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Managing Radiation Use in Medical Imaging: A Multifaceted Challenge[1]

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This special report aims to inform the medical community about the many challenges involved in managing radiation exposure in a way that maximizes the benefit-risk ratio. The report discusses the state of current knowledge and key questions in regard to sources of medical imaging radiation exposure, radiation risk estimation, dose reduction strategies, and regulatory options.

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That medical imaging continues to revolutionize clinical medicine is beyond doubt (1). The direct benefits of modern-day imaging, to list but a few, include the following: more effective surgical treatment (2), shorter hospital stays (3), elimination of exploratory surgery (4), better diagnosis and treatment of cancer (5), more efficient treatment after injury (6), better treatment of stroke (7), better treatment of cardiac conditions (8), and rapid diagnosis of life-threatening vascular conditions such as mesenteric ischemia (9).

The issues of perceived, potential, and known risks associated with ionizing radiation exposure from medical imaging have been in the background for several decades, and a series of events and publications have now brought them fully into the foreground of the medical profession. A striking number of journal and newspaper articles published over the past year, as well as recent congressional hearings, testify to the increasing visibility of these issues.

It is well established that the collective dose to the U.S. population resulting from medical imaging has increased sixfold in the past quarter century (10,11), but the importance of this observation and what, if any, response is required from the medical community, remains unclear. Our goals should be to use imaging only when the potential clinical benefit outweighs the potential risk and to strive for an imaging examination that delivers the lowest dose necessary to obtain the desired information: In short, we must aim for justification and optimization of each imaging procedure (12). Inherent in these simple concepts, however, are many different questions, such as how to define standard metrics for dose, clinical benefit, and low-dose radiation risks and how to minimize the dose per procedure.

Added to the challenges of resolving these scientific questions are the challenges to the medical community of choosing and implementing solutions. What do we need most? More reliable risk estimation? Improved technology? Better and/or more clinical decision support? More training in the optimal use of imaging equipment? More regulation?

This special report expands on the presentations and discussions that occurred at the 2009 Gilbert W. Beebe Symposium, which focused on radiation exposures from imaging and image-guided interventions and was hosted by the U.S. National Academy of Sciences. Summarized here are the nature and extent of the many challenges involved in managing the radiation exposure from medical imaging, including computed tomography (CT), in a way that maximizes the benefit-risk ratio for every patient. This article is divided into four main sections comprising a series of brief reports, as follows: *(a)* Radiation Exposure from Medical Imaging: Sources and Trends, (i) Overview and (ii) Fluoroscopically Guided Complex Interventions: Special Concerns; *(b)* Radiation Risk Estimation, (i) Factors Influencing Radiation Risks and (ii) Ongoing Epidemiological Studies; *(c)* Dose-Reduction Strategies, (i) Dose Reduction in CT: Technological Advances, (ii) Dose Reduction in CT: Decision Guidelines and Education, (iii) Dose Reduction in Fluoroscopy, and (iv) Dose Reduction in Nuclear Medicine; and *(d)* Controls and Standards: Voluntary versus Mandatory Approaches.

Radiation Exposure from Medical Imaging: Sources and Trends

Overview

Medical radiation is the largest source of average annual radiation exposure that is under our direct control. Currently, in the United States, medical uses of radiation account for more than 95% of radiation exposure from man-made sources (Fig 1) and about one-half of all radiation exposure. It is estimated that, in 2007, 3.1 billion radiographic procedures and 37 million diagnostic nuclear medicine examinations took place worldwide, of which roughly 377 million (12%) and 18 million (49%), respectively, were performed in the United States (10,11,13). The estimated numbers and percentages of radiologic and nuclear medicine procedures in the United States for 2006 and the associated collective effective doses are summarized in the Table (10). While the benefits of such procedures have been documented, data and practical methods to quantify the benefits relative to the radiation risks the procedures may pose are as yet unavailable (14).

From 1980 to 2006, the per-capita effective dose from diagnostic and interventional medical procedures in the United States increased almost sixfold, from 0.5 to 3.0 mSv, while the contributions from other sources varied very little (10). During the same period, the collective dose to the U.S. population increased from 124000 person-sievert to 899000 person-sievert, with the increase being almost entirely due to medical imaging (10).

Over the past 15 years, the most significant changes in medical imaging have involved major increases in higher-dose procedures, particularly CT and cardiac nuclear medicine. In 2006, approximately 67 million CT examinations were performed in the United States; fluoroscopic and radiographic examinations

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Abbreviations:
ACR = American College of Radiology
BEIR = Biological Effects of Ionizing Radiation
ERR = excess relative risk
FDA = Food and Drug Administration
MQSA = Mammography Quality Standards Act of 1992

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accounted for nearly three quarters of all radiologic and nuclear medicine procedures but only 11% of the total collective effective dose from such procedures (10). The increased use of CT is due to a number of factors; however, it stems primarily from technological improvements that have resulted in higher spatial and temporal resolution and shorter scanning times, which in turn have made CT an appropriate examination for more clinical indications. CT scanning has also displaced a number of nuclear medicine procedures, such as liver-spleen scans and lung scans. It now accounts for almost one-half of the collective effective dose from medical procedures in the United States and about 17% of all medical procedures (10,11,15). The number of CT scans has increased more than 10% per year over the past 15 years, while the U.S. population has increased by less than 1% annually. The rate per capita of CT usage in the United States (223 scans annually per 1000 population) is among the highest in the developed world, exceeded only by that of Japan (13).

In regard to diagnostic nuclear medicine, cardiac procedures accounted for almost 60% of the total number of examinations and more than 85% of the total collective effective dose in the United States in 2006 (10). The types of nuclear medicine procedures performed most often have shifted markedly over time, owing to the development of radiopharmaceuticals with newer capabilities, as well as replacement of some nuclear medicine procedures with magnetic resonance imaging and CT. Cardiac procedures increased from 1% of the total in 1973 to 57% in 2005, while brain studies decreased from 43% to less than 2%, gastrointestinal scans decreased from 15% to 7%, and lung studies decreased from 12% to 4% (10). Positron emission tomographic (PET)/CT studies have markedly increased in the past 5 years and now number approximately 1.5 million annually in the United States (16); these procedures often deliver larger radiation doses than do CT scans, particularly to the bladder wall (17).

In summary, radiation exposure from medical imaging has increased dramatically in the past 3 decades as imaging technology has improved. As we have discussed, the immediate clinical benefits associated with the increased use of medical imaging are clear and demonstrable (2–9).

Estimated Number and Collective Effective Doses from Various Categories of Imaging Procedures in the United States in 2006

Procedure Type	No. of Procedures*	Percentage of Procedures	Collective Effective Dose		
			Person-sieverts	Percentage	Per- capita Dose (mSv)
Radiographic and fluoroscopic†	293	74	100 000	11	0.33
Interventional	17	4	128 000	14	0.43
CT	67	17	440 000	49	1.47
Nuclear medicine	18	5	231 000	26	0.77
Total	395	100	899 000	100	3.00

Source–Reference 10.

* In millions.

†Includes mammographic examinations but not dental radiographic examinations.

Figure 1

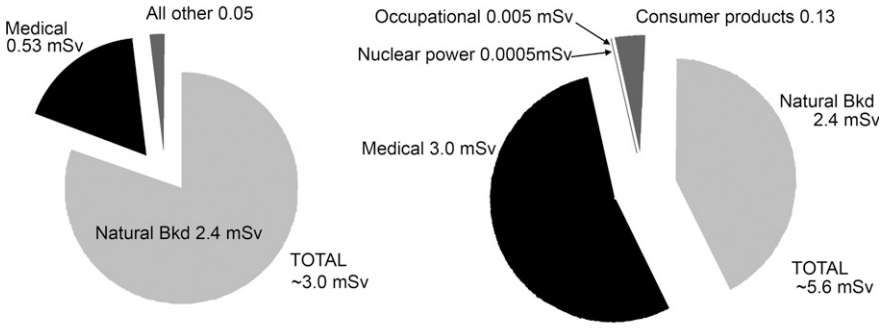

Figure 1: U.S. annual per-capita effective radiation dose from various sources. Left: Chart for 1980. Right: Chart for 2006. *Bkd* = background. (Adapted from reference 10.)

Fluoroscopically Guided Complex Interventions: Special Concerns

In 2006, approximately 17 million interventional radiologic procedures were performed in the United States, resulting in about 14% of the collective effective dose from all radiologic and nuclear medicine activities (10). Because of the duration of these procedures and the repeated uses of cine fluoroscopy, digital angiography, or digital subtraction angiography, radiation doses to patients far exceeded those of previous, mostly diagnostic, uses of fluoroscopy. However, these newer procedures provided patients with minimally invasive alternatives to conventional surgery. The benefits of avoiding conventional surgery with anesthesia, its long recovery periods, and its associated potential complications typically far outweigh the stochastic radiation risks associated with the fluoroscopically guided procedures. Deterministic risks, however, were not initially anticipated.

The dose to a patient from a fluoroscopically guided complex intervention depends on a complex interaction of methodological factors. These include fluoroscopy time, fluorography use (number of frames of cine or digital images), size of the patient, beam trajectory through the patient, proximity of the image receptor and the x-ray source to the patient's body, image quality settings of the machine, beam filters, and operator training and experience.

Figure 2

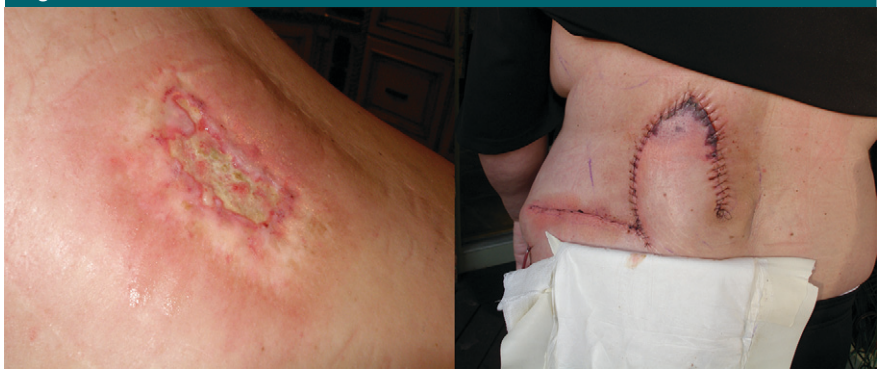

Figure 2: Radiation injury to back of patient. Left: Several months after coronary intervention. Right: After surgical correction.

In the early stages of development, almost no dose-monitoring capability existed. The first feature available to monitor radiation use in the patient was fluoroscopy-on time, which was, and still is, recorded for all procedures. Every 5 minutes, the timer set off an alarm to advise the physician how much fluoroscopy time had expired. For procedures that routinely used 20–40 minutes of fluoroscopy time, this alarm became a nuisance and was akin to "crying wolf." Further, the fluoroscopy-on time was of limited use as a radiation-dose monitor because time is only one of multiple factors that contribute to dose. Whereas a procedure using 40 minutes in a small person, for whom a short beam trajectory is used, might result in a dose inconsequential for deterministic concerns, the same time in an obese patient, for whom a severely oblique trajectory is used, could result in a dose exceeding the threshold level for skin desquamation. Thus, the dose-management equipment used for these procedures was woefully inadequate.

The first documented case of severe skin injury was recorded in 1992 in a patient who had undergone fluoroscopically guided coronary intervention (18). In the years that followed, more cases of severe skin injury (Fig 2) were reported to the Food and Drug Administration (FDA). The FDA worked with professional societies to hold meetings and develop information on the risks for this phenomenon. By 1994, the FDA issued an advisory to all health care professionals about the increasing occurrence of these types of severe skin injuries (18,19). A second FDA advisory followed in 1995, recommending that information about the potential for serious x-ray–induced skin injuries after fluoroscopically guided procedures be recorded in the patient's medical record (18).

Since these warnings were issued, injuries have continued to occur (20,21) and have been documented for a variety of complex interventions, including percutaneous transluminal angioplasty, electrophysiologic and ablation procedures, transjugular intrahepatic portosystemic shunt placement, vascular embolization, and stent and filter placement. Severe injuries, though rare (their estimated frequency of occurrence is less than 0.01% [22]), can require years of medical care and treatment of intense pain. A discussion of recent efforts to prevent them is provided later in this article.

Operator doses.—Occupational radiation doses to interventionalists are probably among the highest received by any medical practitioners (23). The difficulty with this statement is that interventionalists wear lead aprons while they work and, thus, their radiation exposure is high for unshielded body parts and much less, by a factor of 10–20, under the lead apron. In the United States, the standard lead apron is 0.5-mm lead equivalent. At many facilities, interventionalists are trained to wear their personal dosimeters both inside and outside their lead apron. Typical annual doses recorded by the outside badges for interventionalists range from 10 to 40 mSv (24–26). These are fairly representative of the doses that are received by unprotected eyes and head.

Often, interventionalists practice at multiple sites. They may have dosimeters at each site, and the radiation safety program of each site may not take the exposures incurred at other sites into account. Moreover, it is clear that interventionalists do not always wear their badges while on duty (24–26). Thus, there is ample scope for interventionalists to receive doses that are considerably higher than documented through their dosimeters.

Definitive evidence indicates that occupational radiation exposures accumulated to large doses over long periods of time place workers at a significant risk for health maladies later in life (27). So, as an additional educational requirement, special attention should be paid to radiation management for the worker (28). Education emphasizing that radiation management for the patient also reduces occupational radiation risk can provide a marked motivation for radiation workers to control and limit radiation use.

Radiation Risk Estimation

Factors Influencing Radiation Risks

What we know and do not know about the cancer risks associated with doses of radiation comparable to those from CT scans has been summarized elsewhere (29–31). In brief, there is reasonable, though not definitive, epidemiological evidence that organ doses in the range from 5 to 125 mSv result in a very small but statistically significant increase in cancer risk. These results come primarily from studies of approximately 30000 A-bomb survivors who were several kilometers away from the explosions and were thus exposed to low doses (32). Findings in other low-dose epidemiological studies from the occupational exposure of radiation workers are generally consistent with the finding of increased cancer risk (33,34). Because low-dose risks are stochastic in nature, and undoubtedly far smaller

than the background cancer risk (35), there is considerable uncertainty as to the numerical values of low-dose radiation risks (36). Indeed, the possibility of a practical threshold dose for radiation carcinogenesis (ie, a dose below which there is no demonstrable increase in cancer risk) cannot be excluded (31). Despite these uncertainties, what can be stated with certitude is that the radiogenic excess cancer risk associated with diagnostic radiation levels, if any, is orders of magnitude smaller than the spontaneous cancer risk (35).

A number of factors significantly influence the risk of developing cancer following exposure to a given dose of ionizing radiation. We discuss here the four dominant factors: genetic considerations, age at exposure, sex, and fractionation and protraction of exposure.

Genetic considerations.—Two reports from human epidemiological studies clearly imply the existence of radiosensitive subpopulations. The first is from a study of young women with scoliosis who were regularly exposed to diagnostic x-rays to follow the progress of their disease over a period of many years (37). There was a borderline significant dose response for breast cancer in the whole cohort but a much greater and significant dose response in a subset of women with a family history of breast cancer in first- or second-degree relatives. The second report is from an Israeli study of children epilated with x-rays for the treatment of tinea capitis (38). A subset of the children involved came from 525 large families with five or more siblings. Overall, about 1% of the children irradiated developed meningioma, but the incidence was not random. There was a marked clustering, with multiple children in some families developing the malignancy. In neither case have the genes responsible for the observed radiosensitivity been identified.

There have also been several reports in which the significance of specific gene mutations, such as *ATM, BRCA1,* and other repair-pathway genes, have been studied with regard to radiation sensitivity in human populations (39). The results for specific genes have been somewhat equivocal, although analogous studies with genetically modified mice have indicated that haploinsufficiency for genes such as *Atm, Brca1,* and *Rad9* result in sensitivity to radiation for end points such as ocular cataracts and oncogenic transformation in embryo fibroblasts (40,41).

Figure 3

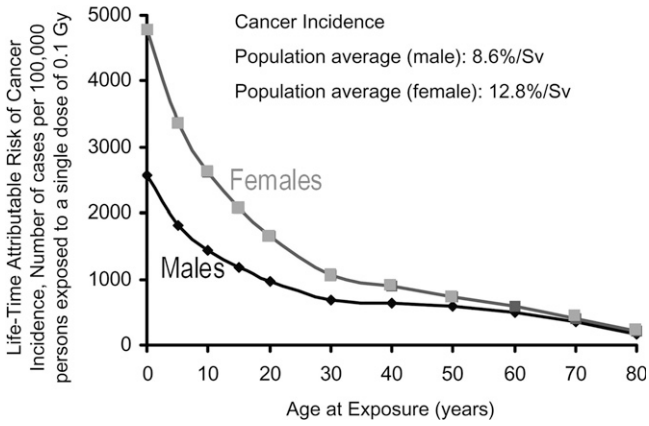

Figure 3: Graph shows lifetime attributable risk of radiation-induced cancer incidence, as a function of age at exposure for males and females. Graph is based on data about the A-bomb survivors as analyzed by the Biological Effects of Ionizing Radiation (BEIR) VII committee; data are from reference 30.

Age at exposure.—Figure 3 is a plot of data derived from the BEIR VII report (30) showing the relationship between life-time attributable risk of cancer incidence and age at exposure. While it is certainly true that children are, in general, more radiosensitive than adults, this monotonic decline in risk with age fitted to the data hides a number of complications. Figure 4 compares the ERR at ages 10 and 40 years for a number of specific solid cancers in the A-bomb survivors. Some solid cancers do indeed show this rapid decline in risk with age, but for many there is little difference in risk between 10 and 40 years of age (42), while for lung cancer there appears to be a significant increase of risk with increasing age (43).

Sex.—Figure 3, derived from the BEIR VII report (30), indicates a substantially higher lifetime attributable risk of cancer incidence in females compared with males. To examine this factor in more detail, Figure 5 compares the ERR for males and females for a number of different solid cancers (32); of course, breast cancer poses a risk in females that is rarely seen in males, but in fact by far, the largest effects of sex on the relative risk are for lung and bladder cancer, two malignancies greatly influenced by smoking. In the Japan of 1945, men were heavy smokers, while smoking was uncommon in women, and as a result, the background level for lung and bladder cancers is much higher in men than in women, making the radiation risk smaller. When sex-specific cancers are excluded, excess absolute risks are much less different between the sexes.

Fractionation and protraction of exposure.—In general, radiation risks per unit dose at low doses and at low dose rates are smaller than those at higher doses and dose rates, because of the influence of DNA damage repair. The dose and dose-rate effectiveness factor is the factor by which risk per unit dose from high doses of short-term radiation exposure can be extrapolated to risk per unit dose at low dose and low dose rate. In 1990, and subsequently, the International Commission on Radiological Protection suggested a value of two (44), while BEIR VII (30) suggested a value of 1.5. We now have cancer risk estimates from several nuclear worker studies involving protracted exposures over many years to compare with the short-term exposure of the A-bomb survivors. In particular, the International

Figure 4

Figure 4: Graph shows comparison of the excess relative risk (ERR) at age 70 years for exposure at age 10 or 40 years for specific solid cancers in the A-bomb survivors. (Reprinted, with permission, from reference 32.)

Figure 5

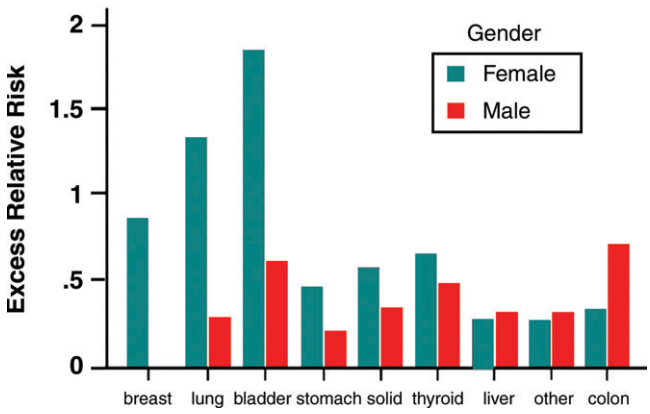

Figure 5: Graph shows comparison of the ERR between males and females for specific solid cancers in the A-bomb survivors. Breast cancer poses a risk in females that is not seen in males, but in fact the largest ERRs to females are posed by lung and bladder cancer, two malignancies greatly influenced by smoking. (Reprinted, with permission, from reference 32.)

Agency for Research on Cancer 15-country study (34) involved some 600 000 nuclear workers exposed to an average cumulative dose of 19 mSv; the estimated ERR per unit dose for all solid cancers from this study is almost four times larger than that for the A-bomb survivors, although the difference is not significant. There are two major caveats in regard to this study: First, the result is driven by the Canadian contribution, and in Canada, there are relatively few nuclear workers but many deaths from cancer. Second, the predominance of lung cancer suggests a possible confounding effect of smoking, although this is unlikely to explain all of the observed excess risk. For both reasons, the results of this study must be considered preliminary.

A more recent pertinent study is an update of the National Registry of Radiation Workers in the United Kingdom (33). This study involved 175 000 workers exposed to a mean cumulative dose of 25 mSv who were followed up for many years. Cancer risk increased with dose, and the estimated ERR per sievert was very similar to that for the A-bomb survivors. When results in nuclear worker studies are compared with the A-bomb data, one is led to the conclusion that the reduction of cancer risks with dose protraction is surprisingly small. A similar conclusion was reached some years ago from a study in which the incidence of radiation-induced breast and lung cancers in the various tuberculosis fluoroscopy cohorts was compared with the incidence in A-Bomb survivors (45–47). However, the confidence intervals of the various risk estimates are sufficiently large that they can accommodate a dose and dose-rate effectiveness factor of 1.0, 1.5, 2.0, or an even larger value, or even a value of less than one.

Ongoing Epidemiological Studies

Epidemiology studies are invaluable for radiation protection purposes. While risk models are useful and often relatively quick to calculate, they become more credible when complemented and validated by the results of epidemiological studies that directly observe health effects of radiation in the exposed populations. The patient group of most concern is children, who are more susceptible than are adults to the effects of radiation, not only because of their greater radiosensitivity but also because of their longer postirradiation life expectancy (48). In the past, children often received higher radiation doses than necessary, as the pediatric scanning protocols used the same CT settings designed for adult patients, but awareness of this issue has led to appropriate changes in the protocols at many institutions. As CT use continues to grow and as technologies change, the understanding of any risks to patients is crucial. This was emphasized in the BEIR VII report, which recommended that epidemiological studies, where feasible, include follow-up of cohorts of patients undergoing CT scanning, including children (30).

To address the need for more data, a cohort study assessing risk of subsequent cancers in individuals exposed to radiation through CT scanning during childhood or as young adults is under way in the United Kingdom. The health care system in the United Kingdom has marked advantages over the health care systems of some other large developed nations for research in this area: Specifically, CT scans are primarily obtained in public rather than private hospitals, and the United Kingdom has a nationwide registry for cancer and death notifications, to which patient data can be linked. A cohort of nearly 250 000 patients first scanned with CT (for noncological reasons) while under 22 years of age has been constructed in the United Kingdom, primarily from electronic records held in radiology departments nationwide (it is augmented by small numbers of scan records abstracted from radiologic images or paper records, which would be too time- and resource-intensive to collect for an entire cohort of this size). Scan data have been collected from as far back as 1985 for a small number of hospitals, with later scans up to 2007

Figure 6

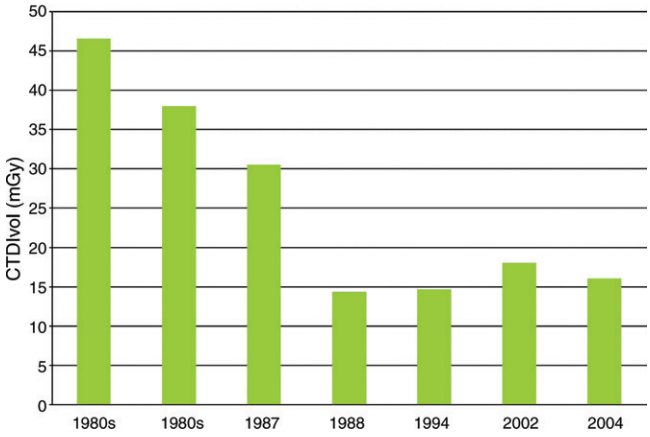

Figure 6: Graph shows typical scanner output level (expressed as volume CT dose index *[$CTDI_{vol}$]*) for a routine abdominal CT examination from the 1980s, when xenon detectors were used, to 2004, when 64–detector row CT systems were introduced. Data from the 1980s represent different scanner models in use during that period. Solid-state detectors were used on the systems represented here from 1988 onward. Until the mid-1990s, the typical image represented a 10-mm section of anatomy, and scans required several minutes to acquire. Much improved image quality is now obtained by using 3–5-mm section widths and scan times of 10–20 seconds.

also included to allow repeat exposures to be assessed. Dosimetric modeling is under way, incorporating not only the patient information collected from radiology departments but also data on the scanners used, the time periods they were in use, and available scanner protocols. This factor will result in the individual assignment of organ-specific doses, with cumulative doses recorded for patients in whom more than one scan was obtained. All study members are being linked with the records held by the National Health Service Central Registry, such that cancers and deaths, with causes, among the individuals in the cohort will be identified. A second phase of the study will include nested case-control studies for specific cancer types.

Other studies addressing the same questions and following similar protocols are being performed around the world in countries such as Australia, Canada, France, Israel, and Sweden. Given the likely small magnitude of any radiation effects in these cohorts, the rarity of the outcomes under investigation, and the likely long latency of radiation-related risks, combined analyses of many international cohorts must be performed to ensure adequate statistical power. All of these studies need time to complete their main objectives as they currently stand; furthermore, they will need to be maintained for follow-up well into the future. The risk models from these cohorts are likely to evolve because of the need for longer follow-up times than are currently possible. Further epidemiological studies of CT exposures are also taking place with adult patient populations; these studies can balance the reduced length of follow-up time available with a wider range of CT uses, including whole-body screening of asymptomatic patients, which is the subject of new regulations in the United Kingdom aimed at limiting unnecessary radiation exposures (49).

Ongoing epidemiological studies concerning medical imaging are not limited to CT, although this is currently the area of greatest interest. BEIR VII also called for studies, again where feasible, of infants undergoing cardiac catheterization and premature babies exposed repeatedly to x-rays (30). Given the smaller numbers of patients involved, such studies would require the establishment of international cohorts, preferably following similar protocols to ease combined analyses. With continuing technological advances in medical imaging, it is increasingly important that epidemiological research keeps pace, to be able to provide improved risk estimates that will be essential for optimizing the benefit-risk profile.

Dose-Reduction Strategies

Dose Reduction in CT: Technological Advances

The dose from a given CT acquisition of the abdomen and pelvis has decreased by a factor of two to three since the 1980s owing to a number of technical innovations (Fig 6) (50). This decrease has been accomplished in conjunction with a reduction in scan times from several minutes to several seconds and the reduction of routine image thicknesses from 10 to 3–5 mm. Some of the advances responsible for these improvements include the use of the following: *(a)* solid-state scintillating detectors, which have a very high absorption efficiency; *(b)* electronic circuits with lower levels of background noise; *(c)* multi–detector row arrays, which eliminate dose inefficiency at the edge of the x-ray beam; *(d)* more powerful x-ray tubes and generators, which can be strongly filtered to selectively remove low-energy photons; and *(e)* beam-shaping filters that vary the x-ray intensity across the patient cross section.

A number of additional dose-reduction techniques are gaining widespread use (51–53), including the following: *(a)* manual or automated adjustment of scanner output according to patient size by using (i) tube current modulation that is based on patient attenuation or an electrocardiogram and (ii) selection of the most dose-efficient tube potential, *(b)* iterative reconstruction methods, and *(c)* increased spiral pitch or nonspiral (eg, volumetric) methods in cardiac CT.

Despite the availability of these devices and techniques, the radiation doses received from common CT examinations vary substantially within and across institutions and are often greater than necessary (54).

Tube current modulation and automatic exposure control.—It is a fundamental responsibility of the CT operator to take patient size into account when

selecting the parameters that affect radiation dose, the most basic of which is the tube current (55,56). Tube current should ideally be adjusted as a function of thickness, or overall attenuation, of the anatomy of interest in the patient (57).

Clinical evaluations of tube current–adjusted images have demonstrated that radiologists do not find the same noise level acceptable in small patients as they do in larger patients (58). For CT imaging of the head, tube current reduction from an adult to a newborn of approximately a factor of two to 2.5 is appropriate; for CT imaging of the body, a reduction in tube current by a factor of four to five from adult techniques is acceptable in infants, while for obese patients, an increase by a factor of two is appropriate (53).

Tube current modulation is used to adapt to variations in patient thickness throughout the scan region and can occur angularly about the patient and/or along the long axis of the patient (Fig 7). These methods of adapting the tube current to patient attenuation, known generically as automatic exposure control, are analogous to photo-timing in general radiography and have demonstrated reductions in dose of 20%–50% when image quality is appropriately specified. Automatic exposure control encompasses not only modulating the tube current (to adapt to changes in attenuation within a patient) but also determining and delivering the optimal dose for any given patient to achieve the required diagnostic performance. As with all automated techniques, care must of course be taken to ensure that automatic exposure control is applied appropriately (59).

Adjusting tube potential on the basis of patient size.—For contrast material–enhanced CT examinations, the optimal tube potential is highly dependent on the patient size and the specific diagnostic task. However, for nonenhanced CT, the benefit of a lower tube voltage has not been established because soft-tissue contrast in this setting is less affected by the tube potential. In all cases, image noise must be maintained at a level appropriate to the diagnostic task. Strategies to select an optimal tube potential for a given patient size and diagnostic task have been published and demonstrate up to 70% and 40% reductions in dose for very small patients for the chest and abdomen, respectively, compared with the use of 120 kV (53). Use of lower tube potential values (80 or 100 kV) for coronary CT angiography in smaller patients has been shown to reduce radiation dose by up to 50% without compromising the image quality (60,61).

Figure 7

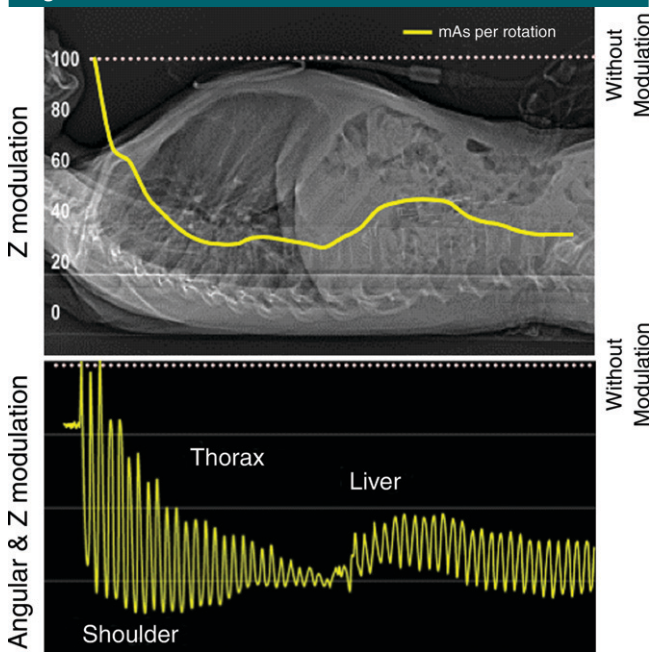

Figure 7: Images show that, with automatic exposure control, the tube current is modulated according to the attenuation of the patient at any projection angle and z-axis position. This factor helps reduce dose by up to 50% compared with use of a fixed tube current throughout the scan, even when that tube current has been adjusted for the overall patient size (eg, infant versus obese patient).

Cardiac CT.—Electrocardiographically based tube current modulation is an important dose-reduction tool in cardiac CT (62–64), allowing doses 30%–90% lower than those delivered with continuous x-ray spiral techniques. The width of the 100% tube-current window must be carefully chosen to make sure that the data for the desired cardiac phase (typically the one with the least motion) will be acquired with 100% of the tube current required for a given patient and imaging task. Dose reductions of up to 90% can also be achieved by using nonspiral (ie, "step-and-shoot") acquisitions (65,66), in which the x-ray beam is completely off except during the desired reconstruction phase. Finally, dual-source CT systems enable a very high pitch spiral scan mode in which a complete cardiac data set can be acquired within one heartbeat. Dose reductions up to a factor of 10–12 have been reported with this mode (67). Figure 8 demonstrates the dose reductions in cardiac CT angiography since the introduction of this application in the early 2000s (68).

Iterative reconstruction.—Iterative reconstruction techniques have demonstrated the potential for improving image quality and reducing radiation dose in CT (69–73) relative to the currently used filtered backprojection techniques. Iterative reconstruction is also superior to filtered backprojection in handling insufficient data. Recent advances in iterative reconstruction allow a significant reduction in the number of required projection views while still

Figure 8

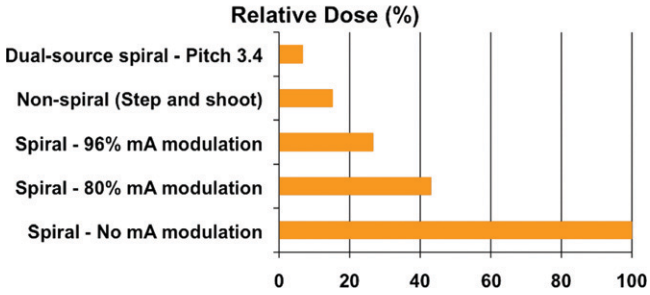

Figure 8: Graph shows dose reductions in cardiac CT angiography. Cardiac spiral CT was introduced into clinical practice around 2000 after the introduction of the four-section scanner. Electrocardiographically controlled milliampere *(mA)* modulation was introduced to clinical practice in about 2002, the step-and-shoot mode for cardiac imaging was introduced in about 2006, and dual-source spiral CT with high pitch was introduced in around 2009. For cardiac examinations that do not require images of the heart throughout the entire cardiac cycle, the radiation can be turned down with the use of tube current (milliampere) modulation, or off in the case of nonspiral scans. This is often done for phases of the cardiac cycle where the heart is moving fastest, when motion blurring or artifact would be most severe. (Image from reference 68.)

producing acceptable image quality. Thus, iterative reconstruction techniques have the potential to substantially reduce the radiation dose in CT (74). With computational power growing quickly, the clinical implementation of iterative reconstruction algorithms is within reach (73).

Dose Reduction in CT: Decision Guidelines and Education

As noted earlier, dose reduction strategies must be based not only on the use of dose optimization technology but on appropriate use of imaging. A substantial fraction of CT scans could be replaced by practical alternate approaches, or could simply be eliminated. There is scope for reducing the use of many common CT examinations in favor of other diagnostic modalities. Examples are CT for renal colic, abdominal pain, abdominal and chest trauma, minor head injury, and pulmonary embolus.

Of course when a radiologic imaging procedure is clinically appropriate, the benefit-risk balance is almost always overwhelming. The key questions are as follows: What diagnostic procedure is best suited for a given indication in a given patient? Is a radiologic procedure clinically justified (12)? If so, which radiologic imaging procedure is best suited for the indication? With the use of these and/or other metrics, how many of the more than 70 million CT scans being obtained in the United States this year are actually clinically justified?

For many scenarios, we can answer this question quite well, because of the burgeoning number of available clinical decision guidelines (clinical decision support systems, appropriateness criteria, etc). On the basis of a mix of clinical data and expert judgment, these decision guidelines specify scenarios in which a given imaging procedure is medically justified. The American College of Radiology (ACR), the Royal College of Radiologists, and the European Commission have all published decision guidelines for the appropriate use of CT in different settings, as have various organizations associated with specific subspecialties.

These decision guidelines can be used to assess current CT use. For example, in a retrospective study (75), imaging use was examined in 200 trauma patients, for whom imaging decisions were made without the use of formal decision rules; in 169 of 200 patients, one or more CT scans were obtained, resulting in a total of 660 CT scans. Had ACR appropriateness criteria been applied, 44% of these CT scans would not have been obtained, and none of the patients with substantial injuries identified on CT scans would have been excluded from CT imaging. Findings in other larger retrospective (76), prospective (77), and modeling studies (78) also suggest that 20%–40% of CT scans could be avoided if decision guidelines were followed, without compromising patient care. Recently, the Centers for Medicare and Medicaid Services in the United States initiated a demonstration project to determine the appropriateness of advanced diagnostic imaging services in relation to established criteria (79).

Naturally, decision guidelines are not useful if they are not applied, and prior research indicates that this is too often the case (80). Reducing the number of CT scans that are not clinically justified is a hard task, because there are a variety of very real factors pushing in the other direction, ranging from throughput, to economic concerns, to patient preference, to legal issues (81). When applied, however, decision guidelines have the potential to help reduce the influence of these other factors, and so they represent a potentially powerful tool for optimizing CT use.

A successful approach to increasing use of CT decision guidelines has been to incorporate them into computerized imaging order entry systems (82–86). To date, incorporating decision guidelines into a managed care preauthorization system has been less successful in changing CT use patterns, at least in the United States (87).

The factors that feed into decision guidelines are complex and the available data often are incomplete or contradictory, so the guidelines need to be constantly reassessed to take newer evidence into account. Comparative effectiveness research, for which increased government funding has recently become available in the United States, can help to extend and improve current decision guidelines in the medical imaging arena (88).

In summary, it is impossible to imagine the current practice of medicine without modern-day imaging. However, along with all the high-tech imaging

tools that are now available, optimizing imaging use with the aid of clinical decision guidelines is essential (12). Having established that an imaging procedure is clinically justified, the physician (and the whole imaging team) has a further responsibility to optimize the radiation exposure to the individual patient. Technical advances such as tube current modulation, or iterative reconstruction, have been discussed above and represent a key component of dose optimization. However, strategies for dose optimization must also embrace educational efforts in regard to modern radiologic modalities, directed to all interested stakeholders; in light of the constantly evolving and complex medical imaging environment, these educational efforts must be continuous and regularly updated.

Recently, a survey of 39 institutions, including children's hospitals, university-based children's centers, and community-based hospitals with pediatric radiology expertise, indicated a significant decline in the number of CT examinations in both academic and community programs (89); this was especially evident in centers with fewer than 250 beds. While the causes of change in CT use were multifactorial, educational initiatives in regard to radiation awareness were important for these smaller centers.

While training courses, professional society meetings, journal and text material, and Web-based information are all available, broader initiatives can be successful. One such recent initiative for radiation protection in children is the Alliance for Radiation Safety in Pediatric Imaging (90). The principal actions of the Alliance have been through national campaigns, specifically the Image Gently Campaign for pediatric imaging (90,91) and the Step Lightly Campaign for pediatric interventional radiology (92). Both campaigns focus very much on advocacy in regard to dose management by using simple on-target messages (93) rather than an alarmist approach. The ACR and Radiological Society of North America have recently put together a task force to get the same message out with regard to adult CT imaging. This ACR–Radiological Society of North America Joint Task Force on Adult Radiation Protection has initiated an Image Wisely campaign to educate stakeholders on the potential risks of radiation exposure from adult CT scans.

Dose Reduction in Fluoroscopy

In 2004, two key articles (94,95) were published calling for improvements in dose management for fluoroscopically guided interventions. Taken together, these articles laid out two basic needs: First, better dose-monitoring technology had to be installed on all equipment, and second, physicians had to be trained in how to use it. The FDA incorporated many of the called-for requirements into the regulations for equipment manufactured after June 10, 2006 (96). These new safety-related regulations included requirements such as last image hold, display of cumulative exposure time, cumulative air kerma, and real-time display of the air kerma dose rate.

Although incidents of radiation-induced severe skin injury have since occurred, awareness of this potential complication has improved markedly, and dose management is being instituted gradually. As has already been pointed out, dose delivery is the product of a complex interaction of numerous factors. These factors have been reviewed extensively in the literature (94,97), but education of interventionalists in the lessons of these publications is a challenge (98). Continued improvement of dose management will require further educational efforts. It will also require further improvement of dose management technology. A dose-mapping tool incorporated into angiographic equipment was previously available for purchase, but it proved to be ahead of its time. It was sold as an option to angiographic equipment, and few facilities purchased it, primarily because it was not required for use and was considered an unnecessary added cost. The product is no longer available. Instead, a feature called the cumulative dose at a reference point has been made available on all angiographic equipment sold in the United States since mid-2006. This cumulative dose (actually the cumulative free-in-air air kerma) provides information on the total amount of radiation delivered to a specific point located a fixed distance from the x-ray source. This reference air kerma correlates reasonably well with the absorbed dose at a specific skin site (99), but the correlation factor is complex because it is procedure specific and varies with the operator and the dynamic changes between the patient's anatomy and the fluoroscopic x-ray beam. Its use as a tool to manage patient dose requires education and implementation of certain policies when the air kerma reaches a specific threshold level.

Dose Reduction in Nuclear Medicine

Among nuclear medicine examinations, cardiac examinations are the greatest source of radiation exposure (10), although rapid increases in the use of PET/CT for staging and treatment of cancer are also now contributing. As with CT, dose reduction efforts have focused on improving imaging technology, as well as use. Technological innovations have increased the sensitivity of single photon emission computed tomographic (SPECT) instrumentation, currently the principal modality for nuclear studies of the heart. Newer cadmium-zinc-telluride detectors and other technical advances have facilitated the development of higher-speed, higher-resolution gamma cameras that reduce imaging time. Higher detector sensitivity translates into the ability to obtain equivalent image quality with less administered radioactivity. One important ongoing development is the phasing out, where possible, of the use of radionuclides that produce higher doses, as, for example, in the gradual replacement of thallium 201 chloride with technetium 99m in cardiac studies (100). Finally more practice guidelines are being developed, such as those for the selection and use of noninvasive imaging tests in patients with manifest coronary artery disease or in individuals who are suspected of having coronary artery disease (101).

In nuclear medicine, exposure of children is also of concern, particularly because of their greater radiation sensitivity. A recent study showed considerable variation in the quantities of radioactivity administered for the same pediatric

studies at several nuclear medicine clinics (102). As a result, pediatric standards are being developed by the Medical Internal Radiation Dose Committee of the Society of Nuclear Medicine for administration of radiopharmaceuticals that scales commensurate with body surface area and will optimize image quality while minimizing absorbed doses.

Improvements in software (eg, spatially varying filtration of planar studies and iterative tomographic reconstruction by using resolution recovery) are also leading to increases in image quality that should help reduce the administered activity required for procedures. Such software improvements are being applied to many nuclear medical applications, including cardiac SPECT and PET/CT, as well as pediatric studies.

Finally, looking to the future of nuclear medicine, the radiation dose to the patient must be an important consideration in the radiopharmaceutical design. The optimum agent would maximize the specificity of targeting (high imaging signal) consistent with rapid elimination from the rest of body (low dose).

Controls and Standards: Voluntary versus Mandatory Approaches

Initiation of controls and standards typically starts with dissemination—good ideas, professional knowledge, and experience presented, discussed, and published. With consensus eventually being considered good practice, de facto voluntary standards can emerge for appropriateness, justification, optimization, and training. However, voluntary standards such as those encompassed in committee reports, recommendations, or guidelines, without compliance, can lack credibility in that there is no assurance that users actually meet the standards of practice outlined in such documents. As one example, fluoroscopy has evolved along this path, with much attention focusing on education, better practice, and mandatory equipment regulations (as discussed earlier in the section about fluoroscopy). A more developed example is mammography, where standards, now mandatory, are more comprehensive and not just limited to the equipment, but apply also to the interpreting physician, the technologist, and the medical physicist.

Figure 9

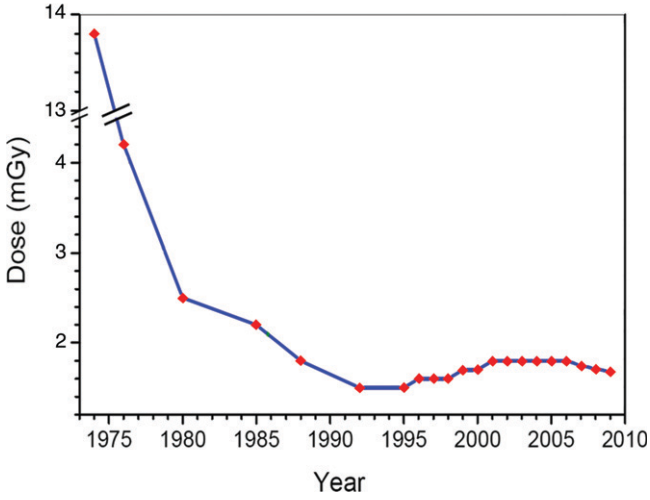

Figure 9: Graph shows trends in mammographic dose, 1975–2010. (Adapted from reference 105 [David Spelic, written communication, May 26, 2010].)

Education, especially of the public, was particularly important in the early development of quality control for mammography. Breast cancer awareness and the potential value of mammography received widespread visibility when, in September 1974, first lady Betty Ford's mastectomy was followed, 2 weeks later, by Happy Rockefeller's mastectomy; the role that mammography played in their cancer detection resulted in mammography becoming much more widely accepted (103). During this period, reports of very high radiation exposures alerted the radiation protection community and culminated in a shift from high-dose direct film imaging to newer imaging technologies such as screen-film mammography and xeromammography. This factor resulted in a dramatic decrease in radiation dose (104), which was based entirely on voluntary changes (Fig 9).

During this time the medical community acknowledged the hazards of extremely high radiation doses, but the radiation protection community also learned the value of the imaging examination. Both communities realized that lowering the radiation dose was not an independent task but rather required simultaneous assessment of image quality to maintain the medical benefit of the examination.

After a decade of improving technologies and practice in mammography, in 1987 the ACR launched its voluntary Mammography Accreditation Program (106). This was a comprehensive program, assessing mammographic dose and image quality in a standardized way and also addressing personnel qualifications. The program of the ACR was part of a wider quality assurance effort dating back to the 1970s, which evolved into a broad coalition of professional societies, industry, government, and consumer advocates for quality mammography and culminated with the passage of the mandatory Mammography Quality Standards Act of 1992 (MQSA). Although the voluntary ACR Mammography Accreditation Program model was integral in the new federal legislation, only one quarter of all mammography units in the United States had voluntarily participated in this program by the time the MQSA was passed. Since passage of the MQSA, accreditation has been required of all mammography sites. Mammography is now considered one of the safest and highest-quality imaging examinations in the United States, with dose limits and image quality standards,

implemented by using a standard phantom and protocol. However, to ensure the safety of the patient and the effectiveness of the examination, mandatory, enforceable quality assurance, quality control, and training standards were necessary.

In terms of government legislation, however, mammography is distinctive in the radiologic field. There are no other radiologic modalities covered by such legislation. The FDA has recently proposed newer voluntary initiatives in terms of quality control for all medical imaging (107), while several recent opinion pieces (108,109) have suggested that legislation analogous to that in the MQSA may be desirable for higher-dose radiologic procedures such as CT. These might cover quality control and assurance, as well as training, as with MQSA, but they might potentially also address the issue of overuse. Of course, modalities such as CT involve far more complex issues as compared with mammography, so introducing legislative fiats would need to be done with much care and, critically, with much consultation to reach consensus. Voluntary standards have not been ineffective, but the experience in the mammography field in transitioning from voluntary standards to the mandatory MQSA demonstrates that legislation can potentially be more effective in improving quality control.

The Need for Standardized Dose Specification

Radiation safety can only be assessed meaningfully across all imaging modalities when there is a single standard for radiation dose, a metric for assessment of radiation risk. Modality-specific metrics (eg, administered radioactivity for radiopharmaceuticals, entrance skin kerma for x-rays, CT dose index for CT, and dose-area product and cumulative air kerma for fluoroscopy) are only of value to those familiar with the modality. Arguably, use of these modality-specific metrics may no longer be necessary.

Today, methods exist—and more are under development—to estimate organ doses from a variety of radiation sources. Although some of these methods are more difficult and time consuming to execute than others, some of the authors believe that, with incorporation of software into imaging technologies and with knowledge of the radiation source output, as well as the patient's size and geometric orientation, routine patient-specific organ dose estimation will eventually be possible (110–113). The Consortium of Computational Human Phantoms has a Web site (*www.virtualphantoms.com*) that identifies many organizations that have published or are actively engaged in developing such computational methods for organ dose estimation.

Industry participation will be required to incorporate these methods into automated or user-friendly protocols and achieve successful standardization and broad adoption. The biggest challenge will be agreement on such standardization.

The origins of the methods can be traced back to formalism and Monte Carlo techniques developed by the Medical Internal Radiation Dose Committee of the Society of Nuclear Medicine (114,115). Organ doses, expressed as mean energy per unit mass absorbed by an organ, were calculated by using Monte Carlo methods to trace photon histories throughout standard mathematical phantoms. These models and methods have now reached a level of realism (116) well beyond the original simple geometric shapes of the original Snyder phantom (117), with voxel phantoms that can be customized with scaling (118), and spatial dimensions commensurate with cellular and multicellular structures (119).

Peer-reviewed publications, handbooks, and software are now available to estimate organ doses from radiopharmaceuticals and from x-ray examinations, including fluoroscopy and CT. Organizations that have published this information include the Medical Internal Radiation Dose Committee, the International Commission on Radiological Protection, the U.S. FDA, the UK Health Protection Agency, the German National Research Center for Environment and Health, and the Finnish Radiation and Nuclear Safety Authority. In addition, many academic institutions are actively involved in this area of research.

Standardization of organ radiation dose can and should be achieved for all radiation sources. Dosimetry that is based on organ doses is the generally accepted method, although the limitations of using organ doses to predict biologic response are well appreciated (120). The concept of effective dose was introduced to provide a mechanism for assessing the radiation detriment from partial-body irradiation. It thus indicates the amount of whole-body irradiation that would yield the equivalent radiation detriment resulting from the diagnostic examination performed. It is useful when relative doses for different procedures are compared (121,122). However, effective dose does not take account of age at exposure. Furthermore, because the parameters used to calculate effective dose are subject to change, the underlying organ doses, tissue-weighting factors, and radiation-weighting factors ideally should always be reported together.

In light of these capabilities, a pressing question today is whether we could or should ensure standardized dose specification for all medical imaging technologies without formal regulations. One issue is whether standardized dose specification can be accomplished with a single quantity and corresponding unit for both stochastic and deterministic effects. Many quantities have been adopted for dose specification related to risks associated with stochastic effects of ionizing radiation, and the unit of the sievert has been defined as a metric for this purpose. However, a quantity and corresponding unit have not been adopted by international committees for deterministic effects; while suitable units are being proposed (123), this is still very much a work in progress.

Conclusion

In summary, it is the responsibility of the entire medical community, from industry through referring physicians, radiologists, nuclear medicine physicians, medical physicists, and radiologic and nuclear medicine technicians, to ensure

that the benefit-risk ratio is as high as can reasonably be achieved for every individual imaging procedure. This involves the following: *(a)* providing evidence-based guidelines as to when and which imaging techniques should be used and ensuring that physicians follow these guidelines yet have the latitude to deviate from them when clinically appropriate and *(b)* implementing low-dose protocols that minimize radiation exposure while achieving appropriate image quality.

Meeting these requirements demands a multifaceted approach. High-technology tools for reducing the dose per procedure are available, as are many clinical decision guidelines. Unless they are accepted and adopted by physicians and physicists, they are of no value. In the United States, it is clear that continuing education in modern imaging is not as universal as it should be. Likewise, it is clear that quality control and quality assurance are not uniform and optimized in all U.S. imaging facilities (54,124).

We are embarking on a long journey toward universal individually optimized medical imaging. It is undoubtedly a journey worth traveling, because the gains from modern-day imaging are major in many aspects of current medical practice. The more imaging we do, the more the risks of the population become a potential concern and reinforce our obligation to maximize the benefit-risk ratio for every single patient. Whether the voluntary approaches in regard to quality control, training, and utilization that have been used to date represent the right path for the future, or whether legislation along the lines of the MQSA is required, is a key question that needs to be addressed sooner rather than later (108).

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