mammography and breast tomosynthesis
Incident air kerma rate	$\dot{K}_{a,i}$	mGy.s^{-1}			
Entrance surface air kerma	$K_{a,e}$	mGy	ESAK	Entrance-surface dose (ESD)*	
Air kerma at the patient entrance reference point**	$K_{a,r}$	mGy	CAK (Cumulative reference air kerma)		Fluoroscopy and fluoroscopy guided interventional procedures
Air kerma-area product	P_{KA}	mGy.cm^2***	KAP	Dose-area product (DAP)*	Radiography, fluoroscopy, image guided interventional procedures, dental panoramic radiography and dental CBCT
Weighted CT air kerma index	C_w	mGy [30]		Weighted CT dose index (CTDI$_w$)*	CT
Volume CT air kerma index	C_{vol}	mGy [30]		Volume CT dose index (CTDI$_{vol}$)*	CT
Air kerma-length product	P_{KL}	mGy.cm [30]		Dose-length product (DLP)*	CT
Activity of a radiopharmaceutical	A	Bq			Nuclear medicine
Activity of a radiopharmaceutical administered per unit body mass	A/body mass	Bq.kg^{-1}			Nuclear medicine

*Because "air kerma" and "dose in air" are numerically equal in diagnostic radiology energy range.
**Also names "cumulative dose", "reference air kerma" and "reference point air kerma" have been used in the literature.
***Further recommendation for the unit of 'air kerma-area product' of X-ray equipment for interventional procedures is provided in Ref. [29].

Recent advances have offered solutions to patient-specific organ dosimetry by matching a patient to an atlas of diverse, realistic human models (Fig. 2) [39-44]. The matched patient model representing the patient is then geometrically aligned with the specific irradiation output from the imaging system and inputted into a radiation transport simulator that emulates the imaging procedure [45, 46]. Likewise, machine learning methods are emerging which offer data-driven organ segmentation and characterization informed by the patient attributes [47]. The energy deposited in each organ is then tallied and normalized by the organ mass to estimate the organ dose and associated uncertainties in the estimates [48]. This method has shown to give dose values with high accuracy with errors in doses to sensitive organs below 10% [49].

It is recommended to accompany reports of patient organ dose by documented estimates of the uncertainty of these estimates [50, 51].
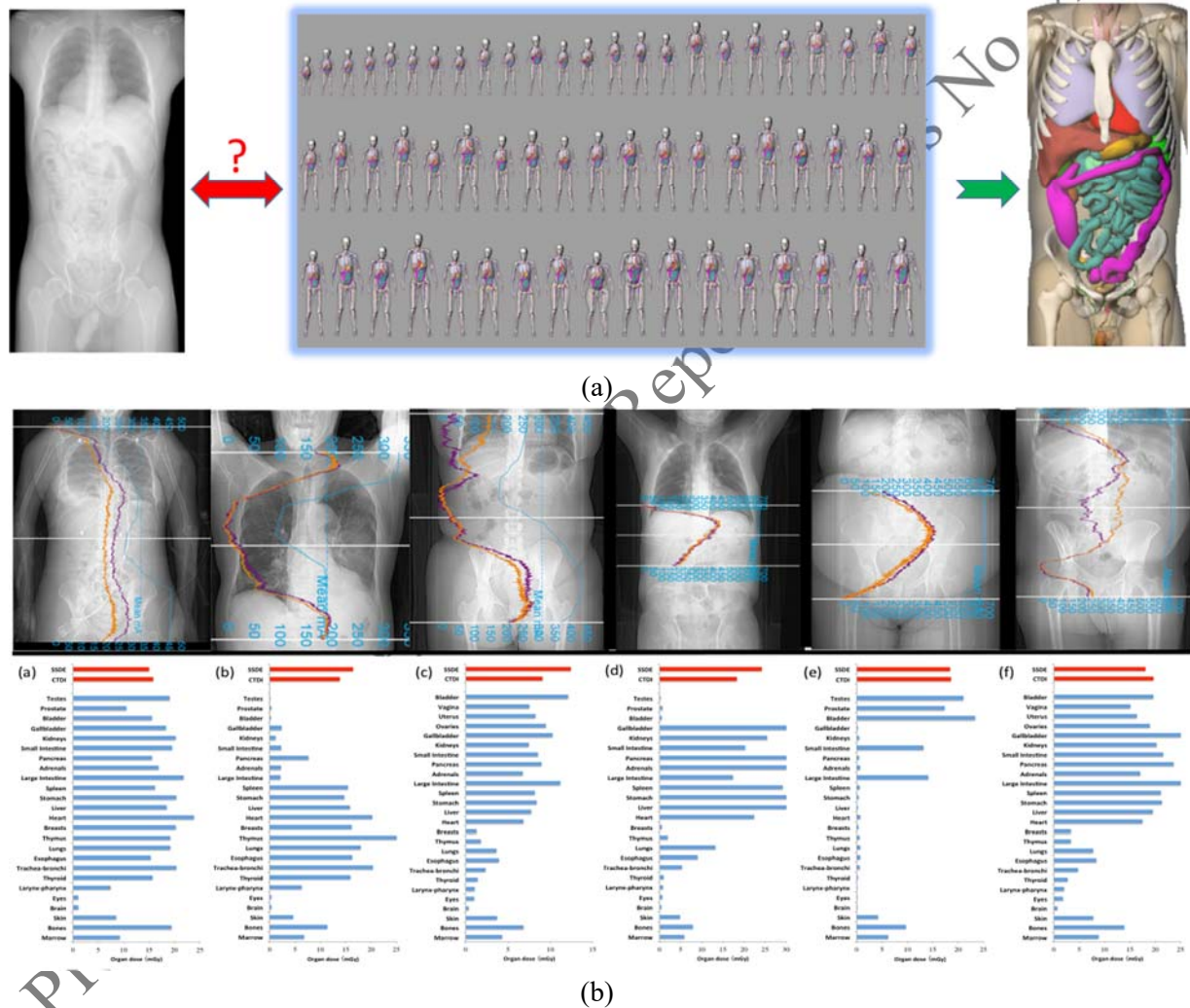
FIG. 2. (a) An atlas of patient models that can be matched to a patient and used for accurate estimation of organ dose. (b) Example application of the method to assess organ doses of individual CT examinations of varying patients of varying irradiation conditions (courtesy of E. Samei, Duke University Medical Center, USA)

In a number of imaging procedures, there are certain organs or organ components that receive much higher doses. In other procedures, the radiation sensitivity of a particular organ or organs is higher than others. One example is mammography where breast dose (and that namely the average glandular breast dose) is the key organ dose of relevance; compared to the breasts, other organs receive a lower

dose [52]. Another example is fluoroscopy where compared to all other organs, the skin has the highest dose, often at levels that can lead to deterministic radiation effects. While these two examples are extreme, there are similar situations where an organ commands a higher degree of scrutiny due to its radiosensitivity. Examples include eye dose in head CT or neuroradiology procedures, breast dose in chest CT of females, and foetal dose in pregnant patients. In these situations, the dose to the organ (or organs) of highest interest can be recognized as the relevant dose value for optimisation actions and can serve as a singular metric of dose for the desired monitoring purposes.

3.2.4. Effective dose and other risk estimates

While organ dose is considered the most relevant representation of the radiation risk in many clinical situations, it represents a utilization challenge: a patient has multiple organs, each with its own organ dose. Ideally, a radiation risk to the whole of the patient can be represented with a singular number and not a multiplicity of numbers. Singular numbers enable more effective communication with patients or referring physicians and a more straightforward strategy for comparison of doses from medical procedures that expose different regions of the body and for evaluation of the efficacy of optimization of imaging examinations. Effective dose is used as such a metric [51, 53].

Effective dose is calculated as a weighted sum of tissue equivalent doses over all organs and tissues of the human body considered to be sensitive to the induction of stochastic effects, applying age- and sex-averaged tissue weighting factors [13]. Effective dose represents the uniform whole-body irradiation, which causes the same detriment as an actual non-uniform irradiation with different values for the equivalent doses to the various tissues and organs [28]. Effective dose is calculated for a reference person and not for an individual and was initially devised as a metric of radiation protection for radiation workers and public, with simplifying assumptions that limit its applicability to patients [13]. However, its use for patient exposure in medical imaging is deemed appropriate with caution for application to individual risk [13, 51, 53].

There are generally three different methods to estimate effective dose from medical imaging procedures. The most common method, denoted as E_k here, is through modality-specific generic conversion factor as

$$E_k = c.F,$$

where F is a modality-specific quantity such as entrance surface air kerma or kerma-area product for radiography and fluoroscopy, or the dose-length product for CT, or administered activity in nuclear medicine, and c is a conversion factor [54-65]. Such conversions are based on modelling of the patient by a model of person of average size, adjusted to the body and organ masses of reference adult [51]. Ignoring the heterogeneity of body habitus and irradiation field, the results are useful for comparison purposes but are less applicable to the patient exposure.

Effective dose, denoted here as E_0, can be computed with closer representation of the patient exposure using a generic patient model and Monte Carlo toolset to provide organ doses (e.g., computer programmes PCXMC, CTExpo, ImpactDose) [66-68].

The most patient-relevant technique uses patient-specific organ doses (as described in section 3.2.3) to compute a patient-specific effective dose, E_H [46, 53, 69, 70]. The three methods do not result in identical estimates, with E_k values reported to be different from E_H for CT by as much as 75% [71-74].

A quantity related to the stochastic risk is the energy imparted, $\bar{\varepsilon}$, to the patient. It is a reflection of a total energy deposited in the body [28, 75-77]. When derived from volumetric measurements of individual patients [78], it eliminates the need to assess organ doses individually and still offers a patient-specific quantity. As stated in Ref. [28], "owing to the dependence of effective dose on the anthropomorphic model used for calculating organ doses, the energy imparted to the patient or the mean

absorbed dose in the patient may serve as an alternative risk related quantity for optimization". However, while energy imparted can be of value in ascertaining an overall dose to the patient body, it ignores variations in radiation sensitivity across organs.

Radiation risk is the driving force behind any dose estimation. As a first-order approximation, radiation risk as the probability of fatal cancer can be estimated from effective dose using the approximated overall fatal risk coefficient of 5 % per Sv [13, 28, 79][1]. However, the method has limited applicability to individual patients, as it ignores differences in age, sex and health status between the population undergoing medical imaging procedure and the population for which the nominal coefficients were derived.

To overcome some of the limitations of effective dose, Brenner proposed a quantity termed 'effective risk', defined as a weighted sum of organ doses, with age-specific tissue weighting factors based on lifetime cancer incidence [80, 81]. ICRP warned that "While this approach takes direct account of the available data on age specificity of the different cancer types, it may give a spurious sense of accuracy unless associated uncertainties are considered" [51].

An alternative risk estimate termed 'radiation risk index' was proposed by Li et al. [82]. This risk assessment is based on estimates of mean absorbed doses to individual organs, taking into account the anatomical specifics of the patient and the irradiation condition of the examination, size of the patient and other factors influencing the distribution of dose within the organs. Then, the 'radiation risk index' is calculated as a sum of these organ doses specific to the patient, weighted with organ-specific age- and sex- specific risk coefficients [13, 39]. This quantity, relying on a granular knowledge of organ doses of the patient, is more reflective of the patient specifics of age, sex, size and the heterogeneity of dose distribution when compared to the alternative strategy of converting effective dose to risk. A similar approach is used in the software PCXMC to calculate "risk of radiation-induced cancer death" [67].

In reality, age and sex dependency are not the only contributors of an individual risk for patients. This formalism may be extended to include other radiation risk related factors such as genetic disposition, non-oncologic risk, neurological risk, cardiac risk, and cataract risk [83].

It is also important to note that many factors, such as limitations in the epidemiologic data and uncertainties in dose estimates, contribute to the uncertainty of the risk estimation. When reporting any risk metric derived from measurable dose quantities, the values need to be quoted only to an appropriate level of precision and with details of the underlying models and calculation methods, and the uncertainties in both dose and risk estimates have to be considered.

3.3. IMAGE QUALITY METRICS

The focus of this report is patient exposure as a primary risk factor to be managed in the practice of medical imaging. However, characterizing medical imaging in terms of radiation risk alone is short-sighted as the magnitude of the exposure and thus the risk changes the quality of the images and thus the anticipated benefit of the procedure itself. The practice of medical imaging, as in the practice of many other medical procedures, involves balancing the benefit of the procedure with its potential risk, or as noted earlier, balancing the clinical risk and radiation risks. Thus, the radiation risk can only be properly understood and possibly mitigated taking into consideration the desired diagnostic information or quality of the images to provide the anticipated benefits. Characterizing imaging in terms of image quality provides the needed quantitative foundation to ensure an appropriate level of patient exposure is applied for the examination.

Characterizing image quality involves quantitative metrology. Just as in the case of patient

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[1] http://www.xrayrisk.com.

exposure, the metrics are most relevant to the extent that they relate to the actual utility of the image towards clinical outcome for the patient. As the clinical outcome for the patient is often difficult to quantify, a host of 'surrogates' are used that range along a spectrum from phantom-based, modality-specific quantities to those that are more patient-oriented (Fig. 3). Phantom and modality-specific metrics tend to be easier to ascertain and ascribe to an imaging examination. However, they are relevant only to the extent that they can be related to clinical quality (or its inverse, clinical risk) of the actual patient examination as described earlier in Section 2.1.
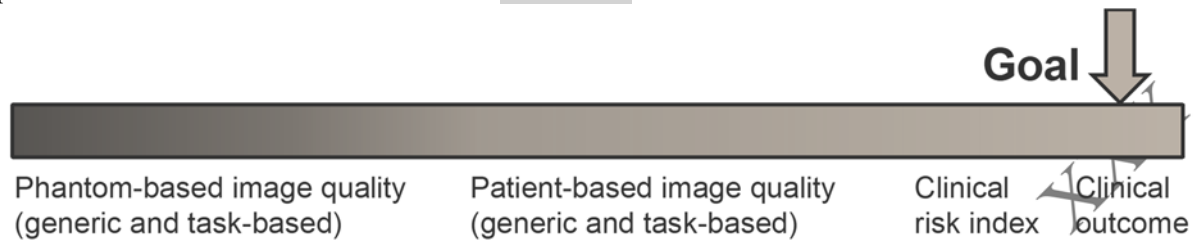
FIG. 3. The spectrum of image quality metrics ranging from phantom-based modality-specific (left) to patient-oriented (right) surrogates falling into a relevance hierarchy in terms of how well they can be related to the quality of the images towards definitive clinical outcome for the patient.

In characterizing an imaging study in terms of the overall information content derived from the examination and image quality, however quantified, it is important to realize the multiplicity in quantities across multi-view and multi-series studies. An imaging study that has multiple series or views has an associated exposure and image quality for each series or view. While the exposure values can sometimes be added to compute the total exposure to the patient associated with the series (e.g., adding DLPs or an organ dose across CT series to compute a total DLP or organ dose for the study), that is not the case for image quality values (e.g., one cannot add or average the resolution or noise of multiple series to compute values associated with the entire study). Thus, image quality assessment and balance of image quality and exposure values have to be made at the level of individual series. Such a balance at the level of a study, which may have multiple series, or views, can be determined by analyses for a representative series, or the data from multiple series combined using principle-informed or data-informed combinatorial mathematics.

3.3.1. Phantom-based image quality

The most common metrics of physical image quality include phantom-based resolution, contrast, and noise (Table 2). Resolution reflects the sharpness of the spatial details in the image, contrast describes the relative magnitude of the signals within the image with respect to one another (e.g., an imaged lesion against its background), and noise describes the statistical fluctuations of the signals in the image not actually originating in the patient. These concepts are generic to all imaging modalities including both 2D and 3D emission and transmission imaging technologies. The aforementioned metrics are also sometimes often combined into metrics that reflect their influence on image quality together through metrics such as Contrast to Noise Ratio (CNR) [25]. Such combined metrics are particularly important to modern imaging systems that deploy non-linear image processing in which not only noise but also image resolution and contrast are influenced by changes in patient exposure.

Resolution, contrast, and noise, as well as their derivatives of CNR and Signal Difference-to-Noise ratio (SdNR), are usually measured in phantoms. The closer the phantoms are to emulating the patients (e.g., emulating the size of the patient), the more representative are the results in relation to clinical quality. The phantoms are often designed differently for different imaging modalities, making

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the resulting metrics modality-specific. Just as in the case of modality-specific patient exposure metrics, these metrics can be ascribed to an imaging examination (such as anticipated CNR associated with a specific patient imaging procedure). Even so, they do not fully describe the image quality in the patient images, raising the need for patient-oriented metrics of quality.

TABLE 2. BASIC PHYSICAL IMAGE QUALITY CONCEPTS AND METRICS

Attribute	Common symbol	Description
Signal	Pixel value, PV	The image signal intensity associated with an area of interest, e.g. a lesion
	Hounsfield units, HU	Linear rescaling of the linear attenuation coefficient measurement to a scale where the radiodensity of the water is 1 and the radiodensity of the air is -1000
Contrast	Absolute contrast	The signal difference in the image signal intensity between two areas of interest, e.g., a lesion and background tissue. A.k.a. Signal Difference
	Relative contrast	The differential contrast normalized to the background signal
Noise	Absolute noise	The stochastic mottle present in the image that confers it a grainy appearance
	Relative noise	The mottle presents in the image that confers it a grainy appearance divided by the background signal
Noise texture	Noise Power Spectrum, NPS	The spatial frequency distribution of noise power in the image
Contrast-to-Noise Ratio	CNR	The ratio of the contrast of a defined feature of interest to its background relative noise
Signal Difference-to-Noise ratio	SdNR	The ratio of the absolute contrast of a defined feature of interest and absolute noise
Spatial Resolution	Modulation Transfer Function, MTF/ Target Transfer Function, TTF	An index of sharpness of image indicating how two objects can be differentiated from one another spatially, expressed in terms of spatial frequencies

With the aid of phantoms, the generic image quality metrics described above provide important but isolated signatures of singular aspects of image quality with limited ability to reflect how these aspects might impact a particular diagnostic process. It is possible to incorporate the knowledge of the specific imaging features of the pathology of interest (clinical task) for which the image is captured into a task-specific metrics of image quality. The 'observer model' combines the components of image quality, including clinical task, resolution, contrast, and noise, as well as the characteristics of the human visual system, into a singular metric of quality, such as detectability index (aka d') or estimability index (known as 'e') depending on the task [84, 85]. These indices are analogous to radiation risk index, reflecting the quality aspect of the imaging performance into a singular value.

Depending on how the constituent components are integrated, task-specific metrology uses different observer models [86] with different levels of applicability and relevance to different imaging applications. These models have proven invaluable in relating physical metrics to diagnostic accuracy (Fig. 4) as a way to assess the feasibility of different imaging systems or techniques [87].
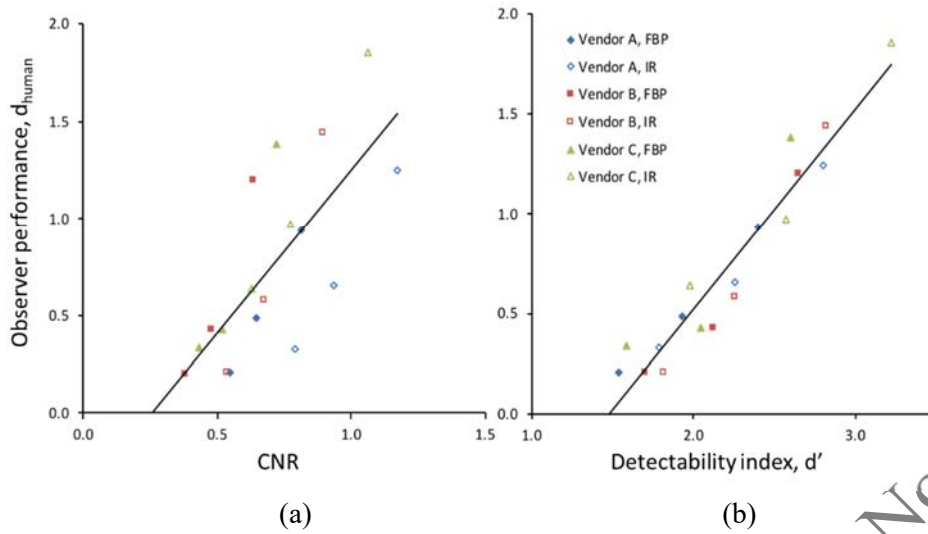
FIG. 4. Correlation of CNR (a) and detectability index, d' (b) with observer performance (d_{human}; the likelihood of detection of a subtle target as measured by human readers) across three CT systems (A, B, C) with their associated filtered back projection (FBP) and iterative reconstructions (IR). The data demonstrate stronger correlation of d' with observer performance ($R^2 = 0.93$) compared to CNR ($R^2 = 0.47$). (courtesy of E. Samei, Duke Medical Center, USA)

3.3.2. Patient-based image quality

The foundational metrics of image quality, resolution, contrast, noise, CNR, and their reflection in the task-based metrics such as detectability index and estimability index noted above are traditionally measured in phantoms. Phantom measurements are robust when corresponding to attributes in clinical images such as patient size. However, phantoms do not represent variability present in patients' habitus. Further, most modern imaging systems deploy adaptation technologies by which the imaging condition is changed in response to the specific attributes of the patient (e.g., the patient size and habitus). An example is automatic tube current modulation (ATCM) in CT. However, such adaptations are not perfect, leading to variations across patient data not captured in phantom data. In addition, there are other sources of fluctuations and artifacts in clinical practice (e.g., temporal changes) not present in static phantom setups. As a result, the data obtained from phantoms do not necessarily fully predict image quality attributes in patients.

Image quality can be assessed using patient data. This can be done in two different ways, generic and task-based. The generic method, like task-generic metrics from phantoms, such as contrast, does not pertain a specific task. Often done through preference studies, a common method is for radiologists to measure or judge images in terms of their adequacy to provide the needed information for diagnosis, using simple quality criteria. This is the most common approach to assess image quality and score images [55, 88-95]. However, preference-based methods tend to be subjective and while likely correlated with clinical outcome, not direct relationship can be certain.

Alternatively, patient images can be assessed in a task-based fashion with clinicians evaluating a set of images in terms of an imaging task, such as detecting lesions, assessing proper placement of an interventional apparatus, or characterization of an abnormality [96]. This approach is more objective but is subject to significant inter-case and inter-observer variability making the number of cases needed large to improve statistics, which renders the method impractical for optimization purposes.

Recent advances have demonstrated that it is also possible to measure image quality directly from individual patient images in either a generic or task-based fashion automatically and efficiently without

the observer reading of cases. That includes the assessment of preference aspects of image quality [97], as well as the foundational attributes of noise, resolution, and contrast. Noise is measured by decomposing the image data to fluctuations that are anatomical in nature from those that are stochastic [98]. A demonstration is the measurement of resolution and contrast assessed by clinical CT images from characterizing specific geometrical interfaces and tissues in the body [99]. Contrast can likewise be measured by segmenting and characterizing signal in target organs of interest [100]. The latter is particularly relevant in the contrast of imaging examinations that deploys optimizing contrast-enhanced imaging medium where the risk of contrast medium has to be balanced against that of the derived benefit (enhanced image contrast).

This technique has also been extended to task-based measurements. Noise is similarly measured by decomposing the image data to fluctuations that are anatomical in nature from those that are stochastic [98]. Recent progress has also derived via in vivo indices of detectability index, validated against diagnostic performance [101, 102].

Automatic patient-based image quality measurements enable informatics based on image quality analogous to those based on patient exposure, thus the radiation risk of an imaging examination can be put into perspective with the associated diagnostic content, thus providing crucial guidance to judge and optimize image quality and patient exposure.

3.3.3. Clinical risk index

Image quality measurement is relevant as it aims to reflect the quality of the needed clinical information. Thus, underlying any image quality metrology is an implied inherent risk of sub-optimal clinical image quality being recognized as a clinical risk. Such clinical risk is related to the achieved benefit of imaging reflected in the image quality. Clinical risk can be defined as "the risk associated with lowered diagnostic confidence in either the detection or quantification of the pathology of interest or affirmation of its absence, and the associated reduced likelihood of accurate interpretation leading to misdiagnosis" [20]. In either case, risk is defined based on the indication and the patient. The clinical risk can be defined as the reverse of the image quality for a specific task, for example, the confident detection of a renal stone, or a small, non-obstructive embolus in the pulmonary vasculature. As in radiation risk index, this clinical risk index serves as a closest reflection of actual clinical quality of an image for its intended clinical purpose. In the future, it may extend the clinical risk beyond misdiagnosis to mortality, year of life lost within the broader context of combinatorial risk from multiplicity of sources including the risk associated with the contrast medium, the risk of intervention, etc.

3.4. OVERALL PATIENT RISK

As described in Section 2.1, optimization in imaging can be framed as a balance in the two elements of risk in medical imaging, radiation risk and clinical risk.

When considering patient at the centre of the radiation exposure monitoring activity, image quality and dose are not isolated considerations, but both need to be incorporated in the overall goal of the imaging procedure as described in Ref. [20]: "safely obtaining useful information relevant to a target indication of interest for accurate and precise management of patient care". Thus, image quality and dose have to be balanced so as to provide an assurance that the goal of the imaging procedure is achieved. This includes the risk associated with the use of the ionizing radiation in the process, i.e., radiation risk, but also the clinical risk that is "the likelihood of not delivering the very purpose of imaging, i.e., delivering the desired benefit" [20]. Figure 5 offers a schematic illustration of optimization. Assuming the radiation risk follows the linear-no-threshold model, increasing dose will

increase the radiation risk to the patient. As the dose increases, it is expected that the image quality and associated information content improve, thus resulting in reduced 'clinical risk' of sub-optimal diagnosis. These two risk models follow reversing trends such that the total risk to the patient exhibits a minimum 'valley' of lowest net risk, which provides a target for the objective of optimization of overall risk. Comprehensive optimization of medical imaging needs to combine the radiation and clinical risks as a unified total risk estimate (or index) within an indication-informed process. In dealing with both radiation risk and clinical risk, optimization is characterized in a patient-centred manner.
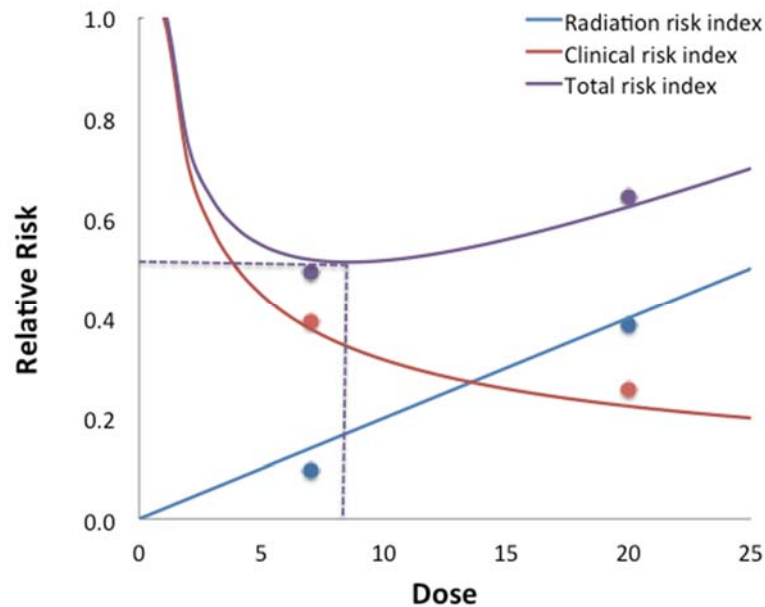
FIG. 5. Conceptual illustration of overall patient risk including radiation risk and clinical risk as a function of dose. Dashed lines represent the optimum target. Two examples of individual imaging procedures, each represented with three corresponding risk values, demonstrate different degree of accuracy in meeting the optimization target

The risks noted above are not the only ones that may be at play in the care of patients in clinical departments. Among these other risks, a notable one is associated with imaging examinations enhanced by the contrast media used in many imaging procedures for contrast enhancement for vascular, and or perfusion studies (volume and concentration). This implies two levels of risk, one is associated with the multiplicity of imaging series that is inherent in contrast imaging, thus exposing the patients to multiple irradiation events, and another is associated with increased nephrotoxicity. Some patient radiation exposure monitoring systems even offer enhanced functionality to manage contrast media dose alongside radiation dose. While the focus of this particular document is radiation dose, it is prudent to take all such sources of risk into consideration when aiming to minimize the total patient risk.

4. PATIENT RADIATION EXPOSURE MONITORING WORKFLOW

Patient radiation exposure monitoring includes different steps, the complexity and scope of which will vary depending on the available tools and resources (Fig. 6). These steps are briefly described here and further detailed in Sections 5, 6 and 7. Throughout these steps, the application of systematic and coherent examination classification and coding systems (Section 6.3) is crucial for the consistent application and comparability of patient radiation exposure data.

RECORDING
- Electronic recording of exposure data in standard objects (e.g. DICOM objects)
- Recording of single events in a unique object (DICOM Radiation Dose Structured Report, RDSR)
- Manual recording (handwriting when electronic means not available)

Storing
- Dose objects sent to an archive to be permanently stored

COLLECTING
- Collection of data from different dose objects (patients, X ray units/ modalities/ healthcare units/ regions/ countries/… according to specific schemes and templates, reflecting the purpose of data collection
- Manual collection when electronic means not available

Storing
- A selection of data stored for further purposes

ANALYSING AND REPORTING
- Statistical analysis (mean, median, ranges, quartiles,…)
- Trending analysis (per protocol, per size, per room,…)
- Tracking analysis (temporal changes,…)
- Population analysis (DRLs, collective doses, …)
- Comparisons
- …

Storing
- Results stored if needed
- Standard objects exist (i.e: DICOM Patient RDSR)

FIG. 6. Steps in the process of patient radiation exposure monitoring

4.1. RECORDING OF PATIENT RADIATION EXPOSURE DATA

As defined in Section 2.2, recording is a process of documenting patient exposure data manually or automatically.

Modern digital X rays based imaging modalities automatically export radiation exposure details in a standard format (e.g. DICOM objects) [103]. The system can record details for each irradiation event, defined as discrete or continuous irradiation applied to a patient, e.g., a CT topogram and the associated helical scan are two separate events as are two different presses of the fluoroscopy pedal in a fluoroscopy equipment. Typically, one dose object, e.g. a DICOM Radiation Dose Structured Report (RDSR) is created at the end of each procedure performed on the modality. That object collects all irradiation events from the procedure and also adds summary values of radiation exposure data. The details need to include patient demographics, study information, imaging technique and geometry and values of typical dose metrics.

Some imaging systems output dose values in non-DICOM formats (e.g. displayed dose reports). Such dose image objects are part of the same study as the images and can be submitted to an Image Manager/Archive in order to be permanently stored. Such objects can be integrated with automatic dose recording methods using optical character recognition (OCR) systems that extract numerical values from the objects into a database.

Some imaging systems do not output dose information in either DICOM or non-DICOM formats. For such systems, data recording of exposure information could be performed manually.

Further information on recording patient radiation exposure data is provided in Section 5.

4.2. COLLECTING PATIENT RADIATION EXPOSURE DATA

Collecting patient radiation exposure data is a process of gathering patient exposure data into a common system. The term can be used synonymously as recording and collecting together.

The recorded data are collected according to different schemes and structures that normally reflect the purpose of the collection. For example, collections may include data for specific facilities, modalities, equipment, examination types, and patients. Sub-samples of data can be stored, accordingly to the objectives of the follow-up analysis. A significant component of collecting is data classification into multiple categories. The collection can take place both digitally and manually in real-time or at specific time intervals as needed.

Further information on collecting patient radiation exposure data is provided in Section 6.

4.3. ANALYSING AND REPORTING PATIENT RADIATION EXPOSURE DATA

Analysing patient exposure data is a process of acting upon patient radiation exposure data to provide summaries with statistical, comparative and trend information, to be used for optimizing radiation protection and clinical practice, and to investigate and verify individual doses (incidental and cumulative values) when needed.

Collected data can be combined and processed to perform relevant dose analyses, which might include statistics, trending, tracking both the individual (e.g. organ dose, risk estimates) as well as collective stored data (e.g. typical dose values to compare to DRLs, collective dose to a population).

The results of these analysis can also be stored. Standard objects exist to store the results of detailed dose analysis performed for single individuals (i.e. DICOM Patient Radiation Dose Structured Report).

Although some of the steps can be manually fulfilled, the electronic recording, collecting and storing can automate and facilitate a purposeful analysis of patient radiation exposure data. In this case, these technological mechanisms have to follow a workflow, in order to provide an efficient collection and distribution of exposure information. Radiation Exposure Monitoring (REM) as developed by the Integrating the Healthcare Enterprise (IHE) provides a tool to allow patient radiation exposure monitoring using existing standard objects [104] (see Section 5.2.3).

Depending on the purpose of the analysis, the data may need to be reported to registries (local, national, or international), providers, insurance companies, authorities or patients.

Further information on analysing patient radiation exposure data is provided in Section 7.

5. RECORDING PATIENT RADIATION EXPOSURE DATA

5.1. PATIENT RADIATION EXPOSURE DATA TO BE RECORDED

Information about the dose to which a patient is exposed in an imaging procedure is represented by different quantities as denoted in Section 3. To enable more patient-oriented monitoring with an accurate estimation of the individual dose for a patient, patient data (e.g.: height, weight) as well as procedure data available from the equipment (e.g.: kVp, mA or mAs, filtration, geometry, …) are needed. The more data are available the more the estimation can be patient-oriented.

The information available from the imaging equipment varies depending on the manufacturer,

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the model, the year of production and installation, and the implementation. For this reason, there exists different levels of availability, depending on the purpose of data collection, such as quality control, DRL, personalized dosimetry. Adapted from a national guideline [105], three different levels can be defined as follows:

1) First level, or minimum requirements: At this level, the data are relevant to characterize the exposure and contain information that can be easily derived from the patient and examination records and values of dose quantities that the equipment can provide (calculated or measured). This level of information is appropriate for limited resourced countries with prevalence of manual data recording and collection.

2) Second level, or standard requirements: At this level, the data contain more detailed information. In particular, data for the single irradiation events are included for every modality. Scope of this set of data is to refine the exposure conditions in order to allow for optimization of imaging protocols, or to estimate dose metrics specific to an individual patient. The level of accuracy in the calculations depends on the amount of information collected.

3) Third level, or advanced requirements: At this level, the data are used for personalization and optimization of the imaging procedures. This includes calculated personalized dosimetric data such as organ doses and further details related to the procedure, such as reconstruction and post-processing settings, organ doses or relevant image quality metrics (see Section 3.3).

These three different levels are applied to each type of imaging modality (general radiography, mammography, CT, interventional and fluoroscopy, nuclear medicine, CBCT, dental), as well as to the information related to the patient. Examples are provided in the Appendix.

5.2.   METHODS OF RECORDING PATIENT RADIATION EXPOSURE DATA

5.2.1.   Automated versus manual data recording

In many countries recording and archiving of radiation exposure parameters is a legal obligation. This was the case even before electronic tools like Hospital Information Systems (HIS), Radiology Information Systems (RIS), Picture Archiving and Communication Systems (PACS) or software tools for dose monitoring were available. Hence, for many years, paper forms tailored to the examination and dose parameters of each modality were used. This procedure is time consuming to complete, and the validity of the results depends on the accuracy of data entry and subsequent data transfer sometimes affected by unreadable paper-based text entries, missing dose entries, too few or too many entered digits, sequence of images or series not fitting the sequence of dose parameters, the use of wrong characters and delimiters like letter "o" for number "0" or period for comma, and the use of wrong units like mGy for cGy.

While simple resources such as templates and spreadsheets will still be needed for data acquisition for some time into the foreseeable future, for the above reasons, electronic data recording and automated systems are to be preferred whenever available. The advent of RIS enabled the replacement of paper-based entry by keyboard entry with all advantages of storage and post processing, but still involved all the listed errors. Some of these errors can occur even in computer keyboard entry, which can be as high as 50% [106].

The advent of proprietary vendor interfaces, RIS, and the DICOM standard facilitated the electronic capturing of dose parameters with correct dose data and correct link between dose data and

exposed patient. In particular, there now exists DICOM and IHE standards that are used in the recording and collection of patient exposure data [103, 104]. A brief summary of these standards is provided below. In the IHE structure, the patient radiation exposure monitoring system is referred to as Radiation Dose Information Reporter System [107].

While exposure data recorded in DICOM and IHE standards can be transmitted to the PACS, this data access is not straightforward. Digital patient radiation exposure monitoring systems are now available which facilitate the establishment of databases as repositories of dosimetric data [108-114]. Alternatively, dosimetric data can be transmitted to a separate, stand-alone dose data archive intended to aid in radiation protection quality assurance and quality improvement [104].

5.2.2. Digital Imaging and Communications in Medicine (DICOM) standard

DICOM[2] has made multiple provisions for recording, as well as collecting and exchanging, radiation exposure information as detailed below.

5.2.2.1. DICOM Image headers

The exposure information in the image headers is kept together with the image data, it cannot be dissociated. Different data are stored depending on the modality and on the imaging system. Typically, the image header contains information about the acquisition techniques, acquisition geometry, and estimated radiation exposure quantities related to the creation of the image data stored in a series of images.

The positive aspect of this solution is that the dose information is stored persistently; it can be archived in PACS. However, a number of limitations make it not suitable for a complete, accurate and error-proof solution:

- There is no standard method to decouple the image itself from the exposure information. Therefore, to access and store the exposure information, it needs to be accompanied by the image data, resulting in vast increases in storage space and transmission time.
- When the images are not stored, no exposure data is stored. This may be the case when only fluoroscopy is performed and where the storage of the image data is optional. Further, if the images are deleted because they are not clinically relevant (e.g. patient movement, poor image quality), the exposure data will be deleted as well.
- When the images are duplicated (e.g. extra reconstructions, post-processing), the exposure data can be copied to the new images, thus leading to apparently more dose.
- The exposure information included with the image is only related to the irradiation event used directly to create the data in the accompanying image. For example, the information on the low-dose preimage exposure in digital mammography used by the automatic exposure control process to determine the correct acquisition technique is not included in the header of the resulting mammographic image.
- Missing complete exposure details. Even if the DICOM standard may evolve to add new exposure attributes, these will be optional. Therefore, private fields are common, and it involves a special relationship with the equipment vendor to obtain or interpret this private data.
- Large amount of data, because of the image data.
- For some modalities like X ray projection angiography, the coded anatomy information is not mandatory and thus rarely present, e.g., the Body Part Examined and Anatomic Region

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[2] DICOM (dicomstandard.org)

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Sequence fields are usually empty or absent in the image headers.

5.2.2.2. DICOM Modality Performed Procedure Step (MPPS)

MPPS is a DICOM message to notify the status of the examination from the modality to the RIS and/or PACS. The MPPS message is designed for workflow management; it is not stored persistently with the patient data objects. The MPPS message collects dose information of the whole procedure step independently from the storage of the image data. The information in the MPPS message includes a summary of the total dose and exposure time of the procedure step, average values of the acquisition techniques and system geometry, patient anatomy as well as some details for each exposure (including fluoroscopy) like the kVp, current, exposure time and filters used [112, 115, 116].

Recording exposure data through MPPS is advantageous to the image header approach as the exposure information is stored independent of the management of the image data, thus there is no missing or duplicated information. Yet, a number of limitations still make it non suitable for a complete, accurate, and error-proof solution: MPPS does not offer complete dose details and the information is transient and designed for workflow, not for persistent archiving. RIS/PACS can read the information of MPPS and store them in the database. However, there is no rule and no standard that indicates which information to be stored in the database. Moreover, MPPS is communicated once and can be lost if not captured. Finally, the dose module of the MPPS has been recently retired by DICOM, meaning that no future update in the content will be provided and the object will eventually become obsolete.

5.2.2.3. DICOM Radiation Dose Structured Report (RDSR)

The RDSR for projection X ray was added to the DICOM standard in 2005 as a non-image Information Object Definition (IOD) to address the limitations of other methods. The RDSR was developed to create a standardized format to record all the information related to the exposure parameters used for each irradiation event undergone by the patient, independent of the image data acquired or stored [117, 118]. Since its initial inclusion in the standard, specific templates have been added to include additional information needed to estimate patient dose with increasing accuracy in all modalities that use ionizing radiation, i.e. Projection X ray (plain X ray, CR, DR, angiography and fluoroscopy), CT, mammography, and radiopharmaceutical administration [118, 119]. The development of DICOM standards is continuous[3], and the implementation of the RDSR into new systems by manufacturers is ongoing.

In 2021 an enhanced RDSR was added to the standard that utilizes a generic framework for the description of radiation dose that does not involve the use of specific modality templates but retains the capability to store legacy dosimetric values (e.g., CTDI, DAP) [118]. This allows reduced dependence on modality-specific conditions for populating fields and provides a method to use the enhanced RDSR for new modalities without requiring changes to DICOM to handle the nuances in their production and acquisition methods. The enhanced RDSR also includes two fundamental concepts that were missing from the modality specific RDSR. These are:

1) Decoupling of irradiation events and dose descriptions allowing dose-related characteristics to span multiple irradiation events, or breaking irradiation events into smaller segments to better explain the changing irradiation characteristics. By recording the information in this manner, characteristics that remain constant (e.g., focal spot size) can be encoded once for the entire RDSR, while characteristics that change within irradiation events (e.g., tube current) can have multiple values encoded.

2) Improved geometric description of the system that defines the spatial relationship of different

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[3] Current official version of DICOM standards is available at https://www.dicomstandard.org/current

system components (e.g., X ray source, field size, filter size and locations) to allow modelling of the spatial distributions of dose.

The use of DICOM RDSR objects overcomes weaknesses of MPPS or image headers as dose monitoring methods. The SR templates provide far more complete and hierarchical details in a consistent format. Dose details are recorded for each irradiation event of an examination with associated exposure related information collected and combined together into summary dose values for the examination as a whole. Patient radiation exposure monitoring systems may re-organize the data at a higher or lower level of granularity.

The RDSR provides information on the parameters relevant to the X ray exposure output by the imaging system only and does not provide information on patient exposure metrics related to the specifics of the patient (See Section 3.2).

5.2.2.4. DICOM Patient Radiation Dose Structured Report (PRDSR)

The RDSR is a DICOM object used to convey exposure related information and dose indices. However, as explained in Ref. [120]:

"The RDSR contains only information about the irradiation system or information the system can determine, i.e., radiation output, geometry, X ray source, detector system, etc. Yet, it does not include sufficient information about the patient, which is required to adequately estimate the radiation dose to the patient. In addition, there are multiple methodologies and models that can be used to estimate patient dose and these methods are rapidly changing. Once an estimate of the radiation dose absorbed by a patient is performed, storing and transferring the method and the parameters used as well as the resulting dose estimate in a standard format will facilitate recording of such information."

To this purpose, and in response to the requirements or recommendations by professional, public-health and regulatory authorities for recording dosimetric information from diagnostic studies in the patient's medical records, a new object was added to the DICOM standard in 2017: the Patient Radiation Dose Structured Report (PRDSR) [118-120]. This new object contains the information concerning the recording of the estimated radiation organ doses to a patient, including the radiation source data, the calculation methods, the models and the parameters used in the estimation. This includes radiation dose from CT, projection X ray, angiography/fluoroscopy, and radiopharmaceutical administration (diagnostic and therapeutic). The PRDSR is meant to be independent of the images and the MPPS, and it could be routed to a patient radiation exposure monitoring system. This allows the flow and management of the dose data to be maintained separated and independent from the data flow and data management of images.

It is assumed that the best location for the PRDSR data would be to send this data to the patient radiation exposure monitoring system, a standalone system or actor (in the IHE sense), that may or may not be combined with a RIS, a PACS, or maybe a HIS.

5.2.2.5. DICOM Protocol Storage

The DICOM Protocol Storage (Fig. 7) has been introduced to provide a tool for the distribution of *planned* protocols (i.e., protocols defined at the equipment) and to record *performed* protocols (i.e., actual values used in a performed acquisition) [119, 121]. The details include patient preparation and positioning, equipment characteristics, acquisition technique, reconstruction technique, preliminary image processing such as filtering and enhancement.

The protocol object provides support for simple textual instructions relevant to the protocol such

as premedication and patient instructions. It also introduces a private tag dictionary to permit description of unique scanner model characteristics and system-specific features and settings.

The primary applications of this object include the following:
- Managing protocols within a site for consistency in terms of repeatable technique, performance, quality and image characteristics, and dose management;
- Recording protocol details for a performed study so the same or similar values can be used when performing follow-up or repeat studies, especially for oncology;
- Vendor troubleshooting image quality issues that may be due to poor protocol or technique;
- Distributing departmental, "best practice" or reference protocols to modality systems;
- Making more detailed protocol information available to rendering or processing applications which would allow them to select processing that corresponds to the acquisition protocol, to select parameters appropriate to the acquisition characteristics, and to select the right series to process/display;
- Recording and distributing clinical trial protocols to participating sites.

DICOM Storage Protocol is available only for certain DICOM objects (CT and angiography) [119]
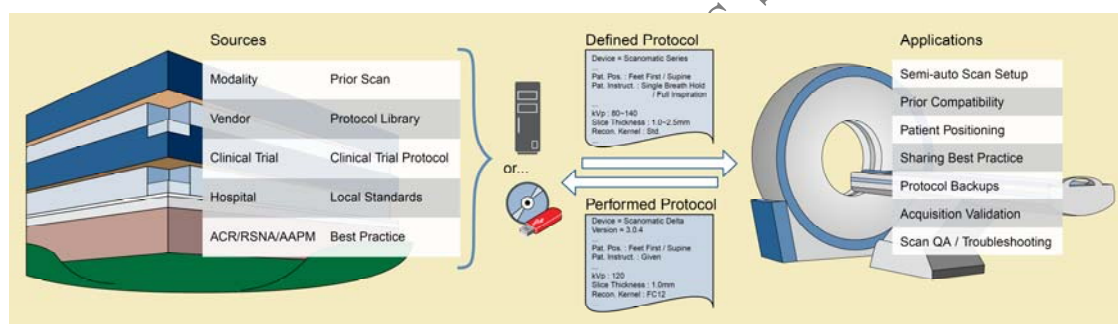
FIG. 7. DICOM Protocol Storage (reproduced with permission from DICOM Part 3, Figure AAAA.1.1-1. Protocol Storage Use Cases, © NEMA [119])

5.2.3. IHE Profile

The DICOM standard is vital to provide a common syntax and semantics for information exchange. Essentially, DICOM provides 'tools' and 'technologies'. However, the DICOM standard alone is insufficient: it may be open to interpretation, and some information remains optional, preventing a common implementation that guarantees interoperability for all the use cases and applications. There is a need for specifications about how to apply the standards to real-world scenarios.

IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information[4]. IHE promotes the coordinated use of established standards such as DICOM and Health Level Seven (HL7)[5] to address specific clinical need in support of optimal patient care. An IHE profile describes how to use existing standards to address a specific problem scenario, and thus serves as an implementation guide for vendors. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively.

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[4]https://www.ihe.net/
[5] http://www.hl7.org/

5.2.3.1. REM profile

The IHE profile that regulates the communication of the exposure data in X Ray imaging is the Radiation Exposure Monitoring (REM) Profile[6] [104]. As defined in Ref. [122],

"The REM profile specifies communications between systems generating reports of irradiation events (generally acquisition systems and workstations), and systems which receive, store, or process those reports (generally local dose information management systems and/or national/regional dose registries). It defines how DICOM RDSR objects "are created, stored, queried, retrieved, de-identified, and may be processed and displayed".

The REM profile facilitates the collection and distribution of the estimated patient radiation exposure information resulting from imaging procedures, including submission to local or centralized dose registries. Examples of such registries are given in Sections 6.1 and 7.

The REM Profile requires imaging modalities to export radiation exposure details in a standard format. Radiation dose monitoring systems can either query for these "*Dose objects*" periodically from an archive or receive them directly from the modalities. Here below are the actors involved in this profile, and their roles adapted from Ref. [107], see also Fig. 8 [122]:

Fig. 8. IHE Radiation Exposure Monitoring Profile (reproduced with permission from Ref. [122], Figure 22.1-1: Radiation Exposure Monitoring - Actor Diagram)

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[6] https://wiki.ihe.net/index.php/Radiation_Exposure_Monitoring

- *Acquisition Modality*: Creates and stores RDSR.
- *Image Manager/ Image Archive*: Accepts/Commits dose data and supports Query/Retrieve.
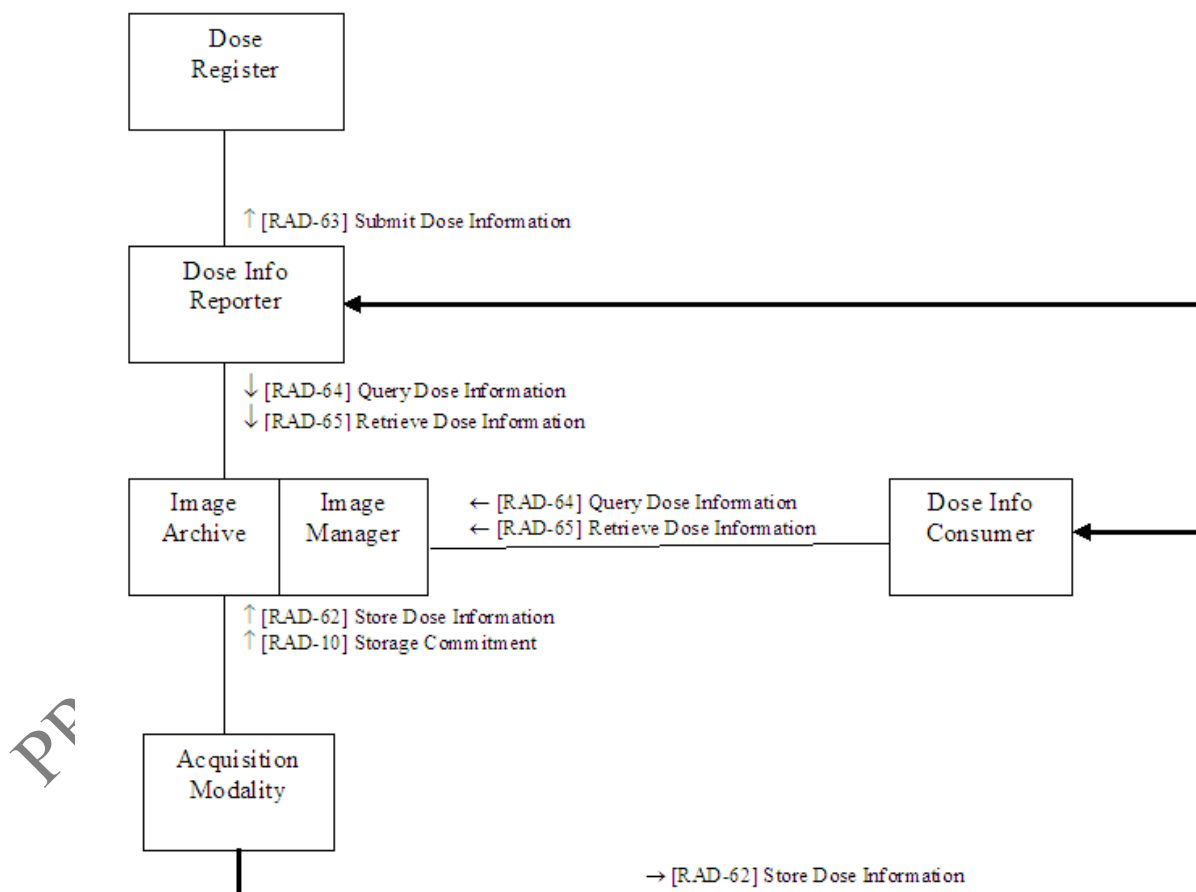- *Dose Information Consumer*: Responsible for supplemental handling of irradiation events, generally on an individual basis, e.g., display, analysis, or further processing.
- *Dose Information Reporter*: Responsible for the aggregation, analysis, reporting related to irradiation events, which may include meeting facility obligations to de-identify and submit data to various dose registries.
- *Dose Registry*: Collates information about irradiation events from a number of facilities, generally to perform analysis.

5.2.3.2. Workflow

Typically, irradiation events occur on the X ray based *Acquisition Modality*, which records them in *Dose objects* that are part of the same study as the images and stored to the *Image Manager/Image Archive*. In many organizations, a *Dose Information Reporter* will collect *Dose objects* covering a particular period (e.g., today, this week or last month), analyze them, compare to site policy, and generate summary reports. A *Dose Information Consumer* will perform real-time dose mapping and real-time alerting. In addition to composing *Dose objects* upon completion of a procedure step, the *Acquisition Modality* may also compose and send a *Dose object* upon completion of an irradiation event (quasi-real time). This mechanism is also called 'dose streaming'. Such objects could enable applications like dose mapping by a workstation during a procedure. The irradiation events will duplicate events reported in the Dose object for the procedure step.

The IHE REM profile describes how reporting systems can submit radiation dose reports to centralized registries such as those of professional societies, national accreditation groups, or national authorities. *Compliant Dose Information Reporters* are capable of de-identifying and submitting dose reports to a national dose register over Secure FTP, making it relatively simple for groups to collect and process dose data from participating sites. Such data collection may also be undertaken for clinical trials to record and collect dose and image data. These utilities are currently not commonly used because national registries are not yet common. Further, the utility of capturing cumulative radiation exposure, which such registries may offer, has not been fully established. For comparison purposes, a harmonized nomenclature (naming of radiological examinations and procedures) is needed, both locally and nationally (see Section 6.3).

5.2.3.3. Implementation

The IHE REM Profile provides effective shorthand for sites to use in purchase specifications. Sites with programmes to monitor patient radiation exposure have to review the IHE REM profile for applicability to their goals, and consider requiring compliance with the profile in future purchases and upgrades using language such as "The system shall support the IHE REM Profile as the Acquisition Modality actor." Vendors can respond with their IHE Integration Statement.

The IHE REM profile addresses the efficient collection and distribution of dose information. It is, however, just a tool. A radiation exposure management programme that defines the policies and procedures for radiation safety and dose management remains, appropriately, the responsibility of the imaging facility. Site medical physicists and radiological medical professionals responsible for imaging procedures have to work with their dose reporting system vendor to discuss how to best analyse the data and format the reports so as to meet the needs of their dose management policy and plans, as well as to

ensure quality of data (see Section 8.3).

The profile removes data collection and management burdens, but it does not define such policies, reports, or processing. It is up to the imaging facility to put the information to use.

5.2.3.4. Other IHE profiles

The IHE Radiation Exposure Monitoring for Nuclear Medicine (REM-NM) Profile[7] addresses dose reporting for imaging procedures in nuclear medicine, including Single Photon Emission Computed Tomography (SPECT) and Positron Emission Tomography (PET).

The REM-NM Profile is based on the REM Profile with few key differences. The first is the use of DICOM Radiopharmaceutical Radiation Dose Structured Report (RRDSR) instead of DICOM X Ray RDSR. The system that creates RRDSRs is a *Radiopharmaceutical Activity Supplier*, typically a system in the 'hot lab' that prepares the dose to be administered to a patient before the procedure. Like other DICOM objects, RRDSR dose objects are created, stored, queried, retrieved, de-identified, and may be processed or archived. The imaging modality such as SPECT or PET is expected to retrieve the dose report, use the details in decay corrections and copy relevant details into the headers of generated images.

The IHE Management of Acquisition Protocols (MAP) Profile[8] supports the collection of scan protocols from imaging modalities, their periodic review and approval and re-distribution to imaging modalities. The transactions are based on storage, query and retrieval of DICOM objects containing scan procedure protocols and protocol approvals. MAP Profile helps monitor imaging acquisition protocols in use, detect variants, and achieve consistent use of optimized protocol. Currently, MAP Profile includes DICOM Storage Protocols (planned and performed) for CT and angiography.

The recently added IHE Contrast Administration Management (CAM) Profile[9] records details for the administration of contrast agents for imaging and image-guided procedures. It is intended to provide the necessary infrastructure for reporting and analysis, such as investigating adverse events or driving regular QA processes. The profile standardizes storage, query, and retrieval of Imaging Agent Administration Structure Report (IAASR) instances, which are DICOM objects containing details of a planned or performed administration of imaging agents, such as radiopaque contrast, in the context of an imaging procedure. The transactions are intentionally analogous to the IHE REM Profile.

6. COLLECTION OF PATIENT RADIATION EXPOSURE DATA

Once patient radiation exposure data is recorded, they need to be collected into databases and repositories for systematic analysis. The collection of the data may be done for the purpose of examining an individual or a population exposure.

In population-based patient exposure data analysis, a key issue is the definition of the patient cohort. A patient cohort can be defined based on the characteristics of the patients, for example paediatric patients of a specific age or weight group, or adults of specific size range. It may also be based on the specificity of the examination, facility, location, or other such specifications. For example, a cohort can represent all abdominal CT examinations or all portable chest X ray examinations at a particular facility or a particular working shift. The specification of the cohort may also be based on the

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[7] https://wiki.ihe.net/index.php/Radiation_Exposure_Monitoring_for_Nuclear_Medicine

[8] https://wiki.ihe.net/index.php/Management_of_Acquisition_Protocols

[9] https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_Suppl_CAM_Rev1-1_TI_2021-04-30.pdf

combination of the attributes of both the patient and the examination. The precise specification of the cohort calls for classification of examinations and procedures (Sections 6.2 and 6.3).

The conclusions drawn from cohort-based analysis will be specific to the chosen cohort. This makes a priori selection of a cohort a pre-eminent consideration in monitoring patient exposure data. As such, cohort-based data collection needs to be informed by the questions of interest.

6.1. TECHNIQUES FOR COLLECTING PATIENT RADIATION EXPOSURE DATA

The collection of patient radiation exposure data occurs at different levels. At the first level, the recorded patient radiation exposure data are collected locally (e.g., inside a given hospital, or radiology department). The data are then classified according to desired purposes. At the second level, the classified data are collected for the purpose of regional, national, or international analyses.

Local data collection can be done manually, but it is recommended to be automated by means of digital patient radiation exposure monitoring systems. As explained in Section 5.2.2, the dissemination of the DICOM standard enables the use of different standard objects to store dosimetric data in the PACS thus allowing for further data collection, analysis, or processing. Exposure data recorded in DICOM standards can be transmitted to the PACS. Currently, digital patient radiation exposure monitoring systems are available which facilitate the establishment of databases as repositories of dosimetric data [108-112]. Alternatively, dosimetric data can be transmitted to a separate, stand-alone dose data archive intended to aid in radiation protection quality assurance and quality improvement (as foreseen in the IHE REM profile).

At the second level of data collection, typical examples of national and international data collections are mostly to establish national DRLs (Section 7.1) or to make national or global estimates of the collective dose to population (Section 7.4). For these purposes, the development of patient radiation exposure monitoring systems will allow the building of large dose registers with reliable data. For example, the UK now has a system whereby dosimetric data collected by medical physicists in hospitals throughout the UK are sent to Public Health England for collation and analysis [123]. The Australian Radiation Protection and Nuclear Safety Agency provides a web portal for reporting doses from facilities (collected either manually or electronically) and comparing to the national DRLs[10]. Similar web-based dose reporting platforms are used in other countries [124-126]. The American College of Radiology's (ACR) Dose Index Registry[11] has used fully automated methods to collect data from CT examinations [127].

The patient radiation exposure monitoring systems will provide a helpful tool for optimization of imaging procedures, as well as for fulfilling legal requirements such as dose reporting to authorities, or for the purposes of clinical audits or to meet international or national requirements to identify unintended overexposures. As discussed in Section 5.2.3, IHE standard workflow ensures interoperability among modalities, PACS, dose monitoring systems and even national archives.

Despite the availability of the automatic patient radiation exposure monitoring systems, data collection for national or international purposes in most cases still relies on manual or semi-manual methods: the patient exposure data is typically inserted into specific templates or Excel files, which are then transmitted to the organization responsible for the collection either electronically or directly with web-based collection templates. The templates provide a necessary way of sorting and organizing the large number of data points and enable efficient starting point for data analysis and reporting.

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[10] https://www.arpansa.gov.au/research-and-expertise/surveys/national-diagnostic-reference-level-service
[11] https://www.acr.org/Practice-Management-Quality-Informatics/Registries/Dose-Index-Registry

6.2. DEFINITION OF THE PATIENT EXPOSURE DATA COHORT

Data collection and analysis involve an explicit definition of a category/ cohort of patient exposure data. Such a definition enables the effective use of the data for patient dose determination and comparisons, setting and use of DRLs, setting and use of referral guidelines and decision support systems, and procedural optimization, along with other purposes outlined in Section 7.

Figure 9 offers an illustration of the classification approach.
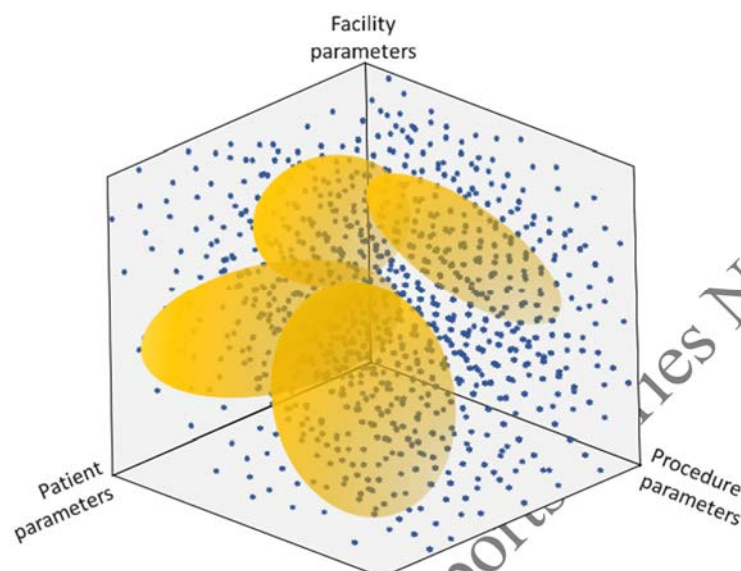
FIG. 9. A schematic illustration of classification and cohorting of patient exposure data for a given modality. Each individual star datapoint represents a whole or a part of a patient examination. The overlapping circles represent classifications based on specific imaging system, procedure and patient conditions.

The pool of the patient exposure data can be recognized as samples across a wide range of continuous and discrete operational and patient parameters. These fall into three categories:

1) *Procedure parameters*: These include the modality (e.g. radiography, CT), the procedure (e.g., chest radiography, abdominal CT), sub-procedure (e.g., arterial or venous phase series, PA or lateral view), the indication targeted for the examination (e.g., ascertaining the presence and attributes of liver lesions), and the complexity of procedure. The latter is particularly relevant to interventional radiology and cardiology to differentiate the level of difficulty in carrying out the procedures in terms of time and techniques (e.g. number of projections, number of arteries involved, number of stents). This complexity typically correlates with the total patient dose: higher complexity usually means higher dose [4, 128-131]. A coding is implied in the examination definition and execution. See more on procedure classification in the next section.

2) *Patient parameters*: These include the patient type (e.g., adult, paediatric, inpatient, outpatient, emergency patients), and patient characteristics (e.g., gender, age, weight, body mass index, diameter, percentile categories based on any particular attribute).

3) *Facility parameters*: These include specific imaging system used to acquire the images (make and model, software version), the room used to perform the examination, the timing of the examination (e.g., morning or evening shift, or all images in the first quarter of the year), the

radiological facility in which the examination is performed, the medical radiation technologist[12] performing the examination, and the specific imaging protocol invoked in the data acquisition.

The patient exposure data can be classified into specific categories based on the combination of any of the associated parameters. For example, one may identify all abdominal adult CT images within a one year period, or narrow the categorization further down to a narrower range of time (e.g., one month), or patient weight (70-90 kg), or examination room. The definition of the category has to be informed by the purpose of the subsequent analysis, the statistical power of the resultant comparison, and by the anticipated dependency of the extracted patient exposure data with respect to its governing parameters, again informed by the planned analysis.

Imaging examinations have a different frequency depending on the prominence and role of the examination and the population distribution. Therefore, cohort-based patient radiation exposure monitoring is subject to variable statistical power. The cohorts need to be carefully defined to enable solid conclusions. For example, if a cohort is defined across all patients regardless of modality or examination type, the resultant analysis would have very limited utility, considering the broad range of data present in that cohort. In contrast, drawing conclusions about an infrequently performed procedure might be impossible unless the data can be collected over a long period of time to provide for sufficient statistical power. This is a particular challenge in paediatric imaging, which is generally performed less frequently. For example, narrowing down the category to head CT of 5-year old paediatric patients within a one month period in a single examination room would likely provide very small number of datapoints to offer any statistically significant comparisons.

For characterizing a cohort, the sample size needs to be at least 20-30 procedures (patients) provided that the classification is sufficiently narrowly defined (e.g., one X ray room, an agreed clinical indication, standard size patients). This minimum sample size provides a 20% confidence interval at a 95% level of confidence. A larger sample size will provide a higher degree of precision (a sample size of 100 procedures (patients) reduces the confidence interval to 10%). The larger the variability in the metric being examined, the larger the sample size needs to be. This is reflected in the latest recommendations for establishing DRLs [17, 132, 133].

A given patient examination can take different identity depending on the cohort in which it is being associated. As such, each examination can be thought as having different associated tags, any of which can be claimed in a cohort definition. For example, an examination can be tagged as a chest examination as well as a paediatric examination, so that it can be included in multiple cohorts for associated analyses. Sometimes different imaging protocols may be used for the same clinical indication, or different indications use similar protocols. This may be taken advantage of for the purpose of cohort definitions.

In terms of the anticipated dependency of the extracted exposure data with respect to its governing parameters, the patient size is of notable importance. The reason is the well-established relationship between patient size, exposure, and resultant image quality. Attenuation of the X ray beam depends on the amount of tissue the beam has to penetrate, thus leading to different levels of patient dose to obtain the same image quality. Therefore, comparisons need to take size into consideration. Comparisons are meaningful when made within the same size categories. For example, adults usually vary in weight by a factor of 4 (40 – 160 kg bodyweight). Paediatric patients vary in size more dramatically, from premature babies (e.g., 300 – 400 g) to obese adolescents (> 80 kg body weight) representing a factor

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[12] GSR Part 3 [16] defines medical radiation technologist as "a health professional, with specialist education and training in medical radiation technology, competent to perform radiological procedures, on delegation from the radiological medical practitioner, in one or more of the specialties of medical radiation technology".

of more than 200. To facilitate meaningful benchmarking and comparisons, several weight and age grouping have recently been recommended [132, 133] (Table 3).

TABLE 3. APPROXIMATE EQUIVALENCE OF WEIGHT AND AGE GROUPS FOR THE PURPOSE OF COMPARING WEIGHT-BASED DRLs WITH AGE-BASED DRLs. Adapted from Ref. [133].

Description	Weight group	Age group based on weight-for-age charts	Most common age groups used for the NDRLs (or equivalent)
Neonate	< 5 kg	< 1 m	0 y
Infant, toddler and early childhood	5 - < 15 kg	1 m – < 4 y	1 y
Middle childhood	15 - < 30 kg	4 – < 10 y	5 y
Early adolescence	30 - < 50 kg	10 – < 14 y	10 y
Late adolescence	50 - < 80 kg	14 – < 18 y	15 y

In terms of categorization, the influence of size on exposure parameters needs to be taken into consideration. For example, CTDI is expected to change as a function of patient weight but not as much as a function of patient height while DLP is affected by both patient weight and height. Sub-examination categories have to be further considered. For example, in multi-phase CT, the DLP of a CT examination is more influenced by the number of phases of the acquisitions then by the attributes of the patient. In two-view chest radiographs, the lateral view commands 2-10 times more exposure than the frontal view. The categorizations and trend analysis take these dependencies and sub-examination conditions into consideration.

6.3. CLASSIFICATION OF MEDICAL RADIOLOGICAL PROCEDURES

6.3.1. General features of classification and coding systems for medical procedures

Patient exposure data collection and analysis is dependent on the effective use of a procedure classification system. The most detailed classification systems involve a mechanism for harmonized nomenclature for radiological examinations and procedures. Lack of a good classification framework can lead to inconsistencies in examination and protocol nomenclature, affecting dose data integrity. The nomenclature inconsistencies can be magnified when comparing radiation doses across institutions and nationally or internationally. Detailed specification is needed to allow meaningful comparison of truly similar examinations or procedures conducted for similar purpose and requiring similar technique. Classification is also essential to enable the optimization of procedures (Section 7.1). It is for these reasons that the patient radiation exposure monitoring needs to include a systematic data classification mechanism, ideally along with a validation process of the classification accuracy.

A large variety of classification systems have been introduced in various countries and internationally. There is little harmonization between these systems, in particular with regard to the most detailed classification through established nomenclature and coding systems. As an example, Fig. 10 presents significant variation in the number of examination codes reviewed in European countries [134, 135].
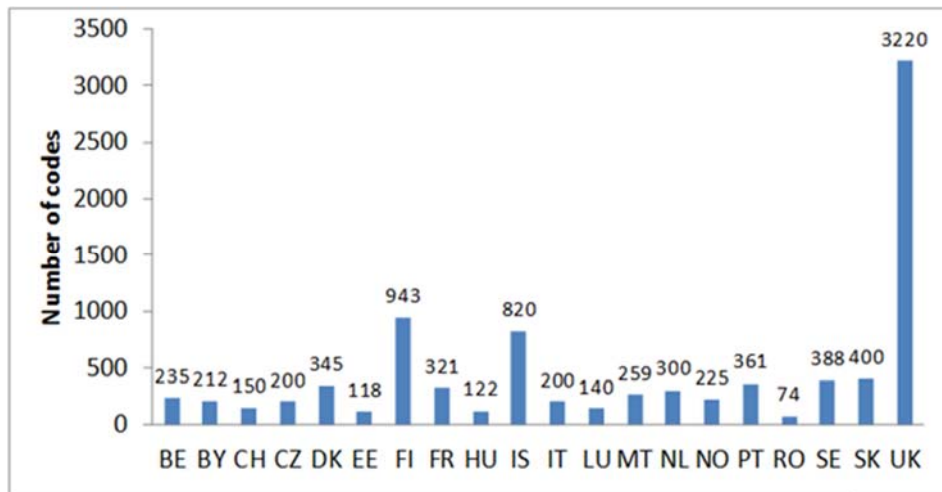
FIG. 10. Number of X ray examination classifications/codes in European countries (reproduced from Ref. [135] with permission).

In addition to the variation between the classification and coding systems, the imaging procedures are often interpreted and labelled differently, not only between institutions, but also within a single institution. Even the basic definition of what constitutes one 'examination' is not always clear. One recommended approach could be to use the following definition proposed by the EC [134]:

"An X ray examination or interventional procedure is defined as one or a series of X ray exposures of one anatomical region/organ/organ system, using a single imaging modality (i.e. radiography/ fluoroscopy or CT), needed to answer a specific diagnostic problem or clinical question, during one visit to the radiology department, hospital or clinic."

An ideal classification system will distinguish the following main attributes:
- Modality (e.g. CT, fluoroscopy);
- Population (adult, paediatric group);
- Body region;
- Anatomic area;
- Clinical indication (reason for examination);
- Technique;
- Radiopharmaceutical (in nuclear medicine);
- View.

6.3.2. Practical examples of classification and coding systems for medical procedures

There are a variety of classification and coding systems for medical procedures for different purposes (e.g., billing, referrals). The most detailed and systematic coding approaches like the RadLex Playbook in the USA[13] are recommendable for the overall future development of radiology information systems. Further, the development of indication-based classification systems have to take due considerations of the international standard for reporting diseases and health conditions, established by the WHO[14].

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[13] http://playbook.radlex.org/playbook/SearchRadlexAction
[14] https://www.who.int/standards/classifications/classification-of-diseases

Classification systems in broader categories are still needed for many practical purposes, for example for estimations of population dose (see section 7.4). For the latter, a categorization of specific radiological examinations systems was developed by the EC [134, 135] and used by UNSCEAR in its Global Survey on Medical Exposure[15] , which offers a relative compact and manageable approach for large scale national or global patient exposure data management.

6.3.2.1. RadLex Playbook and ACR Common

The RadLex Playbook is a project of the Radiological Society of North America (RSNA), aimed at providing a standard set of nomenclature for examination protocols, based on the elements defining an imaging examination such as modality and body part. RadLex Playbook codes have been harmonized with the radiology portion of the LOINC standard codes[16], leading to the LOINC-RSNA Radiology Playbook.. The RadLex Playbook is a part of a larger consolidation of categorization effort by the ACR called ACR Common[17] (including SNOMED[18], Current Procedural Terminology (CPT)[19], and International Classification of Diseases (ICD)[20] classes). It is a set of standardized codes and names that can replace or complement legacy procedure codes and names in systems that track imaging procedures, including PACS, RIS, reporting applications, physician order entry systems and electronic medical records. RadLex Playbook addresses imaging examinations as radiology 'orderables', which are studies a referring medical practitioner can request through an order entry system. Depending on institutional practice, orderables may be more general than the full description of the examination actually performed. For example, the orderable "CT abdomen/pelvis with contrast" is more general than the examination actually performed, "CT abdomen/pelvis with contrast, liver protocol".

Institutions are expected to map their protocol names to the RadLex Playbook, facilitating radiation dose comparisons across institutions. Implementing a new set of procedure names is likely to involve collaboration between site staff with knowledge of local needs and practices and vendors or consultants with knowledge of systems capabilities. While representing a big step forward, this solution is incomplete since it relies on the mapping being performed consistently across all institutions.

6.3.2.2. Classification system used in the European studies of population dose

While not as comprehensive as a coding system, related to the population dose estimations, the European guidelines in Ref. [134] proposed a common approach for categorizing the examinations, so that the frequencies may be compared between countries. Three optional methods to estimate population dose were proposed, namely based on:
- 225 specific examination types (based on clinical indications);
- 72 broader categories of examinations;
- TOP20: List of 20 examinations recognized to be the most important for the total population dose.

Only the first two methods give a direct assessment of the total population dose, while the last one (TOP20) can be used for a rough estimation due to the need to extrapolate to cover all types of examination. The examinations or categories are systemized according to the four modalities: plain radiography, radiography and fluoroscopy, CT, and interventional procedures. In addition, the list of examinations or categories is sorted according to regions of the body or organ system (Table 4). For

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[15] http://www.survey.unscear.org/lib/exe/fetch.php/unscear_medical_exposure_survey_manual_v2.pdf
[16] https://loinc.org/collaboration/rsna/
[17] https://www.acr.org/Practice-Management-Quality-Informatics/Informatics/Terminology
[18] https://www.snomed.org/snomed-international/who-we-are
[19] https://www.ama-assn.org/amaone/cpt-current-procedural-terminology
[20] https://www.who.int/standards/classifications/classification-of-diseases

more details of using the system for population dose estimation, see Section 7.4.

TABLE 4. THE NUMBER OF SPECIFIC EXAMINATIONS AND CATEGORIES OF EXAMINATIONS ACCORDING TO THE METHODOLOGY OF REF. [132]

Imaging modality	Examinations or categories of examinations
Plain radiography (from Table 2 of Ref [134])	72 specific examinations – 27 categories of examinations Regions of body: head, neck, chest/thorax, abdomen, pelvis, limbs, trunk, head&trunk, teeth&gums, breast
Radiography & fluoroscopy (from Table 3 of Ref [134])	57 specific examinations – 17 categories of examinations Regions of body: gastrointestinal tract, biliary tract, urogenital tract, spinal cord, joints, angiography, lymphangiography
Computed tomography (from Table 4 of Ref [134])	52 specific examinations – 18 categories of examinations Regions of body: head, neck, chest, abdomen, pelvis, neck+chest+abdomen, chest+abdomen, abdomen+pelvis, chest+abdomen+pelvis, limbs
Interventional procedures (from Table 5 of Ref [134])	38 specific examinations – 10 categories of examinations Regions of body: head & neck, chest, abdomen, pelvis, limbs

6.3.2.3. UNSCEAR classification system

UNSCEAR has regularly provided information on medical exposure since its first report in 1958 [21]. However, since its 1988 report, UNSCEAR has attempted to estimate global exposure rather than simply presenting country-specific data [1, 2, 22-24]. For its latest survey, UNSCEAR prepared, in cooperation with the World Health Organization (WHO), a survey questionnaire and distributed it to all Member States of the United Nations. The surveys aimed to acquire data on medical exposure following a predefined classification of radiological examinations and nuclear medicine procedures.

For its present purpose of periodic reviews of the survey on global medical exposure to ionizing radiation, UNSCEAR uses four general categories of medical practice involving exposure to ionizing radiation: diagnostic radiology, image-guided interventional radiology, nuclear medicine, and radiation therapy. Doses from radiation therapy are not included in the global estimates of population doses, but are considered in trend analyses) [2]. The first category is further classified in three sub-categories: projection radiography (without contrast media), radiography and fluoroscopy (mostly with contrast media) and CT. For each main category, 9-19 sub-groups (total 62) have been defined for data reporting and collection, with "other (please specify)" used as the last category in each main group. The sub-groups are roughly similar to the 72 broader categories defined by the EC and presented in Table 4 [134].

Independent from the classification used, for the projection radiology it has to always be made clear whether dental procedures are included or not. Further, UNSCEAR recommends national or regional surveys of medical exposure to include, where possible, information on age and sex distribution of the major types of examination. In particular, estimations of collective dose to paediatric patients and a framework for evaluating the uncertainties of the estimates are needed.

7. ANALYSING PATIENT RADIATION EXPOSURE DATA

The patient exposure data, casted into relevant metrics, once recorded and collected, are analysed towards tangible benefits. This document details these analyses towards four specific goals described in Section 2:

a) Ensuring optimised radiation protection and consistent practice of medical imaging;
b) Ensuring safe and precise imaging of individual patients;
c) Supporting the process of justification and appropriateness;
d) Providing information on collective dose to population from different sources of medical exposure;

This section highlights specific analytical considerations, with the understanding that additional interrogations of the data can be sought based on the goals and objectives of the user. These may include additional operational goals beyond optimization of protection such as workflow optimisation, billing, and image exchange, topics that are not the focus of this particular report.

7.1. OPTIMISATION OF PROTECTION AND PRACTICE CONSISTENCY

Patient exposure data can be used to optimize radiation protection, ascertain variability and improve operational consistency across clinical operation. Among sources of variability are those across and within imaging systems, across time, across facilities, and across operators. The examinations are considered collectively for a particular clinical indication (such as CT abdomen in relation to liver metastases), rather than simply broad categories based on just anatomical region (such as CT abdomen) (Section 6.2). Factors that affect variability include acquisition parameters (e.g., kVp, mA, table height, magnitude of over or under scan, etc), patient positioning, imaging system, patient attributes (e.g., patient size, indication, and the level of difficulty). Any and all of these involved quantitative attributes can be audited through the patient radiation exposure monitoring to ascertain whether or not examination values (dose values or image quality) are within expected ranges. The results are used to reduce variability across the imaging operation, a hallmark of quality patient care.

Sections below detail some of the analyses for optimization of protection and practice.

7.1.1. Diagnostic reference levels and typical values

The utilization of the DRL concept is a mechanism for optimisation of protection through management of exposure values for groups of patients [16, 17]. The DRLs are established based on 75th percentile of data relevant to a chosen cohort collected in several facilities, locally, nationally, or internationally (in a region) [132]. A "typical value" is likewise defined in terms of dose (i.e., typical dose), or typical administered activity in nuclear medicine, as the median value of patient dose parameters distribution for that cohort in a facility. Comparing typical values with corresponding DRLs determines how a clinical imaging procedure is positioned in reference to a broader standard.

The terminology recommended by the ICRP and definitions are summarised in Table 5, adapted from Ref. [132].

It is essential that the typical values and DRLs apply to similar specifications of the cohort and that the data is recorded and collected in the framework of patient exposure data specifications using the patient dose metrics recommended for each imaging modality. Essential elements of the cohort specifications include the class (or code) of the procedure (the clinical description), preferably based on clinical indications (clinical tasks is the term used by ICRP), and appropriate grouping of patients in accordance with age, size, or weight, as noted in Section 6.2. The clinical indications need to correspond

with the definitions by the national medical professional societies and health authorities. Examples of classification of procedures based on clinical indications for establishing DRLs and typical values for CT is given in Refs. [136-140]. Recently, the European project EUCLID defined ten clinical indications for setting DRLs in CT and four for DRLs in interventional radiology [141].

TABLE 5. TYPICAL VALUES AND TYPES OF DIAGNOSTIC REFERENCE LEVELS (DRLs), METHODS OF DERIVATION, AND AREAS OF APPLICATION, ADAPTED FROM REF. [132]

Term	Area and facilities surveyed	Method of derivation	Application
Typical value	Healthcare facility consisting of several X ray rooms or a small number of facilities or single facility linked to a new technique	Median value of the distribution, as there are insufficient data to use the third quartile	Local use to identify X ray units requiring further optimisation
Local DRL	X-ray rooms within a few healthcare facilities (e.g. with at least 10–20 X ray rooms) in a local area	Third quartile of median values for individual X ray rooms	Local use to identify X ray units requiring further optimisation
National DRL	Representative selection of facilities covering an entire country	Third quartile of median values for individual X ray rooms or of national values	Nationwide to identify X ray facilities where optimisation is needed
Regional DRL	Several countries within one continent	Median values of distributions of national values or 75th percentile of distribution for representative selection of healthcare facilities throughout the region	Countries within region without a relevant DRL or for which national DRL is higher than regional value

For interventional procedures, it is convenient to specify the complexity of the procedures [4, 128-131] (see Section 6.2). Initially, three bands of complexity (low, medium and high complexity) could be used. If complexity is not evaluated and reported, it may be supposed that the collected data correspond to medium complexity.

In collecting patient radiation exposure data to establish or to use the DRLs, likewise in daily imaging practices, there has to be a system in place to judge whether image quality (or diagnostic information when many images are used) is adequate for the diagnosis according to the indication of the examination. This could be based on image quality assessment of typical test cases by several radiologists, or by automated image quality metrics noted in Section 3.3.

7.1.1.1. Establishing DRLs

As shown in Table 5, ICRP defines three different types of DRL: national, local and regional.

National DRL for a given cohort is established by collecting and analysing patient radiation exposure data for a representative sample of imaging examinations from different healthcare facilities in the whole country. National DRL is determined from the third quartile of the distribution of median values obtained from different health care facilities [17, 132]. Figure 1 offers an example of how the distribution of median exposure values across institutions is used to establish the DRL.
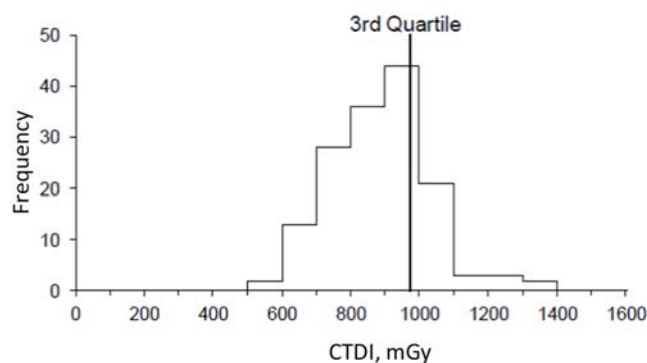
FIG 11. Comparison of DLP distribution values for setting DRL for head CT

To establish a local DRL for a given cohort, patient radiation exposure data from a few imaging rooms in a few local healthcare facilities need to be collected and analysed. The local DRL is determined from the third quartile of the distribution of median values obtained in these imaging rooms in a few healthcare facilities. As stated in Ref [132], "Local DRLs may be set for procedures for which no national DRL is available, or where there is a national value but local equipment or techniques have enabled a greater degree of optimisation to be achieved so that a value less than the corresponding national DRL can be implemented".

Different healthcare facilities (e.g., public and private hospitals, outpatient centres, small clinics) and different levels of existing imaging technology have to be included in the surveys to collect patient radiation exposure data. Each of the healthcare facilities has to guarantee the quality of the exposure data, including appropriate correction or calibration factors (see Section 8.3) and the use of the agreed radiation quantities and units, whether the data is used locally or sent to the national organisation in charge to set the national DRLs. Automated data collection is recommended whenever available (Sections 5.2.1 and 6.1).

For interventional procedures, ICRP recommends the use of the full set of available data from different healthcare facilities when available [132]. For paediatric patients, the use of a smaller number of minimum cases per cohort might be unavoidable considering the difficulty of having enough patients of different weights and sizes; the recent EC guidelines [133] recommend that the sample size to be at least 10 patients per procedure type and per patient group for non-complex examinations such as radiography and CT and at least 20 patients per procedure type and per patient group for complex procedures such as fluoroscopy and fluoroscopically guided procedures. The problem of small statistics may be addressed with the use of a DRL curve [142]. When automated systems are available to collect dosimetric data, samples for both adult and paediatric patients could ideally be much larger than the above minimums.

In course of time, updates of DRLs and regular comparisons of typical values with DRLs will provide a useful database to enable versatile analysis and comparisons of trends in patient doses and the impact of optimization programmes on patient dose levels. ICRP recommends intervals of no longer than 3-5 years for this update depending on the changes in technology and post processing. Automatic patient radiation exposure monitoring systems facilitate more frequent and regular updating of DRLs.

7.1.1.2. Comparing typical values with DRLs

Typical values are median values of the dose distribution for the given cohort, e.g., from a single X ray room or a small sample of X ray rooms [132]. The typical values have to be periodically determined, at least once a year, and compared with relevant local and/or national DRLs. If such DRLs are not available, typical values can be still used for comparison with published data or between different

facilities. An automated registry can highly facilitate frequent comparisons not only in terms of the typical values (medians) but the whole dose distribution, as shown in Fig. 12 [143].
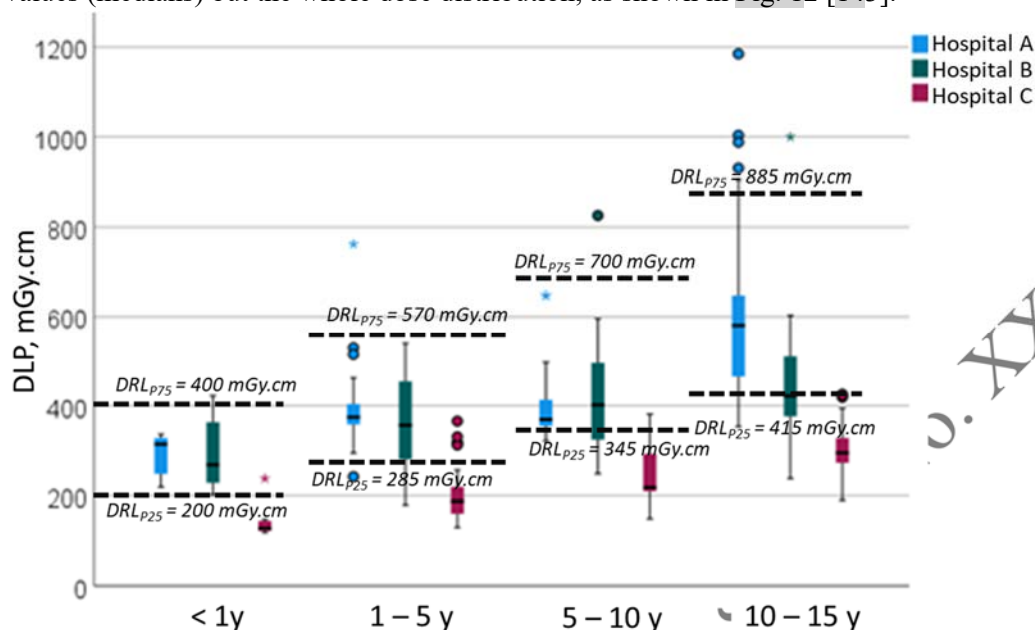
Fig. 12. A box plot of the dose length product (DLP) of paediatric head CT procedures for four age groups in three hospitals (A, B, C), compared to the national DRL range (25th-75th percentile). (courtesy of F. Zanca, Palindromo Consulting, Belgium)

The comparison of typical dose values with DRLs is made based on statistical significance of differences for like-sized patients. Whenever the DRLs are statistically consistently exceeded, appropriate investigations need to be conducted, without undue delay, to identify the reasons. If differences are deemed unjustified and corrections feasible and necessary, corrective actions have to be taken to improve the clinical practice. As with all such interventions to the practice, the process needs to be documented and tracked.

For more information on DRL establishment and use, refer to Ref. [17] and [132]. Practical examples are given in the IAEA e-learning module on DRLs[21].

7.1.2. Protocol- and size-specific dose boundary range

As a mechanism to improve practice consistency in a particular X ray system or gamma camera, the full set of exposure data can be used to define meaningful operational exposure levels for a given acquisition protocol as a function of patient size. An example of this strategy for CT is demonstrated in Fig. 13. Dividing the patients into four size groups (in this case using the effective diameter), the minimum and maximum target levels for patient dose value can be established based on 5th and 95th percentile data, so-called protocol- and patient size-specific boundary range of an exposure quantity of interest [113]. This data can be used in the protocol definitions and guidelines for medical radiation technologist to improve examination consistency across an operation. Note that using dose boundary range, as in the case of any dose-based guidance, the dose is optimized based on existing dose ranges in the facility and not on targeted image quality (which would be an ideal approach).

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[21] https://elearning.iaea.org/m2/course/view.php?id=628
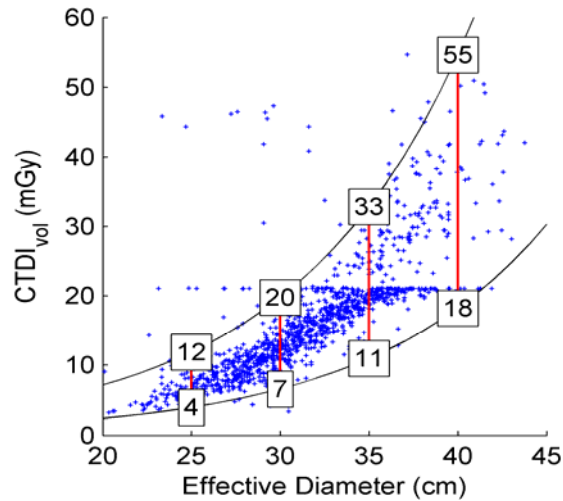
Fig. 13. An example of protocol- and size-specific dose boundary range based on the existing examination profile at an institution to provide guidance during image acquisition (reproduced with permission from [113])

7.1.3. Consistency analyses

DRL- or typical values-based analysis described in Section 7.1.1 minimizes the likelihood of overexposure by benchmarking doses to singular values (i.e., 75th and 50th percentile). However, it is possible that two similar imaging systems performing the same examination or procedure produce the same 75th percentile dose values, and thus judged equivalent in terms of adherence to DRL, but obviously the operation offering a tighter distribution would be superior as it offers less variability of dose across individual patients. Such variability, or the tightness of the dose distribution, can be characterized in terms of a spread range based on the 25-75th percentile range of the data within a cohort. Narrower the spread range, more superior would be the overall operation. The spread range can further be compared and benchmarked against corresponding data from national/reference data. In this way, the patient radiation exposure monitoring can be used towards improved consistency across systems.

There are many factors that lead to broadening the dose distribution. One example is the imaging system variability. An imaging operation would ideally offer consistent performance independent of the imaging system or conditions used. However, in facilities with different systems, this is hard to achieve. Figure 14 provides an example of the stratification of data across fluoroscopy systems of different makes and models. The spread range of the data for a particular cohort is characterized and compared.

FIG. 14. Variability in air kerma at patient reference point across multiple fluoroscopy systems (K1 – K5). The boxes represent the 25th to 75th percentiles of dose values (spread range), and whiskers the 5-95% range (courtesy of E. Samei, Duke Medical Center, USA)

The above analysis can further be performed on stratified data based on patient size. In modern CT, different systems have different ATCM strategies to adjust the radiation exposure to patient size. Figure 15 illustrates how the ATCM algorithm behaves for the same CT protocol for three CT systems. In this case, the proto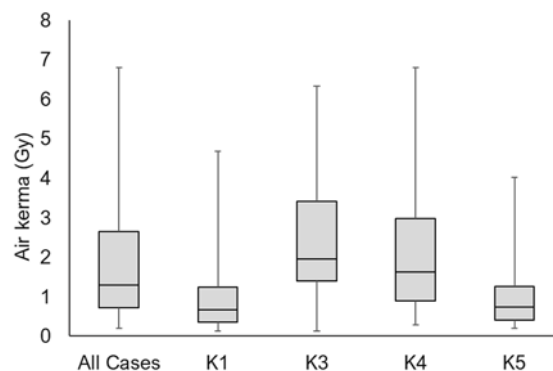cols deliver roughly the same $CTDI_{vol}$ for the median patient size (31 cm), however, the $CTDI_{vol}$ differs substantially for the large patients due to the differences in the ATCM algorithms. Therefore, $CTDI_{vol}$ changes with the patient size in a system-dependent manner. This dependency, characterized through the dose monitoring program, can be used as a basis from which to adjust system-based protocols via different ATCM setting for different patient sizes to achieve a higher level of consistency across systems and models.
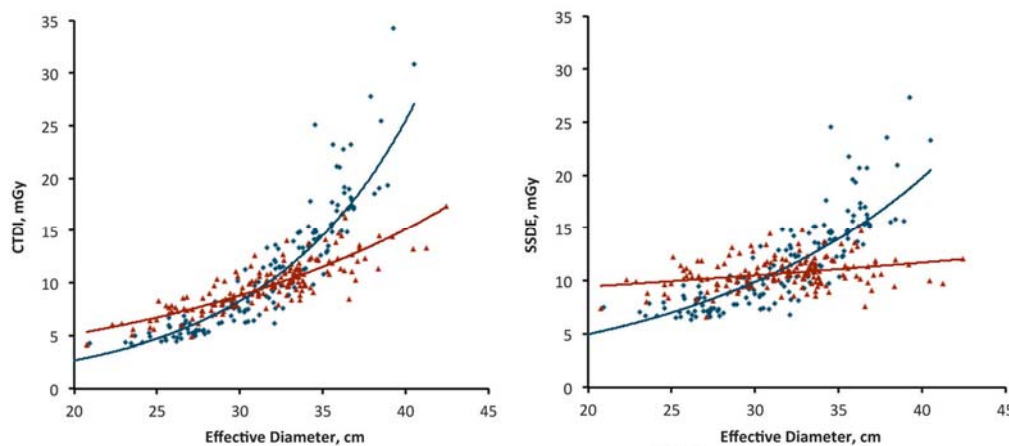
FIG. 15. Variation in dose across two different CT systems (represented in different datapoint-lines) for the chest-abdomen-pelvis examinations. In this case, the protocols deliver roughly the same $CTDI_{vol}$ and SSDE for the median patient size (31 cm); however, the $CTDI_{vol}$ and SSDE differ substantially for the very large and small patients due to the differences in the AEC algorithms. Note that regardless of whether $CTDI_{vol}$ or SSDE is used, dose metrics change as function of patient size. (reproduced with permission from Ref. [113])

The consistency assessment and optimisation would ideally be applied not only to dose metrics but also other factors of relevance to imaging practice namely image quality. Figure 16 illustrates the application of assessment and application of spread range to image noise values as a function of patient size and scanner type. Such data can be used to reduce variability of examinations across different makes and models of CT systems [144].

Consistency analyses might also take place as a function of time. Valuable information can be gained in the clinical operation by analysing trends in the dose data over both short and long periods of time. Short-term trends, like differences in radiation dose as a function of time of day, reveal differences in how imaging examinations are administered between shifts. Long-term dose trends can aid in evaluating the overall efforts of the facility to work toward optimizing patient exposure. The tracking statistics can focus on radiological procedures (irrespective of dose quantities) to ascertain changes in the frequency of different radiological examinations (Section 7.14). Further, this tracking can also be used to estimate values and trends of collective dose to population using typical value of dose per examination.

The tracking analysis, when applied to dose quantities within cohorts helps in establishing DRLs, typical values, spread ranges, and boundary ranges over time, further facilitating inter and intra institution comparisons. Such data, generally anonymized, contribute to patient dose registries. Such registries facilitate comparing one's own facility doses in any examination with dose with other facilities, thus promoting optimization.

(a)	(b)
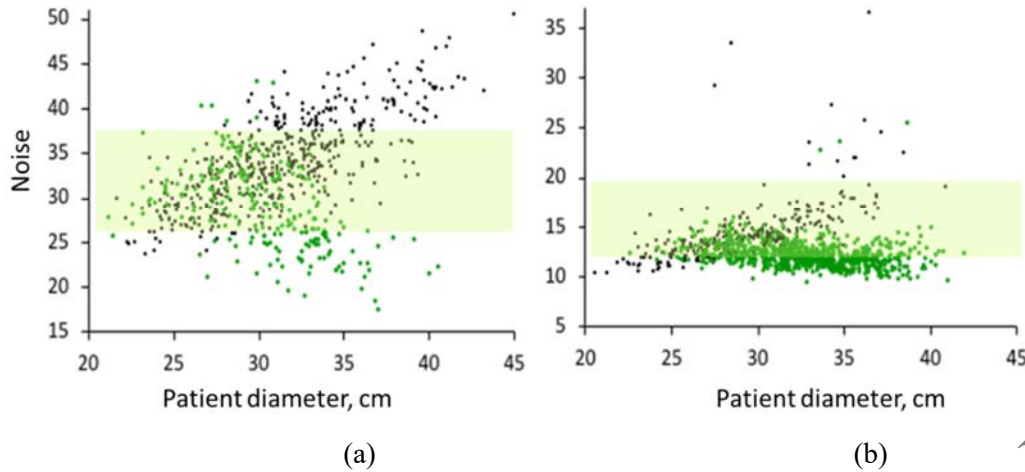
FIG. 16. Patient-based noise in abdominal (a) and chest (b) CT examinations across patients imaged by two different CT scanner models. Measuring noise for each imaging case demonstrates the variability of noise across patients, patient sizes, protocols, and scanners, enabling optimizing the examinations to output consistent image quality through protocol-specific ranges of acceptability, the shaded areas. For example, the points below spread range (shaded areas) represent lower noise than necessary. These cases would have been acquired with higher dose (reproduced with permission from Ref. [113])

One use of tracking analysis is in ascertaining changes in imaging protocols, as well as in evaluations for purchases of new equipment based on how much they may minimize radiation dose. Figure 17 shows the SSDE to a 32 cm patient, based on an exponential relationship between SSDE and patient size, for standard chest examinations on a commercial CT system over time. A protocol change was made in which the order of the posterior-anterior and lateral localizer images was swapped in December. As this particular system uses the last-acquired localizer to determine the tube current modulation, there was some concern that this protocol change could alter the delivered radiation dose. These data illustrate that there was no negative impact on patient exposure as a result of the protocol change.
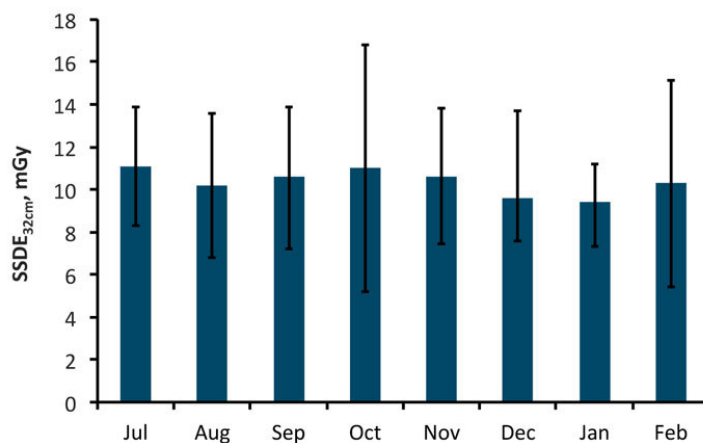
FIG. 17. Trends in SSDE over time for evaluating protocol changes. The SSDE shown is that to a 32 cm patient over time. The protocol change for standard chest examinations took place in December and had no statistically significant impact on patient dose levels. The error bars are based on the uncertainty in the exponential fit between SSDE and effective diameter. They represent one standard deviation in the expected SSDE for a 32 cm patient (reproduced with permission from Ref. [113])

7.1.4. Tracking frequency of equipment utilization

An indirect yet valuable use of patient radiation exposure monitoring is to ascertain the most frequently performed examinations. Figure 18 demonstrates an example. Such analysis would have obvious value for operational oversight and planning beyond radiation dose, but it also provides crucial information to identify protocols that are most frequently performed as well as those delivering the highest patient exposure, so that resources for protocol oversight and optimization can be directed towards protocols with highest relevance for population and individual exposures. Analyses can also include patient load, system utilization, and examination lengths.
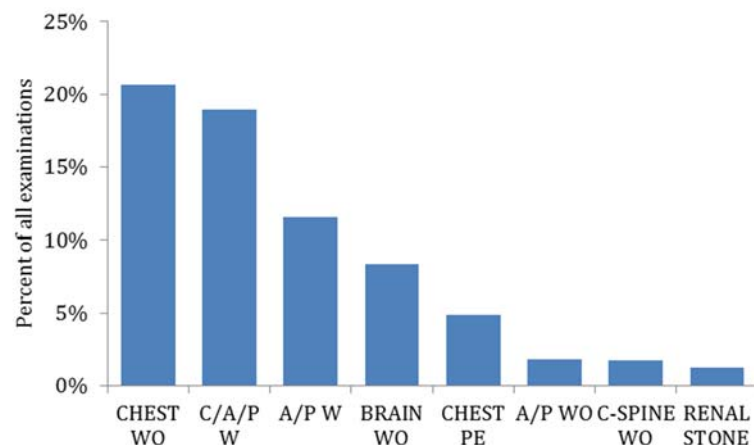
FIG. 18. Frequency of the most common CT examinations performed at one institution (Chest WO = Chest examination without contrast, C/A/P W = Chest abdomen pelvis examination with contrast, A/P W = Abdomen pelvis examination with contrast, Brian WO = Brain examination without contrast, Chest PE = Chest pulmonary embolism examination, A/P WO = Abdomen pelvis examination without contrast, C-spine WO = Cervical spine examination without contrast, Renal stone = Renal stone examination) (courtesy of E. Samei, Duke Medical Center, USA)

7.1.5. Protocol discrepancy and optimization

The protocol applied in an imaging examination has to ideally match what was prescribed. Patient radiation exposure monitoring, apart from exposure as an outcome, provides a window into the applied protocol and enables an interrogation of whether the applied protocol matches the prescription. This is not to claim that the applied protocol has to always match that of the prescription. There are instances when an adaption is necessary in order to accommodate a particular examination condition. For example, for a bariatric patient undergoing CT, a higher exposure is necessary. If the mA is set to the maximum value, the rotation time needs to be lengthened to provide the necessary exposure. However, such adaptations might not be applied correctly or consistently, or a justifiably modified protocol for an individual patient might accidentally be saved as the default protocol on the system. By comparing the doses delivered to patients against an expected value based on the documented protocol definition, such instances can be identified and corrected.

Figure 19 shows the dose relationship with patient size for the abdomen-pelvis protocol before and after initiating a protocol review on a CT scanner [113]. Investigation revealed that the primary cause of over-exposures was a software error in which changes in patient orientation (i.e., the supine rather than prone position) caused the tube current modulation to be deactivated. After training the medical radiation technologists to be aware of this problem and providing dose boundary ranges (see Fig. 13) to verify that the correct CTDI was used prior to imaging the patient, the frequency and magnitude of over-exposures were dramatically reduced (see Fig. 19b).

(a) *(b)*
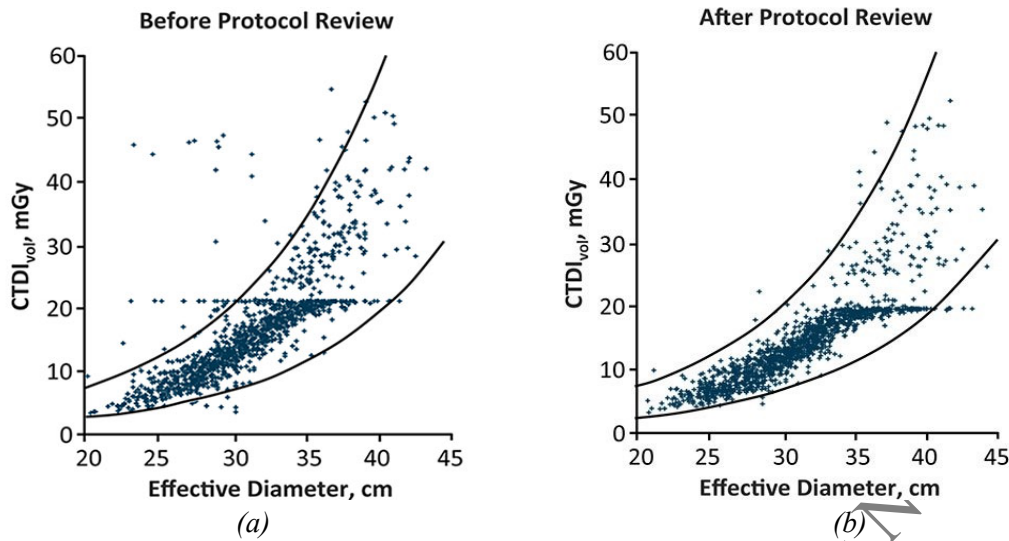
FIG. 19. Identifying and investigating outliers reduces the number of over-exposures. CTDI before (a) and after (b) a protocol review. Educating the medical radiation technologist on the primary causes of over-exposures and providing size-specific boundary ranges reduced the number of individual over-exposures. The frequency of outliers fell from 5.0% to 1.8%. The magnitude of the difference between the outliers and the reference levels fell from 50.0% to 10.8% (reproduced with permission from Ref. [113])

Figure 20 illustrates a comparison across scanners demonstrating how protocol review processes enabled a more consistent patient exposure across the clinical operation using the spread range concept (Section 7.1.3).

(a) *(b)*
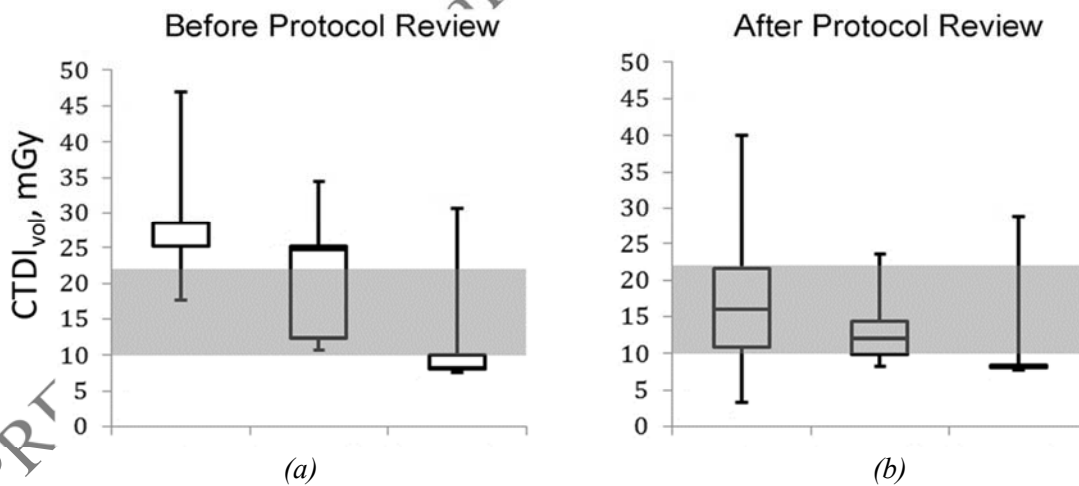
FIG. 20. Pulmonary embolism protocol before (a) and after (b) protocol review. The shadowed area represents the 25th to 75th percentiles of targeted dose levels (SR) based on national data. The three columns in each figure represent three different scanner models (courtesy of E. Samei, Duke Medical Center, USA)

7.2. INDIVIUAL PATIENT EXPOSURE ANALYSIS

The prior section focused on protection and practice optimisation across cohorts of patients. In contrast, individual patient exposure analysis focuses on radiation exposure and tracking of relevant metrics of patient examination to ensure safe and high-fidelity imaging of individual patients.

7.2.1. Setting and using trigger and alert levels

At the individual level, the priority for a patient radiation exposure monitoring is to analyse the data in terms of dose alert level and trigger level values. Alert levels have been introduced to give a warning if an individual patient exposure value has exceeded a particular threshold level. Likewise, a trigger level denotes a level above which a patient exposure needs follow up investigation, [17, 145-150]. Alert levels and trigger levels are mostly based on the avoidance of tissue reactions (deterministic effects) to radiation (e.g., skin reaction), sometimes provided by national standards. Alert levels and trigger levels are of particular relevance to interventional procedures but have also been used across other modalities. The IAEA Safety in Radiological Procedures (SAFRAD) database uses a set of trigger levels for patient follow-up in fluoroscopy guided interventional procedures[22].

In this analysis, the examination data of individual patients are evaluated in terms of their conformance with alert levels and trigger levels and appropriate warnings and alerts are generated (e.g., via emails) for follow-up actions. The system may also provide provision to set and adjust alert levels and trigger levels per user preference.

7.2.2. Outlier identification

Investigation of individual examinations is needed to identify outliers in the distribution of exposure parameters. The interest here lies solely in incidental values of modality-specific exposure metrics. Tracking the dose history of a patient, i.e. determining the cumulative dose to a patient will be addressed in Section 7.2.5.

The analysis of alert and trigger levels provide the assurance that the exposure values are well below the threshold for tissue reactions. But even at lower values, patient radiation exposure data can be used to identify individual examination outliers or mis-exposure cases, i.e., patient dose values which are exceptionally high (i.e. because any exposure has an associated stochastic risk) or low (i.e. because this might compromise image quality). Towards this purpose, an acceptable 'inlier' dose range can be defined, based on 5th and 95th percentile data (the boundary range defined in Section 7.1.2). The outlier will then be individual examinations where their associated quantity falls outside of the protocol- and patient size-specific inlier range. In terms of dose, those cases can be identified as either over- or under-exposure. Such cases need to be investigated to ascertain and correct root causes of their deviation so as to improve the consistency and quality of the imaging operation.

It is crucial to ensure that the boundary ranges are defined per protocol and per patient size (Fig. 21). A too-broadly defined cohort (e.g., all abdominal CT examinations) does not offer sufficient granularity to ascertain if a particular case is an outlier. The appropriateness of a dose level is a strong function of the anatomical region and the clinical indication.

In the outlier identification, the under-exposure cases are as important as the over-exposure ones. A dose that is too low to provide sufficient diagnostic information unnecessarily exposes a patient for the sake of questionable medical benefit. This further highlights the need that awareness and characterization of about image quality is essential to ascertain the appropriateness of a patient radiation

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[22] See www.iaea.org/resources/rpop/resources/databases-and-learning-systems/safrad

exposure.

Quantifying and sorting the outliers in terms of their deviation from the expected value enables the most significant outliers to be investigated and acted upon first. The expected value is the typical value of a metric appropriate for the examination. In cases where the expected value is dependent on patient size, the typical level for that size will be used (e.g., the regression line in Fig. 21b). Otherwise, where there is no such dependency (e.g., fluoroscopic time), the typical value of that quantity, irrespective of the patient size, will serve as the expected value.

(a)   (b)
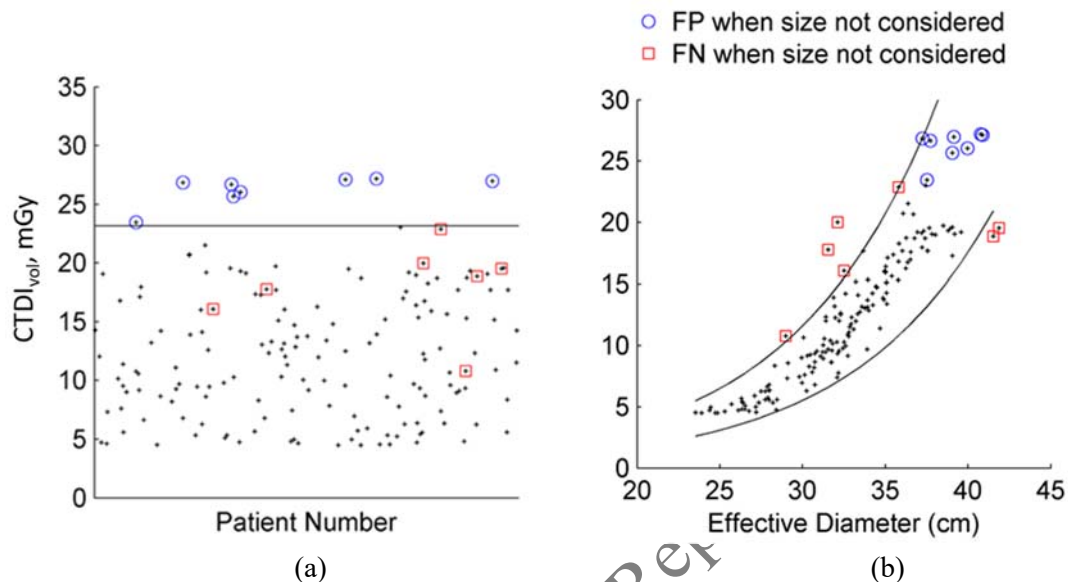
Fig. 21. CTDI$_{vol}$ per patient number (a) and patient size (b). The circles indicate cases where the CTDI$_{vol}$ was justified given the patient size. The squares indicate cases where an inappropriate CTDI$_{vol}$ was used given the patient size. FP: false positive, FN: false negative (positive: recognized as outlier; negative: not recognized as outlier) (reproduced with permission from Ref. [113])

7.2.3. Special patients

Some examinations such as imaging of pregnant women involve special attention to radiation exposure. If pregnancy is known prior to an exposure, the case has to be flagged for easier identification and further analysis. Following relevant regulations or guidelines [17, 147, 148, 151-153] a graded approach to estimate the uterus/fetus dose is to be undertaken. Exposures where the uterus was not in the field of view are normally not critical. In case of direct uterus/fetus exposure and high dose procedures above 20-50 mSv, a medical physics consultation is recommended. In addition, in high dose procedures an additional dosimetry at the level of the uterus has to be considered. The same measures as above need to be undertaken in case of a pregnancy was identified after the examination.

Additional patient groups, such as paediatric patients (i.e. premature newborns, neonates, infants and children), and those with higher sensitivity to radiation, the patient radiation exposure monitoring can be used to closely monitor their exposure levels and use that information for optimization purposes with closer consideration of patient size and age.

7.2.4. Unintended and accidental exposures

Unintended medical exposures (e.g., wrong patient, wrong body part, wrong view, wrong imaging protocol, duplicated examinations) are rare events and in most cases the result of human communication errors. Some of these errors can be revealed by patient radiation exposure monitoring

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programmes, and facilitated by automatic monitoring systems. The types of unintended and accidental exposure that can be identified include duplicated examinations, examinations with excessively high or low exposure values, examinations with discrepancies in the number of series or views, and examinations in which the recorded patient exposure data includes wrong protocol.

All these unintended exposures (real events but also near misses) have to be recorded or flagged, worked on by all involved professionals, reported within the institution and to authorities according to national requirements and finally, corrective actions implemented whenever needed [17, 147, 148]. Ideally, the patient radiation exposure monitoring system needs to have provisions to enable timely and comprehensive reporting of all unintended events. Many hospitals or institutions have introduced incidence reporting systems to handle such events.

7.2.5. Tracking patient exposure history

Tracking implies analysis of radiation exposure data for an individual patient over time. Tracking for individual patients can be applied to radiological procedures, listing various radiological examinations an individual patient has undergone, or to cumulative patient dose associated with the examinations [154, 155]. The Joint Position Statement[23] by the IAEA with six other international and professional bodies encourages the use of patient exposure tracking and indicates its potential benefits.

Although exposure tracking can be applied in any settings, the process is highly facilitated by automatic patient radiation exposure monitoring systems implemented at a level of facility (e.g. hospital), multi-facility level, national or even international level. The IAEA, through its SmartCard project[24], provided templates for exposure tracking and models for its proper utilization [156, 157]. Exposure tracking involves patient identifiers within and across facilities, either through individual patient identifiers or codes ascribed to deidentified patients. There are other aspects that need to be considered, e.g. data privacy, which are further discussed in Section 8.

7.2.5.1. Tracking of radiological procedures

Tracking of radiological procedures of individual patients is useful for individual patient protection as it provides clinical information that can avoid performing redundant radiological examinations. Paragraph 3.15(e) of GSR Part 3 [16] requires consideration of previous examinations in the justification of an individual medical exposure. SSG-46 [17] further recommends the results (images and reports) of previous examinations to be made available, not only at a given radiology facility but also for consultation at different facilities to assist in the justification process. Avoiding an unnecessary examination provides 100% dose reduction even without consideration of dose from previous examinations.

A first step, which might applicable in countries with less resources, is to encourage patients to keep records of their examinations in a simple document, examples of which are provided by Image Gently[25] and Image Wisely[26]. Such a document, accompanied with information about procedures and related risks, would create awareness that is needed as a first step in the process [157]. Electronic health records that include information about radiological procedures are a better solution for exposure tracking.

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[23] https://www.iaea.org/sites/default/files/documents/rpop/iaea-smart-card-position-statement.pdf

[24] https://www.iaea.org/resources/rpop/resources/smart-card

[25] https://www.imagegently.org/Roles-What-can-I-do/Parent

[26] https://www.imagewisely.org/-/media/Image-Wisely/Files/Patient-Medical-Imaging-History.pdf

7.2.5.2. Tracking of patient dose

There is no common consensus about tracking radiation dose across all radiological examinations of patients, even though recently published Joint Position Statement of the IAEA with eight other organizations[27] emphasized the need for including in the automatic patient radiation exposure monitoring system provision for tracking of exposure history of individual patients in one or more of the following more generic metrics: type of radiological procedure, estimated effective dose or patient-specific organ dose estimates, and encouraged researchers and the industry to refine standardized and reliable approaches for dose estimates while accounting for the uncertainties of these estimates.

Cumulative radiation dose is useful in radiation protection of patients undergoing recurrent imaging procedures. This is based on the fact that radiation risk has a cumulative effect and repeated exposures multiply the risk.

For an imaging procedures with potential for tissue reactions, such as prolonged interventional procedures, knowledge of cumulative dose to the skin from previous procedures can be a factor when planning the proper timing of the next procedure and its optimization, as well as for patient's follow up for potential tissue reactions [112, 145, 146].

For an individual imaging procedure with potential for stochastic effects, each examination adds an incremental risk. Justification for that examination needs to be primarily based on a benefit-risk consideration for that particular examination. Even so, the patient's prior radiation history and the knowledge of his/her cumulative exposure have to be taken into account but not override the net benefit of the examination under consideration. In that way, while no dose limit applies to patient exposure, the knowledge of cumulative dose would add the process of individual justification based on the particularity of the case. This can also play a role in the optimisation of the entire patient care.

As an example, one particular patient group that has to be noted is neonates. Premature neonates and neonates in intensive care units often receive tens to hundreds of radiographs [158]. There are also other groups of patients with long-term illnesses and clinical conditions that involve recurrent imaging in acute or chronic settings [19, 159, 160]. When a series of imaging procedures can be reasonably foreseen for a patient, the most appropriate procedures for the patient and the clinical condition need to be chosen, weighing their frequency and cumulative benefits and risks. As far as reasonably practicable, clinical and radiation dose information from the patient's previous imaging procedures needs to be made available to help strengthen the appropriate decision-making process[27] [161].

Knowledge of patient's exposure history plays role also in optimization. Some situations requiring recurrent imaging might entail lesser radiation exposure than other examinations of the same anatomical region but in other clinical contexts [96, 162]. Thus, in patient-centric care, including cumulative dose in the appropriate metric as a standard part of a patient's medical record will help provide a holistic reflection of the overall quality and safety of patient's care while also encouraging physician's awareness of patient's radiation protection.

Modality-specific metrics (e.g., KAP, CTDI, DAP) are not appropriate for dose cumulation. Cumulative radiation dose has to be stated in terms of patient-oriented metrics of dose (e.g., organ dose, effective dose, or other radiation risk estimate) (see Section 3.2). Estimated values from different procedures are added together. Further standardisation is needed of the methods for these estimates. It is also important that modality-specific measurable dose metrics and relevant exposure data associated with the imaging procedure are always recorded so that organ doses and effective dose can be calculated as required using the most recent methodology [53]. Special consideration needs to be given to the uncertainty in the estimates and their appropriate interpretation and use.

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[27] https://www.iaea.org/resources/article/joint-position-statement-and-call-for-action-for-strengthening-radiation-protection-of-patients-undergoing-recurrent-radiological-imaging-procedures

7.3. SUPPORTING THE PROCESS OF JUSTIFICATION AND APPROPRIATENESS

Paragraph 3.158 of GSR Part 3 [16] requires referral guidelines to be used for justification of imaging procedures. Referral guidelines or appropriateness criteria include generic information on typical patient doses for standard patients and have been developed in many countries. The referring medical practitioner (referring physician) needs up-to-date information on the patient doses expected in imaging procedures in reference to referral guidelines. Information about radiation dose can help the referring medical practitioner to order the most appropriate examination. For this purpose, effective dose is an appropriate quantity to provide information on magnitudes of doses and associated risks from different procedures [53]. Patient radiation exposure monitoring system can provide up-to-date information on typical effective dose values.

Clinical decision support (CDS) electronic tools have become available during the last decade and they provide meaningful way to improve the justification process [163]. CDS in imaging is a process designed to aid directly in clinical decision making, in which characteristics of individual patients (e.g. symptoms, results of physical examinations, suspected diagnosis, laboratory results) are used to suggest the most appropriate examination(s). CDS tools also offer an ideal way of providing training for referring physicians, and the systems can even be used to check and monitor learning through the consistency between the recommended selections and actual practices.

The maximum benefit of CDS and automatic patient radiation exposure monitoring systems would be achieved by integrating them with the overall healthcare electronic systems. There are however many legislative, logistic and technical aspects to be considered as further discussed in Section 8.5. Such an integration enables easy follow-up of the implementation of the justification in clinical practice, and also updating of the relevant information such as typical patient doses. The selectable types of examination and procedures need to be specified as clearly and unambiguously as possible, within the framework of classification introduced in Section 6.3.

7.4. POPULATION DOSE ESTIMATIONS

The development of the patient radiation exposure monitoring systems will greatly facilitate the estimation of collective population dose (most relevantly quantified in terms of effective dose), both at a country level and globally. Such estimations are important to enable follow-up of trends, to make comparisons between examinations and between countries, to identify the relative importance of specified examinations and procedures to the overall population dose, and consequently, to prioritize and focus efforts and resources in radiation protection.

An example of the typical pie chart on the relative contributions resulting from population dose estimations is shown in Fig. 22 [2].
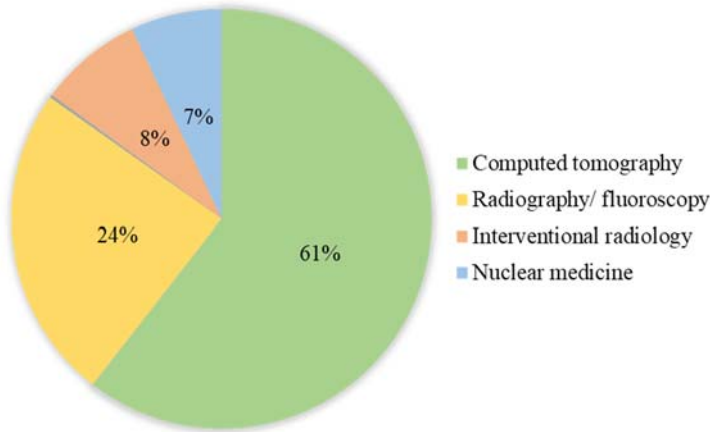
FIG. 22. Relative contributions of the four main groups to the overall collective effective dose (based on data from Ref. [2])

When data are available, the total number of X ray examinations performed annually in the study regions (whole world, country, hospital district etc) can be computed as:

$$N = \sum_{i,j} N_{i,j},$$ (1)

where $N_{i,j}$ is the annual number of examinations of type i carried out in region j and the summation includes all regions and types of examination. Similarly, the population dose of the regions from diagnostic radiology, in person-Sv, is given by

$$S = \sum_{i,j} N_{i,j} E_{i,j} / 1000,$$ (2)

where $E_{i,j}$ is the typical effective dose (mSv) for examination i in region j,
and the per caput dose in the regions (for population P of the regions), in mSv, is given by

$$E_{per\ caput} = \frac{S}{P} \cdot 1000.$$ (3)

The annual numbers of examinations and procedures have to be ideally available through patient radiation exposure monitoring systems based on automatic data collection and linked to national registries. At the present time, these numbers are usually obtained from central statistics held by governmental bodies or insurance companies, or from questionnaire-based data collection from a sample of healthcare facilities, scaled up to cover the whole country or region.

Typical effective doses for each type of examination or procedure, which are needed for the population dose estimation, can be obtained from any of the three methods detailed in Section 3.2.4, or from literature. The method used to calculate effective dose needs to be specified. Estimates of the typical effective dose for each type of examination in a given country or region are currently based mainly on E_k, often applied to the data collected from a sample of hospitals or clinics in this country or region.

Evaluation of collective effective dose to population would ideally be implemented within the framework of classification introduced in Sections 6.2 and 6.3. However, very detailed categories might not always be practicable due to the huge amount of data needed and problems of accurate data collection, in particular when making global estimates of population dose. Several categories can be combined into a limited number of main categories, such as those introduced by the UNSCEAR and EC (see Section 6.3.2), in order to simplify the process and achieve higher statistical power for calculations and comparisons thus reducing the uncertainty. For example, the "Top 20" method uses 20 procedures that have generally been shown to comprise 50 to 70% of the total number of the X ray procedures and 70 to 90% of the total population dose (Table 6) [134, 135]. The importance of various examinations

will vary between countries and change over time, but such a list may be useful to follow trends and compare countries in a consistent manner. The "Top 20" method provides an estimate of the overall population dose to within 60-90%, and this can be significantly improved by supplementing the analysis with 4-6 extra examinations [135].

TABLE 6. TOP 20 EXAMINATIONS IN EU COUNTRIES [135]

Examination type or category	% of total frequency	% of total collective dose
Plain film radiography		
1. Chest/thorax	12 – 29	0.7 – 5.2
2. Cervical spine	2.0 – 5.4	0.05 – 2.3
3. Thoracic spine	1.0 – 3.1	0.5 – 3.7
4. Lumbar spine (incl. LSJ)	2.8 – 9.6	2.0 – 17.0
5. Mammography	0.3 – 15	0.6 – 4.7
6. Abdomen	1.1 – 4.3	1.1 – 4.7
7. Pelvis and hip	6.3 – 10	2.8 – 9.4
Radiography/ Fluoroscopy		
8. Barium meal	0.3 – 0.9	0.8 – 5.9
9. Barium enema	0.1 – 2.0	0.5 – 13.0
10. Barium follow	0.05 – 0.3	0.2 – 1.6
11. Intravenous urography (IVU)	0.3 – 2.0	1.2 – 8.7
12. Cardiac angiography	0.2 – 1.3	1.0 – 9.9
All angiography	*1.1 – 2.4*	*6.4 – 16.0*
Computed tomography		
13. CT head	1.8 – 5.4	3.0 – 7.9
14. CT neck	0.06 – 0.9	0.1 – 1.1
15. CT chest	0.5 – 1.5	6.1 – 12.0
16. CT spine	0.3 – 2.8	1.5 – 13.0
17. CT abdomen	0.01 – 3.0	1.9 – 26.0
18. CT pelvis	0.03 – 1.5	0.3 – 9.7
19. CT trunk	0.1 – 5.6	1.1 – 27.0
All CT	*4.5 – 15.0*	*28.0 – 59.0*
Interventional		
20. PTCA	0.1 – 0.3	0.5 – 3.6
All interventional	*0.2 – 1.3*	*3.5 – 14.0*
Total 1-20	**50 – 70**	**70 – 90**

An important example of the evaluation of collective effective dose to population is the global assessments carried out by the UNSCEAR to provide regularly information on medial exposure. Since its 1988 report, UNSCEAR applies a health-care level model (HCL I, II, III or IV) to estimate the annual number of medical radiological examinations and nuclear medicine procedures performed using ionizing radiation, according to the number of physicians per population [1, 2, 21-24]. Extrapolation to derive a global estimate is performed by determining both the population weighted average frequencies for procedures and the population-weighted average dose per procedure within each health-care level and then applying these population-weighted averages to the whole population within each health-care level. A possible alternative classification is to use the World Bank income classification for countries, which also comprises four levels: 1) high, 2) upper-middle, 3) lower-middle, and 4) low. This approach would allow comparing medical exposure with other health indicators as WHO uses the same

classification; however, it is still a global estimation with uncertainties depending on the data quality and the model used. Figure 23 shows the development of annual per caput effective dose from diagnostic examinations [135].
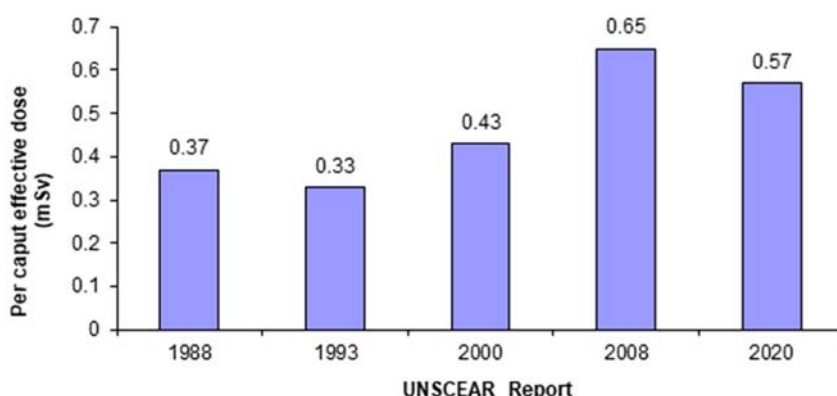
FIG. 23. Trend in annual per caput effective dose from diagnostic medical radiological examinations (reproduced with permission from Ref. [2])

8. IMPLEMENTATION OF PATIENT RADIATION EXPOSURE MONITORING

The information in the following sections, except for sections 8.2. and 8.5, is generally applicable to all patient radiation exposure monitoring systems, regardless of being implemented manually or by automatic means. Sections 8.2. and 8.5. are particularly focused on the features which are essential for the implementation of automatic patient radiation exposure monitoring systems.

When implementing a patient radiation exposure monitoring system, it is important to aim at developing and maintaining best practices. Countries with limited resources may neds to first aim for partial solutions but with a long term objective of matching best practice.

Due to the variation in infrastructures and imaging resources in various countries, it is difficult to specify a generic list of minimum actions for patient radiation exposure monitoring. In the case of limited resources, the focus needs to be on developing patient radiation exposure monitoring systems for the needs of hospital professionals (physicians and medical physicists) and radiation protection or health authorities. In the first step, the most common examinations and procedures need to be included, which are also expected to yield the highest contribution to the population dose.

8.1. ORGANIZATIONAL STRUCTURE FOR PATIENT RADIATION EXPOSURE MONITORING

8.1.1. Healthcare facility structure

Patient radiation exposure monitoring within a healthcare facility involves a suitable organizational structure including a dedicated committee. Ideally, this committee combines expertise from several professional groups with complementary expertise [164]. This team needs to involve the following, depending on the stage of implementation or use:
   a) A medical physicist to ensure that the process is based on sound scientific basis, including validation of dosimetric values.
   b) A lead physician to ensure that the process is based on relevant clinical questions.

c) A lead medical radiation technologist who executes the analytical assessments and ensures follow up corrective or improvement actions in the clinical operation.

d) An individual from the PACS/IT department to ensure robust IT integration and operation.

e) A senior administrator with authority over all departments that use radiation sources for imaging.

f) A physician from each department using radiation-generating imaging equipment to ensure ownership and engagement of all relevant departments.

g) Additional specialised staff allocated to undertake specific tasks and analyses as needed.

h) A biomedical statistician considering the statistical aspects of the data analysis, to ensure soundness of data processing steps.

It is very important that the expectations and the roles and responsibilities of each member are clearly defined and understood. The committee may initiate sub-committees for specific tasks (e.g., initial installation, oversight). The committee needs to be formalized within the institutional structure and report to the chief safety officer or operating officer of the clinical facility or equivalent to ensure adequate oversight and visibility.

8.1.2. Multi-facility, national, or international structure

The maximum benefit from multi-facility and national patient radiation exposure monitoring systems would be achieved if these systems are integrated with the overall national information system for medical imaging (Section 8.5). Therefore, such systems have to be established through effective cooperation between the key actors in the field, such as the radiation protection authority, health ministry, health and welfare research and development institution, and the national social insurance institution. The imaging equipment manufacturers and IT providers need to be involved as appropriate, in accordance with existing technology and national and local rules of procurement.

The basic specifications and the development of the integrated patient radiation exposure monitoring system need to be supported by an appropriate multi-professional steering group, composed of the representatives of the key national organizations, health-care units, and information technology (IT) experts. The role of the IT experts is crucial as the development and implementation of the system will rely on demanding or challenging applications of the modern information technology. The problems of IT technology compatibility and national regulations on information security and access control are often the main obstacles for developing an integrated wide scale system. The steering group will guide and follow-up the technological development, in conformity with the national regulations, and will ensure that the needs of the various user groups will be surveyed and met. This can be achieved by organizing regular workshops which may include imaging equipment and information technology providers.

The accountability and financial impact of the national patient radiation exposure monitoring system can be examined and tested through national pilot projects. Such a pilot testing of the system would be part of wider testing of national healthcare informatics, to ensure suitable projects that are efficiently financed or funded through successful participation in research calls for healthcare development. The national pilot projects could address the data recording, transfer and storing, as well as data search, collection, and analysis for selected radiological examinations, at first in limited operational environments but eventually at full national level. The limited or national pilots would establish prototype user interfaces for different user groups and test their wide-scale applicability within the national patient radiation exposure monitoring system.

On an international scale, the multi-facility and national approaches would provide an optimal basis for international exchange of information and reporting to regional or global surveys (such as the UNSCEAR global survey on medical exposure discussed in Section 7.4).

8.2. SPECIFICATIONS AND FUNCTIONALITIES OF A PATIENT RADIATION EXPOSURE MONITORING SYSTEM

In selection and implementation of a patient radiation exposure monitoring system, the user might wish to consider certain specifications. Key specifications pertaining informatics, features, and access are listed below.

8.2.1. Informatics

A viable patient radiation exposure monitoring system will interface with a number of other clinical imaging information systems, possibly including PACS, RIS, HIS, electronic medical records (EMR), CDS, voice recognition and dictation systems, critical results reporting systems, and operational and quality dashboards. The guidance provided in Ref. [164] on implementation of digital imaging in radiology need to be considered. To ensure adequate interconnectivity, data security and data integrity, the informatics specifications shown in Table 7 apply to all patient radiation exposure monitoring systems.

TABLE 7. INFORMATICS SPECIFICATIONS OF A PATIENT RADIATION EXPOSURE MONITORING SYSTEM

Specification	Detail
Modalities	Modalities monitored (i.e., CT, X ray radiography, X ray fluoroscopy, angiography, mammography, nuclear medicine)
Data source	Source of data per modality (e.g., PACS, Imaging Systems, RIS/HIS, EMR)
Data collection mechanism	Method to collect data per modality (e.g., automatic, manual, query, auto-send)
System integration	Communication provision with additional IT system (e.g., EMR, RIS/HIS, CDS, contrast administration system, dictation system) *Note: For most effective use, the system needs to be integrated within the healthcare IT.*
Data repository location	Location to store data (e.g., local server, virtual server, offsite server, cloud, etc.)
Computational security	Provision for data encryption, access authentication (stand-alone or integrated within the IT integrated access system of the facility), firewall, etc.
Data communication	Communication systems supported (e.g., DICOM, HL7, IHE)
Data portability	Ownership of the data *Note: The patient exposure information database has to remain the property of and accessible to the specified user groups (e.g., the health care institution after the termination of any software subscription or support agreement.*
Privacy	Provision for securing data privacy *Note: Patient protected health information transmitted to and stored in patient radiation exposure monitoring system is subject to the requirements of relevant laws and regulations.*
Vendor neutrality	Vendors supported. *Note: System needs to support vendors represented in the facility.*

Data backup and retention	Frequency and length of historical backup *Note: Means for backup of the system data needs to be provided.*
Data types	The types of the data supported and used per modality (e.g., RDSR, CT dose summary, images, MPPS messages, exposure and quality metrics, etc.)
Access mechanism	Accessing the system (e.g., launched from PACS, Stand-alone system)

8.2.2. Features

The features of a system define its primary utility. Table 8 lists key features to be considered in the implementation of the system. Additional information is provided in Refs. [165, 166].

TABLE 8. FEATURE SPECIFICATIONS OF A PATIENT RADIATION EXPOSURE MONITORING SYSTEM

Specification	Detail
Procedure identification	Provision for identifying procedures
Protocol mapping	Protocols mapping provisions (e.g., manual, automatic, classification system used, both at the study and series levels)
Transfer support	Provision for communication to offsite databases (e.g., registries, authorities) including type of data transfer (e.g., aggregate data) and applied anonymization and aggregation methods
Reporting	Type, content, format, frequency (for automated ones), and customization of the generated reports
Frequency query	Query for frequency of specific types of examination over specified time periods, facility, etc and data export support and format (e.g., Excel, CSV)
Exposure tracking	Tracking functionality for procedures and cumulative dose
Exposure query	Dose query for an individual examination or collection of examinations per specific cohort definitions and data export support, content, and format (e.g., PRDSR, Excel, images)
Exposure metrics	Exposure metrics supported and methods and phantoms to obtain them (e.g., organ dose, effective dose, etc.) including their estimated uncertainty
Quality metrics	Image quality metrics and methods to obtain them including their estimated uncertainty
Patient size estimation	Method for estimation of patient size
Alert and trigger support	Availability of alerts and trigger function setup per protocols, patient age ranges, and/or patient size (height, weight, diameter), alert notification provision and method (e.g., email, text)
Outlier analysis	Method of identifying and ranking outliers (based on the magnitude of the deviation from the expectation based on examination type and patient size) and investigate them via image view.
Flagged case processing	Provision to follow up and record actions pertaining outlier, trigger, and alert cases in the systems (e.g., a drop-down menu for common factors including

	image quality, examination type complexity)
Paediatric support	Specific analytics for paediatric patients at multiple size or age-based cohorts, or as scalable curve models
Repeat and reject analysis	Analyses of images that are not acceptable and need an additional exposure of the patient
Consistency analyses	Provisions for analysis per time period, scanner, shift, facility.
Protocol consistency analyses	Provisions for analysis of deviation between prescribed and applied protocols for each examination
Fetal dose support	Estimation of dose to the embryo or fetus
Skin dose mapping	Skin dose mapping in X ray fluoroscopy and angiography (fixed or customizable, family of phantoms available) including reporting the uncertainty in the estimates
Statistical analysis	Types of data aggregations and statistical analyses used per data types (e.g., mean, median, quartiles, comparisons, multi-variant analysis, sensitivity to factors, and trend analysis, to assess the key contributing factors to inconsistencies)
Integrated quality control	Provision to incorporate physics test results in the patient radiation exposure monitoring system for compressive analysis and quality control
Quality control	Provisions for quality control of exposure data (Section 8.3)

8.2.3. Access

Among the different user groups of an overall patient radiation exposure monitoring system are the following:

- Radiological medical professional
- Medical physicist(s) in charge of patient exposure and quality data management
- Medical radiation technologist(s) having a specified role in data management
- Referring medical professional
- Health care organizations ordering radiology services
- Radiology department and/or hospitals providing radiology services
- IT expert services of the hospital (for maintenance and development)
- System, technology or equipment vendors (for maintenance and development)
- Radiation protection and/or health authorities
- Research institutions
- Patients and patient advocates' associations.

Various user groups have specific need and specific rights for extracting and analysing data from the patient radiation exposure monitoring system, and the access to the system has to be customized to the need of different users. It is important that information provided is channelled with the appropriate context in order not to raise undue concerns, especially when access is given to patients or referring physicians. Utilization of any patient radiation exposure monitoring programme needs to be done in parallel with providing appropriate training and building communication skills as outlined in Section 8.4.

Table 9 details the access features of a patient radiation exposure monitoring system and Table 10 identifies the types of access that need to be enabled for most notable user types. Access levels for

other user groups (listed above but not in Table 10) can be devised based on the institutional needs and priorities. The access levels given to different professional groups and individuals need to be defined carefully, considering the local specifics, needs and legislation.

TABLE 9. ACCESS SPECIFICATIONS

Specification	Detail
Permission levels	Availability of multiple permission levels with varying privileges and interfaces per user
Access mechanism	User privilege and passwords through common institutional access
Audit trail	History tracked of user interactions
Deidentified access	Provision to provide access to deidentified data to certain users

TABLE 10. USER ACCESS TYPES

Feature	Medical physicist	Radiological medical professional	Medical radiation technologist	Referring medical professional	Authorities
Examination classification system	x	x	x	x	x
Examination numbers	x	x	x		x
Patient dose data	x	x	x		x
Supplementary data (all other information in the Appendix)	x	x	x		
Protocol data	x	x	x		
Diagnostic reference levels	x	x	x		x
Trigger and alert levels	x	x	x		
Boundary ranges	x				
Unintended and accidental exposures	x	x	x		
Patient exposure history	x	x		x	
Referral guidelines and decision support	x	x		x	

The features of Table 9 need to cover all modalities, equipment, and examinations and procedures carried out within the radiological units of the healthcare facility, or in the country, addressed in accordance with nationally accepted or locally agreed (in case no national standardization exist) classification of examinations and procedures.

The desired features of the user platforms (interfaces, work stations) providing the access types defined in Table 9 need to include analytical and statistical tools that enable preparing summaries, trend

analysis, and reporting of examination and procedure frequencies and patient doses (values of exposure metrics).

As an example, for medical physicists this needs to include tools for the following:

- Analysis of dose distributions for the establishment of typical values and local DRLs and comparisons with national DRLs (Section 7.1.1).
- Analysis of dose distributions for the setting of dose alert and trigger levels, boundary ranges, etc. (Section 7.2).
- Analysis of image quality information and other characteristics important for conclusions and development of optimization of practices (Section 3.3).

For radiation protection authorities and health authorities, the desired features of the user platform need to include analytic and statistical tools that enable preparing summaries, trend analysis and reporting of statistical data on examination frequencies, typical effective doses, and collective effective dose to population (population doses) in the country (Section 7.4).

Table 10 provides suggested features to be considered when defining the access level; whom to give access will be defined considering the local legislation, needs and specifics.

8.2.4. Administration and support

In addition to the above features, there are key administrative and support considerations for a patient radiation exposure monitoring system. The key such considerations are listed in Table 11.

TABLE 11. ADMINISTRATION AND SUPPORT SPECIFICATIONS

Specification	Detail
Needed local resources	Needed steps and local resources at the facility (e.g., hardware, software, manpower, physical servers, virtual servers, cloud access)
Upgrades	Number of anticipated upgrades per year and steps for system upkeep, provision for version control when metrics calculations have been updated
Servicing	Service access to the system by the developers for upgrades and troubleshooting
Cost	Purchase options (service or one-time fee), annual service fee

8.3. QUALITY CONTROL FOR DATA INTEGRITY IN PATIENT RADIATION EXPOSURE MONITORING

Regardless of the method and metrology deployed to represent patient radiation exposure data, there is a strong need for data accuracy. Any monitoring would be effective only to the extent that the data integrity is assured. A good patient radiation exposure monitoring programme would therefore have an explicit process for interrogation of the data, prior to any higher-order processing of the data, to ensure confidence in data accuracy and integrity.

The evaluation of the accuracy of the data needs to cover all the steps of patient exposure data monitoring. These include:

- Data production, i.e., the measurements and calculations to provide the values of patient radiation exposure and quality metrics;
- Data recording and collection, both manual and automatic systems;
- Data analysis, with particular attention to the uncertainties of the methods of analysis (e.g.

inadequate sample sizes, inconsistent coding).

The basic testing of the integrity of the data provided by the imaging equipment and software systems for patient radiation exposure monitoring has to be implemented by the manufacturers and system providers before the product delivery and at the time of acceptance testing in the health care facility.

The quality control of the data production is achieved mainly by calibrations and quality control tests of the imaging equipment. The quality control of the other steps, while also applicable to data production, include audits and sensibility tests to ensure correctness of single cases or parts of workflow, and a comprehensive test run to verify the correctness of overall operation (from data production to analysis).

8.3.1. Calibration and quality control

The accuracy of dosimetric instruments or dosimetric calculation systems (software) of different imaging equipment needs to be initially assured by the manufacturer in accordance with international codes and standards (e.g., IEC) and the national legislation, and the accuracy verified at the time of acceptance testing of the equipment [16, 17]. Thereafter, the dosimetric instruments and calculation systems need to be regularly checked and calibrated, as a part of the established quality assurance and quality control programmes for medical exposure, following recognized protocols such as those in Refs. [28, 167]. This applies to dosimeters integrated into the medical radiological equipment, or used externally, such as KAP meters in fluoroscopic systems, and to software of the medical radiological equipment itself that calculates, displays and reports dose metrics such as CTDI and DLP in CT, reference air kerma at the patient entrance reference point in image guided interventional procedures, or mean glandular dose in mammography.

The quality assurance programme has to also ideally include appropriate tests of image quality. The patient radiation exposure monitoring systems that include this provision have to include the quantities described in Section 3.). Image quality is most relevant to be applied for each series or views of an imaging study, as such results and their corresponding exposure values are only relevant in the context of individual image series (as opposed to exposure that can be summed across multiple series). The values can be ascertained either through direct patient image measurements or measurements on patient-emulating phantoms imaged using protocols used for patients. The accuracy of image quality assessments has to be verified through medical physics evaluations and applicable guidelines.

Calibration requirements for medical radiological equipment and dosimetry equipment are established in para. 3.167 of GSR Part 3 [16]. Responsibility is assigned to the radiology facility's medical physicist. While the initial calibration of radiological equipment is primarily the responsibility of the manufacturer, in consultation and oversight by the medical physicist, the accuracy of the data is to be independently verified by the medical physicist. After the initial calibration, the intervals for periodic re-calibrations may differ, depending on the complexity of the medical radiological equipment. This is to ensure that such instrumentation has a current calibration, typically conducted within the last two or three years, and that it is functioning correctly [17].

Recently the DICOM RDSR has been modified to include the calibration factors measured by the medical physicists during acceptance and constancy quality control, in order to track the accuracy of the dosimetric indicator over time and to enable appropriate corrections when the data are used to compare the practice among different facilities or institutions or to the DRLs [168].

8.3.2. Integrity in data recording, collection and analysis

After the verification of the data produced by the equipment, it is necessary to verify the integrity

of the data transmitted to the archives (e.g., PACS, RIS, patient radiation exposure monitoring system, dose registry), or recorded and collected manually. This is the responsibility of the medical physicists, who, in the case of automatic data recording and collection, works in concert with the IT specialists.

The integrity of data collection and transmission can be checked by appropriate tests. This could include sensibility tests, where the transmitted data, either the raw data or the data collected and sorted in appropriate ways, are compared with established reference data, e.g., earlier data from similar imaging procedures, typical values, or values computed or estimated by other means. This is to verify that the transmitted data is credible. The credibility tests typically address a single or limited part of the workflow. The quality assurance programme for data integrity also needs to include a specific test run to test the overall workflow from data production to data analysis. This comprehensive test could be based for example on test imaging with appropriate phantoms.

Several uncertainties or shortcomings in the data collection and analysis procedures can have impact on data integrity which can jeopardize meaningful summaries and comparisons of the results, depending on the purposes of data collection and analysis. For example, problems occur if different classifications are used for one specific procedure (see Section 6.3). Non-unique separation of one procedure into different steps of exposure is another significant problem. For a chest radiography performed in two projection, RDSR will store the dose of both the PA and lateral images (the dose of the lateral view is higher by a factor of 2-4) in separate records. Also, the DICOM image headers are filled with the correct dose of each image. In certain types of data transfer, some vendors transfer only the sum dose of all images or in case of CT and fluoroscopy the sum dose of all series. For correct data analysis, these differences in data storage and transfer need to be considered so the processing downstream can be explicitly directed to series level or study level analyses. Particular to image quality and image quality-dose balance, the data needs to be structured such that image quality can be ascribed at series level.

DICOM RDSR needs a unique identifier for each irradiation event. The specification permits exposure data to be stored separately for each exposure, or grouped together in any logical grouping, for example for a series or for an imaging procedure. A modality might even store individual exposures in "realtime" so other systems can follow along, and then store another RDSR containing all the exposures for the procedure together in one object. The unique identifier ensures that each exposure can be counted/analysed while allowing duplicates to be identified and avoided.

Furthermore, non-unique application of the established concepts of analysis, such as the DRL, may hinder the comparability of the collected and analysed data. For example, some countries establish CT DRLs with one DLP as a sum of all series; others define DLPs for each single series. Such differences are particularly important considering the variable nature of population-based data analysis. Even if a small percentages of data points is erroneous, that can undermine the utility of dose analyses, as the total data may be based on only a small number of suboptimal procedures. The quality control of data has to be set up such that data analyses can be performed with clarity on the study or series level processes.

8.4. TRAINING AND COMMUNICATION IN PATIENT RADIATION EXPOSURE MONITORING

All user groups of patient exposure monitoring system, as described in Section 8.2.3, need to have adequate initial and periodic training relevant to their role and responsibilities in patient exposure monitoring.

In addition to training on specific technical aspects of patient radiation exposure monitoring, enhancing communication skills needs to be considered among the learning objectives, since efficient

and continuous communication between various stakeholders is needed on various topics related to the patient radiation exposure monitoring. This includes both the methods and infrastructure of dose monitoring and the resulting dose information. When communicating any patient dose information, in particular to stakeholders outside the dedicated committee of the steering group (Section 8.1), it is paramount to put the dose in the context of the benefit gained from the imaging examination. Otherwise, the dose alone can be misleading. For example, if the dose from interventional cardiac imaging is compared to that of mammography, the former is higher. It could be concluded that the cardiac procedure needs to be assessed for dose reduction, but obviously the two examinations are very different in terms of the goals that they seek and standards of one do not apply to the other. Each need to be considered on their own merit and condition. Image quality metrics might be used to communicate the targeted values and the needs for the consistency of image quality for each type of examination.

Professionals collecting and analysing dosimetric data to establish DRLs or to compare typical patient dose values (median values) with local or national DRLs, have to be familiar with the concept of DRLs, including the used dose quantities and units, and the fundamentals of the clinical protocols involved. They have to also recognize the need to verify the consistency of the received data and to confirm the calibration of the dosimetric values introduced in the database.

Professionals investigating individual exposure events have to be familiar with the differences of the concepts of DRL, typical value and boundary levels for outlier analysis, and have to manage sound statistical means to identify outliers in the patient dose and quality distribution. They have to also be familiar with the features of the patient radiation exposure monitoring systems concerning tracking and reporting unintended exposures.

All professionals involved in medical imaging have to understand the principles and means how the data from patient radiation exposure monitoring can be used to improve the clinical operation including image quality (Section 7.1). Medical physicists need to have skills to analyse the data and the trends by sound statistical methods, to balance image quality and dose, and to provide necessary guidance and training on these concepts to other key professionals (in particular radiological medical professionals and medical radiation technologist).

Radiological medical professionals and medical physicists need to understand the purposes, benefits and techniques for individual dose tracking, in particular how this can have impact on the local optimization of image quality (Section 7.2).

Experts involved in population dose estimations (e.g. experts from national authorities, professional societies or research institutions, clinical consultants) need to be familiar with the concepts of population dose and the method for its determination, including the necessary allowances in sorting or categorizing the examinations (Sections 6 and 7.4). They need to also attain knowledge on which examinations contribute most to the overall population dose from medical imaging.

Referring medical practitioners and radiological medical professionals responsible for justification of imaging procedures have to be trained on principles of justification, referral guidelines, and use of DCSs. As explained in Section 7.3, the referral guidelines and DCS can themselves provide ideal means of providing targeted training on this topic area. The range of typical patient dose values for the most common clinical indications need to be known. In some cases, factors to estimate organ and effective doses could also be used for educational purposes. This could allow the relative radiation risk between different imaging modalities to be compared. Uncertainties in estimation and limitations on the use of these factors and these radiation quantities need to be always highlighted.

Paediatric patients need special consideration. Effective communication with patients and parents of paediatric patients about the patient's radiation exposure supports informed decision-making, but the information content provided to patient needs to be properly explained and adapted [169].

8.5. INTEGRATION OF A DIGITAL PATIENT RADIATION EXPOSURE MONITORING SYSTEM WITH OTHER HEALTHCARE SYSTEMS

The need for patient-centric and more real-time information in medical imaging has been increasing, imposing the need for comprehensive digital information systems and speeding up their technical development. To gain maximal benefits from this improved flow of information, to ensure its timely and cost-effective distribution to all counterparts, and to enable meaningful comparisons against benchmarks and between institutions, nationally and internationally, integrated digital information systems have to be the target of development. Whenever practical, automatic patient radiation exposure monitoring system need to be therefore integrated with the national information system of medical imaging, including the development of national image archives, referral guidelines and CDS, and ideally, with the overall health care information system covering all aspects of patient care.

The ongoing developments of artificial intelligence, machine learning and deep learning for medical applications are seen as a possibility to further utilise multidimensional healthcare big-data including patient radiation exposure data, and to offer relevant analysis and outcome predictions and for improved effectiveness [170, 171]. Due to the many challenges in this wide scope, the development towards the optimal national infrastructure typically needs appropriate phasing and milestones. Detailed guidelines for the technical solutions of such an integration are outside the scope of this document and would also be premature in the present fast development of health care information technology.

The implementation of an integrated patient radiation exposure monitoring system at a national level will provide an optimal tool to improve patient safety. It provides effective flow of information for the purposes of justification of examinations, avoiding unnecessary examinations, improving the consistency of image quality, and optimization of radiation protection, imaging practices, and risk communication, for both general and patient-centric purposes. It improves the maintenance of comprehensive health care statistics, further improving the preparedness for appropriate clinical trials and research, including research for radiation protection and optimization purposes. It improves the possibilities to undertake national and international comparisons to ensure quality of medical imaging in accordance with international recommendations and the available knowledge of best practices.

The national implementation of patient radiation exposure monitoring can provide a marked improvement for the operation of various multi-facility or national stakeholders, e.g., for the relevant tasks of healthcare or radiation protection authorities, or national professional societies, or other specific organizations such as organizations for external clinical audit. Such tasks include collecting patient dose data (e.g., through national patient dose registries) and follow-up of their trends for various patient and age groups, for the purposes of estimations of typical values, setting national DRLs, assessing population doses, collecting and analyzing abnormal events (unintended or accidental exposures), epidemiological research and reviews for radiation protection, clinical auditing, and international comparisons and reporting for international purposes (such as the UNSCEAR surveys on medical use of radiation). Similar analyses can be applied to image quality factors.

Major beneficiaries include also the healthcare institutions themselves, as the integrated patient exposure monitoring system can greatly facilitate the necessary reporting outside the institutions (e.g., to the authorities), thus leaving more time for the actual patient care.

8.6. PRIORITIES FOR IMPLEMENTATION OF A PATIENT RADIATION EXPOSURE MONITORING SYSTEM

Patient radiation exposure data covers a large number of operational entities encompassing large cohorts of patients imaged across modalities. In initiating a patient radiation exposure monitoring programme, particularly from the start, strategies need to be developed to identify the priorities in terms

of the modalities and subsets of data to be addressed first. The highest dose modalities are the highest priorities. These include CT and interventional imaging. Then follows nuclear imaging, conventional fluoroscopy examinations, mammography, radiography, and dental radiography. Others including magnetic resonance imaging (MRI) and ultrasound imaging are next with the focus on image quality. For each modality, the most sensitive population groups have to be the first subject of management. These include paediatric patients, with the highest priorities given to younger ages, followed with patients with enhanced sensitivity to radiation (e.g., due to Crohn's disease), patients undergoing recurrent examinations, pregnant patients, and screening population. Finally, for a given modality, and population, the highest priority has to be given to examination type (or protocols) that deliver the highest dose, followed by those that are most frequent.

8.7. OBSTACLES AND CHALLANGES IN IMPLEMENTING PATIENT RADIATION EXPOSURE MONITORING

While most of the goals detailed in this report can be achieved in current health care systems, there are certain challenges that need special attention. Among those are financial challenges, including the lack of resources in developing countries; regulatory challenges, including the diversity of regulatory requirements and expectations across countries; and logistical challenges, including the lack of implementation frameworks for the integration of diverse dose and image quality metrics into a comprehensive risk assessment and optimization system. We also note that cooperation with registries, while offering strong peer calibration, creates legal challenges in terms of data privacy and disclosure of institutional data. The processes and limits of data privacy, access, and use need to be fully justified and facilitated. These remain key areas that involve active development and ownership by all stakeholders in the medical radiation protection community.

APPENDIX

EXAMPLES OF METRICS FOR THE THREE LEVELS OF PATIENT RADIATION EXPOSURE DATA

	Level I: Data relevant to exposure characterization; minimum needed to make sense of exposure	Level II: Data needed for additional refinements of the exposure condition and for optimization	Level III: Data for personalization and optimization
Patient and examination information	– Patient identification (name, hospital ID) – Procedure type (including indication) – Equipment – Date – Time – Age – Gender	– Weight	– Height – BMI – BSA (NM) – Glucose level (PET)

Radiography	– Number and type (e.g. AP/PA/Lat) of radiographic projections (incl. rejected)
	Per projection:
	– KAP value
	– If KAP meter is not available:
	  - kVp
	  - mAs
	  - Source-detector distance
	  - Tube output
	  - ESAK (for standard patient)
	  - User calibration factors
		– kVp
		– mAs
		– Source-detector distance
		– Source-patient distance
		– ESAK
		– Exposure time
		– Filtration
		– Field size
		– Grid
		– Film-screen combination speed
		– Exposure index (for CR/DR)
		– Deviation Index (for CR/DR)
			– Focal spot size
			– Post-processing settings
			– AEC (Y/N; chamber location)
			– Matrix size
			– Pixel size
			– Bit stored
			– Organ dose
			– Image quality metrics

Mammography	– Number and type of views (e.g. CC/MLO...) (incl. rejected)
	– Laterality
	– Breast thickness
	– Source-detector distance
	Per projection:
	– AGD value
	– If AGD not available:
	  - kVp
	  - mAs
	  - Tube output
	  - ESAK
	  - User calibration factors
		– kVp
		– mAs
		– Exposure time
		– Entrance surface air kerma
		– Anode
		– Filter
		– Film-screen combination speed
			– Focal spot size
			– Compression force
			– Post-processing settings
			– AEC (Y/N; chamber location)
			– Matrix size
			– Pixel size
			– Bit stored
			– Image quality metrics
			– Breast density

Computed tomography	– Number and type of series (e.g. localizer, phase, …) – Total DLP *Per series and tube:* – Target region – Scan mode (axial, helical) – $CTDI_{vol}$ – CTDI phantom – DLP – If $CTDI_{vol}$/ DLP not available: - $CTDI_w$ - CTDI per mAs - kVp - mA - Rotation time - Pitch - Filter (bowtie) - User calibration factors	*Per series and tube:* – Gantry tilt – kVp – mA – Rotation time – Pitch – Filter (Bowtie) – FOV – Collimation width – Slice thickness – SSDE – Effective diameter – Modulation use (Y/N) and type (longitudinal, angular, organ based) – Number of acquisitions and timing (perfusion)	– Reconstruction type and kernel – Water equivalent diameter – CT dose check: – DLP alert value – $CTDI_{vol}$ alert value – Scanning length – Length of reconstructable volume – Organ dose – Image quality metrics
Fluoroscopy	– Total number of series/ images – Total fluoroscopy time – KAP (total, fluoro/cine) – Cumulative reference air kerma (if available) – User calibration factors	*Per irradiation event:* – kVp – mA or mAs – fr/s or p/s – Pulse width – Filtration (material and thickness) – Fluoroscopy time – Number of images – KAP – Air kerma at the patient entrance reference point – Source detector distance (if selectable) – Primary and secondary gantry position – FOV	– Spatial and temporal processing – Organ dose – Matrix size – Pixel size – Bit stored – Image quality metrics
Interventional radiology	– Total number of series/ images – Total fluoroscopy time – KAP (total, fluoro/cine) – Cumulative reference air kerma (if available) – User calibration factor(s)	*Per irradiation event and tube:* – Protocol – kVp – mA or mAs – Pulse width – fr/s or p/s – Filtration (material and thickness) – Focal spot size – Number of images – Fluoroscopy time	– Water-equivalent thickness (per series) – Peak skin dose – Skin dose map – User calibration factor/s – Organ dose – Spatial and temporal processing – Matrix size – Pixel size – Bit stored – Image quality metrics

		– KAP (tot, fluoro/cine) – Cumulative reference air kerma – Primary and secondary gantry position – Source detector distance – Table height – FOV – Shutter edges – Wedge filter	
Nuclear medicine	– Radionuclide – Radiopharmaceutical – Administered activity	– Pre-administration measured activity – Post-administration measured activity – Activity per weigh	– Organ dose – Calculation method – Extra-venous injection – Matrix size – Pixel size – Bit stored – Image quality metrics

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GLOSSARY

Alert level. The threshold above which the patient dose index is considered too high and a warning and investigation is needed. The concept is mostly relevant to tissue reactions (deterministic effects) from radiation exposure (e.g., skin reaction).

Analysing patient radiation exposure data. A process of acting upon patient radiation exposure data to provide summaries with statistical, comparative and trend information, to be used for optimizing radiation protection and clinical practice, and to investigate and verify individual doses when needed.

Boundary range. The range representing the 5-95th percentile of quantitative data within a cohort. The concept can be applied to any dose or image quality quantity, which has to be specified, unless it is clear from the context.

Clinical decision support (CDS). An electronic tool to aid directly in clinical decision making, in which characteristics of individual patients like symptoms, results of physical examinations, suspected diagnosis, laboratory results and more are used to suggest the most appropriate examination(s).

Clinical risk. The risk associated with lowered diagnostic confidence in either the detection or quantification of the pathology of interest or affirmation of its absence, and the associated reduced likelihood of accurate interpretation leading to misdiagnosis. It can be defined as the reverse of the image quality for a specific imaging task.

Collecting patient radiation exposure data. A process of gathering patient radiation exposure data into a common system. The term can be used synonymously as recording and collecting together.

Data encryption[1]. Mathematical algorithms which convert information which is readable into something which is unreadable to anyone except to those who possess special knowledge (often referred to as a key or cypher). Encryption is used to ensure the protection of sensitive data such as patient records and images. There are a wide range of standards of encryption with varying levels of security.

Diagnostic reference level (DRL)[2]. A level used in medical imaging to indicate whether, in routine conditions, the dose to the patient or the amount of radiopharmaceuticals administered in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure.

Digital Imaging and Communications in Medicine (DICOM) standard[1]. A standard for the management of information (including images) in medical imaging. The DICOM standard is based on industry standards such as the TCP/IP network protocol.

Dose[2]. A measure of the energy deposited by radiation in a target. There are different applications of this quantity in medical imaging, for example organ dose, glandular dose, effective dose, dose index. In the context of this report, the word dose when used generically, refers to any such dose quantity.

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[1] INTERNATIONAL ATOMIC ENERGY AGENCY, WORLD HEALTH ORGANIZATIONS, Worldwide Implementation of Digital Imaging in Radiology, IAEA Human Health Series No. 28, IAEA, Vienna (2015)

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection (2018 Edition), IAEA, Vienna (2018)

Electronic medical record (EMR)[1]. Electronic version of the traditional medical chart. Its advantages are that patient information is available instantaneously at multiple locations. Sometimes called an electronic patient record (EPR).

Integrating the Healthcare Enterprise (IHE)[1]. IHE is an initiative by healthcare professionals and industry to utilize standards (such as DICOM and HL7) to support the integration of different clinical information systems through the use of well-defined profiles based on clinical workflow, content and display.

Hospital information system (HIS)[1]. Hospital information systems are comprehensive, integrated software systems designed to manage the medical, administrative, financial and legal aspects of a hospital. HIS systems would normally be a repository of patient demographics and often provide the patient data input for the RIS and PACSs.

Medical radiation technologist[2]. A health professional, with specialist education and training in medical radiation technology, competent to perform radiological procedures, on delegation from the radiological medical practitioner, in one or more of the specialties of medical radiation technology.
A wide variety of terms are used throughout the world for such health professionals, such as radiographer, radiological technologist, nuclear medicine technologist.

Modality. Generic term which describes an image acquisition system such as an X-ray radiography or fluoroscopy system, CT scanner or gamma camera.

Modality Performed Procedure Step (MPPS). A DICOM message to notify the status of the examination from the modality to the RIS and/or PACS. The MPPS message collects dose information of the whole procedure step independently from the storage of the image data. No further updates will be provided in the dose module of the MPPS.

Patient radiation exposure monitoring. Components, mechanisms, and operational processes related to recording, collecting, and analysing patient radiation exposure data associated with clinical imaging operation. Here monitoring refers to capturing and meaningfully evaluating patient radiation exposure data and not the actions for quality improvement, an ultimate goal undertaken by managing patient radiation exposure data.

Patient radiation exposure data. A collection of metrics characterizing patient radiation exposure in medical imaging including demographic, acquisition and processing parameters, dosimetric, and image quality data.

Picture archiving and communications systems (PACS)[1]. Computer system for the storage and display and transmission of medical images. Often combined with a radiology information system (RIS) so that the system can display images as well as clinical information and final diagnosis.

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[1] INTERNATIONAL ATOMIC ENERGY AGENCY, WORLD HEALTH ORGANIZATIONS, Worldwide Implementation of Digital Imaging in Radiology, IAEA Human Health Series No. 28, IAEA, Vienna (2015)
[2] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection (2018 Edition), IAEA, Vienna (2018)

Quality control[1]. Part of quality management intended to verify that structures, systems and components correspond to predetermined requirements.

Radiology information system (RIS)[1]. A radiology information system (RIS) is software used to acquire, store, manipulate, and distribute patient radiological data and imagery. The system generally consists of patient tracking and scheduling, result reporting and image tracking capabilities. RIS often interfaces with a HIS (hospital information systems) for patient demographic, and with a PACS for image data, and is critical to efficient workflow in radiology

Recording patient radiation exposure data. A process of documenting patient radiation exposure data manually or automatically.

Tracking patient radiation exposure data. An analysis process of ascertaining and monitoring temporal trends in individual or collective stored data, including individual cumulative dose evaluation.

Radiation exposure monitoring (REM) profile[2]. The REM profile specifies communications between imaging systems generating reports of exposure and systems which receive, store, or process those reports, such as local dose information management systems and/or national/regional dose registries). It defines how DICOM dose objects are created, stored, queried, retrieved, de-identified, and may be processed, displayed and distributed.

Radiological medical practitioner[3]. A health professional with specialist education and training in the medical uses of radiation, who is competent to perform independently or to oversee radiological procedures in a given specialty. Health professionals that could take on the role of the radiological medical practitioner in medical imaging, depending on the laws and regulations in a State, include radiologists, nuclear medicine physicians, cardiologists, orthopaedic surgeons, dentists and other specialist physicians who perform image guided interventional procedures.

Radiation risks[2]. Detrimental health effects of exposure to radiation (including the likelihood of such effects occurring), and any other safety related risks that might arise as a direct consequence of exposure to radiation.

Referring medical practitioner[2]. A health professional who, in accordance with national requirements, may refer individuals to a radiological medical practitioner for medical exposure.

Size specific dose estimate (SSDE)[4]. A patient dose estimate for computed tomography (CT) scans that considers corrections based on the size of the patient, using linear dimensions measured on or determined from the patient or on patient images. The American Association of Physicists in Medicine (AAPM) Report 204 bases SSDE values on the CT dose index (volume) reported on CT scanners, but future modifications may include SSDE correction factors based on attenuation data of the patient acquired during the projection

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[1] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection (2018 Edition), IAEA, Vienna (2018)

[2] INTEGRATING THE HEALTHCARE ENTERPRISE, IHE Radiology (RAD) Technical Framework, Volume 1, 10 IHE RAD TF-1 Integration Profiles, Revision 19.0, IHE International, Inc. (2020).

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[4] TOTH, T. L. Size-Specific Dose Estimates (SSDE) in Pediatric and Adult Body CT Examinations, The Report of AAPM Task Group 204. AAPM (2011).

scan(s) of the scanned patient.

Spread range. The range representing the 25-75th percentile of quantitative data within a cohort. The concept can be applied to any dosimetric or quality quantity, which has to be specified (e.g., spread range of CTDI) unless it is clear from the context.

Structured report[1]. Part of the DICOM Standard. A standard and structured method to exchange data produced in the course of image acquisition, post-processing and reporting. Structured reports use DICOM data elements and DICOM network services such as storage, query/retrieve etc.

Typical value[2]. The value representing 50th percentile (median) of quantitative data within a cohort. The concept can be applied to any dose or image quality quantity, which has to be specified (e.g., typical value of CTDI) unless it is clear from the context.

Trigger level. The threshold above which the patient dose is considered too high and follow-up action is needed. The concept is mostly relevant to tissue reactions (deterministic effects) of radiation (e.g., skin reaction).

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[1] INTERNATIONAL ATOMIC ENERGY AGENCY, WORLD HEALTH ORGANIZATIONS, Worldwide Implementation of Digital Imaging in Radiology, IAEA Human Health Series No. 28, IAEA, Vienna (2015)
[2] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Diagnostic Reference Levels in Medical Imaging, Publication 135, Ann. ICRP 46 1, SAGE (2017).

LIST OF ABBREVIATIONS AND SYMBOLS

AEC	Automatic Exposure Control
AP	Anterior Posterior (projection)
ATCM	Automatic Tube Current Modulation
BSA	Body Surface Area
BMI	Body Mass Index
CBCT	Come Beam Computed Tomography
CC	Craniocaudal (projection)
CDS	Clinical Decision Support
CNR	Contrast to Noise Ratio
CR	Computed Radiography
CT	Computed Tomography
CTDI	Computed Tomography Dose Index
DICOM	Digital Imaging and Communication in Medicine
DLP	Dose-Length Product
DR	Digital Radiology
DRL	Diagnostic Reference Level
EMR	Electronic Medical Records
ESAK	Entrance Surface Air Kerma
FOV	Field of View
HIS	Hospital Information Systems
HL7	Health Level Seven
IHE	Integrating the Healthcare Enterprise
IOD	Information Object Definition
IR	Iterative Reconstruction
IT	Information Technology
KAP	Air Kerma Area Product
kVp	Peak kilovoltage
Lat	Lateral (projection)
mAs	Milliampere-seconds
MLO	Mediolateral (projection)
MPPS	Modality Performed Procedure Step
MTF	Modulation Transfer Function
NPS	Noise Power Spectrum
OCR	Optical Character Recognition

PA	Postero-anterior (projection)
PACS	Picture Archiving and Communication System
PET	Positron Emission Tomography
PRDSR	Patient Radiation Dose Structured Report
RDSR	Radiation Dose Structured Report
REM	Radiation Exposure Monitoring
RIS	Radiology Information Systems
SdNR	Signal Difference-to-Noise ratio
SPECT	Single Photon Emission Computed Tomography
SSDE	Size Specific Dose Estimate

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