Medical Radiation: An Overview of the Issues

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Mr. Chairman and Members of the Committee,

I want to thank you - honestly and very sincerely - for holding these hearings today. It is an honor to be here and to speak to you regarding the safety of x-ray computed tomography, which is more commonly referred to as CT scanning.

I would like to begin by reviewing the differences between the radiation dose levels used in diagnostic imaging versus from radiation therapy. At extremely high doses, such as what is required for the effective treatment of cancer, radiation can cause severe biological effects. In this high dose region, the effects are predictable based on the dose delivered, and can include cell death, skin reddening and hair loss.

In contrast, medical imaging uses 1000 times lower doses of radiation. At the low doses used in medical imaging, there is a chance an effect might occur, but there is considerable controversy about the level of risk of developing a cancer from these low doses. In fact, the National Academy of Sciences report on the Biological Effects of Ionizing Radiation and the Health Physics Society state that the uncertainties in the data do not support making <u>any</u> estimates of risk in this region. The risk is either so small as to be nearly impossible to definitively measure, or the risk is zero.

With regard specifically to CT, modern systems are equipped with feedback systems that monitor the amount of radiation passing through the patient and reaching the detectors, and then adjust the radiation output to deliver the required level of image quality using the lowest possible dose. These systems automatically adapt the dose to differences in patient size, both within an individual patient and across the full spectrum of humanity, from newborns to morbidly obese patients.

It is important for to realize that the patient dose for a single CT exam of the chest, abdomen, or pelvis is a factor of 2 - 3 times lower now than it was approximately 20 years ago. And current technical innovations continue to drive the dose even lower.

However, CT is a sophisticated medical device. And, as with any medical device or procedure, both human and electrical/mechanical systems can fail. That is why I am incredibly grateful for the interest of this committee, the Food and Drug Administration, and the imaging community in ensuring that medical imaging is performed in as safe a manner as possible, whether the exams involve ionizing radiation or not.

The technology is not, however, our fundamental problem. Rather, education and training of the technologists who operate the equipment, the medical physicists who test and optimize the equipment, and the radiologists who prescribe the exam protocols has not kept up with the rapid developments in the technology. The single most important contribution we can make to patient safety is to ensure that all personnel involved in the operation of CT systems meet nationally-prescribed, minimum levels of training and competency. The needed accreditation and certification programs exist, but without mandatory requirements for a consistent level of advanced education, we are allowing, in some cases, minimally-trained personnel to operate extremely advanced medical equipment.

As one example of the numerous multi-disciplinary efforts being made to ensure patient safety through education, the American Association of Physicists in Medicine is holding a CT Dose Summit in April of this year. We organized this meeting specifically to teach users how to be sure that the scan protocols used are appropriate to the specific diagnostic task and the specific patient. The faculty and attendees include medical physicists, radiologists, technologists, and regulators. The meeting is endorsed by a large number of professional societies, and received educational grants from the National Institute of Biomedical Imaging and Bioengineering, the American College of Radiology, and the Medical Imaging Technical Alliance. We will offer repeat presentations at any society meeting that will have us, and we will repeat the Summit as long as demand continues. This is but one example of the many educational and quality initiatives from the imaging community.

In summary, today's medical imaging uses some absolutely amazing technology and can non-invasively diagnose and guide treatment for injuries and diseases that could not be accomplished in any other way. Without CT, there would be more unnecessary surgeries, such as for suspected appendicitis that turned out to not be appendicitis, more invasive diagnostic tests, and less effective treatments. Before the advent of CT, exploratory surgery was not uncommon.

But clearly, medical tests, with ionizing radiation or not, should only be performed when medically justified. When they are medically appropriate, the benefit far outweighs any potential risk. In fact, there is a very real risk that the patient's health will be harmed if the necessary medical information is not obtained through the appropriate imaging exam. But, unfortunately, patients are being unnecessarily frightened by media reports about the danger of radiation at the dose levels associated with CT. We are seeing patients come to us with symptoms of potentially severe illnesses or needing life-saving surgeries who are refusing CT exams, because they have heard on television or read in the paper about that "cancer-causing stuff," even though the standard of care would be to have a CT exam. The reality is that the risk of radiation injury from a CT scan is virtually non-existent. Patients and their loved ones should be concerned only about whether or not an imaging exam is needed to help the physician make the best possible diagnosis and treatment decision. If the information is of potential benefit to that patient's medical care, then the patient should absolutely proceed with having the CT exam.

When my 11-year-old daughter fell from a bunk bed and landed on the edge of a piece of furniture, the portable ultrasound scanner in the emergency room showed a large, ominous shadow consistent with a lacerated spleen. Because ultrasound imaging can "be fooled" and her condition was stable, a CT was recommended - to give us a definitive diagnosis. I did not hesitate to agree to the CT examination. Thankfully, the CT was negative, showing no abdominal injuries. I do not consider that CT exam, even though it was "normal," to be unnecessary. Rather, I consider it to have been invaluable, as it avoided unnecessary emergency abdominal surgery.

Thank you for allowing me to share this information with you, and for taking the time and interest to consider the best interest of our patients.

As a supplement to my oral testimony, I include here additional information for your consideration.

Radiation Dose and Safety During Computed Tomography

In general, the radiation dose levels from most diagnostic medical imaging examinations, including CT, nuclear medicine, and fluoroscopy, may increase a patient's risk of a fatal cancer by only fractions of a percent. This can be compared with the background rate of a fatal cancer in the U.S., which is about 22%. Because the potential risks are so small, there is considerable uncertainty as to the exact numerical value of risk at the low dose levels associated with medical imaging and prudent assumptions are made to assign this value that are consistent with the existing data so that the medical community may have some guidance when making risk/benefit decisions. The risks may, however, be zero.

Radiation induced cancers can not be distinguished from cancers caused by other sources, and the cancers can take from years to decades to occur. Because the risks at the low doses associated with medical imaging are so small compared to at higher doses, definitive observational evidence of increased risk due to medical imaging that uses ioinizing radiation is not likely to ever be able to be demonstrated. For the dose associated with a typical cardiac CT or a CT of the abdomen and pelvis, between 1- to 10-million exposed individuals would need to be followed over their entire life to discern any statistically valid increase in risk compared to background cancer rates! Thus, ionizing radiation is at worst case a very weak carcinogen. Particularly in adults, where 85% of CT examinations are performed, the risk of a radiation induced cancer from the naturally occuring amounts of background radiation received each year of one's childhood exceeds the incremental risk from any diagnostic imaging exam received in adulthood.

In light of the very small level of potential risk and the absence of consensus as to whether there is any risk at the low levels associated with medical imaging, why is the concern about cancer from CT exams, for example, so great? The answer is primarily because of the large numbers of CT exams performed each year (an estimated 60-70 million exams per year in the U.S.). The concern is amplified by the generally held perception that radiation is extremely dangerous, the lack of familiarity with radiation units and effects, and the tendency to underestimate risk associated with more familiar behaviors. The risk of death by drowning is greater than the risk of death from a cardiac or body CT exam, yet the CT exam is widely perceived as having a much higher risk.

What then is a rationale response to concerns regarding the radiation associated with medical imaging exams such as coronary angiography, body CT, or radionuclide imaging? First, steps must be taken to ensure that exams are medically justified. Even a small amount of risk, as may be the case for medical imaging, is inappropriate if there is no anticipated benefit. Secondly, steps to keep doses as low as possible, such as dose

reduction technology, accreditation programs, and improved user training must continue to be a high priority thorughout the medical imaging community. Much progress has been made in radiation dose reduction and dose management techniques over the last decade, but best practices in the field of dose management must by dispersed across the spectrum of practice types and sizes.

Modern CT systems, and by this I mean systems manufactured within the last 5 or so years, are equipped with sophisticated software algorithms that automatically adjust the amount of radiation coming out of the scanner according to the size and shape of each particular patient and according to the diagnostic imaging task. The systems know how to dial down the radiation output and how to increase the radiation output for obese patients. Systems are also able to automatically adjust the acceptable level of image quality according to the type of examination the physician prescribed. Low-dose CT scans of the chest or colon for cancer screening produce extremely noisy images that are nonetheless highly accurate at seeing soft tissue lesions against a background of air. Other examinations, such as CT exams of the small bowel to detect very small amounts of bleeding in the small bowel, for exams to detect small and subtle cancerous liver lesions, require images of much higher quality. All current systems allow the user to select from a variety of protocols according to the individual needs of the specific patient.

The imaging community, including the manufacturers and professional societies, has been actively engaged in a quest for lower and lower doses, and as a result, modern CT exams use doses that are factor of 2 or 3 lower than in the 1980s and early 1990s. Not only are the doses lower, but the image quality is much, much better. Instead of 10 mm thick slices of anatomy, images representing thicknesses of less than 1 mm are routinely available. Instead of performing several overlapping scans to allow the patient to take a breath every so often during the exam, current scanners can scan a 6-foot adult from head to toe in less than 20 seconds. The downside of these tremendous advances in technology is the difficulty in maintaining adequate training in such a rapidly-changing field. Professional organizations offer continuing education courses and special sessions on advances in dose reduction methods at numerous times through any scientific meeting.

In April of this year, I will be co-directing a CT dose summit that is sponsored by the American Association of Physicists in Medicine and is financially supported by the American College of Radiology, the National Institute of Biomedical Imaging and Bioengineering, and the Medical Imaging Technology Alliance. It is co-sponsored by the Radiological Society of North America, the Health Physics Society, the Conference of Radiation Control Program Directors, and the Americal Board of Radiology Foundation. AAPM organized this meeting as a direct response to the reports of overexposures for neuro CT perfusion scanning in just over a month’s timeframe. Registration is capped at 200 participants, and we sold out after only one week of open registration. I point to this as an example of the engagement of the medical imaging community in providing education related to CT dose management.

What is the typical radiation dose associated with CT?

Today's CT scanners use a much lower dose of radiation than was used even 5 years ago. This is a result of recent concerted efforts by imaging scientist and manufacturers of imaging equipment to decrease the radiation doses associated with CT imaging. The dose used in a CT examination is now tailored specifically to each patient's body size and the diagnostic questions being asked. Particularly in pediatric patients, the imaging community clearly understands that a "one dose fits all" approach is not appropriate.

The risk of radiation exposure from a medical imaging examination, often expressed in terms of effective dose, should be put into proper perspective. The increased risk of a fatal cancer from a 10-mSv cardiac CT or abdomen/pelvis CT examination is very small. Some data suggest that at such low doses, there is actually no increase in cancer risk. However, to err on the side of safety, a non-zero risk is assumed for any radiation exposure, no matter how small, with the risk increasing linearly with the effective dose.

Using the most current consensus risk estimates from the National Academy of Sciences, the risk of death from a 10-mSv cardiac or abdomen/pelvis CT is lower than a person's lifetime risk of drowning (0.9 in 1,000) or being killed after being hit by a vehicle while walking (1.6 in 1,000).

The radiation doses associated with a CT examination (≈1-14 mSv) depend on the specific equipment and examination type. This range of doses is comparable to the dose received annually from naturally occurring sources of radiation such as radon and cosmic radiation (≈3 mSv per year). However, depending on the elevation and soil type where a person lives, the amount of naturally occurring (i.e., background) radiation can vary from 1 to 10 mSv.

Some communities with very high background levels of radiation have been extensively studied for carcinogenic effects from ionizing radiation. Interestingly, these population groups have a decreased cancer rate relative to similar communities in which the background radiation level is much lower. In some parts of the world, background radiation levels are 10 to 400 times higher than the typical background in the United States, yet no increase in the frequency of cancer has been documented in populations living in these areas of high natural background radiation.

When should CT be used? How does the radiation dose from CT compare with that from other imaging examinations?

CT examinations should be performed only when the expected information from the examination has a potential clinical benefit to the patient. The American College of Radiology has professional guidelines detailing the appropriateness of a CT examination for

various symptoms or conditions. Compared with magnetic resonance imaging, CT is a much quicker examination and has far fewer patient contraindications (e.g., implanted electronic medical devices such as pacemakers). Relative to ultrasonography, CT has much better spatial resolution, is a quicker examination, and has minimal variability in image quality due to different skill levels of the imaging technologist or sonographer. Hence, CT is frequently considered the first-line recommendation when diagnostic imaging is required.

The radiation dose from a CT examination is similar in magnitude to that from nuclear medicine examinations, such as cardiac stress testing, or from some fluoroscopic procedures, such as invasive angiography. It is important to remind patients that although CT does involve more radiation than conventional radiography, it also provides much more information. For example, a chest CT scan can image a thorax in a few seconds with submillimeter resolution. From this one scan, hundreds of images can be produced for detailed views of a patient's anatomy. Such detailed information allows for making more rapid and accurate diagnoses and more efficient and effective treatment decisions than is possible with standard radiography.

What is being done to decrease the radiation dose received during CT scans?

First, CT scans are optimized to use doses as low as reasonably achievable without compromising the diagnostic task. The most basic step to minimize radiation dose for a medically justified examination is to adjust the technique factors to ensure that the right dose is delivered based on the patient's size (attenuation) and the specific diagnostic question. This is considered the current standard of care in CT imaging. In some cases, this may mean that increasing the dose is the most appropriate action (e.g., in obese patients or those with traumatic injuries).

Since the mid 1990s, automated exposure techniques have been used to further tailor the dose used in CT examinations to the specific patient and diagnostic task. These sophisticated systems automatically set the dose to the lowest appropriate level. These automatic exposure control systems can lower patient doses substantially, typically by 20% to 50%. In addition, as CT technology has progressed, the dose inefficiencies of earlier multislice systems have been resolved.

In the 1980s, 10-mm wide images and multiple breath-holds were considered state-of-the-art in body CT imaging. Now, a 5-mm image width and a single breath-hold is considered routine, with 2- to 3-mm image widths used for many applications (e.g., CT enterography or angiography); reconstructions of 1 mm or less are routinely used for multiplanar reformations (e.g., coronal or sagittal views) or 3D surface or volume renderings. Thus, today's CT systems provide thinner image widths with improved spatial and low-contrast resolution at a fraction of the scanning time and patient dose used just a decade ago.

Key Facts

- Every day, people are exposed to ionizing radiation from many naturally occurring sources such as radon gas in the home, radiation from outer space, radiation in rocks and soil, and naturally occurring radioactive elements in the body (e.g., small amounts of radioactive potassium are present in the human body).
- After a computed tomography (CT) study, no radiation remains in the body.There is no limit placed on the number of CT images a person can have. Each scan should be justified by the current medical situation.
- CT may be ordered in pregnant patients if the mother's medical condition requires imaging to make an accurate diagnosis or guide treatment. Even from a CT examination of the abdomen and pelvis, the radiation exposure to the fetus is considered negligible. In a woman who has not been exposed to ionizing radiation, the probability of the baby having no congenital malformations or defects is approximately 96%; a CT scan directly over the fetus, even with multiple contrast phases, changes the odds to approximately 95.99%. In fact, no diagnostic imaging examination delivers a high enough dose to the fetus to consider termination of the pregnancy.
- A report on sources of ionizing radiation in the United States (NCRP report No. 160, titled "Ionizing Radiation Exposure of the Population of the United States"), caused many people concern about increased radiation doses from CT scans. Although the use of CT has increased considerably in the past decade, the dose per examination is decreasing. There is no increased risk to the population in general, since only those receiving a medical exposure incur any potential increase in risk. It is essential to remember that the increased use of CT is due to the increased number of clinical applications for which CT now is the most appropriate diagnostic tool.

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