White Paper

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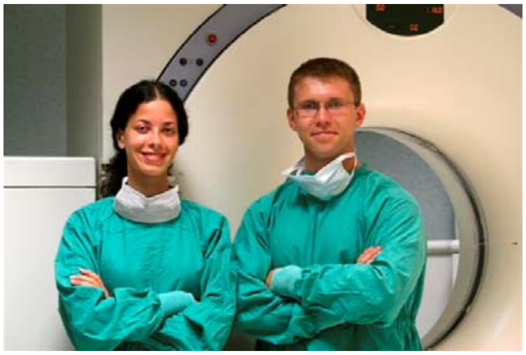
Computed tomography (CT) radiation dose, patient safety, and diagnostic imaging quality assurance

Computed tomography: overview

Computed tomography (CT) is a procedure that combines a series of x-ray images taken from different angles to digitally produce cross-sectional pictures of the body that yield better overall image quality than conventional x-ray practices. CT diagnostic procedures have become instrumental in the diagnoses and treatment planning of a multitude of ailments ranging from soft tissue damage and organ injuries, blood clots and strokes, pulmonary embolisms and heart disease, appendicitis, pancreatitis, aneurysms, complex fractures and dislocations, and many more serious and sometimes life-threatening conditions.



Since its inception in the late 1960's, CT technology has been hailed as one of the top five medical developments of the 20th century.[1] According Dr. John Boone, chairman of the American Association of Physicists in medicine (AAPM), 70 million CT scans are performed each year in the United States alone, and play a critical role in saving the lives of thousands of people every day.[2]

CT overdose in the news

In August of 2009, a patient at Cedars-Sinai Medical Center in Los Angeles reported hair loss after receiving a CT brain perfusion scan. As reported by the hospital, because hair loss is not a common side effect (and is traditionally regarded as evidence of radiation poisoning), an immediate investigation began into the equipment and protocols involved.[3] In October of 2009, the same hospital released information disclosing over the course of 18 months a total of 206 patients had been mistakenly administered up to eight times the normal radiation dose during CT procedures.

Just as experts, the FDA and the general public began to take notice, more stories of CT radiation overdose concerns began to surface. A two-year-old patient at Mad River Community hospital in Arcata, California was reported to have received radiation burns and permanent chromosomal damage from excessive radiation exposure after a CT technologist took repeated scans of the boy's face and neck.[4] The facility faulted improper procedure and lack of manufacturer safeguards, and

Robert Schlag, chief of the state's division of Food, Drug and Radiation Safety, said it was "one of the more egregious, extreme cases that I have ever seen."[5]

During that time, the FDA released a series of communications regarding their involvement in an investigation into radiation overdoses from CT brain perfusion scans. In partnership with Cedar's Sinai, as well as local and state health departments, the FDA began to uncover more cases of excess radiation exposure during CT perfusion scans. "This situation may reflect more widespread problems with CT quality assurance programs and may not be isolated to this particular facility or this imaging procedure," they reported. "If patient doses are higher than the expected level, but not high enough to produce obvious signs of radiation injury, the problem may go undetected and unreported, putting patients at increased risk for long-term radiation effects."[6]

Cases of radiation overdose poisonings began surfacing in other facilities in California, then Alabama, elevating concerns worldwide over the safety of CT radiation dose. "Given the fact that we are dealing with two manufacturers and multiple institutions, we wouldn't be surprised" to find problems elsewhere, said Dr. Jeffrey Shuren, acting director of the FDA's Center for Devices and Radiological Health.[7] The FDA began urging facilities to review their protocols and patient histories for evidence of similar problems, and to implement quality control procedures to protect their patients. They advised manufacturers of CT equipment review their training for users, reassess information provided to healthcare facilities, and put into place new surveillance systems to quickly identify problems.[8]

CT technology safety questioned

The diagnostic imaging community quickly found itself in the midst of a media storm on the issue of CT radiation dose and patient safety. The Los Angeles Times, New York Times, and Wall Street Journal all released reports questioning the safety of CT diagnostic procedures. Countless regional and worldwide publications followed, along with reports from top industry news-watch groups like AuntMinnie.com, Health Imaging and Imaging Technology News. And as the stories unfolded, probes into accidental radiation overdose began to be accompanied by questions about the overall safety of normal CT procedures.

CT Scans Linked to Cancer: Study Warns Radiation Dose From Single Test Can Trigger Disease in Some People. [9] This Wall Street Journal headline quickly proved both alarming to the public and damning to the medical physics community. Citing recent studies in the Archives of Internal Medicine, the article showcased major concerns regarding the effect of CT radiation exposure and possible links to a multitude of deadly cancers. Adding to these concerns was the fact that CT scans have more than tripled since the early 1990's, in what the Journal referred to as a "scanning surge." The question raised by this article was clear: are CT scans causing cancer, and if they are is the magnitude of this problem quickly growing?

Radiation dose and CT explored

Concerns regarding radiation exposure and diagnostic imaging procedures are a valid, ongoing topic in healthcare today. Medical Physicists and manufacturer experts alike readily explain the relationship between radiation dose and image quality: in simplistic terms, the greater the dose the better the image. While it's clear a relationship exists between radiation exposure and cancer, the rate at which radiation dose causes cancer is difficult to measure.

Regulatory bodies, in opting for a conservative approach to radiation safety, favor a concept called the Linear Hypothesis, which states every radiation dose of any magnitude can produce some level of detrimental effects which may be manifested as an increased risk of genetic mutations and cancer.[10] Simply put, the Linear Hypothesis says there is no such thing as a safe dose of radiation; and under this assumption, it's important to keep radiation dose as low as possible.

Ionizing radiation is capable of damaging DNA, which can lead to mutations, chromosomal translocations, and gene fusions—all of which are linked to cancer development.[11] The FDA reports ionizing radiation has a "small potential to harm living tissue." Among those risks are:

- A small increase in the possibility that a person exposed to x-rays will develop cancer later in life; and
- Cataracts and skin burns only at very high levels of radiation exposure and in only very few procedures.

The FDA further reports the risk of developing cancer from radiation exposure is generally small and depends on dose, age at exposure, and sex of the person exposed.[12]

CT scans expose patients to elevated levels of ionizing radiation compared to general x-ray procedures. CT radiation dose can be influenced by a multitude of factors and device settings, as well as scanner make/model and technology type. CT dose measurements are also expressed from multiple points of view using different methodologies, including exposure, CT dose index (including variations), absorbed dose, and effective dose.

From a patient's perspective, effective dose measurement is important because it quantifies the risk and compares it to what they might expect to receive from naturally-occurring background radiation in their daily lives. Radiology Info, a public information group established by the American College of Radiology (ACR) and the Radiological Society of North America (RSNA) lists the effective dose of a sample of x-ray procedures for such reference.[13] Note the effective dose for CT procedures in yellow, and how they compare to other digital imaging procedures:

Procedure	Effective radiation dose	Comparison to natural background radiation
Abdominal region:		
Computed Tomography (CT)-Abdomen and Pelvis	10 mSv	3 years
Computed Tomography (CT)-Body	10 mSv	3 years
Computed Tomography (CT)-Colonography	10 mSv	3 years
Intravenous Pyelogram (IVP)	3 mSv	1 year
Radiography-Lower GI Tract	8 mSv	3 years
Radiography-Upper GI Tract	6 mSv	2 years
Bone:		
Radiography-Spine	1.5 mSv	6 months
Radiography-Extremity	0.001 mSv	Less than 1 day
Central Nervous system:		
Computed Tomography (CT)-Head	2 mSv	8 months
Computed Tomography (CT)-Spine	6 mSv	2 years
Myelography	4 mSv	16 months
Chest:		
Computed Tomography (CT)-Chest	7 mSv	2 years
Computed Tomography (CT)-Chest Low Dose	1 to 3 mSv	4 months to 1 year
Radiography-Chest	0.1 mSv	10 days
Children's imaging:		
Voiding Cystourethrogram	*5-10 yr. old:* 1.6 mSv	6 months
	Infant: 0.8 mSv	3 months
Face and neck:		
Computed Tomography (CT)-Sinuses	0.6 mSv	2 months
Heart:		
Cardiac CT for Calcium Scoring	3 mSv	1 year
Men's Imaging:		
Bone Densitometry (DEXA)	0.001 mSv	Less than 1 day
Women's Imaging:		
Bone Densitometry (DEXA)	0.001 mSv	Less than 1 day
Galactography	0.7 mSv	3 months

Hysterosalpingography	1 mSv	4 months
Mammography	0.7 mSv	3 months

This table shows the effective radiation dose of CT procedures can range in comparison from approximately four months to three years of the amount of radiation exposure the average person may expect from natural background radiation. And, as noted, CT procedures in general do provide a greater effective dose to the patient than other diagnostic imaging procedures. However, the AAPM, ACR, RSNA, FDA, US National Cancer Institute, US National Institutes of Health, Health Physics Society and like organizations around the world have unanimously reported the risk to the patient associated with CT radiation dose is very small.

The Science Council and Executive Committee of the AAPM recently released a statement noting concern regarding "several [recent] misleading statements made with respect to radiation hazards from CT scanning."[14] Among these were the articles cited by the Wall Street Journal that projected thousands of future cancer cases resulting from CT diagnostic procedures. AAPM, along with medical physicists worldwide, calls into question certain assumptions used to calculate those risks, and subsequently the validity of the data and science of those conclusions. In addition, the AAPM statement highlights the difficulty in determining causal relationship between cancer and radiation exposure. "Because radiation induced cancers are exactly the same clinically as normally occurring cancers, there is no way to know who died from a radiation induced cancer and who died from a naturally occurring cancer. This issue is compounded by the fact that the number of predicted radiation induced cancers is tiny compared to the very large cancer incidence rate in humans (~25-30%), making the impact of radiation on cancer rate very hard to measure."

ALARA and continuous improvement

The International Commission on Radiological Protection, an advisory body that provides recommendations and guidance on radiation protection, along with the US FDA and most medical physics programs and associations worldwide recommends all exposures be kept "as low as reasonably achievable," a goal known as the ALARA principle.[15] ALARA is the governing principle behind medical physics radiation safety programs worldwide, as well as a main driver behind the continued scientific review of the relationship between dose and image quality in order to continuously drive toward lower-dose, high-quality imaging technology. This industry-wide dedication to ALARA is clearly implied in the preface to that same AAPM statement:

> "…medical physicists are partnering with technologists, radiologists, regulators, manufacturers, administrators and others to strive for CT scans that are medically

> indicated; and when they are performed that the minimum amount of radiation is used to obtain the diagnostic information for which the CT scan was ordered."

In using the somewhat ambiguous language of "as low as reasonably achievable," ALARA provides a flexible-enough framework to allow each patient and procedure an individualized approach to determining acceptable dose along with the mandate to minimize exposure for the benefit of patient safety. And as a result of the ALARA principle, experts across the field of diagnostic imaging will continue to facilitate public discussion and research into issues about dose reduction and patient safety.

CT benefits and patient outcomes

As noted by the AAPM, the medical information derived from appropriate diagnostic CT saves thousands of lives every day for patients experiencing a variety of serious medical conditions and/or trauma.

> Before the invention of CT (in 1972), exploratory surgery was common practice. CT and other imaging procedures have virtually eliminated the need for exploratory surgery, since these technologies allow doctors to peer inside the patient without the use of a scalpel. Nobody wants to go back to the days of exploratory surgery, which has a number of significant risks including that of bleeding to death, infection, or debilitating nerve damage. …[AAPM maintains] the steadfast belief that the medical information gained by medically indicated CT studies leads to better medical decisions, better patient care, and a significant improvement in human health.[16]

A recent study published in the Journal of the American College of Radiology reported hospitals where patients were more likely to receive imaging services—including CT, MRI, ultrasound and x-ray—during admissions had lower mortality. "In short," the researcher noted, "our results suggest that performing imaging on more patients may improve outcomes."[17]

FDA, Congress, and the industry response

In February 2010 the leading trade group for the medical imaging industry announced General Electric Co. (GE), Siemens AG, Toshiba Corp., Philips and Hitachi all plan to install safety controls to prevent patients from receiving excessive radiation doses. [18] As a result of this dose-check initiative, CT manufacturers committed to do three things. First, implement a new radiation dose alert feature designed to provide a clear indication that the settings for the CT exam will result in a dose higher than a predetermined reference dose for routine scans. Second, include a dose warning feature to prevent CT scanning at higher, potentially dangerous radiation levels. Third, standardize dose reporting to help better understand dose levels and facilitate the development of the National Dose Registry.[19]

The next day, the United States Subcommittee on Health of the House Committee on Energy and Commerce held a hearing entitled "Medical Radiation: An Overview of the Issues" to examine the potential benefits and risks of the use of radiation in medicine. During this hearing, members of the Committee heard from several industry experts regarding the use, benefits, risk, and regulatory oversight of CT scan technology. They also heard accounts from patients and family members who had personally benefitted from the use of medical radiation therapy and diagnostics, and of those who had experienced tragedy as a result. Throughout this hearing, officials, experts, patients and families alike agreed on several points:

1. Medical radiation used in therapies and diagnostics is both lifesaving and potentially deadly, and the use of radiation in medicine continues to grow.
2. Patient safety in both radiation therapy and diagnostic radiation is of critical importance.
3. Professionals involved in the administering of medical radiation need to be properly trained and educated to ensure patient safety. Currently there exists opportunity for minimum requirements to be set and regulated to achieve this.
4. Device manufacturers, industry professionals and regulators should work together to reduce radiation exposure, improve dose standardization for CT procedures, and report and track doses patients receive in order to improve patient safety.
5. Radiation-related medical errors should be reported to the patient, the hospital, and to regulatory authorities via a centralized, regulated data source.

It is likely legislation will follow as regulators, industry experts and device manufacturers continue to work toward the safest-possible CT technologies and oversight. The United States Subcommittee on Health of the House Committee on Energy and Commerce and the FDA both continue to work with groups like AAPM, RSNA, ASTRO, ASRT, ACR, MITA, as well as experts and researchers to explore the issues of medical radiation safety and quality assurance with top patient safety and patient outcomes as their goal.

CT radiation dose and quality assurance

Though experts worldwide agree the benefits of CT technology far outweigh the risks, diagnostic imaging quality assurance teams are urged to take appropriate steps to ensure the safety of patients and staff who interact with these devices. ECRI Institute, an independent nonprofit organization that researches best approaches to patient care, recently named high radiation dose from computed tomography number three on its “Top Ten Health Technology Hazards for 2010” and urged healthcare organizations to protect against possible occurrence.[20] And in lieu of the recent issues surrounding accidental CT radiation overdose, in an action supported by the AAPM, the FDA has released recommendations for imaging facilities, radiologists, and radiologic technologists to help prevent additional cases of excess exposure. [21]

"There is no excuse for such radiation overexposures. Improved training as well as new machine interface features may be needed to prevent future occurrences," notes the AAPM statement. "News of these incidents has led to a nationwide mobilization of medical physicists, working with hospital administrators, radiologists, and CT technologists to get a better handle on CT protocols at each individual institution."


Fluke Biomedical AAPM CT Performance Phantom

For in-house diagnostic imaging quality assurance and biomedical/clinical engineering teams, Fluke Biomedical offers an array of QA tools and devices to assure the quality and safety of diagnostic x-ray imaging systems. A complete line of CT quality assurance phantoms provide everything from tissue-equivalent lesion detectability testing, CT performance evaluation, computed tomography dose index for pediatric and adult head and body, axial and spiral scanning QA, and ultrasound CT 3D simulation.

In addition, Fluke Biomedical has recently released the next generation in precision CT dose measurement and analysis tools with the TNT 12000 DoseMate dosimeter. The TNT 12000

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DoseMate with ion chambers provides the precision dose measurements needed for absolute dose measurement integrity. Offering customizable measurement protocols, the DoseMate dosimeter provides comprehensive, repeatable testing for radiographic, dental, fluoroscopic, and CT imaging systems in just a few keystrokes. The TNT 12000 DoseMate is compatible with existing TRIAD and NERO external ion chambers, offering the newest dosimeter technology with minimum investment.

Fluke Biomedical TNT DoseMate Dosimeter for precision CT dose measurement

The TNT 12000 X-Ray Test Tools system is the newest and most comprehensive family of instruments available for all varieties of x-ray quality assurance and periodic maintenance testing. With selection of all-in-one-exposure solid-state detector, dosimeter, ion chambers, optional mA/mAs invasive shunt or non-invasive clamp device, and choice of handheld display or laptop interface (both completely wireless), the TNT 12000 X-Ray Test Tools provide state-of-the-art solutions for any x-ray test protocol.

Fluke Biomedical TNT 12000 X-Ray Test Tools

Frederic Mis, PhD, CHP recently recommended the TNT 12000 as a good investment to industry professionals, “and not only to other physicists but also state agencies who need to go in and test equipment. This is something they can hang their hat on and call it the industry standard for test accuracy.”

For more information about diagnostic imaging quality assurance, or for assistance with a healthcare radiation-safety quality assurance program, contact Fluke Biomedical at (800) 850-4608, international (440) 248-9300 or visit our website at www.flukebiomedical.com.

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