Improving the Safety of Medical Imaging

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Examining The Appropriateness Of Standards For Medical Imaging Technologists

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Chairman, Ranking Member, and members of the Health Subcommittee, thank you for this opportunity to testify today. I am Dr. Rebecca Smith-Bindman, Professor of Radiology, Epidemiology and Biostatistics, Obstetrics, Gynecology and Reproductive Sciences, at the University of California, San Francisco School of Medicine. I am a clinical radiologist and I conduct research focused on assessing the risks and benefits of medical imaging.

My testimony today focuses on computed tomography (CT) because it is one of the most common imaging tests that we use in medical diagnosis, and it is the test with the greatest potential for causing harm because it uses high doses of radiation to create its images. It is a test where I believe we need more consistent education and certification of the radiology technologists who conduct these studies, and where we need closer oversight in how these examinations are conducted to ensure that when patients undergo these examinations, they receive the lowest dose of radiation possible for diagnosis.

CT uses x-rays to obtain extremely detailed images of internal organs, and the development of CT is widely considered among the most important advances in medicine. It is truly an extraordinary test, allowing the accurate diagnosis of disease, and treatment planning for children and adults. In part because it is so useful, the use of CT has risen dramatically. The number of CTs performed annually has increased by 3 times during the last 15 years. Last year approximately 75 million CT examinations were performed in the United States, approximately 1 in 10 individuals underwent a CT, and among those individuals, they underwent an average of 2 CT examinations.

Although CT is useful, it delivers much higher doses of radiation than do conventional x-rays, and exposure to radiation can lead to the development of cancer. To help put this into context, when you go to the dentist and you are offered dental x-rays, you may pause, to consider the benefits and the potential harm associate with getting x-rays. The most common type of CT scan patients undergo in the U.S. is a CT scan of the abdomen, and this delivers approximately the same amount radiation as getting 1,500 dental x-rays. Additionally, newer applications of CT, such as those used to assess the heart, or to assess blood vessels in the brain, require even higher doses of radiation, as much as 5,000 dental x-ray. In other contexts, some people have worried about the x-rays at our airports to screen passengers. One CT scan is equal to approximately 200,000 airport screens

The Variation in Radiation Dose for Each CT Scan Across Patients and Facilities

My research team at UCSF has conducted several studies to assess the radiation doses patients receive when they undergo CT. We have collected radiation dose information on over 7,000 patients who have undergone CT scanning across a large number of institutions and hospitals across the country. We found that for every type of CT, the radiation doses were far higher than most physicians or physicists are aware. Further we found that the radiation doses vary substantially between different facilities, and that e*ven within the same facility*, these doses vary dramatically between patients evaluated for the same clinical problem. For example, we found that one patient had 20-times the radiation dose of another patient for a routine head CT or routine abdominal CT when both studies were done at the same institution. This means that two patients at the same hospital, who have the same need, for the same test, are getting very different amounts of radiation, and will have very different risks for subsequent cancer, without any benefit to the person who got more radiation. Put another way, if a patient goes to a facility to get a CT scan of her abdomen, she has no idea if she will receive a low dose or a very high dose, and yet the patient who receives the higher dose scan may be ten times more likely to develop a cancer from that examination, while receiving no extra benefit from the extra radiation to which she was exposed. These differences in how much radiation is used to create the CT image picture are not accidental and currently are not recognized as errors but are labeled, I believe incorrectly, as the *art* of medicine. This sadly is more like Russian roulette than personalized care.

Risks

There are clear-cut cases of errors in the use of CT when the technologist delivers a dose much higher than was intended. *When errors are made* in how CT scans are performed, patients can be exposed to much higher doses of radiation than necessary and these doses can lead to skin burns, hair loss and even more severe damage to the tissue in the area scanned, for example confusion and memory loss if the brain is over radiated. Hundreds to thousands of cases have been reported where patients who underwent CT scans of their brains were exposed to radiation doses that were 100 times higher than intended or needed. Many of these errors happened because of errors in how the technologist programed the scanner.

However, *even when CT scanning is done correctly*, CT scanning is associated with an increased risk of cancer and the higher the dose of radiation that is delivered the greater the risk of cancer. There have been a large number of research studies that have found that people who receive radiation doses in the same range as a *single* CT scan are at increased risk of cancer, and many patients receive multiple CT scans over time- so their risks are even higher. We know from a very large number of research studies that the doses that are used for CT can be harmful. An important research study was published yesterday in the medical journal *the Lancet* that directly showed that healthy children who underwent CT scans of their brains were more likely to develop brain cancer and leukemia following these scans. Thus the doses that we experience every day as part of routine CT scanning are potentially dangerous. The cancers may not develop for 5, 10 or 20 years. But the use of CT today can result in a patient developing a cancer that they would otherwise not have had. This is in direct conflict with the notion that a physician should do no harm. Thus even though we can't see the harms from CT immediately we must take them seriously.

My research team has studied millions of individuals who were enrolled in large integrated health care systems across the United States and we found large number of patients – children and adults alike- received unnecessarily high doses of radiation because some CT examinations delivered doses that were higher then necessary.

Why The Doses Patients Receive When They Undergo CT Are So Variable: Technologist Training

CT scanners are highly sophisticated machines, and the complexity of these machines has increased over time. While Radiologists order scans and provide the overall direction on what protocol, or set of instructions, should be used, a technologist actually performs the examination. The console of a CT scanner looks very much like the control panel of a fighter plane. It is not possible for a technologist to simply press a button on a CT scanner to generate the desired image, or to generate an image that uses as little dose of radiation as possible. Instead the technologist must make a large number of independent decisions and follow a complex set of instructions on how to program each individual CT scan. Yet despite the complexity of the machines and the profound importance of the decisions they must make –if the technical parameters are not adjusted correctly for the size of the patient or the clinical question that is being asked, the dose the patient receives can be much higher than needed- the technologists who conduct CT examinations receive little education on what doses are excessive, receive no consistent education on how to lower the doses they deliver to their patients, and there are no consistent standards for certification of these technologists. In some states, there is virtually no required training for technologists to learn how to use a CT scan, and they may receive only minimal on-the-job training on how to use these sophisticated, powerful and potentially dangerous machines.

Further, because there are no uniform design standards or naming standards within the machinery itself across the different manufacturers, technologists may have to scan patients on different machines that all work differently. For example, GE has defined a measure known as the noise index, and the *higher the* values in the noise index, the *lower* the dose. Siemens has defined reference mAs –and the *higher* values in the effective mAs, the *higher the* dose. Thus, if a technologist who has a small patient and would like to reduce the dose the patient receives, they need to turn the noise index *up* on a GE machine, whereas they need to turn the effective mAs *down* on a Siemens machine - seemingly opposite directions to achieve the lower dose. A technologist who is working on a GE machine all morning, but who covers for a colleague on a Siemens machine over lunch, may have no knowledge of how to use the machine on which they now are working. There is surprisingly little education of the technologists in how to obtain the lowest dose images across the different machines.

As part of a research project I am leading to standardize the radiation doses across the University of California Medical Centers - the UC DOSE Project (The University of California Dose Optimization and Standardization Endeavor) - we have organized a large virtual meeting available to all to be held in February of 2013. The meeting is targeted to physicians, technologists, physicists, radiology administrators, referring physicians and trainees, although its primary focus is to educate and certify radiology technologists on how to understand, monitor and lower the doses to which they expose their patients, and how to do so across different manufacturer's platforms. The meeting will include a competency and certification program for technologists as my collaborators and I believe it will help technologists improve their knowledge, their performance, their comfort and satisfaction in conducting CT examinations. We will make this meeting widely available to anyone who is interested in participating, as we believe there is a dire need for this type of education. I believe this type of education and certification should be available and required of every technologist who conducts CT in the US. As part of the same meeting participants can upload samples of their CT examination data to our web site and will receive instant audit feedback on how their doses compare with national benchmarks we create. This is the type of direct assessment and feedback that should be widely adopted to help facilitate understanding how the doses they use compare with benchmarks.

Every patient who undergoes CT should know that the technologist who conducts their examination is knowledgeable and qualified to ensure that their CT examination is not only diagnostic, but that it also minimizes the dose to which they will be exposed. If technologists do not understand the doses they use and how to minimize them, they can't possibly be expected to provide the safest examination possible. I strongly believe the US Congress should pass the CARE Bill (H.R. 2104, The Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy) as a way to improve the training of those who order and conduct imaging examinations. The training and certification of technologists is an essential first step in ensuring the safety of CT.

Why Are The Doses Patients Receive So Variable: Absence of Standards

While technologist training is extremely important, there is a second and equally important problem that must be addressed to improve the safety of CT, and to ensure patients receive the lowest doses possible when they undergo CT.

Radiologists together with technologists determine how the CT tests are performed. However, there are few national guidelines on how these studies should be conducted or what target doses should be used for most imaging examinations. Thus each radiologist starts from scratch in creating the protocols for scanning at their institution. The general principle is that doses should be as low as reasonably achievable (ALARA), but there are few guidelines regarding what doses are reasonable or achievable, and in the absence of explicit guidelines, dramatic practice variation introduces unnecessary harm from excessive radiation exposure. We have found this variation in even our recent research studies – and this problem of variation is getting worse not better over time, as machines now have greater capacity to perform specialized and often higher dose studies, but are also more difficult to use. Not only is there variation, but many physicians who conduct CT are ill informed of the doses they are delivering to their patient. If a patient asks their physician about the dose they are likely to receive, or have received as part of a prior CT examination, or even asks about the dose that most patients who go to that institution receive when they undergo a chest or abdominal CT, their physician and institution would most likely not be able to provide an answer.

To Improve the Safety of CT We Need To Generate and Adopt Standards

In order to improve the safety of CT we need very clear standards for what are acceptable levels of radiation exposure associated with CT and there should be regulatory oversight for the setting of these standards. These standards would lead to consistency and optimization of CT examination protocols and techniques. There is evidence that for many types of CTs the radiation dose can be reduced 50% or more without reducing quality. Further the dose used in actual patients needs to be collected and monitored.

The National Quality Forum, a leading national organization that develops and endorses measures of quality across all areas of health care, has endorsed a measure focused on the radiation delivered for CT. If facilities began to follow this quality measure, they would quickly learn how they are doing and this would facilitate activities to lower doses where necessary. Facilities should be encouraged to adopt this measure, through quality efforts of the Centers for Medicare and Medicaid Activities.

Lastly, the dose associated with each CT examination should be documented and recorded in each patient's medical record and this information should be tracked over time. Recording and tracking this information would help educate patients and providers about radiation exposure and would lead to activities to minimize dose. It will also lead allow us to ensure the safety of these doses over time through epidemiologic analysis. Further, monitoring patient doses will protect them against unnecessary or repeated scans, or doses that are higher than they need to be. It is only by measuring the doses that they deliver to their patients that clinicians can begin to do everything in their power to keep those doses as low as possible. California has recently enacted legislation that goes into effect on July 2012 (Senate Bill 1237) requiring the dose used for CT exams be recorded in every patient's medical record, and further requires inadvertent CT radiation over-doses to be immediately reported to the State. This will inform patients and referring providers about dose, and will further encourage facilities to begin assessing and reducing the doses they are delivering to their patients. The California legislation provides a good template for consideration of national legislation.

Oversight

Oversight for CT radiation dosing is currently fragmented. The FDA oversees the approval of the CT scanners, as medical devices, but does not regulate how the tests are used in clinical practice. The FDA recently asked for public comment on a proposal encouraging manufacturers to provide education for radiologists and technologists when using their scanners on children, but have no legislative oversight to demand compliance with guidelines.

Through a provision in MIPPA (The Medicare Improvements for Patients and Providers Act) of 2008 that went into effect on January 1, 2012, the Center for Medicare and Medicaid Services has an accreditation process in place for suppliers that bill Medicare for the technical component of CT and other advanced imaging services. Under this requirement, the Secretary of the Department of Health and Human Services designates accrediting organizations that establish standards for these services. Five areas are covered in the standards the accrediting organizations must have: non-physician medical personnel, medical directors and supervising physicians, safety of equipment, patient and personnel safety, and quality assurance and control. The role of CMS through the implementation of MIPPA includes oversight of organizations that ensure the certification of technologists and physicians who conduct CT. Separately, CMS has other authorities to encourage the adoption of quality standards, such as those adopted by the National Quality Forum, to facilitate facility assessment, reporting and ultimately standardization of the radiation dose used for CT. As of yet, CMS has not incorporated such quality measures into their payment systems, but should be encouraged to do so in the near future. It is time for the adoption of more consistent national oversight to ensure the safety of this important examination.

Manufacturers' Efforts

Manufacturers are developing and marketing devices that can create diagnostic images using considerably lower doses of radiation, although it may take decades for these devices to replace those currently in operation. The manufacturers also have developed innumerable software upgrades that can allow existing machines to generate diagnostic images using much lower doses of radiation. The manufacturers should be encouraged to work closely will all facilities who use their equipment to provide these software upgrades to immediately reduce the doses to which patients are exposed.

Additionally, a large number of dose-monitoring software companies have been created over the last several years. In California, a large number of these companies are marketing their products because of the impending legislation that requires the radiation dose information for each examination be included in the medical record. Ideally, the manufacturers, dose monitoring-software vendors, and radiology decision support and information system providers will begin working together using a shared set of standards that will enable the electronic capture of patient information and dose and transmission of that information to electronic medical systems.

Reduce The Number of CT Scans Performed

Although not the primary focus on my testimony today, an important approach to minimize medical radiation exposure should focus on reducing the number of CT examinations. There is growing awareness that advanced diagnostic imaging, and in particular CT, is over-utilized. The European Commission Office of Radiation Protection and the Canadian Association of Radiologists developed guidelines highlighting where CT imaging should be curtailed including repeating investigations that have already been done; investigations unlikely to affect patient management because a positive finding is irrelevant, such as assessment and surveillance of incidental findings; investigating too often—before the disease could have progressed or before the results could influence treatment; performing the wrong investigation; and over-investigating. Many CT examinations in the United States almost certainly fall into these categories. Much more explicit discussion and guidelines are needed on how to reduce these unnecessary CT studies. While there are many reasons CT scanning is over utilized, in part this stems from a lack of research and evidence regarding when imaging tests should be used to improve patient health outcomes. It is imperative that we support the creation of evidenced-based guidelines for imaging and this will need to be supported through research funding at organizations such as the National Institutes of Health, the Agency for Health Research and Quality and the Centers for Disease Control and Prevention.

Summary

It has generally been thought that if a patient is sick enough to get a diagnostic CT scan, the benefit of the test out weighs any risk. However, we have started to use CT so often, and in patients who may actually be not very sick, that we need to think about whether the test is really necessary and whether it could cause more harm than benefit. Many physicians and patients are not aware of the risks associated with CT, nor the importance of limiting exposures. Patients need to be educated that CT scanning comes with both risks and benefits, and unnecessary exposure to radiation should be limited. Further, alternative tests need to be used, such as ultrasound, wherever possible, as this test does not use radiation. Given the importance of CT and its potential for causing cancer, it's imperative that we make CT scanning as safe as possible. We need to lower the radiation dose of routine CT and ensure patients receive the minimum dose necessary to produce a medical benefit. These efforts must include education of technologists and creation of clear benchmarks in order to reduce the dose per study, and the variation in dose across patients and facilities; but it must also include efforts to reduce unnecessary studies.

Thank you for allowing me the privilege of contributing to this discussion.

References

Board of Radiation Effects Research Division on Earth and Life Sciences. Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2 Washington, D.C. The National Academies Press, 2006.

Caoili EM, Cohan RH, Ellis JH, Dillman J, Schipper MJ, Francis IR. Medical decision making regarding computed tomographic radiation dose and associated risk: the patient's perspective. *Arch Intern Med.* Jun 8 2009;169(11):1069-1071.

Choosing Wisely, a multi year effort by the American Board of Internal Medicine Foundation, to help physicians be better stewards of finite health care resources. Choosing Wisely partners include a large number of medical specialty organizations. http://www.abimfoundation.org/Initiatives/Choosing-Wisely.aspx.

Keegan J, Mehta P, MacGregor K, Smith-Bindman R. The National Quality Forum Patient Safety Measure: Radiation Dose of Computed CT. Abstract submitted for the Radiological Society of North American 2012 Annual meeting.

McCollough C, Branham T, Herlihy V et al, Diagnostic Reference levels from the ACR CT Accreditation Program. Journal of the American College of Radiology. 2011; 8:11

Food and Drug Administration. FDA Makes Interim Recommendations to Address Concern of Excess Radiation Exposure during CT Perfusion Imaging. 2009 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm193190.htm.

Food and Drug Administration. Draft Guidance for Industry and Food and Drug Administration Staff - Pediatric Information for X-ray Imaging Device Premarket Notifications, May 10, 2012, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm300850.htm

Greess H, Wolf H, Baum U, et al. Dose reduction in computed tomography by attenuation-based on-line modulation of tube current: evaluation of six anatomical regions. *Eur Radiol.* 2000;10(2):391-394.

Griffey RT, Sodickson A. Cumulative radiation exposure and cancer risk estimates in emergency department patients undergoing repeat or multiple CT. *AJR Am J Roentgenol.* Apr 2009;192(4):887-892.

McBride J, Paxton BE, Wandrop RM. CT Scans: Most Doctors Lack Knowledge of Radiation Exposure Risks 2009 American Roentgen Ray Society, Annual Meeting in Boston, MA, April 26-30.

Medicare Payment Advisory Commission. A Data Book: Healthcare Spending and the Medicare Program, June 2007, http://www.medpac.gov/documents/Jun07DataBook_Entire_report.pdf (accessed 15 November 2008).

Mehta P, Smith-Bindman R. Airport full-body screening: What is the risk? Archives of Internal Medicine 2011 ;171:1112-5.

Mettler FA, Jr., Thomadsen BR, Bhargavan M, et al. Medical radiation exposure in the U.S. in 2006: preliminary results. *Health Phys.* Nov 2008;95(5):502-507.

Pearce MS, Salotti JA, Little MP, et al. Radiation Exposure from CT scans in Childhood and Subsequent Risk of Leukaemia and Brain Tumors: A Retrospective Cohort Study. The Lancet early on-line publication, June 7, 2012, http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60815-0/abstract

Semelka RC, Armao DM, Elias J, Picano E. The information imperetive: is it time for an informed consent process explaining the risks of medical radiation? Radiology 262:1: 15-

Smith-Bindman R, Johnson E, Feigelson H, al. e. Utilization of Diagnostic Imaging in the HMO Research Network: Modality and Organ System Trends 1994-2008. *Abstract to be presented at the The 16th Annual HMO Research Network Conference "Emerging Frontiers in Healthcare Research and Delivery" March 21–24, 2010, Austin, Texas.* Vol 2010.

Smith-Bindman R, Miglioretti DL, Larson EB. Rising use of diagnostic medical imaging in a large integrated health system. *Health Aff (Millwood).* Nov-Dec 2008;27(6):1491-1502.

Smith-Bindman R, Lipson J, Marcus R, et al. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. *Arch Intern Med.* Dec 14 2009;169(22):2078-2086.

Smith-Bindman R, Miglioretti D, Johnson E, et al. Use of Diagnostic Imaging Studies and Associated Radiation Exposure for Patients Enrolled in Large Integrated Health Care Systems, 1996-2010. Journal of the American Medical System (JAMA) In press, will be published June 13, 2012 Vol 302, 22, p2400-2409

Sodickson A, Baeyens PF, Andriole KP, et al. Recurrent CT, cumulative radiation exposure, and associated radiation-induced cancer risks from CT of adults. *Radiology.* Apr 2009; 251(1):175-184.

Symposium on Radiation Safety and Computed Tomography, February 26-28, 2013, organized by the Radiology Outcomes Research Laboratory (RORL) of The University of California San Francisco, and the University of California CT DOSE Project. http://rorl.ucsf.edu/Symposium.html

Twombly R. Full-body CT screening: preventing or producing cancer? *J Natl Cancer Inst.* Nov 17 2004;96(22):1650-1651.