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Manufacturer's Association Cooperates on Dose Safety

IMAGING Management spoke to David Fisher, Executive Director of the Medical Imaging & Technology Alliance (MITA) and Vice-President of the National Electrical Manufacturers' Association (NEMA) about recent momentum in the drive to address potential health hazards caused by radiation exposure through medical imaging and related procedures. Also concerned about health impacts of radiation exposure, the Federal Drug Agency (FDA) has turned their attention to three types of medical imaging procedures: computed tomography (CT), nuclear medicine studies, and fluoroscopy, said to be "the greatest contributors to total radiation exposure within the U.S. population." The FDA is advocating the adoption of two principles of radiation protection: appropriate justification of the radiation procedure and optimisation of the radiation dose used during each procedure.

The FDA has also commenced development of targeted requirements for manufacturers of CT and fluoroscopic devices to incorporate important safeguards into the design of their machines to develop safer technologies and to provide appropriate training to support safe use by practitioners. The goal is development of a patient medical imaging history card that will allow patients to track their medical imaging history and share it with relevant healthcare providers.

Moreover, manufacturers will include an additional safeguard to allow hospitals and imaging facilities to set maximum radiation dose limits that would prevent CT scanning at higher, potentially dangerous radiation levels. This feature will help prevent the use of hazardous levels of radiation that could negatively impact patient health. The new software can be installed on CT scanners to alert operators with a yellow "alert" warning message or red "scans at this dose level are unadvisable" pop-up screen, when recommended radiation dose levels would be exceeded by continuing with the scan. Dose levels are intended to be set by the healthcare providers themselves, in order to begin implementing them as soon as possible. Manufacturers will include the software in new scanners and offer them to existing customers before the end of the year. The software would allow dose information to be standardised and archiveable in a dose registry for monitoring and study. Here, David Fisher explains.

DG: MITA recently announced a new industry-wide commitment to including new radiation dose safeguards on CT technology – can you tell us more about this?

DF: Imaging manufacturers have a long history of reducing radiation dose and the MITA-led CT Dose Check Initiative is one more example of the commitment to reducing medical radiation and medical errors. Currently, CT machines provide radiation dose information. The CT Dose Check Initiative provides additional information for CT operators. MITA's CT manufacturer members have committed to including the new radiation dose check feature on CT machines. This feature will provide an alert when dose levels, as determined by hospitals, imaging centres and clinicians, exceed a level associated with routine use. In addition, manufacturers will include an additional alert when the parameters associated with a scan could potentially be dangerous. This alert is also configurable to prevent scanning at these radiation levels.

DG: Aside from the risks posed by CT for patients, it has had quite an impact on how imaging is performed. How has it transformed healthcare delivery?

DF: The high-resolution, detailed images that CT scans provide play a critical role in disease prevention, early detection, diagnosis and treatment. Not only has The New England Journal of Medicine proclaimed medical imaging one of the top "developments that changed the face of clinical medicine" during the last millennium, but physicians on the front lines of patient care reinforce that belief every day. As one example, in the Dartmouth-Stanford Survey of Medical Innovations, leading general internists ranked MRI and CT technology as the most valuable medical innovations in the last 30 years.
These scans have revolutionised healthcare delivery and saved millions of lives. For example, a study from the National Bureau of Economic Research found that increased utilisation of advanced medical imaging, such as CT and MRI, improved life expectancy by 0.62 to 0.71 years. Also, new applications of CT technology for screenings such as CT colonography for colon cancer and CT angiography for heart disease have improved screening rates and lowered costs.

DG: Medical imaging professionals have called on the industry to do more to regulate and continually re-evaluate reference dose levels – how has the industry responded?

DF: The medical imaging industry collaborates proactively to tackle all issues related to radiation safety. Beyond our Dose Check Initiative and continuous technology innovation, MITA looks forward to assisting stakeholders in the development of radiation dose reference levels, or reference values. Developing reference values will promote additional understanding of radiation dose. Once determined, the radiation dose reference level serves as a data point at which physicians, physicists and technologists can compare the radiation dose level of the specific procedure they are administering to a wide sample of similar tests.

DG: What sort of guidelines can you give our readers, to help them in managing dose levels in CT exams?

DF: Firstly, patients should speak with their physicians to better understand radiation dose and how it is best applied in their specific medical situation. In addition, MITA endorses the following key principles:

- Expanding and integrating appropriateness criteria into physician decision-making.
- Creating a national dose registry to ensure longitudinal tracking of dose levels for patients across America.
- Adopting standardised storage of diagnostic imaging information within electronic health records.
- Expanding mandatory accreditation for advanced imaging facilities.
- Establishing minimum standards for hospital and imaging facility personnel who perform medical imaging exams and deliver radiation therapy treatments.
- Developing minimum standards for training and education for hospital and imaging facility personnel and checklists to reduce medical errors.
- Expanding and standardising the reporting of medical errors associated with medical radiation across stakeholders in a manner that is transparent for patients, families and physicians.

- Working with stakeholders to develop radiation dose reference values to provide a data point to compare the dose level of a specific procedure.

DG: What role does training and education play in dose management?

DF: Training operators on the specific functions of unique machines is important to maintain the proper use of complex medical imaging and radiation therapy equipment. To that end, imaging and radiation therapy equipment manufacturers currently provide comprehensive training and education to the users of their equipment. Some examples of training delivery include:

1. Onsite training at the customer facility using their own installed equipment;
2. Instructor-led classroom training, including lab work as appropriate, delivered at the manufacturer's training centre;
3. Remote instructor led training done via the internet and/or,
4. Customer self-directed e-learning modules produced by the manufacturer.

Training is especially important when radiation is involved. Our members have noted the importance of medical imaging and radiotherapy equipment operators having prerequisite clinical competence and professional training in order to leverage advanced education on specific equipment.

It's also important to remember that training doesn't end when our equipment is installed. Instead, training is an ongoing effort by the hospital and imaging facilities including continuing education, training of new employees, and achieving and maintaining certifications and accreditations. MITA's members work continually with stakeholders to develop additional operational safety procedures and checklists to reduce medical errors and incorporate those new standards into our training offerings.

DG: How close is the United States to having a national electronic registry for patients' dose histories?

DF: MITA endorsed the President's proposal in the fiscal year 2011 budget to provide funds for a National Dose Registry. This registry builds on the MITA-managed Digital Imaging and Communication in Medicine (DICOM) standards, which is the universal language that allows for interoperability of medical images. Thanks to these standards, imaging is without a doubt, the most "networked" aspect of healthcare in the clinical setting.

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