Radiation Exposure in CT Scanning and Risk: Where Are We?[1]

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Computed tomography (CT) is by far the most important source of medical radiation exposure in the United States (1), with more than 70 million examinations performed each year. The large number of patients receiving radiation exposure from CT has raised concerns about patient safety, most importantly, the risk of radiation-induced cancers and cancer deaths later in life.

In trying to estimate cancer risks for patients undergoing CT, two issues come to light. First, the effective doses of radiation associated with most CT examinations are very low, on the order of 1.0–12.0 mSv (1). Second, statistical uncertainties in available data, such as data from atomic bomb survivors in Japan and radiation workers in the United Kingdom, make direct estimates of cancer risk highly problematic for effective doses of less than 100 mSv. For this reason, investigators seeking to calculate risks for cancer induction following CT have typically used an extrapolation model called the "linear no-threshold" model. This model is endorsed by the prestigious Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation of the National Academies of the United States (Biologic Effects of Ionizing Radiation [BEIR] VII phase 2) (2–5).

The use of the linear no-threshold extrapolation model for estimating cancer risk remains controversial despite its wide use and endorsement in the BEIR VII report (2–9). However, it is time to recognize that the debate about extrapolation models is unwinnable on either side without more information (2,8,9). Moreover, stakeholders, including patients, referring physicians, and the public at large, are not likely to be interested in or understand the nuances of scientific debate about linear no-threshold extrapolation models versus threshold models for radiation injury and cancer induction but they are intensely interested in the safety of medical procedures.

Although the development of more accurate risk estimation models for very low effective doses of radiation is unlikely in the near term, there are a number of very promising avenues available to reduce and otherwise mitigate CT radiation risks that will help address stakeholder concerns. Several of the most important of these are summarized in an article in this issue of *Radiology* by McCollough and colleagues (10) entitled "Achieving Routine Submillisievert CT Scanning: Report from the Summit on Management of Radiation Dose in CT." This article and the framework for its thesis are the result of a conference sponsored by the National Institutes of Biomedical Imaging and Bioengineering (NIBIB) and cosponsored by several other governmental and nongovernmental entities involved in medical imaging. Conference attendees included public and private representatives with expertise in all aspects of CT imaging, including basic scientists, clinically oriented physicists, practicing radiologists, and regulators. Congratulations to Dr Rodney Pettigrew, Director of the NIBIB, and the conference participants for having the vision to convene the conference and to set such an important and ambitious goal.

McCollough and colleagues, on the basis of survey data reported by the National Council on Radiation Protection (NCRP), point out that the average CT examination in the United States results in an effective dose of 6.5 mSv (1,10). Correspondingly, the achievement of submillisievert CT imaging (ie, average <1.0 mSv) would result in a reduction in exposure on the order of 10-fold compared with the NCRP reference data and therewith a corresponding decrease in downstream cancer risks and

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See also the article by McCollough et al in this issue.

risks of cancer death, whatever those really are.

McCollough et al (10) report that conference attendees agreed that CT imaging at a fraction of natural background levels (average, 3.1 mSv in the United States) would reduce concerns about long-term risks to negligible levels. Thus, if achieved, submillisievert imaging would substantially mitigate concerns about CT radiation risks and measurably shift the balance of discussion because the positive benefits to patient outcomes derived with imaging will likely continue to increase.

The especially good news is that the technology necessary to achieve the submillisievert goal is largely in hand. Many of the needed advances are close to being realized and will be predictably achieved in the course of time. Such advances include, among others, the incorporation into CT scanner platforms of new detectors, new x-ray sources and beam filters, new imaging geometries, new approaches to data acquisition, and new iterative reconstruction methods (10). Industry is moving rapidly on all these fronts. It should also be noted that it is unrealistic to replace every existing CT device each time a technologic breakthrough occurs, so there will always be a lag of several years after a new low-dose technology is fully in hand before the national fleet of CT devices reflects all of the advances.

Once new dose-lowering technologies become available, it will be necessary to perform further research to determine how they can be best exploited in new CT protocols. McCollough and colleagues note that there are objective and subjective approaches to protocol optimization and correctly point out that the number of parameters requiring consideration is very large (10). They suggest that image quality surrogates or metrics could be developed and correlated with the definitive arbiter of image quality, the diagnostic performance of the human observer. Once quality standards are understood for each diagnostic task and validated by human observers, subsequent optimization could be based on data from phantoms. McCollough et al further suggest the use of an approach based on mathematic simulations to develop task-based image quality metrics. Given the rapid pace of technology development, this is an important recommendation because the repetition of trials using human observers will be too costly and impractical from the standpoint of time.

Before declaring victory, radiologists and others in the imaging community must recognize that achieving the maximum benefit in dose reduction will require the active participation of radiologists, medical physicists, and technologists and the support of hospital administrators and operators of imaging centers. Professional organizations will also have major roles to play as conveners of standards-setting committees and teachers of new protocol methods.

Radiologists have the overall responsibility of performing CT imaging and control one of the most important input functions governing CT radiation dose—the selection of clinical imaging protocols. Realization of the optimal protocols envisioned by McCollough et al will encompass using the empirical and theoretical data described in their report and turning it into new clinical protocols for specific applications.

In some respects, the challenges faced in the development and management of new dose-optimized clinical protocols are more problematic than those faced in the development of new CT technology per se because the task requires the time and attention of thousands of individual practitioners. There is simply no easy fix at a national level or a corporate vendor level for the need to select and implement optimized protocols within the thousands of hospitals and imaging centers that offer CT imaging. Protocol management is a resource-intensive process and can only be achieved with the commitment and diligence of radiologists working in concert with medical physicists and technologists to design and implement new dose-optimized protocols that take advantage of new technical capabilities.

Even with the best of intentions, the challenges facing radiologists in CT protocol management and optimization are enormous. At Massachusetts General Hospital, we have more than 170 basic clinical protocols. These expand to more than 380 secondary protocols when further optimized for age, sex, body part, body habitus, type of CT device being used, and disease or condition under evaluation—including when in the care cycle the scan is being obtained (ie, initial diagnosis or follow-up). Further customization is often necessary to address individual patient needs. Keeping protocols up to date to reflect changing technology will challenge radiology departments large and small.

Thus, although McCollough and colleagues have done a remarkable job in framing the issues and pointing us in the right direction, in the end, to achieve their vision of submillisievert CT imaging will still come down to the actions of practicing physicians. Patients have a fundamental trust in their physicians to do the right things on their behalf. Radiologists need to step up and commit to the optimization of protocols, something that can begin today without waiting for additional new technology. The principles of Image Gently for pediatric imaging and Image Wisely for adults should be adopted (11,12). In their turn, hospitals and imaging centers will need to step up and acquire new low-dose technology when it becomes available.

The benefits of protocol optimization even with current technology are notable. Researchers have reported major reductions in routine effective doses from CT compared with NCRP reference levels. Results in children have been particularly gratifying (13–15).

A corollary to the foregoing discussion of commitment to protocol optimization is the commitment by radiology practices to participate in the National CT Dose Registry sponsored by the American College of Radiology (16,17). By submitting CT dose data to the registry, a practice can compare itself to the regional and national experience and further benchmark its radiation doses against similar organizations according to size and scope of procedures.

The benefits of participation in the CT Dose Registry are both individual and collective. For a given practice, participation will quickly indicate where it falls on the spectrum of doses used. Outliers on the high side can then act accordingly. Arguably, some of the unfortunate experience with gross overexposures witnessed in the past few years would have been recognized much earlier if the involved institutions had had timely access to benchmark comparison data. Collectively, data gathered in the registry will allow us to objectively document the benefits of new technology as it is adopted and to establish new reference standards. Each new generation of technology will require protocol revisions, and the registry can help guide and document the benefits of that activity. Data from the registry tracking ever-lower radiation doses will be important in our national dialogue about the safety of CT scanning.

While the submillisievert technology and protocol optimization stories play out, there is another important initiative that stakeholders should undertake: optimization of imaging utilization. In a real sense, the most hurtful radiation is radiation from a procedure a patient does not really need in the first place. Dose optimization of a protocol is a moot point if a patient did not need to undergo imaging in the first place.

Radiology practices should work with their institutions to adopt the use of appropriateness criteria such as the American College of Radiology Appropriateness Criteria (16,17) to help guide the decision making of referring physicians. We have had substantial success in doing this at Massachusetts General Hospital, with an emphasis on higher-cost examinations (18).

Financially motivated self-referral is an especially troubling source of overutilization of medical imaging. This issue is well documented in the U.S. health care system but has been looked at primarily as an economic problem. Radiation from medically unnecessary imaging studies performed in the context of financially motivated self-referral adds to both the population exposure burden and the individual patient exposure burden. Self-referral imaging has been a substantial factor in the overall increase in radiation exposure seen in the past 20 years. Ethical radiologists and other ethical providers of medical imaging services must continue to bring this issue forward to the attention of regulators and legislators for resolution.

On a positive note, there are other opportunities to reframe the national dialectic on radiation risks. For years, we have used the concept of ALARA (as low as reasonably achievable) to guide our thinking and remind us to use as little radiation as possible. However, this concept is one-dimensional. The primary thought in the use of the term ALARA is really only about reducing radiation risk, not recognizing benefit. It is time to consider changing our thinking to AHARA—as high as reasonably achievable—to indicate that the real goal is not just the use of as little radiation as possible but to achieve as high a benefit-to-risk ratio as possible on behalf of our patients.

A recent study by Zondervan et al (19) provides support for the AHARA concept. The investigators looked at risks of dying from radiation-induced cancers per linear no-threshold modeling versus the risks of dying from the underlying conditions for which CT was performed. The study population was composed of 21 359 younger adults aged 18–35 years. Even when patients with preexisting cancers were excluded, the observed risk of a patient dying within 3 years was a factor of 35 to 1 greater for abdominal CT and 70 to 1 greater for chest CT than the theoretical risk of dying remotely from a CT-induced cancer. Achieving routine submillisievert CT imaging would increase these ratios by a factor of 10.

The study by Zondervan et al is among a growing body of research that will allow patients, referring physicians, radiologists, and other stakeholders to answer better the fundamental benefit-versus-risk question and illustrate the potential power of the AHARA concept. An obvious weakness in the data is that they address risks for a patient population and not for individual patients, but they point the way. Much more data are needed for specific subgroups of patients—pretest phenotypes—to personalize benefit-to-risk assessments. Research to this end should be supported.

In the final analysis, all stakeholders concerned with radiation exposure should want the same thing: the safest and highest quality of care for patients. The path to achieve this is clear—better technology, better attention to imaging protocols, better utilization management, and a better way of framing and sharing the fundamental benefit-risk equation with patients. McCollough and colleagues point out in their forward-looking article that many of the necessary CT technology tools are available today and others are on the way (10). All radiologists should now make the commitment of the time and attention necessary to take advantage of current and future dose-lowering methods. It is the right thing to do for our patients.

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