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The role of dose tracking systems in radiation safety programs

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In 2009 dozens of patients undergoing CT head examinations were accidentally overexposed leading to hair epilation and concerns for cancer induction. These events were an eye-opener for the radiology industry, as up to this point no other significant diagnostic radiology incident had occurred. This drove the need for far more attention on how to manage radiation exposure for patients, not necessarily from a clinical image quality perspective, but from a patient safety perspective. What the industry quickly realized is that within the current healthcare framework there is no clear owner of managing cumulative radiation dose to patients and how this information should be used throughout their care. The goal of this whitepaper is to drive this conversation and offers the Philips perspective on how we use the data available from radiation dose tracking solutions to contribute to patient care.

What is dose tracking and why is it important?

We have been exposing patients to medical radiation in the healing arts for over 100 years. The focus up until now has primarily been on image quality to ensure an accurate diagnosis and deservedly so, as the lack of evidence regarding low levels of medical radiation exposure are largely unknown to this day. The key to medical radiation exposure is ensuring that the procedure is justified for the patient and that the radiation exposure is managed for the desired balance between image quality and radiation dose to that patient. This has always been done on an individual basis, per patient and per procedure. It has not been common practice to use this exposure data retrospectively as part of the patient's care or as part of the hospital's equipment quality or safety program at a larger level.

This is where dose tracking is important and can be a value-added tool to hospitals, providing improved quality control and cumulative dose management (managing patient risk). Hospitals and imaging clinics have never before been able to capture radiation dose across all their equipment, regardless of modality or vendor. The advent of dose tracking software allows radiology departments to assess variability across their equipment. This also allows for the patient's dose to be sent to the EMR and attached to their records via the radiology dictation system, which is a convenience to the radiologist while simultaneously reducing transcription errors. Surprisingly, to this day, most patient radiology exam radiation doses are not recorded as part of their medical records.

Regulatory requirements and standards

In the United States, the Nuclear Regulatory Commission is the regulating authority for all radioactive materials (including Nuclear Medicine radiopharmaceuticals), and the States are the regulating authority for radiation generating machines such as X-ray machines and linear accelerators. In many instances, States have also been delegated the authority over radioactive materials (called "Agreement States"), therefore having responsibility for all sources of radiation.

Historically, the only regulations that existed with regard to medical patient radiation exposure were specifically for excessive dose in Nuclear Medicine, reportable to either the NRC or the local Agreement State, but no standards existed for reporting X-ray exposure. In recent years, partly in response to the overexposure events and also due to heightened awareness of radiation exposure in general, Agreement States began to adopt local regulations such as California where AB510 was adopted in 2012, requiring hospitals to report excessive CT exposures to the state - a first in the nation. Other states, such as New York and Texas, have begun to add local State requirements for CT image quality and protocol optimization, a trend that is likely to continue.

As of 2015, the Joint Commission requires routine analysis of patient exposures in CT in an effort to optimize and normalize exam protocols (and dose) across their enterprise. It is likely that these standards and regulations will continue to evolve and cover other X-ray modalities and applications over time, particularly in fluoroscopy.

In February 2018 the EU is slated to also codify new laws through a European Commission Council Directive "laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation" that will implement very similar rules for tracking and monitoring patient exposure. These new rules are even more explicit than the 2015 Joint Commission Standards, calling for medical providers to exercise justification, optimization, protocol management, additional staff training and clinical audits.

In the US there is a new law being enacted referred to as "MACRA", short for Medicare Access and CHIP Reauthorization Act, which went into effect April 2015. This is a bold move for Medicare that shifts reimbursement from a pay-per-service model to a "value-based care" system. Value-based care will be measured by metrics that healthcare providers must keep to ensure reimbursement from CMS. While the scope of MACRA is massive, buried in the metrics are patient radiation dose requirements which dose tracking software can help manage.

Framework of existing hospital process

Radiation is ubiquitous in today's worldwide healthcare environment; X-ray machines are standard tools employed by clinicians in diagnosis and in treating people; and radioactive materials are used in diagnosing symptoms, in treating cancer, and in sterilizing blood. The hazards associated with radiation requires that the sources of radiation be tightly regulated and controlled.

Hospitals are required to have the administrative resources to manage the purchase, use and disposal of radiation sources, including policies, programs and procedures. They must also have the facilities and personnel needed to implement these policies, programs and procedures. The standard model is to have a Hospital Radiation Safety Committee (RSC) that essentially works on the State's behalf to oversee the implementation of programs, and ensure that all activities are performed in compliance with applicable regulations. The RSC is required in the United States per Federal Code 10 CFR 35.24 (and local Agreement State regulations) to provide this organization.

The hospital or imaging clinic is also required to delegate the authority to manage all radiation safety related activities to a Radiation Safety Officer (RSO). The RSO is usually an employee that has been delegated the responsibilities either as part of their part-time job, or as their full-time job and must meet minimum educational and practical experience. The RSO usually has a staff to assist with the day-to-day implementation of the programs and procedures. In the US this is usually a dedicated role within the hospital and in Europe it is usually a role owned by the Medical Physicist or Radiologist.

As part of radiation dose management in general, the RSC legally requires a routine meeting of the following hospital staff to provide oversight of all byproduct radioactive materials used in the hospital:

- The Radiation Safety Officer
- A representative of the nursing staff
- A management representative (non-radiology)
- At least one authorized user for each type of radioactive material use by the hospital

In the US, the terms "authorized users" and "byproduct material" may be foreign to most people:

- Authorized users are hospital staff with specialty academic and practical training in radiation dosimetry, protection, radiobiology, mathematics, medical use and research use of radioactive materials, to name a few.
- Byproduct materials are radioactive materials that are produced by a nuclear reactor. These are usually "byproducts" of nuclear fuel such as uranium and thorium that are recovered to make medical radio-isotopes. Iodine-131 and Molybdinum-99 generators are examples of these materials.

Notice, however, in these definitions that X-rays are NOT covered in the Radiation Safety Committee requirements. This is the gap that has left out X-ray medical radiation dose to patients from being supervised and reviewed as part of a formal process.

Who assumes responsibility for patient radiation safety?

Who actually carries out the duties of the RSO often is related to an individual's professional area of expertise. It is not uncommon for the RSO to have radiation safety responsibilities for radioactive materials only, and a diagnostic imaging Medical Physicist having responsibilities for X-ray machines. Radiation used for therapeutic purposes are most commonly the responsibility of Medical Physicists that specialize in radiation therapy. So although the RSO may be responsible for radiation safety across the institution in name, in practice, there are other individuals that may have narrow responsibilities in their specific area of expertise and report program status to the RSO. It's worth mentioning that even though the regulatory framework requires that the RSO be delegated this authority of oversight of radioactive materials, that delegation is made usually by the CEO/ President of the organization. This is because the application to the NRC or Agreement State to use radiation is signed by the highest office in the institution.

Historically, radiation safety was applicable to the hospital's workers and the general public that visited the hospital; radiation safety for patients was considered "not applicable" because they were intentionally being exposed to radiation for their benefit. The only exception to this was radiation therapy because the high levels of radiation exposure to kill cancers also carry a significant risk to the patient if their personal safety was not addressed as part of the treatment protocol. However, recent data has forced the diagnostic imaging community to also address patient radiation safety. As a result, computer technology now allows the healthcare community to monitor and track radiation exposures to patients to ensure their safety is maximized.

The question facing healthcare professionals today is "what data are clinically important and useful for monitoring, tracking and controlling patient radiation exposures?" and, more importantly, "what should we do with this data?" The answer to the question as to who owns patient radiation dose therefore depends on the resources available in the hospital. Some hospitals will not employ a Medical Physicist, and although some hospitals contract RSO work to consultants they are more likely to have a resource. RSOs also own the management of hospital staff occupational dose, so it is preferable that they manage patient dose and have the responsibility to track patient dose and bring it to the RSC meetings for discussion in close collaboration with Medical Physicists and other radiology professionals.

NCRP report 172 also prescribes the creation of a "Clinical Dose Optimization Team", or CDOT, to own this responsibility. Their responsibility is to review image quality, patient radiation doses, procedures and imaging protocols as compared to national values. This team should consist of:

- Imaging Physicians
- Qualified Medical Physicist
- Radiographic Technologist
- Ancillary staff from imaging department

Working with the data from dose tracking software

Integrating patient radiation safety related data into the institution's Radiation Safety Program is a great challenge for many. The primary focus has been first on patient radiation dose delivered by CT scanners, and second from the fluoroscope used for guided interventional procedures. The reason why these modes of radiation exposure were chosen over the others is because they are performed on a larger proportion of the worldwide population as compared to the other modalities, and the exposure to each patient can be a significant amount of radiation compared to other radiology modalities such as digital radiography and mammography.

Radiation dose tracking software brings all patient exposures into one place allowing hospitals to segment, analyze and track dose to individual patients. It also allows hospitals to discover trends in their data across their imaging suite of machines, allowing protocol adjustments and normalizing exam exposure.

DRL/Achievable dose targets

The National Commission on Radiation Protection Report 172 established levels for general types of procedures that most institutions perform using X-rays for the purpose of providing benchmark values. They produce average values for a variety of procedures from all modalities for comparison allowing institutions to generate average values of their own, and if they are higher than the published values, then they should take steps to possibly manage radiation exposure. These benchmark or reference values are referred to as Diagnostic Reference Levels (DRLs). These DRLs are typically the 75th percentile of the dose distribution for patients in that exam protocol.

Report 172 also provided more challenging lower levels that institutions should try to attain, referred to as Achievable Doses (ADs). The intention is that when the institution is hovering at or below the DRL, there should be a lower target to aim for. The ADs are typically defined as 50th percentile of the dose distribution and meant to manage dose even further while maintaining adequate image quality.

Certain countries in Europe, such as France's ASN Guide No. 11, have also established local DRLs that healthcare institutions should target. In fact, there are many ways of managing the data. For example, the UK PM77 Guidance re a complete rescan needed this would be a recordable (and potentially reportable) event to the government agency. We still have a ways to go to harmonize the best approach to managing patient exposure, however DRLs seem like the most probable path.

One thing should remain clear however, that DRLs are not meant to be for regulatory or commercial purposes nor are they to limit exposure to patients for a certain procedure. Justification and optimization are the keys to managing dose to a particular patient. DRLs are valuable to manage equipment optimization and protocol management.

Methods of analyzing data

The RSC is responsible for ensuring that the use of radiation for diagnostic purposes in the hospital is purchased, used and disposed of according to applicable regulations, and that the safety of workers, the public, and now patients are appropriately managed. The collected data is used for two purposes. The first are as quality measures – to ensure that the programs and procedures are being performed as intended and that the outcomes are consistent with the respective design goals. The second is to identify outliers, i.e., those instances where things did not go as expected.

Dose monitoring and tracking is extremely useful for both purposes. For example, the patient-specific radiation dose metric for CT scans (i.e., Dose Length Product, volumetric Computed Tomography Dose Index or Size Specific Dose Estimate) can be aggregated by protocol type (e.g., head scan, abdomen scan, etc.) and described and compared through statistics. Comparing actual values to appropriate benchmarks can reveal whether the institution is comparable to other institutions performing the same types of scans on the same types of patients. The data can also be used to identify outliers. Dose metrics used on the individual level can be used to identify those patients that received far more radiation than the protocol or other controlling factors can explain. This can help Medical Physicists to identify areas of improvement, or unknown operational practices, that could help manage equipment use and normalize dose per exam across the patient population.

Because DRLs and Achievable Dose work within the concept of "percentile" of the dose distribution, the statistical boxplot graph is a very effective method of analyzing the data.
A boxplot indicated the distribution of data with a min/max/median while also identifying the 75th percentile and also the 25th percentile. If you participate in the American College of Radiology's Dose Index Registry (DIR) then you are probably already familiar with this type of graph, as this is what they use to distribute data to participants. See Figure 1 below for an example of a box plot.

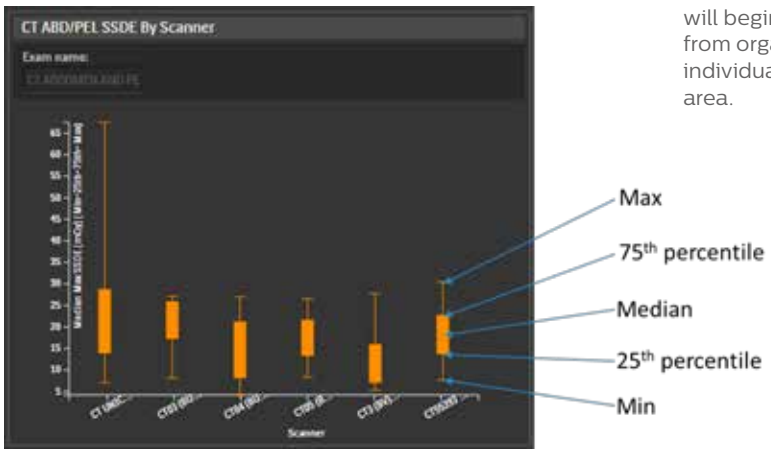

Figure 1. Example of a boxplot data distribution

Goals/Review of progress

Healthcare institutions are expected to manage patient exposure having probably never done it before, so where do you start?

The concept of dose management is one that entails patient safety, risk, regulatory compliance and now facility accreditation As such, it is important that hospital executives "buy-in" to this philosophy to ensure that staffing, funding and other adequate resources are available with accountability established. A robust hospital infrastructure builds the foundation for success. This is where the concept of the CDOT, as mentioned above, comes into play. The CDOT should serve as the central owner of patient dose that reports into the Radiation Safety Committee for that institution. Vendors and manufacturers are keen on the needs of users and can also help provide training, content and support for developing your patient radiation safety program. Education of stakeholders is key after programs are established and infrastructure is complete. Of course all relevant staff should be educated on the processes and teams established to monitor dose, but patients should also be included. Patients have never been as educated on dose as they are today. The reality is that the internet is full of content that may be either too technical, or misleading based on the source, for patients to educate themselves. A proactive and transparent patient education campaign with factual data is a good path to follow.

The first step to managing patient dose is data. Using a commercial dose tracking software, or data mining from your PACS or RIS, allows you to benchmark yourself with retrospective data. Set goals to understand your current dose results against DRL values and make modest targets to improve aggregate dose. Reviewing the data will also identify unknown practices, such as variation among Technologists, and help standardize ways of working in an environment with equipment from multiple vendors and with different levels of technology due to age.

The path forward for patient dose management will take some time, but small steps with some organizational support will begin to yield successful results. This is the expectation from organizations such as Joint Commission as well as individual States as they promulgate more regulation in this area.

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