

Editorial

RADIATION PROTECTION AND DOSE MONITORING IN MEDICAL IMAGING: A JOURNEY FROM AWARENESS, THROUGH ACCOUNTABILITY, ABILITY AND ACTION...BUT WHAT IS THE DESTINATION?

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RADIATION AWARENESS

Radiation awareness and protection of patients have been fundamental responsibilities in diagnostic imaging since the discovery of x-rays late in 1895 and the first reports of radiation injury in 1896 (1). In the ensuing years there have been significant advancements in equipment that uses either x-rays to form images, such as fluoroscopy or computed tomography (CT) (2), or the types of radiation emitted during nuclear imaging procedures (e.g., positron emission tomography, or PET). These advancements have allowed detailed and indispensable evaluation of a vast array of disorders. In fact, in 2001, CT and MRI were cited by physicians as the most significant medical innovations in the previous three decades (3). Rapid

technological advancements in the last decade with CT, especially, have required imaging professionals to keep pace with increasingly complex technology in order to derive the maximum benefits of improved image acquisition and display techniques, in essence the improved *quality* of the examination. It has also been challenging to fulfill the fundamental responsibilities of *safety* during this period of rapid growth (e.g., radiation protection, management of the risk of additional interventions driven by incidental findings (4), performing studies that were not indicated). The purpose of this paper is to define critical issues pertinent to ensuring patient safety through the appropriate assessment, recording, monitoring, and reporting of the radiation dose from CT.

CT Scanning and 4A Innovation Model

The 4A Innovation Model, which includes awareness, accountability, ability, and action (5, 6), is a framework that has been successfully used for adoption of new technologies, including the NQF Safe Practices. These are defined in the National Quality Forum *Safe Practices for Better Healthcare – A Consensus Report – 2010 Update* (6, 7) (Table 1), which provides a description of how leaders can use the 4A Model to innovate and improve their CT practices. For this paper, we suggest use of the 4As to define improvements and innovations in CT scanning practices that can be put into clinical practice.

AWARENESS: The medical community and the general public have become increasingly aware of the radiation delivered to the U.S. population by medical imaging. There have been substantial efforts directed towards improvements in techniques and applications of strategies for radiation protection in medical imaging, but we need to take further actions in appropriate radiation-dose recording. The term *appropriate* is pivotal here. Efforts in radiation-dose recording must be accurate, practical, adaptable, consensus-based, and applicable

to all patients undergoing medical imaging, *and must be meaningful*. This recipe can be found in models and guidelines such as those exemplified by the highly successful advocacy and educational *Image Gently Campaign* for radiation protection in children (8, 9); as a template for The National Quality Forum (NQF) *Safe Practices for Better Healthcare Safe Practice 34, “Pediatric Imaging”* (10); the Society of Interventional Radiology’s guidelines for recording radiation dose (11); and the Image Wisely campaign (12). The Image Wisely campaign was launched to apply similar strategies and a positive, science-based approach to the radiation protection of adults as is being applied to children.

ACCOUNTABILITY: Radiation protection for medical application has two fundamental principles: justification (ensuring the examination is warranted) and optimization (using only as much radiation as is necessary for that examination) (13, 14).

While these principles should be applied for each individual examination, there is a growing emphasis on added accountability for the collective radiation used in medical imaging (15), both for individual patients and for more global practice performance, such as adherence to reference levels (benchmarks), as discussed below.

Leaders of imaging practices and individual providers must be accountable for the radiation safety of all patients, both as a group and individually, entrusted to their care. Leaders are particularly responsible for closing gaps in performance.

Although accurate radiation-dose recording and tracking are challenging with current technology and systems, radiology, medical physics, and industry are collaborating to achieve this worthy goal. Recording this information will not only provide a dose profile for a patient or a practice over time, but will also increase our ability to monitor and adhere to radiation protection principles such as optimization. Table 2 provides a list of potential benefits from dose monitoring.

ABILITY: Measures, standards, and practices, when coupled to knowledge and resources, provide an organization and its leaders with the tools to close performance gaps and ensure safety. We can’t be aware of and accountable for gaps in performance, however, if we are not able to measure and close them by direct action. Hence, we will fail in our charge if we lack the ability to measure radiation-dose levels in an appropriate (i.e., contemporary) manner.

ACTION: The National Quality Forum (NQF) *Safe Practices for Better Healthcare* (8) is a set of formalized consensus-based standards for hospitals created through a National Harmonization Program. Performance measures, also developed by the NQF, provide the opportunity to ensure quality in performance, including CT (10,16). Recent efforts to address the challenges of radiation-dose monitoring have been made by national and international organizations (17-22).

Table 1: The 4A Model of How Leaders Can Implement Adoption of New Technologies

- **Awareness:** Leaders must be aware of performance gaps before anything can be achieved. Awareness requires that adequate information is provided to leaders at all levels. The practice requires that structures and systems are in place to provide a continuous flow of information to leaders from multiple sources about the risks, hazards, and performance gaps that contribute to patient safety issues. Leaders at any level need a clear understanding of performance shortfalls in order to act.
- **Accountability:** Accountability of leaders to closing performance gaps is a key success factor – someone needs to “own” the changes that must be made to processes, systems, and expectations of staff. Due to the slow but critical transformation from the legacy “command and control” accountability structures to “team-based” approaches, few leaders are directly accountable for specific and measurable patient safety performance gaps. High-performing organizations have seen the light and have teamed clinical with administrative leaders with joint goals.
- **Ability:** A team or unit may be aware of gaps, and may be accountable for those gaps. However, if they are not able to make changes, change will not occur. Worse, “learned helplessness” can set in, galvanizing the troops to the status quo. The dimension of ability may be measured as capacity for change. It requires investment in knowledge, skills, compensated staff time, and the “dark green dollars” of line-item budget allocations. Preliminary results from the TMIT Research Test Bed, which is studying the impact of patient safety practices and solutions in hundreds of community hospitals, indicate that few hospitals have made adequate investments in patient safety.
- **Action:** Finally, to accelerate innovation adoption, organizations need to take explicit actions toward line-of-sight targets that close performance gaps, that can be easily measured, and that can generate early wins. Multiple objectives that can be achieved by direct action must be designed into an improvement program, improvement that can be easily scored.

Adapted from [6]

Radiation-Dose Monitoring

Radiation-dose monitoring is also a concern to U.S. federal and state government agencies. One of the main goals of the U.S. Food and Drug Administration's Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging is supporting the establishment of voluntary dose registries (23). The Centers for Medicare & Medicaid Services, which uses measures endorsed by NQF and other quality organizations as part of its quality measures programs (24), has submitted a list of measures under consideration for 2012 to the NQF-convened Measure Applications Partnership (MAP) for multi-stakeholder input (25). A number of the measures under consideration relate to radiation-dose optimization for medical imaging (e.g., percentage of CT exams reported to a radiation-dose index registry and percentage of pediatric CT imaging studies that use individualized protocols in compliance with widely used guidelines). California recently enacted the "dose reporting law" (SB 1237), which includes a requirement for recording of CT-dose indices on the patient's medical record and provisions for dose-related medical event reporting (26).

Accreditation organizations such as the American College of Radiology, the Intersocietal Accreditation Commission, and The Joint Commission also have an important role in taking action to enforce dose monitoring as part of a facility's overall quality assurance program. Recently, The Joint Commission recommended that facilities "record the dosage or exposure as part of the study's summary report of findings" (27). While this is a good goal, it is also challenging, and facilities need clear guidelines on how to implement it.

While facility-level dose monitoring and comparison to national reference levels have been required by law in many European countries for the last decade, there is no such national requirement in the U.S., and national reference levels for the U.S. are beginning to be addressed (28, 29). As more states and accreditation organizations consider regulations or guidelines on this topic, the need for practical, consensus-based dose-recording quality measures becomes even more important. Also, any measure should be accompanied by clear guidelines for implementation by the facility and third-party auditors (e.g., by regulators or accreditation organizations).

While recent measures (16) may be correct in concept and should be applauded for their objectives regarding radiation dose, care must be taken to make sure that such measures generate real safety at the front line and do not contradict existing measures that have stood the test of time and

appropriately address individual patient characteristics. The following material from radiology and medical physics specialists indicates what is known and unknown in three major areas: (1) background information of radiation doses and potential risks from medical imaging (2); dose estimations for CT (3); and dose recording, monitoring, and reporting. As a basis for improved quality measures for CT radiation protection through radiation dose estimation and recording across all patient ages and sizes, the following sections propose some solutions to the challenges faced in these three areas.

#1 Background: Dose and Risk in CT

Radiation exposure and risk from medical imaging examinations is a leading safety issue in radiology (2). Overall, an estimated 85 million CT examinations are performed annually in the United States (30). The general trend for CT has been about a 10% increase annually (31), although this trend seems to have slowed recently in both pediatric and adult patient populations. Still, CT accounts for about 25% of the total radiation exposure to the U.S. population annually (32).

An article in *USA Today* in 2001 brought to the public's attention the potential for radiation induced cancer from CT scans in children (33), and more recent scholarly publications and reports of events and overexposures to patients from CT continue to be highly visible in the lay press as well as in medical journals (34-40).

When discussing radiation risk, it is necessary to recognize that CT is an invaluable diagnostic, and that the benefit from a medically-appropriate CT exam almost always far exceeds the potential risk. Still, the risk aspect of the benefit-to-risk ratio must be considered (40, 41). There is little debate that effective doses (discussed further in the next section) over 100-150 mSv are associated with a small but statistically significant increase in risk of cancer (42); doses between 50-100 mSv are much debated (the effective dose from a single CT can range from less than 1.0 mSv to more than 30 mSv, although most provide between 2-20 mSv). While there is little direct evidence for a link to cancer with effective doses below 50 mSv (43), a recent study showed an association between leukemia and brain tumors and childhood CT scans (40). The conservative perspective taken for radiation protection of patients is that no amount of radiation should be considered "safe." If the required clinical information can be obtained at a lower dose, without compromising the accuracy of the exam, then the lower dose should always be used. This conservative

approach is especially appropriate with children, who are, in general, more vulnerable to the effects of radiation and who absorb more radiation relative to an adult at the same equipment settings

The potential risk (again, the presence of risk is not certain) of any individual developing a fatal cancer from a single CT examination depends on a number of variables, such as age, gender, region examined (the ankle is much less radiation-sensitive than the chest), and genetic susceptibility. The range of estimated additional risk for a fatal cancer is quite large, varying from approximately under 1 in 100 (1%, for a young patient and several higher-dose exams) to 1 in 10,000 (0.01% for older patients and lower-dose exams or exams to the extremities) (40). This is a factor of 100, and those discussing risk need to be mindful of this variability. Discussions should also include the estimates of baseline (naturally occurring) lifetime risk of developing cancer (40%) or of dying from cancer (23%).

While we have a general understanding of the limitations of risk estimations, we currently lack the following: tools to provide patient specific dose estimates; diagnostic reference levels for many of the CT exams performed in the U.S., particularly as a function of examination indication and patient size/age; consensus on the method of and objectives for tracking an individual's medical radiation dose; and guidance on how to interpret and act upon individual cumulative dose estimates (15, 44).

#2 Dose Estimations:

There are several measures of radiation dose, each of which is used for a different purpose. The most readily available are dose indices known as the Volume Computed Tomography Dose Index (CTDI_{vol}) and dose length product (DLP) which are displayed on the CT scanner console (45). These values are obtained in the factory by scanning two acrylic cylinders (one with a 16-cm diameter, and the other with a 32-cm diameter) on a representative sample of each CT scanner. In clinical use, when the CT settings for a patient examination are selected, the machine calculates the CTDI_{vol} for these cylinders ("CTDI phantoms"). This method is highly accurate for estimating the radiation dose to the *phantom*, thus characterizing the radiation output of the scanner (46, 47). However, these dose indices are not an estimate of the actual patient's dose, as the patient's size and absorption characteristics are not considered. When exam parameters are manually set, the exposure displayed CTDI_{vol} would be the same even if no patient was in the scanner. Again, these indices tell the user how much radiation the scanner produces, not how much a patient receives.

Nonetheless, CTDI_{vol} and DLP are tools for assessing radiation safety practices, both at the individual and practice levels; if data are binned properly according to patient size and exam clinical indication, they can be used to evaluate the dose settings used in a practice for purposes of protocol optimization.

The determination of actual radiation dose absorbed by an individual is highly complex. A complete characterization of dose to the individual patient would include estimates of individual organ doses which must take into account the patient's gender, age and body habitus (essentially the size and shape). Currently, a clinical tool to estimate organ doses to individual patients is not available. What then are the currently available methods for dose estimations? Further, risk *estimates* are based on estimates of doses to individual organs and age- and gender-specific risk coefficients. These risk coefficients are associated with a relatively large uncertainty, about an order of magnitude, especially for doses below 100 mSv. It is important to recognize this so that the level of precision required in dose estimates is set in a manner consistent with the uncertainties in subsequent risk estimation.

Effective dose (reported in mSv) is a common method for deriving the *risk* associated with a radiation exposure. It is a population-based average for patients of standard size. While there are other units of dose used in medical imaging, effective dose in mSv is one of the most commonly encountered units. While *effective dose* is a commonly used dose metric, it was not developed as an estimator for individual patient dose or risk, and is not well suited for this purpose (48, 49). One critical point is that effective dose, including its use in the CT clinical literature, is really a *risk estimation tool for a non-gender-specific, standard-size patient, and not an actual patient dose* (50). Any references to "dose" in this paper assume that this caveat is understood.

The effective dose represents the risk from CT exam in terms of the risk from a total body (uniform) irradiation. It is the sum of the radiation doses to exposed organs, multiplied by the differing risk-weighting coefficients for different organs. A proper calculation of effective dose is complicated, and the DLP from the CT scanner is often used in clinical practice as a very simplified effective dose estimation for patients. However, effective dose was not designed to describe the dose to an individual patient; it is a useful measurement for comparing doses from different imaging modalities (e.g., a barium enema with an abdominal and pelvic CT) which all have different dose indices, or different

regions with the same modality (e.g., a brain CT versus a chest CT) (51).

An example of a limitation of the DLP method for determination of dose follows. Patient dose depends on patient size: for the same values of CTDI and DLP, a small patient will actually receive a higher dose than will a large patient, even though the effective dose, calculated according to the DLP method, is the same. To address this, the American Association of Physicists in Medicine (AAPM) report (Task Group 204) (52), through scientific investigations by Boone, Strauss, McCollough, and McNitt-Gray, developed an improved estimate of patient dose (the size-specific dose estimations, or SSDE) based on patient body size. SSDE can be calculated easily using the information available on the scanner console. SSDE is derived from the CTDI, knowledge of the reference phantom used, a patient-size measurement, and a simple conversion table. It is a more accurate dose estimator of the mean patient dose over a certain body region (accurate to 10-20%).

While allowing a significant improvement in CT dose estimation, SSDEs do not provide as accurate an estimation of patient dose as does the estimation of individual organ doses that is possible through newer investigations by both medical physicist and radiology investigators (including those used for development of the SSDE method) (52-55). While this more advanced work will provide more detailed patient-specific dose information and risk estimations for individual organs such as the lungs, liver, or kidneys, these methods are not currently suitable for routine clinical use.

In summary, both SSDE and the organ-specific dose-estimation methods demonstrate that approaches to dose estimation in CT are rapidly evolving. *Methodology based on the current CTDI and DLP method is often inaccurate, and may provide a false sense of security about doses, particularly in the younger population.* This runs contrary to the goals of the Image Gently Campaign and NQF Safe Practice 34, "Pediatric Imaging" (10), which advocates for appropriate dose management for CT in the pediatric population.

The imaging community has a responsibility for accurate dose assessment. These accurate estimates serve as a foundation, for dose recording and analysis, and are essential for realization of the benefits of dose recording (Table 2) (17). This point cannot be overemphasized, since reference levels (standard dose ranges) using CTDI and DLP measures will not reflect the effect of variation in patient sizes and will render inaccurate the dose estimates (and broad risk considerations) for patients

or patient populations from medical radiation exposure.

#3 Radiation Dose Recording, Monitoring, and Reporting: an essential quality metric

The imaging community has a responsibility to manage radiation risks just as we do for other procedural risks such as bleeding, infection, thrombosis, and adverse drug effects. These other adverse events are often recorded in databases. What about recording information about radiation dose from medical imaging? Imaging professionals, who are most knowledgeable about the technology and examinations, are the most appropriate members of the medical and safety community to develop the methodology needed to record dose information with reasonable accuracy. If the dose-estimation methods and doses recorded, and how they are recorded and reported, are inappropriate, the resulting data would be questionable, and may cause patients to refuse necessary imaging exams that could be crucial to their or their child's health care. The responsibility for radiation management, through dose estimation and reporting, must be reflected through a *consensus* regarding dose metrics, dose-estimation methods, dose-recording methods, and dose-interpretation methods. Dose estimates need to be useful (discussed above), easily determined, and recorded in an electronic health care record (for individual dose monitoring) or centralized database (for an anonymous dose registry to compare facilities). Paper copies, manual dose entry, and dose cards fall short in this respect.

As elaborated in Table 2, monitoring of radiation exposure and exam history can be used for different purposes: justification; optimization; individual risk assessment; and research. Each of these purposes requires different types of data which could provide for individual patient-based records and quality assessment and improvement functions (e.g., variations in similar protocols among different CT scanners, or variations over time). On a larger scale, dose information would permit determination of reference levels that can serve as benchmarks for individual examinations, including age/size-based ranges, and promote quality improvement. Other benefits of dose archiving can be found in the table.

Importantly, dose estimations using age alone are poor for establishment of reference levels. Based on recommendations from the International Commission on Radiological Protection (ICRP) (14), FDA's Center for Devices and Radiological Health promotes grouping dose data based both on patient size and clinical indication (56). The medical

community is actively addressing challenges associated with appropriate grouping of dose data based on patient size and clinical indication. For example, new methodology such as SSDEs discussed above provide improved methods for recording dose based on patient size and should be considered when estimating CT doses. The American College of Radiology (ACR) Dose Index Registry (57), the Radiological Society of North America (RNSA) RADLEX program (58), and the American Association of Physicists in Medicine (AAPM) working group on standardization of CT nomenclature and protocols (59) are addressing the lack of standardized nomenclature for CT exams, which makes grouping, based on clinical indication (and body part) and comparisons of dose indices across different facilities, a significant challenge. For instance, the identical examination may be named differently at different institutions: an abdomen CT may also be labeled abdominal CT; abdomen pelvis CT; AP CT; or abdominal-pelvic CT. Conversely, CT examinations may have the same name, but may be done with different protocols and different doses, and for different purposes, at different institutions. ACR's work on standardized exam names and AAPM's work on SSDEs are crucial, as improper assignment of a regional CT exam due to failure to account for clinical indication or patient size factors would render invalid the establishment of reference levels or comparisons against existing reference levels and across different facilities.

Needs for dose recording include agreed-upon dose indices for CT. Should the measure be $CTDI_{vol}$ or DLP, SSDE, organ dose, or effective dose? Some difficulties with dose recording were recently discussed (18). One critical consideration is the audience for dose-estimation information. Can “one size (one measure) fit all” – radiologist, medical physicist, referring healthcare provider, patient (through patient portals and access to radiology reports), patient’s loved ones, supervising regulatory and/or governmental agencies? Physicists, radiologists, regulatory or governmental organizations, and patients will likely have different levels of needs and understanding with respect to dose records. What does “ $CTDI_{vol}$ of 24.2 mGy” mean to a patient? Do all patients want this information? Should it be on the picture archiving and communication system (PACS), but not the patient report? How can one justify this? These are critical questions to address before we can begin to approach radiation-dose recording for medical procedures. Instead of dose, should it actually be a risk estimate that is recorded and reported? This has been recently debated (15). While the dose is a

number that can be useful for facility-level dose optimization and quality-assurance purposes, some measure of risk underlies arguments for the reporting of doses to individual patients as part of their medical record (15). Suffice it to say that it would be extremely difficult, given large uncertainties and controversy with radiation risk from medical imaging (60), to effectively communicate this among ourselves and to patients

We must be mindful of the scope of our diverse “customer” base (e.g., patients, referring clinicians, administrators, regulators) when planning for dose recording. It has been suggested that report statements might best focus on (re)assurance indicating that the equipment, personnel, and the program (whether CT, interventional radiology, fluoroscopy, nuclear medicine, or conventional radiography) meet standards of excellence for expertise, safety (including radiation protection), and quality in a fashion similar to the Good Housekeeping Seal program (18). Most individuals don’t really care what ingredients are in their toothpaste as long as there is clear evidence that some respected authority has “approved” the product. The regulatory or scientific community might want the list of toothpaste ingredients, and it should be available. For medical imaging, more specific dose and risk discussion could be accessible through readily available links within the report to potentially satisfy the needs of the customer base.

CONCLUSIONS

Medical imaging from radiography, fluoroscopy, computed tomography, and nuclear medicine exams does deliver low levels of radiation exposure to patients. The risk associated with low-level radiation is small, if it even exists, and exactly how small is widely debated. Nonetheless, the recommended approach in scientific and medical circles for managing medical radiation exposures is to justify the need for the examination, and to use only the amount of radiation necessary to answer the questions at hand.

There is a growing trend towards accountability, both nationally and internationally, including recording, monitoring, and reporting of medical radiation (15). We must work together as a community (including radiologists and other imaging specialists, technologists, medical and health physicists, regulatory and governmental representatives, practice/hospital administrators, industry representatives, and the public through advocacy groups) to be sure that the dose metrics we adopt are as accurate and adaptable as possible and that these measures serve the purposes of all

stakeholders. For example, to say that CTDI is the measure that should be recorded for CT does not fully consider the issues related to, and meaningful objectives of, radiation-dose recording.

Simply stated, we must be careful that what we select as a dose measure is as accurate as possible; is able to be modified to reflect the evolution in dose estimations; is suitable for both pediatric and adult patients; doesn't require manual input of data; and can be embraced by all stakeholders.

The measures adopted and programs developed must have clearly defined objectives that are amenable to monitoring and modification. This is the very essence of a quality practice.

Table 2: Potential Benefits from Patient Radiation Exposure Monitoring

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| I. | Benefits to patients | <ol style="list-style-type: none"> a. Optimize radiation exposure b. Accountability for radiation protection by healthcare providers c. Provides opportunity for informed discussions between patients and healthcare providers |
| II. | Benefits to healthcare providers referring patients for imaging/intervention | <ol style="list-style-type: none"> a. Potential benefits from decision support b. Improved/justified resource utilization |
| III. | Benefits to healthcare providers involved in performance of imaging/intervention | <ol style="list-style-type: none"> a. Potential benefits from decision support b. Improved/justified resource utilization c. Realistic comparison of facility exposures with nationally available diagnostic reference levels d. Protocol optimization and quality improvement |
| IV. | Benefits to policymakers | <ol style="list-style-type: none"> a. Quantitative tools protect the public health and safety b. Improved quantitative approaches to radiation safety policymaking c. Manage imaging utilization |
| V. | Benefits to regulators | <ol style="list-style-type: none"> a. Encourage facilities to implement the diagnostic reference level process b. Improved data to aid facilities in conducting reliable self-audits |
| VI. | Benefits to researchers | <ol style="list-style-type: none"> a. Provide radiation safety data sets b. Incorporate patient-specific radiation metrics into research studies c. Provides quantitative basis for development of best practices, guidelines, and appropriateness criteria |
| VII. | Benefits to industry | <ol style="list-style-type: none"> a. Promotes partnership with other stakeholders in establishing radiation exposure monitoring technology |

Modified with permission from Madan Rehani, PhD IAEA [17]

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